

ASN REPORT

on the state of nuclear safety
and radiation protection in France in 2024

The French Authority for Nuclear Safety and Radiation Protection presents the Report of the Nuclear Safety Authority on the state of nuclear safety and radiation protection in France in 2024.

This Report is required by Article L. 592-31 of the Environment Code.

It was submitted to the President of the Republic, the Prime Minister and the Presidents of the Senate and the National Assembly and transmitted to the Parliamentary Office for the Evaluation of Scientific and Technological Choices, pursuant to the above-mentioned Article.

ASN Report on the state of nuclear safety and radiation protection in France in 2024

This report, which describes the state of nuclear safety and radiation protection in France in 2024, was drawn up by the French Authority for Nuclear Safety and Radiation Protection (ASNR). ASNR was itself created from the merging on 1 January 2025 of the Nuclear Safety Authority (ASN) and the Institute for Radiation Protection and Nuclear Safety (IRSN). The Commission and the departments speak on behalf of ASN concerning the year 2024, and on behalf of ASNR when it comes to more general considerations or projections.

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Only regulatory news for the year 2024 is presented in this report.
The regulations as a whole can be consulted on asn.fr.

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Overview of Basic Nuclear Installations as at 31 December 2024

Maintaining a high level of rigorous nuclear safety and radiation protection in an ambitious context



From left to right

Pierre-Marie ABADIE, Chairman
Stéphanie GUÉNOT BRESSON, Commissioner
Olivier DUBOIS, Commissioner
Géraldine PINA, Commissioner
Jean-Luc LACHAUME, Commissioner

Montrouge, 1 March 2025

The safety level of the nuclear facilities was satisfactory in 2024, with considerable mobilisation around the performance of the fourth periodic safety reviews of the 900 Megawatts electric (MWe) reactors, stabilised production levels in the Melox plant and efforts by the industrial sector to improve manufacturing quality. In the medical field, the level of radiation protection is also considered to be satisfactory, despite some points warranting particular vigilance.

At a time when nuclear energy is set to be a key component of the French energy system for the long-term, the French Authority for Nuclear Safety and Radiation Protection (ASNR) recalls that:

- anticipation is required in order to take decisions informed by the best knowledge and underpinned by a questioning attitude that is attentive to weak signals;
- the long-term future of the facilities must aim for the best safety standards, including by comparison with the projects for more modern facilities that will be replacing them;
- physical and time margins must be maintained to be able to deal with contingencies without compromising safety.

A strategy to examine the service life extension of the reactors is deployed on the occasion of the fourth and fifth periodic safety reviews and in anticipation of the possible continued operation beyond then. This strategy enabled these examinations to be industrialised. The launch of studies into the long-term future and upgrading of the fuel plants is a positive point with respect to the aim of balancing the “cycle”.

With the up-turn in the construction of new reactors and new fuel plants, highly active innovation in the medical sector, or Small Modular Reactors (SMRs), as well as new prospects for service life duration, the nuclear safety and radiation protection stakeholders must meet new challenges: acquisition of new knowledge, dissemination of the safety and radiation protection culture to all the stakeholders, including in the subcontracting chain, mobilisation of resources and skills on behalf of nuclear safety and radiation protection, at a time of extreme competition for resources.

ASN, and now ASNR, are adapting to this new context. After the passage of Act 2024-450 of 21 May 2024 ratifying the merger of the Nuclear Safety Authority (ASN) with the Institute for Radiation Protection and Nuclear Safety (IRSN), the collective preparation work enabled ASNR to be immediately operational on 1 January 2025, with respect to all of its missions. ASNR covers research, expert assessment, examination and oversight, and comprises a full range of disciplines and skills ranging from the acquisition of knowledge, to decision-making and regulation/oversight. It is more independent, more robust and more visible, in France and internationally. The coming months will enable its organisation to be consolidated, enable ASNR to establish itself within its ecosystem, and gradually build an integrated strategy for research, expert assessment, oversight and transparency, and dialogue with society.

The continued operation of the nuclear power plant fleet remains a major subject

The provisions of Article L. 593-18 of the Environment Code stipulate that ASNR shall issue a position statement on the continued operation of the nuclear facilities every ten years, following their periodic safety review.

The fourth periodic safety review of the 900 MWe reactors (RP4 900), is continuing reactor by reactor, in order to significantly improve the level of safety. In 2024, ASN issued a position statement on the guidelines to be followed for the fifth periodic safety review of these reactors, which will enable the conditions to be defined for their continued operation beyond 50 years, while maintaining the same safety objectives. EDF intends to focus the fifth periodic safety review on the one hand on verifying the conformity of the installations, maintaining equipment qualification and management of ageing. On the other hand, it will focus on reassessing the management of risks and detrimental effects, taking account of the effects of climate change. ASN considered that the general guidelines adopted by EDF are pertinent and consistent with the current level of knowledge.

With regard to the fourth periodic safety review of the 1,300 MWe reactors (RP4 1,300), ASN's examination of the main generic safety issues continued in 2024 with the support of IRSN. At the same time, in the opinion of

the guarantors of the consultation appointed by the High Committee for Transparency and Information on Nuclear Safety (HCTISN), the public consultation on the conditions for improving the safety of the 1,300 MWe reactors as part of their fourth periodic safety review, conducted under the aegis of the HCTISN with the participation of EDF, IRSN, the National Association of Local Information Committees and Commissions (Anccli) and ASN, was able *“to publicly and successfully tackle essential questions concerning society as a whole, over and above the ongoing regulatory authorisation procedure”*.

The examination was conducted efficiently thanks to the reutilisation of the governance processes put into place for examination of the fourth periodic safety review of the 900 MWe reactors with EDF and IRSN, while also making full use of Operating Experience Feedback (OEF). This result, along with the division of future modifications into batches, and the continuity of the objectives with the fourth periodic safety review of the 900 MWe reactors, aims to allow standardised deployment of the safety modifications on the 1,300 MWe reactors as of the first reactors concerned, while giving priority to the high-stakes modifications, starting in 2026.

With regard to the possible operation of the current fleet of reactors beyond 60 years and on the basis of the work done by EDF, the year 2023 saw identification of the main technical subjects requiring specific analysis, or even research and development, ahead of the periodic safety reviews. The conclusions of EDF's early analyses will be reviewed so that ASN can issue a position statement in 2026.

Finally, since they began operating, the operational baseline requirements of the reactors, in particular their General Operating Rules (RGEs), have become increasingly complex, notably to take account of OEF

and reassessment of the threats from external hazards. This increased complexity may result in problems with applying the RGEs, or the operators may even lose sight of the purpose of their actions, which has consequences for risk management. EDF has started a short, medium and long-term simplification process, which has already led to exchanges with ASN and IRSN. At the same time, ASN called the profession together in 2024, for a round of discussions with the Steering Committee for Social, Human and Organisational Factors. A summary of this work will be published in 2025.

Stress corrosion lessons to be consolidated

The existence of the stress corrosion phenomenon affecting certain auxiliary piping was discovered at the end of 2021 and led to a strategy of systematic replacement of the lines considered to be susceptible in 2023, and increasingly wide-ranging inspections which will continue on the entire fleet up until 2025.

On the occasion of the next periodic safety reviews, the lessons learned will need to be incorporated by EDF into its maintenance programmes. ASN in particular considers that the hypotheses concerning the lack of susceptibility to degradation mechanisms, adopted for certain zones which are not monitored by a preventive maintenance programme, must be backed up by a programme of additional investigations.

Monitoring the commissioning of the Flamanville EPR and the EPR 2 programme

Following the examination carried out by ASN with the support of IRSN, and after consulting the public about EDF's dossier, the ASN decision of 7 May 2024 authorised commissioning of the Flamanville EPR reactor, thus allowing EDF to load nuclear fuel and carry out start-up tests. This authorisation comprised technical prescriptions concerning the performance of the tests, defining the deadline for replacement of certain components and stipulating provisions for the incorporation of OEF.

Since this authorisation, ASN holds daily discussions with the site and, in 2024, carried out ten or so commissioning follow-up inspections, notably at the most important stages. The licensee encountered various equipment issues, which delayed the reactor's power-up, but ASN has not at this stage identified any anomaly in the results of the start-up tests. About fifty significant safety

events were however declared by the licensee between commissioning and the end of 2024, a rate that is significantly higher than expected, even for a new reactor. ASN was particularly vigilant on this subject, notably during inspections, and at this point considers the measures taken by the licensee to be pertinent.

EDF has started a programme to build EPR 2 type reactors in France. The first reactor pairs will be built at Penly, Gravelines and Bugey. The creation authorisation application for a Basic Nuclear Installation (BNI) on the Penly site, submitted by EDF in 2023, is being examined and should reach a conclusion in 2027. Given the lessons learned from the Flamanville EPR project, ASN has initiated a process to monitor EDF's project organisation and management, as well as management of the supply chain for safety-important equipment.

Reception of the first examination files for small modular reactor projects confirms ASN's prior positions regarding the need for a systemic approach

In 2024, interest in SMRs, with more or less ambitious innovations, remained high, in the search for decarbonised energy production solutions. This context confirmed the pertinence of the organisation and the preparatory exchanges framework created by ASN in 2023 to support the new players, start-ups in particular, lead national and international discussions on the safety objectives to be applied to these objects and understand the diversity of designs and innovations. In 2024, the first creation authorisation application files or requests for opinions on

the safety options were submitted for projects supported by the "France 2030" programme.

In this context, a number of issues are crucial. First of all, most of these reactors should be located on the non-nuclear sites of their customers. This type of site can be in areas comprising major industrial or natural risks, or in immediate proximity to densely inhabited areas, which would make it complicated to implement population and environment protection measures in the

event of an accident. When envisaging locating reactors on such sites, the safety objectives to be achieved must be adapted, consistently with the method used to take account of malicious attacks. ASN set up a pluralistic exchange framework involving the stakeholders, to inform its thinking and thus be able to define a position on the safety objectives of these reactors.

The most innovative reactors also need specific fuel for which the industrial production and reprocessing chains do not yet exist and would require significant investment. ASN recalls the importance of developing a systemic approach incorporating the industrial chain, supply of nuclear fuel, management of spent fuels and other waste generated, as well as management of the risk of malicious acts and the proliferation of nuclear materials.

Faced with quality and safety culture challenges along the subcontracting chain, the industry has launched numerous initiatives

The revival of the nuclear industry represents a challenge for the sector, not only in terms of recruitment, but also with respect to growth not seen for several decades, as well as in terms of guaranteeing the required quality of all components involved in safety. Industrial rigour and the safety culture are essential and the sector, in particular within the French Nuclear Energy Industry Players Group (GIFEN), is fully aware of this.

However, 2024 again saw significant deviations and even irregularities, which were dealt with by the licensees concerned and examined by ASN's departments. Faced with these persistent deviations, the Commission held a hearing of the EDF Chief Executive Officer to ensure that

there is a true collective mobilisation to avoid a recurrence of the manufacturing and construction defects that beset the construction of the Flamanville EPR, notably on the new nuclear construction sites. ASN considers that the plans proposed by EDF and the GIFEN are a step in the right direction, but finds that the mobilisation by the industrial players as a whole is insufficiently robust. In 2024, ASN produced a practical guide concerning the quality of equipment intended for nuclear facilities, which notably recalls the importance of accurately identifying the requirements and the need for appropriate and timely monitoring of the production chain.

Considerations on the long-term development of the “fuel cycle” plants

For several years now, ASN has been warning of the pressure on the “fuel cycle” in France. The “cycle” facilities are vulnerable and each unit is a unique link in the processing chain. Saturation of the spent fuel storage facilities at La Hague would also have consequences for the operation of the Nuclear Power Plants (NPPs). The significant drop in production by the Melox plant and the faster than anticipated corrosion of the evaporators at La Hague, used to concentrate the nitric acid solutions of fission and transuranic products, illustrated this vulnerability in recent years.

This situation is however improving, with the gradual rise in Melox production over the past two years and replacement of the evaporators at La Hague which was completed this year.

With regard to pressure on the “cycle”, the decision to continue to operate reactors consuming MOX fuel (those of 900 MWe), pushes back the prospect of saturation of spent fuel storage capacity. Following the Nuclear Policy Council meeting of February 2024, active consideration was given to the long-term future and upgrading of the “cycle” plants, with a view to continuation of the reprocessing policy up until the end of the century.

In this context, EDF abandoned its centralised pool project in favour of a facility integrated into Orano's industrial programme on the La Hague site. The new facilities will need to be designed taking account of the most recent safety standards, at least equivalent to those of EDF's centralised pool project. While waiting for these future facilities and given the fact that they will not be able to take over instantaneously from the existing ones, it is essential to continue to implement countermeasures against the risk of saturation.

Over and above simple announcements, it is essential that decisions be taken immediately so that the projects can move to the implementation phase and be completed as rapidly as possible, starting with commissioning of new pools in 2040. The major upcoming milestones are Orano's submission of the Safety Options Dossiers (DOS) for the new facilities and then referral to the National Commission for Public Debate (CNDP) concerning a dossier presenting the projects for new spent fuel storage ponds. Following the current study phase, the Future Back-End project should ideally be the subject of debate and consultation.

Continued examination of the Cigéo dossier

Following the January 2023 submission by the National Radioactive Waste Management Agency (Andra) of the creation authorisation application dossier for Cigéo, a geological disposal project for high- and intermediate-level, long-lived waste (HLW and ILW-LL), ASN – with the support of IRSN – began a technical examination of the dossier, which will end with an ASNR opinion in 2025 and a public inquiry in 2026.

This technical examination continued in 2024, notably with two meetings of the Advisory Committee of Experts for Waste dealing with the basic data and hypotheses used to establish the safety case, and then with safety during the operating phase. On these two thematic subjects, this work enabled an evaluation of the extent to which the dossier presented by Andra complied with the requirements for the possible issue of the authorisation decree, but also identification of the additional data that will have to be provided in order to successfully pass the future milestones in the life of the facility. Andra will thus have to provide additional data before the beginning of excavation work, currently scheduled for 2035, notably on the safety case

for operation of bituminous waste disposal, closure of the ILW-LL vaults and operation of the high-level vaults.

The long-term safety issues of the repository, following its closure, are studied in 2025 as part of the third and final phase of the technical examination of the dossier. At this stage, ASNR considers that there are no obstacles to the continuation of the examination procedure in accordance with the envisaged calendar, which schedules work for a period of five years.

As described earlier, with a view to continued operation of the reactors for 50 to 60 years and the creation of six EPR 2 reactors, the adaptability of Cigéo was evaluated and nothing has as yet emerged to rule this out. However, the adaptation of the facility to changes such as the service life extension of the reactors beyond 60 years, the construction of eight additional EPR 2, or a fleet of SMRs and/or fast neutron reactors, would be evaluated after publication of the Creation Authorisation Decree on the basis of future adaptability studies, once the corresponding scenarios have been defined.

A contrasting situation in the medical field

In 2024, the level of radiation protection remained at a satisfactory level in the medical field, despite a contrasting situation and points warranting particular attention that have persisted for several years.

The context remains marked by pressure, notably on human resources, and constantly rising activity levels. Working organisations are increasingly complex, with pooling of resources, multi-site working, increasingly frequent use of outside contractors and increasing outsourcing of radiation protection skills, including among the most advanced facilities. This situation is creating new technical, operational and organisational constraints. In this context, ASN alerts all the stakeholders to the risk of a lesser assimilation of the radiation protection issues and recalls the need to evaluate the radiation protection impact of any organisational change. Certain significant events and the findings made during inspections in 2024 confirm the weak signals indicative of a context that is prejudicial to radiation protection, as already mentioned in 2023. ASN recalls that the main guarantee of a high level of radiation protection lies in a robust radiation protection culture, promoted by trained professionals. This culture must be regularly maintained in order to adapt good practices to the new risks, maintain an efficient optimisation approach and prevent the repetition of previous incidents.

ASN still observes an unsatisfactory situation regarding fluoroscopy guided interventional practices carried out in the operating theatre. In this field, where the indications and the number of patients concerned are increasing

and diversifying, optimisation actions and the conformity of the facilities with the layout rules are essential to managing the radiation protection issues. Enforcement measures have been taken in the past two years owing to notable deficiencies in the registration of X-ray emitting equipment, as well as persistent deviations concerning the conformity of the premises and patients and personnel radiation protection training. In radiotherapy, target errors, notably wrong-side errors, were again observed in 2024. Nationwide operating experience feedback was collected, in collaboration with the professional organisations, and shared with the professionals, so that these admittedly rare errors are not repeated. In 2024, a radiotherapy accident with serious consequences affected a patient whose radiotherapy antecedents had not been taken into account. In the light of progress in the treatment of cancers, ASN draws the attention of the professionals to the increase in the cases of patients who could benefit from a second radiotherapy treatment and the over-exposure risks associated with these situations.

In nuclear medicine, two particular situations can pose problems and are made more frequent by the development of Internal Targeted Radiotherapy (ITR). This involves on the one hand care of the patient in the event of extravasation during administration of the treatment; on the other, the waste management route when waste contaminated by radioactivity produced at the home of patients after out-patient treatment triggers the alarms on the detection portals at the entrance to the collection

centres. Owing to their radiological nature, these events mobilise considerable response resources and specific operational and support procedures, even if the health implications remain limited. Their increased frequency

in 2024 is a subject of concern, given the expected rise in the number of patients eligible for these treatments. ASN calls on the professionals to be extremely attentive to preventing such situations.

Anticipating and supporting innovation in the medical field

The deployment of new techniques and practices in therapy is a source of hope for the patients, but a subject requiring vigilance in order to ensure that they are integrated into the health care system rapidly and safely. This entails being fully aware of the corresponding radiation protection issues, for the patient, their entourage, the workers and the environment, and identifying and then implementing the means needed to manage them. This vigilance is particularly important given the growth of ITR, the arrival of the ZAP-X® platform, or the development of flash radiotherapy, pulsed fields and adaptive radiotherapy. ASN recalls that the radiation protection issues are not limited to the performance of the procedure, but begin as of the design phase and, as applicable, continue up to management of waste and effluents. These radiation protection issues must be integral to the thinking at each step along the way. This means that data pertinent for

radiation protection must be input and, as applicable, looked for or studied by the designers and developers.

In 2025, ASNR will continue its research, expert assessment and regulation work, with the assistance of its Advisory Committees of Experts, such as the Committee for the analysis of new medical techniques and practices using ionising radiation, or the Advisory Committee of Experts for Radiation Protection, together with the various institutional stakeholders in the field of health and the professional organisations. It will capitalise on the lessons learned from European projects in order to mobilise all stakeholders and develop the regulation and oversight system, both nationally and at the European level, so that radiation protection issues remain at the heart of the decision-making process in an innovative and constantly evolving health system.

Sustained international activity

International activities continued apace. Numerous meetings with its counterparts enabled ASN to discuss its practices and share the challenges linked notably to the launch of new projects and the use of innovative technologies – such as Artificial Intelligence – in the nuclear sector.

Work relative to the second thematic peer review (TPR ENSREG), chaired by an ASN representative, concerning protection of nuclear facilities against fire risks, has ended and will enable each country to draft its national action plan in 2025. Two seminars, held in Luxembourg, were a forum for discussions on best practices and identifying areas for improvement in each country.

With regard to radiation protection, ASN – which is chairing the Heads of the European Radiological Protection Competent Authorities association (HERCA) – the aim of which is to promote a high level of radiation protection in Europe, was actively involved in encouraging sharing of experience between the European authorities regarding the practical implementation of international standards and contributing to balanced updating of them.

Finally, the creation of ASNR will make it possible to reinforce France's representation internationally on the subject of nuclear safety and radiation protection. With this in mind, the international teams at ASN and IRSN together laid the groundwork for the creation of a unified international department that is operational as of 1 January 2025. ■

Unprecedented mobilisation in order to be ready by 1 January 2025



Olivier GUPTA

Montrouge, 1 March 2025

The reform of the governance of nuclear safety and radiation protection oversight and regulation, as a result of the Act of 21 May 2024, represents a historic milestone with the creation of the Authority for Nuclear Safety and Radiation Protection (ASNR). It is independent of the licensees and the Government and not only has considerable oversight and regulatory powers but also significant expert assessment and research capabilities. Therefore, each decision that it takes, each check that it performs, each authorisation that it issues, will be based on state-of-the-art investigations and expert assessments, backed by the results of research.

Preparation for the creation of ASNR required unprecedented mobilisation of the personnel of the Nuclear Safety Authority (ASN) and the Institute for Radiation Protection and Nuclear Safety (IRSN) along with the partner administrations, in order to be ready by 1 January 2025. ASNR is now operational. The founding documents have been adopted, its governance structure is in place and the internal organisation has been set up. The emergency response organisation is functional with a single centre. Yet the ASNR creation work is far from over: even if the fundamentals are in place, many aspects still have to be dealt with day after day, in order to ensure harmonious routine operations. Thought must also continue to be given to a more complete organisation, making full use of synergies.

This work has not however distracted the personnel from their primary role of protecting people and the environment.

Unprecedented mobilisation of the departments so that ASNR can be operational as of 1 January 2025

Legislative and regulatory work

It was essential for several Decrees needed for implementation of the 21 May 2024 Act to be published before 1 January. This is for example the case of the Decree transferring the goods, rights and obligations of the former IRSN to the Alternative Energies and Atomic Energy Commission (CEA), to the Ministry of the Armed Forces and to ASNR, or the Decree creating ASNR's interim social bodies. A total of seven Decrees were published after the mandatory consultation of several bodies and review by the *Conseil d'État* (Council of State). This demanded extensive work by the partner administrations and the ASN and IRSN personnel, within a very short period of time, and I must thank them for their commitment and efforts.

Work on operation and organisation

While contributing to the preparatory work carried out by the Government on the specific Bill for this reform, the ASN and IRSN senior managements wished to see work started on defining the organisational and operating principles of the future entity by the autumn of 2023. Joint working groups were therefore set up, for individual fields of activity, with the aim of proposing broad outlines for the organisation and operation of the corresponding activity sector in the future ASNR. They mobilised the teams throughout the year 2024. A list of "essential" actions was drawn up to prepare for the creation of ASNR, mainly in the cross-cutting and support activities (human resources, budget and finance, IT, legal affairs, etc.). The work was extended to the Government departments whose support was needed, notably to determine

the budgetary and financial architecture and set up a new budget programme dedicated to financing of the ASNR.

The positioning of the personnel in the new structure had to be prepared. To do this, the ASN Commission, in its capacity as the future ASNR Commission, submitted a draft organisation of the departments for consultation by the ASN and IRSN social bodies in July 2024. An Executive Committee was created, then first Directors of the future ASNR entities were appointed in November 2024, and the personnel of the two entities were assigned to their posts during the course of December.

The essential actions identified include ASNR's ability to provide a unified response to its mission in the event of a nuclear accident, or more generally any radiological emergency situation. The joint work on this question ended in the summer of 2024 with the creation of a single Emergency Centre, staffed by personnel from the two entities, with integrated working arrangements. The organisation thus defined was tested by several exercises in the autumn of 2024, confirming its validity.

Finally, as requested by Parliament, the ASNR internal rules of procedure, referred to by several Articles of the Act, notably to clarify the interface between "expert assessment" and "decision-making", were submitted to the social bodies for consultation, then presented to the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST), before being adopted by the ASNR Commission in January 2025.

This work as a whole guaranteed the continuity of the missions performed before and after 1 January 2025.

Dialogue with and support for the personnel

At the end of 2023, the ASN and IRSN senior managements, the IRSN personnel representative trades union organisations and the ASN personnel representative trades union organisations reached a consultation agreement regarding implementation of the reform project.

This agreement made provision for the creation of a consultation commission for the merger project, in addition to the personnel representative bodies for each entity, so that joint discussions could be held up to the end of 2024 between the two senior managements and the personnel representatives of the two organisations.

The personnel representatives took part in the working groups set up to prepare for the creation of ASNR.

Finally, given the scope of the reform, the psychosocial risks prevention and treatment system was reinforced, both at IRSN and at ASN. The personnel were questioned and their responses were input into a “barometer” which, despite concerns surrounding the reform, revealed no particular negative aspects. A support unit staffed by occupational psychologists was also set up.

Continuing to deploy ASNR in the future, adapting it to the new context, while performing its missions in full

Despite the scale and scope of the preparatory work, much remains to be done. Future work will focus on two key areas.

Continuing with setting up ASNR

Setting up ASNR first of all entails implementing day-to-day operations. The beginning of the year 2025 is essentially devoted to smoothing out the differences in the operating and management methods between the two merged entities.

As with any merger, good day-to-day working involves the creation of a unified information system and identical digital tools for all the personnel: this is a colossal and costly endeavour in the short term, even if it will eventually lead to savings.

The overhaul of the management system (mapping of processes, management meetings cycles, internal oversight, etc.) has started, but is far from over. The Scientific Council and the Code of Conduct and Professional Ethics Committee, both required by law, should be set up in the first months of 2025.

With respect to budget and finance matters, the creation of the new budgeting and purchasing processes is underway: these processes were not the same at ASN, an independent administrative Authority, and at IRSN, an industrial and commercial public establishment. The construction of a medium-term budget plan is in progress, even if the “voted services” period represented an additional constraint on the start of the works. In mid-2025, ASNR will present Parliament with its evaluation of the anticipated human, technical and financial resources it will need for the coming five years in order to carry out its duties in the new nuclear context, along with the essential steps to ensure the attractiveness of the working conditions of its personnel on the labour market in the nuclear field.

With regard to human resources, a project is needed to harmonise employment conditions, which nonetheless respects the public or private status of the personnel. The long-term success of ASNR entails constructing an attractive framework for employment and skills. This involves setting up a legible hiring process, developing an “employer brand” which helps create an “ASNR” identity and stimulation of recruitment through an ambitious policy to take on young people in internships and apprenticeships.

Building on IRSN’s experience, ASNR will be able to rely on an in-house tool, with the “Nuclear Safety and Radiation Protection University”, tasked not only with developing and transmitting in-house knowledge and skills to ASNR, but also making it available to all nuclear safety and radiation protection stakeholders in France and abroad.

Setting up ASNR, also means building a collective mind-set. The general management decided to create joint integration days for the new arrivals at ASNR. Participative work was initiated around ASNR’s values: it will have to be taken further and expanded to involve more personnel. The managers involved in the construction of this collective mind-set will make a decisive contribution. The collective mind-set also involves high-quality social dialogue, bringing together the representatives of the personnel, regardless of their status.

Finally, ASNR will have to be consolidated in its ecosystem in France and internationally, by reaffirming its legitimacy as the successor to ASN and IRSN, in the bodies where these two organisations were present. This also entails defining an ASNR integrated roadmap, in terms of dialogue with the stakeholders, notably with the support of the High Committee for Transparency and Information on Nuclear Safety (HCTISN).

Adapting working methods and organisations to the new context

It is clear that today's French and global nuclear context is no longer that which existed in the aftermath of the accident at the Fukushima Daiichi Nuclear Power Plant (Japan). From the technical viewpoint, there are many challenges: the prospect of nuclear reactors operating up to 60 years and beyond represents technical challenges requiring the acquisition of new knowledge able to deal with these remote time-frames. The construction of several EPR 2 and the refurbishment of the "fuel cycle" plants requires the construction of an oversight strategy for this large number of worksites.

The development of innovation and the integration of new technologies, whether they concern small modular reactor or nuclear medicine projects, mean that ASNR must take a fresh look at how it dialogues with the stakeholders it regulates and oversees, so that it can anticipate future issues. The development of artificial intelligence will also modify interactions between ASNR and those responsible for nuclear activities, but will also offer new prospects for researchers, experts and inspectors. War at the gates of Europe raises the question of monitoring nuclear installations in areas of armed conflict.

More broadly, over and above the nuclear field, the organisations in charge of regulation or oversight are facing queries about their role and how they carry out their missions. Finally, the increasingly tight budget situation for public organisations is to be taken into account.

This changing context in which ASNR is carrying out its missions and today's nuclear safety and radiation protection challenges will have to be taken into account in future changes to ASNR.

The aim here is not simply change for change's sake, but to take account of the fact that the current working methods and organisations, to a large extent inherited from the existing situation, were designed to allow the coexistence of two separate organisations, whereas the corresponding missions are now carried out by just one.

As has just been done with management of emergency situations, a review will be needed of the extent to which these missions can be carried out differently, giving new meaning to the work of the personnel – taking account of their integration into ASNR – to benefit the protection of people and the environment, while ensuring that the processes are robust, notably in expert assessment and decision-making.

The personnel concerned will be involved in these reviews.

Giving absolute priority to our primary mission of protecting people and the environment

Despite the scale of this work, which is to a large extent based on support or cross-cutting functions, the ASNR technical teams will remain fully committed to performing their mission to protect people and the environment.

2025 will be a decisive year for ASNR, which will have to continue with its transformation and conduct its essential missions to protect people and the environment. I know that to achieve this, I can count on the commitment of all the personnel, driven by a single goal: the public interest. ■

Notable events 2024



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Flamanville EPR reactor

The first months of reactor operation

On 7 May 2024, ASN authorised commissioning of the Flamanville EPR reactor. This was the first commissioning of a nuclear power reactor in France since that of Civaux Nuclear Power Plant (NPP) reactor 2 in 1999. The EPR is the first third-generation reactor in France. Its design allows a significant reduction in the probability of core melt and radioactive releases in the event of an accident by comparison with the previous generation of reactors. Despite the considerable difficulties encountered during construction, the reactor was commissioned in good conditions of safety. However, the first months of operation showed that EDF needs to reinforce its oversight and control of operational activities.

Completion of the start-up tests

In the commissioning authorisation, ASN regulated the various phases of the reactor's power increase, so that – throughout the process – the start-up tests were performed correctly until nominal power was reached.

Once the commissioning authorisation was given, EDF initiated fuel loading into the reactor vessel. First criticality, that is the beginning of the nuclear chain reaction in the reactor, took place on 3 September 2024.



EDF then carried out gradual power increases. The reactor was coupled to the electricity grid for the first time on 21 December 2024.

When the reactor is started for the first time, EDF has to perform a large number of specific tests to check the correct operation of the systems which could not be tested before fuel was loaded. The purpose of these tests is to check that:

- The core, its instrumentation and its protection systems behave as expected at the various power levels.
- The nuclear steam supply system and turbine controls are correctly adjusted.

- The secondary system, the turbine and the generator work correctly. These tests can only be carried out once enough steam is being produced.

- Certain situations, such as reactor trip or turbine shut-down for example, are correctly managed.

These tests are particularly closely monitored by ASN, which is kept informed in detail about their performance, the results and any incidents encountered. It also carries out inspections, most of which are unannounced. At the end of 2024, the tests already performed on the reactor's safety-important systems had taken place satisfactorily.

The various events which occurred since reactor commissioning

Since the reactor was commissioned, EDF has notified a number of significant safety events that was higher than expected, even for the start-up of a new reactor.

These events are primarily related to the learning curve followed by the teams when carrying out initial operation of the reactor and the transition between management of a construction site and actual operation of an installation. The causes of the vast majority of the events are organisational and human, with few being linked to equipment failures. Most of the human errors are rapidly detected and lead to the installation being restored to conformity almost immediately.

Faced with this finding, and even if these events had no consequences for the installations, people and the environment,

EDF implemented a number of measures to reinforce the oversight and control of its activities. These measures notably consist in stabilising the activity schedules and more clearly identifying and managing the risks before starting an operation. EDF also reinforced the support provided by its national teams.

ASN considers that these measures are pertinent and appropriate for the difficulties encountered during this particular phase in the life of the installation.

The next steps

ASN authorisation was required for the first reactor increase to a power of more than 25% its nominal power. Beyond this power level, the systems required for core protection are different and the Authority for Nuclear Safety and Radiation Protection (ASNR) will in particular check that they are able to perform their function.

ASNR approval will again be required before the first increase to a power higher than 80% nominal power. Most of the start-up tests will then have been carried out.

After the start-up testing phase, EDF will continue with reactor operation up until the first refuelling outage. During this outage, EDF will conduct specific checks, notably a complete requalification of the main primary system. The licensee will also have to incorporate modifications to the installation and in particular replace the reactor vessel closure head. ASNR will examine these modifications and will check the operations carried out during this outage, as it does for any nuclear reactor. It will pay particular attention to capitalising on the Operating Experience Feedback (OEF) acquired during this phase.

Finally, six months after the end of this outage, EDF shall send ASNR an end of start-up file presenting the results of other start-up tests, the OEF from the first operating cycle and shall update the reactor's safety analysis report and general operating rules. ♦



The challenges involved in preparing for the upcoming examination of numerous small modular reactor projects

In 2024, ASN was faced with a significant acceleration in contacts from Small Modular Reactor⁽¹⁾ (SMR) project developers. The steps taken as of 2023 to set up new frameworks for technical exchanges meant that it was possible to deal with this unprecedented situation and prepare for effective examination of the first dossiers. One of ASN's main findings following these exchanges concerns the frequently unrealistic nature of the deployment schedules announced by many of the project developer.

Acceleration in technical exchanges in 2024 with companies developing small modular reactor projects

In 2024, ASN and the Institute for Radiation Protection and Nuclear Safety (IRSN) had to deal with a very large number of contacts from all the companies developing SMR projects and who wished to initiate technical exchanges as rapidly as possible, while others wished to continue those already started in 2023.

The fact of having to deal with about ten SMR projects, all promoted by as many different project developers, is an unprecedented situation in the French context and represents a very real challenge to the examination capacity of both ASN and IRSN.

Given this challenge, ASN considered that it was essential to be able to initiate technical exchanges with the project developers rapidly, ahead of submission of the forthcoming applications required by the applicable regulatory procedures. Advance exchanges such as these have the advantage of making it possible to understand the innovations and new safety issues of these projects early on, and thus be as well prepared as possible to effectively examine the future dossiers to be submitted.

In 2023, ASN had thus carried out a reorganisation of its departments, by creating a new entity specifically for these innovative reactor projects, and had also adapted its

methods for technical exchanges with the project sponsors (see details in chapter 11) so that the commitment of its resources and those of IRSN was proportionate to the development level of these various projects.

These new technical exchange frameworks, gradually put into place in 2023 with the first France 2030 "Innovative reactors" award winners, were thus able to deal with a first significant increase in contacts from project developers in 2024. As shown in the diagram opposite, although these contacts in 2024 primarily concern preparatory technical exchanges (follow-up on screening phase and preparatory reviews), it should be noted that the developers of two projects this year decided to actually submit an examination request within a regulatory framework:

- on 3 May 2024, a creation authorisation application was submitted by the Jimmy Energy company to the Minister responsible for nuclear safety for its SMR project designed to provide high-temperature heat for an industrial site;
- on 31 October 2024, a request for an opinion on the main safety options of its SMR project designed to provide steam to an urban district heating network was submitted to ASN by the Calogena company.

Creation of a specific Advisory Committee of Experts for innovative SMRs

ASN can consult Advisory Committees of Experts (GPEs) for opinions and recommendations when preparing its most important resolutions relative to nuclear safety or radiation protection issues.

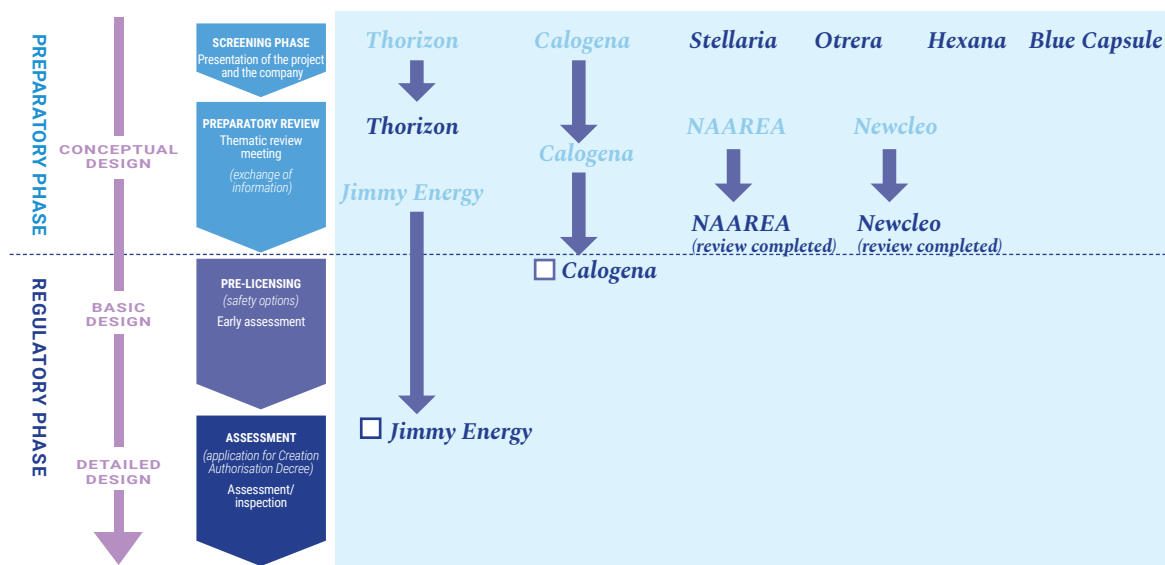
As part of its preparation for the forthcoming examinations of innovative SMR projects, ASN set up a Cross-cutting Advisory Committee of Experts in 2024⁽²⁾ from

1. Several SMR projects are currently being developed around the world. These are reactors with a power of less than 300 Megawatts electric (MWe), built mainly in a factory. They use a variety of technologies: that of the pressurised water reactors or advanced technologies (high-temperature, molten salt, fast neutron, etc. reactors).

2. asn.fr/reglementation/bulletin-officiel-de-l-asnr/fonctionnement-de-l-asnr/decisions-nominatives/decision-n-codep-mea-2024-019956-du-directeur-general-de-l-asn

Framework of technical exchanges with ASN and IRSN

Over the course of 2024, change in the situation of the nine SMR project developers (except for Nuward, which is a project promoted by EDF)



various existing GPEs, which is intended to be consulted on technical subjects dealing with new innovative SMR projects.

The experts appointed to this “GT-RI” (Cross-cutting Group for Innovative Reactors) were thus involved in the summary and closing seminars of the preparatory reviews set up by ASN for the Jimmy Energy, NAAREA

and Newcleo projects. This participation enabled them to familiarise themselves with the design and safety approaches adopted by these innovative SMR projects and thus improve their readiness for dealing with queries from ASNR regarding these projects in the context of the forthcoming examinations and reviews.

The announced industrial schedules are often unrealistic

The development of these new companies is leading to significant time pressure on the projects because of:

- competition between the various projects to commission an industrial demonstrator and thus be the first to move to large-scale marketing of their SMR model nationally and internationally;
- the financial challenges to development, in particular the balance between raising and consuming capital, pending the commissioning of their first industrial reactor.

In this context of time pressure on the projects, one of ASN’s main findings following these discussions in 2024 concerns the frequently unrealistic nature of the deployment schedules announced by many of the project developers.

ASN in particular identifies several time-frames related to its safety concerns which all too often tend to be under-evaluated by the project developers:

- The time needed for an innovative reactor project to acquire a sufficiently solid base of knowledge for validation of its technological choices, in order to ensure the industrial feasibility and viability of the project, during both the construction and operating phases, and to establish the required safety case in support of a creation authorisation application with all the necessary rigour.

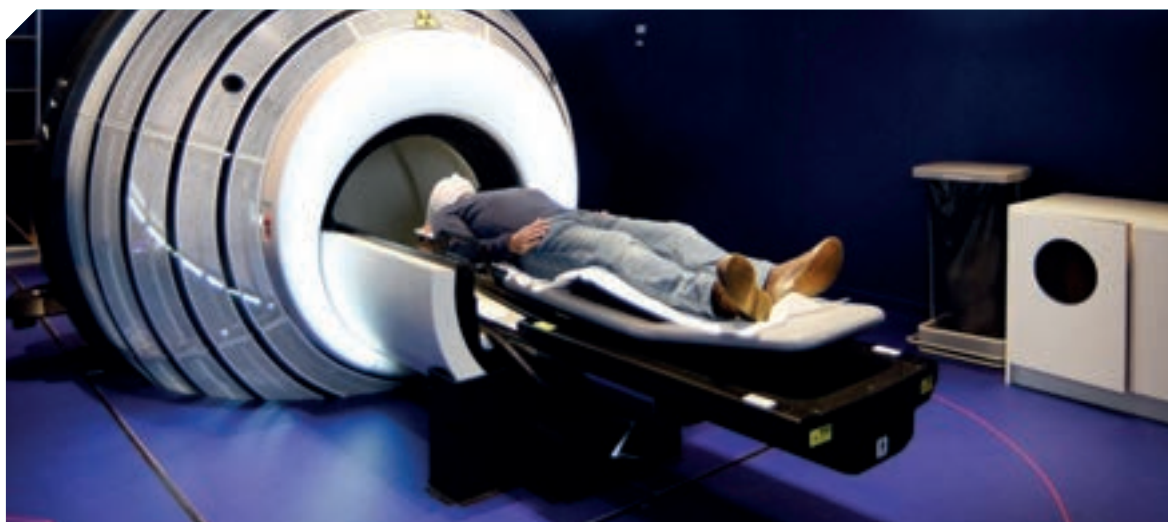
- The duration considered for examination of the creation authorisation application for their first reactor; the project developers generally imagine a time-frame for examination of their experimental reactor or their industrial demonstrator shorter than actually set out in the current regulations. Whereas a shorter time-frame such as this could be envisaged for the examination of the subsequent reactors which could benefit from the series effect, it is hard to imagine this for particularly innovative reactors. ASN thus recalls that the dossiers for these SMRs will be examined with the same rigour as any other nuclear installation, in a way that is proportionate to the safety issues and that the examination time-frames will above all depend on the quality and complexity of the safety cases presented to it.

ASN also points out that over and above the actual reactor project, the industrial deployment schedules announced sometimes under-estimate the potential critical paths, in particular related to:

- the time needed to develop and commission the basic nuclear installations required to produce their specific nuclear fuel;
- the time needed for development and approval, when necessary, of any new packaging for the transport of their fuel on the public highway. ♦

Radiation protection faced with the challenges of innovative medical techniques

In a medical sector experiencing perpetual innovation, 2024 was marked by an unprecedented acceleration in the development of innovative medical techniques using ionising radiation.



Innovations in all medical fields

This acceleration is particularly noteworthy in the field of Internal Targeted Radiotherapy (ITR) where, following the generalised use of therapies employing lutetium-177, there are an increasing number of clinical trials with new radionuclides of interest such as actinium-225 or lead-212. In the radiotherapy field, pre-clinical research is being developed on the flash effect, which consists in delivering a very high dose rate in a very short period of time, which could significantly reduce the time needed for certain treatments. In the field of fluoroscopy-guided interventional practices, the multiplication in the number of indications and the increasing complexity of the procedures reflect the variety of practices and the conditions in which they are performed.

Innovation sometimes lies in the design of the technical dispensation platform, as is the case with the ZAP-X® self-shielded external radiotherapy system, which would make it possible to provide treatment with less constraints concerning the layout and outfitting of the premises.

These innovations offer new hope for the patients, and there is significant pressure to rapidly incorporate them into the health care system. Their rapid development, unlike the lengthy time-frames inherent in the nuclear industry, nonetheless constitutes a radiation protection challenge. Measuring the radiation protection challenges and even more so identifying and then implementing the means needed to manage them, are based on developing professional knowledge and skills, on acquiring and sharing data, some of which will only be available in the medium term, on providing appropriate infrastructures and on mobilising a large network of stakeholders and players.

The particular case of internal targeted radiotherapy

In the field of ITR, the medical procedure entails particular radiation protection issues for the patients and their carers and comforters, the workers and the environment. These issues are sometimes incompletely evaluated, notably when new radionuclides or new vectors are being used. It is essential that knowledge of dosimetry and metrology be developed for the alpha and beta emitters used in ITR,

and the data in the possession of the promoters, or collected by research teams during clinical trials, must be better shared with all the stakeholders. Finally, the health care system must become organised so that the additional data needed are collected, notably those concerning medium and long-term patient monitoring, radiological surveillance of the health care personnel, and the experience feedback

from undesirable and Significant Radiation Protection Events (ESRs), as of the first times the procedures are used for treatment. These data must be collected and analysed so that the steps to be taken to ensure safe treatment and worker protection can be defined and, if necessary, regulated, and shared with the other departments which will be using these same treatments. These must be able to plan or adapt the layout and outfitting of their premises, train their personnel, and conduct the required risk assessments for their quality management system and for occupational risk prevention.

Upstream of the delivery of a radiopharmaceutical, there can be nuclear safety issues for certain radionuclides of interest, notably when their production implies the use of research reactors or specific cyclotrons, and facilities for the purification and then preparation of radiopharmaceutical drugs. These processes also require numerous intermediate shipment operations with significant time constraints owing to the short half-life of the radionuclides. Despite the European level coordination efforts made to secure the supply of essential radionuclides to nuclear medicine units, there are often few synthesis alternatives, which makes continuity of the available treatments vulnerable to the contingencies that can affect these facilities.

Once the medical procedure has been completed, the management of effluents and waste contaminated by the radionuclides raises its own new problems. The particular

case of waste contaminated by radionuclides produced at the home of patients and detected when it reaches waste collection centres, when disposed of in the household waste without adhering to decay management times, causes blocking situations or even emergencies in the waste management route and for its workers. The increase in the frequency of such events observed in 2024 is therefore of concern, given the expected increase in the number of eligible patients. The effect of the preference for out-patient treatments transfers the responsibility for managing this waste from the hospital units, which are generally organised to deal with this, to the patients when back home and the municipalities in charge of household waste management, for which operational procedures and support remain difficult to implement or may even be non-existent.

Similarly to the particular case of lutetium-177, which was the subject of an ASN Circular of 12 June 2020, these issues must now be taken on-board across the disciplines, taking account of a broad range of radionuclides and vectors. This implies close collaboration between the professional organisations, the authorities (Ministry responsible for health, National Authority for Health – HAS, Health Products Safety Agency – ANSM, Authority for Nuclear Safety and Radiation Protection – ASNR), the manufacturers and promoters of clinical trials, and the health care services, to ensure a complete and coherent approach.

Anticipating for improved regulation and decision-making

In this context, it is essential that the decisions by all the health care system stakeholders be informed by adequate upstream consideration of the radiation protection issues.

For the medical services, this entails anticipating what their future will look like in order to adapt to the needs (reception capacity, sizing, technologies, regulatory compliance, etc.) and prepare the corresponding investments, including in terms of skills. For the manufacturers of radiopharmaceutical drugs, this for example implies limiting impurities and the presence of long half-life radionuclides, packaging the radiopharmaceuticals in an appropriate form such as to limit occupational exposure or ensure their safe dispensation. For the promoters of clinical trials, the licence application file shall include pertinent data so that the users can comply with the regulatory obligations for radiation protection of the patients and their entourage, the professionals and the environment, and carry out their risk assessment. For the manufacturers of new medical devices, it is essential that the necessary data be delivered with the equipment.

To identify the new techniques and emerging practices using ionising radiation and analyse their radiation protection implications, ASN calls on Advisory Committees of Experts (GPEs) and the Committee for the Analysis of New Medical Techniques and Practices using Ionising Radiation (Canpri), with the support of the Institute for Radiation Protection and Nuclear Safety (IRSN). In 2024, ASN issued a position statement on the ZAP-X⁽¹⁾, based on the opinion issued from the Canpri, as well as on pulsed

fields⁽²⁾, based on an opinion from the Advisory Committee of Experts for Radiation Protection (GPRP). The Canpri opinion on flash therapy is expected in 2025. Finally, ASNR will issue an opinion in 2025 on the basis of the work done by IRSN and the GPRP to draw up recommendations intended for the promoters and investigating centres to promote access to innovative care treatments. The GPE opinions were presented to the HERCA network (Heads of the European Radiological Protection Competent Authorities) for forwarding to the European Union, and the Simplerad project was also able to identify areas for improvement to enhance the interface between pharmaceutical legislation and radiological safety standards.

Numerous exchanges took place with the professional organisations to make up for the lack of information on the important radiation protection data and to facilitate the collection of this information in order to allow the issue of authorisations. For ITR, ASN conducted exchanges with the ANSM to optimise and simplify the administrative approaches.

In 2025, ASNR will continue its efforts to mobilise all the stakeholders and change the regulatory system, ensuring that each stakeholder assumes its responsibilities and that radiation protection issues are at the heart of the decisions in an innovative and constantly evolving health care system. ♦

1. asn.fr/information/archives-des-actualites/premier-avis-du-canpri-et-position-sur-l-installation-et-l-utilisation-de-la-plateforme-zap-x-r

2. asn.fr/reglementation/bulletin-officiel-de-l-asnr/activites-medicales/avis/avis-n-2024-av-0445-de-l-asn-du-3-septembre-2024

The guidelines of the fifth periodic safety review of the 900 MWe reactors

On 10 December 2024, ASN issued a position statement⁽¹⁾ on the guidelines for the generic phase of the fifth periodic safety review of the 32 reactors of 900 Megawatts electric (MWe) operated by EDF. ASN considers that this review should primarily look at conformity and installations ageing management and at reinforcing how the effects of climate change are addressed. It shall allow consolidation of the important safety improvements made to the reactors during their fourth periodic safety review.

The 900 MWe reactors are currently the oldest in France. They were commissioned between 1978 and 1987. This fifth periodic safety review will define the conditions for their fitness for service beyond 50 years.

The fourth periodic safety review, which is currently being implemented on each reactor, is particularly detailed. Its aim is to move towards the safety level of the third-generation reactors and to complete the deployment of the “hardened safety core” defined in the wake of the accident at the Fukushima Daiichi Nuclear Power Plant (NPP – Japan). This review will continue until the last reactor in 2036.

In the light of the major modifications made as a result of the fourth periodic safety review, not all the hazards and environmental impacts will be reassessed during the fifth periodic safety review. This will primarily focus on:

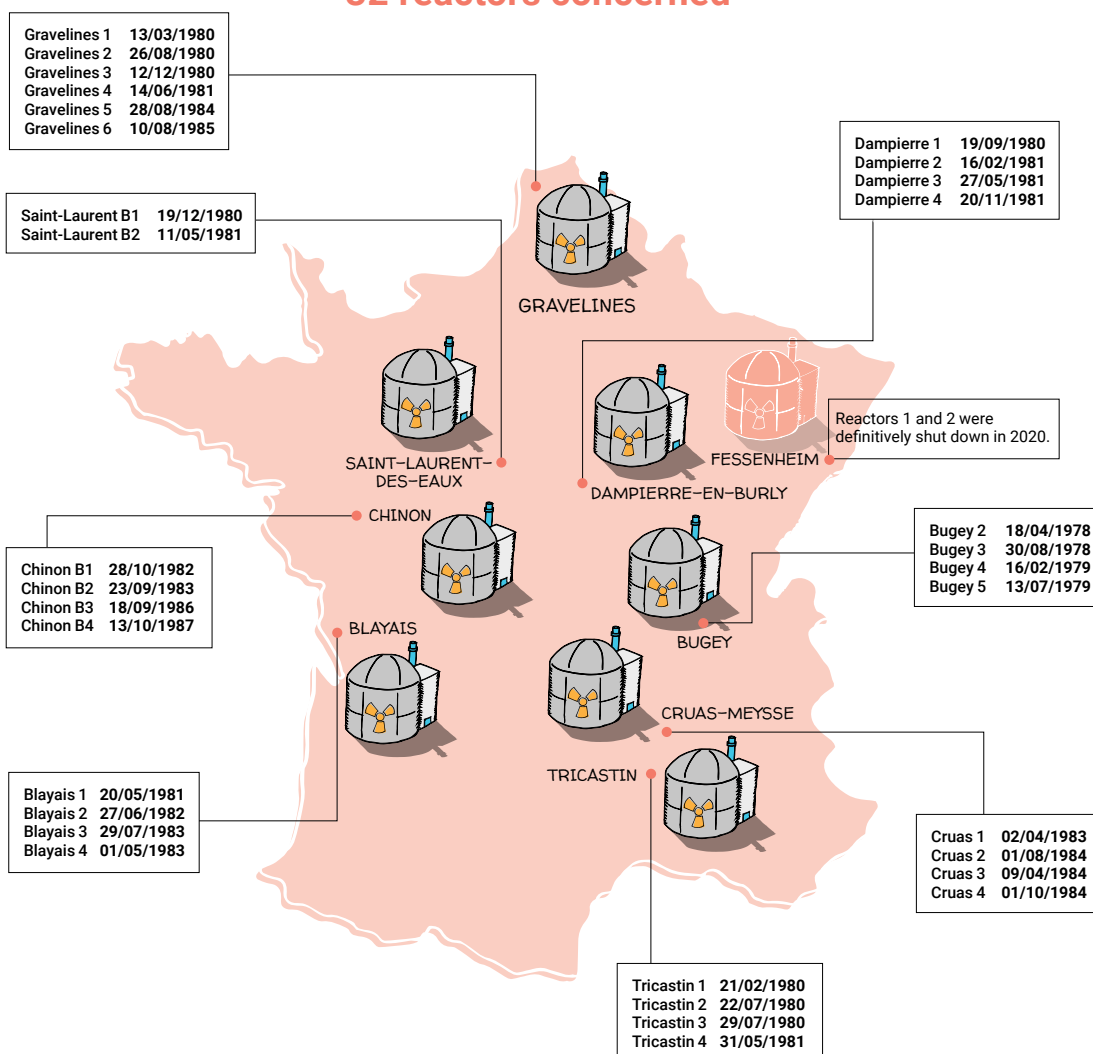
- verifying the conformity of the installations with their applicable requirements, maintaining equipment qualification and managing ageing, for operation up to 60 years;
- the effects of climate change, whether regarding managing the risks of accident (rise in sea level, heat-waves, etc.), or the impact on the environment (water intake and consumption).



1. asn.fr/information/archives-des-actualites/l-asn-prend-position-sur-les-orientations-du-5e-reexamen-periodique-des-reacteurs-de-900-MWe

900 MWE REACTOR START-UP DATES

32 reactors concerned



In its position statement, ASN drew EDF's attention to the particularities of the Bugey NPP reactors, the design of which predated that of the other 900 MWe reactors and which require a specific review process. With respect to the lessons learned from the stress corrosion cracks discovered since 2021, it also pointed out that EDF must improve its verification methods in areas where no degradation mode is to be feared.

As with the previous periodic safety reviews and in order to take advantage of the standardised nature of its 32 reactors of 900 MWe, EDF intends to carry out this fifth periodic safety review in two stages:

- A "generic" periodic safety review phase, covering subjects common to all the 900 MWe reactors, both for risk management and for management of the drawbacks presented by the installations. This generic approach is a means of pooling and sharing studies for management of facility ageing, obsolescence and conformity, as well as those for the safety reassessment and the design of potential modifications to the facilities.

- A "specific" periodic safety review phase, concerning each individual reactor and to be staggered between 2030 and 2041. This phase will make it possible to incorporate the specific characteristics of the installation and its environment, for example such as the level of natural hazards to be considered, the specific nature of the local environment, the other uses of the water resource and the condition of each installation.

Before issuing a position statement, ASN obtained the opinion of the French Institute for Radiation Protection and Nuclear Safety (IRSN) and the Advisory Committee of Experts for Nuclear Reactors (GPR) regarding the EDF guidance file.

ASN also consulted the public about its draft position statement, from 15 October to 11 November 2024. Upstream, in partnership with IRSN and the National Association of Local Information Committees and Commissions (Anccli), it organised two webinars intended for the members of the Local Information Committees (CLIs) and the general public, so that they could familiarise themselves with the guidelines proposed by EDF, the assessment made by IRSN, and the draft ASN position statement submitted for consultation. ♦

ASN Assessments



The French Nuclear Safety Authority (ASN) carries out its oversight role by using the regulatory framework and individual resolutions, inspections, and if necessary, enforcement measures and penalties, in a way that is complementary and tailored to each situation, to ensure optimal control of the risks nuclear activities represent for people and the environment. ASN reports on its duties and produces an assessment of the actions of each licensee, in each activity sector.

— ASN assessments per licensee

EDF

The nuclear power plants in operation

The quality of operation of the Nuclear Power Plants (NPPs) remained satisfactory in 2024.

The year 2024 was marked by the commissioning authorisation for the Flamanville EPR reactor issued by ASN on 7 May 2024. This authorisation allowed EDF to load nuclear fuel into the reactor vessel and begin the start-up tests. The assessment below concerns the other EDF reactors in operation. The Flamanville EPR reactor is dealt with in the Regional Overview of this report.

Reactor improvements and continued operation

The modifications made to the facilities and operational methods by EDF within the framework of the periodic safety reviews of the 900 Megawatts electric (MWe) reactors are significantly improving the safety of the facilities, making it possible to aim for the same safety objectives as those of the third generation reactors. EDF is devoting considerable resources to these reviews. ASN notes that deployment of the safety improvements is taking place in good conditions.

As EDF embarks on the fourth periodic safety review of the 1,300 MWe reactors, ASN considers that EDF must continue its efforts to prepare for and implement modifications to the installations in good conditions, despite the considerable workload on the engineering teams. Particular attention must also be paid to the assimilation of these modifications by the operators and to their training.

The conformity of the facilities

The steps taken by EDF for several years now to improve the detection and correction of deviations and to ensure that ASN is informed are satisfactory. More particularly, the specific inspections implemented during the fourth ten-yearly outages are bearing fruit and reinforcing the conformity of the facilities. In 2024, EDF also initiated multi-year programmes which are leading to concrete targeted oversight actions. ASN considers that these new measures will reinforce control of the conformity of the facilities throughout their lifetime.

Maintenance

EDF correctly managed the reactors outage campaign, which overall indicates that maintenance was well carried out in 2024. ASN also observes that the number of significant events caused by an anomaly during a maintenance operation has fallen since 2022.

EDF must continue its ongoing work on the competence of the personnel and improve preparation for maintenance activities, how experience feedback is taken into account and the quality of the risk assessments, against a backdrop of a significant industrial workload linked to continued operation of the reactors and the “Major overhaul” programme.

In addition, as in 2023, ASN considers that EDF’s monitoring of manufacturing operations for safety-important equipment in supplier plants is unsatisfactory. EDF has implemented an action plan to address this.

Operation

The quality of reactor operation and control remained at a satisfactory level in 2024, but certain NPPs are experiencing difficulties.

ASN noted positive results in 2024 concerning the measures taken to manage the actual configuration of the systems, including during maintenance work. It also noted efforts made by EDF to improve the situation of the independent safety organisation, notably those aiming to gradually increase its workforce up until 2027. Overall management of the fire risk was also improved, even if the situation is not the same across all the NPPs.

However, monitoring in the control room has not been satisfactory for a number of years. Certain anomalies are detected too late by the operating teams. In addition, certain notable events concerning reactivity control should lead EDF to look again at the prevention measures in place.

Inspections focusing on the emergency organisation and resources confirmed, as in recent years, that the organisation, preparedness and management principles for emergency situations have been correctly assimilated. EDF must however continue to improve the through-life support of the resources that could be called on in an emergency situation, along with the training of and situational exercises carried out by the personnel concerned. ASN inspections also revealed that EDF must

conduct an in-depth revision of the operational documentation defining the steps to be taken outside the control room in an accident situation with core melt. Finally, EDF must continue its efforts regarding preparedness for emergency situations of non-radiological origin.

Environmental protection

ASN considers that the management of intakes and discharges into the environment of the various NPPs is on the whole satisfactory. However, deviations regarding checks on and monitoring of effluents or the environment, increased in 2024, in particular with regard to bypassing of the normal discharge routes.

ASN also expects to see improvements in the use of containment systems capable of managing an accidental spillage of dangerous substances.

With regard to waste management, ASN observes that – as in previous years – the situation is continuing to improve. However, progress is still needed regarding the duration and conformity of interim storage facilities, notably with respect to the fire risk and inventory keeping.

Worker radiation protection and occupational safety

ASN is encouraging EDF to continue its proactive approach to control the sources of worker exposure to ionising radiation, notably with respect to identifying and eliminating the most heavily irradiating areas on the worksites. It also observes that the number of significant events reported concerning industrial radiography work, the radiological consequences of which can be significant, fell by comparison with 2023. ASN however considers that improvements are needed in managing the risk of contamination dispersion within facilities and contamination of workers, as well as in the approach to preventing risks of exposure to ionising radiation for the most vulnerable workers (apprentices under 18 years of age or personnel with a fixed-term contract).

With regard to occupational health and safety, the inspections carried out by the labour inspectors show that worksite

preparation needs to be improved, notably to limit the risks of exposure to asbestos and lead. Lifting operations and on-site

traffic rules remain points meriting attention.

The EPR 2 reactor projects

In 2023, EDF submitted the creation authorisation application for two EPR 2 reactors on the Penly site (Seine-Maritime *département*). The technical examination of this dossier is currently under way.

The design of the EPR 2 reactor is more advanced than the Flamanville EPR reactor at the same stage, which is a positive point. ASN also finds that EDF and Framatome are making efforts to incorporate the

lessons learned from the Flamanville EPR reactor in the design and manufacture of the nuclear steam supply System for the EPR 2 reactors.

Individual nuclear power plant assessments

The ASN assessments of each NPP are detailed in the Regional Overview in this report.

With regard to safety, the Cattenom and Penly NPPs stood out positively in 2024. The Dampierre-en-Burly, Blayais and

Saint-Laurent-des-Eaux NPPs under-performed by comparison with the other NPPs operated by EDF.

With regard to radiation protection, the Saint-Alban and Chooz B NPPs stood out positively. ASN considers that the Tricastin

and Saint-Laurent-des-Eaux NPPs had under-performed.

With regard to environmental protection, the Saint-Laurent-des-Eaux, Tricastin and Chinon NPPs stood out positively.

Nuclear power plants being decommissioned and waste management facilities

ASN considers that the EDF facilities undergoing decommissioning or being prepared for decommissioning are well managed and that the licensee is correctly meeting its commitments. ASN considers that the decommissioning or Decommissioning Preparation Operations (DECPROs) on the facilities other than the Gas-Cooled Reactors (GCRs) are progressing at a satisfactory pace. With regard to the GCR reactors, the deadlines for completion of the decommissioning operations envisaged by EDF remain a subject requiring vigilance according to ASN.

Installations shut down or undergoing decommissioning

The reactors operated by EDF finally shut down or undergoing decommissioning (Brennilis, Chooz A, Fessenheim, Superphénix, GCRs) no longer contain any spent fuel. The main safety issues therefore concern the containment of radioactive substances and radiation protection. Some installations also present an additional risk linked to the presence of asbestos, sometimes combined with the presence of radiological contamination, which makes the intervention conditions more complex.

With regard to radiation protection, the organisation put into place by EDF in its radiation protection expertise centres is satisfactory. With respect to these projects, EDF gives priority to risk mitigation in its facilities.

The DECPROs of the Fessenheim NPP are continuing so that the installation achieves its initial state planned for entry into force of the future Decommissioning Decree. ASN takes a positive view in 2024 of the initiation of decommissioning of the EL4-D facility (Brennilis NPP). EDF also intends to carry out post-operational clean-out operations on the structures of facilities undergoing decommissioning (Chooz A, Bugey 1), the methodology of which is currently being examined by ASN.

With regard to the GCRs, in 2024 EDF continued the “out of vessel” decommissioning work on the reactors at Saint-Laurent A, Bugey 1 and Chinon A3 in satisfactory conditions of safety, notably completing removal of the shells of the four Chinon A2 exchanger premises.

In 2025, as part of the continued examination of the decommissioning files for these reactors, the French Authority for Nuclear Safety and Radiation Protection (ASNR) will thus pay particular attention to the planned time-frames for decommissioning of these reactors, along with the robustness of the graphite waste management strategy presented by EDF.

ASNR will also remain vigilant with regard to the satisfactory performance of the various steps in the decommissioning of the Irradiated Material Facility (AMI – BNI 94) in Chinon, for which operations were halted during 2024 as a result of water infiltration.

The spent fuel and radioactive waste management facilities

With regard to its facilities in operation, EDF is carrying out numerous equipment upgrades in the Superphénix spent fuel storage unit (Apec), which is satisfactory. ASN considers that EDF must continue to consolidate the radioactive waste retrieval projects, notably the soda blocks stored in the Apec and the graphite sleeves contained in the Saint-Laurent-des-Eaux silos.

ORANO

ASN considers that Orano's current efforts, both to improve the overall working of the existing facilities and to anticipate the future issues of the cycle back-end, as a result of the Government's announcements in early 2024 regarding reprocessing-recycling strategy post-2040, are positive.

In 2024, on the La Hague site, Orano completed replacement of the previous fission products evaporator-concentrators, in which corrosion was more advanced than imagined at the design stage. The projects aiming to safeguard the management of radioactive materials and waste on the La Hague site continued. On the Tricastin site, the construction work on the containers maintenance facility 2 (AMC2) is continuing with a view to commissioning in 2025; that on the extension to the Georges Besse II plant (BNI 168) began in September 2024, following a public inquiry in the spring of 2024. Finally, deployment of the action plan intended to overcome the

production difficulties at the Melox production plant in Marcoule is continuing. ASN considers that these points contribute to the continued improvements to the operation of all the facilities.

On 15 October 2024, during the plenary meeting of the High Committee for Transparency and Information on Nuclear Safety (HCTISN), Orano announced that it was taking over the project to build new "underwater" storage capacities for spent fuels, with a view to commissioning the first pond before 2040, in place of the centralised storage pool project, hitherto promoted by EDF. ASN considers that the studies leading to the transmission to ASN of a

Safety Option Dossier on the new spent fuel "underwater" storage capacities in 2026 must be continued and intensified with a high level of rigour, in the same way as those started in 2024 on the continued operation of the existing facilities, in the light of the issues associated with the ageing of all the facilities, in terms of both safety and the robustness of the "fuel cycle".

Orano shall also ensure that the resources committed to these new projects are not to the detriment of other projects to improve support functions or process legacy radioactive substances stored on the site, which have just as high a priority.

Installations in operation

ASN considers that the level of safety of the Orano sites at La Hague and Tricastin remained satisfactory. ASN observes good management of control and operation, while calling for greater rigour concerning adherence to technical prescriptions and periodic checks.

With regard to the Melox plant, ASN considers that its safety level is on the whole satisfactory and takes a positive view of compliance with its production targets as well as stabilisation of production of "MOX scrap" by comparison with 2023.

Personnel radiation protection

With regard to radiation protection, ASN is encouraged by the operation of the

expertise centre within the facilities, even if there are still radiation protection deviations to be dealt with by means of specific ongoing action plans. ASN welcomes the work to harmonise practices carried out on the Tricastin platform.

ASN remains vigilant with regard to the Melox facility, owing to the high number of preventive and corrective maintenance operations carried out on the facility's equipment, against a backdrop of a major maintenance programme intended to enhance the availability of the facilities. These operations entail dosimetric risks that are often significant.

Environmental protection

On the La Hague sites, with regard to measures taken to control non-radiological risks, ASN considers that across the facility in-depth lessons must be learned from the occurrence of a leak from a nitric acid tank in an outdoor reagents storage unit.

ASN also notes recurring deviations concerning management of coolant fluids and fluorinated greenhouse gases, as a result of which Orano must improve the steps taken to prevent, detect and reduce the corresponding emissions to the lowest level possible.

The safety reassessments of the facilities

ASN considers that the organisation put into place by Orano for evaluating the conformity of its facilities and for reassessing their safety during the periodic safety reviews, is satisfactory. It nonetheless urges Orano to increase its vigilance concerning the implementation of the action plans drawn up during each periodic safety review

and compliance with the deadlines for the regulatory requirements and the commitments made.

Generally speaking, ASN considers that Orano must take advantage of the upcoming periodic safety reviews to reinforce and consolidate the safety improvements made to the facilities and anticipate management

of the modifications given the prospects for the continued operation of the "fuel cycle" facilities. These reassessments shall in particular contribute to deploying a robust ageing management approach, including for the utilities or support functions directly or indirectly needed for the operation of the facilities' safety systems.

Legacy waste retrieval and conditioning and decommissioning on the La Hague site

Large quantities of legacy waste at La Hague are not stored in accordance with current safety standards and present major risks. The retrieval and conditioning of this legacy waste (WRC) is a key step in the progress of decommissioning of definitively shut down plants.

ASN periodically monitors the progress of these complex projects and takes a positive view of good assimilation of the project maturity assessment by Orano, as well as the deployment of management tools.

ASN considers that Orano must nonetheless make progress concerning the robustness of the waste retrieval and processing scenarios and in ensuring the reliability of the operational waste retrieval processes, in order to guarantee the schedules for the various WRC and dismantling projects announced.

ASN also considers that Orano must make progress in anticipating the interactions between the facilities in operation and certain equipment in the facilities being

dismantled, which are currently still in use for operational purposes.

The decommissioning of the Tricastin facilities is progressing on the whole satisfactorily, notably in 2024 with the end of the detailed studies for decommissioning of the diffusion cascades in the Georges Besse I plant. However, Orano must improve management of the legacy material on the site, notably in BNI 105, where there is significant delay in removing materials and waste from storage in areas 61 and 79.

Legacy waste retrieval and conditioning and decommissioning on the La Hague site

The ASN assessments of each nuclear facility are detailed in the Regional Overview in this report.

CEA

Most French nuclear research facilities have been historically operated by the Alternative Energies and Atomic Energy Commission (CEA). Although some are still contributing to CEA's scientific and technical research programmes, a good number of them have been shut down and CEA is faced with major challenges in order to decommission them and manage the legacy waste satisfactorily.

ASN considers that the safety of the facilities operated by CEA is still under control but that the results of the projects to maintain the facilities in operation, decommission shutdown facilities, and legacy WRC projects still differ widely and remain exposed to potential major contingencies.

Despite the gradual reinforcement of the project management practices, performance remains limited by the resources available and by the operational capacity of the contractors in the sector. In addition, the operational reality of the worksites is nearly always more complex than anticipated, to the extent that an entire project is sometimes called into question, or at the very least the deadlines are significantly pushed back. In this respect, ASN considers that management of these projects remains a point warranting particular attention.

Finally, ASN deplores the fact that there was no significant improvement in 2024 regarding the organisation of emergency situations management, and the monitoring of outside contractors.

CEA's decommissioning and materials and waste management strategy

In order to keep track of the progress of the projects with the highest priority for safety, the authorities and CEA set up regular and high-level reporting of the deadlines with the greatest safety implications; ASN underlines the commitment by the CEA managers to the oversight and monitoring of these milestones. In 2024, CEA notably continued with the removal of a certain number of radioactive substances from its facilities that had been definitively shut down, which helped substantially reduce the residual risks. CEA notably started up the DECAP process to allow the moving of araldited fuel from storage in the Pégase facility to the Cascad facility and completed the

removal of fuel stored in the structures and pools of BNI 72. ASN however observes that CEA is encountering considerable difficulties with conducting the decommissioning operations on the facilities and with WRC, as well as with meeting the deadlines initially set. These delays are notably caused by technical or contractual difficulties. ASN also notes that its alerts regarding certain weaknesses in CEA's waste and effluent management strategy have led to no improvements. CEA is proposing no large-scale measures to safeguard this management, which is to a large extent based on unique facilities, for which there is no operational alternative, and which

therefore each determine the satisfactory performance of the numerous projects using them. In this respect, ASN is particularly attentive to the measures to be put into place by CEA following the civil engineering defects found in 2024 on the waste treatment station (BNI 37-A) located in the Cadarache centre.

ASN also notes that CEA's annual budget to finance provisions for nuclear costs is limited. If it wishes to finance unexpected spending for priority projects, this budgetary constraint could cause CEA to smooth the budget for lower priority projects, thus delaying their performance schedules.

Research facilities in operation

There are safety issues around the research facilities in operation linked to the development of their R&D activities (support for the current and future nuclear fleet), their activities to support other CEA facilities, and their being maintained in safe and operational conditions in compliance with the prescriptions stipulated further to their

periodic safety reviews (renovation and seismic reinforcement works, removal of radioactive substances and waste from storage, etc.). As with the decommissioning and waste management projects, ASN observes that CEA is encountering major difficulties with meeting the deadlines initially set for the refurbishment of old facilities or the removal

of legacy substances and waste present in these facilities.

The main new research facility project sponsored by CEA, the Jules Horowitz Reactor (JHR), is being carried out satisfactorily and transparently with regard to the safety issues.

BNI operations

Risk control and emergency management

ASN considers that the safety of the facilities is satisfactory. During the course of the inspections carried out in 2024, it nonetheless identified certain topics which require improvements. This mainly concerns the performance of periodic checks and tests, waste reconditioning operations, the safety of shielded cell handling operations and the traceability of outside contractor monitoring, and analysis of the results. For the year 2024, the number of significant safety-related events notified by CEA remains of the same order of magnitude as in 2023. A

large number of these notifications concern non-compliance with the frequency of performance of the periodic checks and tests mentioned in the BNI general operating rules. CEA shall pay particular attention to these subjects.

In 2024, for the Cadarache site, CEA notified ASN of further delays in the construction of all the emergency management buildings with enhanced robustness, in order to take account of the lessons learned from the accident at the Fukushima Daiichi NPP (Japan). These delays can mainly be explained by contractual difficulties being encountered by CEA and are

currently being investigated by the ASN departments. With regard to the Saclay site, CEA has finalised start-up of the facility housing the robust emergency situations management premises. In 2025, ASN will check that these premises are operational. With regard to the Marcoule centre, examination of the reinforcements envisaged by CEA or the emergency situations management building is continuing. Finally, the inspections carried out in 2024 showed that the CEA's national emergency management system needs to be improved, notably in terms of formalisation, traceability and control.

Personnel radiation protection

The operation of CEA's radiation protection expertise centres was inspected in 2024 and this showed that the organisation put into place for worker radiation protection, as well as the action taken for the performance of the duties of these centres, were satisfactory.

It should however be noted that the Significant Radiation Protection Events (ESRs) notified by CEA are up in 2024. As had been observed in 2023, a significant share of these deviations is related to problems with wearing of dosimeters. Half of these ESRs actually concern outside contractors. CEA must reinforce its actions to raise awareness among these workers.

Environmental protection

Control of detrimental effects and the impact on the environment by CEA's facilities, for the year 2024, is satisfactory. The number of significant environmental events notified in 2024 is of the same order of magnitude as in previous years, with no notable events.

ASN however considers that CEA must continue its efforts to take measures on several subjects associated with environmental protection and in particular upgrading of the network of piezometers, and management of the discharges continuous monitoring devices, notably with regard to pollution of soil and groundwater.

Since 2021, CEA has produced an inventory of the conformity of the outfalls from its facilities. An update of this inventory was provided in 2024 with regard to the outfalls from the Cadarache site. CEA also stated that it would be continuing its work to identify the corrective action to be taken. All of these points are currently being assessed by the French Institute for Radiation Protection and Nuclear Safety (IRSN). On the basis of its conclusions, ASN will be attentive to the pertinence of the measures finally adopted by CEA.

Finally, in 2024, CEA transmitted a consolidated impact assessment for the Cadarache centre and a limited impact assessment for that in Marcoule. These are currently being analysed by ASNR.

Safety reassessment of facilities

ASN considers that the organisation put into place by CEA to evaluate the conformity of its facilities and reassess their safety during the periodic safety reviews, is appropriate. The inspections carried out by ASN on the topic of the periodic safety reviews identified some points for improvement

which must be addressed by CEA, notably concerning monitoring of the action plan as a result of the periodic safety review. CEA will also have to continue its efforts in the coming years in order to comply with the schedule for implementation of the compliance and safety improvement work defined

by these periodic safety reviews, so that in all cases a new review can be started once the deployment of the action plan from the previous review has been completed.

Individual facility assessments

The ASN assessments of each centre and each nuclear facility are detailed in the Regional Overview in this report.

ANDRA

ASN notes a positive dynamic around the examination of the creation authorisation application file for the Cigéo deep geological repository, submitted on 16 January 2023 by the National Radioactive Waste Management Agency (Andra).

The Cigéo project

The technical examination of the Cigéo creation authorisation application continued in 2024, notably with two meetings of the Advisory Committee of Experts for Waste (GPD) during which the basic data and the hypotheses adopted to establish the safety case were examined, along with the safety of the facilities in the operations phase.

ASN considers that, without calling into question the design of Cigéo at this stage of the examination, Andra must provide additional data before excavation work begins, notably concerning the safety case for operation of bituminous waste disposal, the closure of the intermediate level, long lived vaults (ILW-LL) and the operation of the high level (HLW) vaults. ASN considers that Andra is reactive and

constructive in its responses during examination of this dossier, a point which was also underlined during the meetings of the GPD. These points confirm the demonstration that Andra has the technical capabilities needed to successfully complete the Cigéo project. In 2025, ASNR will continue its oversight of the management of the Cigéo project.

Operation of Andra's existing facilities

ASN considers that operating conditions in Andra's facilities remained satisfactory in the areas of nuclear safety, radiation protection and environmental protection in 2024. It also underlines the good quality of the safety assessments produced by Andra and the fact that the periodic

safety reviews of the disposal facilities are carried out satisfactorily. The evaluation of the long-term impacts on fauna and flora of the radiological and chemical substances in the disposal facilities, as well as the approach adopted to take account of organisational and human factors for all

of its activities and its operational implementation in these centres and head office departments, remain subjects for which management needs to be consolidated by Andra.

— ASN assessments by area for activity

THE MEDICAL SECTOR

On the basis of the inspections carried out in 2024 and of an analysis over the period enabling the entire base of facilities with safety implications to be covered, ASN considers that the state of radiation protection in the medical sector is being maintained at a satisfactory level, relatively comparable from one year to the next, although with a number of persistent shortcomings.

ASN notes that the clinical audit experiments started at the end of 2023, in radiotherapy and radiology only, under the control of the Ministry for Health, are being deployed satisfactorily but will need to be continued before they can be generally adopted. It encourages their extension to higher-risk activities, primarily radio-surgery, as well as therapeutic nuclear medicine, and urges the National Professional Councils (CNPs) to immediately mobilise in order to construct the audit tables. It also encourages the radiotherapy units to participate in the evaluation of the new practices, similarly to that put into place for adaptive radiotherapy. It encourages the CNPs to take account of the need to update the radiation protection training guides they produced, based on the results of the evaluation of the new patient radiation protection training system published by ASN in 2024.

ASN draws attention to the fact that the signals identified in 2023, and recalled below, lead to a deterioration in radiation protection culture. They are identified as a factor contributing to the occurrence of ESRs and are found during inspections to explain the fall in regulatory compliance:

- a finding that resources are on the whole shrinking, with pressure on radiographer (MERM), medical practitioner, medical physician staffing levels, with the expansion of temporary work and the postponement of tasks;

- in imaging, the use of insufficiently well-understood services to assist the Radiation Protection Expert-Officers (RPE-Os) and the medical physicians in the plants, liable to lead to a loss of radiation protection expertise and a lack of flexibility in implementing the regulation radiation protection requirements (training, verifications, etc.);

- constant growth in teleradiology with technical and organisational constraints linked to this type of organisation that are under-estimated by the facilities (communication problem, software interface); in 2025, ASNR will publish the lessons learned from a study it conducted on this subject;

- increasingly complex organisations, with sharing of resources and the risk of dilution of responsibilities, against a backdrop of health care authorisation reforms and buy-out of centres.

ASN thus maintains its demand for vigilance on the part of the decision-makers, regarding the need to assess the impact of these changes on the organisations and on the work of the participants and to precisely define the roles and responsibilities of all parties involved, so that the radiation protection requirements are met.

In radiotherapy, although the fundamentals of safety are in place, the radiotherapy departments are struggling to drive the experience feedback process, with fewer experience feedback committee meetings, insufficiently detailed ESR analyses and persistent difficulties with assessing the robustness of the corrective measures taken. The repetition of target errors (wrong-side, delineation or positioning errors in particular), the multiplication of simultaneous treatments of several locations, as well as re-irradiations, at a time when more and more patients will benefit from several radiotherapies during their lifetime, underlines the need on the one hand for regular assessment of the barriers in place, taking advantage of national Operating Experience Feedback (OEF), and, on the other, for updating of the preliminary risk assessments on the basis of local and national experience feedback. These studies are still insufficiently conducted upstream of technical and organisational changes.

In brachytherapy, the inspections confirm that the radiation protection rules are well taken into account. The challenges linked to maintaining the resources and skills needed for this activity will remain in the coming years. The new requirements concerning the protection of high-level sources against malicious acts are continuing to be gradually deployed, in particular through implementing a protection policy, measures to prevent unauthorised access to these sources and the identification and control of sensitive information. The situation is gradually improving although it cannot yet be considered to be conforming.

In nuclear medicine, the inspections indicate that patient radiation protection is adequately taken into account, through implementation of the optimisation principle with the collection and analysis of Diagnostic Reference Levels (DRLs), while underlining the fact that further progress is still required in the deployment of Quality Management Systems (QMS). The ESRs show that the administration processes must be regularly evaluated in order to ensure that the drug circuit is fully controlled, in particular those which could lead to errors involving several patients (use of the dose calibrator). ASN draws the attention of the entities Responsible for Nuclear Activities (RNAs) to the risk of extravasation with treatments using lutetium-177, which can lead to significant exposure on the injection site and, in collaboration with the professionals, is currently working on collecting experience feedback from the ESRs reported. It has also made available an “experience feedback” sheet concerning complications arising during liver cancer treatment by radioembolisation using yttrium-90. Particular attention must also be paid to management of the effluents (operation of the decay tank alarms) and the waste generated by the patients, linked to the emergence of new radiopharmaceuticals. Finally, despite progress regarding the training of professionals, a less satisfactory situation was observed in 2024 with regard to occupational radiation protection and monitoring of equipment and sources (analysis of dosimetry, verifications, coordination of prevention measures during concomitant activities).

In the field of Fluoroscopy Guided Interventional Practices (FGIPs) and more particularly in the operating theatre, regulatory nonconformities persist, year after year, whether the technical rules for layout of facilities, radiation protection training requirements for workers and patients, and coordination of prevention measures during concomitant activities. ASN observes that the centres are increasingly calling on Radiation Protection Organisations (RPOs), and that if insufficiently well managed, this subcontracting leads to a dilution of the responsibilities of the RNAs with less consideration for

and even deterioration of radiation protection. In addition, the inspections carried out on private practitioners employing staff reveal a lack of understanding of the regulatory radiation protection obligations in the Labour Code, with regard to both themselves and their employees. Finally, ASN found that several medical centres had not registered their X-ray emitting equipment and decided to initiate sanctions against a hospital.

In 2025, ASNR will continue with its inspections in the priority sectors, that is radiotherapy, radio-surgery, nuclear medicine, FGIP and computed tomography. In radiotherapy, after conducting a review involving all the stakeholders, ASNR will update its inspection guidelines and will start its new four-year inspection programme in 2025. In nuclear medicine, it will adapt the frequency of the inspections to take better account of the radiation protection issues, notably for departments carrying out clinical trials. In radiotherapy and nuclear medicine, based on the lessons learned from the ESRs reported in recent years, it will continue with specific inspections on management of the accelerator calibration process and verification of non-contamination respectively.

With regard to FGIPs, ASNR will continue with its targeted inspections on private practitioners employing staff. Finally, on the occasion of the work carried out to update ASN resolution 2019-DC-0667 on DRLs, having found inadequacies in correct use of Cone Beam Computed Tomography (CBCT) by dental surgeons as well as in the deployment of the optimisation approach, it will launch an inspections campaign in this field. It will thus provide the RNA with a chart enabling the dental surgeons to carry out a self-assessment.

In regulatory terms, ASNR will in 2025 review ASN resolution 2019-DC-0667 of 18 April 2019 setting DRL values to update the values applicable to mammography procedures and CBCT. It will continue the preparatory work for revision of ASN resolution 2008-DC-0095 of 29 January 2008 setting out the technical rules for the elimination of effluents and waste contaminated by radionuclides. In addition, ASNR will in 2025 publish the lessons learned from the study it is conducting on teleradiology.

Finally, the deployment of new therapy techniques and practices (radiotherapy, ITR) remains a subject requiring

particular vigilance. ASNR will continue its work together with the various institutional stakeholders in the health field, the learned societies, and with the help of the Advisory Committees of Experts, in particular the Committee for the Analysis of new Techniques and Practices using Ionising Radiation (Canpri), notably with regard to flash therapy and the project group set up to define the procedures for evaluating adaptive radiotherapy, which will be deployed as of 2025. In therapeutic nuclear medicine, radiation protection issues for the patient, their entourage, and the workers, the management of effluent and waste, are a priority against the backdrop of the emergence of new radiopharmaceuticals, projected growth in the number of patients eligible for these new treatments, with limited infrastructures and with the out-patient method being the preferred choice for health care. ASNR will issue an opinion at the beginning of 2025 on the basis of the work done by IRSN, the Advisory Committee of Experts for Radiation Protection (GPRP) and the lessons learned from the SimpleRad⁽¹⁾ project run by the European Commission.

THE INDUSTRIAL, VETERINARY AND RESEARCH SECTOR

The licensees of the industrial, veterinary and research sector are characterised by their diversity: they are numerous and carry out their activities in structures of widely varying size and status; they also use ionising radiation sources for a wide variety of applications. With regard to radiation protection, ASN's assessment of these licensees remains more or less unchanged and reflects a widely contrasting picture as in previous years.

Among the nuclear activities in the industrial sector, industrial radiography and more particularly gamma radiography are priority sectors for ASN oversight owing to their radiation protection implications. ASN observes that the vast majority of companies maintained the necessary degree of rigorousness to meet the regulatory obligations concerning the organisation of radiation protection, training and dosimetric monitoring of the workers, the use of operators holding the required Certificate of proficiency in handling industrial radiology devices (CAMARI) and maintaining gamma radiography devices. However, significant efforts are still required on the part of many companies to correctly define the programme of verifications required by the Labour Code, implement it, correct any nonconformities found on this occasion and ensure the traceability of the corrections made. If the risk of incidents and the doses received by the workers are on the whole well managed by the licensees when this activity is performed in a bunker in accordance with the applicable regulations, ASN is

still concerned by the observed shortcomings in the signalling of the operations area during on-site work, even if a slight improvement has been observed every year since 2022. ASN underlines that the lack of preparation and cooperation ahead of the work, between the ordering customers and the radiography contractors, is frequently one of the causes of these nonconformities. Progress is in particular needed regarding the content of the prevention plans, and familiarity with and implementation of the provisions contained in them. More generally, ASN considers that the ordering parties should, whenever possible, give priority to industrial radiography services in bunkers and not on the worksite. As recalled by the event that occurred in Colmar in the spring of 2024, the repercussions of a radiological incident (impossibility of returning the radioactive source to the secure position in the gamma ray projector) are often considerable given the precautions to be taken to manage it. When the radiographic inspection takes place in a bunker, the consequences of such incidents are far more limited, provided that

they are detected before someone enters the bunker and approaches the radioactive source. In this respect, in nearly one in three inspections in 2024 (bunkers and worksites), the operators did not correctly use their radiation meters to confirm that the radioactive source was actually in the safe position, from the moment they began to approach the gamma ray projector.

In the other priority sectors for ASN oversight in the industrial field (**industrial irradiators, particle accelerators including cyclotrons, suppliers of radioactive sources and devices containing them**) the state of radiation protection is considered to be on the whole satisfactory. With regard to suppliers, ASN considers that advance preparations for the expiry of the sources administrative recovery period (which by default is ten years), information for the purchasers regarding future source recovery procedures, and the checks prior to delivery of a source to a customer, are areas in which practices progressed by comparison with 2023, but still need to improve further.

1. SimpleRad – EANM EARL – Research4Life: earl.eanm.org/simplerad/

As for the distributors of accelerators or X-ray emitting devices, the monitoring tools that they put into place to identify the devices distributed and who acquired them often need to be reinforced, to avoid compromising any recall or OEF processes. The actions carried out by the licensees in recent years are continuing to improve radiation protection within the **research laboratories**, even if these efforts appear to be flagging somewhat. Correctly taking account of radiation protection is to a large extent based on the involvement of the radiation protection advisers and depends on the resources placed at their disposal. It should be recalled that the radiation protection issues in many research laboratories tend to be minor or are decreasing owing to the use of techniques other than those using ionising radiation. The conditions for the storage and elimination of waste and effluent remain the primary difficulties encountered by the research units or universities, including with regard to

the performance and traceability of checks prior to elimination, the recovery of “legacy” unused sealed radioactive sources or the regular elimination of stored radioactive waste. On these latter points, the lack of forward planning for the funding needed to manage “legacy” sources or waste and their prior characterisation if necessary, is often observed. In 2024, two significant events – both correctly managed – recalled that vigilance is required during maintenance of particle accelerators or in the event of any changes to their conditions of use. Finally, the facilities are also still experiencing difficulties in taking on board and correctly implementing checks on equipment, workplaces and instrumentation, as a result of changes to the Labour Code and Public Health Code in 2018, in particular in the case of joint research units.

With regard to the **veterinary uses of ionising radiation**, ASN can see the results of the efforts made by veterinary bodies

over the past few years to comply with the regulations, notably in conventional radiology activities on pets. For practices concerning large animals such as horses, or performed outside veterinary facilities, ASN considers that the implementation of radiological zoning and the radiation protection of persons from outside the veterinary facility who take part in the radiographic procedure, are points requiring particular attention.

There are however rare cases of veterinary structures with a highly unsatisfactory radiation protection organisation, which, if explanatory measures are not sufficient, may lead ASN to take more rigorous steps, or even enforcement measures.

In addition, the growing outsourcing of the RPE-O function, with large-scale use of RPOs from outside the facilities, must not lead to veterinarians abdicating their prime responsibility for the level of radiation protection in their facilities.

THE PROTECTION OF RADIATION SOURCES AGAINST MALICIOUS ACTS

The inspections conducted by ASN show that the licensees are gradually implementing the measures needed to comply with the requirements set out in the Order of 29 November 2019, more particularly when high-level radioactive sources or batches of equivalent sources are used.

Thus, on the basis of the inspections conducted in 2024:

- Source categorisation, an essential step in identifying the applicable requirements and implementing an approach proportionate to the risks, was carried out for the vast majority of facilities.
- The source protection policy, supported by the facility’s general management and promoting the concrete measures to be taken, leads to no comments on the part of ASN in two-thirds of the industrial facilities and half the medical facilities, which constitutes progress by comparison with previous years.
- Even if all the facilities inspected have taken steps to protect the sources, a little over half of them had not formally identified the physical barriers guaranteeing this protection, or demonstrated that they offered adequate intrusion resistance. On the other hand, only 20% of the medical facilities had carried out this analysis, which is a deterioration by comparison with the results of the inspections carried out in 2023.

- In one third of the industrial facilities and half the medical facilities, no preventive maintenance programme is defined for the equipment designed to detect intrusions. In addition, when there is a programme, it is only correctly implemented in less than half the facilities.
- The issue of nominative permits for access to sources has barely progressed and still needs to be implemented in nearly half the facilities.
- Half of the industrial facilities do not take steps to identify and protect sensitive information concerning source security. This finding is less severe for medical facilities, because only one third of them are in this situation, which is a clear improvement on 2023.

Compliance with the requirements set for source protection against malicious acts usually implies modifications to the facilities and organisational and human changes, which may prove costly given the resources available to the facility. In the gamma radiography sector for example,

ASN finds that the requirements for the protection of sources against malicious acts sometimes led the licensee to close certain facilities or branches to avoid having to upgrade them, with the result being increased operational constraints, notably longer transport times to the sites where the non-destructive inspections are to be conducted.

ASN asks the gamma radiography contractors to take greater account of this question in their responses to invitations to tender and in the preparation of their work. It also recalls that it is the responsibility of the ordering parties to ensure correct performance conditions for the inspections they order.

Overall, whether in the industrial or medical sector, ASN considers that considerable progress is still needed. In 2025, ASN will continue its actions to raise licensee awareness on these subjects.

TRANSPORT OF RADIOACTIVE SUBSTANCES

The Transport of Radioactive Substances (TSR) involves numerous players, the carriers of course, but also the consignors, the package designers and manufacturers, etc. The vast majority of shipments is linked to the needs of the non-nuclear industry, the medical sector or research.

ASN considers that in 2024, the safety of TSR is on the whole satisfactory, as in previous years. Although a few transport operations - mainly by road – did suffer incidents, these must be put into perspective against the 770,000 transport operations carried out each year.

The number of significant TSR events on the public highway is up on 2023, with a handful of events rated level 1 on the INES scale. This increase is essentially the result of events rated level 0 on the INES scale, with 16 more events than in 2023. This increase reflects increasing awareness on the part of the licensees of the good reasons for notifying a significant event. In 2024, nearly one quarter of the significant events notified to ASN concern road transport of radiopharmaceutical products, even if this proportion has fallen in recent years; a slight upturn in the number of events concerning the transport of gamma ray projectors is also observed.

On the whole, the events mainly comprise:

- material non-conformities affecting a package (notably damaged packaging) or its stowage on the conveyance, thereby weakening the strength of the package (whether or not an accident occurs). These cases do not concern transports of spent fuels or highly radioactive waste and primarily concern transports for small-scale nuclear activities;
- exceeding of the limits set by the regulations, usually by a small amount, for the dose rates or contamination of a package;
- errors or omissions in package labelling, mainly for transports concerning small-scale nuclear activities;
- delivery errors concerning radiopharmaceutical products. As these products are often similar from one hospital unit to another, most of them could be used for patient treatment without any impact.

The inspections carried out by ASN also frequently identify such deviations. The consignors and carriers must therefore demonstrate greater rigorousness in day-to-day operations.

With regard to **transports for Basic Nuclear Installations (BNIs)**, ASN finds that the licensees carry out numerous checks and are therefore better able to detect any deviations. Package tie-down, the radiological cleanness of the spent fuel packages, and the tightening of the

package screws remain points requiring particular vigilance, in particular at EDF. For BNIs performing research programmes, ASN considers that the consignors must further improve how they demonstrate that the contents actually loaded into the packaging comply with the specifications of the package model approval certificates and the corresponding safety files, notably when this demonstration is carried out by a third-party company. In addition, at the La Hague plant, Orano Recyclage reinforced the safety of on-site transports using mobile docking chambers (EMEM), capable of transporting samples, equipment or irradiating technological waste, adding mechanical protection and using a new transport trailer.

With respect to **transports concerning small-scale nuclear activities**, the ASN inspections confirm significant disparities from one carrier to another. The deviations most frequently identified concern the content and actual implementation of the worker radiation protection programme, the QMS, or actual compliance with the procedures put into place. The checks to be carried out prior to shipment of a package must therefore be improved. For example, the inspections concerning the transport of gamma ray projectors regularly reveal inappropriate stowage or tie-down.

At a time when the uses of radionuclides in the medical sector are generating a high volume of transport traffic, progress is still needed regarding familiarity with the regulations applicable to these transport operations and the arrangements made by certain hospitals or nuclear medicine centres for the shipment and reception of packages. The QMS have not yet been formally set out and deployed, more specifically with regard to the responsibilities of each of the personnel involved. ASN considers that the radiation protection of carriers of radiopharmaceutical products, who are significantly more exposed than the average worker, remains a point warranting particular attention.

For transport operations involving packages that do not require ASN approval, progress continues to be observed by comparison with previous years, along with better application of the recommendations given in ASN Guide No. 7 (volume 3). The improvements still to be made generally concern the description of the authorised contents per type of packaging, the demonstration that there is no loss or dispersion of the radioactive content under normal transport conditions, and that is impossible to exceed the applicable dose rate limits with the maximum authorised content.

Finally, ASN points out that TSR may be a limiting factor for certain projects, concerning both BNIs and small-scale nuclear activities (for example, the transport of irradiated targets needed for medical applications). In terms of forward planning, ASN therefore asks the licensees to exercise vigilance regarding packaging availability, if necessary ensuring that they are available in sufficient numbers, as well as the existence of other package models which could replace those normally used in the event of any problem affecting them.

Regulatory News



The year 2024 was marked by the publication of Act 2024-450 of 21 May 2024, relative to the organisation of nuclear safety and radiation protection governance, in order to address the challenges of the nuclear industry's renewal, and most of its implementing texts.

It also saw the completion of a certain number of important texts, in particular a Decree implementing Act 2023-491 of 22 June 2023 relative to the acceleration of the procedures linked to the construction of new nuclear installations in close proximity to existing nuclear sites and to the operation of the existing installations, and texts relating to protection against the risks from ionising radiation and prevention of the radon risk.

This year also saw continued work on revising the 7 February 2012 Order setting the general rules relating to Basic Nuclear Installations (known as the "BNi Order").

— National news

Acts and Ordinances

- **Act 2024-450 of 21 May 2024, relative to the organisation of nuclear safety and radiation protection governance, in order to address the challenges of the nuclear industry's renewal**

This Act follows on from the President of the Republic's speech in Belfort on 10 February 2022, which underlined the need to move away from fossil fuels by reducing energy consumption and through a large-scale acceleration in the production of decarbonised energy, electrical energy in particular: renewable energies, which were the subject of a specific Act (Act 2023-175 of 10 March 2023), and nuclear energy, notably with the construction of six new Pressurised Water Reactors (Evolutionary Power Reactor – EPR) by 2035.

The adoption on 22 June 2023 of Act 2023-491 accelerating administrative procedures will simplify and speed up the implementation of new nuclear power reactor construction projects in France, in close proximity to existing nuclear sites (construction of the future EPR 2 reactors on the Penly, Gravelines and Bugey sites).

In the light of the above-mentioned challenges, which will exert significant pressure on the competent public authorities, and in order to maintain excellence in the oversight of nuclear safety and radiation protection in the future, the Government wished to conduct a reorganisation of the

governance of nuclear safety and radiation protection, in order to respond to the unprecedented nuclear sector renewal process, both in terms of safety levels and the pace of the work to be done.

This change, as set out by Act 2024-450 is based on the creation of an independent civil nuclear and radiation protection Authority: the French Authority for Nuclear Safety and Radiation Protection (ASNR), combining the activities of the Nuclear Safety Authority (ASN) and the Institute for Radiation Protection and Nuclear Safety (IRSN), with the status of an independent administrative Authority.

ASNR will house all the activities contributing to the creation of efficient oversight and robust decision-making, which are split between ASN and IRSN: internationally reputed research, general and specialist expertise, inspection of installations and extensive knowledge of the field, contribution to drafting of regulations, enforcement and sanctions powers, management of emergency situations, environmental monitoring and information of the public. Furthermore, as in the previous system, ASNR will be able to call on Advisory Committees of Experts for an exchange of viewpoints.

Certain provisions of the Act require implementing Decrees and the adoption of the ASNR's internal rules of procedure, either currently under preparation or already published.

- **Constitutional Act 2024-448 of 21 May 2024, modifying Constitutional Act 2010-837 of 23 July 2010 relative to application of the fifth section of Article 13 of the Constitution**

This Act draws the consequences of the ASN and IRSN merger, with the status of an Independent Administrative Authority (AAI) and defines the procedures for appointing the ASNR Chairman, following on from the existing procedures for appointing the ASN Chairman and the IRSN General Director. It also states that this appointment is made by the President of the Republic in the conditions set out in the fifth section of Article 13 of the Constitution, that is “*further to the public opinion of the competent standing committee of each Assembly*”. Constitutional Act 2024-448 thus modifies the table appended to Constitutional Act 2010-837 of 23 July 2010 relative to application of the fifth section of Article 13 of the Constitution, on the one hand to supplement the reference to the Chairmanship of the Nuclear Safety Authority, which becomes the Authority for Nuclear Safety and Radiation Protection, and on the other, to delete the reference to the general directorate of the Institute for Radiation Protection and Nuclear Safety.

Decrees and Orders

- **Decree 2023-1261 of 26 December 2023 specifying the categories of operations linked to the construction of nuclear power reactors, which could be initiated as of issue of the environmental authorisation**

This Decree, issued in application of the provisions of III of Article 11 of Act 2023-491 of 22 June 2023 relative to the acceleration of the procedures related to the construction of new nuclear installations in close proximity to existing nuclear sites, and to the working of the existing installations, specifies the operations linked to the construction of a nuclear power reactor from among those which can only be performed following issue of the creation authorisation and those which can be initiated as of the date of issue of the environmental authorisation.

- **Decree 2024-296 of 29 March 2024 defining the notion of immediate proximity with respect to the measures to accelerate procedures linked to the construction of new nuclear installations in close proximity to existing nuclear sites and containing various procedural adaptations**

This Decree defines the notion of immediate proximity, which appears in Article 7 of Act 2023-491 of 22 June 2023 relative to the acceleration of the procedures linked to the construction of new nuclear installations in close proximity to existing nuclear sites and to the working of the existing installations, and specifies the framework for modifications to the environmental authorisation following issue of the nuclear power reactor creation authorisation pursuant to the provisions of Article 11 of the same Act.

- **Decree 2024-758 of 6 July 2024 relative to the assistance bonus for civil servants further to the creation of the Authority for Nuclear Safety and Radiation Protection**

This Decree creates an assistance bonus further to the creation of the Authority for Nuclear Safety and Radiation Protection, for the civil servants actively working at or delegated to Nuclear Safety Authority as at 1 November 2024. It specifies the conditions and procedures regarding payment.

• **Decree 2024-1103 of 3 December 2024, issued in application of the provisions of Article 14 of Act 2024-450 of 21 May, 2024, relative to the organisation of nuclear safety and radiation protection governance, in order to address the challenges of the nuclear industry's renewal**

Act 2024-450 of 21 May 2024, relative to the organisation of nuclear safety and radiation protection governance, in order to address the challenges of the nuclear industry's renewal, created a new independent administrative Authority, the Authority for Nuclear Safety and Radiation Protection (ASNR), which on 1 January 2025 replaces the Nuclear Safety Authority (ASN) and the Institute for Radiation Protection and Nuclear Safety (IRSN). The purpose of this Decree is to define the working procedures of the social dialogue bodies within the ASNR during the transitional period, before the creation of the ASNR's Administration Social Committee (CSA), which is to take place no later than 31 March 2026.

• **Decree 2024-1135 of 4 December 2024 relative to the qualifications and training of pharmacists using radiopharmaceutical drugs or active implantable medical devices, with unsealed sources emitting ionising radiation**

The purpose of this Decree is to regulate the conditions for access to the activity of radiopharmacist (pharmacists operating within the framework of authorised nuclear medicine activities), through the inclusion of a new regulatory provision to the Public Health Code, requiring issue of an Order to define the diplomas and levels of qualification or experience determining this access.

• **Decree 2024-1186 of 19 December 2024 relative to the transfer of employment contracts and secondments set out in II and III of Article 11 of Act 2024-450 of 21 May 2024 relative to the organisation of the governance of nuclear safety and radiation protection**

This Decree concerns the employees of the Institute for Radiation Protection and Nuclear Safety (IRSN) who, on 31 December 2024, were carrying out duties within the Institute's nuclear expert assessment division, or duties relative to the supply and operation of passive dosimeters. It is issued in application of II and III of Article 11 of Act 2024-450 of 21 May 2024 relative to the organisation of the governance of nuclear safety and radiation protection, and specifies the procedures for the transfer of the employment contracts of the above-mentioned employees to the French Alternative Energies and

Atomic Energy Commission (CEA) and the procedures for the secondment of certain of them to the Ministry of the Armed Forces.

• **Decree 2024-1194 of 19 December 2024 modifying various texts, to draw the consequences of the creation of the Authority for Nuclear Safety and Radiation Protection**

Act 2024-450 of 21 May 2024 relative to the organisation of the governance of nuclear safety and radiation protection in order to meet the challenges of the renewal of the nuclear sector, created a new independent administrative Authority, the Authority for Nuclear Safety and Radiation Protection (ASNR), which, as of 1 January 2025, replaces the Nuclear Safety Authority (ASN) and the Institute for Radiation Protection and Nuclear Safety (IRSN), to carry out oversight and regulation, expert assessment and research activities with regard to the nuclear safety of civil installations, as well as radiation protection. The Decree contains the necessary updates to the Environment Code, the Administrative Justice Code, the Transports Code, the Domestic Security Code, as well as the Decrees in force, to take account of ASNR replacing ASN and IRSN and the coexistence within this new entity of public and private sector employees.

• **Decree 2024-1203 of 23 December 2024 relative to the transfer of the assets, rights and obligations of the Institute for Radiation Protection and Nuclear Safety to the State and the French Alternative Energies and Atomic Energy Commission, and modifying the latter's activities**

This Decree organises the transfer of the assets, rights and obligations of the Institute for Radiation Protection and Nuclear Safety to the State and the French Alternative Energies and Atomic Energy Commission, and the legal conditions of this transfer. This text also specifies the procedures for producing, closing and approving IRSN's financial accounts for the 2024 financial year.

• **Decree 2024-1238 of 30 December 2024 relative to the protection of workers against the hazards of ionising radiation**

The creation of the Authority for Nuclear Safety and Radiation Protection (ASNR) on 1 January 2025 requires modification of all the Articles of the Labour Code which mention the Institute for Radiation Protection and Nuclear Safety (IRSN), replacing it with ASNR, except for passive dosimetry activities which are taken over by the Alternative Energies and Atomic Energy Commission. In addition to replacing the names of the IRSN and ASN by that of ASNR, certain provisions relative

to these duties must be changed to take account of the independent administrative Authority status of the new entity, and the merging within a single entity of regulation and expert assessment activities, as well as the provision of services to third parties against remuneration. This Decree also creates the "radiological safety zone", for particular situations and clarifies the approach for preventing the risk of occupational exposure to radon from the soil (radon directly generated by rocks in the soil or secondarily by water circulating through these rocks, or the materials extracted from these rocks). Finally, this Decree transforms the certificates of the Radiation Protection Advisors (RPAs) and Certificates of competence for the handling of industrial radiology equipment (CAMARI) into professional certifications consistent with common vocational training law as derived from Act 2018-771 of 5 September 2018 concerning the freedom to choose one's professional future. It also completes the recognition of the systems of radiation protection experts and operatives required by Directive 2013/59/Euratom of 5 December 2013.

• **Decree 2024-1240 of 30 December 2024 modifying various regulatory provisions relative to protection against ionising radiation**

This Decree draws the consequences of Act 2024-450 of 21 May 2024, relative to the organisation of nuclear safety and radiation protection governance, in order to address the challenges of the renewal of the nuclear sector, by modifying the provisions of the Public Health Code and the non-codified regulatory texts. Its purpose is notably to replace the former names of the Nuclear Safety Authority (ASN) and the Institute for Radiation Protection and Nuclear Safety (IRSN) by the new name Authority for Nuclear Safety and Radiation Protection (ASNR).

• **Decree 2024-1241 of 30 December 2024 relative to the conditions for the performance of remunerated activities by the departments of the Authority for Nuclear Safety and Radiation Protection and to the procedures for the approval of technical regulations issued by this Authority**

This Decree specifies the conditions in which the departments of the Authority for Nuclear Safety and Radiation Protection can carry out the activities set out in Article L. 592-14-2 of the Environment Code, the procedures for the approval of certain decisions set out in Article L. 592-20 of the same Code, as well as the conditions in which the results of research programmes set out in Article L. 592-28-2 of the same Code can be commercially exploited.

• **Decree 2024-1278 of 31 December 2024 relative to the remuneration and hourly compensation for on-call work and interventions within the Authority for Nuclear Safety and Radiation Protection**

The Nuclear Safety Authority (ASN) and the Institute for Radiation Protection and Nuclear Safety (IRSN) had two on-call and emergency situation organisations. The creation of the Authority for Nuclear Safety and Radiation Protection on 1 January 2025 requires modification of the texts governing on-call work, applicable only to public sector employees, to allow the operation of a single on-call organisation based on public sector and private sector employees, these latter being governed by IRSN's existing collective bargaining agreements. The proposed changes are also designed to allow harmonisation of the amount of the compensation received by public and private sector employees, as set out in Article 10 of the Act of 21 May 2024, relative to the organisation of nuclear safety and radiation protection governance, in order to address the challenges of the nuclear industry's renewal.

• **Order of 14 May 2024 relative to the protection of ionising radiation sources against malicious acts within the scope of responsibility of the Ministry of the Armed Forces**

In order to take account of the organisation of the specific working methods of the Ministry of the Armed Forces, this Order adapts several provisions of the Order of 29 November 2019, as amended, concerning the protection of ionising radiation sources and batches of radioactive sources of categories A, B, C and D against malicious acts. It takes up many of the provisions of the above-mentioned Order

of 29 November 2019, thus adopting an approach proportionate to the issues and ensuring consistency between the applicable requirements, whether the ionising radiation sources are held, used, or transported within the framework of civil or military nuclear activities.

• **Order of 15 May 2024 relative to radon risk prevention and the implementation of a radon zone and the corresponding checks, within the framework of the reinforced worker protection system**

This Order is issued in application of Article R. 451-35 of the Labour Code, to set the terms and conditions specific to radon from the soil for implementing the "radon zone" mentioned in Article R. 4451-23 of the Labour Code, and the technical conditions for ensuring the intermittent nature of this zone. It also stipulates certain provisions for the risk prevention and reduction approach, as well as implementation of the reinforced measures to prevent the radon risk. Man-made radon resulting from a professional activity (industrial processes, residues, waste, etc.) is not covered by this text.

• **Order of 6 August 2024 relative to the training of occupational physicians and other occupational health professionals providing reinforced individual monitoring of a worker exposed to ionising radiation and to the conditions for the issue of the supplementary approval of occupational health departments**

This Order is issued in application of Articles R. 4451-85 and R. 4451-86 of the Labour Code, to set the terms and conditions for the specific training and supplementary modules required for the occupational health professionals

mentioned in the first section of I of Article L. 4624-1 of the Labour Code, to allow supplementary approval of various types of occupational health departments for the performance of the reinforced individual monitoring set out in Article R. 4451-82 of the same Code and Article R. 717-16 of the Rural and Maritime Fishing Code.

• **Order of 10 December 2024 designating the restructuring operation within the Institute for Radiation Protection and Nuclear Safety entitling the staff to compensation and assistance**

This Order is relative to the reorganisation of the Institute for Radiation Protection and Nuclear Safety accounting office.

• **Order of 31 December 2024 relative to the transfer of assets, rights and obligations of the Institute for Radiation Protection and Nuclear Safety**

This Order is issued in application of Article 9 of Act 2024-450 of 21 May 2024, relative to the organisation of nuclear safety and radiation protection governance, in order to address the challenges of the nuclear industry's renewal.

Pursuant to the provisions of Decree 2024-1264 of 31 December 2024 relative to the immediate entry into force of Orders, the Order of 31 December 2024 enters into force with immediate effect as of its publication in the *Official Journal of the French Republic*, that is 1 January 2025.

• **Modification of the Order of 7 February 2012, setting the general rules concerning Basic Nuclear Installations ("BNI Order")**

The work to revise this Order continued in 2024.

— ASN resolutions

Basic Nuclear Installations

Reminder of a resolution issued in 2023 (included in the 2023 annual report), but approved in 2024:

• **ASN resolution 2023-DC-0770 of 7 November 2023 modifying ASN resolution 2017-DC-0616 of 30 November 2017 relative to noteworthy modifications to basic nuclear installations (approved by the Order of 9 February 2024 approving ASN resolution 2023-DC-0770 of 7 November 2023 modifying ASN resolution 2017-DC-0616 of 30 November 2017 relative to noteworthy modifications to basic nuclear installations)**

This resolution defines the requirements applicable to the noteworthy modifications made during the construction phase of a basic nuclear installation. Prior to this modification, resolution 2017-DC-0616 was in fact only applicable to the modifications made after commissioning of the installations.

This resolution in particular defines the list of modifications subject to notification

during the construction phase and those requiring ASN authorisation. It also adapts certain criteria concerning the notification system, to take account of lessons learned from application of resolution 2017-DC-0616 since it entered into force on 1 July 2019.



Regional overview

of nuclear safety and radiation protection

ASN, the French Nuclear Safety Authority, has **11 regional divisions** through which it carries out its regulatory duties throughout metropolitan France and in the French overseas *départements* and regions.

Several ASN regional divisions may have to coordinate their work in a given administrative region.

As at 31 December 2024, the ASN regional divisions comprise 222 employees of whom 168 are inspectors.

Under the authority of the regional representatives (see chapter 2), the ASN regional divisions carry out on-the-ground inspections of the Basic Nuclear Installations (BNIs), of Radioactive Substance Transport (TSR) operations and of small-scale nuclear activities; they examine the majority of the licensing applications submitted to ASN by those Responsible for Nuclear Activities (RNAs) within their regions. For these activities and in these facilities, they check application of the regulations relative to nuclear safety, radiation protection, Pressure Equipment (PE) and Installations Classified for Protection of the Environment (ICPEs). They ensure the labour inspection in the Nuclear Power Plants (NPPs).

In radiological emergency situations, the ASN regional divisions check the on-site measures taken by the licensee to place the facility in a safe condition and they assist the Prefect of the *département*, who is responsible for protecting the public. To ensure preparedness for such situations, they participate in the development of the emergency plans drawn up by the Prefects and in the periodic exercises.

The ASN regional divisions contribute to the mission of informing the public. They take part, for example, in the meetings of the BNI Local Information Committees (CLIs) and maintain regular relations with the local media, elected officials, associations, licensees and local administrations.

This section of the Report presents ASN's oversight action in each region and its assessment of nuclear safety and radiation protection.

Actions to inform the public and cross-border relations are addressed in chapters 5 and 6 respectively.

IMPORTANT

Oversight of small-scale nuclear activities (medical, research and industry, transport) is presented in chapters 7, 8 and 9.

Medical sector
Chapter 07



Research and industry
Chapter 08



Transport sector
Chapter 09



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Auvergne-Rhône-Alpes

The Lyon division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 12 *départements* of the Auvergne-Rhône-Alpes region.

339

inspections

23

significant events
rated level 1
or higher

ASN conducted 339 inspections in the Auvergne-Rhône-Alpes region in 2024, of which 115 were in the Bugey, Saint-Alban, Cruas-Meysses and Tricastin Nuclear Power Plants (NPPs), 100 in plants, research facilities and sites being decommissioned, 89 in small-scale nuclear activities, 15 in the Radioactive Substance Transport (TSR) sector, and 20 in organisations and laboratories approved by ASN.

ASN also carried out 22 days of labour inspections in the four NPPs and on the Creys-Malville site.

In 2024, 21 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES) were reported to ASN, of which 19 occurred in BNIs and two in small-scale nuclear activities.

Furthermore, one Significant Radiation Protection Event (ESR) at the Tricastin NPP was rated level 2 on the INES scale and one event involving the irradiation by error of a healthy zone of a patient during a radiotherapy treatment was rated level 2 on the ASN-SRO scale (scale specific to radiation protection events affecting patients undergoing a radiotherapy procedure).

Lastly, inspection of one industrial radiography company resulted in the ASN inspectors issuing a violation report concerning the conditions of prevention of the occupational risks associated with ionising radiation. This same inspection detected a potential case of fraud in the provision of a service, which was reported to the Public Prosecutor under Article 40 of the Penal Procedure Code.

— Bugey site

The Bugey industrial site comprises various facilities, including the Bugey NPP operated by EDF on the municipality of Saint-Vulbas in the Ain *département*, 35 km east of Lyon. It comprises four Pressurised Water Reactors (PWRs), each with a power of 900 Megawatts electric (MWe), commissioned in 1978 and 1979. Reactors 2 and 3 constitute BNI 78 and reactors 4 and 5 constitute BNI 89.

The site also accommodates Bugey 1, a graphite-moderated Gas-Cooled Reactor (GCR) commissioned in 1972, shut down in 1994 and currently undergoing decommissioning, the Activated waste conditioning and interim storage facility (Iceda) and the Inter-Regional Warehouse (MIR) for fuel storage.

Lastly, the site accommodates one of the regional bases of the Nuclear Rapid Intervention Force (FARN), the special emergency response force created by EDF in 2011 following the Fukushima Daiichi NPP accident in Japan. Its role is to intervene in pre-accident or accident situations, on any NPP in France, by providing additional human resources and emergency equipment.

Bugey nuclear power plant

Reactors 2, 3, 4 and 5 in operation

ASN considers that the performance of the Bugey NPP with regard to nuclear safety, radiation protection and environmental protection is in line with ASN's general assessment of the EDF plants.

With regard to nuclear safety, ASN notes that the facilities have been operated and maintained relatively satisfactorily despite an industrial programme with a particularly heavy workload. The fourth ten-yearly outage of reactor 3, the last for the site, was affected by many unforeseeable difficulties which considerably extended its duration. ASN discovered several deviations in the management of Pressure Equipment (PE) in 2024, particularly during this fourth ten-yearly outage, revealing the weaknesses in this area. The

configuring of systems and the management of periodic tests and requalification tests have been the subject of EDF improvement plans since 2023, which must be continued. Nevertheless, ASN noted improvements in prevention of the risk of introducing foreign materials and management of the fire risk compared with the previous years.

ASN considers that the radiation protection performance of the NPP is improving and is now in line with ASN's general assessment of EDF plant performance. Although occupational exposure is controlled, ASN nevertheless still notes shortcomings in the radiation protection culture of the workers. Improvements are also required in the tracking of the radiation protection measuring aids provided for the workers and the cordoning off of zones that are, or risk becoming, contaminated.

ASN also considers that the NPP's performance in environmental protection has improved and is now in line with its general assessment of the EDF plants. Problems with leaks in retention structures which led to bypassing of the normal discharge routes in 2023 - without harming the environment - are still waiting for a long-term solution. ASN considers that the waste management remains at a satisfactory level; the site must nevertheless continue the actions initiated on the management of storage facilities.

With regard to occupational health and safety, ASN considers the site's results to be satisfactory, despite the high workload of the industrial programme. Appropriate measures were put in place reactively to take account of the accident levels during the year. ASN notes however that particular attention must be paid to the risks associated with lifting operations.

Reactor 1 undergoing decommissioning

Bugey 1 is a GCR. The first-generation reactor used natural uranium as the fuel, graphite as the moderator and was cooled by gas.

The facility decommissioning operation were authorised by decree in 2008, but in 2022 EDF requested its amendment to take into account a radical change in decommissioning strategy for the GCRs. This request is currently being reviewed by the French Authority for Nuclear Safety and Radiation Protection (ASNR).

In 2024, EDF continued the decommissioning of the buildings, equipment and systems that are not necessary for reactor vessel decommissioning in application of ASN Chairman's resolution CODEP-CLG-2020-021253 of 3 March 2020. Today this work has been completed, apart from the demolition of some structures and the putting out of service and decommissioning of the plant for treating effluents originating from the installation, pending completion of the commissioning tests of the new replacement facility built between 2022 and 2024. Alongside this, the licensee also continued work on the installation in view of the future operations, notably by adapting certain ventilation systems and fitting out a waste sorting and conditioning unit.

ASN considers that the Bugey 1 reactor decommissioning operations are proceeding under satisfactory conditions of safety and radiation protection. In the area of occupational radiation protection, the licensee must nevertheless continue its actions to control the risk of internal exposure from alpha-emitting radionuclides.

Activated waste conditioning and storage facility

The Activated waste conditioning and interim storage facility (Iceda), which constitutes BNI 173, is intended for the conditioning and storage of various categories of radioactive waste on the Bugey site (in the Ain *département*). It is designed for the reception, conditioning and storage of:

- low-level long-lived (LLW-LL) graphite waste from the dismantling of the Bugey 1 reactor, intended – after interim storage – for near-surface disposal in a facility which is still at the concept study stage;

The installations and activities to regulate comprise:



- **Nuclear Power Plants operated by EDF:**
 - Bugey (4 reactors of 900 MWe),
 - Cruas-Meysses (4 reactors of 900 MWe),
 - Saint-Alban (2 reactors of 1,300 MWe),
 - Tricastin (4 reactors of 900 MWe);
- **the nuclear fuel fabrication plants operated by Framatome in Romans-sur-Isère;**
- **the "nuclear fuel cycle" plants operated by Orano on the Tricastin industrial platform;**
- **EDF's Tricastin Operational Hot Unit (BCOT) undergoing decommissioning;**
- **the High Flux Reactor (RHF) operated by the Laue-Langevin Institute in Grenoble;**
- **the Activated waste conditioning and storage facility (Iceda) on the Bugey nuclear site and the Bugey Inter-Regional Warehouse (MIR) for fuel storage operated by EDF;**
- **reactor 1 undergoing decommissioning at the Bugey NPP operated by EDF;**
- **the EDF Superphénix reactor undergoing decommissioning and its auxiliary installations;**
- **the Ionisos irradiator in Dagneux;**
- **the international research centre of the European Organisation for Nuclear Research (CERN), situated on the French-Swiss border;**

• small-scale nuclear activities in the medical sector:

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- 23 external-beam radiotherapy departments,
- 6 brachytherapy departments,
- 23 nuclear medicine departments,
- 123 centres performing fluoroscopy-guided interventional procedures,
- 170 computed tomography scanners in 120 facilities,
- some 10,000 medical and dental radiology devices,

• small-scale nuclear activities in the industrial, veterinary and research sectors:

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- 1 synchrotron,
- about 490 veterinary practices (surgeries or clinics),
- 34 industrial radiography agencies,
- about 600 users of industrial equipment,
- about 75 public or private research units;

• activities associated with the transport of radioactive substances;

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• ASN-approved organisations and laboratories:

- 1 organisation and 3 agencies approved for radiation protection verifications under the Public Health Code,
- 13 laboratories approved for environmental radioactivity measurements,
- 11 organisations approved for taking radon activity concentration measurements under the Public Health Code.

- intermediate-level long-lived (ILW-LL) activated metallic waste from operation of the in-service NPPs, for example parts installed near the reactor core such as the control rod clusters, intended for deep geological disposal after interim storage;
- certain types of low-level or intermediate-level short-lived waste (LL/ILW-SL), baptised “deferred dispatch” waste, intended for above-ground disposal but necessitating a period of radioactive decay ranging from a few years to a few tens of years before being accepted at the Aube repository (CSA – BNI 149), operated by the French National Radioactive Waste Management Agency (Andra).

By letter of 5 May 2021, EDF submitted to the Minister responsible for nuclear safety a request to amend the Iceda Creation Authorisation Decree (DAC), to allow the acceptance of decommissioning waste from the Fessenheim NPP, which is currently being examined by ASN.

The year 2024 was marked by a long production-free period, scheduled to continue until March 2025. The licensee devoted this time to maintenance operations, operator training,

updating of the facility’s baseline operating requirements and applying technical modifications in order to integrate the lessons learned from the first production campaigns.

Based on the inspections conducted in 2024, ASN considers that safety and radiation protection are duly taken into account in the operation of Iceda. The licensee must make sure that this good level of operating quality is maintained over time when the production operations resume and increase in intensity.

Inter-regional warehouse

The inter-regional warehouse (MIR – BNI 102) operated by EDF at Bugey is a storage facility for fresh nuclear fuel intended for the NPP fleet in operation.

ASN conducted an inspection in 2024 to check the licensee’s periodic verifications and its meeting of the commitments made to ASN. The inspection conclusions are positive and ASN deems the meeting of commitments to be satisfactory.

SAINT-ALBAN NUCLEAR POWER PLANT

The Saint-Alban NPP, operated by EDF in the Isère département on the municipalities of Saint-Alban-du-Rhône and Saint-Maurice-l’Exil, 40 km south of Lyon, comprises two 1,300 MWe PWRs commissioned in 1986 and 1987. Reactor 1 constitutes BNI 119 and reactor 2 BNI 120.

ASN considers that the nuclear safety and environmental protection performance of the Saint-Alban NPP is in line with ASN’s general assessment of EDF plant performance. Its radiation protection performance stands out positively with respect to this general assessment.

With regard to nuclear safety, ASN finds that the site’s facilities are operated and maintained satisfactorily despite a context of intense industrial activity. ASN considers that the reactor refuelling outages were carried out under suitably safe conditions with a well-managed activities schedule. The safety-significant activities such as preventive cleaning of the reactor 1 Steam Generators (SGs) were carried out in accordance with the safety and environmental protection requirements. With regard to reactor operation, monitoring in the control room and operating team skills management are satisfactory.

With regard to occupational radiation protection, ASN considers the operational results to be satisfactory. ASN’s tightened inspection in this area and the site’s results indicators have revealed an improvement in the radiation protection culture and rigour in marking out worksites.

Regarding protection of the environment, ASN considers that the handling of unforeseen technical issues affecting the environmental protection devices is improving. The site’s facilities are in satisfactory technical condition, which prevented the surrounding environments from being harmed in loss of liquid effluent containment situations.

In the area of occupational health and safety, ASN observes that the site is continuing the deployment of national actions, particularly with regard to electrical risks, lifting operation risks and the implementation of a tool for better managing the asbestos risk. Specific measures relating to the lead contamination risk have been successfully implemented on the site. Thanks to the vigilance applied during the outages in 2024, the accident rate low remained low.

CRUAS-MEYSSE NUCLEAR POWER PLANT

Commissioned between 1984 and 1985 and operated by EDF, the Cruas-Meyssse NPP is situated in the Ardèche *département* on the municipalities of Cruas and Meyssse and comprises four PWRs of 900 MWe each. Reactors 1 and 2 constitute BNI 111 and reactors 3 and 4 constitute BNI 112.

ASN considers that the performance of the Cruas-Meyssse NPP with regard to nuclear safety, radiation protection and environmental protection is in line with ASN's general assessment of the EDF plant performance.

With regard to nuclear safety, ASN considers that the large number of significant events related to inappropriate actions during operational operations reveals inadequacies in activity preparation and monitoring or incomplete operating documents. ASN therefore considers that the operating rigour improvement plan put in place by EDF in 2023 and prolonged in 2024 must be pursued. From the maintenance aspect, the site is tackling an intense industrial programme with a significant increase in the number of maintenance activities,

particularly during the fourth ten-yearly outage of reactor 3 and the replacement of its SGs. This ten-yearly outage began in August 2024 and is proceeding with satisfactory levels of safety and a well-managed activities schedule.

Concerning radiation protection, improvements in practices were observed in 2024 compared with the preceding years, particularly in the management of containment air locks and worksite zones. The radiation protection controls on leaving the reactor building have been reinforced.

ASN notes that the site's environmental protection results are stable with respect to 2023. Control of liquid containment and the prevention effluent spillages remain the main areas in which ASN wants to see improvements.

The site's occupational health and safety results are satisfactory. ASN has nevertheless identified a point concerning occupational safety that requires particular attention, namely compliance with working times, given the intensity of the industrial programme.

— Tricastin site

The Tricastin nuclear site, situated in the Drôme and Vaucluse *départements*, is a vast industrial site accommodating the largest concentration of nuclear and chemical facilities in France. It is situated on the right bank of the Donzère-Mondragon Canal (a diversion channel of the river Rhône) between Valence and Avignon. It occupies a surface area of 800 hectares covering three municipalities, namely Saint-Paul-Trois-Châteaux and Pierrelatte in the Drôme *département*, and Bollène in the Vaucluse *département*. The site harbours a large number of installations, with a nuclear power plant comprising four 900 MWe reactors, "nuclear fuel cycle" facilities, and a facility which fulfilled maintenance and storage functions and is now undergoing decommissioning.

Tricastin nuclear power plant

The Tricastin NPP comprises four 900 MWe PWRs: reactors 1 and 2, commissioned in 1980, constitute BNI 87, while reactors 3 and 4, commissioned in 1981, constitute BNI 88.

ASN considers that the nuclear safety performance of the Tricastin NPP is in line with ASN's general assessment of EDF plant performance. Its radiation protection performance, however, is considered to be below the general assessment of the EDF power plants. Lastly, ASN considers that the plant's environmental protection performance has improved thanks to the implementation of an ongoing action plan in this area.

As regards nuclear safety ASN considers that the plant's performance remains satisfactory. With regard to operational management of incidents and accidents and emergency situation organisation and means, ASN considers that the operating teams' knowledge of the instructions and equipment is satisfactory. As far as routine operating activities are concerned, however, weaknesses have been observed in system configuration management and the associated lockout/tagout operations, and in control room monitoring. With regard to maintenance, the marking event in 2024 was the fourth ten-yearly outage of reactor 4, the last

of these outages for the site, which ran satisfactorily. For the other two reactor outages performed in 2024, ASN considers that EDF carried out the planned activities proficiently, complying with the corresponding safety requirements. ASN nevertheless expects to see improvements in the application of the regulatory requirements associated with work on PE.

The radiation protection performance of the Tricastin NPP shows some weak points, particularly concerning radiological cleanliness during the reactor outages. This situation led to several ESRs, one of which was rated level 2 on the INES scale after a site employee received a dose to the skin that could exceed the authorised annual limit. ASN expects to see improvements in worksite preparation, in the monitoring of radiological cleanliness and in practices for checking workers for contamination on leaving worksites involving a contamination risk.

With regard to environmental protection, ASN considers that the site's organisation to meet the regulatory requirements in this area has improved. This area is covered by an action plan that is presented regularly to ASN and the site's results have progressed.

As regards occupational safety, ASN considers the site's results to be satisfactory but not as good as in 2023. In effect, although no event led to serious consequences for the workers, the number of minor accidents is increasing.

THE “NUCLEAR FUEL CYCLE” FACILITIES

The Tricastin “fuel cycle” facilities mainly cover the upstream activities of the “fuel cycle” and are operated by Orano Chimie-Enrichissement, called “Orano” hereinafter.

The site comprises:

- **the TU5 facility** (BNI 155) for converting uranyl nitrate $\text{UO}_2(\text{NO}_3)_2$ resulting from the reprocessing of spent fuels into triuranium octoxide (U_3O_8);
- **the W plant** (ICPE within the perimeter of BNI 155) for converting depleted uranium hexafluoride (UF_6) into U_3O_8 ;
- **the former Comurhex facility (BNI 105) and the Philippe Coste plant** (ICPE within the perimeter of BNI 105) for converting uranium tetrafluoride (UF_4) into UF_6 ;
- **the former Georges Besse I plant** (BNI 93) for the enrichment of UF_6 by gaseous diffusion;
- **the Georges Besse II plant** (BNI 168) for centrifuge enrichment of UF_6 ;
- **the uranium storage areas** at Tricastin (BNIs 178, 179 and 180) for storing uranium in the form of oxides or UF_6 ;
- **the maintenance, liquid effluent treatment and waste conditioning facilities** (IARU – BNI 138);
- **the Atlas process samples analysis and environmental monitoring laboratory** (BNI 176);
- **a Defence Basic Nuclear Installation (DBNI)**, which more specifically accommodates former facilities undergoing decommissioning, radioactive substance storage areas and a liquid effluent treatment unit.

Following the inspections it conducted in 2024, ASN considers that the level of safety of the Orano facilities on the Tricastin site is satisfactory. ASN noted an improvement in the organisation for monitoring conformity with regulatory texts, better tracking of commitments made to ASN and efforts to be continued in the closing of modification files. The inspections of the organisational setup to prevent irregularities and fraud showed that the planned measures are applied.

In 2024, ASN conducted a campaign of simultaneous unannounced inspections focusing on occupational radiation protection in BNIs 93, 138, 155, 168, then in BNI 105, with the aim of checking Orano's organisation in this area. To this end the inspectors visited the facilities to verify the operational practices. These inspections found that the licensee had made progress in this area.

To ensure progress in dealing with the backlog of diverse radioactive substances stored on the site, ASN has asked Orano to present an annual progress report on its action plan for addressing this issue. In 2024, ASN continued its monitoring of the operations to prepare for the gradual clearing of areas 61 and 79 of BNI 105. These operations began very slowly and in 2024 Orano put into service various items of equipment capable of improving the conditioning of the substances for transfer to the site's storage yards.

The Tricastin site has two main liquid effluent management facilities: the Chemical Effluents Treatment Station (STEC – DBNI) and the Uranium-containing Effluents Treatment Station (STEU – BNI 138). Orano is planning for substantial changes in the treatment of the effluents from the Tricastin platform and has started to provide the Safety Options Dossiers (DOS) for these projects. These projects will ultimately lead to facilities ensuring better performance and higher safety standards.

In 2023, Orano started work on the AMC2 project which consists in adding a new facility for washing and rinsing containers dedicated to the transport of UF_6 . This facility was authorised by Decree 2023-1220 of 19 December 2023.

In addition, to increase its enrichment capacities, Orano started construction work in 2024 to extend the Georges Besse II (GB II) North enrichment plant, which underwent a prior consultation in 2023. In June 2023, Orano submitted the application for a substantial modification to the facility authorisation decree in order to build this extension. The public inquiry was held in April 2024.

Lastly, Orano plans building the two other buildings of the reprocessed uranium storage facility “FLEUR” (BNI 180), whose commissioning was authorised by ASN in January 2023.

Orano's uranium chemistry plants TU5 and W

The “TU5” plant (BNI 155) can handle up to 2,000 tonnes of uranium per year, enabling it to reprocess all the uranyl nitrate ($\text{UO}_2(\text{NO}_3)_2$) produced by the Orano plant at La Hague, converting it into U_3O_8 , a stable solid compound guaranteeing safer uranium storage conditions than in liquid or gaseous form. Once converted, the reprocessed uranium is placed in storage on the Tricastin site. The W plant situated within the perimeter of BNI 155 can process the depleted UF_6 from the GB II enrichment plant, to stabilise it as U_3O_8 .

ASN considers that the facilities situated within the perimeter of BNI 155 are operated with a satisfactory level of safety. In 2024, ASN nevertheless kept careful track of the licensee's actions to maintain the operating rigour of its facilities.

ASN has noted a delay in the submission of the files associated with the consequences of the project to increase the capacity of the GB II North plant on the activities of the W plant. Orano has changed the schedule of these projects and the Authority for Nuclear Safety and Radiation Protection (ASNR) will be attentive to the conditions of work performance in the W plant, as it will to the management of the depleted uranium on the site should an offset in production capacity between the W plant and the GB II enrichment plant be maintained.

Orano uranium fluorination plants

Pursuant to the ASN requirement, the oldest fluorination facilities were shut down definitively in December 2017. The shut down facilities have since been emptied of the majority of their hazardous substances and are now being decommissioned.

The decommissioning of BNI 105 is authorised by Decree 2019-1368 of 16 December 2019 and should be completed by 31 December 2034. The main issues associated with decommissioning concern the risks of dissemination of radioactive substances, as well as exposure of the workers to ionising radiation and the criticality risk, on account of the residual uranium-bearing substances present in some items of equipment.

ASN notes that the decommissioning operations on the BNI part are falling behind schedule due to operational difficulties. Further to ASN's requests and inspections, the licensee has started transferring the radioactive and hazardous substances from areas 61 and 79 to the site's storage areas that meet today's safety standards. Areas 61 and 79 of BNI 105 were not completely emptied by the end of 2024 as planned. This is because the necessary reconditioning operations and the modalities of on-site transport started late and with sometimes inappropriate technical means, even though in 2024 Orano gradually put into service various items of equipment capable of improving the conditioning of the substances for transfer to the site's storage yards. ASNR will continue its tightened monitoring of these operations and now expects Orano to ensure rigorous technical and time frame management of the project.

ASN considers that the level of safety of the Philippe Coste uranium fluorination plant is satisfactory. ASN checked progress of the modernisation of the support functions in 2024. The works to replace the old surface treatment facility and the on-line fluorine conditioning facility have begun. On the other hand, the design of non-uranium-bearing effluent treatment units is still at the project stage.

Georges Besse I enrichment plant

The Georges Besse I (Eurodif) uranium enrichment facility constituting BNI 93 consisted essentially of a plant for separating uranium isotopes using the gaseous diffusion process.

After this plant stopped production in May 2012, the licensee implemented the "intensive rinsing followed by air venting" operations (Prisme operation) from 2013 to 2016. These operations allowed the extraction of virtually all the residual uranium deposited in the diffusion barriers. The main residual risk of BNI 93 is now associated with the UF₆ containers in the storage yards, which are still attached to the perimeter of the installation. These yards should in the short term be attached to the Tricastin uranium storage yards (BNI 178).

The Decree ordering Orano to proceed with the decommissioning of the Georges Besse 1 plant was published on 5 February 2020. The decommissioning issues particularly concern the large volume of very low-level waste (VLLW) produced, including 160,000 tonnes of metal waste which is undergoing specific studies.

The licensee continued the decommissioning preparation operations in 2024, dismantling certain equipment items and conducting investigations to enhance knowledge of the residual contamination, and starting the works associated with the future unit in which the facility's 1,400 diffusers will be cut up and conditioned in packages.

In 2024, ASN also gave its approval for the dismantling of the facility's two cooling towers. The dismantling of these towers by mechanical "nibbling" should begin in 2025.

ASN considers that the BNI 93 decommissioning operations were carried out under satisfactory conditions of safety and radiation protection in 2024.

Georges Besse II enrichment plant

The Georges Besse II (GB II) plant, which constitutes BNI 168, has been the site's enrichment facility since the Georges Besse I plant was shut down. It separates uranium isotopes using the centrifugation process.

The standard of safety of the plant's facilities in 2024 was satisfactory. The technologies used in the facility enable high standards of safety, radiation protection and environmental protection to be achieved. Refrigerant losses into the atmosphere dropped significantly in 2024 compared with 2023, but the hot weather temperatures were not as high in 2024.

In 2022, Orano began the project to extend the GB II North enrichment plant in order to increase its production capacities by adding centrifuge modules. The GB II North plant extension project underwent a prior consultation from 1 February to 9 April 2023, organised by the French National Commission on Public Debate (CNDP). In June 2023, Orano submitted the substantial modification application file in order to build this extension. This extension project underwent a public inquiry in April 2024 and construction work began in September 2024. ASN conducted a first inspection in December with satisfactory results.

Maintenance, effluent treatment and waste conditioning facilities

The effluent treatment and uranium recovery facility (IARU), which constitutes BNI 138, ensures the treatment of liquid effluents and waste, as well as maintenance operations for various BNIs.

The level of safety in the BNI's various units in 2024 was satisfactory. ASN notes positively the fact that the treatment capacity of the new waste treatment unit can now absorb the waste from the site's temporary storage areas. ASN also considers that fire risk prevention is improving. Lastly, the commissioning of building 57L in 2024 improves the safety of certain storage areas.

Orano is planning for substantial changes in the treatment of the effluents from the Tricastin platform and has started to provide the DOS's for these projects. These projects will ultimately lead to facilities ensuring better performance and higher safety standards. The periodic safety review of BNI 138 obliged Orano to consider creating new units for certain effluent treatment steps given the technical/economic impossibility of reinforcing or improving the existing facilities. ASNR will remain attentive to the progress of these projects.

Tricastin uranium-bearing material storage yards, P35 and FLEUR

Following the delicensing of part of the Pierrelatte DBNI by decision of the Prime Minister, the Tricastin uranium-bearing materials storage yards (BNI 178) were created. This installation groups the uranium storage yards and the platform's new emergency management premises.

Following on from this delicensing process, facility "P35" (BNI 179) was created. It comprises ten uranium storage buildings. An additional storage area called "FLEUR" was authorised by a Decree of 18 March 2022. Commissioning of this new BNI (BNI 180) was authorised by ASN resolution 2023-DC-0750 of 3 January 2023.

At the end of the periodic safety review of the yards, ASN ordered complementary measures in its resolution CODEP-CLG-2023-012740 of 8 March 2023. Among these measures figure the emptying or the decommissioning of material packagings.

ASN considers that the level of safety of the storage yards in 2024 was satisfactory. In 2024, these yards started accepting some of the substances removed from storage in BNI 105, which necessitated some rearrangements.

In mid-2023, Orano started work on the AMC2 project which consists in adding a new facility for washing and rinsing containers dedicated to the transport of UF_6 . This facility will replace the existing AMC which is situated in the DBNI. The creation of AMC2 was authorised by Decree 2023-1220 of 19 December 2023 following a public inquiry held from 10 December 2021 to 12 January 2022. ASN's inspection of this worksite led to requests for several justificatory documents which will be examined before commissioning, planned for 2025.

Lastly, Orano plans building the two other buildings of the reprocessed uranium storage facility "FLEUR" (BNI 180), whose commissioning was authorised by ASN in January 2023.

— Romans-sur-Isère site

Framatome nuclear fuel fabrication plants

On its Romans-sur-Isère site in the Drôme *département*, Framatome operates BNI 63-U, baptised "Nuclear fuel fabrication plant" resulting from the merging of two old BNIs, namely the unit fabricating fuel elements for research reactors (formerly BNI 63) and the unit fabricating nuclear fuel for the PWRs (formerly BNI 98).

The fabrication of fuel for nuclear power plant reactors involves transforming UF_6 into uranium oxide powder. The pellets fabricated from this powder in Framatome's Romans-sur-Isère plant are placed in zirconium metal clads to constitute the fuel rods, then brought together to form the fuel assemblies to be used in the NPP reactors. In the case of experimental reactors, the fuels are more diverse, with some of them using, for example, highly-enriched uranium in metal form. These fuels are also fabricated in the Romans-sur-Isère plant called "Cerca".

The Cerca plant features a "uranium zone" in which the compacted powder cores placed in aluminium frames and plates to form the fuel elements are produced, as are the irradiation targets for the production of medical radionuclides. The licensee has undertaken to replace this "uranium zone" by a "new uranium zone" called NZU, in order to improve more specifically the containment of the premises, the process and the prevention of risks in the event of an extreme earthquake. The NZU construction work began in late 2017. These new buildings shall accommodate the current activities of the existing "uranium zone". Due to technical problems and the impact of the

Covid-19 pandemic, the NZU construction work has fallen significantly behind schedule. In 2022, Framatome applied to ASN for a partial commissioning authorisation for the NZU to enable it to transfer materials between the existing buildings and the NZU. ASN issued this authorisation in October 2022. Difficulties with the tests of certain equipment items arose in 2023, leading Framatome once again to postpone commissioning of the NZU until 2024. Framatome mobilised its forces in order to put the NZU into service and in November 2024 ASN authorised commissioning of the process equipment.

In 2024, Framatome conducted further fuel production campaigns with Enriched Reprocessed Uranium (ERU). An application for a substantial modification to the unit fabricating nuclear fuels for PWRs, with the aim of increasing the production of fuels based on ERU is currently being reviewed by ASN and underwent a public inquiry in February 2024.

Based on the inspections it conducted in 2024, ASN considers that the level of safety of the Framatome facilities is satisfactory. However, after discovering a situation of noncompliant storage of inflammable liquid waste, ASN had to tighten its monitoring of the compliance work which obliged the licensee to temporarily transfer the waste in question to a safer building on the site pending procurement of technical means appropriate for the risks specific to this liquid waste. More broadly, Framatome gave ASN confirmation of its intention to apply an action plan to reduce the quantities of waste stored on the site, an issue that will be addressed in the periodic safety review, which is currently being examined.

THE INDUSTRIAL AND RESEARCH FACILITIES

High flux reactor of the Laue-Langevin Institute

The Laue-Langevin Institute (ILL), an international research organisation, accommodates a 58 Megawatt thermal (MWth) heavy-water High-Flux Neutron Reactor (RHF) which produces high-intensity thermal neutron beams for fundamental research, particularly in the areas of solid-state physics, neutron physics and molecular biology.

The RHF constitutes BNI 67 and occupies a surface area of 12 hectares between the rivers Isère and Drac, upstream of their confluence, near the CEA Grenoble centre.

After operating for a little over one year, the RHF began a long outage in July 2024 to incorporate various modifications to improve the safety of the facility, the need for which was detected at its last periodic safety review. This involves large scale works, including in particular the installation of a sprinkler fire extinguishing system in part of the reactor building and reinforcing the seismic resistance of the polar crane in accordance with ASN resolution 2022-DC-0738 of 28 July 2022.

In 2024, ASN also finalised the review of the public information notice transmitted by the licensee in July 2022 in order to establish new technical requirements for discharges and environmental monitoring. The associated new draft ASN resolutions underwent a public consultation in late 2024 and have been sent to the Local Information Committee (CLI) of the ILL for its opinion. The procedure should be concluded in 2025.

In view of the oversight actions it conducted in 2024, ASN considers that the RHF is operated safely and radiation protection is satisfactory. The site's challenges in 2025 will particularly concern the correct performance of the work planned during the outage and dealing with the residual tritium inventory from the former detritiation facility, to be completed by 30 June 2025.

Ionisos irradiator

The company Ionisos operates an industrial irradiator in Dagneux, situated in the Ain *département*. This irradiator, which constitutes BNI 68, uses the radiation from cobalt-60 sources for purposes such as sterilising medical equipment (syringes, dressings, prosthesis) and polymerising plastic materials.

The licensee submitted the periodic safety review concluding report for BNI 68 to ASN in 2017. ASN completed its analysis of this report in 2024 and has no objection to the continued operation of the facility.

In October 2021, the licensee filed an application for authorisation to build a new irradiator. This application is currently being reviewed by ASNR. The construction of this new facility also requires the licensee to finalise the Post-Operational Clean-Out (POCO) and dismantling of the site's old irradiators D1 and D2.

In 2024, the licensee renewed and reorganised the teams responsible for safety following several concomitant personnel departures in 2023 which had weakened its organisation. The new organisation is now in place and in September 2024 the licensee submitted to ASN an action plan to ensure the facility's conformity with the BNI regulations.

ASN considers that the operational safety of the facility was broadly satisfactory in 2024, given the risks it presents. The licensee must nevertheless, without further delay, finalise the updating of the facility's operating baseline requirements following its periodic safety review and the operational implementation of certain requirements.

CERN accelerators and research centre

Following the signing of an international agreement between France, Switzerland and the European Organisation for Nuclear Research (CERN) on 15 November 2010, ASN and the Swiss Federal Office of Public Health (OFSP) – the Swiss radiation protection oversight body – are contributing to the verification of the safety and radiation protection requirements applied by CERN, including with regard to nuclear waste management and TSR.

CERN is not directly subject to Swiss or French regulations, but it must implement the best practices with regard to international regulations, standards and recommendations.

Two joint inspections by the Swiss and French authorities were held in 2024 on the themes of protecting workers against ionising radiation and periodic inspections and tests respectively. These inspections found the practices to be satisfactory.

SITES UNDERGOING DECOMMISSIONING

Superphénix reactor and fuel storage facility

The Superphénix fast neutron reactor (BNI 91), a 1,200 MWe sodium-cooled industrial prototype is situated at Creys-Malville in the Isère *département*. It was definitively shut down in 1997. The reactor has been unloaded and the majority of the sodium has been neutralised and conditioned in concrete blocks. Superphénix is associated with another BNI, the Apec fuel storage facility (BNI 141). The Apec essentially comprises a pool containing the fuel unloaded from the reactor pressure vessel and the area for storing the soda concrete packages resulting from neutralisation of the sodium from Superphénix.

In 2018, ASN authorised commencement of the second Superphénix decommissioning phase, which consists in opening the reactor pressure vessel to dismantle its internal components. In 2024, the licensee finalised the decommissioning of the reactor core closure plug and extracted the lateral neutron shield support – a massive activated and particularly irradiating part – from the reactor vessel, for cutting up in a dedicated unit using remotely-operated means.

Alongside the decommissioning operations, the licensee has started a major equipment obsolescence management programme, mainly concerning BNI 141, which in the coming years will lead to the replacement of the pool cooling system air heaters, the emergency diesel generator sets and complete renovation of the instrumentation and control of BNI 141.

In view of the inspections conducted in 2024, ASN considers that the safety of the Superphénix reactor decommissioning operations and of operation of the fuel storage facility is ensured satisfactorily.

Tricastin Operational Hot Unit

The Tricastin Operational Hot unit (BCOT) constitutes BNI 157. Operated by EDF, it was intended for the maintenance and storage of equipment and tooling, fuel elements excluded, originating from contaminated systems and equipment of the nuclear power reactors. The BCOT is situated in the Orano's Tricastin site.

In a letter dated 22 June 2017, EDF declared final shutdown of the BCOT in June 2020 and its decommissioning was authorised by Decree 2023-1049 of 16 November 2023. On completion of decommissioning, planned for 31 December 2033 at the latest, the cleaned-out buildings shall be returned to Orano.

EDF completed the removal of obsolete tools and decontamination and transfer of the cylindrical control rod cluster guide tube containers to Andra's Industrial centre for collection storage and disposal (Cires) in 2024. The licensee also carried out work to prepare the facility for the next decommissioning operations and continued investigations into the radiological status of the structures with a view to cleaning them out. On 22 March 2024, ASN authorised deployment of the facility's decommissioning baseline safety requirements.

In view of the conclusions of the two inspections of the BCOT in 2024, ASN considers its level of safety to be satisfactory.

Bourgogne-Franche-Comté

The Dijon division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 8 *départements* of the Bourgogne-Franche-Comté region.

60

inspections

ASN conducted 60 inspections in small-scale nuclear activities in the Bourgogne-Franche-Comté region in 2024, comprising 21 inspections in the medical sector, 24 in the industrial, research and veterinary sectors, seven concerning radon exposure, four to monitor approved organisations and laboratories, and four specific to the transport of radioactive substances.

ASN also devoted particular attention to the Framatome nuclear pressure equipment manufacturing plants situated in the Bourgogne-Franche-Comté region. The actions conducted by ASN in this context are described in chapter 10. ASN carried out ten inspections in these plants in 2024, of which five were in the Creusot plant and five in the Chalon Saint-Marcel plant.

In 2024, the company Jimmy Energy submitted to the Ministry responsible for nuclear safety an application for authorisation to create a plant for assembling fuel elements for its high-temperature Small Modular Reactor (SMR) project (see box page 330 of chapter 11) at Le Creusot, in the Saône-et-Loire *département*.

The installations and activities to regulate comprise:



• small-scale nuclear activities in the medical sector:

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- 8 external-beam radiotherapy departments,
- 4 brachytherapy departments,
- 16 nuclear medicine departments, of which 3 practise internal targeted radiotherapy,
- 36 centres practising fluoroscopy-guided interventional procedures,
- 64 computed tomography scanners for diagnostic purposes in 51 centres,
- about 800 medical radiology devices,
- about 2,000 dental radiology devices;

• small-scale nuclear activities in the industrial, veterinary and research sectors:

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- about 250 veterinary practices, of which 5 have a computed tomography scanner and 16 practice equine radiology,
- about 400 industrial and research centres, including 27 companies with an industrial radiography activity,
- 1 industrial irradiator using radioactive sources,
- 1 computed tomography scanner dedicated to research,
- 2 accelerators, 1 for the production of drugs for medical imaging and 1 for industrial irradiation;

• activities associated with the transport of radioactive substances;

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• ASN-approved organisations and laboratories:

- 1 organisation approved for radiation protection controls,
- 5 organisations approved for measuring radon,
- 1 laboratory approved for taking environmental radioactivity measurements.

Bretagne

The Nantes division regulates radiation protection and the transport of radioactive substances in the 4 *départements* of the Bretagne region. The Caen division regulates the nuclear safety of the Brennilis Nuclear Power Plant (NPP), currently undergoing decommissioning.

61
inspections

1
significant event
rated level 1
or higher

In 2024, ASN carried out 61 inspections, three at the Monts d'Arrée NPP currently being decommissioned, 13 in the transport of radioactive substances and 41 in small-scale nuclear activities (21 in the medical sector, 20 in the industrial, veterinary and research sectors) and four concerning natural radioactivity (radon).

In 2024, one significant event in the veterinary sector was rated level 1 on the International Nuclear and Radiological Event Scale (INES scale). The failure of an electrical device emitting ionising radiation resulted in a worker being exposed to more than a quarter of the annual regulatory limit.

Lastly, in the course of their inspection duties the ASN inspectors issued one violation report to a company for taking radon measurements without the requisite approval.

BRENNILIS NUCLEAR POWER PLANT

The Brennilis NPP is situated in the Finistère *département*, on the Monts d'Arrée site 55 km north of Quimper. Baptised "EL4-D", this installation (BNI 162) is an industrial electricity production prototype (70 Megawatt electric – MWe), moderated with heavy water and cooled with carbon dioxide, and it was definitively shut down in 1985.

Decree 2011-886 of 27 July 2011 authorised the NPP decommissioning operations, with the exception of the reactor block. In July 2018, EDF submitted an application file for the complete decommissioning of its facilities, and this file was subject to a technical review followed by a public inquiry from 15 November 2021 to 3 January 2022. Decree 2023-0898 of 26 September 2023, published on 28 September 2023, requires EDF to completely decommission BNI 162 and amends Decree 96-978 of 31 October 1996 authorising the creation of this facility.

ASN issued the authorisations to implement the general operating rules and the on-site emergency plan for complete decommissioning in June 2024. During 2024, ASN also continued updating of the resolutions regulating the plant's water discharges and intakes which were published on 21 November 2024. Consequently, in 2024, ASN issued all the authorisations necessary for deployment of the complete decommissioning operations.

During the same year, EDF continued its preparatory work for complete decommissioning, including in particular civil engineering adaptations in preparation for decommissioning of the peripheral systems, planned as of 2025.

The installations and activities to regulate comprise:



• one Basic Nuclear Installation:

- the Monts d'Arrée (Brennilis) NPP, undergoing decommissioning;

• small-scale nuclear activities in the medical sector:

- 9 external-beam radiotherapy departments,
- 5 brachytherapy departments,
- 11 nuclear medicine departments,
- 36 centres practising fluoroscopy-guided interventional procedures,
- 63 computed tomography scanners for diagnostic purposes,
- some 2,500 medical and dental radiology devices;

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• small-scale nuclear activities in the industrial, veterinary and research sectors:

- 1 cyclotron,
- 15 industrial radiography companies, including 3 performing gamma radiography,
- 23 research units,
- about 400 users of industrial, veterinary and research devices;

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• activities associated with the transport of radioactive substances;

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• ASN-approved organisations and laboratories:

- 8 organisations approved for measuring radon,
- 3 head-offices of a laboratory approved for environmental radioactivity measurements.

ASN notes that the discovery of asbestos is delaying the upgrading of the handling cranes necessary for removal of the reactor vessel fuel channels, without yet calling into question the date of start of operations, planned for 2027.

Broadly speaking, ASN considers that the management of the NPP decommissioning project remains satisfactory. Nevertheless, concerning the state of the facilities, EDF must ensure that all the infiltrations are dealt with and guarantee the upgrading of the facilities with respect to the fire risk within the planned times. EDF must also continue its actions to better control the temporary storage conditions and to define management routes for the waste than cannot be removed immediately.

Within the framework of the national inspection campaign on frauds, ASN also notes that the licensee must improve its organisation to counter this risk.

In 2025, the Authority for Nuclear Safety and Radiation Protection (ASNR) shall be particularly attentive to the application of the facility's new complete decommissioning baseline requirements and to equipment maintenance. ASNR shall moreover maintain its vigilance concerning the radiation protection plan, particularly regarding compliance with the rules for entering controlled areas.

Centre-Val de Loire

The Orléans division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 6 *départements* of the Centre-Val de Loire region.

170	12
inspections	significant events rated level 1 or higher

In 2024, ASN conducted 170 inspections in the Centre-Val de Loire region, of which 123 were in the nuclear installations of the EDF sites of Belleville-sur-Loire, Chinon, Dampierre-en-Burly and Saint-Laurent-des-Eaux, 38 in small-scale nuclear activities, four in the transport of radioactive substance and five concerning approved organisations or laboratories.

ASN also carried out 39 days of labour inspections in the four Nuclear Power Plants (NPPs) of the region.

In 2024, ASN was notified of 11 significant events rated level 1 and one event rated level 2 on the International Nuclear and Radiological Event Scale (INES scale).

BELLEVILLE-SUR-LOIRE NUCLEAR POWER PLANT

The Belleville-sur-Loire NPP is situated in the north-east of the Cher *département*, on the left bank of the river Loire, at the crossroads of four *départements* (Cher, Loiret, Nièvre and Yonne) and two administrative regions (Bourgogne-Franche-Comté and Centre-Val de Loire). The NPP has two 1,300 Megawatt electric (MWe) reactors commissioned in 1987 and 1988, which constitute Basic Nuclear Installations (BNIs) 127 and 128 respectively.

ASN considers that the performance of the Belleville-sur-Loire NPP is in line with the general assessment of EDF in the areas of nuclear safety, the environment and radiation protection.

From the nuclear safety aspect, ASN considers that with regard to management of the facilities, operational rigour in the control room was maintained at a satisfactory level. ASN nevertheless considers that the NPP must continue its efforts in the management of system configurations (alignments, padlocking, administrative lockouts) through the action plan it has applied since early 2023.

As far as the maintenance of the facilities is concerned, the performance of the Belleville-sur-Loire NPP is considered satisfactory. More particularly, ASN considers that the management of the reactor 2 outage in 2024 was broadly satisfactory.

In the area of radiation protection, ASN considers that the action plan deployed implemented by the Belleville-sur-Loire NPP to reinforce the radiation protection fundamentals is appropriate. Its robustness will be assessed during the 2025 inspections, particularly during the reactor outages.

With regard to environmental protection, effluent management and the monitoring of discharges are deemed satisfactory. ASN notes positively the commissioning of the new legionella and amoeba treatment station. It will keep track of the renovation of the site's demineralisation station, which was delayed due to an incident that led to a spillage of hydrochloric acid inside this station, with no consequences for persons or the environment. Regarding nuclear waste management, ASN notes that the anomalies observed in early 2024 concerning the temporary storage of concrete shells in the effluent treatment building were resolved during the year.

In the area of labour inspection, ASN notes that no serious accidents occurred. Nevertheless, although the inspections have revealed progress in electrical risk prevention, ASN expects the site to take strong measures regarding prevention of the chemical risk in of its findings on the subject in 2024.

DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT

The Dampierre-en-Burly NPP is situated on the right bank of the Loire river, in the Loiret *département*, about 10 km downstream of the town of Gien and 45 km upstream of Orléans. It comprises four 900 MWe nuclear reactors which were commissioned in 1980 and 1981. Reactors 1 and 2 constitute BNI 84, and reactors 3 and 4 BNI 85. The site accommodates one of the regional bases of the Nuclear

Rapid Intervention Force (FARN), the special emergency response force created by EDF in 2011 following the Fukushima Daiichi NPP accident (Japan). Its role is to intervene in pre-accident or accident situations, on any NPP in France, by providing additional human resources and emergency equipment.

ASN considers that the nuclear safety performance of the Dampierre-en-Burly NPP is below ASN's general assessment of EDF plant performance. The radiation protection and environmental performance is broadly in line with ASN's general assessment of the EDF plants.

With regard to nuclear safety, following the significant deterioration observed in reactor operational management in 2022, the licensee implemented a rigorous recovery plan. Several measures to improve the performance of the service responsible for reactor operational management were thus applied during 2023 and 2024. Improvements were observed in 2024, notably in the management of the facilities in compliance with the General Operating Rules (RGEs) and in documentation management. Efforts are however still required to align the site's performance with the national average, particular regarding the management of configuration changes and control of reactivity. The in-depth inspection carried out by ASN in June 2024 also revealed the strong involvement of the site's managerial line in the turnaround in safety performance. The various actions of the recovery plan must now be fully assimilated and implemented in the field by all personnel involved.

With regard to maintenance of the facilities, the Dampierre-en-Burly NPP's performance is in line with the national average, in a high workload context marked by the fourth ten-yearly outage of the site's reactor 4. The site must nevertheless be particularly attentive to the quality of the first-level analyses, which aim to rule on the conformity of the maintenance operations performed and on the conducting of preventive maintenance at the specified intervals. Further to the technical difficulties encountered in 2023 on the emergency diesel generator sets, the licensee took measures in 2024 to improve the availability of these generators, even though some difficulties appear to subsist.

In the area of radiation protection, the performance of the Dampierre-en-Burly NPP is in line with the national average and has remained stable with respect to 2023. Although the site has one of EDF's lowest rates of worker contamination, progress must still be made in the management of the radiological work regimes, in the performance of the radiological checks of equipment leaving controlled areas – numerous hot spots were detected in 2023 and 2024 on the site's roadways – and in the management of the marking out of limited-stay areas.

The environmental protection performance of the Dampierre-en-Burly NPP remained at a good level in 2024, particular as regards management of the microbiological risk, management of copper and zinc discharges in the liquid effluents and waste management. The site must nevertheless continue its work to improve the containment of hazardous substances and undertake the necessary actions to increase the number of effluent storage tanks to take into account the effects of climate change and the ageing of the existing tanks.

The installations and activities to regulate comprise:



• Basic Nuclear Installations:

- the Belleville-sur-Loire NPP (2 reactors of 1,300 MWe),
- the Dampierre-en-Burly NPP (4 reactors of 900 MWe),
- the Saint-Laurent-des-Eaux site: the NPP in operation (2 reactors of 900 MWe), and the 2 Gas-Cooled Reactors (GCRs) undergoing decommissioning and the irradiated graphite sleeve storage silos,
- the Chinon site: the NPP in operation (4 reactors of 900 MWe), the 3 GCRs undergoing decommissioning, the Irradiated Material Facility (AMI) and the Inter-Regional Fuel Warehouse (MIR);

• small-scale nuclear activities in the medical sector:

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- 9 external-beam radiotherapy departments,
- 3 brachytherapy departments,
- 11 nuclear medicine departments,
- 31 centres using interventional procedures,
- 38 centres using one or more diagnostic computed tomography scanners,
- some 2,700 medical and dental radiology devices;

• small-scale nuclear activities in the industrial, veterinary and research sectors:

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- 15 companies with an industrial radiography activity,
- about 330 industrial, veterinary and research radiography devices;

• activities associated with the transport of radioactive substances;

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• ASN-approved organisations and laboratories:

- 1 organisation approved for radiation protection controls,
- 5 laboratories approved for taking environmental radioactivity measurements.

With regard to labour inspection, although the deviations found in the employment of young workers were rectified by reactive corrective actions, ASN considers that the management of the workplace airing and sanitation systems also requires corrective actions and close involvement of the site. Following the deviations observed when ASN inspected the employment conditions of employees of outside contractors working on the site, several work contracts were regularised. ASN also notes that there were no serious accidents on the site in 2024.

– Chinon site

Situated in the municipality of Avoine in the Indre-et-Loire *département*, on the left bank of the river Loire, the Chinon site accommodates various nuclear installations, some in operation, others undergoing decommissioning. On the south side of the site, the Chinon B NPP comprises four in-service reactors of 900 MWe; the first two commissioned in 1982 and 1983 constitute BNI 107, while the second two commissioned in 1986 and 1987 constitute BNI 132. To the north, the three old graphite-moderated GCRs designated Chinon A1, A2 and A3, are currently being decommissioned. The site also accommodates MIR and the irradiated materials facility AMI which is currently being decommissioned and whose former expert assessment activities have been transferred to a new laboratory at Chinon called “Lidéc”.

Chinon nuclear power plant

Reactors B1, B2, B3 and B4 in operation

ASN considers that the environmental performance of the Chinon NPP stands out positively, while the nuclear safety and radiation protection performance is in line with ASN's general assessment of the EDF plants.

With regard to nuclear safety, ASN considers that the results for 2024 are in line with the average for the NPPs but show a decline compared with 2023. The reason for this is that although performance in the area of operational management of the reactors remained at a satisfactory level, improvements are required in the management of the fire risk and the availability of systems involved in controlling reactivity.

The site's performance in maintenance of the facilities deteriorated over the year 2024. The equipment items inspected appear to be in good condition but the quality of the first-level analyses has regressed and several events have brought to light a lack of skills or training of the actors involved.

ASN considers that the radiation protection performance of the Chinon NPP is progressing. The level of worker contamination remains among the lowest of the EDF NPPs. The measures taken in response to the difficulties encountered in performing industrial radiography work in the last few years seem to have borne fruit in 2024. ASN nevertheless notes an increase in the number of triggerings of radiation portal monitors at the site exit and in the detection of contamination on the site roads, despite some progress being observed.

The environmental performance of the Chinon NPP is progressing and ranks among the best of the EDF plants. The site controls its discharges and the containment of hazardous liquid substances. Waste management however remains below expectations. The year 2025 should be used to continue the treatment and removal of the waste resulting from reactor maintenance that has been accumulating on the site for several years.

The year 2024 was marked by numerous accidents requiring labour inspection investigations by ASN, which revealed the need to improve some worksite procedures. ASN considers that the site must improve worksite preparation, particularly

by taking full account of all risks, such as those related to potential asbestos and lead exposure. Lastly, ASN notes that the site has made significant efforts to address the risk of falls from height, through the implementation of a verification of all relevant collective protection measures.

Reactors A1, A2 and A3 undergoing decommissioning

The graphite-moderated GCR series comprises six reactors, including Chinon A1, A2 and A3. These first-generation reactors used natural uranium as the fuel, graphite as the moderator and were cooled by CO₂ gas. This plant series includes “integrated” reactors, whose heat exchangers are situated under the reactor core inside the vessel, and “non-integrated” reactors, whose heat exchangers are situated on either side of the reactor vessel. The Chinon A1, A2 and A3 reactors are “non-integrated” GCRs. They were shut down in 1973, 1985 and 1990 respectively.

Reactors A1 and A2 have been partly decommissioned and transformed into facilities for the storage of their own equipment (Chinon A1 D and Chinon A2 D). These operations were authorised by the Decrees of 11 October 1982 and 7 February 1991 respectively. Chinon A1 D is partially decommissioned at present and has been set up as a museum – the Museum of the Atom – since 1986. Chinon A2 D is also partially decommissioned and, until the end of 2022, housed GIE Intra (robots and machines for interventions on accident-stricken nuclear installations). Complete decommissioning of the Chinon A3 reactor was authorised by the Decree of 18 May 2010, with a decommissioning “under water” scenario.

In March 2016, EDF announced a complete change of decommissioning strategy for its definitively shut down reactors. In this new strategy, the planned decommissioning scenario for all the reactor pressure vessels involves decommissioning “in air”⁽¹⁾ and the Chinon A2 reactor pressure vessel would be decommissioned first (see chapter 14). In this context, ASN has analysed the periodic safety review concluding reports submitted by EDF concerning the six GCRs, supplemented further to the request from ASN. On completion of its analysis, ASN indicated in December 2021 that it has no objection to the continued operation of BNIs 133 (Chinon A1 reactor), 153 (Chinon A2 reactor) and 161 (Chinon A3 reactor). The Authority for Nuclear Safety and Radiation Protection (ASNR) will verify,

1. Among the possible scenarios for decommissioning the highly activated or contaminated structures, we find decommissioning “in air” and decommissioning “under water”. In the case of the GCRs, the “under water” approach consists in filling the reactor core (reactor pressure vessel) with water in order to benefit from the protective effect of a layer of water with respect to the radiation-related risks, but it is more complicated to implement than the “in air” approach. In view of the major technical difficulties (sealing of the reactor pressure vessel and treatment of the contaminated water), but also the technological advances bringing other solutions, such as remote operation, EDF has finally adopted the decommissioning “in air” scenario, which overcomes the problems linked to the use of water.

during the examination of the decommissioning files for these reactors, submitted by EDF at the end of 2022 and still being examined, that the decommissioning operations will be carried out under suitable conditions of safety and radiation protection, within controlled time frames.

For the Chinon A2 reactor, in 2024, EDF continued the decommissioning preparation operations situated outside the reactor pressure vessel, particularly as concerns removal of the shells from the heat exchanger premises, and continued the investigations inside the pressure vessel. The shells have been removed from the four heat exchanger rooms. EDF also continued the decommissioning of the Chinon A3 heat exchangers.

The action plan undertaken by EDF following water infiltrations in several parts of Chinon A1, Chinon A2 and the AMI (BNI 94) in 2023 turned out to be insufficient to prevent new infiltrations during a heavy storm episode in June 2024. This plan has subsequently been reinforced, in particular through additional curative and preventive measures, such as waterproofing work and updating the emergency procedures in the event of a weather alert. ASN considers that EDF must continue its efforts to improve the monitoring and management of infiltrations and the civil engineering structure maintenance work. ASN will be particularly attentive to the implementation of the action plan in 2025.

ASN considers that the level of safety of the Chinon nuclear installations undergoing decommissioning (Chinon A1, A2 and A3) is satisfactory. The inspections carried out in 2024 revealed good preparation of the decommissioning worksites, good upkeep of a worksite to ensure safe conditions linked to the asbestos risk and meeting the defined schedules. Furthermore, the organisation in place to prevent and address the risk of counterfeiting, falsification and suspicions of fraud was found to be operational and capable of dealing with the situations encountered. Lastly, additional information is required to clarify the lists of applicable Protection Important Components (PICs) for protection of the interests.

"NUCLEAR FUEL CYCLE" FACILITIES

Inter-regional fresh fuel warehouse

Commissioned in 1978, the Chinon Inter-Regional Fuel Warehouse (MIR) is a facility for storing fresh fuel assemblies pending their utilisation in various EDF reactors. It constitutes BNI 99. Along with the Bugey MIR, it contributes to the management of flows of fuel assembly supplies for the reactors.

The facility was equipped with a new handling crane in 2019 and operations have resumed since 2020, with the reception and storage of fresh fuel assemblies. EDF reported no significant events in 2024 and responded to the requests made further to the inspection conducted in 2023. The second periodic safety review concluding report is to be given to ASN in 2025 and the facility will undergo an inspection.

RESEARCH FACILITIES UNDERGOING DECOMMISSIONING

Irradiated materials facility

The Irradiated Material Facility (AMI), which was declared and commissioned in 1964, is situated on the Chinon nuclear site and operated by EDF. This facility (BNI 94) is being decommissioned. It was intended essentially for performing examinations and expert assessments on activated or contaminated materials from pressurised water reactors.

The expert assessment activities were entirely transferred in 2015 to a new facility on the site, the Lidec.

Decree 2020-499 for AMI decommissioning was published on 30 April 2020 and the new RGEs were approved by ASN in April 2021, thereby enabling the Decree to enter into application. ASN also subjected the starting of several future decommissioning operations to its approval.

Further to the updating of the resolution regulating the installation's discharge limits in July 2022, a new discharge monitoring system has been put into service and decommissioning operations have started that include equipment cutting-up and interventions in several facilities.

The legacy magnesian waste from the expert assessments of certain parts requires inerting operations⁽²⁾ in order to meet the disposal criteria of Andra, the French Radioactive Waste Management Agency. As the characterisation results differed from what was initially expected, the necessary waiver was obtained from Andra in late 2022, thereby allowing the waste to be accepted. A work school was set up in early 2023. During an inspection in 2024, before the resuming the inerting work, ASN observed that the licensee had correctly implemented certain fire risk control measures relating to this project. The inerting operations were completed in 2024 and the transfers of waste to Andra began in late 2024.

ASN granted a decommissioning authorisation for the highly active liquid effluent systems in August 2023. Due to technical and contractual difficulties encountered by EDF in 2022, these operations – initially planned for 2023 – were rescheduled and they began in 2024. The treatment of the legacy chemical products present in controlled areas continued and the transfer of this nuclear waste, which began in 2022, is still in progress.

EDF resumed its "Thermip" pollution monitoring (non-radiological pollution by hydrocarbons and naphthalene) in 2023 and supplemented its management plan in 2024 with technical elements to be approved by ASN. Examination of this file will continue in 2025.

As was the case with certain areas of the Chinon reactors A1 and A3, infiltrations were observed in certain areas of the AMI during heavy rainfalls in 2023 and 2024. The overall action plan implemented by EDF includes measures specific to the AMI, notably pumping and on-site storage of the waters that infiltrated into the basement. In April and October 2024, ASN issued two authorisations allowing EDF to store this

2. Inerting in this instance is a process enabling the radiological activity of the magnesian waste to be contained in an enclosure of specific materials to allow risk-free transportation and storage.

water in two tanks in a dedicated area, pending their routing by truck to a treatment facility.

Based on inspections carried out, ASN considers that the safety management applied at the AMI is satisfactory. Particular attention must nevertheless be paid to the

monitoring of the civil engineering structures and water infiltration in the basement retention area. In 2025, ASNR will monitor the progress of EDF's action plan to prevent further infiltrations.

— Saint-Laurent-des-Eaux site

The Saint-Laurent-des-Eaux site, situated on the banks of the river Loire in the municipality of Saint-Laurent-Nouan in the Loir-et-Cher *département*, comprises various nuclear installations, some of them in operation and others undergoing decommissioning. The Saint-Laurent-des-Eaux NPP has two 900 MWe reactors in operation, B1 and B2, which were commissioned in 1980 and 1981 and constitute BNI 100. The site also features two old GCRs, A1 and A2, currently in the decommissioning phase, and two silos for storing the graphite sleeves from the operation of reactors A1 and A2.

Saint-Laurent-des-Eaux nuclear power plant

Reactors B1 and B2 in operation

ASN considers that the environmental performance of the Saint-Laurent-des-Eaux stands out positively with respect to its general assessment of the EDF plants. In the areas of nuclear safety and radiation protection however, the performance falls short of the general assessment.

ASN notes that the nuclear safety results of the Saint-Laurent-des-Eaux NPP deteriorated in 2024. An overall lack of training and communication was noted in operational management, particularly regarding control room monitoring and system configuration management. ASN does however observe a distinct improvement in fire safety on the site thanks to the robust corrective measures implemented following numerous deviations identified during inspections in 2023. Improvements are nevertheless still required in the management of the fire load and hot work permits.

With regard to maintenance, Saint-Laurent-des-Eaux NPP's performance is deemed insufficient in support function systems, control of reactivity and cooling. ASN considers that the licensee must make progress in the development of action plans tailored to operational issues, in the preparation of maintenance activities, the management of work orders and the monitoring of outside contractors.

In the area of radiation protection, ASN considers that the Saint-Laurent-des-Eaux NPP's results remain below the national average. Work site preparation and the monitoring of radiological cleanliness must be improved. Several cases of worker contamination were also reported in 2024.

The site's organisation to meet the regulatory environmental requirements is considered to perform well, thanks in particular to satisfactory management of extinguishing water containment, good control of discharges, adequate monitoring of the environment and appropriate management of the microbiological risk.

One accident in 2024 led to major labour inspection investigations by ASN which revealed the need to improve worksite procedures. Furthermore, in the light of the inspections, significant improvements are required in the areas of lifting and the management of explosive atmosphere risks.

Reactors A1 and A2 undergoing decommissioning

The former Saint-Laurent-des-Eaux NPP constitutes a BNI comprising two "integrated" GCRs A1 and A2. These first-generation reactors used natural uranium as the fuel, graphite as the moderator and were cooled by gas. Their final shutdown was declared in 1990 and 1992 respectively. Complete decommissioning of the installation was authorised by the Decree of 18 May 2010.

On completion of the analysis of the periodic safety review concluding reports for all the GCRs, ASN indicated in December 2021 that it has no objection to the continued operation of BNI 46 (Saint-Laurent reactors A1 and A2). ASNR will verify during the examination of the new decommissioning files for these reactors, which were submitted by EDF in late 2022 to set out the new "in air" decommissioning strategy, that the decommissioning operations will be carried out under suitable conditions of safety and radiation protection, within controlled time frames.

ASN has completed the examination of the management plan for the soils polluted with hydrocarbons in the zone of the old transformers of the Saint-Laurent A2 reactor and has authorised EDF to proceed with the soil clean-up operations by a resolution of 10 February 2023. These operations began in the last quarter of 2024 and will continue in 2025.

EDF continued the decommissioning work sites in 2024, particularly the decommissioning work outside the reactor pressure vessel (Saint-Laurent A2). After stopping some works in 2023 due to the discovery of lead in the worksite dust, the activities resumed in 2024 after cleaning out the areas concerned. ASN considers that the level of safety of the Saint-Laurent A reactors is satisfactory.

During its inspections, ASN found that the overall upkeep of the premises and worksites was good. However, although management of the periodic inspections and tests is judged satisfactory on the whole, efforts must be made to guarantee that deadlines are met and certain internal procedures are updated. Furthermore, additional information is awaited in order to clarify the list of PICs in effect.

Saint-Laurent-des-Eaux silos

The installation, which was authorised by Decree of 14 June 1971, comprises two silos which are used to store irradiated graphite liners from operation of the GCRs of Saint-Laurent A. The static containment of this waste is ensured by the concrete structures of the silo bunkers which are sealed by a steel liner. In 2010, EDF installed a geotechnical containment around the silos, reinforcing the control of the risk of dissemination of radioactive substances, which is the main risk presented by the installation.

Operation of this installation is limited to surveillance and upkeep measures: radiological monitoring inspections and measurements in the silos, checking there is no water ingress, checking the relative humidity, the dose rates around the silos, the activity of the water table, monitoring the condition of the civil engineering structures.

In the context of the change of decommissioning strategy for the GCRs, EDF announced in 2016 its decision to start removing the graphite sleeves from the silos without waiting for a definitive graphite waste disposal route to become available. To this end, EDF envisages creating a new graphite sleeve storage facility on the Saint-Laurent-des-Eaux site.

The final shutdown notification for the facility was sent by EDF in March 2022. At the end of 2022, EDF submitted the silo decommissioning file, integrating the silo emptying operations for the recovery and repackaging of the graphite waste and creation of the future graphite waste package storage facility. Based on the current assumptions made in the file currently being examined, silo emptying should begin in the early 2030's.

Corse (Corsica) collectivity

ASN conducted three inspections in the Corse collectivity in 2024, two in the medical sector and one in an organisation approved for measuring radon.

No significant event in small-scale nuclear activities was rated level 1 or higher on the International Nuclear and Radiological Event Scale (INES).

The Marseille division regulates radiation protection and the transport of radioactive substances in the Corse collectivity.

3

inspections

The installations and activities to regulate comprise:



- **small-scale nuclear activities in the medical sector:**

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- 2 external-beam radiotherapy departments,
- 2 nuclear medicine departments,
- 8 centres practising fluoroscopy-guided interventional procedures,
- 8 computed tomography scanners,
- some 330 medical and dental radiology devices;

- **small-scale nuclear activities in the industrial, veterinary and research sectors:**

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- some 40 veterinary surgeons using diagnostic radiology devices,
- some 40 industrial and research centres, including 2 companies exercising an industrial radiography activity;

- **activities associated with the transport of radioactive substances;**

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- **ASN-approved organisations and laboratories:**

- 2 organisations approved for measuring radon.

Overseas *départements* and regions

The regulation of radiation protection and the transport of radioactive substances in the five overseas *départements* and regions (Guadeloupe, Martinique, Guyane, La Réunion, Mayotte) and in certain overseas collectivities is ensured by the Paris division. It also acts as expert to the competent authorities of Nouvelle-Calédonie and French Polynesia.

Nine inspections were carried out in the small-scale nuclear activities sector in the French Overseas *départements*, regions and collectivities in 2024. Three on-site inspection campaigns were carried out by ASN.

No significant events in small-scale nuclear activities were rated level 1 or higher on the International Nuclear and Radiological Event Scale (INES).

9

inspections

The installations and activities to regulate comprise:



- **small-scale nuclear activities in the medical sector:**

- 5 external-beam radiotherapy departments,
- 1 brachytherapy department,
- 5 nuclear medicine departments,
- 21 centres practising fluoroscopy-guided interventional procedures;

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- **small-scale nuclear activities in the industrial, veterinary and research sectors:**

- 3 industrial radiology companies using gamma radiography devices;

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- **activities associated with the transport of radioactive substances.**

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Grand Est

The Châlons-en-Champagne and Strasbourg divisions jointly regulate nuclear safety, radiation protection and the transport of radioactive substances in the 10 *départements* of the Grand Est region.

164	8
inspections	significant events rated level 1 or higher

In 2024, ASN conducted 164 inspections in the Grand Est region, of which 62 were in the Nuclear Power Plants (NPPs) in service, ten in radioactive waste disposal facilities and on the sites of the Fessenheim and Chooz A NPPs currently being decommissioned, 81 in small-scale nuclear activities, five in the transport of radioactive substances and six concerning approved organisations or approved laboratories.

ASN also carried out 15 days of labour inspections in the NPPs.

During 2024, three significant events reported by nuclear installation licensees in the Grand Est region were rated level 1 on the International Nuclear and Radiological Event Scale (INES).

In small-scale nuclear activities, two significant events were rated level 1 on the INES scale (one in the industrial sector and one in the medical sector) and three significant events concerning patients were rated level 1 on the ASN-SFRO scale.

Lastly, within the framework of their inspection duties and pursuant to Article 40 of the Penal Procedure Code, the ASN inspectors filed a report for suspicions of falsification in a facility manufacturing equipment intended for nuclear installations.

CATTENOM NUCLEAR POWER PLANT

The Cattenom NPP is situated on the left bank of the river Moselle, 5 km from the town of Thionville and 10 km from Luxembourg and Germany.

It comprises four 1,300 Megawatts electric (MWe) Pressurised Water Reactors (PWRs) commissioned between 1986 and 1991. Reactors 1, 2, 3 and 4 constitute Basic Nuclear Installations (BNIs) 124, 125, 126 and 137 respectively.

ASN considers that the performance of the Cattenom NPP with regard to nuclear safety stands out positively with respect to ASN's general assessment of EDF plant performance. ASN considers that the environmental and radiation protection performance of the Cattenom NPP is in line with ASN's general assessment of the EDF plants.

ASN considers that the performance regarding operations and operational management of the reactors is broadly satisfactory. Weaknesses do however persist in control room monitoring.

Regarding maintenance, 2024 was marked in particular by one ten-yearly outage, one refuelling outage and one three-month outage during summer to economise fuel. The maintenance performance remains satisfactory, in particular with good organisation of activities resulting in a well-controlled ten-yearly outage schedule and good anticipation of unscheduled interventions.

Fire risk prevention, an area in which the site was considered below average for several years, improved in 2024, particularly regarding the control of fire loads. A fire that occurred in June 2024 in a non-controlled area causing activation of the on-site emergency plan, was correctly managed by the site.

In the area of environmental protection, the site's progress observed in 2023 on themes, considered below average in the preceding years, was confirmed in 2024. ASN notes more specifically better management of liquid pollution containment and of the oil separators. However, the consumption of biocides is still high, generating significant discharges.

In the area of radiation protection ASN considers that the site must progress in controlling contamination dispersion and limited stay (orange) areas management. On the other hand, improvements have been noted in the management of radiographic inspections. Although ASN considers that the site is aware of its weaknesses, in-depth actions have to be engaged to improve radiation protection performance.

Lastly, with regard to occupational safety, ASN considers that the working environment is broadly suitable, except for certain rooms situated in non-controlled areas. Moreover, some accidents and near-accidents that occurred in 2024 raise doubts about the identification and taking into account of specific risks during worksite preparation.

CHOOZ NUCLEAR POWER PLANT

The Chooz NPP operated by EDF is situated in the municipality of Chooz, 60 km north of Charleville-Mézières, in the Ardennes *département*. The site accommodates the Ardennes NPP, called Chooz A, comprising reactor A (BNI 163), operated from 1967 to 1991, for which the final shutdown and decommissioning operations were authorised by Decree 2007-1395 of 27 September 2007, and the Chooz B NPP, comprising two 1,450 MWe reactors (BNIs 139 and 144), commissioned in 2001.

Reactors B1 and B2 in operation

ASN considers that the performance of the Chooz B NPP with regard to nuclear safety and the environment is in line with ASN's general assessment of the EDF plant performance. It stands out positively in radiation protection.

Progress must be made in the operation of the facilities, particularly in the management of system configuring operations. Increased attention must also be paid in 2025 to the quality of, and strict compliance with, the reactor operational management documents, a point which, as in 2023, was the cause of significant events.

As far as maintenance is concerned, the year was punctuated by two refuelling outages involving a limited volume of activities, the management of which ASN considered satisfactory. Areas for progress have nevertheless been identified in Steam Generator (SG) maintenance and the in-service monitoring of nuclear pressure equipment.

With regard to occupational radiation protection, ASN considers that the site has made progress compared with the previous year. The radiological cleanliness of the facilities is satisfactory. A few areas for improvement nevertheless deserve particular attention in 2025, namely the radiation protection culture of the workers and control of the risk of contamination dispersion on the worksites.

With regard to protection of the environment, ASN considers that the site's organisation remains satisfactory. Nevertheless, it was found occasionally that the effluents discharge process could be better controlled. In addition, attention must be devoted to the availability of the sampling equipment.

Lastly, the inspections focusing on health and safety at work revealed no particular problem situations. The steps taken by the employer in response to the observations made during the inspections are appropriate for resolving the occasional deviations noted. Some improvements are nevertheless required in the organisational setup for monitoring the ventilation of rooms with specific pollution risks.

Reactor A undergoing decommissioning

The activities carried out in 2024 on the Chooz A reactor undergoing decommissioning mainly focused on the operations in preparation for lifting the reactor vessel, planned for 2025, that is to say final pumping of the bottom of the vessel, renovation of the reactor building handling crane and cutting the primary system pipes at the reactor vessel. Alongside this, decommissioning of all the equipment still present in the fuel building continued.

The installations and activities to regulate comprise:



• Basic Nuclear Installations:

- the Cattenom NPP (4 reactors of 1,300 MWe),
- the Chooz A NPP (1 reactor of 305 MWe undergoing decommissioning),
- the Chooz B NPP (2 reactors of 1,450 MWe),
- the Fessenheim NPP (2 reactors of 900 MWe in final shutdown status),
- the Nogent-sur-Seine NPP (2 reactors of 1,300 MWe),
- the CSA storage centre for short-lived low- and intermediate-level radioactive waste (LL/ILW-SL) located in Soulaïnes-Dhuys in the Aube *département*;

• the Cigéo geological disposal project for long-lived high- and intermediate-level radioactive waste;

• small-scale nuclear activities in the medical sector:

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- 14 external-beam radiotherapy departments,
- 5 brachytherapy departments,
- 20 nuclear medicine departments,
- about 100 computed tomography scanners,
- 74 centres performing fluoroscopy-guided interventional procedures,
- some 2,320 medical and dental radiology centres;

• small-scale nuclear activities in the industrial, veterinary and research sectors:

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- about 220 industrial and veterinary activities coming under the licensing or registration system,
- 30 companies exercising an industrial radiography activity,
- about 40 public or private research units;

• activities associated with the transport of radioactive substances;

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• ASN-approved organisations and laboratories:

- 6 laboratories approved for taking environmental radioactivity measurements,
- 2 organisations approved for measuring radon.

With regard to nuclear safety and the environment, the performance judged by ASN to be satisfactory on the whole over the last few years was maintained in 2024, despite deviations relating in particular to fire sectorisation, which must be specifically monitored.

Concerning radiation protection, the inspection carried out in 2024 confirmed that the actions undertaken in the last few years are appropriate for improving site's performance in this area. The year 2024 was nevertheless marked by a large number of internal contaminations, particularly on the primary cooling system pipe cutting worksite which is exposed to the risk of contamination by "alpha" particles. The specific measures applied on this particular worksite did not enable the targeted level of protection to be attained. The licensee must define and put in place more stringent measures for the future worksites presenting the same type of risk.

FESSENHEIM NUCLEAR POWER PLANT

The Fessenheim NPP is situated 1.5 km from the German border and about 30 km from Switzerland. Its two reactors, which were commissioned in 1977 and definitively shut down in 2020, are currently undergoing preparation for decommissioning.

ASN considers that the site is continuing decommissioning preparation conscientiously. An important milestone in the review of the decommissioning file was reached in the first half of 2024, with the holding of the associated public inquiry.

As in the previous years, the decommissioning preparation activities proceeded satisfactorily and in accordance with the set schedules, with for example, completion of the preparatory work for converting the turbine hall into a waste

management and storage area; preparation of the lower parts of the old steam generators for transportation to Cyclife's facilities in Sweden for decontamination and recovery through a melting process; continuation of treatment of activation products waste; and continuation of boron removal and achievement of the required residual level at the start of decommissioning.

ASN considers moreover that the organisational changes in 2023 and the successive headcount reductions since 2020 have been well managed and have no negative impacts on site operations.

The site's performance in radiation protection is considered broadly satisfactory.

NOGENT-SUR-SEINE NUCLEAR POWER PLANT

Operated by EDF and situated in the municipality of Nogent-sur-Seine in the Aube *département*, 70 km north-west of Troyes, the Nogent-sur-Seine NPP comprises two PWRs each of 1,300 MWe, commissioned in 1987 and 1988. Reactor 1 constitutes BNI 129 and reactor 2 BNI 130.

ASN considers that the performance of the Nogent-sur-Seine NPP is in line with its general assessment of the EDF plants in the areas of nuclear safety, radiation protection and the environment.

With regard to nuclear safety, ASN considers that the results are on the whole satisfactory, but the management of unanticipated situations in the control room needs to be improved. ASN notes a distinct improvement in the management of equipment lockout/tagouts and administrative lockouts.

With regard to maintenance, a notable event in 2024 was the refuelling outage of reactor 2. ASN considers that the maintenance operations during this outage went well on the whole.

As far as occupational radiation protection is concerned, although ASN observes that results regarding the

management of worksite radiological cleanliness remain satisfactory, significant deviations were found during inspections. These deviations concern in particular the management of the maintenance worksite access airlocks and the servicing and tracking of the radioactivity measuring devices, particularly in the site's laundry. Particular vigilance is expected of the licensee in these aspects. Lastly, broadly speaking, ASN considers that further progress must be made in the radiation protection culture of people working on the site.

With regard to environmental protection, ASN notes that the subject is receiving greater attention, but considers that the licensee's organisation in this area can still be improved. Improvements are still required in the management of discharges and the containment of liquid pollutions in particular.

Lastly, the labour inspections did not find any particular weak points, other than the abovementioned deviations in occupational radiation protection. The points to be improved identified during the inspections are moreover addressed conscientiously by the employer.

AUBE WASTE DISPOSAL FACILITY

Authorised by a Decree of 4 September 1989 and commissioned in January 1992, the Aube repository (CSA) took over from the Manche repository (CSM) which ceased its activities in July 1994, while benefiting from the operating experience feedback gained from the latter. This facility, located in Soulaines-Dhuys, has a disposal capacity of one million cubic metres (m³) of low- and intermediate-level, short-lived waste (LL/ILW-SL). It constitutes BNI 149. The operations authorised in the facility include the conditioning of waste, either by injecting mortar into metal containers of 5 or 10 m³ volume, or by compacting 200-litre drums.

At the end of 2024, the volume of waste in the facility had reached about 387,000 m³, or 39% of the authorised capacity. According to the estimates made by the French National

Radioactive Waste Management Agency (Andra) in 2016 in the concluding report on the periodic safety review of the CSA, the repository could be completely filled by 2062 rather than 2042 as initially forecast. This can be explained by having better knowledge of the future wastes and their delivery time frames, as well as by an optimisation of waste management through the compacting of certain packages.

ASN considers that the CSA is operated satisfactorily in the areas of safety, radiation protection and the environment. The inspections conducted in 2024 revealed more specifically that the organisation for selecting and monitoring outside contractors was well managed and appropriate for the risks, and that the quality baseline was robust, well mastered and applied for environmental monitoring on the site.

DEEP GEOLOGICAL DISPOSAL PROJECT

ASN considers that the scientific experiments and work conducted by Andra in the underground laboratory at Bure continued in 2024 with a good standard of quality, comparable with that of the preceding years.

ASN also continued examining the Creation Authorisation Application (DAC) for the Cigéo project that Andra filed with the Minister responsible for nuclear safety on 16 January 2023 (see *chapter 15*).

SMALL MODULAR REACTOR PROJECT IN BAZANCOURT

On 3 May 2024, the company Jimmy Energy filed a DAC for the construction of a Small Modular Reactor (SMR) in the Marne *département*. The intended purpose of this reactor would be to provide industrial heat to a factory of the Cristal Union group.

As at 31 December 2024, ASN had completed analysing the admissibility of the application and the follow-up to be given to the analysis was being examined by the Ministry responsible for nuclear safety (see *chapter 11*).

Hauts-de-France

The Lille division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 5 *départements* of the Hauts-de-France region.

93	15
inspections	significant events rated level 1 or higher

In 2024, ASN carried out 93 inspections in the Hauts-de-France region, of which 36 were in the Gravelines Nuclear Power Plant (NPP), 53 in small-scale nuclear activities and four in the transport of radioactive substances.

ASN also carried out 13.5 days of labour inspection in the Gravelines NPP.

During 2024, the Gravelines NPP notified ASN of nine significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES).

In small-scale nuclear activities, one event was rated level 1 on the INES scale. In radiotherapy, five events were rated level 1 on the ASN-SFRO scale.

GRAVELINES NUCLEAR POWER PLANT

The Gravelines NPP operated by EDF is located in the Nord *département* on the shores of the North Sea, between Calais and Dunkerque. This NPP comprises six 900 Megawatts electric (MWe) Pressurised Water Reactors (PWRs) giving a total power of 5,400 MWe. Reactors 1 and 2 constitute Basic Nuclear Installation (BNI) 96, reactors 3 and 4 BNI 97 and reactors 5 and 6 BNI 122.

ASN considers that the performance of the Gravelines NPP with regard to nuclear safety and environmental protection and radiation protection is in line with ASN's general assessment of the EDF plants.

The nuclear safety performance improved slightly in 2024, particularly in the addressing of significant events. The site has managed to stabilise its performance in the areas of cooling and fire protection. The licensee's recovery plan is continuing, focusing on subjects presenting difficulties such as the control of reactivity and maintenance. Despite the measures in place, ASN has again noted a number of inappropriate practices or behaviours, including noncompliance with procedures and poorly executed maintenance operations. The licensee must therefore continue its efforts to federate all the protagonists.

With regard to maintenance, 2024 was again marked by the substantial extensions in the reactor outage durations, largely due to unforeseeable technical issues. Three reactors were in outage at the same time for 12 weeks from mid-June to early November, putting an unusual amount of pressure on the departments in mid-summer. The intense activity linked to the reactor outages in 2024 included the fourth ten-yearly outage of reactor 4, in addition to an industrial programme including construction of the new local emergency centre and the creation of ultimate

water make-ups further to the lessons learned from the Fukushima Daiichi NPP accident in Japan. This situation led to inadequately prepared maintenance activities. ASN thus observed poorly executed maintenance operations and work postponements due in particular to the unavailability of spare parts.

With regard to environmental protection, ASN considers that the Gravelines NPP's organisation and performance are broadly satisfactory, even though some deviations must be corrected, such as in the management of liquid effluent discharges or the application of the general requirements concerning the competence of the calibration and test laboratories. The efforts made over the last few years have brought an improvement in the management of equipment using SF₆ (a powerful greenhouse gas), but vigilance remains necessary for all greenhouse gas refrigerants.

ASN notes some progress in occupational radiation protection. The site has taken account of the difficulties encountered in the preceding years and the measures deployed are starting to bring positive results on the ground. The downward trend in the number of significant events continued in 2024, but two contamination-related events rated level 1 on the INES scale were reported. This assessment remains contrasted due to persistent shortcomings in the application of the optimisation approach in work preparation and the coordination of radiation protection measures with outside contractors. ASN also observes an increase in deviations linked to deficiencies in the radiation protection culture or rigour of the workers, particularly regarding the conditions of access to controlled areas and taking regulatory zoning into account.

With regard to labour inspection, the site's deployment of prevention actions concerning safety over the last few years brought a reduction in the number of workplace accidents involving outside contractors in 2024. It is still necessary to continue these practices over the long term, and perhaps even reinforce them, given that the accident rate remains high. Deficiencies have been detected in the control of conformity of the ventilation facilities with the regulatory requirements associated with specific pollution areas, occasionally leading to uncontrolled exposures of employees in rooms in which hazardous substances are emitted. Lastly, occasional deviations were noted in the lifting of loads and the use of electrical equipment designed by the services of the NPP.

The installations and activities to regulate comprise:



• one Basic Nuclear Installation:

- the Gravelines NPP (6 reactors of 900 MWe) operated by EDF;

• small-scale nuclear activities in the medical sector:

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- 19 external-beam radiotherapy departments, 3 brachytherapy departments,
- 30 nuclear medicine departments, of which 7 practise internal targeted radiotherapy,
- 97 centres practising fluoroscopy-guided interventional procedures,
- 148 computed tomography scanners,
- some 4,600 medical and dental radiology devices;

• small-scale nuclear activities in the industrial, veterinary and research sectors:

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- about 600 industrial and research establishments, including 23 companies exercising an industrial radiography activity, 6 particle accelerators, including one for inspecting freight trains and 2 cyclotrons, 40 laboratories situated mainly in the universities of the region and 11 companies using gamma ray densitometers,
- 340 veterinary surgeries or clinics practising diagnostic radiology;

• activities associated with the transport of radioactive substances;

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• ASN-approved laboratories and organisations:

- 2 organisations approved for radiation protection controls.

Île-de-France

The Paris division regulates radiation protection and the transport of radioactive substances in the 8 *départements* of the Île-de-France region. The Orléans regional division regulates nuclear safety in the Basic Nuclear Installations (BNIs) of this region.

240

inspections

11

significant events
rated level 1
or higher

ASN carried out 240 inspections in the Ile-de-France region in 2024, of which 90 were in the field of nuclear safety, 127 in small-scale nuclear activities (four of them in the area of polluted sites and soils), 14 in Radioactive Substance Transport (TSR) and nine concerning approved organisations or laboratories.

Seven significant events were rated level 1 on the International Nuclear and Radiological Events Scale (INES) in the small-scale nuclear activities sector, three at level 1 on the INES scale in the BNIs sector and one at level 1 on the INES scale in the area of TSR.

Lastly, pursuant to Article 40 of the Penal Procedure Code, a report was filed against an inspection agency for falsification of documents.

— CEA Saclay site

Since 2017, the Alternative Energies and Atomic Energy Commission (CEA) Paris-Saclay centre accommodates activities previously conducted on several geographically distinct sites close to Paris, and the sites of Saclay and Fontenay-aux-Roses in particular.

The CEA Paris-Saclay centre, of which the main site covers an area of 125 hectares, is situated about 20 km south-west of Paris, in the Essonne *département*. About 6,000 people work there. Since 2005, this centre has been primarily devoted to physical sciences, fundamental research and applied research. The applications concern physics, metallurgy, electronics, biology, climatology, simulation, chemistry and the environment. The main aim of applied nuclear research is to optimise the operation and enhance the safety of the French NPPs. Seven BNIs are located on this site.

Nearby are also located an office of the French National Institute for Nuclear Science and Technology (INSTN) – a training institute – and two industrial firms: Technicatome, which designs nuclear reactors for naval propulsion, and CIS bio international, which produces radiopharmaceuticals for nuclear medicine.

THE INDUSTRIAL AND RESEARCH FACILITIES

Osiris and Isis reactors

The Osiris pool-type reactor, which has an authorised power of 70 Megawatts thermal (MWth), was primarily intended for technological irradiation of structural materials and fuels for various power reactor technologies. Another of its functions was to produce radionuclides for medical purposes.

Its critical mock-up, the Isis reactor with a power of 700 kilowatts thermal (kWth), was essentially used for training purposes. These two reactors were authorised by a Decree of 8 June 1965 and constitute BNI 40.

Given the old design of this facility by comparison with the best available techniques for protection against external hazards and for containment of materials in the event of

an accident, the Osiris reactor was shut down at the end of 2015. The Isis reactor was definitively shut down in March 2019. Following submission of the decommissioning file for the entire facility in October 2018, ASN requested and received additional information giving more details on the operations planned at each stage of decommissioning and substantiating more precisely the initial state envisaged at the start of decommissioning and the results of the impact assessment. In late 2021, the CEA announced a radical change in the decommissioning strategy of BNI 40 with the postponement of commissioning of the equipment for treating and packaging irradiating waste. For the purpose of the examination, further information on the new decommissioning scenario, particularly regarding the management of irradiating waste, had to be provided. The CEA submitted a new decommissioning file at the end of 2023 and it is currently being examined.

Since the shutdown of the Osiris and Isis reactors and pending decommissioning of the facility, the removal of radioactive and hazardous materials and the decommissioning preparation operations are underway, with an organisation adapted to the new state of the facility. More specifically, the last of the irradiated core fuel stored in the facility was removed in 2021.

ASN considers that the level of safety of BNI 40 is satisfactory, particularly with regard to control of external hazards and the management of liquid discharges. Improvements are however required in waste management. The organisation put in place to keep track of the Decommissioning Preparation Operations (DECPROs) is appropriate for the current status of the facility, despite the postponement of operations due to a lack of means. The commitments made to ASN are tracked with rigour and the progress on the whole is in conformity with the set time frames. The Authority for Nuclear Safety and Radiation Protection (ASNR) will focus its attention in 2025 on the licensee's control of the DECPROs, in particular compliance with the critical path to achieve the initial state described in the decommissioning file. It will also be attentive to the measures implemented by CEA to upgrade the waste storage areas in the facility and to the studies and works aiming to reduce the facility's water consumption.

Orphée reactor

The Orphée reactor (BNI 101), a neutron source reactor, was a pool-type research reactor with a licensed power of 14 MWth. The highly compact core is located in a tank of heavy water acting as moderator. Creation of the reactor was authorised by the Decree of 8 March 1978 and its first divergence took place in 1980. It was used for conducting experiments in areas such as physics, biology and physical chemistry. The reactor allowed the introduction of samples to be irradiated for the production of radionuclides or special materials, and to perform non-destructive tests on certain components.

The Orphée reactor, which was definitively shut down at the end of 2019, is now in DECPRO phase. The licensee submitted its decommissioning file in March 2020. The last irradiated fuel from the Orphée reactor was removed in 2020, greatly reducing the radiological risk of the facility. The continuation of the DECPROs and the facility decommissioning scenario were discussed following the CEA's re-prioritising of the DECPROs, resulting in the updating of the decommissioning strategy for BNI 101. A new decommissioning file was submitted at the end of 2023 and it is currently being examined.

The installations and activities to regulate comprise:



• Basic Nuclear Installations regulated by the Orléans division:

- the CEA Saclay site of the CEA Paris-Saclay centre,
- the UPRA (Artificial Radionuclide Production Plant) operated by CIS bio international in Saclay,
- the CEA Fontenay-aux-Roses site of the CEA Paris-Saclay centre;

• small-scale nuclear activities in the medical sector regulated by the Paris division:

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- 26 external-beam radiotherapy departments,
- 12 brachytherapy departments,
- 43 *in vivo* nuclear medicine departments and 12 *in vitro* (medical biology) nuclear medicine departments,
- 150 centres practising fluoroscopy-guided interventional procedures;

• small-scale nuclear activities in the industrial, veterinary and research sectors under the oversight of the Paris division:

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- 9 industrial radiology companies using gamma radiography devices,
- about 143 authorisations and 42 registrations relative to research activities;

• activities associated with the transport of radioactive substances;

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• ASN-approved laboratories and organisations:

- 3 organisations approved for radiation protection controls..

Based on the facility inspections and monitoring carried out in 2024, ASN considers that the level of safety of the Orphée reactor is on the whole satisfactory. However, some points of vigilance require particular attention, particularly with regard to Human and Organisational Factors (HOFs) and the updating of baseline requirement documents. Furthermore, despite progress in the sorting of the equipment dedicated to the researchers, improvements are required in waste management. Clarifications are also expected concerning the actions associated with the periodic safety review, notably their incorporation in an action plan, a precise explanation of their objectives and proof of their completion.

Since the shutdown of the reactor, the DECPRO phase has started, but is subject to recurrent schedule push-backs. It is subject to close scrutiny by ASN, particularly regarding the suitability of the organization and the personnel's competence to manage new activities while maintaining the level of safety of the facility and controlling the schedules of the associated activities.

Spent fuel testing laboratory

The Spent Fuel Testing Laboratory (LECI) was built and commissioned in November 1959. It was declared a BNI on 8 January 1968 by the CEA. An extension was authorised in 2000. The LECI (BNI 50) constitutes an expert assessment aid for the nuclear licensees. Its role is to study the properties of materials used in the nuclear sector, whether irradiated or not.

From the safety aspect, this facility must meet the same requirements as the nuclear installations of the “fuel cycle”, but the safety approach is proportional to the risks and drawbacks it presents.

Further to the last periodic safety review, ASN issued the resolution of 30 November 2016 (amended on 26 June 2017) regulating the continued operation of the facility through technical prescriptions relating in particular to the improvement plan that CEA had undertaken to implement. Some of the CEA's commitments have not been fulfilled within the deadlines.

In particular, the licensee has requested pushing back of the deadlines for removal of the radioactive substances whose utilisation cannot be justified, and the implementation where necessary of measures to place and maintain the BNI in a safe condition in the event of fire in the areas adjacent to the nuclear areas. The decommissioning of Célimène (unit formerly intended for the examination of fuels from reactor EL3) is also concerned by this request. The examination of the provisions relating to fire led ASN to decide to issue a compliance resolution to regulate performance of the works initially expected for the end of 2019. In view of the risks and the work already undertaken by the licensee's personnel, the corresponding technical requirement must be met before 31 December 2026. ASNR will be particularly attentive to the monitoring and implementation of the necessary actions to meet this deadline.

Since the end of 2022, BNI 72 no longer accepts irradiating waste from the CEA Saclay site. Consequently, the CEA has started a new project baptised “GDILE”, a French acronym for “Management of irradiated waste from LECI”, in order to process, package and remove the irradiating waste (existing and future) without saturating the storage capacities of LECI. CEA initiated reflections in 2024 to redefine and size this project, and they will continue in 2025 in collaboration with ASNR. In this context, in 2024 ASN started examining the file for the facility's second periodic safety review which CEA submitted in December 2023.

The inspections of LECI carried out in 2024 were considered satisfactory, even though improvements are required in taking account of risks associated with the use of lifting equipment and with static containment. The time taken to respond to ASNR's requests remains a point requiring particular attention.

Poséidon irradiator

Authorised in 1972, the Poséidon facility (BNI 77) is an irradiator comprising a storage pool for cobalt-60 sources, partially surmounted by an irradiation bunker. The BNI moreover includes another bunkered irradiator baptised Pature, and the Vulcain accelerator.

This facility is used for studies and qualification services for the equipment installed in the nuclear reactors, notably thanks to an immersible chamber, as well as for the radiosterilisation of medical products. The main risk in the facility is of personnel exposure to ionising radiation due to the presence of very high-activity sealed sources.

ASN has regulated the continued operation of the facility following its periodic safety review through ASN Chairman's resolution CODEP-CLG-2019-048416 of 22 November 2019. The major areas for improvement are in particular the resistance of the building to seismic and climatic hazards (snow and wind in particular), and the monitoring of ageing of the Poséidon storage pool.

In 2024, further to its examination of the periodic safety review concluding report submitted by CEA at the end of 2021, ASN considered that it had no objection to the continued operation of BNI 77. Attention must nevertheless be paid to monitoring the ageing of the pool.

ASN considers that the level of nuclear safety of the facility is satisfactory. ASN has observed in the course of its inspections that the licensee provides adequate responses within the set deadlines to its commitments resulting from the preceding periodic safety review (commitments made by licensee, technical requirements or requests from ASN), particularly regarding the management of fire loads. It also underlines with approval the putting in place of visual internal communication tools which facilitate the operators' understanding of the operational management operations. Improvements are nevertheless required in the management of sources. This is because in 2024 the facility's pool was again contaminated by tritium during the provisioning of new cobalt-60 sources. This event highlights the need to reinforce the measures taken following a similar contamination in 2021.

SOLID WASTE AND LIQUID EFFLUENT TREATMENT FACILITIES

The CEA operates various types of facilities: laboratories associated with “fuel cycle” research as well research reactors. The CEA also carries out numerous decommissioning operations. Consequently, it produces diverse types of waste. The CEA has specific processing, packaging and storage facilities for the management of this waste.

Solid radioactive waste management zone

The Solid Radioactive Waste Management Zone (ZGDS – BNI 72) was authorized by the Decree of 14 June 1971. Operated by the CEA, this facility processes, packages and stores the high, intermediate and low-level waste from the Saclay centre facilities. It also stores legacy materials and waste (spent fuels, sealed sources, scintillating liquids, ion-exchange resins, technological waste, etc.) pending disposal.

In view of the “dispersible inventory⁽¹⁾” currently present in the facility, BNI 72 is one of the priorities of the CEA’s decommissioning strategy which has been examined by ASN, who stated its position on these priorities in May 2019 (see chapter 14).

BNI 72 has been definitively shut down since 31 December 2022. Nevertheless, certain wastes can be accepted by the facility until 2025. After analysing the periodic safety review report for BNI 72 submitted at the end of 2017 and examined jointly with the decommissioning file, ASN regulated the conditions of continued operation of the facility through ASN Chairman’s resolution CODEP-CLG-2022-005822 of 2 February 2022. Furthermore, Decree 2022-1107 of 2 August 2022 requiring the CEA to proceed with the decommissioning of BNI 72 was published in the *Official Journal*. This Decree came into effect on 26 July 2023, the date on which ASN approved the revision of the General Operating Rules (RGEs).

ASN has observed numerous delays in the operations to remove fuel or waste from storage. The removal from storage of fuel rods contained in a specific packaging were suspended in 2024 after discovering loss of fuel pellet integrity during handling operations. ASNR will be attentive to CEA’s updating of the safety case and the resumption of operations.

The “EPOC⁽²⁾” project (a French acronym meaning “Removal of fuel drums”) has experienced difficulties due in particular to termination of the project management contract in 2020, and CEA has taken measures to take over said project management. A pit was opened in 2023 and complementary investigations were carried out in 2024 to consolidate the project input data. ASNR will nevertheless remain attentive to CEA’s management of this project, particularly regarding the work to be carried out with a view to recovering the first drum.

ASN takes positive note of the completion of removal of the fifteen fuel cans from a pool in a building and the removal of four isotopic generators containing sources in 2024. These operations contribute to the gradual reduction of the facility’s “dispersible inventory”.

Lastly, the monitoring of outside contractors must be improved. CEA must also be particularly attentive to preserving the site memory, particularly as regards the equipment necessary for the decommissioning and removal from storage operations.

Liquid effluents management zone

The Liquid Effluents Management Zone (ZGEL) constitutes BNI 35. Declared by the CEA by letter of 27 May 1964, this facility is dedicated to the treatment of radioactive liquid effluents. The CEA was authorised by a Decree of 8 January 2004 to create “Stella”, an extension in the BNI for the purpose of treating and packaging low-level aqueous effluents from the Saclay centre. These effluents are concentrated by evaporation then immobilised in a cementitious matrix in order to produce packages acceptable by the French National Radioactive Waste Management Agency (Andra).

The evaporation facility used to treat the radioactive effluents has been out of service since 2019 due to technical anomalies on an equipment item. At present the facility is no longer capable of fulfilling its functions (evaporation of effluents, encapsulation of concentrates in cement, collection of effluents from the Saclay effluent producers). In 2023, ASN authorised a modification concerning the separator shell, enabling the evaporation campaigns to be restarted. The corresponding work began at the end of 2024.

The process of encapsulation in cement, used to treat the concentrates in the facility, was stopped temporarily by CEA in June 2021, following the production of two 12H active packages that did not comply with packaging approval issued by Andra. CEA obtained Andra’s approval in 2024, allowing removal of the 12H packages stored under a derogation provision, which will enable removals to be resumed in 2025. Work is also in progress to obtain a further approval.

Alongside this, the CEA has suspended reception of effluents from other BNIs since 2016, due to the conducting of complementary investigations into the stability of the structure of the room for storing low-level liquid effluents (room 97). The majority of the low- and intermediate-level radioactive effluents produced by the Saclay site production sources are now directed to the Marcoule Liquid Effluent Treatment Station (STEL).

This situation raises questions as to whether management of liquid effluents in the facility will be resumed in the future. ASNR will keep close track of this situation and expects CEA to redouble its efforts to render the facility operational in order to be able to retrieve and condition the stored legacy effluents within appropriate time frames.

1. Part of the inventory of the radionuclides of a nuclear facility that groups the radionuclides that could be dispersed in the facility in the event of an incident or accident, or even, for a fraction of them, be released into the environment.

2. This project involves a process intended to retrieve and package drums containing a mix of waste and fuel fragments which are currently stored in pits in the facility. The retrieval of these drums requires specific equipment, given the uncertainties concerning their integrity.

The emptying and cleaning out of the MA 500 tanks and the pit 99 tanks represent major challenges for the facility. A priority pit 99 tank was emptied in 2024. However, non-pumpable residues remain in the bottom of this tank. The inspections carried out in 2024 highlighted the good execution of this tank emptying work, the improvement in the conditions of waste storage in a hall and the progress of the action plan stemming from the periodic safety review, particularly concerning control of the fire risk. Improvements must however be made in the monitoring of outside contractors and implementation of the recommendations resulting from the fire risk control study.

FACILITIES UNDERGOING DECOMMISSIONING

The decommissioning operations on the Saclay site concern two BNIs, the High Activity Laboratory (LHA) and the solid radioactive waste management zone (BNI 72). DECPROs are being carried out in two definitively shut down BNIs, namely the Osiris and Isis reactors (BNI 40) and the Orphée reactor (BNI 101). Operations are also being carried out on parts of the in-service ZGEL (BNI 35) which have ceased their activity. Two Installations Classified for Protection of the Environment (ICPEs – EL2 and EL3) previously classified as BNIs but which have not been completely decommissioned due to the lack of a disposal route for the low-level long-lived waste, are also concerned by decommissioning. Their downgrading from BNI to ICPE status in the 1980's, in compliance with the regulations of that time, could not be done today.

Broadly speaking, the CEA's decommissioning and waste management strategy has been examined by ASN, which stated its position in May 2019 on the priorities defined by the CEA (see *chapters 14 and 15*).

High-activity laboratory

The High-Activity Laboratory (LHA) comprises several laboratories intended for research work or the production of various radionuclides. It constitutes BNI 49. On completion of the decommissioning and clean-out work authorised by Decree of 18 September 2008, only two laboratories currently in operation should ultimately remain under the ICPE System. These two laboratories are the laboratory for the chemical and radiological characterisation of effluents and waste, and the packaging and storage facility for the retrieval of disused sources.

Despite the progress of the clean-out and decommissioning operations, the accumulated delays have prevented the CEA from meeting the deadline of 21 September 2018 set by the decree authorising LHA decommissioning. The discovery of pollution in certain "intercell yards" in 2017 also led to changes being made in the operations to be carried out. Investigations into the radiological status of the soils were conducted between 2019 and 2021. The licensee submitted a Decommissioning Decree modification file in December 2021. The justification for the time necessary to complete the decommissioning operations authorised by the Decree of 18 September 2008 shall be reviewed in the ongoing examination of this file.

In 2024, after examining the periodic safety review concluding report submitted by CEA in 2017, ASN considered that it had no objection to the continued operation of BNI 49 pending the amendment of its Decommissioning Decree. In the context of this periodic safety review, compliance actions, particular regarding control of fire-related risks, were identified. ASN also asked CEA to take measures to guarantee the integrity of certain items of equipment whose decommissioning has been delayed.

The investigations and studies allowing the management of unidentified waste discovered in late 2022 in the set of structures constituting the TOTEM shielded process continued in 2024.

ASN considers that the safety of the BNI 49 undergoing decommissioning is satisfactory on the whole. However, particular vigilance is expected in monitoring the condition of the ventilation ducts, particularly the internal sections which are inaccessible or display defective areas. Particular attention must also be paid to the operation of the main air manifold extractor in view of the technical problems encountered. Improvements are also necessary to guarantee the monitoring of the lightning protection facilities which, in their current state, cannot guarantee the required level of protection.

ASN remains vigilant with regard to the management of the very low level waste zones of BNI 49, particularly on account of the future decommissioning work which will produce additional waste. Consequently, the adequacy of the existing waste storage areas for the future needs is of major importance to enable the decommissioning operations to run to the planned schedule.

Assessment of the CEA Saclay site



ASN considers that the CEA Saclay site BNIs are operated under suitably safe conditions on the whole, and observes that the operations to reduce the radiological inventory stored in the BNIs – which have been in progress for several years now – continued in 2024.

The DECPROs and decommissioning work continue for the facilities concerned. Managing work progress and keeping to the associated schedules remain a major challenge for CEA Saclay. This area, which forms the subject of regular ASN inspections and meetings, must still be improved given the drifts in schedule observed over the years.

On another note, further to the Fukushima Daiichi NPP accident (Japan), ASN had ordered the creation on the Saclay site of new emergency management facilities capable of withstanding extreme conditions. After discovering reinforcement defects in civil engineering work which led to the suspension of the worksite, CEA failed to meet its commitment to commission the premises before the end of 2021. An inspection conducted in 2022 confirmed that the new premises had not been

commissioned, contrary to a requirement of an ASN resolution of 2016. Following the analysis of CEA's reply to the report established in the presence of both parties, and in view of the reduction in the nuclear risk of the Saclay site further to the shutdown of BNIs 40 and 101, the requirement in question was repealed. A new technical requirement then framed the finalisation of the construction of robust emergency situation management premises, with commissioning planned for 2024. During inspections in 2023 and 2024 ASN observed that work has resumed and was progressing. At the end of 2024 CEA informed ASN of the commissioning of the new premises. An update of the On-site Emergency Plan (PUI) remains necessary to formalise the changes concerning these premises.

With regard to the environment, two ASN resolutions dating from 2009 and updated in 2023 regulate all the discharges from the CEA's BNIs. Following an inspection in 2024 focusing in particular on effluent discharges and groundwater during which samples were taken, ASN observed that the measurements taken by an independent laboratory were consistent with those taken by CEA.

The organisation put in place to prevent the risk of frauds was also inspected. Although personnel training sessions have been organised, efforts must nevertheless be made to put in place an overall process for managing the prevention of irregularities and the risk of fraud.

Two years after setting up radiation protection skills centres, the subject was inspected by the head offices of CEA, which focused in particular on the skills centres of the CEA Paris-Saclay centre and found the situation to be satisfactory.

Lastly, an in-depth inspection involving several inspection teams was carried out in 2024 to examine the monitoring of outside contractors on the CEA Saclay site. ASN considers that outside contractor monitoring is broadly unsatisfactory and insufficient. ASN also underlines the major deficiencies in the application of the regulatory requirements, particularly regarding the identification of protection important components and activities. The first responses on the part of CEA were found to be satisfactory and ASN will monitor the development of the situation in 2025.

ARTIFICIAL RADIONUCLIDE PRODUCTION PLANT OF CIS BIO INTERNATIONAL

The Artificial Radionuclides Production Facility (UPRA) constitutes BNI 29. It was commissioned in 1964 on the Saclay site by the CEA, which in 1990 created the CIS bio international subsidiary, the current licensee. In the early 2000's, this subsidiary was bought up by several companies specialising in nuclear medicine. In 2017, the parent company of CIS bio international acquired Mallinckrodt Nuclear Medicine LCC, now forming the Curium group, which owns three production sites (in the United States, France and the Netherlands).

The Curium group is an important player on the French and international market for the production and development of radiopharmaceutical products. The products are mainly used for the purposes of medical diagnoses, but also for therapeutic uses. They are manufactured using a cyclotron installed on the site or using radionuclides produced by outside suppliers or other facilities of the Curium group. Until 2019, the role of BNI 29 was also to recover disused sealed sources which were used for radiotherapy and industrial irradiation. Removal of these sources, which were stored in the facility, was completed in 2024. The group moreover decided to stop its iodine-131-based productions on the Saclay site at the end of 2019, which has significantly reduced the potential consequences of accident situations on the site. The manufacture of a new radiopharmaceutical was authorised by ASN in 2024, with a view to obtaining a marketing authorisation.

In the light of the inspections and the examination, ASN considers that the deterioration in the overall level of safety of the facility observed in 2023 has not been made up in 2024, despite the licensee's efforts in mobilising the personnel at various levels of the organisation. Although the number of significant events notified to ASN decreased in 2024, HOFs are still over-represented in the identified causes of the events. A large number of events linked to failure to wear or to activate active dosimeters are still observed. The inspections, one of which focused on HOF aspects, identified that within the facility there is a degree of habituation to deviations, which has led ASN to ask the licensee to conduct an overall analysis of this situation to determine its root causes.

With regard to the fire theme, although certain actions identified during the last periodic safety review have been completed, the fire safety system qualification work must still be carried out within time frames appropriate for the risks. Furthermore, the licensee has been unable to transit the required updates of the safety analysis report and the RGEs, in order to demonstrate that the conclusions of the substantial amount of work accomplished in this safety review have been duly taken into account.

Moreover, the inspections revealed that several documents relating to emergency situation management are out-of-date and must therefore be updated. Improvements are expected in the personnel's emergency situation training,

in the sealing of the facility's enclosures and glove boxes, in the conditions of reception of radioactive substance packages and in waste management. On this latter subject, ASN gave CIS bio international formal notice at the end of 2024 to remove, before the end of January 2025, certain nuclear wastes held in storage beyond the deadlines stipulated in the baseline requirements of the facility.

A recurring nonconformity has been observed since 2022 in the effectiveness of the last filtration levels of the facility's ventilation system. The technical causes of these deviations have not yet been found, therefore the investigations must continue in 2025 in order to introduce robust preventive measures. CIS bio international met the deadline set by ASN's formal notice resolution of 2023 on the pressure equipment theme, even though further information is still awaited on this subject.

More broadly, ASN notes – as was the case in the previous year – the difficulties CIS bio international is having in meeting the deadlines for the actions decided further to inspections or significant events and resulting from the

action plan associated with the periodic safety review. Furthermore, and despite the substantial work undertaken, delays are still observed in submitting significant event reports and replying to ASN follow-up letters. This being said, the quality of the content of the significant event reports remains high and this must be maintained.

The numerous projects, studies and works undertaken by CIS bio international require better scheduling so that the files to be addressed to ASN can be prepared and submitted sufficiently early. Operating rigour, maintaining the safety culture and the management of industrial projects or aiming to improve safety or radiation protection remain the areas in which CIS bio international must focus its efforts. To improve the performance in the areas of safety, radiation protection and the environment, the licensee must be particularly vigilant regarding the adequacy of the human and technical resources to be deployed, and ensure that these resources are sufficient to operate the facility in complete safety.

— CEA Fontenay-aux-Roses site

Created in 1946 as the CEA's first research centre, the Fontenay-aux-Roses site is continuing its transition from nuclear activities towards research activities in living sciences.

The CEA Fontenay-aux-Roses site, part of the CEA Paris-Saclay centre since 2017, comprises two BNIs, namely Procédé (BNI 165) and Support (BNI 166). BNI 165 accommodated the research and development activities on nuclear fuel reprocessing, transuranium elements, radioactive waste and the examination of irradiated fuels. These activities ceased in the 1980s-1990s. BNI 166 is a facility for the characterisation, treatment, reconditioning and storage of legacy radioactive waste from the decommissioning of BNI 165.

Broadly speaking, the CEA's decommissioning and waste management strategy has been examined by ASN, which stated its position in May 2019 on the priorities defined by the CEA (see *chapters 14 and 15*).

Decommissioning of the Fontenay-aux-Roses site includes priority operations because it presents particular risks, linked firstly to the quantity of radioactive waste present in the facilities, and secondly to the radiological contamination of the soils under part of one of the BNI 165 buildings. In addition to this, the Fontenay-aux-Roses centre, which is situated in a densely-populated urban area, is engaged in an overall delicensing process.

Procédé and Support facilities

Decommissioning of the two facilities Procédé and Support, which constitute BNI 165 and BNI 166 respectively, was authorised by two Decrees of 30 June 2006. The initial planned duration of the decommissioning operations was about ten years. The CEA informed ASN that, due to strong presumptions of radioactive contamination beneath one of the buildings, to unforeseen difficulties and to a change in the overall decommissioning strategy of the CEA's civil centres, the decommissioning operations had to be extended and that the decommissioning plan would be modified. In June 2015, the CEA submitted an application to modify the prescribed deadlines for these decommissioning operations.

ASN deemed that the first versions of these Decommissioning Decree modification application files were not admissible. In accordance with the commitments made in 2017, the CEA submitted the revised versions of these files in 2018. These files were supplemented over the 2019-2022 period, particularly with respect to the planned decommissioning operations and their schedule. The CEA forecasts end of decommissioning of the BNIs beyond 2050, perhaps even 2060 in the case of BNI 165. These two projects are currently being examined. The new decrees will set the future decommissioning characteristics, and notably their completion time frame.

Assessment of the CEA Fontenay-aux-Roses site



ASN considers that the level of safety of the CEA Fontenay-aux-Roses site is acceptable. CEA must nevertheless maintain its efforts to ensure the operational safety of its facilities.

After delays identified in the preceding years in the performance of the studies, in project programming and in the decommissioning schedule of the nuclear installations of Fontenay-aux-Roses, two of the CEA's major decommissioning-related worksites were stopped for contractual and technical reasons in 2023.

This situation led to technical changes in the choice of equipment design and pushing back of the decommissioning time frames. CEA must be particularly vigilant regarding the coordination of the files and the work planned on the site in order to reduce the dispersible radiological inventory within the facilities. It must also continue to implement strong measures to control and render reliable the project time frames, particularly the

deadlines for submission of the decommissioning worksite preparatory studies.

In 2023, in view of the conclusions of the periodic safety review of BNI 165, ASN regulated its continued operation through a resolution setting technical requirements. With regard to BNI 166, in view of CEA's commitments and the action plan established at the end of the periodic safety review and further to its examination of the concluding report of the said review, ASN considered in 2024 that it had no objection to the continued operation of BNI 166.

The inspections ASN carried out in 2024 found TSR management to be satisfactory and an improvement in waste management in one of the BNI 166 buildings. Nevertheless, the areas requiring close attention – concerning in particular the emergency management means and control of the fire risk – still persist after several years. An update of the PUI is expected further to the changes in the emergency

premises in particular. Despite the compliance work already undertaken on one of the BNI 165 buildings, the efforts must be continued in 2025 to achieve the required level of safety. Although the number of significant events notified is lower than in the preceding years, they mainly relate to fire. In view of the recurrence of this subject, ASN considers that an in-depth analysis of the causes is necessary.

Lastly, ASN underlines with approval the steps taken by CEA in 2024 to improve the safety of the facilities. These include a complete update of the RGEs, which had been obsolete for several years, and the implementation of a maintenance action plan. This plan has two main objectives: improve knowledge and command of the physical configuring of the facilities in relation with the components important for the protection of interests, and tighten daily work monitoring by creating a work coordination office. ASN enjoins the licensee to continue its actions in 2025.

— The polluted sites and soils in Île-de-France

In Île-de-France, the Paris division oversees the depollution activities for contaminated radiological sites, which usually concerns legacy contamination resulting from past industrial or research activities which used radium. The actors can be industrial players, but also private individuals.

The Paris division can, at the request of the *département* Prefect, give technical opinions on the planned pollution management measures and on the effective performance of remediation work (see chapter 15, point 4).

On account of its expertise in the risks presented by polluted sites and soils, the Paris division of ASN issued in 2024:

- three opinions concerning the remediation operations or their follow-ups: stopping of the monitoring in the vicinity of the Orme des Merisiers landfill in Saint-Aubin (Essonne *département*), total clean-out of a construction worksite in Gentilly (Val-de-Marne *département*) and remediation of a private individual's parcel of land in Gif-sur-Yvette (Essonne *département*);
- four opinions concerning management of the pollution of the sites of Budin, Fort d'Aubervilliers and Charvet in the Seine-Saint-Denis *département*, and Vaujours in the Seine-Saint-Denis and Seine-et-Marne *départements*;
- two opinions for the environmental authority concerning the Public Development Zone (ZAC) in Aubervilliers (Seine-Saint-Denis *département*) and the Clamart college ZAC (Hauts-de-Seine *département*);
- one opinion on a verification concerning the flooding of a college near the Federal Mogul site in Gif-sur-Yvette (Essonne *département*).

Furthermore, in 2024 the Paris division carried out four inspections to check the clean-out or development operations on four different sites, namely the old Vaujours Fort, a former Marie Curie laboratory in Arcueil (Val-de-Marne *département*), Charvet – VLM in Île Saint-Denis (Seine-Saint-Denis *département*) and the Curie Institute (Paris).

Furthermore, as part of the monitoring of these long-term clean-out operations which have been in progress for several years, the Paris division also took part in the monitoring commissions of the Vaujours Fort site and the Marie Curie laboratory in Arcueil.

The Paris division also carried out the following actions in 2024:

- three requests to the French Institute of Radiation Protection and Nuclear Safety (IRSN) for verifications and placing in safe condition after radioactive objects were discovered in the homes of private individuals and in a high school in Val-de-Marne;
- various technical meetings with the Prefectoral body and the Regional and Interdepartmental Directorate for the Environment, Development and Transport (DRIEAT) concerning depollution of the Charvet – VLM site;
- drafting of a soil hazard information sector concerning the residual radiological contamination of a land parcel in Gif-sur-Yvette after remediation;
- various technical interchanges bringing together the Prefectoral administration, DRIEAT, ASN, IRSN, the design office and the project sponsor, concerning the diagnosis of the polluted Galeries Lafayette site in Seine-Saint-Denis, with a view to its remediation;
- a technical meeting with the town council of Gif-sur-Yvette and the DRIEAT concerning the future of the Federal Mogul site;
- responses to requests from private individuals faced with radiological contamination problems in certain areas of Gif-sur-Yvette.

Normandie

The Caen division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 5 *départements* of the Normandie region.

213

inspections

20

significant events
rated level 1
or higher

In 2024, ASN carried out 213 inspections in Normandie, comprising 72 in the Nuclear Power Plants (NPPs) of Flamanville, Paluel and Penly, 17 on the Flamanville EPR reactor, 64 on “fuel cycle” facilities, research facilities and facilities undergoing decommissioning, 41 in small-scale nuclear activities, 11 in the transport of radioactive substances and eight in ASN-approved organisations and laboratories.

In addition to this, 21 days of labour inspection were carried out on the NPP sites and the Flamanville 3 EPR construction site.

In 2024, ASN was notified of 20 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES), of which 18 occurred in Basic Nuclear Installations (BNIs) and two in small-scale nuclear activities.

Lastly, in the context of their oversight duties, the ASN inspectors issued one violation report.

FLAMANVILLE NUCLEAR POWER PLANT

Operated by EDF and situated in the Manche *département* in the municipality of Flamanville, 25 km south-west of Cherbourg, the Flamanville NPP comprises two Pressurised Water Reactors (PWRs), each of 1,300 MWe commissioned in 1985 and 1986. Reactor 1 constitutes BNI 108 and reactor 2 BNI 109.

ASN considers that the performance of the Flamanville NPP with regard to nuclear safety, radiation protection and environmental protection is in line with the general assessment of EDF plant performance.

In the area of nuclear safety, ASN observed a stable situation with regard to control of the state of the facilities and application of the fundamental safety principles by the plant personnel and outside contractors. With regard to reactor management and operation, ASN considers that the site's performance is stable but remains tenuous. The restarting of reactor 2 following an outage involving numerous maintenance operations, including the ten-yearly requalifications of the secondary systems, went well on the whole. The year 2024 was nevertheless marked, as in the preceding years, by a large number of significant events notified to ASN linked to a deficiency in facility monitoring and noncompliance with the baseline operating requirements. The licensee must take action on these points to improve work rigour in the service responsible for operational management.

ASN considers that the maintenance operations were carried out proficiently by the licensee during the reactor

outages in 2024, despite the damage that occurred during a test on an emergency diesel generator set at the start of reactor 2 shutdown, making it necessary to review the activities schedule. In 2025, the licensee must be particularly attentive to the coordination and monitoring of subcontracted activities, especially during the reactor 2 outage during which replacement of the four steam generators is scheduled.

The radiation protection performance remained stable in 2024, with an effective process for detecting and analysing significant radiation protection events. Nevertheless, anomalies regarding the wearing of dosimeters and control of the risk of contamination dispersion were still present in 2024. ASN expects to see improvements in these two points.

With regard to environmental protection, ASN observes a stable situation where the licensee controls the impacts of its facilities and seeks to reduce them. The year 2025 must be used to improve responsiveness when anomalies are detected and achieve greater rigour in the treatment of the waste produced during reactor outages.

With regard to labour inspection, despite an apparently robust organisation, ASN considers that the licensee is not making sufficient progress in correcting its weak points for the situation to be deemed satisfactory. The occurrence of several accidents, one of them particularly noteworthy, justified the licensee's deployment of a specific action plan at the end of 2024. The Authority for Nuclear Safety and Radiation Protection (ASNR) will be particularly attentive to the progress and application of this action plan.

PALUEL NUCLEAR POWER PLANT

The Paluel NPP operated by EDF in the municipality of Paluel in the Seine-Maritime *département*, 30 km south-west of Dieppe, comprises four 1,300 MWe PWRs commissioned between 1984 and 1986. Reactors 1, 2, 3 and 4 constitute BNIs 103, 104, 114 and 115 respectively.

The site accommodates one of the regional bases of the Nuclear Rapid Intervention Force (FARN) created by EDF in 2011 further to the Fukushima Daiichi NPP accident in Japan. Its role is to intervene in pre-accident or accident situations, on any NPP in France, by providing additional human resources and emergency equipment.

ASN considers that the performance of the Paluel NPP with regard to nuclear safety, radiation protection and environmental protection is on the whole in line with the general assessment of EDF plant performance.

With regard to nuclear safety, ASN considers the performance of the NPP to be satisfactory. However, even if operational rigour has improved in certain activities, such as monitoring of the facilities when managing transient operating phases, it must be further improved for the activities relating to the configuring of systems and components (lockout/tagouts, administrative lockouts). A marking event in 2024 was a fire in the reactor 3 transformer, during which the operating and fire-fighting teams responded well. The site must nevertheless be particularly attentive to the quality and presentation of the operating documents, especially the procedures used for operational management in incident or accident situations.

With regard to maintenance and the work associated with the reactor outages, ASN considers that the Paluel NPP on the whole maintained good control of the programme and of the quality of performance of the planned activities, despite their very substantial volume. ASN notes that further progress must be made in the management of deviations affecting the facility and that the efforts to improve worker monitoring must be continued. ASN will also be particularly attentive to the in-service monitoring of pressure equipment further to the shortcomings found in 2024.

ASN considers that the site's organisation for radiation protection is broadly satisfactory, particularly in the preparation of operations with high radiation exposure risks. Nevertheless, despite proactive measures on the part of the licensee, inadequacies persist in control of the contamination risk and the radiation protection culture during reactor outages.

ASN considers that the site's organisational setup for environmental protection enables the corresponding requirements to be satisfied on the whole. The fire outbreak on the reactor 3 transformer nevertheless highlighted shortcomings in the management of the fire-extinguishing water effluents. The licensee must define

The installations and activities to regulate comprise:



• Basic Nuclear Installations:

- the NPPs of Flamanville (2 reactors of 1,300 MWe), Paluel (4 reactors of 1,300 MWe), Penly (2 reactors of 1,300 MWe) and Flamanville 3 (1 reactor of 1,600 MWe) operated by EDF,
- the construction site of two EPR 2-type reactors at Penly,
- the Orano spent nuclear fuel reprocessing plant at La Hague,
- the Manche repository (CSM) of the French National Radioactive Waste Management Agency (Andra),
- the Ganil (National large heavy ion accelerator) in Caen;

• small-scale nuclear activities in the medical sector:

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- 8 external-beam radiotherapy departments (27 devices),
- 1 proton therapy department,
- 3 brachytherapy departments,
- 12 nuclear medicine departments,
- 50 centres practising fluoroscopy-guided interventional procedures,
- 70 computed tomography scanners,
- some 2,100 medical and dental radiology devices;

• small-scale nuclear activities in the industrial, veterinary and research sectors:

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- about 450 industrial and research centres, including 20 companies with an industrial radiography activity,
- 5 particle accelerators, including 1 cyclotron,
- 21 laboratories situated mainly in the universities of the region,
- 5 companies using gamma ray densitometers,
- about 260 veterinary surgeries or clinics practising diagnostic radiology, 1 equine research centre and 1 equine hospital centre;

• activities associated with the transport of radioactive substances;

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• ASN-approved laboratories and organisations:

- 9 head-offices of laboratories approved for taking environmental radioactivity measurements,
- 1 organisation approved for radiation protection controls.

a clear management strategy for these effluents that is applicable in incident situations. Lastly, the licensee must continue its efforts in the management of on-site transport of hazardous substances, which was again sub-standard this year.

With regard to labour inspection, ASN observes that the workers generally know and comply with the safety requirements.

PENLY NUCLEAR POWER PLANT

The Penly NPP operated by EDF in the Seine-Maritime *département* in the municipality of Penly, 15 km north-east of Dieppe, comprises two 1,300 MWe PWRs commissioned between 1990 and 1992. Reactor 1 constitutes BNI 136 and reactor 2 BNI 140.

ASN considers that the nuclear safety performance of the Penly NPP stands out positively with respect to its general assessment of EDF plant performance, and that its radiation protection and environmental protection performance is in line with this general assessment.

With regard to nuclear safety, ASN considers that the NPP's performance is progressing slightly, particularly in operating rigour. Some weaknesses nevertheless persist. In effect, there are Significant Safety Events (ESS), linked in particular to shortcomings in the facility configuration management (alignment, lockout/tagout), communication deficiencies within the operational management group (Human and Organisational Factors – HOFs) and in the completeness of the operating documents. ASN considers that particular attention must be paid to the quality of preparation of the activities and the documents associated with the routine operation activities (periodic tests, alignments, etc.) and to improving the way in which HOFs are taken into account.

With regard to maintenance, ASN considers that the organisation in place is robust and capable of guaranteeing the conformity and good overall condition of the equipment. ASN has nevertheless observed shortcomings in the process sheets and procedures used, leading to errors during maintenance operations. Efforts must be continued in order to limit these errors resulting from deficiencies in document presentation or completeness. Alongside this, the overlapping of two reactor outages in the second half of 2024 highlighted the weaknesses in the performance

and traceability of the operations aiming to guarantee the conformity of the facilities. ASN will be particularly attentive to these points in 2025, particularly the restarting of reactor 2 on completion of its ten-yearly outage.

In the area of radiation protection, ASN considers that progress has been made in organisational aspects, particularly with the continued deployment of the centres of competence in radiation protection. The inspections found a good standard of monitoring of the condition of the facilities. ASN considers that the site must continue the ongoing efforts to prevent the risk of contamination and be attentive to the processes involving high radiation exposure risks (industrial radiography work, marking out limited stay areas), which showed weaknesses at the end of the year.

With regard to protection of the environment, ASN considers that the Penly NPP has a robust organisation for managing and monitoring environmental discharges. On the occasion of an unannounced inspection, ASN found the EDF teams' organisation for deploying mobile means for taking environmental samples and measurements to be responsive and appropriate. In addition, the improvement in the measures taken to control discharges of ozone-depleting gases seems to be lasting over the long term.

With regard to labour inspection, ASN observes that the workers generally know and comply with the safety requirements. Inspections have nevertheless occasionally revealed deviations in the prevention of vital risks (such as prevention of the risk of falling from height and those associated with lifting activities), and in the ventilation of workplaces. ASN will therefore be particularly attentive to the steps taken to reinforce the measures to prevent these risks.

EPR REACTOR – FLAMANVILLE 3

Under construction since September 2007, the Flamanville EPR reactor was commissioned on 8 May 2024 after receiving commissioning authorisation from ASN. The first nuclear chain reaction took place on 3 September 2024 and the reactor was coupled to the French electricity grid for the first time on 21 December 2024. The reactor was continuing its startup tests at the end of 2024.

With regard to the pre-commissioning operations, ASN considers that EDF worked very hard to obtain issuance of the reactor commissioning authorisation. ASN consolidated its position essentially on the basis of the inspection of the startup tests, the state of completion of the facilities, the operational capability, and the assessment of the conformity of the Nuclear Pressure Equipment (NPE).

Completion of the pre-commissioning startup test programme underwent two dedicated inspections, and the test results report was examined by ASN. Furthermore, as requested by ASN, EDF conducted several complementary periodic tests to ensure that the safety criteria, verified through tests sometimes performed several years ago, still meet requirements.

With regard to completion of the facility, EDF gave ASN work progress reports on a virtually daily basis right up until the reactor was commissioned. In addition, ASN conducted two inspections dedicated to fuel preparation prior to loading and commissioning of the controlled area, and a campaign of six inspections on preparation for loading and loading of the fuel into the reactor vessel.

The preparation of the teams assigned to reactor operation was subject to a tightened inspection. This inspection, which mobilised six ASN inspectors and one expert from the Institute for Radiation Protection and Nuclear Safety (IRSN) for two days, provided the opportunity to check the effective implementation of the measures decided by EDF in response to ASN's requests after the in-depth inspection conducted from 22 to 26 May 2023. ASN kept close track of the follow-ups to this inspection through to reactor commissioning.

The conformity of the NPE was established on the basis of the quality review, the way the irregularities affecting certain items of equipment were addressed and the appropriate preservation of the equipment. ASN continued the equipment conformity assessments through examinations

and inspections until May 2024, enabling the level-1 NPE conformity assessment reports and the reactor nuclear steam supply system report to be issued.

Thus, between the start of 2024 and issuance of the commissioning authorisation (7 May 2024), ASN's oversight action was equivalent to 18 days of inspection on the Flamanville EPR reactor.

Since the reactor was commissioned, ASN has directed its oversight essentially towards the addressing of significant events, monitoring the action taken further to unforeseen events encountered by the licensee and monitoring the startup tests. For this startup phase, ASN's oversight action was equivalent to nine days of inspection.

As concerns the post-commissioning reactor startup operations, ASN considers that the licensee managed the activities proficiently, particularly the startup tests, and dealt with the unforeseen events adequately.

EDF has notified a large number of safety-significant events since the reactor was commissioned, of which about a third have been rated level 1 on the INES scale. ASN is particularly attentive with regard to the analysis of the root causes of these events and the action taken by EDF to build on the lessons learned from the events and safeguard the forthcoming startup activities and future operation of the reactor. The large number of events notified is linked in particular to the rise in the personnel's competence in the implementation of the first reactor operation actions and the transition from a worksite culture to an operational culture. The large majority of the events have human or organisational causes; few of them are associated with equipment failures. Furthermore, a large proportion of

the events are linked to human errors that are detected immediately with rapid restoration of facility conformity. ASN considers that the measures taken by EDF further to these findings are relevant and appropriate for the difficulties encountered during this phase.

More specifically, ASN expects the licensee to demonstrate greater rigour, notably in the application of the fundamentals of facility operational management. The licensee must remain vigilant regarding the control of reactivity and the assimilation of operation of the main emergency generator sets.

Alongside commissioning and startup, ASN initiated inspections – as it does on the other EDF reactors – on varied themes such as containment, control of the fire risk, environmental discharges, waste management, command of configuring the facility and in-service monitoring of NPE. ASN thus carried out oversight actions on these subjects equivalent to ten days of inspection and considers that EDF's organisation is satisfactory, except for the monitoring and taking of water intakes and effluent discharges, and for waste management. On these points ASN expects the licensee to improve its knowledge and management of the equipment involved in discharge monitoring, and considers that the organisation of waste transfer management must be improved in view of the future reactor outages.

ASN also ensures the labour inspection duties on the Flamanville EPR reactor. In 2024, apart from checking companies' compliance with the provisions of labour law, ASN examined more particularly the conformity of the air purification systems of the work spaces. ASN considers that the safety organisation is appropriate on the whole.

MANCHE WASTE REPOSITORY

The Manche waste repository (CSM), which was commissioned in 1969, was the first radioactive waste repository operated in France. 527,225 m³ of waste packages are emplaced in it. The last waste packages to enter this facility were accepted in July 1994. From the regulatory aspect, the CSM is in the decommissioning phase (operations prior to its closure) until the installation of the long-term cover is completed. An ASN resolution shall specify the date of closure of the repository (entry into monitoring and surveillance phase) and the minimum duration of the monitoring and surveillance phase.

On 29 April 2024, after completing its examination of the periodic safety review report submitted by Andra in 2019, ASN authorised the continued operation of the repository.

It has nevertheless issued a number of requirements aiming to continue the studies on the behaviour of the existing cover, of the long-term cover and preservation of the site memory. One requirement also concerns the continuation of the studies into the retrieval of packagings containing long-lived radionuclides.

ASN also considers that the organisation defined and implemented for operation of the CSM facilities with regard to safety, radiation protection, environmental monitoring and meeting commitments is broadly satisfactory. As part of the continuous improvement process, the licensee must nevertheless consolidate, within its baseline requirements, the information relative to the fraud risk analysis, particularly with respect to outside contractors.

NATIONAL LARGE HEAVY ION ACCELERATOR

The National Large Heavy Ion Accelerator (Ganil) economic interest group was authorised in 1980 to create an ion accelerator in Caen (BNI 113). This research facility produces, accelerates and distributes ion beams with various energy levels to study the structure of the atom. The high-energy beams produce strong fields of ionising radiation, activating the materials in contact, which then emit radiation even after the beams have stopped. Irradiation thus constitutes the main risk created by Ganil.

"Exotic nuclei" are nuclei which do not exist naturally on Earth. They are created artificially in Ganil for nuclear physics experiments on the origins and structure of matter. In order to produce these exotic nuclei, Ganil was authorised in 2012 to build phase 1 of the SPIRAL2 project, whose commissioning was authorised by ASN in 2019.

A new project is currently underway on the site with the “DESIR” facility, standing for Disintegration, Excitation and Storage of Radioactive Ions. The primary function of the DESIR project will be to create new experimentation areas based on beams of radioactive ions produced by the SPIRAL1 and S3 facilities (experimental area of the SPIRAL2 phase 1 facility). This project involves modifying the BNI perimeter. The examination of this file continued in 2024 and ASN issued a favourable opinion on the draft decree on 10 December 2024.

Examination of the second periodic safety review of the facility is also in progress. The review inspection of 20 December 2023 confirmed the GaniL’s progress in characterising the defined requirements associated with the activities and elements important for the protection of interests and the progress in incorporating these changes

into the baseline operating requirements. The licensee must formalise more precisely the methods of taking the human and organisational aspects into account in the modifications made to the facility.

In the context of a national campaign in 2024 focusing on counterfeits, falsifications and suspicions of fraud, ASN observed that the licensee had taken measures to prevent, detect and address such infringements. However, these measures are not structured in a single process in the licensee’s integrated management system. ASNR will be attentive to the setting up of such a structured process.

The licensee presented a change in its organisation in 2024, which should be effective in 2025. ASNR will be attentive to ensuring that the nuclear safety and radiation exposure risks are duly taken into account when it is implemented.

— La Hague site

The Orano site at La Hague is located on the north-west tip of the Cotentin peninsula, in the Manche *département*, 20 km west of Cherbourg and 6 km from Cap de La Hague. The site is situated about fifteen kilometres from the Channel Islands.

THE ORANO RECYCLAGE REPROCESSING PLANTS IN OPERATION AT LA HAGUE

The La Hague plants for reprocessing fuel assemblies irradiated in the nuclear reactors are operated by Orano Recyclage La Hague.

Commissioning of the various units of the fuel reprocessing and waste packaging plants UP3-A (BNI 116) and UP2-800 (BNI 117) and the Effluent Treatment Station STE3 (BNI 118) spanned from 1986 (reception and storage of spent fuel assemblies) until 2002 (R4 plutonium treatment unit), with the majority of the process units being commissioned in 1989-1990.

The Decrees of 10 January 2003 set the individual reprocessing capacity of each of the two plants at 1,000 tonnes per year (t/year), in terms of the quantities of uranium and plutonium contained in the fuel assemblies before burn-up (in the reactor), and limit the total capacity of the two plants to 1,700 t/year. The limits and conditions for discharges and water intake by the site are defined by ASN resolutions 2022-DC-0724 and 2022-DC-0725 of 16 June 2022.

Operations carried out in the plants

The reprocessing plants comprise several industrial units, each intended for a particular operation. Consequently there are facilities for the reception and storage of spent fuel assemblies, for their shearing and dissolution, for the chemical separation of fission products, uranium and plutonium, for the purification of uranium and plutonium, for treating the effluents and for packaging the waste.

When the spent fuel assemblies arrive at the plants in their transport casks, they are unloaded either “under water” in the spent fuel pool, or “dry” in a leaktight shielded cell. The fuel assemblies are then stored in pools to cool them down.

They are then sheared and dissolved in nitric acid to separate the pieces of metal cladding from the spent nuclear fuel. The pieces of cladding, which are insoluble in nitric acid, are removed from the dissolver, rinsed in acid and then water, and transferred to a compacting and packaging unit.

The nitric acid solution comprising the dissolved radioactive substances is then processed in order to extract the uranium and plutonium and leave the fission products and other transuranic elements.

After purification, the uranium is concentrated and stored in the form of uranyl nitrate ($\text{UO}_2(\text{NO}_3)_2$). It will then be converted into a stable solid compound (U_3O_8) in the TU5 facility on the Tricastin site. The uranium resulting from this process is called “reprocessed uranium”.

After purification and concentration, the plutonium is precipitated by oxalic acid, dried, calcined into plutonium oxide, packaged in sealed containers and stored. The plutonium is then used for the fabrication of MOX (Mixed OXide) fuels in the Orano plant in Marcoule (Melox).

The effluents and waste produced by the operation of the plants

The fission products and other transuranic elements resulting from reprocessing are concentrated, vitrified and packaged in Standard vitrified waste packages (CSD-V). The pieces of metal cladding are compacted and packaged in Standard compacted waste packages (CSD-C).

Furthermore, the reprocessing operations described in the previous paragraph involve chemical and mechanical processes which produce gaseous and liquid effluents and solid waste.

The solid waste is packaged on site by either compaction or encapsulation in cement. The solid radioactive waste resulting from the reprocessing of the spent fuel assemblies

The installations at La Hague



Shut down installations undergoing decommissioning

BNI 80 – Oxide High Activity facility (HAO):

- **HAO/North:** Facility for “under water” unloading and storage of spent fuel elements,
- **HAO/South:** Facility for shearing and dissolving spent fuel elements;

BNI 33 • UP2-400 plant, first reprocessing unit:

- **HA/DE:** Facility for separating uranium and plutonium from fission products,

- **HAPF/SPF (1 à 3):** Facility for fission product concentration and storage,
- **MAU:** Facility for separating uranium and plutonium, uranium purification and storage as uranyl nitrate,
- **MAPu:** Facility for purification, conversion to oxide and initial packaging of plutonium oxide,
- **LCC:** Central product quality control laboratory,
- **ACR:** Resin conditioning facility;

BNI 38 • STE2 facility: effluent collection and treatment and storage of precipitation sludge, and AT1 facility, prototype facility currently being decommissioned;

BNI 47 • ELAN IIB facility, research installation currently being decommissioned.

Installations in operation

BNI 116 • UP3-A plant:

- **T0:** Facility for dry unloading of spent fuel elements,
- **Pools D and E:** Storage pools for spent fuel elements,
- **T1:** Facility for shearing fuel elements, dissolving and clarification of the resulting solutions,
- **T2:** Facility for separating uranium, plutonium and fission products and concentrating /storing fission product solutions,
- **T3/T5:** Facilities for purification and storage of uranyl nitrate,
- **T4:** Facility for purification, conversion to oxide and packaging of plutonium,
- **T7:** Fission products vitrification facility,
- **BSI:** Plutonium oxide storage facility,
- **BC:** Plant control room, reagent distribution facility and process control laboratories,
- **ACC:** Hull and end-piece compaction facility,

- **AD2:** Technological waste packaging facility,
- **ADT:** Waste transit area,
- **EDS:** Solid waste storage area,
- **E/D EDS:** Solid waste storage/removal from storage facility,
- **ECC:** Facilities for storage and retrieval of technological waste and packaged structures,
- **E/EV South-East:** Vitrified residues storage facility,
- **E/EV/LH and E/EV/LH 2:** Vitrified residues storage facility extensions;

BNI 117 • UP2-800 plant:

- **NPH:** Facility for “under water” unloading and storage of spent fuel elements in pool,
- **Pool C:** Spent fuel element storage pool,
- **R1:** Facility for shearing and dissolving fuel elements and clarification of the resulting solutions (including the URP: plutonium redissolution facility),

- **R2:** Facility for separating uranium, plutonium and fission products and concentrating /storing fission product solutions (including the UCD: centralised alpha waste conditioning unit),
- **SPF (4, 5, 6):** Fission product storage facilities,
- **R4:** Facility for purification, conversion to oxide and initial packaging of plutonium oxide,
- **BS1:** Facility for secondary packaging and storage of plutonium oxide,
- **R7:** Fission products vitrification facility,
- **AML • AMEC:** Package reception and servicing facility;

BNI 118 • STE3 facility: Effluent collection and treatment and storage of bituminised waste packages:

- **E/D EB:** Alpha waste storage/removal from storage,
- **MDS/B:** Mineralisation of solvent waste.

from the French reactors is, depending on its composition, either sent to the Aube repository (CSA) or stored on the Orano Recyclage La Hague site until a definitive disposal solution is found (particularly the CSD-V and CSD-C packages).

In accordance with Article L. 542-2 of the Environment Code, radioactive waste from the reprocessing of spent fuels of foreign origin is shipped back to its owners. It is however impossible to physically separate the waste according to the fuel from which it originates. In order to guarantee an equitable distribution of the waste resulting from the reprocessing of the fuels of its various customers, the licensee has proposed an accounting system that tracks the entries into and exits from the La Hague plant. This

system, called “EXPER”, was approved by the Order of 2 October 2008 of the Minister responsible for energy.

The gaseous effluents are released mainly when the fuel assemblies are sheared and during the dissolution process. These gaseous effluents are treated by washing in a gas treatment unit. The residual radioactive gases, particularly krypton and tritium, are checked before being discharged into the atmosphere.

The liquid effluents are treated and usually recycled. Some radionuclides, such as iodine and tritium, are channelled – after being checked – to the sea discharge outfall. This outfall, like the other outfalls of the site, is subject to discharge limits. The other effluents are routed to the site's packaging units (solid glass or bitumen matrix).

FINAL SHUTDOWN AND DECOMMISSIONING OPERATIONS ON CERTAIN FACILITIES

The former spent fuel reprocessing plant UP2-400 (BNI 33) was commissioned in 1966 and has been definitively shut down since 1 January 2004.

Final shutdown also concerns three BNIs associated with the UP2-400 plant: BNI 38 (which comprises the Effluents and solid waste treatment station No. 2 – STE2, and the Oxide nuclear fuel reprocessing facility No. 1 – AT1), BNI 47 (Radioactive source fabrication unit – ELAN IIB) and BNI 80 (HAO facility).

Orano submitted two partial decommissioning authorisation requests for BNIs 33 and 38 in April 2018. The schedule push-backs requested by the licensee lead to decommissioning completion deadlines in 2046 and 2043 instead of 2035, the previous deadline prescribed for the two BNIs. Further to Orano's additions to the file concerning firstly the elimination of the interactions between the MAPu facility and the plutonium BST1 facility in the event of an earthquake, and secondly the memorandum in response to the opinion of the environmental authority, a public inquiry was held from 20 October to 20 November 2020. At the end of the inquiry, the inquiry commission issued a favourable opinion. ASN issued an opinion on the draft decrees in July 2022. Decrees 2022-1480 and 2022-1481 dated 28 November 2022 were published in the *Official Journal* of 29 November 2022.

ASN notes that the schedule push-backs requested are significant and largely due to the delays in legacy Waste Retrieval and Packaging (WRP). Consequently, ASNR will continue to monitor the management of these projects in 2025.

LEGACY WASTE RETRIEVAL AND PACKAGING OPERATIONS

Unlike the direct on-line packaging of the waste generated by the new UP2-800 and UP3-A plants at La Hague, most of the waste generated by the first UP2-400 plant was stored in bulk without permanent packaging. The operations to retrieve this waste are complex and necessitate the deployment of substantial means. They present major safety and radiation exposure risks, which ASN monitors with particular attention.

The retrieval of the waste contained in the old storage facilities of the La Hague site is also a prerequisite for the decommissioning and clean-out of these facilities.

Retrieval and packaging of the STE2 sludges

The STE2 station served to collect the effluents from the UP2-400 plant, to treat them and to store the precipitation sludges resulting from the treatment. The STE2 sludges are precipitates that fix the radiological activity contained in the effluents and they are stored in seven silos. A portion of the sludges has been encapsulated in bitumen and packaged in stainless steel drums in the STE3 facility. Following ASN's banning of bituminisation in 2008, Orano studied other packaging methods for the non-packaged or stored sludges.

The scenario for the retrieval and packaging of the STE2 sludges presented in 2010 was broken down into three steps:

- retrieval of the sludges stored in silos in STE2 (BNI 38);
- transfer and treatment, initially envisaged by drying and compaction, in STE3 (BNI 118);
- packaging of the resulting pellets into "C5" packages for deep geological disposal.

ASN authorised the first phase of the work to retrieve the sludges from STE2 in 2015. The Creation Authorisation Decree for STE3 was modified by the Decree of 29 January 2016 to allow the installation of the STE2 sludges treatment process.

At the end of 2017 however, Orano informed ASN that the process chosen for treating the sludges in STE3 could lead to difficulties in equipment operation and maintenance. Orano proposed an alternative scenario using centrifugation and in August 2019 it submitted a Safety Options Dossier (DOS), which is however based on as yet insufficiently substantiated hypotheses. An inspection conducted at the end of 2019 confirmed that the project was not sufficiently mature for ASN to be able to give an opinion on this DOS.

In 2022, during the technical discussions held between Orano, ASN and IRSN, Orano committed itself to a new roadmap for this project. Orano has thus abandoned the centrifugation scenario and undertaken to conduct new studies in parallel aiming firstly to look into the sludge treatment and packaging solutions in more detail, and secondly to put in place an intermediate storage facility (new silos) under suitably safe conditions, enabling the retrieval and safe storage of these sludges to be separated from their final packaging. Orano sent ASN the DOS associated with this project to create new sludge storage silos (project called "NABUCO") in December 2023. It is currently being examined by ASNR.

Silo 130

Silo 130 is a reinforced concrete underground storage facility, with a carbon steel liner, used for dry storage of solid waste from the reprocessing of Gas-Cooled Reactor (GCR) fuels, and the storage of technological waste and contaminated soils and rubble. The silo received waste of this type as from 1973, until the 1981 fire which forced the licensee to flood the waste. The leak-tightness of the water-filled silo is only ensured at present by a single containment barrier consisting of a steel "skin". Furthermore, the civil engineering structure of silo 130 is weakened by ageing and by the fire that occurred in 1981. The water is therefore in direct contact with the waste and can contribute to corrosion of the carbon steel liner.

One of the major risks for this facility concerns the dispersion of radioactive substances into the environment by infiltration of contaminated water into the water table. The leak-tightness of silo 130 is monitored by a network of piezometers situated nearby. Another factor that can compromise the safety of silo 130 is linked to the nature of the substances present in the waste, such as magnesium, which is pyrophoric. Hydrogen, a highly inflammable gas, can also be produced by phenomena of radiolysis or corrosion (presence of water). These elements contribute to the fire and explosion risks.

The WRP scenario comprises four steps:

- retrieval and packaging of the solid GCR waste;
- retrieval of the liquid effluents;
- retrieval and packaging of the residual GCR waste and the sludges from the bottom of the silo;
- retrieval and packaging of the soils and rubble.

Orano has built a retrieval unit above the pit containing the waste and a new building dedicated to the storing and packaging operations.

The licensee validated industrial commissioning of the waste recovery process in 2022, further to the tests carried out in 2020 and 2021. About fifty drums of waste were retrieved in 2023, and the retrieval work in 2024 brought this figure to 200 drums of waste: about a third of the total quantity of waste of phase 1 has thus been retrieved since the operations began in 2020. The increase in the retrieval rate in 2024 is mainly due to the setting up of a maintenance team dedicated to silo 130 and the change, as of November 2023, to teams working three 8-hour shifts a day instead of the initial two 8-hour shifts.

ASN considers that these measures are positive, but the various technical problems observed on the equipment in 2024 confirm the need for Orano to improve the reliability of the waste retrieval facilities.

HAO silo and Organised Storage of Hulls (SOC)

The Oxide High Activity facility (HAO – BNI 80) ensured the first steps of the spent nuclear fuel reprocessing process: reception, storage, then shearing and dissolution. The dissolution solutions produced in BNI 80 were then transferred to the UP2-400 industrial plant in which the subsequent reprocessing operations took place.

BNI 80 comprises:

- HAO North, spent fuel unloading and storage site;
- HAO South, where the shearing and dissolution operations were carried out;
- the “filtration” building, which accommodates the filtration system for the HAO South pool;
- the HAO silo, in which are stored the hulls and end-pieces (fragments of cladding and fuel end-pieces) in bulk, fines coming primarily from shearing, and resins and technological waste from the operation of the HAO facility between 1976 and 1997;
- the SOC, comprising three pools in which the drums containing the hulls and end-pieces are stored.

In 2024, the licensee continued the operations prior to retrieval of the waste from the HAO silo and the implementation of the physical modifications defined on completion of the analysis of hard spots identified during the functional tests of the waste retrieval system. Through ASN resolution 2024-DC-0784 of 3 September 2024, the licensee was authorised to commission the unit for retrieving and packaging the waste from the HAO silo and the SOC pools in ECE drums. However, the licensee encountered several technical difficulties during the tests and suffered delays in delivery of some of the retrieval equipment, leading it to announce that the project schedule was pushed back by two years. In this context, Orano determined the technical, organisational and human causes, then defined and implemented measures to mitigate the consequences. To this end, ASN notes the plan for tightened monitoring of the supplier in question in order to better control the supply times, even if risks of further delays in equipment delivery subsist.

Assessment of the Orano site

ASN considers that the performance of the Orano Recyclage La Hague site in 2024 is satisfactory in the areas of nuclear safety, radiation protection and environmental protection.

With regard to nuclear safety, ASN finds the command of the internal baseline requirements and of operational management to be satisfactory. ASN also takes positive note of the tracking of the operational management teams' skills and staff numbers. However, in the context of the organisational changes linked to the "Convergence" project, the level of serenity in the centralised control room must be improved, notably by eliminating the untimely alarms, by improving the digital shift log functionalities and by limiting external demands. Greater rigour is also still expected in the tracking of periodic inspections.

Alongside this, ASN views favourably the ongoing deployment of an organisational setup aiming to enhance the efficiency of facility maintenance operations. Nevertheless, across-site action must be taken to identify the spare parts for safety-important equipment concerned by a risk of technological obsolescence.

ASN underlines the generally good organisation of outside contractor monitoring. However, the monitoring of maintenance operations must be reinforced. Orano must also ensure that it monitors its contractors' subcontractors sufficiently closely. Lastly, ASN confirms the need to improve the rigour with which the monitoring reports are filled out (reference of the monitoring actions, consistency between what is expected and the final results, etc.).

With regard to fire risk management, ASN takes positive note of the personnel's responsiveness during unannounced exercises, and the proficiency of the operational management teams and the site's emergency response department in fulfilling the tasks incumbent on them. However, improvements are required in the management of fire detection system disabling operations and in the integration of new fire-risk control equipment in the maintenance management system. Across-site action is also required to identify and then correct or justify the deviations from the reference standards relative to the maintenance and periodic inspections of equipment involved in controlling the fire risk.

In the area of radiation protection, ASN has a positive judgement of the functioning of the site's centre of competence. However, a large number of deviations in radiation protection subsist, and shortcomings pertaining to the contract for tracking the radiation protection-related devices are identified. ASN takes note of the specific action plans initiated to address these issues and more broadly remains attentive to the ongoing modernisation and transformation of the radiation protection

professions. Regarding radioactive source management, ASN notes the progress made in the replacement of expired/disused sources, even though it must be continued in 2025. Furthermore, the steps to remove expired/disused sources must be reinforced in 2025.

With regard to environmental protection in 2024, no major deviation was noted concerning compliance with discharge limits, control of effluents or monitoring of the environment. ASN does however consider that take-up of the measures to control non-radiological risks on the site must be improved. In particular, the inspections on this theme showed differences between the safety barriers stipulated by the hazards assessment and practices actually implemented. These findings are supported by the occurrence of a leak in a nitric acid tank in an outdoor reagent storage yard, which must give rise to in-depth analysis on the scale of the site. ASN also notes recurrent deviations involving control of refrigerants and fluorinated greenhouse gases and considers that Orano must improve the measures taken to prevent and detect the associated emissions and reduce them to as low a level as possible.

Concerning the hydraulic structure of the Moulinets Dam, an ASN resolution of 19 June 2024 gives Orano formal notice to make this structure fully compliant before the end of 2025, and to this end it sets intermediate deadlines. ASN considers that Orano met the deadlines for 2024.

Alongside this, ASN considers that the operations to complete the projects concerning the setting up of the new fission products concentration units (NCPF) went satisfactorily, which enabled the NCPF project associated with the R2 unit to be commissioned in June 2024. ASN does however note that modifications incorporated into the project at a late stage led to difficulties at the end of the commissioning review.

ASN observes that the organisation for the off-site and on-site transport of radioactive substances and for the maintenance of the packagings used on the La Hague site remains satisfactory. New on-site transport routes integrating new accident prevention measures were put in place in 2024 to take into account the new tightened protection area, and feedback on its implementation is expected, particularly regarding the impact of the infrastructure on the transport systems. Orano also continued putting in place the improvements to the Mobile Material Evacuation Enclosure (EMEM) transport system. ASN nevertheless finds it regrettable that the licensee has difficulty in carrying out its improvements within the prescribed deadlines.

With regard to the progress of the decommissioning and WRP projects, the work continued in 2024 under suitably safe conditions on the whole.

ASN nevertheless again observes that several decommissioning and legacy WRP projects continue to encounter problems leading to further delays. With regard to decommissioning, Orano must continue its efforts to address the issues that impact the operations schedule.

With regard to silo 130, which is the furthest advanced project and in the industrial operation phase, the rate of waste retrieval has increased following the organisational changes implemented by Orano at the end of 2023 (transition to teams working three 8-hour shifts instead of two 8-hour shifts, setting up of a maintenance team dedicated to the task, etc.). However, numerous unforeseeable events affecting the waste retrieval equipment were again encountered in 2024, leading to several periods of work stoppage. Consequently, ASN considers that Orano must improve equipment reliability and continue to integrate the lessons learned from silo 130 into the other legacy waste retrieval projects.

As concerns the project for retrieval of waste from the HAO silo, in 2024 Orano confirmed the two-year push-back in the project schedule, particularly due to the lateness in delivery of certain retrieval equipment items. In this context, Orano determined the technical, organisational and human causes, then defined and implemented measures to mitigate the consequences. Among these measures, ASN notes the plan for tightened monitoring of the supplier in question in order to better control the supply times, even if risks of further delays in equipment delivery subsist.

With regard to silo 115, ASN takes positive note of the work completed in 2024 to make the structural framework secure. ASN however also notes the delays in the detailed design study and the waste retrieval schedule, delays which remain to be quantified given the change in the retrieval technique that will be used.

Concerning the HAPF unit, some of its evaporators were used to manage the effluents from the plants in service until the end of 2024. The licensee asked ASN for authorisation to continue using these evaporators in the decommissioning of the facilities, but the need to better substantiate the ability of these devices to function for prolonged periods in complete safety prolonged the examination of this file. ASN will be attentive to the defining of alternative solutions that allow the decommissioning operations to continue, whatever the decision concerning prolongation of the use of the evaporators.

Lastly, ASN notes that Orano has taken measures to ensure broadly satisfactory management of the interfaces between the facilities and units in operation and the decommissioning and WRP projects on the La Hague site.

Nouvelle-Aquitaine

The Bordeaux division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 12 *départements* of the Nouvelle-Aquitaine region.

135

inspections

9

significant events
rated level 1
or higher

In 2024, ASN carried out 135 inspections in the Nouvelle-Aquitaine region, comprising 63 in the Blayais and Civaux Nuclear Power Plants (NPPs), 62 in small-scale nuclear facilities, five in the area of radioactive substance transport and five concerning ASN-approved organisations and laboratories.

ASN also carried out 17 days of labour inspection at the Blayais NPP and 12 days at the Civaux NPP.

During 2024, eight significant event rated level 1 on the International Nuclear and Radiological Event Scale (INES) were notified by the NPP licensees in the Nouvelle-Aquitaine region. In small-scale nuclear activities, one significant radiation protection event rated level 2 on the ASN-SFRO scale was notified to ASN.

ASN filed a report with the Public Prosecutor pursuant to Article 40 of the Penal Procedure Code concerning occupational safety.

BLAYAIS NUCLEAR POWER PLANT

The Blayais NPP situated in the Gironde *département*, 50 km north of Bordeaux, is operated by EDF and comprises four Pressurised Water Reactors (PWRs) with a power of 900 Megawatts electric (MWe), commissioned in 1981 and 1982. Reactors 1 and 2 constitute Basic Nuclear Installation (BNI) 86 and reactors 3 and 4 BNI 110.

ASN again considers that the performance of the Blayais NPP with regard to nuclear safety is below ASN's general assessment of EDF plant performance. The radiation protection and environmental performance is in line with ASN's general assessment of the EDF plants.

With regard to nuclear safety, in 2024 the Blayais NPP did not manage to stop the deterioration in performance observed since 2022. In the area of reactor operational management, ASN considers the licensee's performance to be far below average, as evidenced by the number and nature of the notified significant events. With regard to fire risk control, ASN notes a lack of results on the ground, despite the deployment of a plan of rigour. Lastly, with respect to maintenance, where a strong response from the licensee was expected, ASN observed that the site still has difficulties in activity preparation and management, and in the monitoring of maintenance operations. ASN expects results following the action plans initiated in 2023 and 2024 to significantly raise the level of performance, and it will conduct an in-depth inspection in June 2025 to make a detailed assessment of the situation.

With regard to occupational radiation protection, ASN considers that the performance has slightly declined compared with 2023, when it was judged to be improving. ASN underlines the licensee's continued commitment in this area, but observes that its efforts are undermined by

The installations and activities to regulate comprise:



• Basic Nuclear Installations:

- the Blayais NPP (4 reactors of 900 MWe),
- the Civaux NPP (2 reactors of 1,450 MWe);

• small-scale nuclear activities in the medical sector:

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- 19 external-beam radiotherapy departments,
- 6 brachytherapy departments,
- 23 nuclear medicine departments,
- 97 centres practising fluoroscopy-guided interventional procedures,
- 135 computed tomography scanners,
- some 6,000 medical and dental radiology devices;

• small-scale nuclear activities in the industrial, veterinary and research sectors:

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- about 960 industrial and research centres, including 60 companies with an industrial radiography activity,
- 1 cyclotron particle accelerator,
- 45 laboratories situated mainly in the universities of the region,
- some 450 veterinary surgeries or clinics practising diagnostic radiology;

• activities associated with the transport of radioactive substances;

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p. 276



• ASN-approved laboratories and organisations:

- 1 organisation approved for radiation protection controls,
- 12 organisations approved for measuring radon,
- 9 laboratories approved for taking environmental radioactivity measurements.

chronic difficulties some workers have in complying with the radiation protection fundamentals.

With regard to environmental protection, ASN underlines the licensee's efforts in this area over the last few years, for example in waste management, and the way it fully resolved the event declared in late 2023 regarding the deterioration of a retention structure in the demineralisation station. The site nevertheless reported several events revealing malfunctions, particularly concerning gaseous or liquid discharges. In addition, following the tightened inspection in 2024, ASN is waiting for elements to substantiate the liquid containment capacities.

With regard to labour inspection, ASN notes that the results concerning worker safety continue to deteriorate. ASN has asked the licensee to remedy the risk of machines colliding with pedestrians and the risks of falling from height. Accident situations involving the use of machine tools occurred in 2024. ASN also considers that the risk assessments must be improved and underlines that, despite the efforts made, there are still too many accidental exposures to asbestos fibres during maintenance work.

Lastly, ASNR will be vigilant in ensuring that installations maintain long-term compliance with the Labour Code requirements.

CIVAUX NUCLEAR POWER PLANT

The Civaux NPP operated by EDF in the Vienne *département*, 30 km south of Poitiers in the Nouvelle-Aquitaine region, comprises two 1,450 MWe PWRs commissioned in 1997 and 1999. Reactors 1 and 2 constitute BNIs 158 and 159 respectively. The site accommodates one of the regional bases of the Nuclear Rapid Intervention Force (FARN) created by EDF in 2011 further to the accident at the Fukushima Daiichi NPP in Japan. Its role is to intervene in pre-accident or accident situations, on any NPP in France, by providing additional human resources and emergency equipment.

ASN considers that the performance of the Civaux NPP in 2024 with regard to nuclear safety, radiation protection and environmental protection is in line with its general assessment of EDF plant performance.

In the area of nuclear safety, ASN considers that performance improved in 2024, particularly in the operational management of the facilities and in maintenance. Command of the shutdowns and restarting of the two reactors has improved in particular. The safety management improvement measures that brought this progress are to be continued. There is still room for progress in the documentation used, in preparation and assimilation of the various activities, particularly in the area of maintenance, and in the rigour with which they are carried out. The skills of workers in certain specialities also constitute a point requiring close attention. Lastly, ASN took positive note of the satisfactory management of a simulated emergency situation during a national emergency exercise.

In the area of radiation protection, ASN observed an improvement in performance on the particularly sensitive worksites during reactor shutdowns. The site has drawn lessons from the contamination dispersion event that occurred in the reactor building in 2023 during the reactor 2 outage. ASN has nevertheless detected shortcomings outside outage periods, showing that the radiation protection culture among workers and the monitoring by EDF can still be improved.

ASN conducted a tightened inspection focusing on environmental protection in 2024. Even though the prospects are encouraging, with the start of the work to create a fire-extinguishing water containment basin, ASN considers that the current containment of liquid effluents is not sufficiently controlled: more effective verification of the performance level of the isolating material is expected. No major deviation has been observed in the management of liquid effluents during normal operation or in the preservation of the water resource used for the site's needs.

With regard to labour inspection, ASN notes positively the depth of the analyses carried out following near-accidents. However, regarding occupational safety, shortcomings have been observed in the exhaustiveness of the risk analyses. ASN also expects the licensee to mobilise its resources to restore the regulatory conformity of the site's roadways, heavy cranes, and areas presenting an explosion risk.

Occitanie

The Bordeaux and Marseille divisions jointly regulate nuclear safety, radiation protection and the transport of radioactive substances in the 13 *départements* of the Occitanie region.

115

inspections

8

significant events
rated level 1
or higher

In 2024, ASN carried out 115 inspections in the Occitanie region, comprising 53 in the Basic Nuclear Installations (BNIs), 53 in small-scale nuclear facilities, five in the area of Radioactive Substance Transport (TSR) and four concerning ASN-approved organisations and laboratories.

ASN also carried out 12 days of labour inspection at the Golfech Nuclear Power Plant (NPP).

During 2024, four significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES) were notified by the NPP licensees of the nuclear installations in the Occitanie region, and one in the industrial sector. In small-scale nuclear activities, one significant radiation protection event rated level 4 on the ASN-SFRO scale and two events rated level 2 on the ASN-SFRO scale were notified to ASN.

Lastly, in the context of their oversight duties, the ASN inspectors issued one violation report.

GOLFECH NUCLEAR POWER PLANT

The Golfech NPP operated by EDF is located in the Tarn-et-Garonne *département*, 40 km west of Montauban. It comprises two Pressurised Water Reactors (PWRs), each of 1,300 Megawatts electric (MWe), commissioned in 1990 and 1993. Reactors 1 and 2 constitute BNIs 135 and 142 respectively.

ASN considers that the performance of the Golfech NPP with regard to nuclear safety, environmental protection and radiation protection is in line with the general assessment of EDF plant performance.

In the area of nuclear safety, ASN considers that the level of performance is now satisfactory, in an industrial context where the workload is nevertheless lower than in the previous years. During 2024, reactor 2 was shut down several times to save fuel and reactor 1 shut down following the detection of a leak on a secondary system equipment item. ASN takes a positive view of the management of the transient operating conditions associated with these situations. Weaknesses were nevertheless noted in system configuring and control of the documentation. Furthermore, ASN's inspections revealed shortcomings in control of the internal explosion risk and management of emergency resources. With regard to maintenance, several technical incidents involving automatic systems occurred, three of which led to reactor trips. Lastly, the changes in the reactor outage scheduling led to several activity postponements, which caused a few omissions in the planning of periodic inspections.

ASN thus considers that the licensee must consolidate its efforts in 2025 and confirm the stability of the site's nuclear safety performance in the context of the scheduled outages of the two reactors.

The radiation protection situation is considered satisfactory. The number of significant events remained low and ASN underlines that the workers take the radiation protection rules duly into account. Particular vigilance must however

The installations and activities to regulate comprise:



• Basic Nuclear Installations:

- the Golfech NPP (2 reactors of 1,300 MWe),
- the CEA Marcoule research centre, which includes the civil BNIs Atalante and Phénix and the Diadem waste storage facility construction site,
- the Melox "MOX" nuclear fuel production plant,
- the Centraco facility for processing low-level radioactive waste,
- the Gammatec industrial irradiator,
- the Écrin waste storage facility on the Malvézi site;

• small-scale nuclear activities in the medical sector:

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- 14 external-beam radiotherapy departments,
- 6 brachytherapy departments,
- 20 nuclear medicine departments,
- 91 centres practising fluoroscopy-guided interventional procedures,
- 121 computed tomography scanners,
- some 5,000 medical and dental radiology devices;

• small-scale nuclear activities in the industrial, veterinary and research sectors:

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- about 800 industrial and research centres, including 4 cyclotron particle accelerators, 29 companies exercising an industrial radiography activity and 60 laboratories situated mainly in the universities of the region,
- some 600 veterinary surgeries or clinics practising diagnostic radiology;

• activities associated with the transport of radioactive substances;

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• ASN-approved laboratories and organisations:

- 6 laboratories approved for taking environmental radioactivity measurements,
- 7 organisations approved for measuring radon,
- 2 organisations approved for radiation protection controls.

be maintained regarding road contamination and proper completion of the prior exposure evaluations.

With regard to environmental protection, ASN conducted a tightened inspection on the site which revealed improvements in this area, and more specifically in control of the risk of hazardous substance run-off into the environment. Nevertheless, the site is not yet completely up to the required standards, particularly in the management of effluent discharges into the stormwater tank.

With regard to labour inspection, the results concerning occupational safety are stable compared with 2023. However

an accident occurred during the use of a machine tool. ASN has asked the licensee to remedy the risk situations observed in traffic movements and the risk of collisions between pedestrians and machines. Efforts must still be made to ensure better control of work situations involving a risk of falling from height. ASN also considers that the relevance of the risk analyses must be improved. Lastly, the Authority for Nuclear Safety and Radiation Protection (ASNR) will be vigilant regarding in ensuring that installations maintain long-term compliance with the Labour Code requirements.

— Marcoule platform

The Marcoule nuclear platform is situated to the west of Orange in the Gard *département*. Its six civil installations are dedicated to research activities relating to the back-end of the “fuel cycle” and the irradiation of materials, and to industrial activities concerning in particular the fabrication of MOX (Mixed OXides) fuel, the processing of radioactive waste and the irradiation of materials. The majority of the site moreover consists of the Defence Basic Nuclear Installation (DBNI) under the oversight of the Ministry responsible for defence.

CEA MARCOULE CENTRE

Created in 1955, the CEA Marcoule centre accommodates three civil installations: the Atalante laboratories (BNI 148), the Phénix NPP (BNI 71) and the Diadem storage facility (BNI 177).

Atalante facility – CEA CENTRE

The main purpose of the Alpha facilities and laboratories for transuranium elements analysis and reprocessing studies (Atalante – BNI 148), created in the 1980's, is to conduct research and development in the recycling of nuclear fuels, the management of ultimate waste, and the exploration of new concepts for fourth generation nuclear systems. In order to extend these research activities, activities and equipment from the Laboratory for research and fabrication of advanced nuclear fuels (Lefca – BNI 123), were transferred here from the CEA Cadarache centre in 2017.

ASN published resolution 2022-DC-0720 of 19 April 2022 imposing on the Alternative Energies and Atomic Energy Commission (CEA) the requirements applicable to Atalante and designed to regulate the continued operation of the BNI. This resolution more specifically sets the deadline of 31 December 2035 for treating the Radioactive Organic Liquid Waste (ROLW) stored in the facility. Pending removal of this waste, CEA must take measures to ensure that the ROLW storage drums do not corrode and that it has sampling capabilities in order to monitor the physical-chemical quality of the ROLW. In that same resolution, ASN prescribes the implementation of a system for detecting and automatically cutting off the BNI's water and electricity supplies in the event of an earthquake. The commissioning of this system was

authorised in 2023. The deadline for effective commissioning of the system, set by the ASN prescription, was amended by resolution 2024-DC-0785 of 11 September 2024, pushing it back from end of December 2024 to end of August 2027. ASNR remains attentive to the tracking of the ongoing actions.

CEA submitted the Safety review guidance file (DOR) for its next periodic safety review, for which the concluding report is expected in December 2026.

Two significant events linked to prevention of the criticality risk and rated level 1 on the INES scale were notified by CEA in 2024. These events concerned a lack of preparation during fissile material transfers within the Atalante laboratories. CEA examined the causes of these events, which were essentially linked to human and organisational factors, and defined an action plan to correct the observed deviations in the short term and, in the longer term, to improve the prevention of criticality risks. These elements have been communicated to the other CEA BNIs concerned by criticality risks. ASNR will remain attentive to the licensee's implementation of the long-term measures of its action plan, aiming to reinforce the prevention of criticality risks.

ASN considers that the level of nuclear safety of Atalante is only relatively satisfactory, on account of the significant events relating to prevention of the criticality risk. However, the measures taken to monitor outside contractors and to track deviations and periodic inspections and tests are satisfactory on the whole. With regard to nuclear waste management in the facility, ASN expects the licensee to take measures to improve compliance with the waste storage time limits, which are defined in the Atalante baseline safety requirements.

Phénix reactor – CEA CENTRE

The Phénix NPP (BNI 71) is a demonstration fast breeder reactor cooled with liquid sodium. This reactor, with an electrical power rating of 250 MWe, was definitively shut down in 2009 and is currently being decommissioned.

The major decommissioning phases are regulated by Decree 2016-739 of 2 June 2016. ASN resolution 2016-DC-0564 of 7 July 2016 sets the CEA various milestones and decommissioning operations.

Removal of the irradiated fuel and equipment continued in 2024.

However, the reference decommissioning scenario for the facility, set by the Decommissioning Decree of June 2016, is currently being redefined by the licensee. This new definition mainly concerns the phasing of the decommissioning operations to favour treatment of the sodium, in accordance with the decommissioning strategy for all the CEA facilities. CEA plans to file a request to modify the Decommissioning Decree of BNI 71, with the aim of integrating this new reference scenario.

Construction of the NOAH facility, for which the commissioning application was filed in 2022 and which will ensure part of the treatment of sodium from Phénix and other CEA facilities, made progress in 2024. The operating tests prior to commissioning, which CEA plans for 2028, continued.

The facility continues to report deviations concerning compliance with certain physical-chemical parameters of the aqueous discharges. The licensee plans taking lasting measures to guarantee compliance with the physical-chemical limits of aqueous discharges in 2025.

The 2022 periodic safety review report for BNI 71 is currently being examined by ASN.

ASN considers that the level of nuclear safety and radiation protection in the Phénix plant is broadly satisfactory. The recurrent actions concerning the periodic inspections and tests and the monitoring of activities performed by outside contractors are broadly satisfactory. The licensee must nevertheless make sure that it meets its commitments within the deadlines it has set.

Diadem facility – CEA CENTRE

The Diadem facility, currently under construction, shall be dedicated to the storage of containers of radioactive waste emitting beta and gamma radiation, or waste rich in alpha emitters, pending construction of facilities for the disposal of long-lived waste (LLW), or low- and intermediate-level short-lived waste (LL/ILW-SL) whose characteristics – especially the dose rate – mean they cannot be accepted as-is by the existing disposal facilities.

One inspection was carried out in 2024 focusing primarily on the methodology and performance of the fall qualification tests of the future storage containers.

ASN considers that the CEA's efforts to fulfil its responsibilities as nuclear licensee have enabled it to take over project management, but further improvements are required in the identification of the actions and expectations of the Protection-Important Activities (PIAs), and in the qualification of the equipment items and the technical control of the PIAs. Moreover, the control and verification criteria for the specified requirements need to be more clearly defined.

ASN points out that this facility is destined to play a key role in the CEA's overall decommissioning and waste management strategy, insofar as it is the only facility planned for the interim storage of "intermediate-level long-lived" (ILW-LL) waste packages and LL/ILW-SL waste.

Assessment of the CEA Marcoule centre

ASN noted during its inspections in 2024 that the organisation and measures put in place by the licensee to guarantee control of the risks associated with external hazards are broadly satisfactory. The organisational setup for managing emergency situations can be improved. Improvements are required in the defining of emergency management functions and the associated requirements, the tracking of documentation and equipment, and the formalising and tracking of the actions decided upon on the basis of feedback from the exercises.

ASN considers that the Marcoule centre has taken ownership of the policy for the protection of CEA's interests by adapting and applying it to its local particularities. Improvements are required in the allocation of resources, the prioritising of actions, and complying with the indicators of its action plan. Improvements are also required in the assessment of the measures to correct deviations.

In the area of TSR, ASN considers that packaging maintenance is carried out correctly.

In 2020, the CEA submitted its study on the sanitary and environmental evaluation of the liquid and gaseous chemical discharges from the Marcoule platform. Through resolution CODEP-MRS-2023-013061 of 9 March 2023, ASN has required CEA, in association with the other licensees of the Marcoule platform installations, to have an independent organisation perform a third-party assessment focusing on CEA's methodology for evaluating the impact on health and the environment caused by the liquid and gaseous discharges from all the nuclear activities on the Marcoule site. CEA presented the results of this assessment in November 2024 and they will be examined by ASN.

The technical-economic study of the measures to avoid or reduce the discharge of potentially polluted stormwater and its impact on the environment was submitted to ASN in late 2020. The licensee finalised

deployment of the measures adopted following the study in 2022. ASN expects the licensee to give it feedback concerning their effectiveness.

ASN authorised updating of the On-site Emergency Plan (PUI) of the CEA Marcoule centre in December 2024. As the PUI is common to the BNIs and to the individual facilities of the DBNI, its implementation is also subject to the approval of the Defence Nuclear Safety Authority (ASND).

With regard to the conformity of the emergency management building – Centralised Surveillance of Marcoule (SCM) – the examination focuses on the substantiating elements provided by CEA to demonstrate compliance with the safety requirements defined for the "hardened safety core" equipment in ASN resolution 2015-DC-0481 of 8 January 2015. ASN shall be expecting to receive additional information.

ASN considers that the level of nuclear safety and radiation protection of the CEA Marcoule centre is broadly satisfactory.



The request to modify the Creation Authorisation Decree, concerning the change of package closing technology and the increase in the facility commissioning time frame, is currently being examined, as is the facility commissioning authorisation application.

ASN considers that CEA must continue its efforts in the management of the worksite and the work remaining to be done to allow the much-awaited commissioning of this key facility.

MELOX PLANT

Created in 1990 and operated by Orano Recyclage, the Melox plant (BNI 151) produces MOX fuel which consists of a mix of uranium and plutonium oxides.

ASN considers that the level of nuclear safety and radiation protection is broadly satisfactory in the areas of pressure equipment, external hazards, safety management, maintenance, waste, design and constructions, and fraud. An inspection on the follow-ups to the periodic safety review, for which the concluding report was submitted in September 2021, found that the safety review action plan is implemented satisfactorily and it is well tracked.

The effectiveness of the containment barriers is maintained at a satisfactory level. Breaks in containment, which can occur under normal operating conditions, are subject to specific monitoring and measures to limit them, such as using specific reinforced gloves.

In the last few years the licensee has had difficulties in producing the planned quantities of fuel conforming to the safety specifications of the nuclear reactors. This situation has led to the production of a large quantity of manufacturing rejects, which are sent to the La Hague site for interim storage, resulting in a risk in the short term of reaching the maximum capacity of the plant's plutonium-bearing material storage areas. The entire "fuel cycle" and French nuclear power generation could be destabilised by these problems. Making up for several years of degraded operation

of the facility moreover induces substantial maintenance requirements in the Melox plant. The numerous maintenance activities have consequences in terms of radiation protection, with a growing reliance on outside contractors and a very high collective dosimetry.

To overcome the production difficulties, the licensee qualified a new uranium oxide powder in 2022 which has, since 2023, enabled the quantity of rejects generated to be reduced. This improvement must be maintained and confirmed over the longer term. This new powder, produced by a new supplier – the Orano site of Malvési (see *chapter 12*) – is currently being qualified.

Several other actions are implemented to ensure that the improvement in the plant's productivity and the radiation protection of its workers lasts over the long term. First, the licensee is deploying a project called "GOMOX" which includes, among other things, the doubling of certain key elements of the plant production line. The secondary dosing station installation work was thus authorised by resolution CODEP-MRS-2024-040128 of 26 July 2024. The licensee also cleans out the glove boxes regularly and very thoroughly to reduce the ambient dose levels. Lastly, it is deploying a major maintenance programme ("PPRM" project) which aims to restore the production equipment availability rates. This programme continued in 2024. The maintenance teams were reinforced by Orano personnel in 2024.

CENTRACO PLANT

The Centraco plant (BNI 160), was created in 1996 and is operated by Cyclife France, a 100% subsidiary of EDF. The Centraco plant sorts, decontaminates, reuses, treats and packages - particularly by reducing their volume - waste and effluents with low and very low levels of radioactivity. The waste resulting from its process is then routed to the Aube repository (CSA) of the National Radioactive Waste Management Agency (Andra). The facility comprises:

- a melting unit, melting a maximum of 3,500 tonnes (t) of metallic waste per year;
- an incineration unit, in which the incinerable waste is burned, with a maximum of 3,000 t of solid waste and 2,000 t of liquid waste per year;
- and storage areas.

ASN considers that the nuclear safety of the facility in 2024 is broadly satisfactory, particularly regarding the management of deviations observed in inspections. This general assessment of the licensee's organisation must however be nuanced by the consecutive notifications of three significant events relating to the preparation of maintenance

operations. In effect, major shortcomings in the preparation of these operations were discovered during the reactive inspection conducted by ASN. A new organisation to enhance the reliability of safety-related maintenance operations was to be set up by the end of 2024. Furthermore, a situational exercise leading to deployment of the emergency command post ran satisfactorily.

The facility's periodic safety review concluding report was submitted on 18 February 2021 in accordance with ASN resolution 2014-DC-0446 of 17 July 2014. This file is still being examined. An inspection on the theme of meeting commitments found that tracking of commitments made further to the periodic safety review can be improved.

Moreover, ASNR is finalising the revision of the facility's discharge authorisations to take into account, when justified, the European Industrial Emissions Directive (IED) with regard to industrial emissions from incineration plants in order to attain a high level of environmental protection through the prevention and reduction of pollution.

GAMMATEC IRRADIATOR

The Gammatec irradiator (BNI 170) is an industrial irradiator operated by the company Steris since 2013. Gammatec treats products by ionisation (emission of gamma radiation) with the aim of sterilising them or improving the performance of the materials. The installation consists of an industrial bunker and an experimental bunker. Both bunkers contain sealed sources of high-activity cobalt-60 which provide the radiation necessary for the facility's activity.

In October 2024 the licensee provided additional information for the periodic safety review concluding report submitted at the end of December 2023. This file is currently being examined by ASNR.

In addition, the level of nuclear safety and radiation protection remains broadly satisfactory in 2024, particularly on the themes of deviation management and the monitoring of outside contractors.

ÉCRIN FACILITY

The Écrin facility (BNI 175) is situated in the municipality of Narbonne in the Aude *département*, within the Malvési site operated by Orano, which represents the first step of the "fuel cycle" (excluding extraction of the ores). The transformation process produces liquid effluents containing nitrated sludge loaded with natural uranium. The Écrin BNI consist of two storage basins (B1 and B2) containing the legacy sludge from the plant. These two basins have BNI classification due to the presence of artificial radioisotopes. The entire plant is subject to the system governing Seveso high-threshold Installations Classified for Protection of the Environment (ICPEs).

The Écrin facility was commissioned by ASN resolution 2018-DC-0645 of 12 October 2018. The works defined in the Decree of 20 July 2015, which began in 2019, were completed in 2023 with the finalising of installation of the bituminous cover over the zone of the PERLE cell (PERLE is a French acronym standing for "Project for Reversible Lagoon Storage in the Écrin BNI"), excavated to the south of storage basin B2. The final containment provisions for the storage of waste within the BNI are now in place.

An unannounced inspection held in October 2024 focused in particular on the handling of deviations, the performance of periodic inspections and tests and the monitoring of outside contractors.

Along with this, ASN finalised its examination of the report submitted on 12 February 2021 in application of Article 7 of the Decree of 20 July 2015, describing the state of progress of the studies and investigations to assess the feasibility of the disposal options for the waste currently stored in Écrin. It has made requests that are to be taken into account in the report to be submitted in 2025.

ASN has also examined the periodic safety DOR, for which the concluding report must be submitted no later than 20 July 2025.

ASN considers that the level of nuclear safety and environmental protection of the facility remains satisfactory in view of the risks the facility presents. ASN now expects the licensee to make a firm commitment and efforts to assimilate the regulatory requirements specific to BNIs, notably to improve the implementation and traceability of the technical verification of the activities performed, and the management of deviations.

Pays de la Loire

The Nantes division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 5 *départements* of the Pays de la Loire region.

56

inspections

In 2024, ASN carried out 56 inspections, comprising three in the facilities of the company Ionisos in the municipalities of Pouzauges and Sablé-sur-Sarthe (two on the theme of nuclear safety and one on radioactive substance transport), three concerning approved organisations in radon measurements and 50 in small-scale nuclear activities (20 in the medical sector, 29 in the industrial, research or veterinary sectors, and one in the area of natural radioactivity – radon).

No significant event was rated level 1 or higher on the International Nuclear and Radiological Event Scale (INES).

IONISOS IRRADIATOR

The company Ionisos operates two industrial ionisation installations on the sites of Pouzauges (*Vendée département*) and Sablé-sur-Sarthe (*Sarthe département*) respectively, which use high-activity cobalt-60 sealed radioactive sources. These installations constitute Basic Nuclear Installations (BNIs) 146 and 154 respectively.

The gamma radiation emitted is used for sterilisation purposes or to reinforce (by cross-linking) the technical properties of certain polymers, by exposing the products to be ionised (single-use medical equipment, packaging, raw materials and finished products for the pharmaceutical and cosmetic industries, packing films) for a pre-determined length of time.

Each installation comprises a pool for underwater storage of the radioactive sources, surmounted by a bunker in which the ionisation operations are performed, premises for storing the products before and after treatment, and offices and technical rooms.

ASN considers that the level of nuclear safety of operation of the Pouzauges and Sablé-sur-Sarthe irradiators is stable compared with the preceding year. Consequently, in 2024 the licensee renewed and reorganised the teams responsible for safety following several concomitant personnel departures in 2023 which had weakened its organisation. The new organisation is now in place and in September 2024 the licensee submitted to ASN an action plan to ensure the facility's conformity with the BNI regulations. In 2025, the Authority for Nuclear Safety and Radiation Protection (ASNR) will be attentive to the fulfilling and completion of the various commitments made by the licensee, who must prioritise them appropriately and apply requirements compatible with the safety risks of the facilities.

The licensee submitted two noteworthy modification applications for the Pouzauges site in 2024: one to prolong the use of the sources beyond ten years, the other to modify the pool's demineralised water make-up tank.

The installations and activities to regulate comprise:



• Basic Nuclear Installations:

- the Ionisos irradiator in Pouzauges,
- the Ionisos irradiator in Sablé-sur-Sarthe;

• small-scale nuclear activities in the medical sector:

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- 7 external-beam radiotherapy departments,
- 2 brachytherapy units,
- 12 nuclear medicine departments,
- 37 centres practising fluoroscopy-guided interventional procedures,
- 56 computed tomography scanners,
- some 2,500 medical and dental radiology devices;

• small-scale nuclear activities in the industrial, veterinary and research sectors:

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- 1 cyclotron,
- 25 industrial radiography companies, including 7 performing gamma radiography,
- 16 research units,
- about 400 users of industrial, veterinary and research devices;

• activities associated with the transport of radioactive substances;

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• ASN-approved laboratories and organisations:

- 6 organisations approved for measuring radon,
- 1 head-office of a laboratory approved for environmental radioactivity measurements.

A noteworthy modification application was also submitted for the Sablé-sur-Sarthe site to prolong the use of the radioactive sources. Lastly, a modification of the safety baseline requirements was approved in May 2024.

Provence-Alpes-Côte d'Azur

The Marseille division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 6 *départements* of the Provence-Alpes-Côte d'Azur region.

127

inspections

5

significant events
rated level 1
or higher

In 2024, ASN carried out 127 inspections in the Provence-Alpes-Côte d'Azur region, comprising 60 in the Basic Nuclear Installations (BNIs), 60 in small-scale nuclear facilities, five in the area of Radioactive Substance Transport (TSR) and two concerning ASN-approved organisations and laboratories.

During 2024, two significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES) were notified by the nuclear installation licensees.

In small-scale nuclear activities, two significant radiation protection events rated level 1 on the INES scale were reported to ASN, one in the industrial sector and one in the medical sector. One significant event in the area of TSR rated level 1 on the INES scale was notified to ASN.

— Cadarache site

CEA CADARACHE CENTRE

Created in 1959, the CEA Cadarache centre is situated in the municipality of Saint-Paul-lez-Durance in the Bouches-du-Rhône *département* and covers a surface area of 1,600 hectares. This site focuses its activity primarily on nuclear energy and, as concerns its civil installations in operation, on research and development to support and optimise the existing reactors and the design of new-generation systems. A large part of the centre's facilities are moreover involved in conducting the strategy for decommissioning and management of radioactive materials and waste of the Alternative Energies and Atomic Energy Commission (CEA).

The following BNIs are located on the site::

- the Pégase-Cascad installation (BNI 22);
- the Cabri research reactor (BNI 24);
- the Rapsodie research reactor (BNI 25);
- the Plutonium technology facility (ATPu – BNI 32);
- the Solid Waste Treatment Station (STD – BNI 37-A);
- the Active Effluent Treatment Station (STE – BNI 37-B);
- the Masurca research reactor (BNI 39);
- the Éole / Minerve research reactor (BNI 42-U);
- the Enriched Uranium Processing Facilities (ATUe – BNI 52);
- the Central Fissile Material Warehouse (MCMF – BNI 53);
- the Chemical Purification Laboratory (LPC – BNI 54);
- the High-Activity Laboratory LECA-STAR (BNI 55);
- the solid radioactive waste storage area (BNI 56);
- the Phébus research reactor (BNI 92);
- the Laboratory for research and experimental fabrication of advanced nuclear fuels (Lefca – BNI 123);
- the Chicade laboratory (BNI 156);
- the Cedra storage facility (BNI 164);
- the Magenta storage warehouse (BNI 169);
- the Effluent advanced management and processing facility (Agate – BNI 171);
- the Jules Horowitz Reactor (JHR – BNI 172), under construction.

The installations and activities to regulate comprise:



• Basic Nuclear Installations:

- the CEA Cadarache research centre which counts 20 civil BNIs, including the Jules Horowitz Reactor (JHR) currently under construction,
- the ITER installation construction site, adjacent to the CEA Cadarache centre,
- the Gammaster industrial irradiator;

• small-scale nuclear activities in the medical sector:

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- 13 external-beam radiotherapy departments,
- 3 brachytherapy departments,
- 16 nuclear medicine departments,
- 86 centres practising fluoroscopy-guided interventional procedures,
- 96 computed tomography scanners,
- some 8,200 medical and dental radiology devices;

• small-scale nuclear activities in the industrial, veterinary and research sectors:

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- about 400 industrial and research centres, including 3 cyclotron particle accelerators and 11 companies with an industrial radiography activity,
- some 600 veterinary surgeries or clinics practising diagnostic radiology;

• activities associated with the transport of radioactive substances;

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• ASN-approved laboratories and organisations:

- 3 laboratories approved for taking environmental radioactivity measurements,
- 3 organisations approved for measuring radon,
- 2 organisations approved for radiation protection controls.

The CEA Cadarache centre operates numerous installations which vary in their nature and their safety implications. At the Cadarache centre, ten installations are in final shutdown status, nine are in operation and one is under construction. ASN has started or is continuing the examination of the Periodic Safety Review Guidance Files (DOR) or the concluding reports for 15 of the 20 installations: Pégase and Cascad, Cabri, Rapsodie, STE, Masurca, ATUe, MCMF, LECA, the storage area, Phébus, Lefca, Chicade, Cedra, Magenta and Agate, and has issued its conclusions on the periodic safety review of Cascad, ATPu, LPC and STAR. When examining these reports, ASN is particularly attentive to the robustness of the proposed and deployed action plans. It ensures that the installations are in conformity with the applicable regulations and that the risks and adverse effects are effectively controlled.

Pégase-Cascad facility – CEA CENTRE

BNI 22 comprises two separate facilities, Pégase and Cascad:

- the Pégase reactor entered service on the Cadarache site in 1964 and was operated for about ten years. CEA was authorised by a Decree of 17 April 1980 to reuse the Pégase facility for the storage of radioactive substances, in particular spent fuel elements stored in a pool;
- the Cascad facility, authorised by a Decree of 4 September 1989 modifying the Pégase facility and operated since 1990, remains in service, dedicated to the dry storage of irradiated fuel in wells.

The Decree of 4 September 1989 obliges CEA to apply to ASN every ten years for authorisation to prolong the dry storage of irradiated fuel in Cascad. Based on the conclusions of the last periodic safety reviews of the facility and the oversight actions conducted by ASN over the last few years, ASN has authorised, through resolution CODEP-DRC-2024-014408 of 6 June 2024, the prolongation of storage for a further period of ten years.

The examination of the Pégase facility decommissioning file continued in 2024 with the analysis of the complementary elements received from the licensee and the opinion of the environmental authority. Concerning the removal of radioactive substances from the facility, which is necessary for its decommissioning, ASN notes that the licensee adheres to the schedule set by ASN Chairman's resolution CODEP-CLG-2017-006524 of 10 February 2017 for the removal from storage of Pégase's araldite-encapsulated fuels, called the "DECAP" project, a French acronym standing for "removal from storage of Pégase's araldite-encapsulated fuels".

ASN considers that the level of nuclear safety and radiation protection is broadly satisfactory as regards the measures taken to prevent external hazards, the management of effluents and the monitoring of the facility's discharges. The implementation of the actions identified during the last periodic safety reviews is also consistent with the information on action plan progress transmitted to ASN.

In 2025, the Authority for Nuclear Safety and Radiation Protection (ASNR) shall remain attentive to the treatment of the cans containing fuel in the DECAP process, to their on-site transportation to Cascad, and to compliance with the associated requirements.

Cabri research reactor – CEA CENTRE

The Cabri reactor (BNI 24), created on 27 May 1964, is intended for conducting experimental programmes aiming to achieve a better understanding of the behaviour of nuclear fuel in the event of a reactivity accident. The reactor has been equipped with a pressurised water loop since 2006 in order to study the behaviour of the fuel at high combustion rates in accident situations of increasing reactivity in a Pressurised Water Reactor (PWR). Since January 2018, a test programme called "CIP" (Cabri International Program) is in progress in the facility; this programme began in the early 2000's and necessitated substantial modification and safety upgrading work on the facility.

The CIP test programme and the electronic component irradiation tests continued in 2024 with the performance of one test.

ASN's examination of the periodic safety review reports, for which the concluding report was submitted in 2017, continued in 2024, and ASN transmitted its conclusions to the licensee in November 2024. The requirements are essentially linked to control of the seismic and fire risks, but also to the ageing of the facility.

ASN considers that the level of nuclear safety and radiation protection is broadly satisfactory, particularly regarding the tracking of commitments made to ASN, equally well in the context of the periodic safety review as in the tracking of corrective actions implemented further to the inspections.

The licensee must be more rigorous in the performance of periodic inspections and tests and the analysis of their results. Lastly, the licensee must put in place a management strategy along with a projected schedule for retrieval of the sodium-containing waste and the contaminated sodium still present in the BNI.

Furthermore, ASNR is awaiting information from the CEA on the long-term continuation of the reactor's activities beyond the ongoing test programme. CEA has thus started a process to guarantee resources with the specific skills necessary to operate the Cabri reactor. This continued operation is notably conditional upon the repair of a reactor deficiency due to the presence of corrosion on the canal containing the hodoscope.

Rapsodie research reactor – CEA CENTRE

The Rapsodie reactor (BNI 25) is the first sodium-cooled Fast-Neutron Reactor (FNR) built in France. It operated from 1967 to 1978. A sealing defect in the reactor pressure vessel led to its final shutdown in 1983. Decommissioning operations were subsequently undertaken, but have been partially stopped further to a fatal accident in 1994 during the washing of a sodium tank.

The fuel has been unloaded from the core and evacuated from the facility. Furthermore, a large part of the radioactive fluids and components have been removed, and the reactor vessel is contained. The reactor pool has been emptied, partially cleaned out and decommissioned and the waste containing sodium has been removed.

The Decommissioning Decree was signed on 9 April 2021. This Decree sets the perimeter of the facility and regulates, until 2030, the operations for treating the sodium from the reactor through to introducing air into the vessel containing it. An authorisation application file will be submitted to ASN for the reactor vessel washing operation. The decommissioning operations, such as decommissioning of the reactor block and of the civil engineering structures, shall be covered by an update of the decommissioning file.

The decommissioning work involving the characterising, repackaging and removal of waste packages continued in 2024. In order to be able to start the operations to treat the secondary sodium from the Raspodie Reactor, baptised "Recure Na", CEA has submitted an authorisation request to ASN in application of Article R. 593-70 of the Environment Code. CEA has nevertheless announced changes in the scenario of this operation, which would imply extending its duration by more than 20 years. CEA will therefore be unable to meet the deadline of 2030 for completion of these operations as prescribed in the Decree. The licensee must submit a request to modify this Decree, which will be examined by ASN.

Operation "Pétrole", which consists in placing in final shutdown status and removing the equipment involved in the dynamic containment of the cleaned-out hot cells, continued. The work should be completed in 2025.

The licensee submitted its DOR at the end of December 2022. Further to the examination of this file, ASN asked the licensee to take certain additional points into account in the periodic safety review report, whose submission is planned for 2025.

ASN considers that the level of nuclear safety and radiation protection of this facility in 2024 is broadly satisfactory with regard to the monitoring of the condition of the systems, equipment and buildings, external hazards and the management of fire loads, themes that were inspected in 2024.

Solid Waste Treatment Station

– CEA CENTRE

BNI 37 of CEA Cadarache historically comprised the Active Effluents Treatment Station (STE) and the Waste Treatment Station (STD), grouped into a single installation. As the CEA wishes to ensure continued operation of the STD and proceed with the final shutdown of the STE, BNI 37 was divided into two BNIs: 37-A (STD) and 37-B (STE) by ASN resolutions CODEP-DRC-2015-027232 and CODEP-DRC-2015-027225 of 9 July 2015. These records were made further to the Orders of 9 June 2015 defining the perimeters of these two BNIs.

At present, the STD is CEA's only civil BNI licensed for the packaging of intermediate-level, long-lived (ILW-LL) radioactive waste before it is stored in the Cedra facility (BNI 164) pending transfer to a deep geological repository. This situation makes the STD an indispensable part of the CEA's decommissioning and waste management strategy.

In early 2024, several renovation operations were carried out in the facility as planned under the "Pagode" project, with duplication of the equipment for measuring discharges at an outlet, and the installation of minipiles. Continued operation of the STD is conditional upon full accomplishment of the Pagode project work.

However, a significant event was notified in 2024 concerning the discovery of civil engineering defects in the structure of the buildings. The discovery of these defects resulted in the stoppage of operation of the facility and of the renovation work. In particular, the treatment of intermediate-level waste (ILW) and the compacting of low-level waste (LLW) and ILW are suspended. The activities of waste package reception, measurements, cement injection and shipments of LLW waste which are not impacted by the discovered defects are continuing, within the limit of the available storage areas. Restarting the suspended activities is conditional upon conducting additional studies to assess the resistance of the facility's civil engineering structures. The results of these studies are expected in the first quarter of 2025. The elements examined in the first investigations on the concrete structures do not, at this stage, enable a conclusion to be reached regarding the facility's resistance in an accident situation. In view of the significance of the civil engineering defects, ASN rated this event level 1 on the INES scale.

The end-of-works deadline for the Pagode project, set at 30 June 2028, should thus be called into question in view of the investigations and compensatory measures to implement.

The inspections ASN conducted in July and October 2024 show that the situation appears to be broadly under control. However, further information is required, more specifically concerning the implementation of the compensatory measures decided upon, the safety analysis carried out further to this significant event and the consolidated schedule for planned resumption of operating activities.

In view of the facility's degraded mode of operation necessary for management of the civil engineering defects, and a reassessment of the safety case, ASN considers that it is vital to restore the level of safety and radiation protection of the facility. The other themes inspected in 2024 concerning equipment qualification, meeting commitments and fire protection, are broadly satisfactory.

Active Effluents Treatment Station

– CEA CENTRE

The Active Effluents Treatment Station (STE – BNI 37-B) has been shut down since 1 January 2014. The CEA submitted the decommissioning file for this facility in December 2021.

Examination of the facility decommissioning file continued in 2024. The public consultations required by the regulations should be held in 2025 on the basis of a file integrating ASN's demands resulting from its examination of the file's admissibility. The complementary information requests concern the licensee's financial capacity, skills management, the decommissioning plan, the impact study and the safety case.

As part of the Decommissioning Preparation Operations (DECPROs), the licensee is continuing the removal of waste and preparing the worksite for repairing the basemats of building 322.

ASN resolution CODEP-DRC-2024-024338 of 9 October 2024 sets the applicable requirements in view of the conclusions of the periodic safety review of 2017. CEA has thus renovated the domes of the tanks in building 322, commissioned a new system for measuring atmospheric discharges and is preparing the new fire control panel installation worksite.

This resolution also requires the transmission in 2025 of a management plan with time frames for remediating the soils of a field named "La Grande Bastide", containing radiologically contaminated land, and eliminating any source of contamination of the neighbouring stormwater network as quickly as possible. The facility has effectively suffered several stormwater contaminations since 2013, resulting in the presence of artificial radionuclides outside the identified contaminated zones. This has resulted in several significant event notifications to ASN. A stormwater management action plan was implemented to ensure containment of the materials. Nevertheless, in view of the conclusions of the assessment of the effectiveness of this stormwater management action plan, monitoring must be continued and additional measures will have to be taken in 2025, relating to the "Grande Bastide" field management plan.

ASN considers that the level of nuclear safety and radiation protection of BNI 37-B on the inspected themes of ventilation, deviation management and fire protection in 2024 is broadly satisfactory.

Plutonium Technology Facility and Chemical Purification Laboratory

– CEA CENTRE

The Plutonium Technology Facility (ATPu – BNI 32) produced plutonium-based fuel elements intended for fast neutron or experimental reactors as from 1967, then, from 1987 until 1997, for PWRs using MOX (Mixed OXides) fuel. The activities of the Chemical Purification Laboratory (LPC – BNI 54) were associated with those of the ATPu: physical-chemical verifications and metallurgical examinations, treatment of effluents and contaminated waste. The two facilities were shut down in 2003 and are currently undergoing decommissioning.

ASN finalised its examination of the periodic safety review reports of the two facilities in 2024. It considers that the licensee's analysis of conformity with the regulatory and technical requirements, and re-assessment of control of the risks and drawbacks are satisfactory. The additional information provided by CEA in 2024 concerning the modification of the decommissioning files of the two BNIs was also found to be satisfactory.

ASN's inspections during 2024 focused primarily on the management of the complex decommissioning operations, particularly in the former Waste Treatment Unit (ATD) of the LPC, and the management of the waste resulting from these operations. ASN considers that on these themes, the level of nuclear safety and radiation protection of the facility is broadly satisfactory.

However, one significant event rated level 1 on the INES scale was notified by CEA in 2024 after a rod of non-inventoried fissile material was discovered in the ATPu facility. The presence of fissile material in this location constitutes a deviation from the General Operating Rules (RGEs). Additional information is to be provided concerning performance of the emptiness check in all the rooms of the facility. ASN will also maintain its vigilance regarding the operations to remove the dispersible inventory remaining in the facility in 2025.

Masurca research reactor – CEA CENTRE

The Masurca reactor (BNI 39), whose construction was authorised by a Decree of 14 December 1966, was intended for neutron studies, chiefly on the cores of fast neutron reactors, and the development of neutron measurement techniques. The reactor has been shut down since 2007.

Final shutdown of the facility was declared by the CEA on 31 December 2018. The licensee submitted the facility decommissioning file in December 2020 and in the interim has carried out decommissioning preparation work, such as removal of asbestos from the premises, rehabilitation of buildings, dismantling of nuclear buildings and removal of conventional equipment. The decommissioning file is currently being examined. The public inquiry was held in the first quarter 2024 and the file received a favourable opinion. Removal of the items containing sodium should begin in 2025.

The periodic safety review concluding report for the facility is expected in 2025.

ASN considers that the level of nuclear safety and radiation protection concerning waste management, the organisation and management of emergency resources, and the management of risks arising from hazardous substance risks, all of which were inspected in 2024, is broadly satisfactory.

Éole and Minerve research reactors

– CEA CENTRE

The experimental reactors Éole and Minerve are very-low-power (less than one kilowatt) critical mock-ups that were used for neutron studies, in particular to evaluate the absorption of gamma rays or neutrons by materials.

The Éole reactor (BNI 42), whose construction was authorised by a Decree of 23 June 1965, was intended primarily for neutron studies of moderated arrays, in particular those of PWRs and Boiling Water Reactors (BWRs). The Minerve reactor (BNI 95), whose transfer from the Fontenay-aux-Roses studies centre to the Cadarache studies centre was authorised by a Decree of 21 September 1977, is situated in the same hall as the Éole reactor. Teaching and research activities were carried out on these mock-ups until their final shutdown on 31 December 2017. Decree 2023-1176 of 12 December 2023 brought together the two BNIs 42 and 95 in a single BNI (BNI 42-U) called "Éole / Minerve", and prescribed the decommissioning operations for this facility.

Through resolution CODEP-DRC-2024-049444 of 24 September 2024, ASN approved the decommissioning RGEs transmitted by the licensee further to the issuing of the facilities' Decommissioning Decree 2023-1176 of 12 December 2023. These operating rules integrate both the conclusions of the decommissioning file and the conclusions of the examination of the last periodic safety review. This resolution marks a milestone in the life cycle of these two reactors: pursuant to IV of Article R. 593-69 of the Environment Code, the Decree takes effect on the date ASN approved the RGEs update. It thus enables BNIs 42 and 95 to be brought together in a single BNI (BNI 42-U).

ASN considers that the level of nuclear safety and radiation protection of BNI 42-U is broadly satisfactory. The nuclear material conditioning and removal operations carried out before starting certain decommissioning operations are traced rigorously. These operations continued in 2024 in accordance with the schedule set by the licensee. Progress is also observed in the removal of waste and materials with no disposal route.

ASNR nevertheless remains attentive to the performance of the DECPROs that were not completed before the decommissioning decree came into effect. This concerns in particular the progress of the characterisation and conditioning of the last nuclear materials and the removal of disused sources.

The Enriched Uranium Processing Facilities – CEA CENTRE

From 1963 to 1995, the Enriched Uranium Processing Facilities (ATUe – BNI 52) converted uranium hexafluoride (UF₆) from the Cadarache enrichment plants into sinterable oxide, and ensured the chemical reprocessing of waste from the manufacture of fuel elements. Decommissioning of this facility was authorised by Decrees in February 2006 and 2021, accompanied by ASN requirements describing the conditions of performance of the future decommissioning operations dated 14 October 2021.

The activities in the facility in 2024 were essentially routine maintenance and periodic and regulatory inspection operations. CEA is currently drafting specifications to contractualise restarting of the decommissioning operations, which is planned for 2028.

ASN considers that the level of safety of BNI 52 (ATUe) in 2024 is broadly satisfactory.

The actions further to the periodic safety review of 2017 have been completed except for the roof leak proofing work, scheduled for completion by the end of 2025. CEA submitted the guidance file for the next periodic safety review in 2024. This file is currently being examined by ASNR.

Central Fissile Material Warehouse

– CEA CENTRE

Created in 1968, the Central Fissile Material Warehouse (MCMF – BNI 53) was a warehouse for storing enriched uranium and plutonium until its final shutdown and removal of all its nuclear materials on 31 December 2017. Its decommissioning decree was issued on 22 March 2024. It sets 31 December 2034 as the end-of-decommissioning deadline.

ASN considers that the DECPROs continued satisfactorily in 2024. The first phase of commissioning of the simplified ventilation to adapt it to the emptiness of the facility has been completed.

The licensee submitted its periodic safety review report to ASN at the end of December 2024

High-Activity Laboratory LECA-STAR – CEA CENTRE

BNI 55 combines the Active Fuel Examination Laboratory (LECA) and its extension, the Treatment, Clean-out and Reconditioning Station (STAR). These two units constitute the CEA's expert assessment tools for analysing irradiated fuels. Commissioned in 1964, the LECA laboratory enables the CEA to carry out destructive and non-destructive examinations of spent fuel from the nuclear power, research and naval propulsion sectors. As the facility is old, it was partially reinforced in the early 2010's to improve its earthquake resistance.

The periodic safety review concluding report for LECA was submitted in July 2024. In the light of the ongoing examination of this report, ASNR will ask CEA for further information concerning the conformity review it conducted, the reassessment of the control of risks and drawbacks and the associated action plan.

The removal from storage of fissile materials that are not associated with any research programme is continuing in accordance with the schedule set by ASN further to the last periodic safety review.

In 2024, CEA notified one significant event relating to a nonconformity with respect to the welding data packages and the associated design calculation notes, in certain anti-seismic reinforcements in LECA's civil engineering structure incorporated during the 2004-2007 renovation. CEA has implemented an action plan to restore the conformity of the impacted structures and update the associated baseline requirements. CEA must also reassess the adequacy of the internal checks and the provisions for monitoring the activities of outside contractors.

In addition, two significant events occurred in 2024 in LECA, involving two cases of detachment, at the exit of the storage well of LECA's cell 1, of overpacks used for the transfer of ILW-LL radioactive waste. These events had no consequences on nuclear safety or radiation protection. ASNR is waiting for CEA to analyse the lessons learned from these events for the benefit of the other BNIs and propose measures to prevent their recurrence.

Commissioned in 1999, the STAR facility is an extension of the LECA laboratory, designed for the stabilisation and reconditioning of spent fuel.

On completion of the examination of the STAR safety review report submitted in 2018, ASN considered that the analysis of conformity with the regulatory and technical requirements and the reassessment of control of the risks and drawbacks justify continued operation of the facility for the next ten years. CEA must more specifically examine the safety measures to take in the event of an earthquake to avoid an accident induced by electrical problems.

A significant event in June 2024 involving the loss of two of STAR's inverters which led to the ventilation, the radiation protection-related monitoring and the monitoring of the stack discharges being unavailable, is the subject of complementary investigations by CEA. ASNR will be attentive to the follow-ups to this event and to its potentially generic nature.

ASN considers that in 2024 the level of nuclear safety and radiation protection of the LECA-STAR facility is broadly satisfactory, particularly concerning the measures taken by the licensee to ensure static and dynamic containment, the monitoring of outside contractors and the management of nuclear waste. Tracking of the actions further to LECA's periodic safety review is satisfactory, but tracking of the radiological inventory in accordance with the permanent requirements of the resolution of 10 July 2020 needs to be improved. ASNR will also continue to pay close attention to the safety of handling operations in the shielded cells.

Solid radioactive waste storage area

– CEA CENTRE

BNI 56, declared in January 1968 for the disposal of waste, is used for storing legacy solid radioactive waste from the Cadarache centre. It comprises three pools, six pits, five trenches and hangars, which contain in particular ILW-LL waste from the operation or decommissioning of CEA facilities. BNI 56 is one of the priorities identified by the CEA in its new decommissioning and waste management strategy.

Examination of the facility decommissioning file continued in 2024. The public consultations required by the regulations started at the end of 2024 and will continue until mid-2025. The licensee has also submitted its strategy for retrieval of waste from the trenches, in accordance with its commitment.

The Waste Retrieval and Packaging (WRP) operations in the BNI continued in 2024. CEA has completed the transfer of all the stainless steel packages of intermediate-level waste from pit 6 to BNI 164 (Cedra); these packages were the subject of a "major safety commitment" (*grand engagement de sûreté* – GES). ASNR will remain attentive in 2025 to the repackaging and removal of the waste resulting from the retrieval of packages whose content was not blocked in a cement matrix.

The inspections carried out by ASN in 2024 focused primarily on management of the waste produced by the facility, the methods of protection against external hazards, radiation protection and the conformity of the facility with its baseline requirements, which were updated further to the last periodic safety review. ASN considers that the organisational setup put in place by the licensee enables a broadly satisfactory level of nuclear safety and radiation protection to be achieved on these themes. It nevertheless remains attentive to the radiological cleanliness of the BNIs's stormwaters and to the progress of the work necessary for the next repackaging operations.

Prior to the next periodic safety review of the facility, CEA submitted a DOR to ASN in 2024 presenting the methodology, the scope of the verifications and studies, and the conditions governing performance of the conformity review and the safety reassessment.

Phébus research reactor – CEA CENTRE

The Phébus reactor (BNI 92) is an experimental pool-type reactor with a power rating of 38 Megawatts thermal (MWth) which functioned from 1978 to 2007. Phébus was designed for the study of serious accidents affecting light water reactors and for defining operating procedures to prevent core melt-down or to mitigate its consequences.

Decree 2024-256 requiring CEA to proceed with the Phébus decommissioning operations was published on 22 March 2024. CEA plans starting the decommissioning operations at the end of the five year surveillance phase following publication of this Decommissioning Decree. The licensee has submitted the safety analysis report and the decommissioning RGEs which were authorised by ASN in August 2024. The periodic safety review file submitted in 2018 is currently being examined by ASNR.

The facility has been empty of all radioactive material since December 2021, in accordance with the priority objectives of the DECPROs. The start-up neutron source is stored in the reactor building pool pending the identification of a disposal route.

ASN conducted an inspection of Phébus in 2024 and considers that the level of nuclear safety and radiation protection of the facility is broadly satisfactory.

Laboratory for research and experimental fabrication of advanced nuclear fuels – CEA CENTRE

Commissioned in 1983, the Laboratory for research and experimental fabrication of advanced nuclear fuels (Lefca – BNI 123) was a laboratory tasked with conducting studies on plutonium, uranium, actinides and their compounds with the aim of understanding the behaviour of these materials in the reactor and in the various stages of the "fuel cycle". In 2018, Lefca finalised the transfer of part of its research and development equipment to the Atalante laboratories (BNI 148) at Marcoule.

Now Lefca has only one activity, the characterisation and conditioning of liquid and solid wastes. After having considered shutting down the facility definitively, CEA has been planning – since the end of 2021 – to keep the facility operational and use it for the repackaging and storage of nuclear materials. This new activity will require the facility's authorisation decree to be modified.

The licensee submitted its safety review concluding report in December 2023. It is currently being examined by ASNR and presents the prospect of continued operation of the facility.

ASN estimates that the level of nuclear safety and radiation protection of the facility in 2024 is broadly satisfactory as far as occupational radiation protection and waste management – the two themes inspected – are concerned.

Chicade laboratory – CEA CENTRE

Since 1993, the Chicade facility (BNI 156) has been conducting research and development work on low and intermediate-level objects and waste, chiefly involving:

- the destructive and non-destructive characterisation of radioactive objects, waste sample packages and irradiating objects;
- the development and qualification of nuclear measurement systems;
- the development and implementation of chemical and radiochemical analysis methods;
- the expert assessment and inspection of waste packages packaged by the waste producers.

CEA had difficulty in 2024 in obtaining concrete of adequate quality to produce the waste packages in the unit for packaging disused sealed sources in packages baptised "870L Vrac Source", a packaging unit authorised by an ASN resolution in 2023. Five packages were packaged in 2024.

Examination of the request to modify the facility's Creation Authorisation Decree (DAC) continued in 2024. This request aims more specifically to change the perimeter of the facility in order to integrate the gravity drainage well, along with outside storage areas and, concerning environmental protection, permit gaseous discharges of radioactive effluents.

ASN considers that the level of nuclear safety and radiation protection is broadly satisfactory. The licensee must nevertheless be vigilant and inform ASNR of the slippage in the prescribed deadlines for the implementation of certain actions identified further to the conclusions of its last periodic safety review.

Cedra storage facility – CEA CENTRE

Since 2006, the Cedra facility (BNI 164) is used to store ILW-LL waste pending the creation of appropriate disposal routes. The CEA forecasts that this facility will be filled to capacity by 2030. The studies concerning a project to double the storage capacity began in 2020.

CEA presented a first facility extension project to ASN in late 2024 (phase 3) which will be the subject of a noteworthy modification request in order to push back the date by which the storage areas are filled to capacity, today estimated to be approximately 2032.

Complements to the periodic safety review concluding report were submitted to ASN in the course of 2024. The expert assessment of this report has been started and will continue in 2025.

ASN considers that the level of nuclear safety and radiation protection in the facility is broadly satisfactory.

ASN considers that the tracking of the licensee's commitments further to the inspections is satisfactory. Nevertheless, improvements are still required in the monitoring of the work performed in the facilities by outside contractors, particularly as regards the traceability of monitoring, and building on lessons learned from past events, which can be better integrated in the monitoring plans.

Magenta storage warehouse – CEA CENTRE

The Magenta facility (BNI 169), which replaces the MCMF currently being decommissioned, has been dedicated since 2011 to the storage of non-irradiated fissile material and the non-destructive characterisation of the nuclear materials received.

In 2024, CEA submitted the modification authorisation applications to extend the scope of operation of the facility and in particular the type of material received. These applications have been examined and authorised by ASN.

ASN continued the examination of the periodic safety review concluding report submitted in 2021.

ASN considers that the level of nuclear safety and radiation protection of the facility is broadly satisfactory, particularly on the inspected themes of management of the fire risk and risks of counterfeits, falsifications and suspicions of fraud.

Advanced effluent management and treatment facility – CEA CENTRE

The Effluent advanced management and processing facility (Agate – BNI 171), commissioned in 2014 to replace BNI 37-B which is now shut down, uses an evaporation process to concentrate radioactive liquid effluents containing mainly beta- and gamma-emitting radionuclides.

In 2024, CEA submitted a new request to modify the facility's DAC, to allow the treatment of new types of radioactive effluents and to have new outlets for treating the concentrates produced, as ASN deemed inadmissible the first request made in 2023. This request is currently being examined by ASNR. CEA also submitted the concluding report of its first periodic safety review to ASN on 25 April 2024.

ASN considers that the level of nuclear safety and radiation protection of the facility is satisfactory. The licensee must nevertheless consolidate and improve the traceability of outside contractor monitoring.

ASN underlines that this facility plays a central role in the management of the CEA effluents and as such constitutes a sensitive facility in the CEA's decommissioning and material and waste management strategy.

Jules Horowitz Reactor project

– CEA CENTRE

The Jules Horowitz Reactor (JHR – BNI 172), under construction since 2009, is a pressurised-water research reactor designed to study the behaviour of materials under irradiation and of power reactor fuels. It will also allow the production of artificial radionuclides for nuclear medicine. Its power is limited to 100 MWth.

The year 2024 saw the continuation of the construction and equipment manufacturing activities of many workpackages of the JHR worksite, notably in the reactor building with the launching of the primary heat exchanger repairs, and in the nuclear auxiliary building with the finalisation of the storage pools and the channels, and the work on the hot cell equipment.

ASN conducted four inspections in 2024. The verifications focused in particular on the primary system, including the treatment of deviations on the three primary/secondary heat exchangers, components of the reactor pile block, including the "core inlet" natural convection valve and the reflectors and the control rod drive mechanisms of the core, as well as the chemically-sealed anchorings. The repair of the reactor pool liner also underwent inspections, as did the qualification process for various items of equipment involved in the facility's safety functions, the centralised instrumentation and control system and the fire protection of the electric cable raceways.

The thematic examinations of the facility's safety analysis report revision submitted in 2021, taking account of the modifications made since the start of construction, continued in 2024 in preparation for the future commissioning. The

examination of the request to modify DAC 2009-1219 of 12 October 2009 to extend the commissioning date to 14 October 2037 at the latest, taking into account margins for the project, continued in 2024.

ASN considers the project organisation to be broadly satisfactory from the nuclear safety aspect, particularly in the handling of the deviations on the primary heat exchangers and the development of tools to ensure the application and traceability of the defined requirements. The project must ensure that the qualification process for protection important components is carried out conclusively for all the defined requirements. The formalising and application of certain processes must also be improved. Lastly, continued vigilance is required regarding the priority to be granted to the protection of interests, and to the constant efforts to improve the measures taken to protect these interests.

ITER

The International Thermonuclear Experimental Reactor (ITER – BNI 174), under construction on the Cadarache site since 2010 and adjacent to the CEA facilities, will be a fusion experimental reactor used for the scientific and technical demonstration of the control of thermonuclear fusion energy obtained by magnetic confinement of a deuterium-tritium plasma during long-duration experiments with a significant power level (500 MW developed for 400 seconds). This international project enjoys financial support from China, South Korea, the United States, India, Japan, Russia and the European Union, who make in-kind contributions by providing equipment for the project.

The large quantities of tritium that will be brought into play in this installation, the intense neutron flow and the resulting activation of materials have serious implications regarding radiation protection and will represent true challenges for the safe management of waste during the operation and decommissioning of the installation.

ITER Organization (IO) presented a new baseline for the project in 2024 further to the revision initiated in 2022. This new roadmap provides for operation in several phases corresponding to the main sequences of the experimental programme, and contains modifications in some of the facility's design choices, notably the replacement of beryllium by tungsten as the liner material for the first wall of the vacuum chamber.

This new roadmap moreover takes account of the difficulties the licensee has identified in providing a conclusive safety case covering the entire lifetime of the project, and proposes the principle of producing a staged safety case, following the successive phases of commissioning and operation. The reason for this is that the safety case for certain operating phases requires the acquisition of certain information and data that will not be available until the preceding phases have been completed. ASN has taken note of this approach which seems appropriate for the exploratory nature of the ITER project, such as is provided for by its authorisation decree. ASN points out that this approach presents a potential industrial risk for the project should the technical choices made and the knowledge acquired at a given stage finally not enable the licensee to demonstrate control of the nuclear safety and radiation protection risks for the subsequent steps.

ASN observes however that the elements provided in 2024 do not yet make it possible to establish an overall view of the decided changes and their impact on the different project components. This concerns, for example, components that have already been examined but for which some of the hypotheses are being modified. The first revisions of the schedule, integrating more specifically the assessment of the impact of the Covid-19 pandemic, the repair times for the sectors and thermal shields, and the projected modifications to the machine, were submitted in 2024. These elements must still be consolidated with respect to the project's new commissioning strategy and the defining of the technical files to be examined at each stage of the reference scenario. ASNR will be attentive to the assessment of the impact of these modifications on the nuclear safety and radiation protection risks, and to the technical requirements of the amended resolution of 12 November 2013 regulating the design and construction of the facility.

ASNR is thus waiting for conclusive elements to redefine the scheduling of its examinations and to adopt a position regarding the acceptability of the impact of the intended modifications. IO should submit a new application for authorisation to lift the hold point concerning assembly of the vacuum chamber in 2026.

Work on the site and equipment manufacturing continued in 2024, notably with the repair of the first sectors of the tokamak to correct the dimensioning differences and to resolve the problem of stress corrosion affecting the heat shield cooling systems. The quality of manufacture of the tokamak is of major importance for safety because of its role in radioactive substance containment, which must be ensured for all the phases of operation planned for in the reference scenario of the facility.

In 2024, ASN continued the technical examination of the new authorisation application for water intakes and discharges of non-radioactive effluents for the facility construction phase submitted in 2023.

Five inspections were carried out on the site in 2024, focusing in particular on the design and construction and the monitoring of outside contractors. These inspections included checks of the repair of the vacuum chamber sectors, the facility's fuel supply systems and the equipment of the Vacuum Vessel Pressure Suppression System (VVPSS).

Assessment of the Cadarache site



ASN considers that the level of nuclear safety of the CEA Cadarache centre in 2024 remains broadly satisfactory.

With regard to meeting commitments, ASN observes – as in the preceding years – that some deadlines tend to get pushed back. This concerns in particular the action plans established after the periodic safety reviews of the facilities, and certain decommissioning operations.

A large proportion of the activities important for the protection of interests are subcontracted, as much in preventive verification and maintenance operations as in waste management operations. These activities are identified, listed and monitored applying a proportionate approach. ASN noted that it was still necessary to standardise the monitoring programmes to a greater extent, and to update them to better integrate the lessons learned from preceding years. Moreover, ASN underlines the progress in the review of the maintenance process sheets, which must be continued.

Concerning the safety baseline requirements, CEA is continuing its harmonisation between the various BNIs of the centre, particularly as regards management of the fire risk and the periodic inspections and tests, after recasting the radiation protection, waste and transport chapters.

Along with this, the facilities of the centre are making progress in prevention of the impacts associated with external hazards, thanks in particular to the actions taken further to the periodic safety reviews. These actions aim essentially at bringing the facilities back into conformity with respect to the seismic, lightning and flooding risks.

However, improvements are still required in the analysis of risks associated with extreme temperatures, particularly the taking into account of intense heatwave episodes, the frequency and intensity of which are increasing.

ASN considers that improvements are still required in environmental protection. Some projects are going more slowly than planned, notably the work to improve the representativeness of the radiological measurements and monitoring of the water tables in the risk-prone areas. Although efforts have been made in the last few years to restore the conformity of the piezometric structures on the perimeter of the BNIs, ASN's inspections this year again found nonconforming structures. The updating of the impact studies must also progress further in the integration of the various projects being conducted simultaneously on the site. Nevertheless, the progress made in several areas merits being underlined, such as bringing the Chemical Analysis Laboratory (LCE) into compliance with standard NF EN ISO 17025, and the updating of the alarm thresholds for gaseous discharge monitoring.

The decommissioning and waste management strategy deployed by CEA remains a subject on which ASN is extremely vigilant. This vigilance concerns in particular the prioritizing of the different projects, and above all its sensitivity to unexpected events affecting the availability of key facilities involved in the various waste management routes, and the availability of transport packagings. The civil engineering defects that appeared on BNI 37-A and led to the LLW and ILW waste drum production stoppage, expose this waste route to storage capacity problems to which

the licensee must propose solutions. CEA also receives regular requests concerning the retrieval of the waste currently classified as "waste with no immediate disposal route", with the aim of limiting the volumes stocked in the facilities.

With regard to the new projects, in parallel with the ongoing examination of the new construction time frames for the JHR, CEA informed ASN in late 2024 of persistent difficulties with the construction of the new emergency centre baptised "CIRCE", a French acronym standing for "Response centre resistant to extreme conditions". CEA must thus present to ASNR the causes of this situation, the possible compensatory measures, and new robust and substantiated milestones, for which the existing requirements will have to be modified.

A joint inspection with ASND on the theme of radioactive substance transport confirmed compliance with the reception procedure, in accordance with the packaging utilisation manuals.

Lastly, ASN conducted an unannounced inspection in 2024 to test the CEA Cadarache centre's emergency organisation. ASN considers that the organisation in place is broadly satisfactory. Several areas for progress were identified for the centre, more specifically in the overall management of maintaining the main emergency centre in operational condition, in the formalising and traceability of the actions, information and request resulting from activation of an On-site Emergency Plan (PUI) at the centre, and in the inventorying of the material and human resources that can be involved in the missions of the Nuclear Rapid Intervention Force (FARN).

The inspections also checked the tests on the cryostat compensation bellows and the rapid discharge units, and the networks of galleries for routing the electric cables necessary for operation of the facility. One inspection was also dedicated to the general organisation and how it took the risk of fraudulent practices into account.

On the basis of its inspections, ASN notes that improvements must still be made in the handling of deviations, particularly in the defining of appropriate corrective actions and the

cause analysis. Greater integration of the safety risks and application of the defined requirements are also expected, particularly in the equipment qualification processes, in document traceability, and in the continuation of the work relative to control of the risk of fraudulent practices. ASNR will be attentive to the effects of the organisational changes decided by IO in 2024 with a view to improving interfacing between safety, integration and construction, and to increase the independence of the internal inspection body and the integration of internal reviews and experience feedback.

GAMMASTER IRRADIATOR

Since 2008, the company Steris has been operating an industrial irradiator called "Gammaster", situated on the land of the municipality of Marseille. Gammaster treats products by ionisation (emission of gamma radiation) with the aim of sanitising, sterilising or improving the performance of materials. The facility is made up of an industrial bunker and houses high-activity cobalt-60 sealed sources which produce the radiation necessary for the facility's operations.

ASN considers that the level of nuclear safety and radiation protection in 2024 is broadly satisfactory.

ASN carried out two inspections in 2024, one focusing in particular on the management of modifications and deviations, which found management to be fairly satisfactory, with certain traceability aspects needing to be improved, while the other inspection focused on the transport of sources, which was found to be satisfactory.

01

**Nuclear activities:
ionising radiation
and health and
environmental risks**



1

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DÉCHET



GH

polytec

DUTREIX

ZONE EXTREMITÉ



Ionising radiation may be of natural origin or caused by nuclear activities of human origin. The exposure of the population to naturally occurring ionising radiation results from the presence of radionuclides of terrestrial origin in the environment, radon emanations from the ground and exposure to cosmic radiation.

Nuclear activities are defined in the Public Health Code as *“activities involving a risk of exposure of persons to ionising radiation related to the use either of an artificial source, whether substances or devices, or of a natural source, whether natural radioactive substances or materials containing natural radionuclides [...]”*.

These nuclear activities include those carried out in Basic Nuclear Installations (BNIs) and during the transport of radioactive substances, as well as in the medical, veterinary, industrial and research fields.

Over and beyond the effects of ionising radiation, some installations can be the source of non-radiological risks and detrimental effects such as discharges of chemical substances into the environment or noise emission.

The various principles with which the nuclear activities must comply, particularly those of nuclear safety and radiation protection, are set out in chapter 2.

1 — The state of knowledge of the hazards and risks associated with ionising radiation

Ionising radiation is defined as being capable of producing ions – directly or indirectly – when it passes through matter. It includes X-rays, alpha, beta and gamma rays, and neutron radiation, all of which are characterized by different energies and penetration powers.

1.1 Biological and health effects

Whether it consists of charged particles, for example an electron or positron (beta radiation) or a helium nucleus (alpha radiation), or of photons (X-rays or gamma rays), ionising radiation interacts with the molecules making up the cells of living matter and alters them chemically. Of the resulting damage, the most significant concerns the DNA of the cells and this damage is not fundamentally different from that caused by certain toxic chemical substances, whether exogenous (external to the organism) or endogenous (resulting from cellular metabolism).

When not repaired by the cells themselves, this damage can lead either to cell death or to the appearance of harmful biological effects if tissues are no longer able to carry out their functions.

These effects, called “deterministic effects”, have been known for a long time, as the first effects were observed with the discovery of X rays by W. Roentgen (in the

early 1900’s). They depend on the nature of the exposed tissue and are certain to appear as soon as the quantity of radiation absorbed exceeds a certain dose level. These effects include, for example, erythema, radiodermatitis, radionecrosis and cataract formation. The higher the radiation dose received by the tissue, the more serious the effects.

Cells can also repair the damage thus caused, although imperfectly or incorrectly. Of the damage that persists, that to DNA is of a particular nature because residual anomalies in the chromosomes can be transmitted by successive cellular divisions to new cells. A single genetic mutation is far from being sufficient to cause the transformation into a cancerous cell, but this damage due to ionising radiation may be a first step towards cancerisation which appears after a variable lapse of time, up to several years after exposure.

The suspicion of a causal link between exposure to ionising radiation and the appearance of a cancer dates back to 1902 (observation of skin cancer in a case of radiodermatitis). In this case we talk of “radiation-induced cancer”.

Subsequently, several types of cancers were observed in occupational situations, including certain types of leukaemia, broncho-pulmonary cancers (owing to radon inhalation) and jawbone sarcomas. Outside the professional area, the

monitoring for more than sixty years of a cohort⁽¹⁾ of about 85,000 people irradiated during the nuclear bombings of Hiroshima and Nagasaki (Japan) has provided data on the morbidity and mortality due to cancer following exposure to ionising radiation, enabling dose-effects relationships - which form the basis of current regulations - to be described. Other epidemiological work has revealed a statistically significant rise in cancers (secondary effects) among patients treated using radiotherapy and attributable to ionising radiation. We can also mention the Chernobyl Nuclear Power Plant (NPP) accident (Ukraine) which, as a result of the radioactive iodine released, caused in the areas near the accident an excess in the incidence of thyroid cancers in young people exposed during their childhood.

The health consequences of the Fukushima Daiichi NPP in Japan for the neighbouring populations have also formed the subject of work and analyses, some of which are still in progress, in order to learn the epidemiological lessons.

The risk of radiation-induced cancer is not linked to the exceeding of a threshold. It is materialised by an increase in the probability of developing cancer according to radiation dose received, and also depends on age and sex. In this case we talk of effects that can be probabilistic, stochastic (whose appearance further to exposure depends on chance) or random. The probability of developing cancer

1. Cohort: group of individuals considered as a whole and participating in a statistical study of the circumstances of occurrence of diseases.

increases with the dose. However, the impact of low doses on the development of a cancer is a subject of scientific debate (see point 1.2).

The internationally established public health objectives of radiation protection aim to prevent the appearance of deterministic effects and to reduce the probability of development of radiation-induced cancers; the results of the studies as a whole seem to indicate that radiation-induced cancers represent the predominant health risk associated with exposure to ionising radiation

1.2 Assessment of the risks associated with ionising radiation

The monitoring of cancer epidemiology in France is based on disease registries, on the monitoring of causes of death and also, more recently, on the utilisation of data from the Medicalised Programme for Information Systems of healthcare facilities and the Long-Term Disease notifications. The registries are structures that provide “a continuous and exhaustive collection of nominative data concerning one or more health events in a geographically defined population, for purposes of research and public health, managed by a team with the appropriate skills”. Some are “general registers”, concerning all types of cancer and covering one *département* or more; others are “specialised registers”, focusing on a particular type of cancer. Their geographical perimeter can vary (town, *département*, region, or even nationwide). Of the three national registers, one concerns pleural mesothelioma primarily in the context of exposure to asbestos fibres, while the other two cover all the cancerous pathologies in the child and adolescent up to 18 years of age (source: INCa).

The aim of the register for a given area is to highlight differences in spatial distribution, to reveal changes over time in terms of increased or reduced rate of incidence in the different cancer locations, or to identify clusters of cases.

Some registers, depending on the quality of their population database and their age, are used in numerous studies exploring cancer risk factors (including environmental risks).

Epidemiological investigation is complementary to monitoring. Its purpose is to highlight an association between a risk factor and the occurrence of a disease, between a possible cause and an effect, or at least to enable such a causal relation

to be asserted with a very high degree of probability. The intrinsic difficulty in conducting these surveys or in reaching a convincing conclusion when the illness is slow to appear or when the expected number of cases is low, which is the case with low exposure levels of a few tens of millisieverts (mSv) for example, must be borne in mind.

Cohorts such as those of Hiroshima and Nagasaki have clearly shown an excess of cancers for an average exposure of about 200 mSv. Due to insufficient data on the impact of low doses on the occurrence of a cancer, estimates are provided by making linear no-threshold extrapolations of the observed effects described for high doses. These models give estimations of the risks run during exposure to low doses of ionising radiation, which nevertheless remain scientifically controversial. Studies are currently being conducted on very large populations to better characterise these risks. Recent epidemiological studies on nuclear industry workers⁽²⁾ and on children and adolescents exposed to ionising radiation during computed tomography examinations⁽³⁾ find an increase in the risk of cancer that is proportional to the dose received which remains significant, including when the studied interval is limited to low cumulative doses of less than 100 milligrays (mGy), thereby underpinning what until then was simply a hypothesis.

These results consolidate knowledge on the impact of ionising radiation at low doses and confirm the importance of the principles of optimisation and justification for the radiological protection of exposed populations, whatever the cause of exposure (natural radiation, medical exposure, nuclear industry, etc.).

On the basis of the scientific syntheses of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP) has published the risk coefficients for death by cancer due to ionising radiation, i.e. 4.1% excess risk per sievert for workers and 5.5% per sievert for the general public (see ICRP publication 103).

The evaluation of the risk of lung cancer due to radon⁽⁴⁾ is based on a large number of epidemiological studies conducted directly in the home, in France and internationally. These studies have revealed a linear relationship, even at low exposure levels (200 becquerels per cubic metre - Bq/m³) over a period of twenty to thirty years. In 2009, the World Health Organisation (WHO) recommended a reference level

of 100 Bq/m³, and whatever the case to remain below 300 Bq/m³. ICRP publication 115 compared the risks of lung cancer observed through studies on uranium miners with those observed in the overall population and concluded that there was a very good correlation between the risks observed in these two conditions of exposure to radon. The ICRP recommendations consolidate those issued by the WHO which considers that radon constitutes the second-highest risk factor in lung cancer, coming far behind tobacco. Furthermore, for given levels of exposure to radon, the risk of lung cancer is much higher in smokers: three quarters of the deaths by lung cancer that can be attributed to radon reportedly occur in smokers.

In metropolitan France, about 12 million people spread over some 7,000 municipalities are potentially exposed to high radon concentrations. According to the French Public Health Agency (2018), an estimated 4,000 new cases of lung cancer are caused by radon in metropolitan France each year, far behind the number due to tobacco (the estimated number of new cases of lung cancer in Metropolitan France in 2018 was 46,000). A Radon National Action Plan has been implemented since 2004 on the initiative of the French Nuclear Safety Authority (ASN). It is updated periodically. The 4th plan was published in early 2021 and will end at the end of 2026 (see point 3.2.2).

1.3 Scientific uncertainties and vigilance

The action taken in the fields of nuclear safety and radiation protection to prevent accidents and limit detrimental effects has led to a reduction in doses, whether, for example, in terms of the doses received by workers or those associated with discharges from BNIs. Many uncertainties persist; they induce ASN to remain attentive to the results of scientific work in progress in radiobiology and radiopathology for example, with possible consequences for radiation protection, particularly with regard to management of risks associated with low doses.

One can mention, for example, several areas of uncertainty concerning radiosensitivity, the effects of low doses according to age, the existence of signatures (specific mutations of DNA) that could be observed in radiation-induced cancers and certain non-cancerous diseases observed after radiotherapy.

2. Source: Inworks study – IRSN, Information Notice of 3 October 2023, irsn.fr.

3. Source: EPI CT Study – IRSN, irsn.fr.

4. Radon is a natural radioactive gas, a progeny product of uranium and thorium, an emitter of alpha particles and has been classified as a known human pulmonary carcinogen by the International Agency for Research on Cancer (IARC) since 1987.

1.3.1 The individual response to ionising radiation

The effects of ionising radiation on personal health vary from one individual to the next. As early as 1906, Bergonié and Tribondeau stated for the first time that a given dose does not have the same effect when received by a growing child or by an adult.

The variability in individual radiosensitivity is observed at high doses of ionising radiation, notably in terms of tissue responses. It has been well documented by radiation oncologists and radiobiologists. High levels of radiosensitivity have been observed in subjects suffering from genetic diseases affecting the repair of DNA and cellular signalling. Such abnormal responses are also observed in people suffering from neurodegenerative diseases.

This variability in radiosensitivity at low and moderate doses, particularly at cellular level, is increasingly documented, as is the fact that radiosensitivity at a given dose level does not necessarily imply radiosensitivity at other dose levels. Thanks to the lowering of detection thresholds, some recent methods of immunofluorescence of molecular targets for signalling and repairing DNA damage enable the effects of ionising radiation at low doses to be better documented. The results of the research work conducted using these new investigation methods must still be confirmed in the clinical environment before being integrated into medical practices.

The work of the European research group on low doses (Multidisciplinary European Low Dose Initiative – MELODI) and in the medical field (European platform for research activities in medical radiation protection – Euramed) is continuing on this subject. The ICRP task group (TG111) dedicated to this subject has published a review of the state of knowledge on individual radiosensitivity and the possibilities of predicting it with a view to developing international radiation protection recommendations. At this stage however, no valid biomarker allowing such a prediction has been identified. The individual response to ionising radiation remains an important subject of research and application in radiobiology and radiation protection (Euratom 2021-2022).

1.3.2 Effects of low doses

The linear no-threshold relationship

The linear no-threshold relationship is a model used in radiation protection to estimate the probability of risk associated with

Assessment of exposure: the recommendations of the International Commission on Radiological Protection

The ICRP, which published new recommendations for the calculation of effective and equivalent doses (publication 103) in 2007, is gradually updating the values of the effective dose coefficients for internal and external exposure. These coefficients take into account more specifically the improvements made to the biokinetics and dosimetric models and the new tissue and radiological weighting factors defined in publication 103.

The internal dose coefficients for workers were updated in the series of ICRP publications 134, 137, 141 and 151. The Order of 16 November 2023 defining the methods of calculating the effective doses and equivalent doses resulting from the exposure of persons to ionising radiation updated in French law the dose coefficients for workers as of 1 January 2024. The ICRP will publish updated internal dose coefficients for the public in the coming years.

With regard to radon, ICRP publication 115 (2010) updated the risk of lung cancer

associated with radon exposure on the basis of new epidemiological studies. The ICRP had concluded that the risk of death from lung cancer in adults having been chronically exposed to low concentrations of radon was nearly two times higher than that estimated on the basis of the knowledge available in 1993 (publication 65). These coefficients were based on an epidemiological approach. In its publication 137, the ICRP proposed new coefficients based on a dosimetric approach, in the same way as for the other radionuclides. For an equal given level of exposure to radon and its progeny, they lead to a significant increase in the annual effective dose received by workers exposed to radon (nearly two times higher). The Order of 16 November 2023 updated the dose coefficients for radon. This update⁽⁵⁾ changes the calculation of the average effective dose received by the population in France, which thus increases from 3.5 to 6.5 millisieverts per year (mSv/year), with exposure to radon now representing 54% of the overall exposure (compared with 33% previously).

* Exposure of the French population to ionising radiation – Results for 2014-2019, IRSN, 2021.

an exposure to ionising radiation taking into account the principle of precaution. According to this relationship, there would be a risk from the first exposure, proportionate to the radiation dose received. There are nevertheless many uncertainties. This is why some feel that the effects of low doses could be higher, while others believe that these doses could have no effect below a certain threshold, and some others even assert that low doses have a beneficial effect. Research in molecular and cellular biology is progressing, as are epidemiological surveys of large cohorts. The ICRP considers that the hypothesis of this relationship, used to model the effect of low doses on health (see point 1.2), constitutes a cautious basis for managing the risks due to exposure to ionising radiation. It is the obvious option for decision-makers given the uncertainties that subsist faced with the complexity of the phenomena of DNA repair and mutation and the methodological limits of epidemiology, despite the progress of research in molecular and cellular biology.

Dose, dose rate and duration of exposure

The epidemiological studies performed on individuals exposed to the Hiroshima and Nagasaki bombings have given a clearer picture of the effects of radiation on health, concerning exposures due to

external irradiation (external exposure) received in a few fractions of a second at high dose and high dose rate⁽⁶⁾ of ionising radiation. The studies carried out in the countries most affected by the Chernobyl accident (Belorussia, Ukraine and Russia) were also able to improve our understanding of the effects of radiation on health caused by exposure through internal contamination (internal exposure), more specifically through radioactive iodine. Studies on nuclear industry workers have given a clearer picture of the risk associated with chronic exposures at low doses established over many years, whether as a result of external exposure or internal contamination.

Hereditary and teratogenic effects

The occurrence of possible hereditary effects from ionising radiation has not been demonstrated in humans. Such effects have not been observed among the survivors of the Hiroshima and Nagasaki bombings. But hereditary effects have been documented in experimental work on animals; more specifically, the mutations induced by ionising radiation in germ cells (cells that develop into reproductive cells: spermatozoa or ovules) can be transmitted to the progeny. An ICRP Task Group, TG121, is currently working on the heritable effects and their modes of transmission to future generations.

5. The radioactive dose rate determines the absorbed dose (energy absorbed by the material per unit of mass and time). It is measured in Gray per second (Gy/s) in the International System of Units (SI). It is used in physics and radiation protection.

Environmental protection

The purpose of radiation protection is to prevent, mitigate and limit the exposure of individuals to ionising radiation, directly or indirectly, including through deleterious effects on the environment. Over and beyond environmental protection aiming at the protection of humans and present or future generations, the protection of non-human species as such forms part of the environmental protection prescribed in the French constitutional Charter for the Environment. Protection of nature in the specific interests of animal and plant species (*see point 3.4*) has been the subject of several publications since 2008 (ICRP 108, 114 and 124).

1.3.3 Molecular signature in radiation-induced cancers

It is currently impossible to distinguish a radiation-induced cancer from a cancer that is not radiation induced. The reason for this is that the molecular lesions caused by ionising radiation seem no different to those resulting from the normal cellular metabolism, with the involvement of free

radicals – oxygenated in particular – in both cases. Furthermore, to date, neither anatomopathological examinations nor research for specific mutations have been able to distinguish a radiation-induced tumour from a sporadic tumour.

It is known that in the first stages of carcinogenesis (process of cancer formation) a cell develops with a particular combination of DNA lesions that enables it to escape from the usual control of cellular division, and that it takes about ten to one hundred DNA lesions (mutations, breaks, etc.) at critical points to pass through these stages. All the agents capable of damaging cellular DNA (tobacco, alcohol, various chemical substances, ionising radiation, high temperature, other environmental factors, notably nutritional and free radicals of normal cellular metabolism, etc.) contribute to cellular ageing and to carcinogenesis.

Consequently, in a multi-risk approach to carcinogenesis, can we still talk about radiation-induced cancers? Yes we can, given the quantity of epidemiological data which indicate that cancer frequency increases when the dose increases, with

the other main risk factors taken into account. However, the radiation-induced event can also in certain cases be the only event responsible (radiation-induced cancers in children).

Highlighting a radiological signature of cancers, that is to say the discovery of markers that could indicate whether a tumour has a radiation-induced component or not, would be of considerable benefit in the evaluation of the risks associated with exposure to ionising radiation, but has not been demonstrated to date.

The multifactorial nature of carcinogenesis pleads in favour of a precautionary approach with regard to all the risk factors, since each one of them could contribute to DNA damage. This is particularly important in persons displaying high individual radiosensitivity and for the most sensitive organs such as the breast and the bone marrow, and all the more so if the persons are young. Here, the principles of justification and optimisation are more than ever applicable (*see chapter 2*).

2 — The different sources of ionising radiation

2.1 Natural ionising radiation

In France, exposure to the different types of natural radioactivity (cosmic radiation, terrestrial radiation such as that linked to the incorporation of natural radionuclides contained in foodstuffs and drinking water and that associated with the presence of radon in the home) represents on average 76% of the total annual exposure⁶.

2.1.1 Cosmic radiation

Cosmic radiation is made up essentially of ions. They have a directly ionising component and an indirectly ionising component due to the presence of neutrons (the “neutron component”), which vary according to altitude and longitude.

Considering the altitude of each municipality, the average time spent inside the home and a housing protection factor of 0.8 (housing attenuates the ionic component of cosmic radiation), the French Institute for Radiation Protection and Nuclear Safety (IRSN) evaluates the average individual effective dose per person in France at 0.31 mSv with a variation of 0.3 to 1.1 mSv/year depending on the municipalities.

Passengers and flight crew are exposed during air travel, depending on the flight altitude and the journey, to exposure varying from a few microsieverts (μSv) for short-haul domestic flight within France to nearly 80 μSv for a flight from Paris to Ottawa (Canada). The average annual effective dose received by the population in France is 14 μSv.

On account of the increased exposure to cosmic radiation due to extensive periods spent at high altitude, flight personnel must be subject to dosimetric monitoring (*see point 3.1.3*).

2.1.2 Natural terrestrial radiation (excluding radon)

Natural radionuclides of terrestrial origin are present at various levels in all the compartments of our environment, including inside the human body. They lead to external exposure of the population owing to gamma rays emitted by the uranium-238 and thorium-232 daughter products and by the potassium-40 present in the soil.

External exposure to gamma rays of terrestrial origin

Based on the results of a) ambient gamma dose rate measurements taken in France inside buildings, b) the mapping of the

uranium potential of geological formations, c) a correlation between the gamma dose rate of terrestrial origin outside the home and inside the home, and d) assumptions on the time spent by the population inside and outside the home (92% and 8% respectively), the IRSN estimates that the average annual effective dose due to external exposure to gamma radiation of terrestrial origin in France is about 0.63 mSv per person per year. It varies from 0.30 mSv/year to 2.0 mSv/year depending on the municipality.

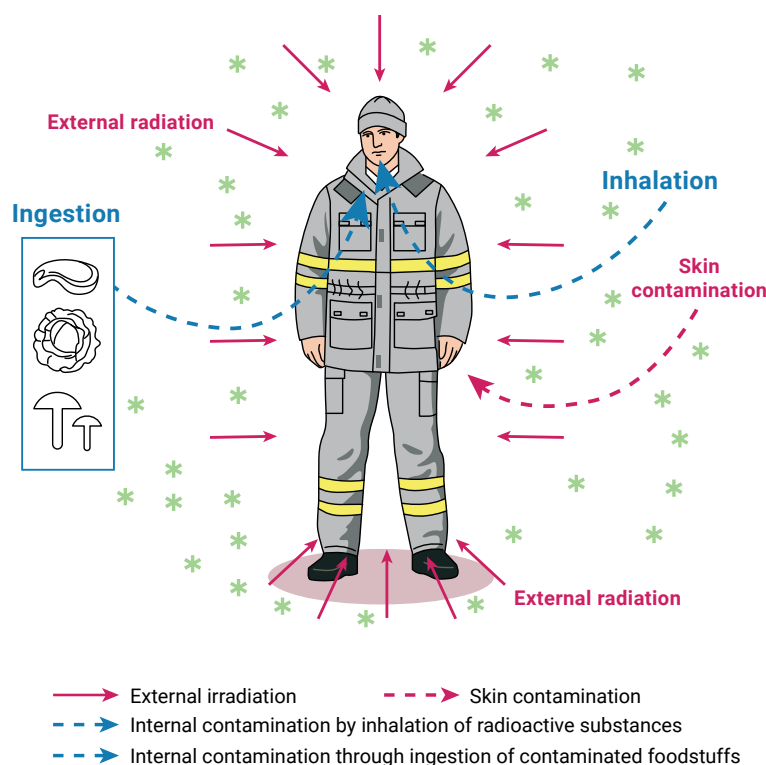
Exposure linked to the incorporation of radionuclides of natural origin

The average internal exposure due to the incorporation of radionuclides of natural origin is estimated at 0.55 mSv/year. The two main components of this exposure are the incorporation through foodstuffs and drinking water of potassium-40 (0.18 mSv) and descendants of the uranium and thorium chains (0.32 mSv).

Depending on the individual consumption habits, in particular the consumption of fish, seafood and tobacco, this exposure can vary greatly: from 0.4 mSv/year up to more than 3.1 mSv/year, respectively, for people who do not consume these products and those who consume them in large quantities.

6. Exposure of the French population to ionising radiation – Results for 2014-2019, IRSN, 2021.

Sources and routes of exposure to ionising radiation



Waters intended for human consumption, in particular groundwater and mineral waters, become charged in natural radionuclides due to the nature of the geological strata in which they lie. The concentration of uranium and thorium daughters and of potassium-40 varies according to the resource exploited, given the geological nature of the ground. The average effective dose linked to the decay products of the U-Th chains in drinking water is estimated by IRSN at 0.01 mSv/year. A high value of 0.30 mSv/year is retained to illustrate the variability of this exposure.

2.1.3 Radon

Some geological areas have a high radon exhalation potential due to the geological characteristics of the ground (granitic bedrock, for example). The concentration measured inside homes also depends on the tightness of the building (foundations), the ventilation of the rooms and the life style of the occupants.

National measuring campaigns have enabled the French *départements* to be classified according to the radon exhalation potential of the ground. In 2011, IRSN published a map of France considering the radon exhalation potential of the ground, based on data from the French Geological and Mining Research Office (BRGM).

Based on this, a more fine-grained classification, by municipality, was published through the Interministerial Order of 27 June 2018 (see search engine by municipality and mapping accessible on asn.fr and irsn.fr).

Working from the available measurement results and the mapping of the geogenic radon potential of the territory, the average time spent inside the home and assumptions on the type of housing concerned (collective or individual), IRSN has estimated the average radon concentration for each municipality: the average concentration of radon-222 inside housing in metropolitan France, weighted for the population and type of housing, is 60.8 Bq/m³. With the dose factor in effect since 1 January 2024, the average effective dose per inhabitant is estimated at 3.5 mSv/year. This effective dose varies from 0.75 mSv/year to 47 mSv/year depending on the municipality (see box page 103).

The new obligation for radon detector analysis laboratories to send IRSN the measurement results and the expected results of action 7 of the fourth French action plan for management of the radon risk (see point 3.2), relative to the defining of organisation methods for collecting the radon measurement data should improve knowledge of radon exposures in France.

2.2 Ionising radiation arising from human activities

The human activities involving a risk of exposure to ionising radiation, called nuclear activities, can be grouped into the following categories:

- operation of BNIs;
- small-scale nuclear activities;
- removal of radioactive waste;
- management of contaminated sites;

- transport of radioactive substances;
- activities enhancing natural ionising radiation.

2.2.1 Basic Nuclear Installations

Nuclear activities are highly diverse, covering any activity relating to the preparation or utilisation of radioactive substances or ionising radiation. These activities are subject to the general provisions of the Public Health Code and, depending on their nature and the risks that they involve, to a specific legal system: BNIs are defined in Article L. 593-2 of the Environment Code:

- 1° Nuclear reactors;
- 2° Facilities, corresponding to characteristics defined by Decree of the Council of State, for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels, or for the treatment, storage or disposal of radioactive waste;
- 3° Facilities containing radioactive or fissile substances and meeting characteristics defined by Decree of the Council of State;
- 4° Particle accelerators meeting characteristics defined by Decree of the Council of State;
- 5° Deep geological repositories for radioactive waste mentioned in Article L. 542-10-1 of the Environment Code.

The installations and facilities are subject to the BNI System, governed by Chapters III and VI of Title IX of Book V of the Environment Code and their implementing texts.

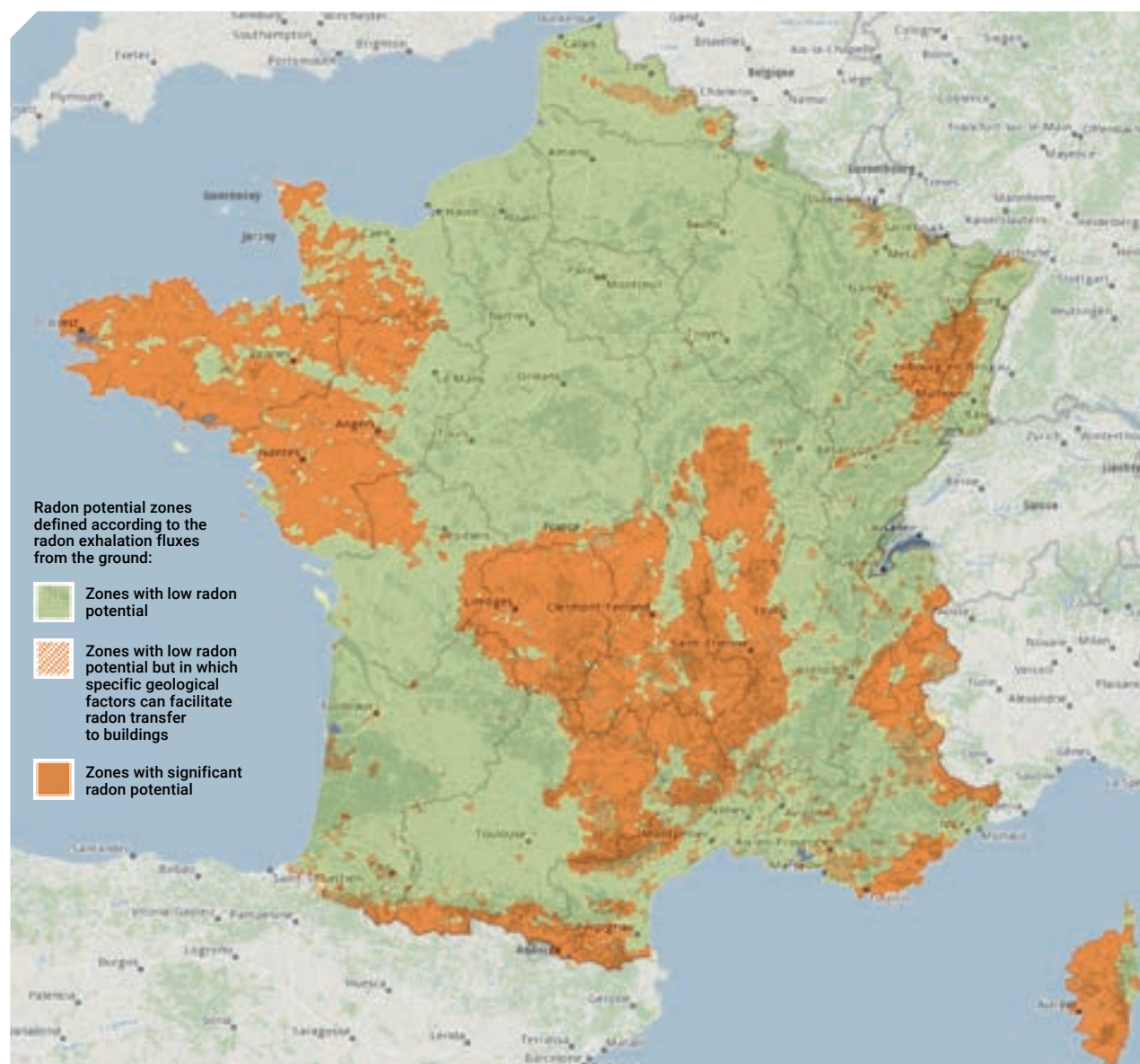
The list of BNIs as at 31 December 2024 figures in an appendix to this report.

Prevention of accidental risks and nuclear safety

The fundamental internationally adopted principle underpinning the specific organisational system and regulations applicable to nuclear safety is that of the responsibility of the licensee (see chapter 2). The public authorities ensure that this responsibility is fully assumed, in compliance with the regulatory requirements. As regards the prevention of risks for workers, BNI licensees are required to implement all necessary means to protect workers against the hazards of ionising radiation. They must more particularly ensure compliance with the general rules applicable to all workers exposed to ionising radiation (work organisation, accident prevention, medical monitoring of workers, including those of outside contractors, etc.).

As regards protection of the population and the environment, the BNI licensee must also take all necessary steps to achieve and maintain an optimum level of protection. More particularly, discharges

Radon potential zones in metropolitan France defined by the Order of 27 June 2018



Source: IRSN.

of liquid and gaseous effluents, whether radioactive or not, are strictly limited (see chapter 3).

2.2.2 Transport of radioactive substances

When transporting radioactive substances, the main risks are those of internal or external exposure, of criticality, and risks of a chemical nature. Safe transport of radioactive substances relies on an approach called “Defence in Depth”:

- The robustness of the packaging is the first line of defence. The packaging plays an essential role and must withstand the conceivable transport conditions and the effects of accidents that could occur.
- The reliability of the transport operations constitutes the second line of defence.
- Finally, the third line of defence is the means of response implemented in the event of an incident or accident.

2.2.3 Small-scale nuclear activities

Ionising radiation, whether emitted by radionuclides or generated by electrical equipment, is used in many areas, including medicine (radiology, radiotherapy, nuclear medicine and Fluoroscopy-Guided Interventional Practices – FGIPs), biology, research, industry, but also in veterinary applications, the sterilisation of numerous products, and the conservation of foodstuffs.

The employer is required to take all necessary measures to protect workers against the hazards of ionising radiation. The facility licensee must also implement the provisions of the Public Health Code for the management of the ionising radiation sources in its possession (radioactive sources in particular) and, where applicable, manage the waste produced and limit discharges of liquid and gaseous effluents.

In the case of use for medical purposes, patient protection issues are also taken into account.

2.2.4 Radioactive waste management

Like all industrial activities, nuclear activities can generate waste, some of which is radioactive. The three fundamental principles on which strict radioactive waste management is based are the accountability of the waste producer, the traceability of the waste and informing the public.

The technical management provisions to be implemented must be tailored to the hazard presented by the radioactive waste. This hazard can be assessed primarily through two parameters: the activity level, which contributes to the toxicity of the waste, and the half-life, the time after which the activity level is halved.

Lastly, management of radioactive waste must be determined prior to the creation of any new activities or the modification of existing activities in order to:

- ensure the availability of processing routes for the various categories of waste likely to be produced, from the front-end phase (production of waste and packaging) to the back-end phase (storage, transport and disposal);
- optimise the waste management routes.

2.2.5 Management of contaminated sites

Management of sites contaminated by residual radioactivity resulting either from a past nuclear activity or an activity which generated deposits of natural radionuclides warrants specific radiation protection actions, in particular if rehabilitation is envisaged.

Depending on the current or future uses of the site, decontamination objectives must be set. The removal of the waste

produced during post-operation clean-out of the premises and removal of the contaminated soil must be managed from the site through to storage or disposal. The management of contaminated objects also follows these principles.

2.2.6 Activities using radioactive substances of natural origin

Exposure to ionising radiation of natural origin, when increased due to human activities, justifies monitoring measures if it is likely to create a hazard for the exposed workers and, where applicable, the neighbouring population.

Thus, certain activities included in the definition of “nuclear activities” can use materials containing naturally occurring radioactive materials at concentration levels that could significantly increase the exposure of workers to ionising radiation and, to a lesser extent, the exposure of populations living near the places in which these activities are carried out.

The natural families of uranium and thorium are the main radionuclides found in these activities, which include:

- the production of thorium compounds, the manufacture of products containing thorium and the mechanical working of products containing thorium;
- the production of oil and gas, geothermal energy, titanium dioxide, phosphate fertilizers and cement;
- the extraction of rare earths and granites;
- the casting of tin, lead and copper.

The radiation protection measures to take in this area target not only the workers (risk of external irradiation and internal contamination, radon) but also the general public, for example in the case of effluent discharges into the environment or the production of residues that could be reused, in construction materials for example. Since 2018, these activities are subject to the system of Installations Classified for Protection of the Environment (ICPEs).

3 — Monitoring exposure to ionising radiation

Given the difficulty in attributing a cancer solely to the ionising radiation risk factor, “risk monitoring” to prevent cancers in the population is performed by measuring ambient radioactivity indicators (measurement of dose rates for example), internal contamination or, failing this, by measuring values (activities in radioactive effluent discharges) which can then be used – by modelling and calculation – to estimate the doses received by the exposed populations

The entire population of France is exposed to ionising radiation of natural or anthropogenic origin, but to different extents across the country. The average exposure of the French population is estimated at 6.5 mSv per person per year, but this exposure is subject to wide individual variability (factor of 1 to 20), particularly depending on the place of residence (radon potential of the municipality, level of terrestrial radiation), the number of radiological examinations the person undergoes, consumption (smoking, foodstuffs) and living habits (air travel). Diagram 1 shows an estimate of the respective contributions to the average total dose of the different sources of exposure to ionising radiation for the French population.

3.1 Doses received by workers

3.1.1 Monitoring occupational exposure to ionising radiation

The system for monitoring the external exposure of persons liable to be exposed to ionising radiation, working in BNIs or in small-scale nuclear facilities for example, has been in place for several decades.

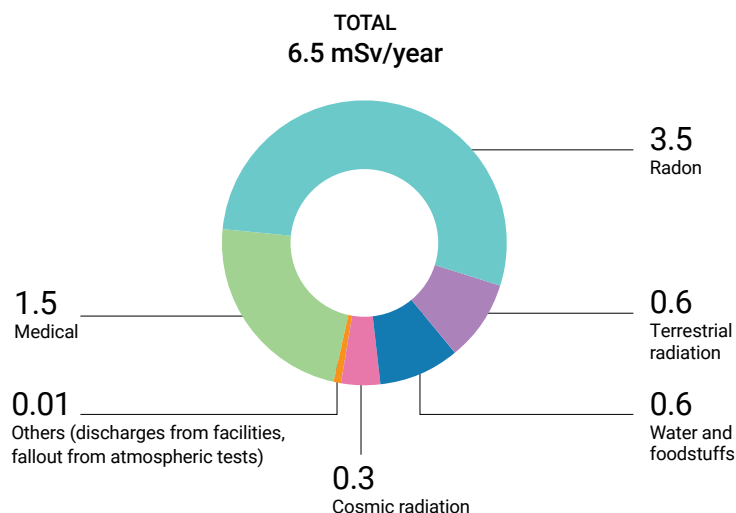
This system is based primarily on the mandatory wearing of passive dosimeters for workers liable to be exposed and enables compliance with the regulatory limits applicable to workers to be checked. These limits concern the total exposure (since 2003, the annual limit expressed in terms of effective dose has been 20 mSv for 12 consecutive months), obtained by adding the dose due to external exposure to that resulting from any internal contamination; other limits, called “equivalent dose limits”, are defined for the external exposure of certain parts of the body such as the hands, the skin and the lens of the eye (see “References” heading on asn.fr).

The recorded data allow the identification of the cumulative exposure dose for a given period which cannot exceed three months, for each worker, including those from outside contractors. They are grouped together in Siseri (Ionising radiation exposure monitoring information

system) managed by IRSN and are published annually.

The results of worker exposure to ionising radiation presented below are taken from the IRSN 2023 assessment entitled *La radioprotection des travailleurs – exposition professionnelle aux rayonnements ionisants en France* (Worker radiation protection - occupational exposure to ionising radiation in France). From the methodological aspect, as in the five preceding years, the IRSN 2023 assessment of external exposure was based exclusively on data from individual monitoring of the external exposure of workers recorded in the Siseri database. Until 2016, the assessments were produced exclusively by aggregating the annual summaries provided by the dosimetry organisations. Consequently, external exposure results for 2023 are not directly comparable with those established since 2017. Nevertheless, in order to establish trends, the results for the years 2015 and 2016 have been reassessed applying the new methodological approach (see Table 3).

Tables 1 and 2 present, per area of activity and for the year 2023, the breakdown of the populations monitored, the collective dose (the collective dose is the sum of the individual doses received by a given group of persons), and the number of times the annual limit of 20 mSv was exceeded. They show a large disparity in the

DIAGRAM 1 Average exposure of the French population

Source: IRSN, 2021.

breakdown of doses depending on the sector.

For example, the medical (including dental) and veterinary activities sector, which comprises a significant share of the population monitored (58.5%), accounts for only 9.7% of the collective dose; on the other hand, the nuclear industry, which represents just 24% of the headcount, accounts for 54% of the collective dose. Moreover, the sector concerned by exposure to natural radioactivity (excluding military aircrew), which represents just 6.2% of the total headcount, accounts for 30.9% of the collective dose. The non-nuclear industry and the research sectors represent 4% and 2.6% of the headcount respectively and account for 4% and 0.2% of the collective dose respectively.

Table 3 shows that for external exposure, the total number of workers⁽⁷⁾ monitored in 2023 was 360,743, a 6.6% decrease compared with 2022. The collective dose is 84.2 man-Sv, a figure that is down by 5% compared with that for 2022. The main cause of this being the decline in staff numbers in the medical, dental and veterinary sectors and the reduction in occupational exposure to natural radioactivity.

With regard to the dosimetry of the extremities (fingers and wrist), 25,852 workers were monitored in 2023, down by 6.3% compared with 2022 (*i.e.* 7.2% of the total number of persons monitored).

With regard to dosimetric monitoring of the lens of the eye, which had been increasing since 2015, it has been stabilising since 2021. It concerned 5,762 workers in 2023.

In 2023, five cases of exceedance⁽⁸⁾ of the regulatory limit of 20 mSv for the whole body effective dose were registered, of which one was confirmed by the occupational health physician and four were not confirmed by the occupational health physician. The case of limit exceedance confirmed by the occupational health physician occurred in the dental sector and was detected in August 2023 for a cumulative dose of 25.9 mSv over 12 months rolling. The four other cases of occasional exceedance of this dose limit, which were not confirmed by the occupational health physician, concern: three cases in the medical field (diagnostic radiology,

interventional radiology, dental sector), while the fourth case concerns a non-destructive testing worker in the non-nuclear industry sector.

One case of exceedance of the regulatory limit for the equivalent dose to the extremities (500 mSv over twelve consecutive months), confirmed by the occupational health physician, was registered in the medical sector (interventional radiology) with cumulative doses of 534.93 mSv.

In addition, three cases of exceedance of the regulatory limit for the equivalent dose to the skin of 500 mSv were registered. One case involved a worker in the nuclear logistics and maintenance sector, for whom the registered dose (520.4 mSv) was confirmed by the occupational health physician. The two other cases, which were not confirmed by the occupational health physician, involved workers who exceeded the effective whole body dose limit mentioned above: a worker in the dental sector and a worker in the industrial non-destructive testing sector.

Lastly, an equivalent dose of 21.34 mSv to the lens of the eye was registered in the medical diagnostic radiology sector, but results from the accumulation of several doses over the calendar year 2023 and the cumulative dose from 1 July 2018 to 30 June 2023 remains below the 100 mSv limit (76.2 mSv)⁽⁹⁾.

To conclude, as in the preceding years, the assessment of monitoring of workers exposed to ionising radiation in France in 2023 published by IRSN in September 2024, shows the overall effectiveness of the prevention system introduced in facilities where sources of ionising radiation are used, because for 92.7% of the population monitored, the annual dose remained below 1 mSv (effective annual dose limit for the public due to nuclear activities). The regular reduction in the number of the most heavily exposed workers over the last ten years should also be noted. Exceedances of the regulatory limit values remain exceptional.

3.1.2 Case of worker exposure to natural radioactivity

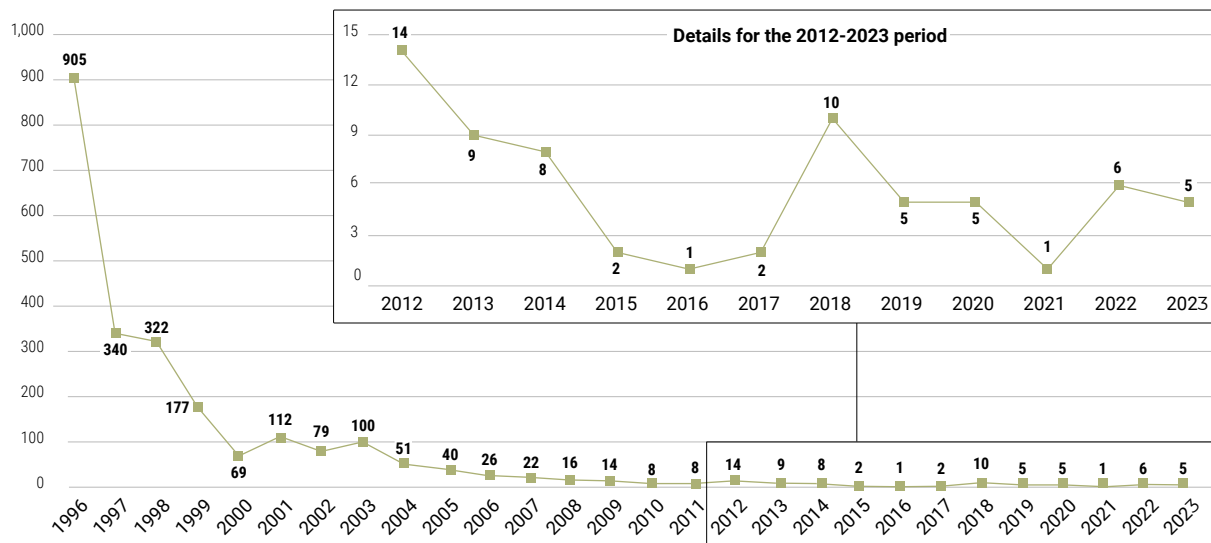
Exposure to radioactive substances of natural origin and to radon of geological origin

Worker exposure to radioactive substances of natural origin results either from the ingestion of dust from materials containing large amounts of radionuclides (phosphates, metal ores), or from the inhalation of radon formed by uranium decay (poorly ventilated warehouses, thermal baths) or from external exposure due to industrial process deposits (scale forming in piping for example).

7. The total number of workers monitored encompasses all the workers, including those involved in military and defence activities.

8. A sixth exceedance recorded by IRSN in its assessment has been reassessed by the occupational health physician since the report was published, the dose finally attributed being below the regulatory limit value.

9. The limit value of 20 mSv over twelve consecutive months came into effect on 1 July 2023 with a transitional period from 1 July 2018 to 30 June 2023 during which the cumulative value for the lens of the eye was set at 100 mSv, provided that the dose received over one year did not exceed 50 mSv.

DIAGRAM 2 Changes in the number of monitored workers whose annual dose exceeds 20 mSv, from 1996 to 2023

Source: IRSN.

In 2023, the individual monitoring of worker exposure in industrial activities leading to exposure to substances of natural origin or to radon of geological origin (exposure to natural radionuclides of the uranium and thorium decay chains) involved about 817 workers monitored for external exposure (including 28 workers exposed to more than 1 mSv) and 332 workers monitored for internal exposure (of whom 19 were exposed to more than 1 mSv).

Flight crew exposure to cosmic radiation

Airline flight crews and certain frequent flyers are exposed to significant doses owing to the altitude and the intensity of cosmic radiation at high altitude. These doses can exceed 1 mSv/year.

Since 1 July 2014, IRSN calculates the individual doses for civil flight personnel using the *SievertPN* application, on the basis of the flight and personnel presence data provided by the airlines. These data are subsequently transmitted to Siseri, the French national worker dosimetry registry.

In 2023, the headcount for civil flight personnel totalled 21,585, a figure that is down by 2%. The average dose for this category of personnel has fallen by nearly 15% compared with 2022 (1.2 mSv). About 39% of the individual annual doses are below 1 mSv and 61% of the individual annual doses are between 1 mSv and 5 mSv. The collective dose has decreased by 11% compared with 2022.

Results of dosimetry monitoring of work external exposure to ionising radiation (exposure to natural radioactivity included) in 2023

(Source: Radiation protection of workers: occupational exposure to ionising radiation in France, results for 2023 – IRSN, June 2024)

- Total population monitored: **360,743 workers**
- Monitored population for whom the annual effective dose remained below the detection threshold: **271,708 workers, i.e. 75.3%**
- Monitored population for whom the annual effective dose remained between the detection threshold and 1 mSv: **62,589 workers, i.e. about 17.3%**
- Monitored population for whom the annual effective dose remained between 1 mSv and 20 mSv: **26,446 workers, i.e. about 7.3% of the total population monitored**
- Monitored population for whom the annual effective dose exceeded 20 mSv: **5 workers^(*)**
- Monitored population for whom the equivalent dose to the extremities exceeded 500 mSv: **1 worker**
- Monitored population for whom the equivalent dose to the extremities exceeded 500 mSv: **3 workers^(**)**
- Monitored population for whom the equivalent dose to the lens of the eye exceeded 20 mSv: **1 worker**
- Collective dose (sum of the individual effective annual doses): **84.2 man-Sv**

- Average annual individual effective dose in the population which recorded a dose higher than the detection threshold: **about 0.95 mSv**

Results of internal exposure monitoring in 2023 (natural radioactivity excluded)

- Number of routine examinations carried out: **238,738** (of which 0.6% were considered positive)
- Number of workers with a positive result (routine monitoring): **785**
- Number of special monitoring examinations: **9,098** (of which 16.6% are above the detection limit)
- Population having recorded a committed effective dose exceeding 1 mSv: **4 workers**

Results of monitoring of internal exposure to natural radionuclides, excluding "geogenic" radon and its daughter products, in 2023

- Internal exposure:
 - collective dose for 302 workers: **58.93 man-mSv**
 - average annual individual dose for the population having registered a dose above the detection limit: **0.32 mSv**

* One of these cases was detected in August 2023 for a cumulative dose of 25.9 mSv over 12 sliding months from June 2022 to May 2023, and not over the calendar year; four of these cases were retained by default as the occupational physician gave no feedback on the conclusions of the investigation.

** Two cases were not confirmed by the occupational physician.

3.2 Doses received by the population

3.2.1 Exposure of the population as a result of nuclear activities

The automated monitoring networks managed nationwide by IRSN (*Téléray*, *Hydrotéléray* and *Téléhydro* networks) offer real-time monitoring of environmental radioactivity and can highlight any abnormal variation. In the case of an accident or incident leading to the release

of radioactive substances, these measurement networks would play an essential role by providing data to inform the decisions to be taken by the authorities and to inform the population. In normal situations, they contribute to the evaluation of the impact of BNIs (see chapter 3).

On the other hand, there is no overall monitoring system able to provide an exhaustive picture of the doses received by the population as a result of nuclear activities. Consequently, compliance with the population exposure limit (effective

dose set at 1 mSv/year) cannot be controlled directly. However, for BNIs, there is detailed accounting of radioactive effluent discharges and radiological monitoring of the environment is implemented around the installations. On the basis of the data collected, the dosimetric impact of these discharges on the populations in the immediate vicinity of the installations is then calculated using models simulating transfers to the environment. The dosimetric impacts vary, according to the type of installation and the lifestyles of the chosen representative persons, from a few microsieverts to several tens of microsieverts per year ($\mu\text{Sv}/\text{year}$). An estimation of the doses from BNIs is presented in Table 4 which shows, for each site and per year, the estimated effective doses received by the most exposed representative persons.

There are no known estimates for nuclear activities other than BNIs owing to the methodological difficulties involved in identifying the impact of these facilities and in particular the impact of discharges containing small quantities of artificial radionuclides resulting from the use of unsealed radioactive sources in research or biology laboratories, or in nuclear medicine units. To give an example, the impact of hospital discharges could lead to doses of a several tens of microsieverts per year for the most exposed persons, particularly for certain jobs in sewage networks and wastewater treatment plants (IRSN studies 2005 and 2015).

Legacy situations, such as atmospheric nuclear tests and the Chernobyl accident (Ukraine), can make a marginal contribution to population exposure. Thus, the exposure due to fall-out from nuclear tests is currently estimated at $2.3 \mu\text{Sv}/\text{year}$ in metropolitan France ($1.3 \mu\text{Sv}/\text{year}$ for strontium-90 and $1 \mu\text{Sv}/\text{year}$ for carbon-14; exposure linked to caesium-137 cannot be distinguished from that due to fall-out from the Chernobyl accident).

The overall exposure due to fall-out from nuclear tests and the Chernobyl accident is $46 \mu\text{Sv}/\text{year}$ for people living in areas of high persistence of this fall-out and $9.3 \mu\text{Sv}/\text{year}$ for people over the rest of the country, that is to say an average dose per inhabitant of $12 \mu\text{Sv}/\text{year}$ for the country as a whole (IRSN 2021).

With regard to the fall-out from France from the Fukushima Daiichi NPP accident (Japan), the results published for France by IRSN in 2011 showed the presence of radioactive iodine at very low levels, resulting in estimated effective doses for the populations of less than $2 \mu\text{Sv}/\text{year}$ in 2011.

TABLE 1 Monitoring of external exposure of workers in the civil nuclear field (year 2023)

	Number of persons monitored	Collective dose (man-Sv ^(*))	Individual dose > 20 mSv
Reactors and energy production (EDF)	24,552	6.54	0
"Fuel cycle", decommissioning	12,579	4.07	0
Transport	442	0.06	0
Logistics and maintenance (contractors)	34,106	32.24	0
Effluents, waste	729	0.15	0
Others	7,823	1.28	1
Total civil nuclear	80,231	44.34	1

* Man-Sv: unit of quantity of collective dose. For information, the collective dose is the sum of the individual doses received by a given group of persons.

(Source: *Worker radiation protection: occupational exposure to ionising radiation in France* – IRSN report 2023)

TABLE 2 Monitoring of external exposure of workers in small-scale nuclear activities (year 2023)

	Number of persons monitored	Collective dose (man-Sv ^(*))	Individual dose > 20 mSv
Medicine	149,950	6.76	2 ⁽¹⁾
Dental	37,819	1.13	2 ⁽²⁾
Veterinary	23,315	0.25	0
Industry	14,519	3.39	1 ⁽³⁾
Research and education	9,429	0.20	0
Natural ^(**)	23,137	26.2	0
Total small-scale nuclear activities	258,169	37.9	5

(1) These cases were retained by default as the occupational physician gave no feedback on the conclusions of the investigation.

(2) These cases were retained by default as the occupational physician gave no feedback.

(3) These cases were retained by default as the occupational physician gave no feedback.

* Man-Sv: unit of quantity of collective dose.

** "Natural" covers flight crew and workers exposed to natural radionuclides of the uranium and thorium decay chains.

(Source: *Worker radiation protection: occupational exposure to ionising radiation in France* – IRSN report 2023)

TABLE 3 Development of number of persons monitored and average collective and individual doses in the exposed population from 2015 to 2023^(*) in all areas combined (A) and in the "natural" area (B)

Year	Number of persons monitored		Collective dose (man-Sv)		Average individual dose (mSv)	
	(A)	(B)	(A)	(B)	(A)	(B)
2015 ^(*)	372,881	352,641	104.41	65.61	0.98	0.76
2016 ^(*)	378,304	357,527	107.53	66.71	0.96	0.73
2017	384,198	360,694	100.58	53.52	1.03	0.72
2018	390,363	365,980	104.14	55.24	1.12	0.80
2019	395,040	369,712	112.31	58.73	1.20	0.85
2020	387,452	364,614	72.43	49.97	0.78	0.71
2021	392,180	370,756	82.71	60.09	0.85	0.78
2022	386,080	363,595	88.43	59.01	0.90	0.77
2023	360,743	337,706	84.23	58.05	0.95	0.87

* For comparison purposes, the results for 2015 and 2016 have been retroactively reassessed applying the new methodological approach.

(Source: *Worker radiation protection: occupational exposure to ionising radiation in France* – IRSN 2023 report, June 2024)

TABLE 4 Radiological impact of the BNIs since 2018 calculated by the licensees from the actual discharges from the facilities and for a "person representative" of the most exposed persons within the population (data provided by the nuclear licensees)

Licensees/Site	Representative persons in 2023	Distance to site in km	Estimation of received doses, in mSv ^(a) (the values calculated by the licensee are rounded up to the next higher unit)					
			2018	2019	2020	2021	2022	2023
Andra / CSA	Multi-activity group Ville-aux-Bois	1.7	3.10 ⁻⁷	3.10 ⁻⁷	4.10 ⁻⁷	3.10 ⁻⁷	2.10 ⁻⁷	3.10 ⁻⁷
Andra's Manche repository	Hameau És Clerges	1.5	2.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴	1.10 ⁻⁴	1.10 ⁻⁴	2.10 ⁻⁴
CEA / Cadarache ^(b)	Saint-Paul-lez-Durance	5	<3.10 ⁻³	<2.10 ⁻³	<6.10 ⁻⁴	<5.10 ⁻⁴	<6.10 ⁻⁴	<2.10 ⁻³
CEA / Fontenay-aux-Roses ^(b)	Achères	30	<2.10 ⁻⁴	<2.10 ⁻⁴	<2.10 ⁻⁴	<2.10 ⁻⁴	<2.10 ⁻⁴	<2.10 ⁻⁴
CEA / Grenoble ^(c)	—	—	(c)	(c)	(c)	(c)	(c)	(c)
CEA / Marcoule ^(b) (Atalante, Centraco, Phénix, Melox, CIS bio)	Codolet	2.4	<2.10 ⁻³	<2.10 ⁻³	<2.10 ⁻³	<2.10 ⁻⁴	<2.10 ⁻³	<2.10 ⁻³
CEA / Saclay ^(b)	Le Christ de Saclay	1	<2.10 ⁻³	<4.10 ⁻³	<2.10 ⁻³	<2.10 ⁻³	<8.10 ⁻⁴	<1.10 ⁻³
EDF / Belleville-sur-Loire	Neuvy-sur-Loire	1.6	4.10 ⁻⁴	4.10 ⁻⁴	3.10 ⁻⁴	4.10 ⁻⁴	3.10 ⁻⁴	3.10 ⁻⁴
EDF / Blayais	Braud-et-Saint-Louis	1.1	5.10 ⁻⁴	4.10 ⁻⁴	5.10 ⁻⁴	2.10 ⁻⁴	5.10 ⁻⁴	4.10 ⁻⁴
EDF / Bugey	Vernas	2.7	2.10 ⁻⁴	2.10 ⁻⁴	9.10 ⁻⁵	2.10 ⁻⁴	1.10 ⁻⁴	2.10 ⁻⁴
EDF / Cattenom	Cattenom	2.2	9.10 ⁻³	1.10 ⁻²	7.10 ⁻³	7.10 ⁻³	5.10 ⁻³	4.10 ⁻³
EDF / Chinon	Savigny-en-Véron	2.4	2.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴
EDF / Chooz	Chooz	0.8	5.10 ⁻⁴	5.10 ⁻⁴	3.10 ⁻⁴	4.10 ⁻⁴	1.10 ⁻⁴	3.10 ⁻⁴
EDF / Civaux	Civaux	1.1	8.10 ⁻⁴	2.10 ⁻³	1.10 ⁻³	1.10 ⁻³	1.10 ⁻⁴	4.10 ⁻⁴
EDF / Creys-Malville	Briord	0.6	2.10 ⁻⁵	2.10 ⁻⁵	8.10 ⁻⁶	2.10 ⁻⁵	4.10 ⁻⁶	3.10 ⁻⁶
EDF / Cruas-Meyssse	La Coucourde	1.1	3.10 ⁻³	3.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴
EDF / Dampierre-en-Burly	Lion-en-Sulias	1.6	5.10 ⁻⁴	5.10 ⁻⁴	3.10 ⁻⁴	5.10 ⁻⁴	4.10 ⁻⁴	5.10 ⁻⁴
EDF / Fessenheim	Fessenheim	1.3	5.10 ⁻⁵	4.10 ⁻⁵	3.10 ⁻⁵	7.10 ⁻⁶	5.10 ⁻⁶	2.10 ⁻⁶
EDF / Flamanville	Flamanville	0.8	2.10 ⁻⁴	7.10 ⁻⁵	2.10 ⁻⁵	6.10 ⁻⁵	2.10 ⁻⁴	7.10 ⁻⁵
EDF / Golfech	Donzac	1.8	2.10 ⁻⁴	2.10 ⁻⁴	1.10 ⁻⁴	1.10 ⁻⁴	1.10 ⁻⁴	4.10 ⁻⁵
EDF / Gravelines	Gravelines	2.2	8.10 ⁻⁴	1.10 ⁻³	8.10 ⁻⁴	7.10 ⁻⁴	1.10 ⁻³	2.10 ⁻³
EDF / Nogent-sur-Seine	La Saulsotte	2.6	5.10 ⁻⁴	4.10 ⁻⁴	4.10 ⁻⁴	5.10 ⁻⁴	6.10 ⁻⁴	4.10 ⁻⁴
EDF / Paluel	Paluel	1.7	4.10 ⁻⁴	3.10 ⁻⁴	3.10 ⁻⁴	2.10 ⁻⁴	9.10 ⁻⁴	5.10 ⁻⁴
EDF / Penly	Petit-Caux	3.5	5.10 ⁻⁴	4.10 ⁻⁴	3.10 ⁻⁴	3.10 ⁻⁴	9.10 ⁻⁴	2.10 ⁻⁴
EDF / Saint-Alban / Saint-Maurice	Saint-Alban-du-Rhône	1.7	2.10 ⁻⁴	3.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴
EDF / Saint-Laurent-des-Eaux	Saint-Laurent-Nouan	1.8	1.10 ⁻⁴	1.10 ⁻⁴	1.10 ⁻⁴	9.10 ⁻⁵	1.10 ⁻⁴	6.10 ⁻⁵
EDF / Tricastin	Bollène	1.3	2.10 ⁻⁴	2.10 ⁻⁴	1.10 ⁻⁴	1.10 ⁻⁴	2.10 ⁻⁴	2.10 ⁻⁴
Framatome Romans	Ferme Riffard	0.2	2.10 ⁻⁵	3.10 ⁻⁵	1.10 ⁻⁵	1.10 ⁻⁵	1.10 ⁻⁵	5.10 ⁻⁶
Ganil / Caen	IUT	0.4	8.10 ⁻³	7.10 ⁻³	7.10 ⁻³	7.10 ⁻³	7.10 ⁻³	8.10 ⁻³
ILL / Grenoble	Fontaine, Saint-Égrève, Grenoble (gaseous discharges) and Saint-Égrève (liquid discharges)	1 and 1.4	2.10 ⁻⁵	3.10 ⁻⁵	5.10 ⁻⁵	2.10 ⁻⁴	3.10 ⁻⁵	2.10 ⁻⁴
Orano Cycle / La Hague	Digulleville	2.6	2.10 ⁻²	2.10 ⁻²	1.10 ⁻²	1.10 ⁻²	1.10 ⁻²	1.10 ⁻²
Orano / Tricastin (Comurhex, Eurodif, Socatri, SET)	Clos de Bonnot	1.7	9.10 ⁻⁵	8.10 ⁻⁵	4.10 ⁻⁵	6.10 ⁻⁵	1.10 ⁻⁴	8.10 ⁻⁵

a. For the installations operated by EDF, only the "adult" values were calculated until 2008. From 2010 to 2012, the dose of the most exposed representative person of each site for the two age classes (adult or baby) is mentioned. As from 2013, the dose of the "representative person" is provided for three age classes (adult, child, infant) for all the BNIs. The dose value indicated is the hardest value in the age classes.

b. For the Cadarache, Saclay, Fontenay-aux-Roses and Marcoule sites, the dose estimates entered in the table are the sum of the dose estimates transmitted by the CEA. As these estimates comprise at least one term of less than 0.01 microsieverts (μSv), the values indicated are preceded by the "less than (<)" sign.

c. As the site has no longer had radioactive discharges since 2014, the radiological impact caused by radioactive discharges has been nil since 2014.

3.2.2 Exposure of the population to Naturally Occurring Radioactive Materials

Exposure due to natural radioactivity in drinking water

The results of the monitoring of the radiological quality of the tap water distributed to consumers carried out by the Regional Health Agencies (ARS) between 2008 and 2009 (DGS/ASN/IRSN report published in 2011) showed that 99.83% of the population receives tap water whose quality complies at all times with the total indicative dose of 0.1 mSv/year set by the regulations.

This generally satisfactory assessment also applies to the radiological quality of bottled water produced in France (DGS/ASN/IRSN report published in 2013).

The water quality control implemented by ARS includes a step of screening the distributed water using gross alpha and gross beta activity concentrations and the tritium content. The associated quality guidelines and reference values are 0.1 becquerel per litre (Bq/L), 1 Bq/L and 100 Bq/L, respectively. If any one of these values is exceeded in the tested water, the radionuclides causing this activity (natural and/or artificial) are identified and an indicative dose is calculated.

The corrective action to be taken if the calculated indicative dose exceeds the quality reference of 0.1 mSv/year depend on both the origin of the radioactivity (natural or artificial) and/or the dose level attained. With regard to tritium, although it can be measured in drinking water at levels that exceed the environmental background radiation (approximately 1 Bq/L), none of these measurements have exceeded the quality reference level in force for this radionuclide (100 Bq/L). Furthermore, none of these measurements have revealed any exceedance of the health reference level established for this radionuclide by the WHO (10,000 Bq/L).

Since 2019, measurement of the radon content of tap water and bottled water has been compulsory. This new obligation was accompanied by an instruction drawn up in consultation with ASN and issued in 2018 to the Regional Health Agencies by the General Directorate for Health (DGS – Opinion 2018-AV-0302 of 6 March 2018 on radon management methods for the health quality control of water intended for human consumption).

Exposure due to radon

In France, the regulations relative to management of the radon risk, put in place in the early 2000's for certain Public Access Buildings (PABs), were extended to certain workplaces in 2008. In 2016, radon was introduced into the indoor air quality policy.

Transposition of Council Directive 2013/59/Euratom of 5 December 2013 laying down Basic Safety Standards for protection against the dangers arising from exposure to ionising radiation led to the amending of the provisions applicable to radon since 1 July 2018. A reference level of 300 Bq/m³ has been introduced. It is applicable to all situations, which enables the health risk associated with radon to be managed with an all-inclusive approach. The regulations have been extended with provisions concerning the three main sectors:

- With regard to the general public, a significant improvement has been introduced: radon is now included in the information to be provided to buyers and tenants of real

estate situated in areas where the radon potential could be the highest (zone 3).

- In workplaces, the regulations have been extended to cover professional activities exercised on ground floor levels (only activities carried out in basements were concerned until now) and in certain specific workplaces. Whatever the radon potential zone in which the workplace is situated, radon must be considered in the risk assessment. If necessary, a measurement can be taken in this context, if there is a risk of reaching or exceeding the reference level of 300 Bq/m³. If the reference level is exceeded, the employer must take action to reduce the radon activity concentration. If the action turns out to be ineffective, the employer must identify, signal and verify the “radon zones” in which the concentration exceeds 300 Bq/m³, and implement radiation protection measures if necessary according to the level of exposure of the workers.

- In some PABs, the radon management methods have been adjusted, more specifically with the inclusion of day-care facilities for children under six years of age and an obligation to inform the public by displaying the radon measurement results¹⁰. The type of action to be taken if the reference level of 300 Bq/m³ is exceeded is graded according to the measurement results: corrective actions for radon concentration measurements between 300 and 1,000 Bq/m³, expert assessment and works if the corrective actions do not restore a radon concentration of less than

or equal to the reference level or if the measurement results are greater than or equal to 1,000 Bq/m³.

ASN issues the approvals to the organizations that measure radon in certain PABs. Fourteen approvals were issued in 2024, 11 of which were level 1 and 3 of level 2, bringing the total number to 72, with 15 level 2 approvals as at 1 September 2024. The list is available in the ASN *Official Bulletin* at asn.fr.

The level-1 organisations take the measurements to evaluate the average annual concentration in the buildings. Four types of measurement can be taken: initial measurement, ten-yearly measurement, measurement to verify the effectiveness of corrective action or works, and measurement after works that significantly modify the ventilation or airtightness of the building. In 2023-2024, 1,181 level-1 measurements were declared, of which over 80% correspond to initial or ten-yearly measurements.

If the reference level is exceeded, additional measurements – corresponding to level-2 approvals – can be taken. They are used to determine the radon sources and the entry and transfer pathways in the buildings. They provide additional data to support the expert assessment, particularly for buildings with a large surface area and complex substructures. Over the last five years, between 30 and 100 additional measurements have been taken out each year.

DIAGRAM 3 Trend in the distribution of initial and ten-yearly measurements per results bracket since 2016

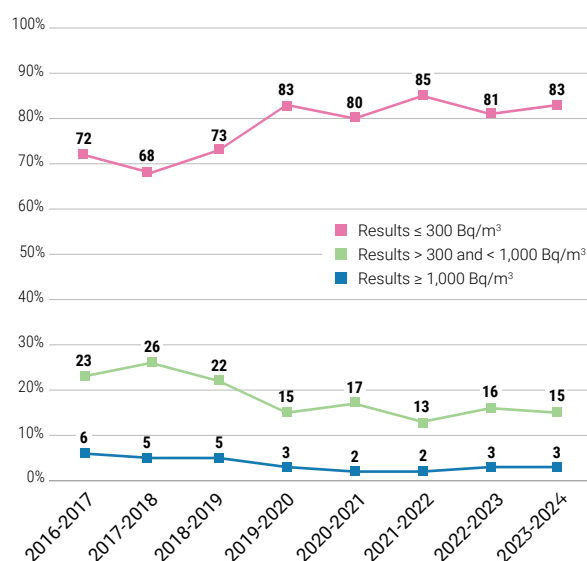
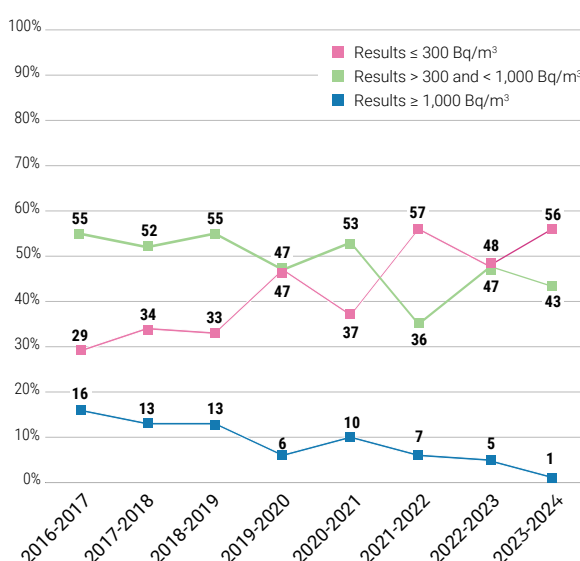


DIAGRAM 4 Trend in the distribution of measurements after corrective actions and works per results bracket since 2016



10. Order of 26 February 2019 on the methods of managing radon in certain public access buildings and dissemination of information to the people frequenting these buildings.

Lessons learned from the first assessment of the national action plan indicators for management of the radon risk

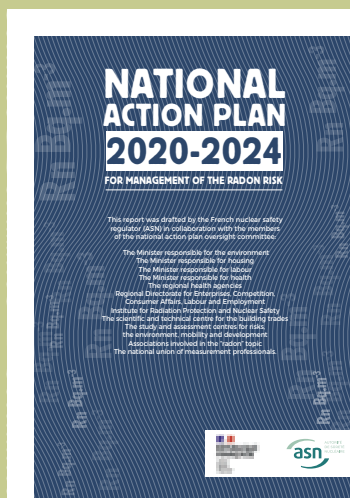
A system of specific indicators, chosen according to their relevance and the data available for monitoring them, has been put in place. The indicators may be supplemented as the years go by, according to the new data available. A first assessment published in 2024 presents the following initial lessons:

Public access buildings

In the PABs subject to radon exposure monitoring, 82% of the buildings that took a measurement over the 2019-2020 to 2022-2023 period present a result below the reference level of 300 Bq/m³ therefore no follow-up action is required. The 18% presenting a result above the reference level of 300 Bq/m³ must implement corrective actions on the building to bring the measurement result below this value. Among these buildings, 2.5% present a result of 1,000 Bq/m³ or higher and must undergo an expert assessment to determine the appropriate remedial work. To date, only half the buildings have managed to attain a value below the reference level after corrective actions or works (see also point 3.2.2 of this chapter).

Workplaces

Employers must take radon in the workplace into account in the occupational risks assessment. Given that certain texts and application guides are not yet completed, it will be a few more years before all the employers have carried out the radon risk assessment. Consequently, the number of notifications to IRSN of workplaces with a result exceeding 300 Bq/m³ after declared radon reduction work is at present still very low. As from June 2024, the second version of the worker ionising radiation exposure monitoring information system database (Siseri 2) will be able to identify the number of workers actually exposed to radon.



Homes

The ARS and the regional authorities are supported in the organisation of annual local operations to raise awareness and support the public regarding the radon risk in the home. The number of radon detectors distributed free of charge via these operations increased greatly between 2019-2020 and 2022-2023, rising from 2,520 to 4,415 detectors. The results collected enhance knowledge of the exposure of the population. Furthermore, the health risk linked to radon is one of the least known to the French public among the environment-related risks. A gradual improvement is nevertheless being observed and the level of information is generally better in the regions concerned by the radon risk.

The full assessment is available at asn.fr.

The data transmitted to ASN each year by these organisations in their annual report concern the measurements taken in the PABs that are subject to monitoring of exposure of the public, defined in Article D. 1333-32 of the Public Health Code (level-1 and -2 approvals). Analysis of the level-1 data over the last eight measurement campaigns continues to show a trend towards an improvement in the situation, with a gradual increase in the number of buildings showing a result less than or equal to the reference level of 300 Bq/m³ in the context of the initial and ten-yearly measurements (see Diagram 3). During the last campaign of 2023-2024, the radon activity concentration was less than or equal to the reference level of 300 Bq/m³ in 91% of the care facilities for children under 6 years of age, 87% of the healthcare, social and medico-social facilities and prisons, 77% of the teaching institutions and 67% of the spas measured.

If the reference level is exceeded, the facility concerned is obliged to carry out corrective action or works, then check the effectiveness through a new measurement. The analysis of the results over the last eight years shows that they are moving in the right direction, with the number of effectiveness verifications whose results are below or equal to the reference level of 300 Bq/m³ increasing as the campaigns proceed (from 29% in 2016 to 56% in 2024). Nevertheless, in the last campaign, slightly less than half of the effectiveness verification measurements (44%) gave results exceeding the reference level, although there is a clear reduction in the proportion of those with results of 1,000 Bq/m³ or higher, which dropped from 5 to 1% (see Diagram 4).

Over the last eight measuring campaigns, the categories of establishments having undergone initial or ten-yearly measurements are broken down as follows: 60% educational institutions (from nursery school to secondary high school), 27.5% healthcare, social and medico-social institutions, 12% care facilities for children under 6 years of age, 0.3% spas and 0.5% prisons (see Diagram 5).

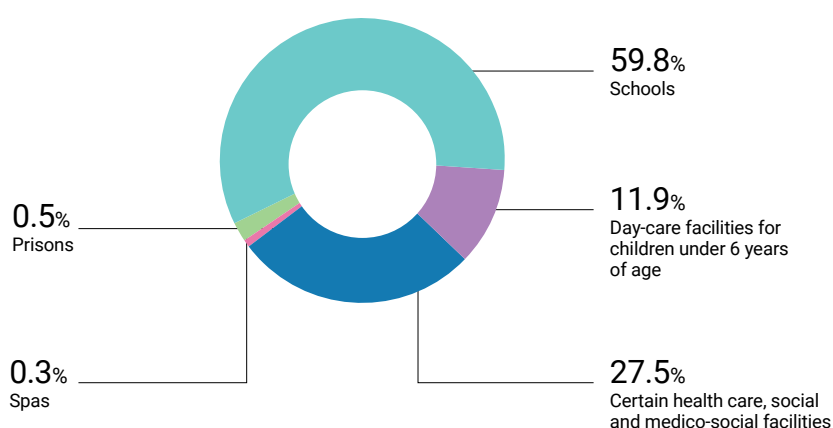
More generally, the management strategy for the radon risk is set out in a national action plan. Implementation of this plan will improve the way the general public and the stakeholders concerned are informed and will enhance knowledge of radon exposure in the home and how it evolves.

The fourth French national action plan was published in early 2021. It fits into the framework of the 4th National Health and Environment Plan which now coordinates all the sector-based plans concerning health or the environment, which is itself driven by the National Public Health Strategy. It should have covered the 2020-2024 period, but the Covid-19 pandemic delayed completion of the regulatory framework and the initiation of certain actions. The plan has therefore been extended for a period of two years and will end in 2026. During this period the plan will undergo an evaluation of the relevance, effectiveness and efficiency of its actions. The lessons learned will be used to develop the next plan.

This plan follows on from the preceding plans (the assessment of the 3rd plan is available on asn.fr). It can be broken down into 13 actions focusing on three lines:

Line 1 aims to implement an information and awareness-raising strategy. The health issue that radon represents requires continuation of the awareness-raising and information measures directed towards all the players (regional authorities, employers, building professionals, health professionals, teachers, etc.) and the general public, both nationally and locally, with the promotion and accompanying of regional measures for the integrated management of the radon risk in the home.

A specific communication campaign shall target smokers, because they constitute the population the most at risk of developing lung cancer linked to cumulative exposure to radon and tobacco. The operational implementation of the information system incorporating all the radon monitoring results, as well as the consolidation and centralising of the existing measures, would appear moreover to be essential for informing the public.

DIAGRAM 5 Distribution of the initial and ten-yearly measurement by PAB category from 2016-2017 to 2023-2024

Line 2 aims to continue to improve knowledge. The publication in 2018 of a new map on the municipal scale, based on three radon-potential zones, enabled a graded approach to radon risk management to be implemented. This map must nevertheless be improved so as to better integrate certain geological factors that could facilitate radon transfer to buildings (karst zones in particular). Furthermore, the 4th Radon Plan provides for the updating of knowledge of exposure of the French population by organising the collection of measurement data obtained in particular during the local awareness-raising operations organised by the ARS and the regional authorities to cover the areas for which insufficient data are available. These operations consist in proposing screening kits to the inhabitants of a given region to raise their awareness of the radon risk.

Lastly, **line 3** aims to take better account of the management of the radon risk in buildings. In order to help members of building trade organisations improve their skills, these organisations have recently developed training courses dealing with methods to prevent and reduce concentration levels and various media to address the needs. The various French-language aids have been listed. To supplement the offering, a guide intended for professionals and private individuals alike was published in 2023. It provides recommendations concerning prevention in new constructions and remediation in existing buildings. The progress made in understanding the effectiveness of construction standards in reducing radon concentrations in indoor air shall be consolidated.

A system of specific indicators, chosen according to their relevance and the data available for monitoring them, has been put in place. Monitoring how these indicators evolve over several years will enable the effectiveness of the national strategy deployed under the national action to be determined. The first assessment of the indicators was published in September 2024 (see box previous page).

3.3 Doses received by patients

In France, exposure for medical purposes represents the greatest part of the artificial exposures of the public to ionising radiation. It has been regularly reviewed by IRSN since 2002. Although exposure has been increasing for the last 30 years, it has tended to stabilise since 2012, whereas at the same time the number of medical procedures has greatly increased. Nuclear medicine, the third-biggest contributor to the collective effective dose,

is the discipline that saw the greatest increase between 2012 and 2017, in terms of both frequency and contribution to the collective effective dose.

The average effective dose per inhabitant resulting from diagnostic radiological examinations was evaluated at 1.53 mSv for the year 2017 (IRSN ExPRI study 2020) for some 85 million diagnostic procedures performed in 2017 (81.6 million in 2012), i.e. 1,187 procedures for 1,000 inhabitants per year. It is to be noted that as before, the individual exposure in 2017 is very varied. Consequently, although about 32.7% of the French population underwent at least one procedure (dental procedures excluded), half the patients received a dose of 0.1 mSv or less, 75% received 1.5 mSv or less, while the most exposed 5% of patients received a dose exceeding 18.1 mSv.

Conventional radiology (55.1%), computed tomography (12.8%) and dental radiology (29.6%) account for the largest number of procedures. It is the contribution of computed tomography to the effective collective dose that remains preponderant and more significant in 2017 (75%) than in 2012 (71%), whereas that of dental radiology remains very low (0.3%).

In adolescents, conventional radiology and dental procedures are the most numerous (about 1,000 procedures

for 1,000 individuals in 2017). Despite their frequency, these procedures in this population represent only 0.5% of the collective dose.

Lastly, it will be noted that:

- A national headcount estimated at more than 30,000 patients was exposed to a cumulative effective dose of more than 100 mSv in 2017 due to multiple computed tomography examinations. This figure reaches 500,000 if a cumulative period of six years is considered. This highly exposed population seems to be increasing in size regularly and relatively rapidly since 2012. Although most people in this population are old, a quarter of them are aged under 55 years. The question of possible radiation-induced effects in the long term is therefore raised for this specific population. It is worth pointing out that these patients are often suffering from serious pathologies and that the computed tomography examinations are important for their care.
- Based on a sample of 120,000 children born between 2000 and 2015, IRSN reports that in 2015, 31.3% of the children in the sample were exposed to ionising radiation for diagnostic purposes (up by 2% compared with 2010). The average effective dose is estimated at 0.43 mSv and the median at 0.02 mSv (down for the average but equivalent for the median value).

TABLE 5 Number of procedures and associated collective effective dose for each imaging method (rounded values) in France in 2017

Imaging method	Procedures		Total collective effective dose: 102,198 Sv
	Number	%	%
Conventional radiology (dentistry excluded)	46,681,000	55.1	11.8
Dental radiology	25,023,000	29.6	0.3
Computed tomography	10,866,000	12.8	74.2
Diagnostic interventional radiology	435,000	0.5	2.4
Nuclear medicine	1,662,000	2.0	11.3
Total	84,667,000	100.0	100.0

Source: IRSN, 2020.

This median value varies greatly according to the age category. For infants of less than one year, it is 0.55 mSv (highest value) and between 6-10 years it is 0.012 mSv.

The substantial uncertainties in these studies with regard to the average effective dose values per type of procedure must nevertheless be taken into account, which justifies the need for progress in estimating doses in the next exposure study of the general population.

Particular attention must be exercised to check and reduce the doses associated with diagnostic medical imaging, particularly when alternative techniques can be used for a same given indication.

Controlling the doses of ionising radiation delivered to persons during a medical examination remains a priority for ASN.

3.4 Exposure of non-human species (animal and plant species)

The international radiation protection system was created to protect humans against the effects of ionising radiation. Environmental radioactivity is thus assessed with respect to its impact on human beings and, in the absence of any evidence to the contrary, it is today considered that the current standards guarantee the protection of other species. Protection of the environment against the radiological risk and more specifically the protection of non-human species, must however be guaranteed independently of the effects on humans. Pointing out that this objective is already incorporated in French legislation, ASN ensures that the impact of ionising radiation on non-human species is effectively taken into account in the impact assessments of nuclear facilities

and activities. On the basis of the IRSN expert assessment report, the Advisory Committee for Radiation Protection of Worker and the Public (GPRP, formerly GPRADE) issued an opinion in September 2015. Following the recommendations of this opinion, at the end of 2017 ASN set up a pluralistic and multi-disciplinary working group coordinated by the IRSN to produce a methodological guide for assessing the impact of ionising radiation on the flora and fauna, based on a graded approach. The draft of the *Methodological guide for assessing the radiological risk for the wild flora and fauna – Concepts, fundamentals and implementation within the impact study* was submitted to ASN at the end of 2020 and presented to the GPRADE in June 2021. The final version of the guide was published in January 2022 on the ASN website taking into account the recommendations of the GPRADE's opinion on the operational nature of the methodology.

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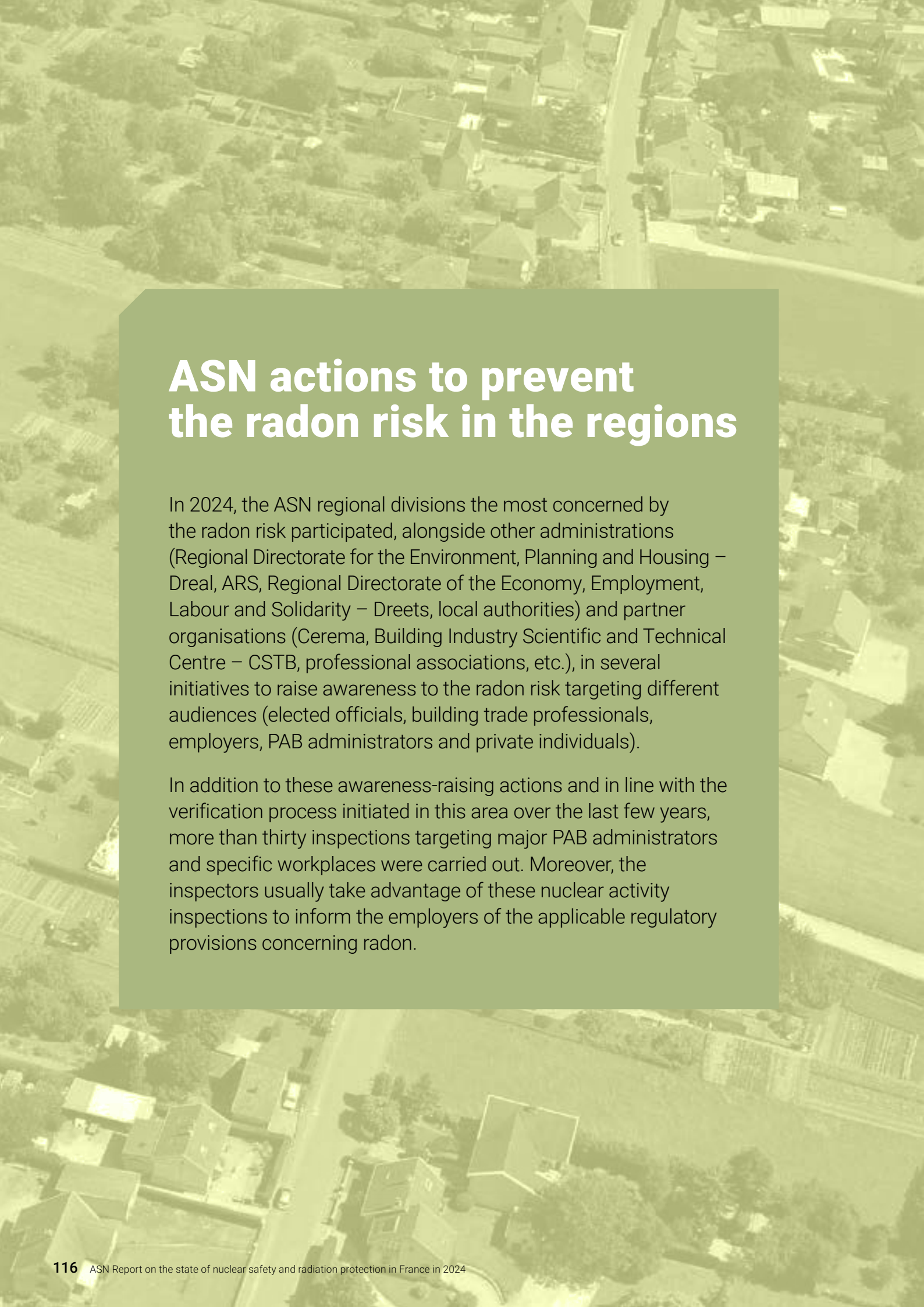
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AP



ASN actions to prevent the radon risk in the regions

In 2024, the ASN regional divisions the most concerned by the radon risk participated, alongside other administrations (Regional Directorate for the Environment, Planning and Housing – Dreal, ARS, Regional Directorate of the Economy, Employment, Labour and Solidarity – Dreetts, local authorities) and partner organisations (Cerema, Building Industry Scientific and Technical Centre – CSTB, professional associations, etc.), in several initiatives to raise awareness to the radon risk targeting different audiences (elected officials, building trade professionals, employers, PAB administrators and private individuals).

In addition to these awareness-raising actions and in line with the verification process initiated in this area over the last few years, more than thirty inspections targeting major PAB administrators and specific workplaces were carried out. Moreover, the inspectors usually take advantage of these nuclear activity inspections to inform the employers of the applicable regulatory provisions concerning radon.

AWARENESS-RAISING ACTIONS

Auvergne-Rhône-Alpes

LYON DIVISION

- Participation in the awareness-raising actions targeting the radon advisors of the Prevention and Occupational Health Services (SPST) under the 4th Regional Occupational Health Plan (PRST 4).

Bourgogne-Franche-Comté

DIJON DIVISION

- The stakeholders were asked to adopt a cautious approach due to the presence of karst subsoils in the Bourgogne-Franche-Comté region. Karsts are effectively likely to influence the levels of radon in the air and are not taken into account at present in the mapping of the radon potential at the municipal scale. IRSN is currently conducting a complementary study to determine the influence of karsts on the radon potential (action 9 of the National Plan for Radon Risk Management).
- Participation in the regional network baptised "Éclaireurs QAI-radon" (Interior Air Quality Pathfinders – Radon) which facilitates the joint development of awareness-raising actions on the theme of radon and indoor air quality in Bourgogne-Franche-Comté. In this context, the Dijon division notably participated in the organisation of a webinar on the regulatory provisions regarding radon risk management in partnership with the ARS and the General Directorate for Labour (DGT). This network is moreover continuing its radon awareness-raising actions and acts as a facilitator in mobilising the partners for the home remediation actions.

Bretagne / Pays de la Loire

NANTES DIVISION

- Confinancing under the 4th Regional Health and Environment Plans (PRSE 4) for the Pays de la Loire and Bretagne regions of **eight new actions to accompany private individuals in conducting voluntary campaigns to measure radon in the home** and participation in several public kick-off meetings for these campaigns, supported by the ASN Head Office and the CSTB.
- Involvement in the various working groups set up for the PRST 4 plans of the two regions having resulted more specifically, in Pays de la Loire, in the **production of a video on the measurement methodology and a list of Frequently Asked Questions (FAQs)** intended for employers.
- **Raising the radon risk awareness of employees and public sector agents working closely with the regional division** (Dreal, ANCOLS¹, DRAAF², OFB³, *Maison de l'Administration Nouvelle* (New Administration House) – to which Cerema⁴ is attached, through five sessions organised for the Risks Action Day and the European Radon Day which were held on 13 October and 7 November 2024 respectively.
- **Development of a communication aid** for the organisations accompanying the deployment of the radon awareness-raising and measurement in the home campaigns.

Grand Est

STRASBOURG AND

CHÂLONS-EN-CHAMPAGNE DIVISIONS

- Within the framework of the PRSE and PRST of the Grand Est region, organisation with the ARS and the

Dreets of a one-day seminar attended by 80 people from different horizons (representing local authorities, prevention and occupational health companies and services) on the challenges concerning public and occupational health, the applicable regulations and lessons learned from experience.

Nouvelle-Aquitaine / Occitanie

BORDEAUX DIVISION

- Within the framework of the PRST 4 of the Nouvelle-Aquitaine region, participation in the project coordinated by CARSAT (Pension Insurance and Occupational Health Fund) with the aim of **producing and distributing an awareness-raising video on the dangers of radon** intended for employers and to develop an on-line application on prevention of the radon risk in the professional environment.

Normandie

CAEN DIVISION

- Participation in the various working groups set up within the framework of the Normandie region PRST 4.

Provence-Alpes-Côte d'Azur / Occitanie

MARSEILLE DIVISION

- **Introduction of two inspectors from the occupational risks prevention service** of the Management Centre of the Gard département (CGD 30) to the regulations concerning radon drawn from the Environment Code, the Public Health Code and the Labour Code. This service is responsible for the occupational health and safety inspections of the 301 local authorities in the Gard département.

1. National Social Housing Inspection Agency.

2. Regional Directorate of Food, Agriculture and the Forest.

3. French Biodiversity Office.

4. Centre of studies and expert assessments on risks, the environment, mobility and development.

OVERSIGHT ACTIONS

Auvergne-Rhône-Alpes

LYON DIVISION

- **Inspection of three local authorities responsible for educational institutions and day-care facilities for children** under six years of age that are subject to the radon monitoring obligation: the town council of Clermont-Ferrand and the Departmental Councils of the Loire and Drôme *départements*. With the exception of the Departmental Council of the Drôme *département* which was not observing the regulatory provisions and which has undertaken to comply with them, the inspected local authorities have embraced the regulations even if their implementation must be monitored more strictly.

- **Inspection of two specific workplaces:** the VICAT Combes quarry and the EDF Grangent dam. The risk prevention procedure has been satisfactorily assimilated on the EDF site, whereas it has been only partially implemented at the quarry, which has made commitments to finalise the procedure.

Bourgogne-Franche-Comté

DIJON DIVISION

- **Inspection of three PAB administrators subject to the radon monitoring obligation:** the municipal federations Rahin and Chérimont, Bazois-Loire-Morvan, and the Aligre Foundation Hospital. These inspections revealed inadequate knowledge of the regulatory requirements applicable under the Public Health and Labour Codes. Commitments have been made to perform the initial measurement of the radon activity concentration in the PABs concerned and to establish the inventory of the exposed workplaces in order to assess the risk for the workers. Furthermore, the municipal federations demonstrated their readiness to support the mayors of their regions by providing them with a negotiated contract for taking the measurements that come under their responsibility.

- **Inspection of two spas** (Bourbon-Lancy and Saint-Honoré-les-Bains) which have been working to meet the regulatory obligations for several years.

In both cases, further to initial measurements, large-scale works have been undertaken on the water systems to significantly reduce the radon concentration in the areas receiving the public. These works are going to continue with a view to lowering the radon concentration to below the reference level. Assessment of the workers' exposure to radon is also in progress.

- **Inspection of two specific workplaces:** the Lac des Settons dam and the Champagny dam, administrated by State organisations. These inspections revealed a good understanding of the regulatory requirements by the various persons in charge. The radon risk assessment procedure should be finalised by the end of the year.

Bretagne / Pays de la Loire

NANTES DIVISION

- **Inspection of two PAB administrators subject to the radon monitoring obligation:** the Babilou Evancia group and the town council of Rezé. The measurements to be taken under the Public Health Code were initiated several years ago, but improvements are required regarding more specifically the defining of the buildings concerned, the tracking of the remediation measures and informing the public.

- **Inspection of two specific workplaces:** the mineral water bottling factories of Roxane Nord and Plancoët. The risk assessment procedure is duly applied in the factories, although a few areas for improvement have been identified concerning the assumptions adopted for the measuring strategy and the informing of the Social and Economic Committee (CSE).

- **Inspection of the Catholic Teaching Management Organisation (OGE) of the Côtes-d'Armor:** the administrator had already taken the initial radon measurements required under the Public Health Code and has planned installing detectors in the winter of 2024-2025 to check the effectiveness of the corrective actions.

Grand Est

STRASBOURG AND

CHÂLONS-EN-CHAMPAGNE DIVISIONS

- **Inspection of the Departmental Councils of four *départements*, namely Haute-Marne, Moselle, Ardennes and Meurthe-et-Moselle.** Three of the four inspected Departmental Councils (Haute-Marne, Moselle and Meurthe-et-Moselle) have clearly identified the radon exposure risk of the PABs. Initial screenings have been carried out and the results show that for the first two Departmental Councils, remediation measures are required in six PABs. The Departmental Council of Meurthe-et-Moselle has already carried out the remediation work and taken the measurements confirming their effectiveness: the radon concentrations in the PABs concerned are below the threshold of 300 Bq/m³.

- **Inspection of three spas** (Morsbronn-les-Bains, Niederbronn-les-Bains and Bourbonne-les-Bains) concerned by the provisions of the Public Health Code and the particular conditions of prevention of the radon risk in specific workplaces. The radon risk has been assessed in these spas and remediation work carried out where necessary. Shortcomings have nevertheless been identified, notably concerning the updating of the risk assessments, the clarification of responsibilities between the owner of the premises and the operator, and the improvement in the traceability of the actions taken to manage the radon risk.

Hauts-de-France

LILLE DIVISION

- **Inspection of a PAB administrator subject to the radon measurement obligation, the PAB in question also being a specific workplace: the spa of Saint-Amand-les-Eaux.** Several measurement campaigns have been conducted in the spa to check the exposure of the clients and the workers, with results always below the reference level. Some areas for improvement have nevertheless been identified, namely the traceability of information and informing of the public and the occupational physician.

Nouvelle-Aquitaine / Occitanie**BORDEAUX DIVISION**

• In Occitanie, inspection – assisted by the ARS – of the Departmental Council of the Tarn *département* in its role as a PAB public administrator subject to the radon monitoring obligation. The regulations are correctly applied in the PABs concerned and remediation measures are always taken if concentrations higher than the reference level are detected.

• In Nouvelle-Aquitaine, inspection of the Departmental Council of the Dordogne *département*. All the lower secondary schools subject to a measurement obligation by virtue of their PAB status underwent a screening campaign in 2019. Only one of these schools

required remediation measures, whose effectiveness will be verified by a new measurement campaign planned in 2025.

Normandie**CAEN DIVISION**

• Inspection of one specific workplace: the former iron mine in May-sur-Orne, where work to fill in a gallery section was in progress. The regulatory provisions applicable for radiation protection are known and taken into account with great diligence.

• Inspection of the Town Council of Cherbourg-en-Cotentin. The local authority is behind schedule in applying the regulations; the initial measurements in the buildings concerned are scheduled for winter 2024-2025.

Provence-Alpes-Côte d'Azur / Occitanie**MARSEILLE DIVISION**

• Inspection, assisted by the ARS Occitanie, of the Departmental Council of the Gard *département* in its role as a PAB administrator subject to the radon measurement obligation. The applicable regulatory provisions are known and the measurements have been taken; tracking of the actions required in view of the results can nevertheless be improved.

• Inspection of the Town Council of Hyères: a record of measurements shows results below the reference level; nevertheless, the obligations to inform the public and check the long-term effectiveness have not been met.

ASN's oversight actions in 2024 led to the identification of two companies having carried out regulatory radon measurements in PABs without holding level-1 approval. Performing radon measurement services without holding the required approval is a violation punishable by the fine provided for under class-five petty offences (Article R. 1337-14-2 of the Public Health Code). A violation report was drawn up against one of the companies and sent to the competent Public Prosecutor.

Twelve organisations approved for measuring radon (including 3 of levels 1 and 2) were inspected. ASN's inspection focused on the verification of compliance with the applicable requirements of the Public Health Code and more specifically its Articles L. 1333-29 to 31 and R. 1333-166, with the Order of 26 February 2019 on the methods of radon management in certain PABs, and three ASN resolutions, two of which came into force in early 2023: ASN resolution 2015-DC-0506 of 9 April 2015, ASN resolution 2022-DC-0743 of 13 October 2022 and ASN resolution 2022-DC-0745 of 13 October 2022.

The results of these inspections are satisfactory on the whole.

The demands formulated by ASN, whether in follow-up letters to previous inspections, in approval notification correspondence or further to reported issues, are generally well taken into account. The applicable regulatory texts and standards are virtually always correctly referenced and accessible. All the persons responsible for installing and removing the radon detectors, then drafting and validating the reports, have a valid training certificate. From the methodological aspect, all the equipment used meets

the regulatory requirements and is correctly stored. The regulatory detector installation time is always observed. The work reports are clear, almost always complete (a few omissions and repetitions are nevertheless still noted from time to time) and submitted within the regulatory deadline. Transmission of the measurement results via the "Simplified-procedures" tool is progressing, although improvements can be made in data entry times and filling out the data fields. In the organisations where qualified personnel numbers so permit, measures are sometimes taken to ensure the quality of the services and the reports (information meeting and pairing of workers at the start of a new season, peer reviewing of reports, etc.); such initiatives, which are still the exception, must be encouraged. With regard to quality, even when there is no certified system, the majority of the radon measurement activities are governed by a methodology and procedures, including within the smallest organisations. Lastly, the annual activity reports are transmitted to ASN within the set deadlines.

Among the main lines of progress identified in 2024, the analysis of the measurement regulatory framework is a major issue. Many reports studied prior to inspections and counted in the organisations' annual reports concern PABs that are not subject to the radon monitoring obligation, and the measurement scope (one or two establishments, number of buildings) is not always correctly defined. Yet these aspects determine the value attributed to the PAB (one or two values) and the follow-ups (obligatory or recommended). As in 2023, the methods of determining homogeneous zones and the methodology of calculating the activity

concentration values to attribute to a homogeneous zone figure among the main lines of progress identified. In effect, an error in the calculation methodology can lead to incorrect conclusions and inappropriate follow-ups, which constitutes a particularly prejudicial deviation. The doctrine applicable in the event of detector loss or damage, which is described in the FAQs published by ASN, is not always set out in the organisations' measurement procedures. Lastly, the information concerning the follow-ups figuring in the reports is not always exhaustive and the deadlines given to the ordering parties for the effectiveness checks are still sometimes incorrect. This year, the departure of experienced qualified personnel (retirement, resignation, etc.) is a factor requiring particular attention because, if not planned for, it can have a direct impact on the quality of the measurement services. If the approved organisations made more systematic use of the FAQs and the self-assessment matrix issued in February and April 2024 respectively, some of the observed deviations concerning the methodology and the content of the reports could be avoided.

Lastly, for the first time, as part of the strategy to combat fraud and falsification, ASN conducted cross-checks of documents during an inspection with the aim of checking more exhaustively the traceability of certain substantiating records relating to the radon measurement services. This check did not reveal any irregularities. In addition to these checks, inspections may be conducted in the future during the intervention of approved organisations in order to examine the strategy and methods of installing the radon detectors.

02

**The principles of
nuclear safety and
radiation protection
and the regulation and
oversight stakeholders**

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Nuclear security is defined in the Environment Code as comprising “*nuclear safety, radiation protection, prevention and combating of malicious acts and civil protection actions in the event of an accident*”. Nuclear safety is “*the set of technical provisions and organisational measures – related to the design, construction, operation, shutdown and decommissioning of Basic Nuclear Installations (BNIs), as well as the transport of radioactive substances – which are adopted with a view to preventing accidents or limiting their effects*”. Radiation protection is defined as “*protection against ionising radiation, that is the set of rules, procedures and means of prevention and surveillance aimed at preventing or mitigating the direct or indirect harmful effects of ionising radiation on individuals, including in situations of environmental contamination*”.

Nuclear safety and radiation protection obey principles and approaches that have been put in place progressively and continually enhanced by a process of Operating Experience Feedback (OEF). The basic guiding principles are advocated internationally by the International Atomic Energy Agency (IAEA). In France, they are included in the Constitution or enacted in law, as well as now figuring in European Directives.

In France, the regulation and oversight of the nuclear safety and radiation protection of civil nuclear activities is – until 31 December 2024 – the responsibility of the French Nuclear Safety Authority (ASN), an independent administrative Authority, together with Parliament and the other State players, within the Government and the offices of the Prefects. This regulation, which covers related areas such as chronic pollution of all types emitted by certain nuclear activities, is based on expert technical analysis and assessment.

Act 2024-450 of 21 May 2024, relative to the organisation of nuclear safety and radiation protection governance, in order to address the challenges of the nuclear industry’s renewal, created an independent civil nuclear safety and radiation protection Authority: the Authority for Nuclear Safety and Radiation Protection (ASNR), combining the activities of the Nuclear Safety Authority (ASN) and a large part of those of the Institute for Radiation Protection and Nuclear Safety (IRSN).

At State level, the prevention of and fight against malicious acts which could affect nuclear materials, their installations and their transportation are the responsibility of the Ministry for Ecology, Biodiversity, Forests, the Sea and Fisheries, which can draw on the services on the High Official for Defence and Security (HFDS). Although clearly separate, the two fields of nuclear safety and the prevention of malicious acts are inextricably linked and the authorities responsible cooperate closely.

1 — The principles of nuclear safety and radiation protection

1.1 Fundamental principles

Nuclear activities must be carried out in compliance with the fundamental principles contained in the legislative texts or international standards.

This primarily concerns:

- at the national level, the principles enshrined in the Environment Charter, which is part of the Constitution, and in the various codes (Environment Code, Labour Code, Public Health Code);
- at the European level, rules defined by Directives establishing a community framework for the safety of nuclear

facilities and for the responsible and safe management of spent fuel and radioactive waste;

- at the international level, the ten fundamental safety principles defined by the IAEA (see box next page and chapter 6, point 3.1) implemented by the Convention on Nuclear Safety (see chapter 6, point 4.1), which establishes the international framework for the oversight of nuclear safety and radiation protection.

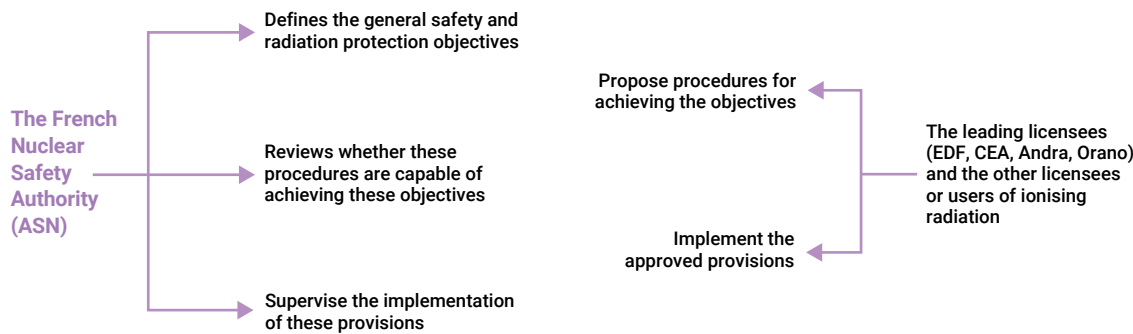
These various measures of differing origins extensively overlap. They can be grouped into the eight main principles presented below.

1.1.1 The principle of licensee responsibility

This principle, defined in Article 9 of the Convention on Nuclear Safety, is the first of IAEA’s fundamental safety principles. It stipulates that responsibility for the safety of nuclear activities entailing risks lies with those who undertake or perform them.

It applies directly to all nuclear activities.

Responsibility of licensees and responsibility of ASN



1.1.2 The “Polluter-pays” principle

The “Polluter pays” principle, contained in Article 110-1 of the Environment Code, stipulates that the costs resulting from the measures to prevent, mitigate and combat pollution must be borne by the polluter.

1.1.3 The precautionary principle

The precautionary principle, defined in Article 5 of the Environment Charter, states that *“the absence of certainty, in the light of current scientific and technical knowledge, must not delay the adoption of effective and proportionate measures to prevent a risk of serious and irreversible damage to the environment”*.

Application of this principle results, for example, in the adoption of a linear, no-threshold dose-effect relationship where the biological effects of exposure to low doses of ionising radiation are concerned. This point is clarified in chapter 1 of this report.

1.1.4 The public participation principle

This principle allows public participation in the decision-making process by the public authorities. Following on from the Aarhus Convention, Article 7 of the Environment Charter defines it in these terms: *“Within the conditions and limits defined by law, all individuals are entitled to access environmental information in the possession of the public authorities and to participate in the taking of public decisions affecting the environment”*.

In the nuclear field, this principle notably leads to the organisation of national public debates, which are mandatory prior to the construction of a Nuclear Power Plant (NPP) for example, or now before certain plans and programmes subject to strategic environmental assessments, such as the National Radioactive Material and Waste Management Plan (PNGMDR). One should also mention the public inquiries, notably during examination of the files

concerning the creation or decommissioning of nuclear installations, consultation of the public on draft resolutions with an impact on the environment, or the submission by a BNI licensee of its file concerning a modification to its installation liable to lead to a significant increase in water intake or discharges into the environment of the installation.

1.1.5 The justification principle

The justification principle, defined in Article L. 1333-2 of the Public Health Code, states that: *“A nuclear activity may only be undertaken or carried out if its individual or collective benefits, more specifically its health, social, economic or scientific benefits so justify, given the risks inherent in the human exposure to ionising radiation that it is likely to entail”*.

Assessment of the expected benefit of a nuclear activity and the corresponding drawbacks may lead to prohibition of an activity for which the benefit would not seem to outweigh the health risk. For existing activities, justification may be reassessed if the state of know-how and technology so warrants.

The fundamental safety principles

The IAEA defines the following ten principles in its “Fundamental principles of safety” publication, IAEA Safety Standards Series – No. SF-1:

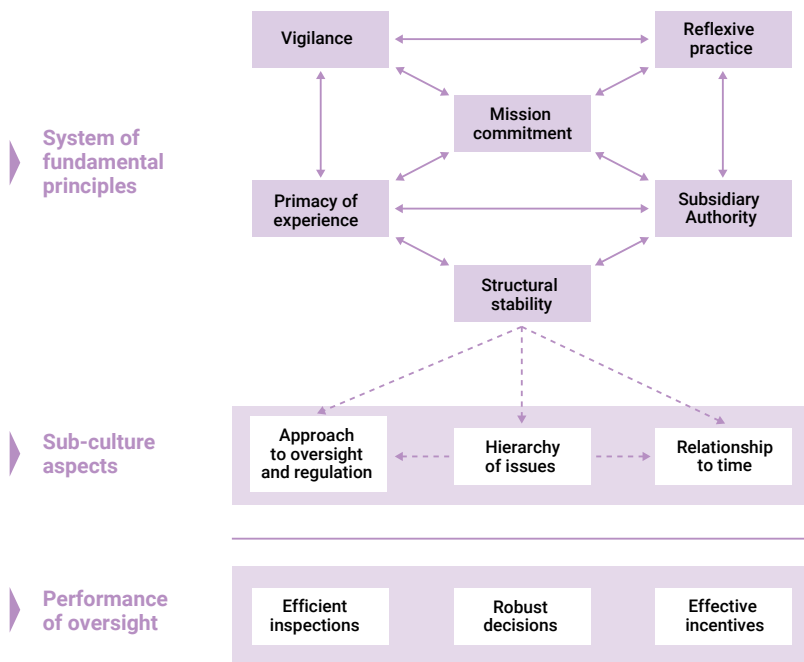
1. Responsibility for safety must rest with the person or organisation responsible for facilities and activities that give rise to radiation risks.
2. An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.
3. Effective leadership and management of safety must be established and maintained in organisations concerned with radiological risks, and in facilities and activities that give rise to such risks.
4. Facilities and activities that give rise to radiation risks must yield an overall benefit.

5. Protection must be optimised to provide the highest level of safety that can reasonably be achieved.
6. Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.
7. People and the environment, both present and future, must be protected against radiation risks.
8. All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.
9. Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.
10. Protective actions to reduce existing or unregulated radiation risks must be justified and optimised.

1.1.6 The optimisation principle

The optimisation principle, defined by Article L. 1333-2 of the Public Health Code, states that: *“The level of exposure of persons to ionising radiation [...], the probability of occurrence of this exposure and the number of persons exposed must be kept as low as is reasonably achievable, given the current state of technical knowledge, economic and social factors and, as necessary, the medical goal in question”*.

System of interdependent fundamental principles, the three sub-culture aspects of ASN's organisational system and the three regulation and oversight performance criteria



This principle, referred to as the ALARA⁽¹⁾ principle, leads for example to reducing the quantities of radionuclides present in the radioactive effluents from nuclear installations allowed in the discharge licenses, to requiring monitoring of exposure in the workplaces in order to reduce it to the strict minimum and to ensuring that medical exposure as a result of diagnostic procedures remains close to the pre-determined reference levels.

1.1.7 The limitation principle

The limitation principle, defined in Article L. 1333-2 of the Public Health Code states that "[...] exposure of a person to ionising radiation [...] may not increase the sum of the doses received beyond the limits set by regulations, except when the individual is exposed for medical purposes or for the purposes of research as mentioned in 1° of Article L.1121-1".»

The exposure of the general public or of workers as a result of nuclear activities is subject to strict limits. These limits include significant safety margins to prevent deterministic effects from appearing, as well as aiming to reduce the appearance of probabilistic effects in the long term to the lowest level possible.

Exceeding these limits leads to an abnormal situation and one which may give rise to administrative or criminal sanctions.

In the case of medical exposure of patients, no dose limit is set, provided that this voluntary exposure is justified by the expected health benefits for the person exposed.

1.1.8 The prevention principle

To anticipate any environmental damage, the prevention principle, defined in Article 3 of the Environment Charter, stipulates the implementation of rules and measures which must take account of "the best available technology at an economically acceptable cost".

In the nuclear field, this principle underpins the concept of "Defence in Depth", presented below.

1.2 Some aspects of the safety approach

The safety principles and approaches presented below were gradually implemented and incorporate the lessons learned from accidents. Absolute safety can never be guaranteed. Despite all the precautions taken in the design, construction and operation of nuclear facilities, an accident can never be completely ruled out. Willingness to move forward and to create a continuous improvement approach is thus essential if the risks are to be reduced.

1.2.1 Safety culture

Safety culture is defined by the International Nuclear Safety Advisory Group (INSAG), an international consultative group for nuclear safety reporting to the Director General of the IAEA, as that complete range of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance.

Safety culture therefore determines the ways in which an organisation and individuals perform their duties and assume their responsibilities with respect to safety. It is one of the key fundamentals in maintaining and improving safety. It commits organisations and individuals to paying particular and appropriate attention to safety. The organisation must take steps (training, mentoring, preparation and planning of work, etc.) enabling the safety culture to be expressed at all levels of the organisation through a rigorous and prudent approach and a questioning attitude, allowing compliance with the rules to be shared and initiatives to be taken. In operational terms, the concept underpins daily decisions and actions relating to activities.

1. The ALARA (As Low As Reasonably Achievable) principle appeared for the first time in Publication 26 from the International Commission on Radiological Protection (ICRP) in 1977. It was the result of a process of reflection on the principle of optimising radiological protection. Over the past thirty years, the acceptance and implementation of the ALARA principle has developed significantly in Europe, with strong backing from the European Commission, leading in 1991 to the creation of a European ALARA network.

ASN carried out research work on its own safety culture, with the assistance of the Nantes-Atlantique Economics and Management Laboratory of the University of Nantes. This work lasted a year and was completed in September 2024, primarily concerning BNI oversight and regulation activities. After a bibliographical analysis, the study turned to an analysis of ASN's organisational culture. The regulator's safety culture being *"that part of the organisational culture that influences the behaviour of individuals (staff and management), organisational units and the organisation in dealing with safety"*⁽²⁾. Through individual and group interviews of its staff, field observations and interactions with the licensee and IRSN, the study was able to highlight six fundamental principles present in the organisational system as a whole, three aspects of the sub-culture of this system and three performance criteria for BNI oversight and regulation on which the ASN safety culture is based.

The six fundamental principles are present at all points of the organisation related to the BNI oversight and regulation activities and constitute ASN's organisational culture and, since 1 January 2025, that of ASNR. They describe a system (see diagram previous page) in which the limits of each principle are compensated for by one or more others. The three sub-cultures identified within ASN each comprise their own practices and attitudes on the part of the staff.

All of these fundamental principles and aspects of these sub-cultures participate in the performance of the BNI oversight and regulation activities and contribute to generating performance in terms of this oversight and regulation. The three performance criteria identified are: efficient inspections, robust decisions and effective incentives.

These criteria are based both on the six fundamental principles and on certain sub-cultures. Each criterion concerns one of the three major activities of BNI oversight and regulation: inspection, decision-making and enforcement-sanction within ASN.

These six fundamental principles concerning the BNI oversight and regulation activities constitute the ASN organisational culture and are just as present in that of ASNR. Their inter-dependence and the existence of the three sub-cultures reflect the complexity of the operation of the organisation which had to be used during the construction of the ASNR and the corresponding organisational and managerial transformations.

1.2.2 The "Defence in Depth" concept

The concept of "Defence in Depth" consists in implementing a series of levels of defence based on the intrinsic characteristics of the installation, material, organisational and human measures and procedures designed to prevent accidents and then, if this fails, to mitigate their consequences. "Defence in Depth" is a concept which applies to all stages in the lifetime of a facility, from design to decommissioning.

These levels of defence are consecutive and independent in order to prevent an accident from developing.

An important element for the independence of the levels of defence is the use of different technologies ("diversified" systems).

The design of nuclear installations is based on a "Defence in Depth" approach. For example, the following five levels are defined for nuclear reactors:

Level 1: Prevention of abnormal operation and system failures

This is a question firstly of designing and building the facility in a robust and conservative manner, integrating safety margins and planning for resistance with respect to its own failures or to hazards. It implies conducting the most exhaustive study possible of normal operating conditions to determine the severest stresses to which the systems will be subjected. It is then possible to produce an initial design basis for the facility, incorporating safety margins. The facility must then be maintained in a state at least equivalent to that planned for in its design through appropriate maintenance. The facility must be operated in an informed and careful manner.

Level 2: Keeping the installation within authorised limits

Regulation and governing systems must be designed, installed and operated such that the installation is kept within an operating range that is far below the safety limits. For example, if the temperature in a system increases, a cooling system starts up before the temperature reaches the authorised limit. Condition monitoring and correct operation of systems form part of this level of defence.

Level 3: Control of accidents without core melt

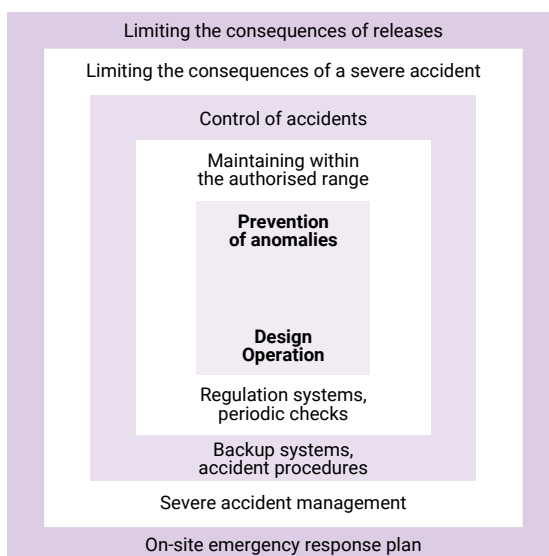
The aim here is to postulate that certain accidents, chosen for their "envelope" characteristics (the most penalising in a given family), can happen and to design and size backup systems to withstand those conditions.

Such accidents are generally studied with pessimistic hypotheses, that is to say the various parameters governing this accident are assumed to be as unfavourable as possible. In addition, the single failure criterion is applied, in other words we postulate that in the accident situation and in addition to the accident, there will be the most prejudicial failure of one of the components used to manage this situation. As a result of this, the systems brought into play in the event of an accident ("safeguard" systems ensuring emergency shutdown, injection of cooling water into the reactor, etc.) comprise at least two redundant and independent channels.

Level 4: Control of accidents with core melt

These accidents were studied following the Three Mile Island accident in the United States (1979) and are now taken into account in the design of new reactors such as the European pressurised water reactor (Evolutionary Power Reactor – EPR). The aim is to preclude such accidents or to design systems that can withstand them.

The 5 levels of "Defence in Depth"



2. Guidelines for safety culture self-assessment for the regulatory body International Atomic Energy Agency (International Atomic Energy Agency, Vienna, Austria, 2019, p. 5).

Level 5 : Mitigation of the radiological consequences of significant releases

This requires implementation of the measures provided for in the emergency plans, including measures to protect the general public: shelter, taking of stable iodine tablets to saturate the thyroid and avoid fixation of released radioactive iodine, evacuation, restrictions on consumption of water and of agricultural products, etc.

1.2.3 Positioning of barriers

To limit the risk of releases, several barriers are placed between the radioactive substances and the environment. These barriers must be designed to have a high degree of reliability and must be monitored to detect any weaknesses before a failure. There are three such barriers for Pressurised Water Reactors (PWRs): the fuel cladding, the boundary of the reactor primary system, and the containment (see chapter 10).

1.2.4 Deterministic and probabilistic approaches

Postulating the occurrence of certain accidents and verifying that, thanks to the planned functioning of the equipment, the consequences of these accidents will remain limited, is known as a “deterministic” approach. This approach is simple to apply in principle and allows an installation to be designed (and its systems to be sized) with good safety margins, by using so-called “envelope” cases. The deterministic approach is however unable to identify the most probable scenarios because it focuses attention on accidents studied with pessimistic hypotheses.

The deterministic approach therefore needs to be supplemented by an approach that better reflects possible accident scenarios in terms of their probability, that is to say the probabilistic approach used in the “Probabilistic Safety Assessments” (PSAs).

Thus for NPPs, the level 1 PSAs consist in establishing event trees for each “initiating event” leading to the activation of a safeguard system (level 3 of “Defence in Depth”), defined by the failures – or the success – of the actions provided for in the reactor management procedures and the failures – or correct operation – of the reactor’s equipment. The probability of each sequence is then calculated based on statistics on the reliability of systems and on the rate of success of actions (including data on “human reliability”). Similar sequences that correspond to the same initiating event are grouped into families, making it possible to determine the contribution of each family to the probability of reactor core melt.

Although the PSAs are limited by uncertainties concerning the reliability data and approximations in the modelling of the facility, they consider a broader set of accidents than the deterministic

assessments and enable the design resulting from the deterministic approach to be verified and supplemented if necessary. They are therefore to be used as a complement to deterministic studies and not as a substitute for them.

The deterministic studies and probabilistic assessments constitute an essential element in the nuclear safety case that addresses equipment internal faults, internal and external hazards, and plausible combinations of these events.

To be more precise, the internal faults correspond to malfunctions, failures or damage to facility equipment, including as a result of inappropriate human action. Internal or external hazards correspond to events originating inside or outside the facility respectively and which can call into question the safety of the facility.

Internal faults for example include:

- loss of the electrical power supplies or the cooling systems;
- ejection of a rod cluster control assembly;
- breaking of a pipe in the primary or secondary system of a nuclear reactor;
- reactor emergency shutdown failure.

With regard to internal hazards, the following in particular must be considered:

- flying projectiles, notably those resulting from the failure of rotating equipment;
- pressure equipment failures;
- collisions and falling loads;
- explosions;
- fires;
- hazardous substance emissions;
- floods originating within the perimeter of the facility;
- electromagnetic interference;
- malicious acts.

Finally, external hazards more specifically comprise:

- the risks induced by industrial activities and communication routes, including explosions, hazardous substance emissions and airplane crashes;
- earthquakes;
- lightning and electromagnetic interference;
- extreme meteorological or climatic conditions;
- fires;
- floods originating outside the perimeter of the facility;
- malicious acts.

1.2.5 Operating Experience Feedback

Operating Experience Feedback (OEF), which contributes to “Defence in Depth”, is one of the essential safety management tools. It is based on an organised and systematic collection and analysis of the signals emitted by a system. It should enable acquired experience to be shared so that the organisation can learn (that is through the implementation of preventive measures in a structure that learns from past experience). The first goal of OEF is to understand, and thus ensure progress in

technological knowledge and knowledge of actual operating practices, so that whenever pertinent, a fresh look can be taken at the design (technical and documentary). As OEF is a collective process, the second goal is to share the resulting knowledge on the basis of the date of detection and recording of the anomaly, the lessons learned from it and how it was rectified. The third goal of OEF is to act on working organisations and processes, on working practices (both individual and collective) and on the performance of the technical system.

OEF therefore encompasses events, incidents and accidents occurring both in France and abroad, whenever their assessment is relevant to enhancing nuclear safety or radiation protection.

1.2.6 Social, human and organisational factors

The importance of Social, Human and Organisational Factors (SHOF) for nuclear safety, radiation protection and environmental protection

The contribution of humans and organisations to safety, radiation protection and environmental protection is decisive in the design, construction, commissioning, operation and decommissioning of facilities, as well as in the transport of radioactive substances. Similarly, the way in which people and organisations manage deviations from the regulations, from the baseline requirements and from the state of the art, plus the corresponding lessons learned, is also decisive. Therefore, all those involved, regardless of their position in the hierarchy and their functions, make a contribution to safety, radiation protection and environmental protection, owing to their ability to adapt, to detect and correct errors, to rectify degraded situations and to counter certain difficulties involved in the application of procedures.

Social, Human and Organisational Factors (SHOF) are defined as being all the aspects of working situations and the organisation which have an influence on the work done by the operators. The elements considered concern the individual (training received, fatigue or stress, etc.) and the organisation within which they work (functional and hierarchical links, joint contractor work, etc.), the technical arrangements (tools, software, etc.) and, more broadly, the working environment with which the individual interacts.

The working environment for instance concerns the heat, sound or light environment of the workstation, as well as the accessibility of the premises.

The variability in worker characteristics (vigilance varies with the time of day, the level of expertise varies according to the seniority in the position) and in the situations encountered (unexpected failure, social tension) explains that these workers constantly need to adapt how they work in order to optimise effectiveness

and efficiency. This goal must be achieved at an acceptable cost to the persons concerned (in terms of fatigue or stress) and provide a benefit to them (the feeling of a job well done, recognition by both peers and the hierarchy, development of new skills). Thus, an operating situation or a task achieved at very high cost to the operators is a potential source of risks: a small variation in the working context, human environment or working organisation can prevent the persons concerned from performing their tasks as expected.

Integration of SHOF

ASN considers that SHOF must be taken into account in a manner commensurate with the safety implications of the facilities and the radiation protection of workers during:

- the design of a new facility, equipment, software, transport package, or the modification of an existing facility. ASN in particular wants to see design focusing on the human operator, through an iterative process comprising an analysis phase, a design phase and an evaluation phase;
- operations or activities performed by the workers during the commissioning, operation and decommissioning of nuclear facilities, as well as during the transportation of radioactive substances.

ASN also considers that the licensees must analyse the root causes (often organisational) of the significant events and identify, implement and assess the effectiveness of the corresponding corrective measures, on a long-term basis.

ASN's SHOF requirements

The Order of 7 February 2012 setting the general rules for BNIs, requires that licensees define and implement an Integrated Management System (IMS) designed to ensure that the safety, radiation protection and environmental protection requirements are systematically taken into account in all decisions concerning the facility. The IMS specifies the steps taken with regard to all types of organisation and resources, in particular those adopted to manage important activities. ASN thus asks the licensee to set up an IMS able to maintain and continuously improve safety, notably through the development of a safety culture.

2 — The oversight stakeholders

The organisation of the regulation and oversight of nuclear safety in France is compliant with the requirements of the Convention on Nuclear Safety, Article 7 of which requires that “Each Contracting Party shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations” and Article 8 of which requires that each Member State “shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework referred to in Article 7 and provided with adequate authority, competence and financial and human resources to fulfil its assigned responsibilities” and [...] “shall take the appropriate steps to ensure an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy”. These provisions were confirmed by European Council Directive 2009/71/Euratom of 25 June 2009 concerning Nuclear Safety, the provisions of which were in turn reinforced by the amending Directive of 8 July 2014.

The regulation of nuclear safety and radiation protection in France depends essentially on three players: Parliament, the Government and ASN until 31 December 2024. The role and missions of this latter were transferred to ASNR on 1 January 2025.

2.1 Parliament

Parliament's principal role in the field of nuclear safety and radiation protection is to make laws. Three major Acts were therefore passed: Act 2006-686 of 13 June 2006 on Transparency and Security in the Nuclear field (TSN Act); Programme Act 2006-739 of 28 June 2006 on the sustainable management of radioactive materials and waste; the Act of 21 May 2024

on the organisation of nuclear safety and radiation protection governance in order to address the challenges of the renewal of the nuclear sector.

In 2015, Parliament adopted Act 2015-992 of 17 August 2015 concerning Energy Transition for Green Growth (TECV Act), an entire section of which is devoted to nuclear matters (Title VI – “Reinforcing nuclear safety and information of the citizens”). This Act reinforces the framework which was created in 2006.

Pursuant to the provisions of the Environment Code, ASN regularly reports on its activity to Parliament, notably to the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST) and to the parliamentary commissions concerned.

The role of the OPECST is to inform Parliament of the consequences of scientific or technological choices so that it can make informed decisions; to this end, the OPECST gathers information, implements study programmes and conducts evaluations. ASN regularly reports on its activities to the OPECST, particularly by submitting the annual *Report on the State of Nuclear Safety and Radiation Protection in France* to it each year.

ASN also reports on its activities to the Parliamentary Commissions of the National Assembly and the Senate, notably on the occasion of hearings held by the commissions responsible for the environment or economic affairs.

The exchanges between ASN and elected officials are presented in more detail in chapter 5.

2.2 The Government

The Government exercises regulatory powers. It is therefore in charge of laying down the general regulations concerning nuclear safety and radiation protection. The Environment Code also tasks it with taking major decisions concerning BNIs, for which it relies on proposals or opinions from ASN. It also has advisory authorities such as the High Committee for Transparency and Information on Nuclear Safety (HCTISN).

The Government is also responsible for civil protection in the event of an emergency.

2.2.1 The Ministers responsible for nuclear safety and radiation protection

On the advice of and, as applicable, further to proposals from ASN, the Minister responsible for nuclear safety defines the general regulations applicable to BNIs and those concerning the construction and use of Pressure Equipment (PE) specifically designed for these installations.

Also on the advice of and, as applicable, further to proposals from ASN, this same Minister takes major individual resolutions concerning:

- the design, construction, operation and decommissioning of BNIs;
- the design, construction, operation, closure and decommissioning, as well as the surveillance, of radioactive waste disposal facilities.

If an installation presents serious risks, the above-mentioned Minister can suspend the operation of an installation on the advice of ASN.

Furthermore – and on the basis of ASN proposals if necessary – the Minister responsible for radiation protection defines the general regulations applicable to radiation protection.

The regulation of worker radiation protection is the responsibility of the Minister for Labour. That concerning the radiation protection of patients is the responsibility of the Minister for Health. These roles are currently held by the Ministry for Labour, Health, Solidarity and Families.

They also approve ASN technical regulations and certain individual resolutions affecting their own particular field (for example: setting BNI discharge limits during operation, BNI delicensing, etc.).

The Nuclear Safety and Radiation Protection Mission

The Nuclear Safety and Radiation Protection Mission (MSNR), within the General Directorate for Risk Prevention at the Ministry for Ecological Transition Biodiversity, Forests, the Sea and Fisheries, is in particular tasked – in collaboration with ASN – with proposing Government policy on nuclear safety and radiation protection, except for defence-related activities and installations and the radiation protection of workers against ionising radiations.

Defence and Security High Official

The purpose of nuclear security, in the strictest sense of the term (IAEA definition, less wide-ranging than that of Article L. 591-1 of the Environment Code) is to protect and monitor nuclear materials, their facilities and their transportation.

It aims to ensure protection of the populations and environment against the consequences of malicious acts, in accordance with the provisions of the Defence Code.

This responsibility lies with the Minister for Ecological Transition, with the support of the HFDS and more specifically its Nuclear Security Department. The HFDS thus acts as the nuclear security authority, by drafting regulations, issuing authorisations and conducting inspections in this field, with the support of the Armed Forces Ministry.

Although the two regulatory systems and approaches are clearly different, the two fields, owing to the specificity of the nuclear field, are closely linked. ASN and the HFDS are therefore regularly in contact with each other to discuss these matters.

2.2.2 The decentralised State services

The decentralised services of the French State are those which locally implement the decisions taken by the central administration and which manage the State's services at the local level. These services are placed under the authority of the Prefects.

ASN maintains close relations with the Regional Directorates for the Environment, Planning and Housing (Dreal), the Regional and Interdepartmental Directorate for Public Works, Development and Transport of Ile-de-France (Drieat), the Regional Directorates for the economy, employment, labour and solidarity (Dreets) and the Regional Health Agencies (ARS) which,

although not strictly speaking decentralised services but public institutions, have equivalent powers.

The Prefects are the State's local representatives. They are the guarantors of public order and play a particularly important role in the event of an emergency, in that they are responsible for measures to protect the general public.

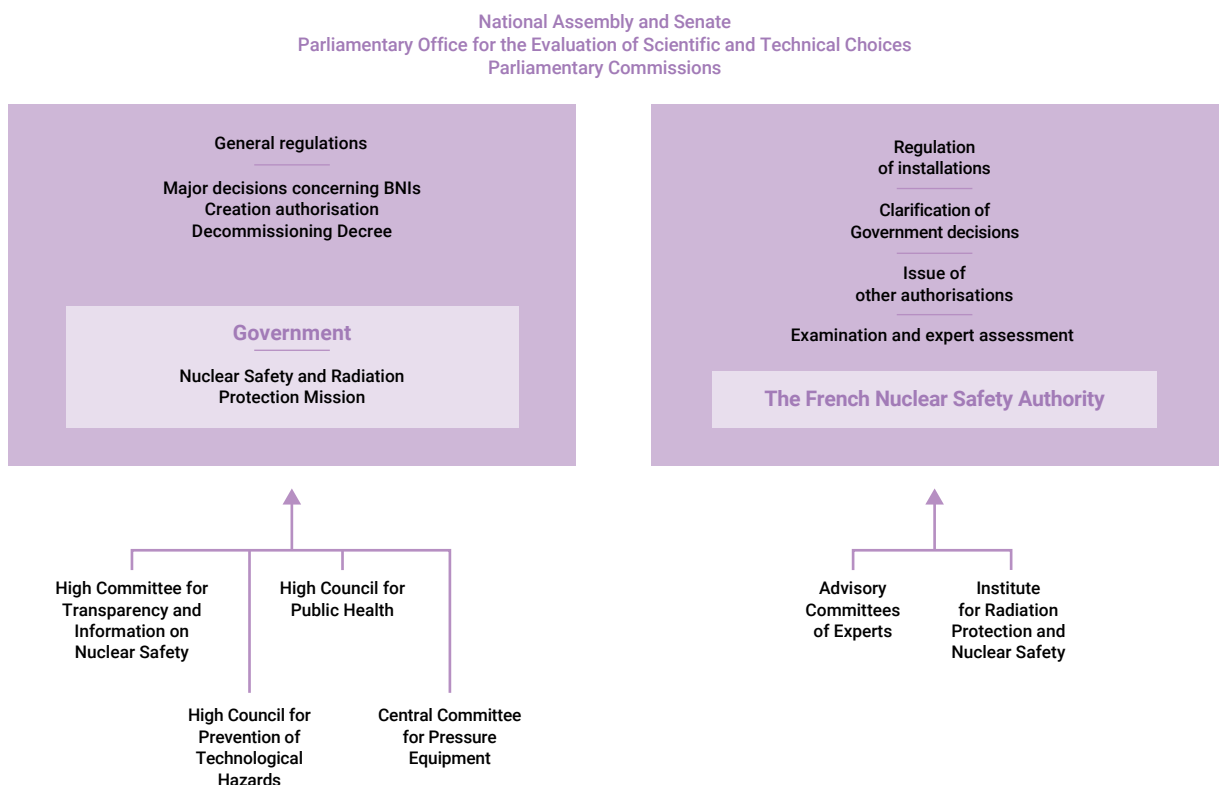
The Prefects intervene in the various procedures. In particular, they send the Minister their opinion on the report and the conclusions from the inquiry commissioner following the public inquiry into authorisation applications.

At the request of ASN, they refer to the Departmental Council for the Environment and Health and Technological Risks for an opinion on the water intake, discharges and other detrimental effects of BNIs.

2.3 From the Nuclear Safety Authority to the French Authority for Nuclear Safety and Radiation Protection

The French Nuclear Safety Authority (*Autorité du sûreté nucléaire* – ASN), created by the TSN Act, is an independent administrative Authority which takes part in regulating nuclear safety, radiation protection and the nuclear activities mentioned in Article L. 1333-1 of the Public Health Code. Its missions consist in regulating, licensing, inspecting, assisting the public authorities in emergency

Regulation of nuclear safety and radiation protection in France (organisation up until 31 December 2024)



situation management, contributing to the informing of the various audiences and to ensuring transparency in its areas of competence.

ASN is governed by a Commission comprising five Commissioners, including the ASN Chairman. They are appointed for a six-year term. Three are appointed by the President of the Republic and one by the President of each Parliamentary assembly. ASN comprises departments placed under the authority of its Chairman.

ASN comprises an Administrative Enforcement Committee (*see point 2.3.2*). For the purposes of technical analysis and assessment, it more particularly draws on the services of IRSN and the Advisory Committees of Experts (GPEs).

Act 2024-450 of 21 May 2024, relative to the organisation of nuclear safety and radiation protection governance, in order to address the challenges of the renewal of the nuclear sector, ratified the creation of an independent civil nuclear safety and radiation protection authority: the Authority for Nuclear Safety and Radiation Protection (ASNR), combining the activities of the Nuclear Safety Authority (ASN) and part of those of the Institute for Radiation Protection and Nuclear Safety (IRSN).

The activities of the new ASNR started on 1 January 2025.

2.3.1 Towards expanded roles

Regulation

ASN is consulted on draft decrees and Ministerial Orders of a regulatory nature dealing with nuclear safety as defined in Article L. 591-1 of the Environment Code.

It can take regulatory decisions of a technical nature to supplement the implementing procedures for Decrees and Orders adopted in the areas of nuclear safety or radiation protection, except for those relating to occupational medicine. These regulations must be approved by the Minister responsible for nuclear safety or the Minister responsible for radiation protection. Approval orders and approved resolutions are published in the *Official Journal*.

Authorisation

ASN reviews BNI creation authorisation or decommissioning applications, issues opinions and makes proposals to the Government concerning the decrees to be issued in these fields. It authorises significant modifications to a BNI. It defines the requirements applicable to these installations with regard to the prevention of risks, pollution and detrimental effects. It authorises commissioning of these installations and pronounces delicensing following completion of decommissioning.

Some of these resolutions require approval by the Minister responsible for nuclear safety.

ASN issues the licenses, carries out registration and receives the notifications provided for in the Public Health Code concerning small-scale nuclear activities and issues licenses or approvals for radioactive substances transport operations. The ASN resolutions and opinions resulting from the deliberations of its Commission are published in its *Official Bulletin* on its website *asn.fr*.

Monitoring

ASN verifies compliance with the general rules and specific requirements for nuclear safety and radiation protection applicable to BNIs, to the PE designed specifically for these facilities and to the transport of radioactive substances. It also regulates the activities mentioned in Article L. 1333-1 of the Public Health Code and the ionising radiation exposure situations defined in Article L. 1333-3 of the same Code. ASN organises a permanent radiation protection watch throughout the national territory.

From among its staff, it appoints nuclear safety inspectors, radiation protection inspectors and inspectors carrying out labour inspectorate duties.

ASN issues the required approvals and certifications to the organisations participating in the verifications and in nuclear safety or radiation protection monitoring, as well as with regard to Nuclear Pressure Equipment NPE.

Ordinance 2016-128 of 10 February 2016, issued pursuant to the TECV Act, reinforces ASN's regulatory and sanction powers and broadens the scope of its competences.

The effect of ASN's reinforced regulation, policing and enforcement powers will be to improve the effectiveness of the regulation of nuclear safety and radiation protection. These policing and sanction powers are extended to the activities, performed outside BNIs and participating in the technical and organisational measures mentioned in the 2nd paragraph of Article L. 595-2 of the Environment Code, by the licensee, its suppliers, contractors or sub-contractors and in the same conditions as within the facilities themselves.

Administrative fines will be imposed by the Administrative Enforcement Committee in order to comply with the principle of separation between the investigation, charging and sentencing functions instituted in French law and in international conventions on the right to a fair trial. Chapter 3 of this report describes all of ASN's oversight actions, including enforcement.

Emergency situations

ASN participates in the management of radiological emergency situations. It provides technical assistance to the competent Authorities for the drafting of emergency response plans, taking account of the risks resulting from nuclear activities.

When such an emergency situation occurs, ASN verifies the steps taken by the licensee to make the facility safe. It assists the Government with all matters within its field of competence and submits its recommendations on the medical or health measures or civil protection steps to be taken. It informs the general public of the situation, of any releases into the environment and their consequences. It acts as the Competent Authority within the framework of international conventions, by notifying international organisations and foreign countries of the accident.

Chapter 4 of this report describes ASN actions in this field.

In the event of an incident or accident concerning a nuclear activity and, pursuant to Articles L. 592-35 and R. 592-23 *et seq.* of the Environment Code relative to technical inquiries into accidents or incidents concerning a nuclear activity, ASN may carry out a technical inquiry.

Information and dialogue

ASN participates in informing the public in its areas of competence. ASN informs the public about the state of nuclear safety and radiation protection in France and participates in ensuring transparency in France. It reports on its activities to Parliament.

ASN enables all members of the public to take part in the drafting of its decisions with an impact on the environment. It supports the actions of the Local Information Committees (CLIs) set up around the nuclear installations.

Chapter 5 of this report describes ASN actions in this field.

Definition of orientations and oversight of research

The quality of ASN's resolutions and decisions relies primarily on robust technical expertise which, in turn, requires the best and most up-to-date knowledge. In this field, Article L. 592-31-1 of the Environment Code comprises provisions giving ASN competence to ensure that public research is tailored to the needs of nuclear safety and radiation protection.

On the basis of the work of its Scientific Committee (*see point 2.5.3*), since 2012, ASN has regularly issued opinions on the need for research on subjects with major nuclear safety and radiation protection implications. In 2024, ASN published two opinions: one opinion on research subjects to be taken further in the field of nuclear safety regarding the ageing of metal components which cannot be replaced or which are hard to replace in the PWRs to ensure operation beyond 60 years, and one opinion in the field of radiation protection regarding active implantable medical devices, the case of microspheres of yttrium-90. Its opinions and those of its Scientific Committee are published on *asn.fr* and are transmitted to

the public and private research programmers. ASN is continuing to reinforce its relations with the research organisations and the institutions in charge of programming and funding research at both national and European levels.

ASN takes part in the steering committee for the “Nuclear safety and radiation protection research” (RSNR) Call for Projects issued in 2013 by the National Research Agency (ANR) as part of the Investing in the Future programme, for which funding came to an end in 2023. This action ended on 31 December 2024. An ANR summary of the results of this action will be sent to ASNR in the first half of 2025.

Since 1 January 2025 and the creation of ASNR, several areas of intervention which were previously the remit of IRSN, have been added to the range of missions and competences of the new safety Authority.

Conducting research

ASNR defines multi-disciplinary research programmes, conducted internally or in partnership with other French or foreign research organisations.

The research carried out by ASNR is in two main areas: maintaining and developing the knowledge and skills needed for expert assessment in the various fields of nuclear safety and radiation protection and progressing fundamental knowledge, notably to understand the effects of ionising radiation on health and the environment.

Expert assessment

ASNR assesses the safety of civil nuclear facilities at each step in their lifecycle, from design to decommissioning.

ASNR also evaluates the hazards for human health and the environment linked to the use of ionising radiation.

It takes part in the permanent radiation protection watch, notably through radiological monitoring of the environment, managing and analysing dosimetric data concerning workers exposed to ionising radiation and analysing patients’ dosimetry data.

Training

ASNR proposes a wide range of nuclear safety and radiation protection training courses for professionals using ionising radiation in their activities. It thus contributes to maintaining a high level of expertise in nuclear safety and radiation protection and helps improve prevention and protection against the dangers of ionising radiation.

Developing a radiation protection culture among the general public

One of the roles of ASNR is to contribute to developing a radiation protection culture among the general public, in other words the ability of the public to adopt appropriate behaviour and responses to an accident situation.

2.3.2 Organisation

ASN Commission

The ASN Commission comprises five full-time Commissioners. Their mandate is for a period of six years and is not renewable. The Commissioners perform their duties in complete impartiality and receive no instructions from either the Government or any other person or institution. The President of the Republic may terminate the duties of any member of the Commission in the event of a serious breach of his or her obligations.

The Commission defines ASN’s strategy. More specifically, it is involved in developing overall policy, i.e. the doctrines and principles that underpin ASN’s main missions of regulation, inspection, transparency, management of emergency situations and international relations.

Pursuant to the Environment Code, the Commission submits ASN’s opinions to the Government and issues the main ASN regulations and decisions. It decides on the public position to be adopted on the main issues within ASN’s sphere of competence. It adopts the ASN internal rules of procedure which set out its organisation and working rules, as well as its ethical guidelines (see page 137). The Commission’s decisions and opinions are published in ASN’s *Official Bulletin*.

In 2024, the ASN Commission met 47 times. It issued 22 opinions and 20 decisions.

Administrative Enforcement Committee

“Nuclear” Ordinance 2016-128 of 10 February 2016 created the ASN Administrative Enforcement Committee (Articles L. 592-41 to L. 592-44 of the Environment Code). It was set up on 19 October 2021. The creation of this Committee supplements the arsenal of enforcement measures available to ASN. When referred to by the ASN Commission, it has the power to issue administrative fines on the licensees of BNIs, those responsible for the transport of radioactive substances or NPE, or indeed those Responsible for Nuclear Activities (RNAs) regulated by the Public Health Code. Its independence is guaranteed by law.

The Committee comprises four regular members, two State advisers appointed by the Vice-President of the Council of State and two advisers from the *Cour de cassation* (Court of Cassation) appointed by the first President of the *Cour de cassation*. It also comprises alternate members. The duration of the members’ mandate is six years.

At their first meeting, on 19 October 2021, the regular members elected Mr. Maurice Meda as Chairman of the Committee for the next three years. They also adopted the internal rules of procedure which were published in the *Official Journal* on 5 November 2021 and in the *ASN Official Bulletin* the following 8 November.

The annual information exchange meeting between the members of the Administrative Enforcement Committee, the ASN Commission and the ASN General Directorate was held on 8 January 2024.

As set out by law, the Committee will meet exclusively when convened by the ASN Commission. This latter may decide to open a procedure leading to issue of a fine after clearly determining that the person responsible for nuclear activities has not complied with a formal notice, in other words has not taken the measures required by this formal notice.

The fines will be proportional to the seriousness of the observed breaches and in particular take into account the extent of the impact on the environment. The maximum amount of the fines is set by law at 10 million euros, in the event of a breach of the provisions applicable to BNIs, one million euros for a breach of the provisions applicable to NPE, €30,000 in the field of transport of radioactive substances, and €15,000 for small-scale nuclear activities.

The administrative fine issue procedure includes compliance with the adversarial principle. No penalty can be imposed without the party concerned or their representative having been heard or summoned. The Committee’s decision may be made public. The decisions pronounced by the Administrative Enforcement Committee may be referred to the administrative jurisdiction (Council of State) by the person concerned, by the ASN Chairman or by the third parties.

Creation of a new organisation of the head office departments

The ASN head office departments (until 31 December 2024) comprise an Executive Committee, a General Secretariat, a Management and Expertise Office, an Oversight Support Office, a delegation in charge of innovative reactors, and nine departments covering specific themes.

Under the authority of the ASN Director General, the Executive Committee organises and manages the departments on a day to day basis. It ensures that the orientations determined by the Commission are followed and that ASN’s actions are effective. It oversees and coordinates the various entities.

The role of the departments is to manage national affairs concerning the activities under their responsibility. They take part in defining the general regulations and coordinate and oversee the actions of the ASN regional divisions:

- The Nuclear Power Plants Department is in charge of overseeing nuclear reactors, whether high or intermediate power, planned, under construction or in operation, using a PWR technology for industrial purposes or as an experimental prototype. Oversight concerns the technical but also the organisational and human aspects of

The members of the Executive Committee



From left to right: P. Bois, P. Deschamps, S. Cadet-Mercier, D. Delalande, M. Enault, J.-P. Goudalle, O. Gupta, P. Dubiau, J. Collet, K. Herviou, C. Quintin, J.-K. Intissar, J.-C. Gariel.

nuclear safety, radiation protection, and protection of the environment. The department is also in charge of coordinating and supporting the action of the ASN labour inspectors.

- The Nuclear Pressure Equipment Department is responsible for overseeing NPE. In this respect, it ensures that the design, construction and operation of this equipment complies with the regulations. The Department also does the same for operation of non-nuclear PE within the perimeter of the BNIs.

- The Transport and Sources Department is in charge of monitoring and overseeing activities concerning ionising radiation sources and radioactive substances transport. In this respect, its role is to organise, with regard to the radiation protection aspects, the oversight of non-medical activities subject to the authorisation, registration and notification requirements of the Public Health Code, examine requests for approval of shipments in the field of radioactive substances transport, and organise the oversight of radioactive substances transport activities on the public highway or on-site transports of dangerous goods within BNIs. It is also in charge of overseeing the security of radioactive sources.

- The Waste, Research facilities and Fuel Cycle Facilities Department is in charge of monitoring and overseeing the “fuel cycle” facilities, fuel fabrication or assembly facilities for Small Modular Reactor (SMR) projects, research facilities, irradiators, subject to the BNI System, as well as “support” activity facilities subject to the BNI System, the decommissioning of BNIs, the management of radioactive waste and the associated BNIs, the management of sites and soils polluted by radioactive substances and the long-term management of former mining sites. Finally, it is in charge of monitoring and anticipating the operation of the “fuel cycle”.

- The Ionising Radiation and Health Department is in charge of updating the regulations for the radiation protection of workers, patients and the general public.

It is also in charge of overseeing medical applications of ionising radiation, and exposure to naturally occurring ionising radiation; in this respect it monitors compliance with the regulations for the radiation protection of workers, patients and the general public.

- The Environment and Emergency Department is in charge of questions relating to protection of the environment, the management of emergency situations and the safety-security interfaces, in support of ASN’s assessment and oversight activities. It also contributes to the national emergency management organisation, as well as preparation of post-accident doctrine, excluding aspects relating to expert assessment. It coordinates oversight of laboratories approved for environmental monitoring, as well as ASN actions interfacing with the protection of nuclear activities against malicious acts.

- The Legal Affairs Department has a cross-cutting advisory, expert assessment and assistance function for the ASN Commission, Executive Committee and various entities, in a legal capacity. It examines enforcement requests submitted to the Administrative Enforcement Committee and assists the Professional Ethics Committee. It defends ASN’s interests before administrative and judicial courts, jointly with the entities concerned. It takes part in the legal training of staff and in coordinating regulations steering committees. It supports all the entities in the preparation of contracts and provides assistance for the data protection delegate. This department merged with the IRSN General Secretariat’s legal department as part of the creation of ASNR.

- The Information, Communication and Digital Uses Department implements ASN information and communication policy in the fields of nuclear safety and radiation protection. It coordinates ASN communication and information actions targeting different audiences, with a focus on handling requests for information and documentation, making ASN’s position

known and explaining regulations. It is responsible for the IT infrastructure, for overseeing the digital transformation and the development of digital services for the parties concerned and the ASN audiences. This department was merged with two IRSN departments as part of the creation of ASNR.

- The International Relations Department coordinates ASN’s bilateral, European and multilateral international actions, both formal and informal. It develops exchanges with ASN’s foreign counterparts in order to promote and explain the French approach and practices with regard to nuclear safety and radiation protection and to gain a greater understanding of their practices. It provides the countries concerned with useful information about the safety of French nuclear facilities, more specifically those which are located close to the borders. The International Relations Department coordinates ASN representation in cooperative structures created under bilateral agreements or arrangements, but also within formal international bodies. This department was merged with its IRSN counterpart as part of the creation of ASNR.

- The General Secretariat helps to provide ASN with the adequate, appropriate and long-term resources necessary for it to function. It is responsible for managing human resources, including with regard to skills, and for developing social dialogue. It is also responsible for ASN real estate policy and its logistical and material resources. It is in charge of implementing the ASN budget policy and ensures optimised use of its financial resources. The various centres of the General Secretariat were incorporated into the departments as part of the creation of ASNR.

- The Management and Expertise Office provides ASN with a high level of expertise and identifies the areas where knowledge is needed in the field of research. It ensures that ASN’s actions are coherent, by means of a quality approach and by overseeing coordination of the workforce. The Office comprises eight members in charge of expert assessment, relations with IRSN, research, quality, archival and transmission of knowledge. The Office is in charge of overseeing the research network and the quality network at ASN. This Office joined the Operations and Performance Department as part of the creation of ASNR.

- The Inspection Support Office ensures that the inspections carried out by ASN are pertinent, consistent, effective and in line with ASN’s values. For this purpose, it more particularly coordinates the processes involved in drawing up and monitoring the ASN programme of inspections and checks on the approved organisations

The members of the management committee



From left to right: A. Clos, J. Husse, S. Kirchenbaum, J.-P. Daubard, E. Bellange, C. Messier, F. Féron, F. Simon, R. Catteau, A. Contesso, S. Tourard, I. Le Bars, M. Gleizes, P. Giordano, C. Rousse, J. Battiston, F. Vallette, M. Agarande, C. Pinel, M. Riet-Hucheloup (not on photo: J.-M. Bonnet, P. Dupuy et M. Enault).

of the departments, as well as actions to prevent and deal with suspected fraud. It coordinates the handling of external alerts.

- The Innovative Reactors Delegation is responsible for checking industrial or experimental prototype new SMR projects which use a technology other than that of the PWRs. Oversight concerns the technical but also the organisational and human aspects of nuclear safety, radiation protection, environmental protection, safety-security interfaces and the management of emergency situations. This Delegation became the Innovative Reactors Department as part of the creation of ASNR.

Further to the work done jointly by ASN and IRSN throughout the course of 2024, in order to be immediately operational as of 1 January 2025 and fully carry out all their duties and roles, with the grouping of the two entities within the new Authority for Nuclear Safety and Radiation Protection, several IRSN departments were merged with those of ASN. ASNR now also has the following departments:

- The Transformation Support Office is charged with running and supporting the change process. In particular, it assists the Executive Committee in overseeing the construction and then the implementation of the required ASNR organisation. This structure hosts the Ideas and Concepts laboratory⁽³⁾.
- The Operation and Performance Department assists the Executive Committee with coordinating the departments, implementing the integrated management system and improving performance, overseeing the GPEs, following up internal or external technical support requests and monitoring external expert assessments. In particular, it coordinates the drafting of agreements. It is in charge of independent oversight and internal audits of the professional departments and takes part in preventing and detecting any drifts or breaches. It also assists the qualified Authority for Information Systems Security (AQSSI),

oversees compliance with the General Data Protection Regulation (GDPR) and is tasked with coordinating the new nuclear safety Authority's CSR policy.

- The Scientific Oversight Department assists the scientific director with drawing up the scientific strategy validated by the Commission. It breaks this strategy down into strategic objectives and monitors their attainment by the departments in charge of carrying out the corresponding research programmes. It assists the Executive Committee and the departments in charge of research activities to prepare and coordinate scientific evaluation. It produces a forward-looking vision of research partnerships. It identifies, if necessary jointly with the International Department, and conducts cross-cutting coordination of research partnerships with research organisations and nuclear industrial companies.
- The Safety Expert Assessment Department conducts expert assessments on nuclear safety and radiation protection of civil basic nuclear installations (other than radioactive waste repositories) and of radioactive substances transports, on behalf of other ASNR departments and outside French entities, notably in the field of defence and security, or foreign entities. Bringing in the other ASNR entities, it oversees deliberations around changes to and formalisation of the safety approaches. It carries out studies to support its expert assessment and, notably in collaboration with the research departments, it develops the tools needed for its expert assessment work. The Safety Expert Assessment Department identifies the needs in terms of knowledge to be acquired in its field of activity. Finally, it is in charge of monitoring and anticipating the operation of the "fuel cycle".
- The Safety Research Department is in charge of drawing up and running ASNR's research and study programmes in the field of the safety of nuclear facilities

and transports. It identifies the needs in terms of development or further exploration of scientific and technical knowledge, the tools or methods needed to perform ASNR's roles in the field of nuclear safety. It translates them into research or study programme proposals which it then implements using its own resources, and which it maintains in operational conditions and develops. National, European and international partnerships enable it to optimise its research programmes.

- The Health Expert Assessment and Research Department implements ASNR research and expert assessment actions regarding:
 - the prevention of occupational and patient exposure, providing medical opinions and analyses, if necessary with regard to the victims of irradiation accidents;
 - preparedness for management of emergencies. These activities cover the development of doctrines, methods and tools needed to assess these situations, produce a development prognosis and predict the consequences. They also concern the organisation and technical and human resources that ASNR should mobilise to deal with such situations, during both the emergency and post-accident phases.
- The Environment Expert Assessment and Research Department implements ASNR research and expert assessment actions regarding:
 - protection of the environment against ionising radiation, notably the behaviour and effects of radionuclides within ecosystems, transfer to humans, radiological monitoring nationwide, exposure of the populations and radiological characterisation interventions;
 - radioactive and mining waste disposal facilities, the management of contaminated sites, characterisation of sites and natural hazards and the behaviour of radionuclides in geological environments.

3. Innovation platform enabling all personnel to experiment with new methods to look for solutions.

The Regional Division Heads



From left to right: M. Rasson, E. Jambu, T. Meisgny, M. Riquart, P. Durliat, G. Lafforgue, P. de Guibert, M. Champion, L.-V. Bouthier, A. Fontaine (not on photo: C. Perier).

Within its field, it contributes to preparedness for and management of emergency situations, in accordance with the priorities set out by the Director delegate for emergencies.

- The International Department is in charge of developing exchanges with ASNR's foreign counterparts and the other foreign and international organisations involved in ASNR's fields of competence. It is also in charge of coordinating relations with all the regional and international networks involved in ASNR's fields of competence. In close coordination with the scientific oversight department, it is the point of contact for the European Commission regarding its research, development and innovation programmes and promotes scientific relationships and partnerships with foreign international research organisations involved in ASNR's fields of competence. The International Department also oversees international services. It supports the Executive Committee and the Commission with respect to international relations.

- The Relations, Participation and Communication Department submits communication, societal openness and public relations strategies to the Commission and is then tasked with implementing them. It coordinates and monitors the consistency of actions to and with the general public, the stakeholders, the professional organisations, the professional public, the institutional public, the media and the ASNR personnel. It is also in charge of public relations and supports the Executive Committee and the Commission with respect to institutional relations, notably with Parliament. This Department is the result of the merger between ASN's Public Communication and Information Office and IRSN's Communication Department and Societal Outreach Policies Service, as part of the creation of ASNR.

- The Human Resources Department is responsible for hiring policy, personnel remuneration, forward-looking jobs and skills management, inspector qualification

management, occupational health, legal questions concerning personnel and social relations. This Department is the result of the merger between ASN's Human Resources Office and IRSN's Human Resources Department.

- The Financial Affairs Department takes part in defining and implementing ASNR's budget and finance strategy, as validated by the Commission. In this respect, it is in charge of programming, implementing and monitoring ASNR's budget and finance policy. It represents ASNR with respect to budget and finance questions. It guarantees the reliability and conformity of the budget procedures, budget preparation and execution, keeps the budget accounting and carries out ASNR's internal financial oversight and oversight of financial management. It defines purchasing policies, conducts procurement and administers ASNR's revenue. It carries out administrative and financial management of the missions and travel of ASNR personnel. It takes part in collection of taxes from BNIs and the additional taxes, together with the Public Finances Directorate General (DGFIP). This Department is a merger of ASN's Budget and Finance Office and the IRSN General Secretariat.

- The Sites, Safety and Heritage Department is in charge of the safety of people and property, protection of the environment, general services, and the management and capitalising on ASNR's moveable and real estate heritage and, more broadly, its sites. Under its prevention duties, it coordinates all the Authority's radiation protection experts/officers, whether their positions are described within the various site departments, or within the Service Competent in Radiation Protection (SCR). This Department is a merger between ASN's Logistics and Real Estate Office and ASN's SCR, and the same dedicated departments within IRSN.

- The Digital and Digital Uses Department is in charge of proposing policies related to information systems and data, and of guaranteeing their implementation. It

coordinates and supports ASNR's digital transformation and data governance. It is responsible for the governance of digital uses, products, services and infrastructures. It sets up the conditions for access, utilisation and exploitation of data. It monitors and forecasts emerging technologies and leads innovative actions. It implements the information systems security policy and ensures that these systems are maintained in operational and secure conditions. It is responsible for assisting the ASNR departments in creating, deploying, maintaining and upgrading their digital products and infrastructures. It proposes and implements the digital working environment and the fixed and mobile distributed infrastructures. The IT and Digital Uses Office merged with IRSN's Information Systems Division (DSI).

- The Nuclear Safety and Radiation Protection University is responsible for developing and coordinating internal systems and actions for learning (notably training) and using the knowledge needed for the various ASNR activities (regulation, expert assessment, research, etc.) and the external sharing and transmission of ASNR knowledge and regulations. The systems and actions concern the preservation, access to, sharing and transmission through training of ASNR's knowledge and skills. It coordinates the network of experts.

ASN regional divisions

For many years, ASN has benefited from a regional organisation built around its eleven regional divisions. These regional divisions operate under the authority of the regional representatives. The Director of the Dreal or of the Driat in which the division in question is located, takes on this responsibility as regional representative. He/she is placed at the disposal of ASN to fulfil this role. This person is delegated with power of signature by the ASN Chairman for decisions at the local level.

The regional divisions carry out most of the direct inspections on the BNIs, on radioactive substance transport operations and on small-scale nuclear activities, and review most of the authorisation applications filed with ASN by the RNAs within their regions. They are organised into two to four hubs, depending on the activities to be regulated in their territory.

In emergency situations, the regional divisions assist the Prefect, who is in charge of protecting the general public, and, as applicable, the defence zone Prefect, and supervise the operations carried out to ensure the safety of the facility on the site. In order to prepare these situations, they take part in drawing up the emergency plans drafted by the Prefects and in periodic emergency exercises.

The Regional Representatives



From left to right: H. Brûlé, O. David, J. Labit, A. Beauval, M. Hoeltzel, C. Grisez, S. Forest (not on photo: J.-P. Deneuvy, V. Jechoux et E. Gay).

The regional divisions contribute to ASN's public information duty. They for example take part in the meetings of the CLIs and maintain regular relations with the local media, elected officials, associations, licensees and local administrations.

2.3.3 Operation in 2024

Human resources

On 31 December 2024, the ASN total headcount amounted to 541, distributed between the head office departments (319 staff) and the regional divisions (222 staff).

This workforce can be further broken down as follows:

- 484 tenured or contract staff members;
- 57 staff members seconded by public establishments (National Radioactive Waste Management Agency – Andra, Alternative Energies and Atomic Energy Commission – CEA, IRSN, Departmental Fire and Emergency Response Service – SDIS).

ASN utilises a diversified hiring policy with the aim of ensuring that there are sufficient numbers of the qualified and complementary human resources needed to perform its duties.

Creation of ASNR

In parallel with the preparatory work on the Bill dedicated to this reform by the Government, the ASN and IRSN managements carried out work to define the organisation and operating principles of the future entity throughout the course of 2024, with all the personnel of both entities being involved in the work in stages. Twelve Working Groups (WG) were thus jointly created for specific activity or mission topics covering the full scope of the activities and missions of ASN and IRSN (review, expert assessment, inspection; Emergency, intervention and monitoring; Legal affairs; etc.). The work as a whole was overseen by a specific committee, the Coordination Committee,

comprising representatives of the ASN and IRSN senior management.

The ASN departments, along with those of IRSN, also took part in the work under the leadership of the DGFIP (notably involving the Ministerial Budget and Accounting Controllers department – CBCM) and the State's Financial Information Technology Agency (AIFE) to study subjects regarding the financial and accounting function. The work carried out in this respect notably concerned on the one hand the creation of a new budget programme dedicated to ASNR, and on the other the definition of resources dedicated to the activities transferred to CEA and to the Ministry for the Armed Forces.

A third aspect of the activity of the ASN departments covered the drafting of Decrees implementing legislation, so that they are ready before 31 December 2024 (see "Regulatory News").

Finally, to enable ASNR to function and guarantee the continuity of its missions, a list of "essential" actions in the functional fields (payment of wages, creation of a joint email address, pre-positioning of personnel within the future Authority, etc.) was defined as of December 2023 and the ASN departments were mobilised in order to remove all obstacles by 1 January 2025.

Skills management

Alongside independence, transparency and rigorousness, competence is one of the core values at ASN. The tutor system, initial and continuing training, whether general, linked to nuclear techniques, the field of communication, or legal matters, as well as day-to-day practices, are essential aspects of the professionalism of ASN staff.

Management of ASN personnel skills is built primarily around a qualifying technical training programme tailored to each staff member, based on professional training requirements that include minimum experience conditions.

Pursuant to the provisions of Articles L. 592-22 and L. 592-23 of the Environment Code, which notably state that "[ASN] appoints the nuclear safety [...] and radiation protection inspectors from among its staff" and Decree 2007-831 of 11 May 2007 setting out the procedures for appointing and qualifying nuclear safety inspectors, which states that "the nuclear safety inspectors and staff responsible for inspecting nuclear pressure equipment [...] are chosen according to their professional experience and their legal and technical knowledge", ASN has set up a formalised process leading to the qualification of a large number of its staff for performance of its inspections and, as applicable, judicial policing duties. ASN also carries out labour inspectorate duties in the nuclear power plants, pursuant to Article R. 8111-11 of the Labour Code. For each of the inspectors concerned, the accreditation decision taken by ASN is based on the match between the skills acquired – both within and outside ASN – and those specified in the professional baseline requirements.

As at 31 December 2024, ASN employed 332 nuclear safety or radiation protection inspectors holding at least one qualification, or nearly 61.4% of the 541 ASN staff.

Training re-engineering work to adapt the modules following the Covid-19 pandemic, led to optimisation of the classroom training time. In 2024, 4,529 days of training were provided for the ASN staff over a wide variety of topics, representing 137 training actions either face to face or by video-conference. These figures are supplemented by a large number of hours devoted to self-training by each trainee.

The training committee ensures that the training system matches the needs and strategic objectives set out in the Multi-year Strategic Plan (PSP).

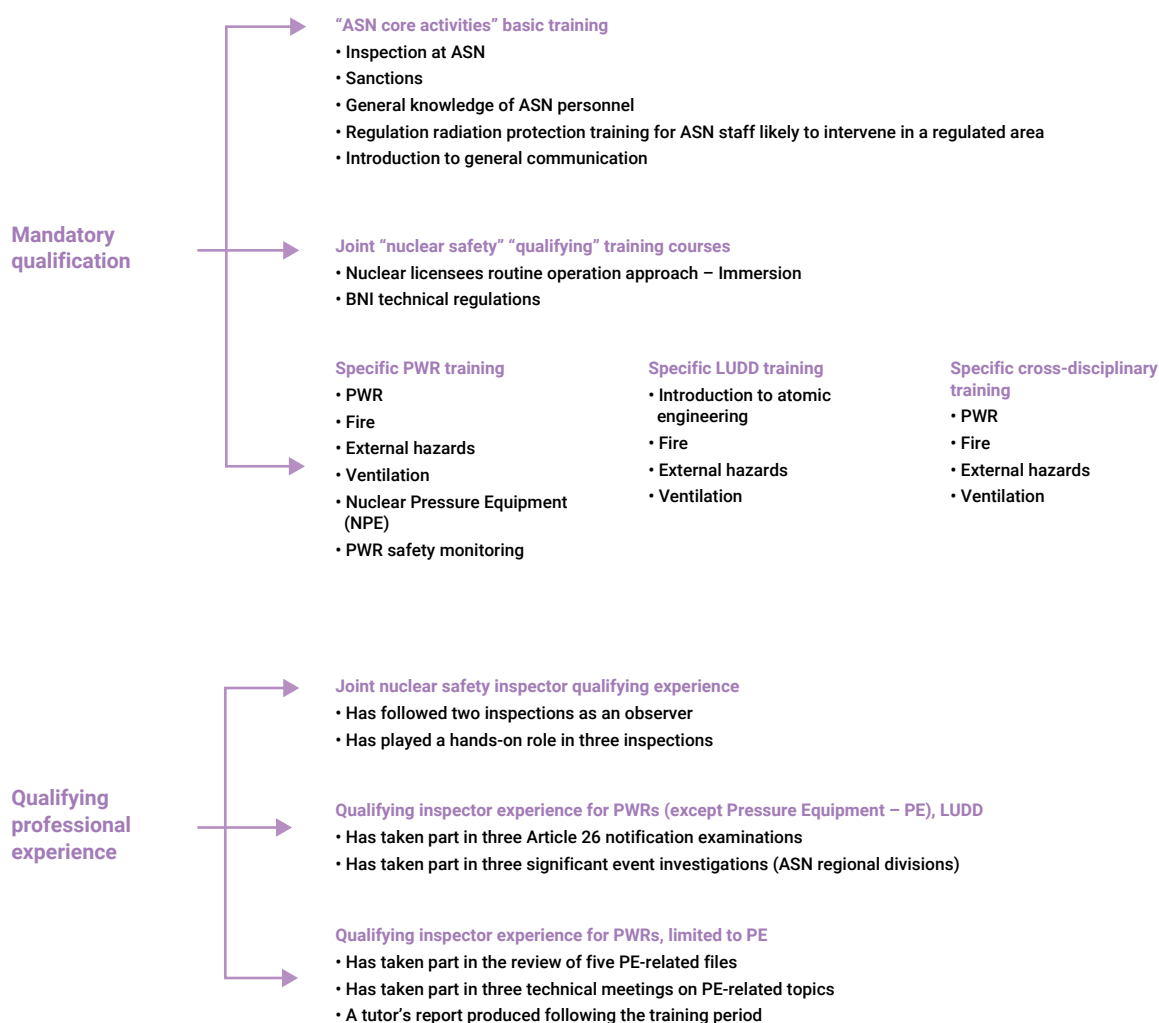
Social dialogue

As a State administration, ASN has three social dialogue bodies:

- the Local Social Administration Committee (CSAP) which replaced the Social Dialogue Committee as of 1 January 2023;
- the Joint Consultative Commission (CCP);
- the Organisation specialising in health safety and working conditions (FSSSCT) set up within the CSAP, as of 1 January 2023, and which takes over most of the duties of the former committee (Committee for Health, Safety and Working Conditions – CHSCT).

The CSAP and its specialist organisation are two bodies which allow extensive and regular discussions on all subjects affecting collective work issues.

2024 “nuclear safety” inspector training programme, Pressurised Water Reactor (PWR), Laboratories, Plants, Decommissioning and Waste (LUDD) and cross-disciplinary qualification



The CSAP deals with questions regarding the organisation and working of the departments, the strategic orientations for human resources policy and the organisation of work.

The specialist organisation is competent for topics regarding the protection of physical and mental health, hygiene, staff safety, the use of digital tools and improvements to working conditions.

The CCP is a body that is competent to examine and be consulted on certain decisions regarding the individual situation of contractual staff.

During the course of 2024, the ASN CSAP met on 14 occasions to deal with various subjects (the staff hiring and remunerations policy put in place to reinforce the attractiveness of ASN and the future ASNR, the ASNR departments organisation project, the organisation of social dialogue within ASNR as of 1 January 2025,

emergency management and the organisation of on-call work within the future ASNR, the draft internal rules of procedure of the future ASNR, incorporating SHOF into the merger between ASN and IRSN, etc.). It issued opinions on the texts presented by the administration (the internal rules of procedure of the bodies, the creation of an MRI mission, the internal procedure for collecting and processing whistle-blower alerts, an assessment of tele-working, the single social report, the travel charter, etc.).

The CSAP was specifically asked for its opinion on the bill concerning the organisation of nuclear safety and radiation protection governance, in order to address the challenge of the nuclear industry’s renewal.

For its part, the FSSSCT met twice in 2024. It placed great emphasis on taking account of occupational health and safety aspects, the prevention of occupational risks, improvement of working

conditions in the projects to modify ASN’s organisation and operations and in the performance of its duties.

It notably examined and monitored a psychosocial risks prevention plan, deployed as part of the creation of ASNR. It also updated the whistle-blower procedure (psychosocial risks, sexist and sexual violence in the workplace).

As part of its role of preventing occupational risks, the FSSSCT was informed of the intended procedure for Psychosocial Risks Management (RPS), as well as the system for sending staff to the site in the event of an emergency.

The FSSSCT also issued opinions on the radiation protection results in 2023.

The CCP, which has competence for contractual staff, had no individual situations to examine in 2024 and therefore was not convened.

Finally, the social dialogue process involved regular meetings between the personnel representatives throughout the year.

As part of the creation of ASNR planned as of 1 January 2025, 11 meetings of the merger project consultation commission met in accordance with the agreement signed in December 2023 with the trade unions of ASN and IRSN. This body supplements the personnel representative bodies of each entity and its purpose is to promote consultation between the general management and personnel representatives of ASN and IRSN. This commission thus regularly reviewed the progress of the work involved in the construction of ASNR, and of the draft decrees submitted in parallel with the respective social dialogue bodies of ASN and IRSN.

Professional ethics

The ethical rules concerning the ASN Commissioners, staff and experts, as set out in several legislative and regulatory texts since 2011, are compiled in the two appendices to the ASN internal rules of procedure adopted in 2018: the first contains provisions regarding the professional ethics of the Commissioners and staff, while the second contains provisions concerning external analysis and assessment performed at the request of ASN, for example by the GPEs (*see below*).

With the aim of preventing conflicts of interest, the rules in force at ASN more specifically include the following declaration obligations:

- Public Declaration of Interests (DPI) stipulated in Article L. 1451-1 (derived from Act 2011-2012 of 29 December 2011 on strengthening the safety of drugs and health products) and Articles R. 1451-1 *et seq.* of the Public Health Code: the 4 July 2012 decision CODEP-CLG-2012-033820 by the ASN Chairman applies the DPI requirements to the members of the Commission, the management committee and the Advisory Committee of Experts for Radiation Protection for Medical and Forensic Applications of Ionising Radiation (GPMED), now incorporated into the Advisory Committee of Experts for Radiation Protection (GPRP) and the regional delegates and regional division heads. Until mid-July 2017, the DPI were posted on *asn.fr*. The DPI are henceforth declared on the single on-line declaration site. About 60 people are subject to the DPI;
- Declarations of Interests and assets to the High Authority for Transparency in Public Life (HATVP) derived from Act 2013-907 of 11 October 2013 on Transparency in Public Life: the members of the Commission submit their declarations on the HATVP website. The same applies to the members

of the Administrative Enforcement Committee, the Director General, the Deputy Director Generals, and the General Secretary since 15 February 2017 following modification of the Act of 13 October 2013;

- “Civil Service” Declaration of Interests, set out in Article L. 122-2 of the General Civil Service Code governed by Decree 2016-1967 of 28 December 2016: the professional ethics coordinator and the ASN staff carrying out labour inspectorate duties in the NPPs are subject to this obligation;

- management by the ASN Director General of his financial instruments in conditions which preclude all right of review on his part, pursuant to Article L. 122-19 of the General Civil Service Code and Decree 2017-547 of 13 April 2017: the ASN Director General submitted justification data to the HATVP before 2 November 2017.

In a decision dated 27 January 2020, the ASN Chairman appointed Alain Dorison as professional ethics officer.

He was also appointed as secularity coordinator for internal alerts in this same decision.

He was reappointed for a further three-year term by a decision dated 30 January 2023.

A procedure (see decision CODEP-SGE-2023-024294 by the ASN Chairman of 14 April 2023) for collecting and processing internal whistle-blowing reports from staff or former staff, unsuccessful hiring candidates, outside and occasional contractor staff, or ASN co-contractors, was put into place pursuant to the “Sapin 2” Act 2016-1691 of 9 December 2016, modified by Act 2022-401 of 21 March 2022 and Decree 2022-1284 of 3 October 2022. It enables the person concerned to issue an internal report and also report information concerning a crime, a threat or a prejudice to the general interest, or a breach of the legislation of which they are personally aware or about which they were told as part of their professional activities.

Over and above implementation of the obligations recalled above, actions were also taken to raise personnel awareness of the internal professional ethics culture and prevent conflicts of interest. These were for example posting practical documents on-line on the intranet (such as prevention of conflicts of interest and the role of professional ethics oversight of departures to the private sector), the insertion of a module concerning professional ethics rules applicable to ASN staff during training sessions organised for newcomers and a video interview in which the professional ethics coordinator uses a number of examples to describe professional ethics and which actions in a person’s professional life demand particular vigilance.

Over the course of 2024, the professional ethics coordinator was contacted for 38 individual cases, broken down as follows:

- 16 opinions on a hiring;
- 8 opinions on continuation of a career;
- 4 opinions on related activities;
- 8 opinions on professional behaviour.

Financial resources

ASN’s financial resources are presented in point 3.

In its opinion 2024-AV-0438 relative to the budget for the oversight and regulation of nuclear safety and radiation protection in France for the years 2024-2025, and in the light of the framework set by Act 2024-450 of 21 May 2024 and the changes to the organisation of regulation and oversight, ASN recalls the need for human and financial resources expressed by ASN and IRSN for the 2025 budget, as an essential pre-condition for achieving the ambitious objectives of the reform. These requests, concerning both credits and jobs, must also enable ASN, and then ASNR, to prepare for the merging of the organisations (notably the convergence of the information systems).

ASN management tools

ASN’s management tools and, since 1 January 2025, those of ASNR, are more specifically evaluated during peer review missions (Integrated Regulatory Review Service – IRRS), devoted to analysis of the French nuclear safety and radiation protection oversight system.

Quality management system

To guarantee and improve the quality and effectiveness of its actions, ASN defines and implements a quality management system inspired by the international standards of the IAEA and the International Standard Organisation (ISO). This system is based on:

- an organisation manual containing organisation notes and procedures, defining the rules to be applied for each task;
- internal and external audits to check rigorous application of the system’s requirements;
- listening to stakeholders;
- performance indicators for monitoring the effectiveness of action taken;
- a periodic review of the system, to foster continuous improvement.

Internal communication

By reinforcing the internal culture and reasserting the specific nature of ASN’s remit, rallying the staff around the strategic orientations defined for their missions, and developing strong group dynamics: ASN’s internal communication, in the same way as human resources management, endeavours to foster the sharing of information and experience between teams and professions.

2.4 The consultative and discussion bodies

2.4.1 The High Committee for Transparency and Information on Nuclear Safety

The TSN Act created the High Committee for Transparency and Information on Nuclear Safety (HCTISN), an information, discussion and debating body dealing with the risks inherent in nuclear activities and the impact of these activities on human health, the environment and nuclear safety.

The HCTISN can issue an opinion on any question in these fields, as well as on controls and the relevant information. It may also examine all questions concerning the accessibility of information on nuclear safety and propose all measures such as to guarantee or improve nuclear transparency. It can be called on by the Government, Parliament, the CLIs or the licensees of nuclear facilities, with regard to all questions relating to information about nuclear safety and its regulation and oversight.

The HCTISN's activities are described in chapter 5.

2.4.2 The High Council for Public Health

The High Council for Public Health (HCSP), created by Act 2004-806 of 9 August 2004 concerning public health policy, is a scientific and technical consultative body reporting to the Minister in charge of health.

It contributes to defining the multi-year public health objectives, reviews the attainment of national public health objectives and contributes to their annual monitoring. Together with the health agencies, it provides the public authorities with the expertise necessary for managing health risks and for defining and evaluating prevention and health safety policies and strategies. It also anticipates future developments and provides advice on public health issues.

2.4.3 The High Council for Prevention of Technological Risks

Consultation about technological risks takes place before the High Council for Prevention of Technological Risks (CSPRT), created by Ordinance 2010-418 of 27 April 2010. Alongside representatives of the State, this Council comprises licensees, qualified personalities and representatives of environmental associations. The CSPRT, which takes over from the high council for classified facilities, has seen the scope of its remit extended to pipelines transporting gas, hydrocarbons and chemicals, as well as to BNIs.

The Government is required to submit Ministerial Orders concerning BNIs to the CSPRT for its opinion. ASN may also submit resolutions relating to BNIs to it.

By Decree of 28 December 2016, the scope of competence of the CSPRT was again expanded. A standing sub-committee responsible for preparing the Council's opinions in the field of PE takes the place of the Central Committee for Pressure Equipment (CCAP). The role of this sub-committee is to examine non-regulatory decisions falling within this scope of competence.

It comprises members of the various administrations concerned, persons chosen for their particular competence and representatives of the PE manufacturers and users and of the technical and professional organisations concerned.

It must be referred to by the Government and by ASN for all questions relating to Ministerial Orders concerning PE. The accident files concerning this equipment are also copied to it.

2.4.4 The Local Information Committees and the National Association of Local Information Committees and Commissions

The BNI Local Information Committees (CLIs) are tasked with a general duty of monitoring, information and consultation on the subject of nuclear safety, radiation protection and the impact of nuclear activities on humans and the environment, with respect to the facilities on the site or sites which concern them. They may request expert assessments or have measurements taken on the installation's discharges into the environment.

The CLIs, whose creation is incumbent upon the President of the General Council of the *département*, comprise various categories of members: representatives of *département* General Councils, of the municipal councils or representative bodies of the groups of municipalities and the Regional Councils concerned, members of Parliament elected in the *département*, representatives of environmental protection associations, economic interests and representative trade union and medical profession union organisations, and qualified personalities.

The status of the CLIs was defined by the TSN Act of 13 June 2006 and by Articles R. 125-50 *et seq.* of the Environment Code. It was reinforced by the 2015 TECV Act.

The duties and activities of the CLIs are described in chapter 5.

The roles of the National Association of Local Information Committees and Commissions (Anccli) are to represent the CLIs in dealings with the national and European authorities and to provide assistance to the commissions with regard to questions of common interest.

2.5 ASN technical support organisations

ASN benefits from the expertise of technical support organisations when preparing its decisions and resolutions. Up until 31 December 2024, the main organisation was IRSN. For several years now, ASN has been devoting efforts to ensuring greater diversification of its experts.

2.5.1 Institute for Radiation Protection and Nuclear Safety

Under the authority of the Ministers in charge of the environment, defence, energy, research and health respectively, the Institute for Radiation Protection and Nuclear Safety (IRSN) was created by Act 2001-398 of 9 May 2001 setting up a French environmental health safety agency and by Decree 2002-254 of 22 February 2002 as part of the national reorganisation of nuclear safety and radiation protection regulation, in order to bring together public expert assessment and research resources in these fields. These texts were subsequently modified in particular by Article 186 of the TECV Act and Decree 2016-283 of 10 March 2016 relative to IRSN.

As a State public authority carrying out industrial and commercial activities, until 31 December 2024, IRSN carried out expert analysis and assessment and research missions in the field of nuclear safety – excluding any responsibility as nuclear licensee. IRSN contributed to information of the public and published the opinions requested by a public authority or ASN, in consultation with them. It organised the publicity of scientific data resulting from the research programmes run at its initiative, with the exception of those relating to defence matters.

As the ASN Chairman was a member of the IRSN Board, ASN contributed to setting the direction of IRSN's strategic planning.

IRSN conducted and implemented research programmes in order to build its public expertise capacity on the very latest national and international scientific knowledge in the fields of nuclear and radiological risks, both nationally and internationally. It was tasked with providing technical support for the public authorities with competence for safety, radiation protection and security, in both the civilian sector, notably ASN, and the defence sector.

IRSN also had certain public service responsibilities, in particular monitoring of the environment and of persons exposed to ionising radiation.

IRSN managed national databases (national nuclear material accounting, national inventory of ionising radiation sources, file for monitoring worker exposure to ionising radiation, etc.), and thus contributed to information of the public concerning the risks linked to ionising radiation.

IRSN workforce

As at 31 December 2024, the IRSN total workforce stood at 1,789 staff; IRSN's technical support for ASN mobilised 422 full-time equivalent personnel in 2024.

IRSN budget

The IRSN budget for 2024 is presented in point 3.

A five-year agreement defined the principles and procedures for the technical support provided to ASN by the Institute. An annual protocol identified the actions to be performed by IRSN to support ASN.

2.5.2 Advisory Committees of Experts

To prepare its resolutions, ASN relies on the opinions and recommendations of seven Advisory Committees of Experts (GPEs) and a cross-cutting Advisory Committee. A distinction is made between the expert assessment requested from IRSN (see point 2.5.1) and that requested from the GPEs.

At ASN's request, the GPEs issue an opinion on certain technical dossiers with particularly high potential consequences prior to decisions being taken. The GPEs consist of experts appointed individually for their competence and are open to civil society. Their members come from university and association backgrounds and from expert assessment and research organisations. They may also be licensees of nuclear facilities or come from other sectors (industrial, medical, etc.).

Participation by foreign experts can help diversify the approach to problems and provide the benefit of experience acquired internationally.

ASN renews the composition of the Advisory Committees every four years.

All the GPEs were renewed on 1 January 2023, except for the GPRP which was created in January 2022. They will be renewed by ASN following the same procedures. In 2024, they were broken down according to their areas of expertise:

- the Advisory Committee of Experts for Nuclear Reactors (GPR),
- the Advisory Committee of Experts for Laboratories and Plants (GPU),
- the Advisory Committee of Experts for Waste (GPD),
- the Advisory Committee of Experts for Transport (GPT),
- the Advisory Committee of Experts for Nuclear Pressure Equipment (GPESPN),
- the Advisory Committee of Experts for Decommissioning (GPDEM),
- the Advisory Committee of Experts for Radiation Protection (GPRP),
- the cross-cutting Advisory Committee for Innovative Reactors (GT-RI).

For most of the subjects covered, the GPEs examine the reports produced by IRSN, by an expert working group or by one of the ASN departments. The representatives of the ASN departments or external

structures which carried out the expert assessment prior to a GPE meeting, present their conclusions to the group. Following each consultation, the GPE consulted can send the ASN Director General a written opinion, plus recommendations where necessary. The contents of the dossier are made available to the members of the GPEs so that they can reach an informed and independent conclusion. This independent perspective is of use for the decision-making process.

In addition to being consulted on the dossiers submitted by a licensee, the GPEs act as guarantor of nuclear safety and radiation protection doctrine and contribute to its development. They can be invited to take part in the debate on changes to regulations, or on a general nuclear safety or radiation protection topic.

As an expert assessment body, the members of the GPEs are required to abide by the provisions of the external expert assessment charter in Appendix 2 to the ASN internal regulations. Each GPE member produces a declaration of interest. Those of the members of the GPRP and its working group on the radiation protection of patients (GTRPP) are made public.

Internal rules of procedure common to all the GPEs are in force and notably provide a framework for identifying and managing links and conflicts of interest.

Since 2009, as part of its commitment to transparency in nuclear safety and radiation protection, ASN has published the GPE letters of referral, the opinions of the GPEs and ASN's position statements based on these opinions. IRSN for its part publishes the summaries of the technical investigation reports it presents to the GPEs.

Advisory Committee of Experts for Nuclear Reactors (GPR)

The GPR, chaired by Thierry Charles, comprises experts appointed for their competence in the field of nuclear reactors. It comprises 36 members.

Advisory Committee of Experts for Laboratories and Plants (GPU)

The GPU is chaired by Alain Dorison and comprises experts appointed for their competence in the field of laboratories and plants concerned by radioactive substances. It comprises 30 members.

Advisory Committee of Experts for Waste (GPD)

The GPD is chaired by Marie-Pierre Comets and comprises experts appointed for their competence in the nuclear, geological and mining fields. It comprises 35 members.

Advisory Committee of Experts for Transport (GPT)

The GPT is chaired by Pierre Maleysis and comprises experts appointed for their competence in the field of the transport of radioactive materials. It comprises 26 members.

Advisory Committee of Experts for Nuclear Pressure Equipment (GPESPN)

The GPESPN is chaired by Matthieu Schuler and comprises experts appointed for their competence in the field of NPE. It has 33 members.

Advisory Committee of Experts for Decommissioning (GPDEM)

The GPDEM comprises experts appointed for their competence in the field of BNI decommissioning. It comprises 31 members and the interim Chair is Dorotheé Conte, vice-chair of the GPDEM.

Advisory Committee of Experts for Radiation protection (GPRP)

Chaired by Mr Jean-Luc Godet, the GPRP comprises 36 experts appointed for their competence in the fields of:

- radiation protection of workers, the public and the environment, for the medical and forensic, veterinary, industrial and research applications of ionising radiation, as well as for naturally occurring ionising radiation (radon, cosmic or terrestrial radiation);
- radiation protection of patients.

Owing to the specific nature of the subjects regarding the radiation protection of patients, a working group dedicated to the radiation protection of patients (GTRPP) reports to the GPRP. The GTRPP is chaired by Thierry Sarrazin and comprises 25 experts, nine of whom are shared with the GPRP.

Cross-cutting Advisory Committee for Innovative Reactors (GT-RI)

The GT-RI, chaired by Thierry Charles, was created in June 2024 in order to shed light on technical subjects relating to the arrival of new and innovative industrial or experimental prototype SMR projects, using a technology other than that of the PWRs. It can be questioned on all the subjects examined, that is the nuclear safety of the reactors concerned, with regard to the technical, organisational and human, radiation protection, environmental protection, safety-security interfaces, or emergency situation management aspects. It comprises 16 members from the Advisory Committees (GPR, GPESPN, GPU, GPD and GPDEM).

2.5.3 Scientific Committee

ASN calls on the expertise of a Scientific Committee reporting to the ASN Commission, in order to assist it with identifying research subjects to be conducted or taken further in the fields of nuclear safety and radiation protection, a mission entrusted to it by the Environment Code. The current members of the Scientific Committee were appointed by the Commission on the basis of their competence, notably in the fields of radiation protection and nuclear safety research. During the course of the year, its chairman Michel Schwarz and three of its members: Philippe Maingon, Jean-Claude Micaelli and Marc Vannerem, decided to leave

TABLE 1 Advisory Committee meetings in 2024

GPE	Date	Main topic
GPR	1 February 2024	• Information meeting – Presentation of the Nuward project.
GPD	22 March 2024	• Meeting to prepare the session of 24 and 25 April 2024 concerning the Cigéo Creation Authorisation Decree – Evaluation of basic data adopted for the Cigéo safety assessment.
GPU	4 April 2024	• GPU opinion on the periodic safety review file of the Orano Recyclage BNI 116 (plant UP3-A) at La Hague devoted to units T1, T3 and T5.
GPD	24 and 25 April 2024	• GPD opinion on the first GP – Cigéo Creation Authorisation Decree – Evaluation of basic data adopted for the Cigéo safety assessment.
GTRPP	23 May 2024	• Presentation of the report on the recommendations to promoters with respect to clinical trials. • Presentation of progress of “CBCT dental”. • Presentation of the IRSN report on “flash radiotherapy” and creation of a collection of data on adaptive radiotherapy techniques in France.
GPU	4 June 2024	• Visit to BNI 151, Melox, Orano Recyclage Marcoule.
GPESPN	7 June 2024	• GPESPN opinion on the stress corrosion cracks detected on the austenitic steel auxiliary lines of the main primary system of various PWRs.
GPRP	11 June 2024	• Presentation of the report on the draft opinion regarding recommendations to promoters with respect to clinical trials. • Presentation of the IRSN report and its recommendations for the use of the effective dose coefficients of publication 144 from the International Commission on Radiological Protection and the Federal guidance Reports 12 and 15, concerning external exposure to radionuclides.
GPDEM	20 June 2024	• GPDEM opinion on the ASN draft Guide <i>Decommissioning Plan for Basic Nuclear Installations</i> .
GPR	25 June 2024	• GPR opinion on the guidelines for the 5th periodic safety review of the 900 MWe reactors.
GPU	27 June 2024	• GPU opinion on the second periodic safety review of BNI 151, Melox, Orano Recyclage Marcoule.
GPR	3 and 4 July 2024	• GPR opinion on the examination of the internal and external hazards studies of the 4th periodic safety review of the 1,300 MWe reactors.
GTRPP	24 September 2024	• Presentation of draft “CBCT Dental” report and discussion of recommendations. • Presentation of report on radiation protection issues linked to the use of digital tools in the health sector.
GPRP	15 October 2024	• Presentation of report and draft “CBCT Dental” opinion. • Presentation and validation of draft mission letter to extend the GIMS WG. • Presentation by the experts of the GPRP who were associated with the GPU on the 2nd periodic safety review of BNI 151.
GPR	17 October 2024	• GPR opinion on experience feedback from EDF PWRs for the year 2022.
GPR	14 and 15 November 2024	• GPR opinion on the severe accident studies carried out for the 4th periodic safety review of the 1,300 MWe reactors.
GPESPN	22 November 2024	• GPESPN opinions on the stress corrosion cracks detected on the austenitic steel auxiliary lines of the main primary system of various PWRs.
GPD	26 November 2024	• Meeting to prepare the session of 10 and 11 December 2024 concerning the Cigéo creation authorisation Decree – Safety assessment in the operations phase of the surface and underground facilities.
GTRPP	28 November 2024	• Presentation of the <i>Equipment Study</i> report. • Presentation of a collection of data on adaptive radiotherapy techniques in France (ICM).
GPDEM	29 November 2024	• Information meeting - ASN feedback on the draft Guide <i>Decommissioning Plan for Basic Nuclear Installations</i> .
GPR	4 and 5 December 2024	• GPR opinion on the accident studies carried out for the 4th periodic safety review of the 1,300 MWe reactors.
GPD	10 and 11 December 2024	• GPD opinion on the 2nd GP Cigéo Creation Authorisation Decree – Safety assessment in the operations phase of the surface and underground facilities.
GPESPN	17 and 18 December 2024	• GPESPN opinion on the in-service resistance of the core zone of the 1,300 MWe reactor pressure vessels during the ten-year period following their 4th ten-yearly outage and the calculation methods used in the revision of the regulatory reference files.

the Committee. At the end of 2024, the Committee consists of Christophe Badie, Benoît De Boeck, Catherine Luccioni and Jean-Marc Cavedon, who acted as interim chairman of the Committee up to the end of the year.

The Scientific Committee held two annual plenary meetings in 2024. It issued an opinion on the research work to be conducted and/or continued on the ageing of the metal materials in components that it is impossible or difficult to replace in nuclear power reactors, with a view to a decision on their continued operation up to and beyond 60 years. The opinion is published on *asn.fr*.

As part of its investigations into the health effects arising from combined exposure to chemical pollutants and radionuclides, the Scientific Committee continued its meetings with research organisations including Andra, the French Agency for Food, Environment and Occupational Health and Safety – Anses, CEA, EDF, IRSN concerning epidemiological and ecotoxicological aspects, *Santé publique France*, and the members of the Anccli. The Committee issued its opinion on the identification of research on the subject at the end of 2024. It will be published on *asn.fr* in 2025.

The mandate of the ASN Scientific Committee ended on 31 December 2024 with the construction of ASNR and the creation of a Scientific Council, the role of which will be to support ASNR in the performance of its duty to identify research subjects to be examined or taken further in the fields of nuclear safety and radiation protection (Article L. 592-28-2 of the Environment Code).

2.5.4 ASN's other technical support organisations

To diversify its expertise and benefit from other particular skills, ASN in 2024 committed credits of about €350,000 and paid €450,000.

ASN was thus able to finance the expert assessments needed for review of the safety analyses submitted by CEA concerning the Cabri nuclear facility, for analysis of the experience feedback from construction of the FA3 reactor with regard to organisational and human factors, in order to identify the areas for monitoring of the EPR 2 reactors, expert assessment of the non-radiological aspects of the safety analysis reports for the EPR 2 reactor in Penly and the 900 MWe reactors in Chinon, as well as expert assessment of the impact assessment for the Penly EPR 2 reactors. It also supported the work by a post-doctoral researcher aimed at analysing ASN safety culture through its regulation

and oversight policy. Finally, it financed the creation of an adaptive technology patient monitoring register, as well as the production of an inventory of teleradiology services and practices, the results of which were published on *asn.fr*.

2.6 The pluralistic working groups

ASN has set up several pluralistic working groups; they enable the stakeholders to take part in developing doctrines, defining action plans or monitoring their implementation.

2.6.1 The working group on the National Radioactive Material and Waste Management Plan

Article L. 542-1-2 of the Environment Code requires the drafting of a National Radioactive Material and Waste Management Plan (PNGMDR), which is revised every five years and serves to review the existing management procedures for radioactive materials and waste, to identify the foreseeable needs for storage and disposal facilities, specify the necessary capacity of these facilities and the storage durations and, for radioactive waste for which there is as yet no final management solution, determine the objectives to be met.

The Working Group (WG) tasked with implementing the PNGMDR notably comprises environmental protection associations, experts, representatives from industry and regulatory authorities, alongside the radioactive waste producers and managers. It is co-chaired by the General Directorate for Energy and the Climate and by ASN.

This WG is part of the new governance system for the PNGMDR, which also comprises a "Guidance Committee" whose role is to inform the Ministry regarding the strategic implications of the Plan and in which ASN is a participant, although it has no voting rights.

Chapter 15 presents the PNGMDR and its governance system in greater detail.

2.6.2 The Steering Committee for Managing the Nuclear Post-Accident Phase

Pursuant to an Interministerial Directive of 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation, ASN – together with the ministerial departments concerned – is tasked with defining, preparing for and implementing the necessary measures to manage a post-accident situation.

In order to develop a doctrine and after testing post-accident management during national and international exercises, ASN brought all the players concerned together within the Steering Committee responsible for Post-Accident Management (Codirpa).

This Committee, headed by ASN, has representatives from the ministerial departments concerned, the health agencies, associations, the CLIs, and IRSN.

The work of the Codirpa is presented in greater detail in chapter 4.

2.6.3 The Committee for the Analysis of New Techniques and Practices using Ionising Radiation

The Committee for the Analysis of New Techniques and Practices using Ionising Radiation (Canpri) was created on 8 July 2019.

This Committee is chaired by ASN and comprises 14 experts from professional organisations, appointed by ASN, along with representatives of the French health institutions (National Authority for Health – HAS, National Agency for the Safety of Medicines and Health products – ANSM, National Cancer Institute – INCa, IRSN) as well as the Ministries responsible for health. Canpri's aim is to identify new techniques and practices in the medical field, analyse their radiation protection implications and to produce recommendations and conclusions, notably on the justification for these new techniques and practices, as well as on patient and worker radiation protection.

The subjects dealt with by Canpri notably concern the installation in France of the ZAP-X gyroscopic radiosurgery platform, and the "flash" effect in radiotherapy. For more details on these subjects refer to point 1.3.2 of chapter 7.

2.6.4 The other pluralistic working groups

Considering that it was necessary to move forward with regard to the deliberations and the work being done on the contribution of humans and organisations to the safety of nuclear facilities, ASN decided in 2012 to set up the Steering Committee for Social, Organisational and Human Factors (Cofsoh). The Cofsoh is a multi-disciplinary, pluralistic body. It is chaired by ASN. It is open to institutional representatives, environmental protection associations, RNAs, experts in human and social sciences, the CLIs, professional federations of the nuclear industries and representative employee trades union organisations. Since 2024, the Cofsoh has been organising thematic cycles lasting one year.

ASN also heads the national committee in charge of monitoring the National Plan for Radon Risk Management. The 4th plan was intended to cover the period 2020-2024. The Covid-19 pandemic crisis delayed the completion of the regulatory system and the launch of certain measures. The plan is therefore prolonged for a period of two years. The indicators analysis was published for the first time in 2024 (see chapter 1). Within the context of this plan, ASN has since 2018 been overseeing a WG in charge of coordinating radon risk management communication actions, which meets twice a year.

2.7 The other stakeholders

As part of its missions to protect the general public from the health risks of ionising radiation, ASN cooperates closely with other institutional stakeholders with competence for health issues.

2.7.1 The National Agency for the Safety of Medicines and Health Products

The National Agency for the Safety of Medicines and Health Products (ANSM)

was created on 1 May 2012. The ANSM, a public institution reporting to the Ministry in charge of health, has taken up the functions of the French Health Products Safety Agency (AFSSAPS) alongside other new responsibilities. Its key roles are to offer all patients equitable access to innovation and to guarantee the safety of health products throughout their life cycle, from initial testing through to monitoring after receiving marketing authorisation. The site ansm.sante.fr presents the Agency and its actions. This agreement is currently being renewed.

2.7.2 French National Authority for Health

The essential role of French National Authority for Health (HAS), an independent administrative Authority created in 2004, is to maintain an equitable health system and improve the quality of patient care. The site has-sante.fr presents the Authority and its actions.

There has been an ASN-HAS agreement since 2008; it was renewed on 2 March 2021 for a six-year period. An ASN-HAS action plan is appended to this agreement and is regularly updated.

2.7.3 French National Cancer Institute

Created in 2004, the French National Cancer Institute (INCa) is primarily responsible for coordinating activities in the fight against cancer. The site e-cancer.fr presents the Institute and its actions. Regular discussions take place between INCa and ASN.

2.8 The safety regulators: an international comparison

Table 2 describes the status and activities of the safety regulators. In terms of status, most of these regulatory authorities are Government or independent agencies. With regard to their activities, most of them regulate and oversee the complete spectrum of nuclear activities, including in terms of protection against malicious acts (except for France with regard to malicious acts).

TABLE 2 Status and activities of the main civil nuclear safety regulators^(*) in 2024

Country / Regulatory Authority	Status			Activities						
	Adminis- tration	Govern- ment agency	Independent agency	Safety of civil facilities	Radiation protection			Security (protection against malicious acts)		Transpor safety
					Large nuclear installa- tions	Outside BNIs	Patients	Sources	Nuclear materials	
Europe										
Germany/Bmub + <i>Länder</i>	■			■	■	■	■	■	■	■
Belgium/AFCN		■		■	■	■	■	■	■	■
Spain/CSN			■	■	■	■	■	■	■	■
Finland/STUK		■		■	■	■	■	■	■	■
France/ASN			■	■	■	■	■	■(**)		■
United Kingdom/ONR		■		■	■			■	■	■
Sweden/SSM		■		■	■	■	■	■	■	■
Switzerland/ENSI			■	■	■				■	■
Other countries										
Canada/CCSN			■	■	■	■	■	■	■	■
China/NNSA	■			■	■	■		■	■	■
Korea/NSSC		■		■	■	■		■	■	■
United States/NRC			■	■	■	■	■	■	■	■(***)
India/AERB		■		■	■	■	■	■	■	■
Japan/NRA		■	■	■	■	■	■	■	■	
Russia/ <i>Rostekhnadzor</i>	■	■		■	■			■	■	■
Ukraine/SNRIU	■	■		■	■	■		■	■	■

* Schematic and simplified representation of the main areas of competence of the entities (administration, independent agencies within government or independent agencies outside government) responsible for regulating nuclear activities in the world's nuclear countries.

** Responsibility for source security was given to ASN by the Ordinance of 10 February 2016. This provision came into force on 1 July 2017.

*** National transports only.

3 — Financing the regulation of nuclear safety and radiation protection

Since 2000, all the personnel and operating resources involved in the performance of the responsibilities entrusted to ASN have been covered by the State's general budget.

In the 2024 Budget Act, the ASN budget (action 9 of programme 181 "Risk prevention") amounted to €75.19 million in payment credits. It included €57.04 million for personnel expenses and €18.15 million in payment credits for operating credits for ASN head office departments and its 11 regional divisions, and intervention credits.

The ASN's budget is divided among five different public policy programmes:

- action 9 "Regulation and oversight of nuclear safety and radiation protection" of programme 181 "Risk prevention" covers the ASN workforce and personnel credits, as well as the operating, investment and intervention spending incurred for the performance of its duties;
- in addition, a certain number of operating costs (for the headquarters and the divisions) are incorporated into the support programmes of the Ministry for the Economy, Finance and industrial and digital Sovereignty (programme 218), of the Ministry for Ecological Transition, Biodiversity, Forests, the Sea and Fisheries

(programme 217) and the Ministry of the Interior (programme 354). ASN's assets for these various programmes, in terms of both actions carried out for ASN and credits, cannot be identified with any accuracy owing to the overall, shared nature of these programmes;

- finally, pursuant to the provisions of Article L. 592-14 of the Environment Code, "ASN is consulted by the Government regarding the share of the State subsidy to IRSN corresponding to the technical support mission performed by this Institute on behalf of ASN". These ASN support credits are part of action 11 "Research in the field of risks" of programme 190 "Research in the fields of sustainable energy, development and mobility".

The total IRSN budget for 2024 amounted to €307 million, of which €88.4 million were devoted to the provision of technical support for ASN. IRSN credits for providing ASN with technical support come in part (€45.1 million) from programme 190 (see below). The rest (€41.3 million) comes from a contribution from the nuclear licensees. This contribution was set up under Budget Amendment Act 2010-1658 of 29 December 2010. It notably aims to finance the expert assessment of

the safety analysis files submitted by the BNI licensees.

Moreover, in the light of a rise in spending linked to inflation effects (mainly concerning salary levels, and operations) affecting all of IRSN's activities, including technical support for ASN, additional funding was obtained by drawing on the establishment's working capital for the financial year 2024.

In total, the State's 2024 budget for transparency and the regulation of nuclear safety and radiation protection in France, amounted to €313.76 million.

By way of comparison, the amount of taxes collected by ASN in 2024 amounted to €758.48 million:

- €557.67 million from BNI taxes (paid into the State's general budget);
- €122.85 million from additional "support", "disposal" and "research" taxes (allocated to various establishments, including Andra, municipalities and Public Interest Groupings – GIP);
- €77.96 million from the special contribution for the management of radioactive waste (allocated to Andra).

BNI TAX, additional "research", "support" and "disposal" taxes, special Andra contribution and contribution to IRSN

Pursuant to the Environment Code, the ASN Chairman is responsible for assessing and ordering payment of the BNI tax, introduced under Article 43 of the 2000 Budget Act (Act 99-1172 of 30 December 1999). The revenue generated by this tax, the amount of which is set yearly by Parliament, came to €557.67 million in 2024. The proceeds go to the central State budget.

For certain BNIs, said Act also creates three additional taxes, known as "research", "support" and "disposal", respectively. The revenue from these taxes amounted to €122.85 million in 2024 and is paid to

the Objectif Meuse et Haute-Marne public interest groupings ("support"), the municipalities and public inter-municipal cooperation bodies ("disposal") and Andra ("research"), in addition to the revenue from the special contribution.

In addition, since 2014, ASN has been tasked with assessing and ordering payment of the special contribution on behalf of Andra created by Article 58 of the 2013 Budget Amendment Act 2013-1279 of 29 December 2013, which will be payable up until the date of the deep geological disposal facility's creation authorisation.

In the same way as the additional taxes, this contribution is due by BNI licensees, as of the creation of their facility and up until the delicensing decision. The revenue from this contribution represents €77.96 million in 2024.

Finally, Article 96 of Act 2010-1658 of 29 December 2010 creates an annual contribution to IRSN to be paid by BNI licensees. This contribution is in particular set aside to finance the review of the safety cases submitted by the BNI licensees. The revenue from this contribution amounts to €60.51 million in 2024.

TABLE 3 Breakdown of licensee contributions

Licensee	Amount for 2024 (millions of euros)			
	BNI tax	Additional waste and disposal taxes	Special Andra contribution	Contribution on behalf of IRSN
EDF	530.60	96.67	63.00	47.48
Orano-Framatome	17.60	6.20	4.00	5.62
CEA	3.90	15.01	10.96	6.30
Andra	4.35	3.30	–	0.40
Others	1.22	1.67	–	0.71
Total	557.67	122.85	77.96	60.51

4 — Outlook

The year 2025 will be marked by the appearance of the new Authority for Nuclear Safety and Radiation Protection. This will be accompanied by new internal rules of procedure, new governance for its operations, and new social dialogue bodies pending the professional elections to be held no later than March 2026. Modifications will be made to the organisation, in the light of the 1 January decision to juxtapose the two existing organisations, with the partial exception of cross-cutting functions. ASNR financing will now be covered by a new budget programme (programme 235) set up under the 2025 Budget Act.

A professional ethics Commission will be created in accordance with the provisions of Article L. 592-13-2. It will notably be tasked with issuing an opinion on general questions relative to the application of the rules of professional ethics in the ASNR departments, or questions relating to individual situations.

A Scientific Council will be created in application of the provisions of Article L. 592-28-3 of the Environment Code. The composition of this Council will reflect the diversity of scientific fields. It will notably be consulted regarding ASNR's scientific strategy and research programmes.

The GPEs will continue their missions as per the provisions set out in Article L. 592-13-3. The same will apply for the Administrative Enforcement Committee which will continue its missions under the ASNR.

No later than 1 July 2025, ASNR will evaluate the anticipated human, technical and financial resources it will need for the coming five years in order to carry out its missions and will present its proposals to the Government and to the OPECST. On this same date, it will submit a first report to OPECST on the conditions of its creation.

TABLE 4 Budget structure of the credits allocated to transparency and the regulation of nuclear safety and radiation protection in France

Mission	Programme	Action	Nature	Budget resources				Revenue
				Initial budget Act 2023 AE (€M)	Initial budget Act 2023 CP (€M)	Initial budget Act 2024 AE (€M)	Initial budget Act 2024 CP (€M)	BNI Tax 2024 (€M)
Ministerial mission Ecology, sustainable development and spatial planning	Programme 181: Risk prevention	Action 9: Regulation of nuclear safety and radiation protection	Staff costs (including seconded employees)	53.79	53.79	57.04	57.04	557.67
			Operating and intervention expenditure	13.13	17.83	13.45	18.15	
			Total	66.92	71.62	70.49	75.19	
		Action 1: Prevention of technological risks and pollution	Operation (evaluation) of High Committee for Transparency and Information on Nuclear Safety	0.15	0.15	0.15	0.15	
		Sub-total			67.07	71.77	70.64	
Ministerial mission Oversight of Government actions	Programme 217: Management and coordination of policies for ecology, sustainable development and mobility Programme 354: State's regional administration	–	Part of the shared operation of ASN's 11 regional divisions (real estate, etc.)	The credits allocated to ASN for these various programmes cannot be identified owing to the overall, shared nature of these programmes				557.67
Interministerial mission Management of public finances and human resources	Programme 218: Implementation and coordination of economic and financial policies	–	Part of the shared operation of the ASN central services					
Interministerial mission Research and higher education	Programme 190: Research in the fields of energy and sustainable development and spatial planning	Sub-action 11-2 (area 3): Institute for Radiation Protection and Nuclear Safety	IRSN technical support activities for ASN	43.70	43.70	45.1	45.1	
		Sub-action 11-2 (3 other areas): French Institute for Radiation Protection and Nuclear Safety	–	135.70	135.70	137.52	137.52	
Annual contribution on behalf of IRSN instituted by Article 96 of budget amendment Act 2010-1658 of 29 December 2010 dedicated to IRSN's activities (apart from technical support for ASN)			–	19.27	19.27	19.2	19.2	
Annual contribution on behalf of IRSN instituted by Article 96 of budget amendment Act 2010-1658 of 29 December 2010 dedicated to IRSN's activities in support of ASN			–	41.43	41.43	41.30	41.30	
			Sub-total	240.10	240.10	243.12	243.12	557.67
Grand Total (excluding IRSN and programmes 217, 218 and 354)				152.20	156.90	156.89	161.59	557.67
ASN and IRSN Grand Total (excluding programmes 217, 218 and 354)				307.17	311.87	313.76	318.31	

ASN's lease was renewed early for a firm period of 9 years in 2021. The commitment was made in 2021 for a total amount of €38.3 million, which includes the rent, charges and estimated taxes, which explains the exceptional amount of the commitment authorisation by comparison with the other years.

03

**Regulation of
nuclear activities
and exposure to
ionising radiation**



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In France, the party Responsible for a Nuclear Activity (RNA) must ensure that this activity is safe and may not delegate this responsibility. They must ensure permanent monitoring of both this activity and the equipment used. Given the risks linked to ionising radiation for humans and the environment, the State regulates nuclear activities, a task it has entrusted to the French Nuclear Safety Authority (ASN). With the aim of ensuring greater administrative efficiency, ASN has also been entrusted with the oversight of regulations concerning the environment and Pressure Equipment (PE) in Basic Nuclear Installations (BNIs).

Control and regulation of nuclear activities is a fundamental responsibility of ASN. Its primary goal is to ensure that an RNA effectively assumes its obligations. ASN has a vision of control and regulation encompassing material, organisational and human aspects. Following safety and radiation protection assessments in each activity sector, ASN implements its oversight action by issuing resolutions, prescriptions, inspection follow-up letters, plus penalties as applicable.

The oversight priorities are defined with regard to the risks inherent in the activities, the means deployed by those responsible for the activities to control them and their behaviour. In the priority areas, ASN must reinforce its oversight. Conversely, for lower-risk areas, ASN must be able to explicitly apply a graded approach in a way of its regulation and oversight.

1 — Verifying that the licensee assumes its responsibilities

1.1 The principles of ASN's oversight duties

ASN's oversight aims primarily to ensure that those responsible for an activity effectively assume their obligations and comply with the requirements of the regulations concerning nuclear safety and radiation protection, in order to protect persons and the environment from the risks linked to radioactivity and to the operation of nuclear facilities.

It applies to all the phases in the performance of the activity, including the decommissioning phase for nuclear installations:

- before the licensee exercises an activity subject to authorisation, by reviewing and analysing the files, documents and information provided by the licensee to justify its project with regard to safety and radiation protection. This verification aims to ensure that the information and demonstration supplied are both relevant and sufficient;

- during exercise of the activity, by visits, inspections, verification of licensee operations entailing significant potential consequences, review of reports supplied by the licensee and analysis of significant events. This oversight includes an analysis of any justifications provided by the licensee.

ASN applies the principle of a graded approach when determining its actions, so that the scope, conditions and extent of its regulatory action are commensurate with the human and environmental protection implications involved.

When applicable, this oversight can call on the support of the French Institute for Radiation Protection and Nuclear Safety (IRSN). Since 1 January 2025, the ASN regulation/oversight and IRSN expert assessment missions have been combined within the Authority for Nuclear Safety and Radiation Protection (ASNR).

1.2 The scope of regulation of nuclear activities

Article L. 592-22 of the Environment Code states that ASN must regulate compliance with the general rules and particular requirements of safety and radiation protection, applicable to:

- the BNI licensees;
- the manufacturers and users of Nuclear Pressure Equipment (NPE) used in the BNIs;
- those in charge of Radioactive Substances Transport (TSR);

- the persons responsible for activities entailing a risk of exposure of persons and workers to ionising radiation, including medical applications of ionising radiation;
- those in charge of implementing ionising radiation exposure monitoring measures, such as both the approved organisations and laboratories;
- the nuclear licensees, their suppliers, contractors or sub-contractors when they carry out activities important for the protection of persons and the environment outside the perimeter of the BNIs.

In this chapter, these persons or entities are called the "licensees".

In addition, within the BNIs, the ASN inspectors have rights and prerogatives given to the environmental inspectors to verify the provisions regarding protection of the environment.

ASN also oversees the organisations and laboratories that it approves in order to take part in the inspections and oversight of nuclear safety and radiation protection.

Finally, ASN carries out labour inspection duties in the NPPs (see chapter 10).

2 — Ensuring that regulation is proportionate to the implications

ASN aims to organise its regulatory work in a way that is proportionate to the implications of the activities. It follows a continuous improvement approach to its regulation and oversight practices in order to consolidate the effectiveness and quality of its actions. ASN uses the Operating Experience Feedback (OEF) from more than forty years of nuclear activity oversight and the exchange of best practices with its foreign counterparts.

The licensee is the key player in the regulation of its activities.

ASN regulates nuclear activities by various means:

- inspection, generally on the site, or in an inspected department, or at carriers of radioactive substances. It consists in performing sample checks on the conformity of a given situation with regulatory or technical baseline requirements but may also include an assessment of the licensee's practices by comparison with current best practices;
- authorisation, following analysis of the applicant's demonstration that its activities are satisfactorily managed in terms of radiation protection and safety;
- OEF, more specifically through analysis of significant events;
- approval of organisations and laboratories taking part in radioactivity measurements and radiation protection inspections, as well as qualification of PE monitoring organisations;
- presence in the field, also frequently outside actual inspections;
- consultation with the professional organisations (trades unions, professional orders, professional organisations, etc.).

The performance of certain inspections by organisations and laboratories offering the necessary guarantees, as validated by ASN approval or qualification, contributes to the oversight of nuclear activities.

2.1 Oversight by ASN

The licensee is required to provide ASN with the information it needs to meet its regulatory responsibilities. The volume and quality of this information should enable ASN to analyse the technical demonstrations presented by the licensee and target the inspections. It should also allow identification and monitoring of the important events marking the operation of a nuclear activity.

Regulation and monitoring of Basic Nuclear Installations

Nuclear safety is the set of technical provisions and organisational measures related to the design, construction, operation, shutdown and decommissioning of BNIs, as well as TSR, which are adopted with a view to preventing accidents or

limiting their effects. This notion includes the measures taken to optimise waste and effluent management.

The safety of nuclear installations is based on the following principles, defined by the International Atomic Energy Agency (IAEA) in its fundamental safety principles for nuclear installations (Safety series No. 110) and then to a large extent incorporated into the European Directive on Nuclear Safety of 8 July 2014, which modifies that of 2009:

- responsibility for nuclear safety lies primarily with the licensee;
- the organisation responsible for regulation and oversight is independent of the organisation responsible for promoting or using nuclear power. It must have responsibility for licensing, inspection and formal notice, and must have the authority, expertise and resources necessary for performance of the responsibilities entrusted to it. No other responsibility shall compromise or conflict with its responsibility for safety.

In France, the Environment Code defines ASN as the organisation meeting these criteria, except for Defence-related nuclear facilities and activities, which are regulated by the provisions of the Defence Code.

Ordinance 2016-128 of 10 February 2016 implementing the Energy Transition for Green Growth Act 2015-992 of 17 August 2015 (TECV Act) expanded the scope of ASN regulation to the suppliers, contractors and subcontractors of licensees, including for activities performed outside BNIs.

In its regulatory duties, ASN is required to look at the equipment and hardware in the installations, the individuals in charge of operating it, the working methods and the organisation, from the start of the design process up to decommissioning. It reviews the steps taken concerning nuclear safety and the monitoring and limitation of the doses received by the individuals working in the facilities, and the waste management, effluents discharge monitoring and environmental protection procedures.

Regulatory oversight of Pressure Equipment

Numerous systems in nuclear facilities contain or carry pressurised fluids. In this respect they are subject to the regulations applicable to PE, which include NPE.

The Environment Code states that ASN is the administrative Authority with competence for issuing individual resolutions and checking the in-service monitoring of the pressure equipment installed within the perimeter of a BNI.

PE operation is regulated. This regulation in particular applies to the in-service monitoring programmes, non-destructive

testing, maintenance work, disposition of nonconformities affecting these systems and periodic requalification.

ASN also assesses the compliance of the most important new NPE with the requirements of the regulations. It approves and monitors the organisations responsible for assessing the conformity of the other NPE.

Regulation and monitoring of the transport of radioactive substances

Transport comprises all operations and conditions associated with movements of radioactive substances, such as packaging design, manufacture, maintenance and repair, as well as the preparation, shipment, loading, carriage, including storage in transit, unloading and receipt at the final destination of the radioactive substance consignments and packages.

Regulation and monitoring of activities comprising a risk of exposure to ionising radiation

In France, ASN is in charge of drafting and overseeing technical regulations concerning radiation protection.

The scope of ASN's regulatory role in radiation protection covers all the activities that use ionising radiation. ASN exercises this duty, where applicable, jointly with other State services such as the Labour Inspectorate, the Inspectorate for Installations Classified for Protection of the Environment (ICPEs), the departments of the Ministry of Health and the French National Agency for Medicines and Health Products Safety (ANSM).

This action directly concerns either the users of ionising radiation sources, or organisations approved to carry out technical checks and inspections on these users.

The methods of regulating the radiation protection players are presented in Table 1. They were updated with the June 2018 publication of the Decrees transposing European Directive 2013/59/Euratom of 5 December 2013 setting the Basic Standards for Health Protection against the dangers arising from exposure to ionising radiation.

Regulating the application of Labour Law in the Nuclear Power Plants

ASN is responsible for labour inspectorate duties in the 18 Nuclear Power Plants (NPPs), the Flamanville EPR reactor commissioned in May 2024 and 11 other installations, most of which are reactors undergoing decommissioning. The regulation of safety, radiation protection and labour inspection very often covers common topics, such as worksite organisation or the conditions of use of outside contractors.

The ASN labour inspectors have four essential duties:

TABLE 1 Methods of ASN regulation of the various radiation protection players

	Examination/Autorisation	Inspection	Cooperation
Users of ionising radiation sources	- Examination of the files required by the Public Health Code (Articles R. 1333-1 et seq.) - Pre-commissioning inspection, mainly in the medical field - Receipt of notification, registration or issue of authorisation (Article R. 1333-8)	Radiation protection inspection (Article L. 1333 -29 of the Public Health Code).	Jointly with the professional organisations, drafting of guides of good practices for users of ionising radiation
Organisations approved for radiation protection checks	- Examination of approval application files for performance of inspections required by Article R. 1333 -172 of the Public Health Code - Audit of the Organisation - Delivery of approval	- Second level inspection: - in-depth inspections at head office and in the branches of the organisations - unannounced field supervision inspections	Jointly with the professional organisations, drafting of rules of good practice for performance of radiation protection checks

- checking application of all aspects of labour legislation (health, occupational safety and working conditions, occupational accident inquiries, quality of employment, collective labour relations);
- advising and informing the employers, employees and personnel representatives about their rights, duties and labour legislation;
- informing the administration of changes in the working environment and any shortcomings in the legislation;
- facilitating conciliation between the parties.

The ASN labour inspectors have the same powers and the same prerogatives as common law labour inspectors. They belong to the labour inspectorate system for which the central authority is the General Directorate for Labour.

The duties of the labour inspectors are based on international standards (International Labour Organisation – ILO – Convention No. 81) and national regulations. ASN carries them out in liaison with the other Government departments concerned, mainly the departments of the Ministry responsible for labour.

ASN has set up an organisation designed to deal with these issues. The action of the ASN labour inspectors (20 staff qualified as labour inspectors by ASN, representing 8.5 Full-Time Equivalent – FTE – two of whom are for the labour inspectorate mission) has been reinforced in the field since 2009, particularly during reactor outages, with inspection visits, advisory roles at the meetings of the Committee for Health, Safety and Working Conditions (CSSCT) and the Inter-company Committees on Safety and Working Conditions, as well as regular discussions with the social partners.

2.2 Internal checks performed by the licensees

2.2.1 Internal monitoring of the licensees of Basic Nuclear Installations

In 2017, ASN issued a resolution (2017-DC-0616 of 30 November 2017) which specifies the criteria for distinguishing the significant modifications requiring ASN authorisation from those simply requiring notification. It also defines the requirements applicable to the management of noteworthy modifications, more particularly the internal check procedures to be implemented by the licensees.

ASN checks correct application of the provisions stipulated by this resolution.

2.2.2 Internal monitoring of radiation protection by the users of ionising radiation sources

The provisions of Articles R. 4451-40 to R. 4451-51 of the Labour Code specify the verifications to be performed during the lifetime of the work equipment or the facilities, in the form of initial verifications (by an accredited organisation), which may be repeated, and periodic verifications (by the Radiation Protection Advisor – RPA).

2.3 ASN approval of organisations and laboratories

ASN can draw on the results of inspections performed by the independent organisations and laboratories that it approves and whose actions it monitors.

Article L. 592-21 of the Environment Code states that ASN issues the required approvals to the organisations participating

in the verifications and monitoring concerning nuclear safety or radiation protection. The list of organisations and laboratories is available on asn.fr.

ASN thus approves organisations so that they can perform the technical inspections or verifications required by the regulations in the fields within its scope of competence:

- radiation protection verifications;
- measurement of radon activity concentration in Public Access Buildings (PABs);
- assessment of NPE conformity and inspection of PE in service.

In order to approve the applicant organisations, ASN ensures that they perform the inspections in accordance with their technical, organisational and ethical obligations and in compliance with the rules of professional good practice. Compliance with these provisions should enable the required level of quality to be obtained and maintained.

ASN ensures that benefit is gained from the approval, in particular through regular exchanges with the organisations it has approved and the mandatory submission of an annual report. Examination of these reports on the one hand makes it possible to check that the mandatory verifications have actually been carried out and, on the other, enables the licensees to be questioned about the steps taken to remedy any nonconformities.

In 2023, a large number of RANs had not identified the need to have checks required by the Public Health Code performed by an Approved Organisation for Radiation Protection (AORP). During the course of 2023, ASN issued communications on the regulatory requirements, notably via the Radiation Protection Expert-Officer (RPE-O) networks and conducted an

TABLE 2 Radiation protection verifications performed in 2024 by the organisations approved for radiation protection verifications^(*)

Medical	Research/Teaching	Industry (Including Veterinary)	Total
228	116	66	410

* Given the changes to the regulations, the number of checks performed is now expressed in the number of facilities checked (rather than the number of sources).

information campaign (by post) targeting the RANs concerned. The actions have been effective. The number of checks performed pursuant to the Public Health Code doubled in all sectors in 2024. The breakdown per field is given in Table 2 (see previous page).

The reports of the verifications performed in each facility by the AORP verifications are at the disposal of and examined by ASN personnel on the occasion of:

- licence renewals or modifications requiring ASN authorisation;
- inspections.

ASN also approves laboratories to conduct analyses requiring a high level of measurement quality if the results are to be usable. It thus approves laboratories to monitor radioactivity in the environment (see point 4.3).

In addition, on the advice of the standing sub-committee in charge of the transport of hazardous goods within the High Council for the Prevention of Technological Risks (CSPRT), ASN approved:

- the training organisations for drivers of vehicles carrying radioactive materials; two organisations have been approved;
- the organisations responsible for certifying the conformity of packaging designed to contain 0.1 kilogramme (kg) or more of uranium hexafluoride (UF₆);
- the organisations responsible for type approval of tank containers and swap tanks intended for the carriage of class 7 dangerous goods;
- the organisations responsible for the initial and periodic inspections of tanks intended for the carriage of class 7 dangerous goods.

Two organisations are approved for the qualification of tank-containers and for certification of the conformity of UF₆ packaging.

As at 31 December 2024, the following are approved or accredited by ASN:

- nine organisations responsible for radiation protection verifications. One approval renewal was delivered in 2024;
- 72 organisations responsible for measuring radon activity concentration in buildings (level 1), 15 of which are also approved to identify sources and routes for entry and transfer of radon in buildings (level 2). In 2024, 14 new approvals or approval renewals were issued, 11 of which were level 1 and 3 of level 2;
- four organisations qualified for NPE inspections as part of the new NPE conformity assessment;
- two organisations qualified for NPE inspections as part of in-service monitoring;
- three organisations qualified for PE and simple pressure vessels within the perimeter of BNIs (in-service monitoring);
- 18 inspection departments qualified for in-service monitoring of NPE and simple pressure vessels within the perimeter of NPPs;
- 67 laboratories for environmental radioactivity measurements covering 966 approvals currently valid as at 1 January 2025, of which 149 are approvals or approval renewals delivered or maintained during the course of 2024.

Since 2020, the regulations have gradually restricted the scope of intervention of the AORP by delegating the verification duties set out in the Labour Code to verification organisations accredited by the French Accreditation Committee (Cofrac). All of these verifications (Labour and Public Health Codes) were carried out under the previous regulations solely by the AORPs. In addition, the Public Health Code verifications no longer concern the BNIs. The number of AORP has significantly fallen as a result of these changes to the regulations.

In 2023, the regulations concerning the verifications and services performed by the AORPs changed.

Since 1 January 2023, the Order of 24 October 2022 relative to the procedures and frequency of the verifications of the rules put in place by the RANs, abrogated ASN resolution 2010-DC-0175 of 4 February 2010 defining the AORP verification procedures. This text modifies the scope of the AORP verifications. The Order applies to medical and industrial nuclear activities subject to the systems set out in Article L. 1333-8 of the Public Health Code when these activities generate effluents or waste contaminated by radionuclides, or liable to be so contaminated, including by activation. It does not apply to nuclear activities from which the only waste generated is inseparable activated parts of a particle accelerator, as defined in Appendix 13-7 to the Public Health Code. ASN resolution 2022-DC-747, which entered into force on 5 February 2023, supplements this Order.

This resolution defines the rules specified in the Order of 24 October 2022, that the party in charge of a nuclear activity is required to have verified by an AORP. This resolution is based on rules defined in ASN resolution 2008-DC-0095 of 29 January 2008, specifying the technical rules to be met by the elimination of effluents and waste contaminated by radionuclides, or liable to be so contaminated as a result of a nuclear activity, as well as resolution 2014-DC-0463 of 23 October 2014 relative to the minimum technical rules for the design, operation and maintenance of *in vivo* nuclear medicine facilities.

Finally, ASN resolution 2010-DC-0191 of 22 July 2010 was replaced by resolution 2022-DC-0748 which entered into force on 5 February 2023. This resolution sets the conditions and procedures for approval of organisations responsible for the verifications mentioned in Article R. 1333-172 of the Public Health Code.

3 — Performing efficient regulation and oversight

3.1 Inspection

3.1.1 Inspection objectives and principles

The inspection carried out by ASN is based on the following principles:

- The inspection aims to verify compliance with the provisions that are mandatory under the regulations. It also aims to assess the situation with regard to the nuclear safety and radiation protection implications; it seeks to identify best practices, practices that could be improved and assess possible developments of the situation.
- The scope and depth of the inspection is adopts a graded approach to the risks inherent in the activity and the way they

are effectively taken into account by those responsible for the activity.

- The inspection is neither systematic nor exhaustive; it is based on sampling and focuses on the subjects with the highest potential significance.

3.1.2 Inspection resources implemented

To ensure greater efficiency, ASN action is organised on the following basis:

- inspections, at a predetermined frequency, of the nuclear activities and topics of particular health and environmental significance;
- inspections of other nuclear activities decided on the basis of topical events (OEF,

whistle-blower reports, context demonstrating difficulties, etc.);

- inspections of approved organisations and laboratories.

The inspections may be unannounced or notified to the licensee a few weeks beforehand. They take place mainly on the site or during the course of the activities (work, transport operation, etc.). They may also concern the head office departments or design and engineering departments at the major nuclear licensees, the workshops or engineering offices of the subcontractors, the construction sites, plants or workshops manufacturing the various safety-related components.

ASN uses various types of inspections:

- routine inspections, usually two inspectors for one day;
- reinforced inspections, which consist in conducting an in-depth examination of a targeted topic by a larger team of inspectors than for a routine inspection;
- joint inspections, which take place over several days, concern a number of topics and involve about ten or so inspectors. Their purpose is to carry out detailed examinations and they are overseen by senior inspectors;
- inspections with sampling and measurements. With regard to both discharges and the environment of the facilities, these are designed to check samples that are independent of those taken by the licensee;
- event-based inspections carried out further to a particularly significant event;
- worksite inspections, ensuring a significant ASN presence on the sites on the occasion of reactor outages or particular work, especially in the construction or decommissioning phases;
- inspection campaigns, grouping inspections performed on a large number of similar installations, following a predetermined template.

Labour inspectorate work in the NPPs entails various types of interventions⁽¹⁾, which more particularly involve:

- checking application of the Labour Code by EDF and outside contractors in the NPPs (verification operations that include inspections);
- participation in meetings of the CSSCT, of Social and Economics Committees and the inter-company committees on safety and working conditions;
- conducting inquiries on request, following complaints or based on information, further to which the inspectors may take decisions as specified by the labour regulations, such as cessation of the works or the obligation to have the work equipment verified by an accredited organisation.

Remote inspections can be performed by the inspectors, in conjunction with on-site inspections. This tool is suitable for certain inspection topics. On-site inspection however remains the preferred method of verification. Only a few percent of the inspections are performed remotely each year.

The implementation of remote inspection measures in 2020 required that ASN modify the inspection indicators. For this type of inspection, the critical review of documents transmitted by a party responsible for a nuclear activity, during the on-site inspection preparation phases, becomes the primary method. It is then no longer possible to differentiate between preparation of the inspection, involving this documentary examination, and the inspection itself.

The following paragraphs will therefore present the number of inspector.days corresponding to the on-site inspections and the number of remote inspections. The number of inspector.days in these paragraphs cannot therefore be directly compared with that of years before 2020, because it only reflects the time spent on the site and does not take account of the remote inspections.

In addition, Table 5 (*see next page*) presents the total number of inspector.days devoted to inspections, whether performed on-site, remotely, or using a combination of the two.

ASN sends the licensee an inspection follow-up letter, published on *asn.fr*, which officially documents:

- deviations between the situation observed during the inspection and the regulations or documents produced by the licensee pursuant to the regulations;
- anomalies or aspects warranting additional justifications;
- best practices or practices to which improvements could be made, even if not directly constituting requirements.

The requests contained in the follow-up letters may concern requests for corrective actions or additional information, in the light of the deviations found during the inspections.

The follow-up letter prioritises the actions requested by ASN, so that the licensees can also implement a graded approach to processing the deviations found and optimise coordination of the means at their disposal.

The actual performance of the actions requested by ASN is followed up in a manner proportional to the issues at stake. Thus the priority action requests undergo exhaustive checks when their deadlines expire. The other requests are monitored by sampling, using appropriate methods (documentary check, follow-up inspection, etc.).

Any non-compliance found during the inspection can lead to administrative or criminal penalties (*see point 7*).

Some inspections are carried out with the support of one or more IRSN representatives specialised in the installation checked or the technical topic of the inspection.

ASN inspectors

ASN has inspectors designated and accredited by its Chairman, pursuant to Article L. 596-2 of the Environment Code for nuclear safety inspectors and Article L. 1333-29 of the Public Health Code for radiation protection inspectors, subject to their having acquired the requisite legal and technical skills through professional experience, mentoring or training courses.

The inspectors take an oath and are bound by professional secrecy. They exercise their inspection activity under the authority of the ASN Director General and benefit from regularly updated practical tools (inspection guides, decision-making tools) to assist them in their inspections.

TABLE 3 Breakdown of inspectors per inspection field as at 31 December 2024

Inspector Categories	Departments	Divisions	Total
Nuclear safety inspectors	142	128	270
including nuclear safety inspectors for transport	31	45	76
Radiation protection inspectors	39	100	139
Labour inspectors	3	21	24
Inspectors for all fields	164	168	332

TABLE 4 Number of inspections per field in 2024

Basic nuclear installation (except pressure equipment)	Pressure equipment	Transport of radioactive substances	Small-scale nuclear activities	Approved Organisations and Laboratories	Total
744	142	91	764	72	1,813

1. The intervention is the unit representative of activity traditionally used by the labour inspectorate.

TABLE 5 Breakdown of on-site inspection days by topic in 2024

Per Field	Number of Inspector.days	Number of on-site inspections performed
Basic Nuclear Installation /Pressurised water reactor	1,268	428
Basic Nuclear Installation/Laboratories plants waste and decommissioning	777	311
Basic Nuclear Installation/Pressure Equipment	393	139
Small-scale nuclear activities/Industry	494	288
Small-scale nuclear activities/Medical	739	364
Small-scale nuclear activities/Natural radioactivity	34	31
Small-scale nuclear activities/Polluted sites and grounds	7	4
Small-scale nuclear activities/Research	89	47
Small-scale nuclear activities/Veterinary	34	22
Small-scale nuclear activities/Other	8	5
Transport of radioactive substances	146	90
Approved Organisations/Approved laboratories	127	69
Total(*)	4,116	1,798

* The fact that the various numbers are rounded off gives a total slightly different from the sum of each line.

As part of its continuous improvement policy, ASN encourages the exchange and integration of best practices used by other inspection organisations:

- by organising international exchanges of inspectors between Safety Authorities, either for the duration of one inspection or for longer periods that could extend to a secondment of up to several years. Thus, after having observed its advantages, ASN has adopted the concept of the joint inspections described earlier. However, it did not opt for the system involving a resident inspector on a nuclear site, as ASN considers that its inspectors must work within a structure large enough to allow experience to be shared and that they must take part in inspections of different licensees and facilities in order to acquire a broader view of this field of activity. This choice also allows greater clarity in the exercise of the respective responsibilities of the licensee and the inspector;
- by welcoming inspectors trained in other inspection practices. ASN encourages the integration into its departments of inspectors from other regulatory authorities, such as the Regional Directorate for the Environment, Planning and Housing (Dreal), ANSM, Regional Health Agencies (ARS), etc. It also proposes organising joint inspections with these authorities on activities falling within their common areas of competence;
- by organising the participation of its staff in inspections on subjects in different regions and fields, notably to promote the uniformity of its practices. Each ASN inspector in a particular region takes part every year in at least one inspection performed in a different region.

Table 3 (see previous page) presents the headcount of inspectors, which stood at 332 on 31 December 2024. Some inspectors operate in several inspection fields, and all the operational entity heads and their deputies fulfil both managerial and inspection functions.

Most of the inspections are carried out by inspectors assigned to the regional divisions, who represent 51% of the ASN inspectors. The 164 inspectors assigned to the departments take part in ASN inspections within their field of competence; they represent 49% of the inspector headcount and carried out about 20% of inspections in 2024, with most of their work being the examination of files.

As previously mentioned, ASN continuously improves the efficiency of its oversight by targeting and modulating its inspections according to the scale of the implications for the protection of persons and the environment.

In 2024, the ASN inspectors carried out a total of 1,813 inspections, representing 4,116 inspection man.days in the field. About 1% of the inspections were carried out remotely. The breakdown per area of activity is shown in Table 4 (see previous page).

ASN inspections programme

To guarantee a distribution of the inspection resources with a graded approach to the safety and radiation protection implications of the various facilities and activities, ASN drafts a forecast inspections schedule every year, taking account of the inspection implications (see point 3.1). The results of the year's priority actions are presented in the specific chapters for nuclear installations and activities. For example, a campaign of inspections on systems configuration management and a campaign of inspections on management of a reactor accident with core melt (see box page 308 of chapter 10) were carried out in 2024, along with continuation of a campaign of inspections on stress corrosion of the auxiliary lines (see box page 304 of chapter 10).

This schedule is not communicated to the licensees or to those in charge of nuclear activities.

ASN monitors the performance of the programme and the follow-up given to the inspections, through periodic reviews. This follow-up enables the inspected activities to be assessed and contributes to the continuous improvement of the inspection process.

Information relative to the inspections

ASN informs the public of the steps taken following the inspections by posting the inspection follow-up letters on-line, on asn.fr.

Moreover, after each in-depth inspection, ASN publishes an information notice on asn.fr.

3.1.3 Inspection of Basic Nuclear Installations and Pressure Equipment

In 2024, 2,438 inspector.days were devoted to the on-site field inspection of BNIs and NPE, corresponding to 878 inspections. Of these, 20% were unannounced. Furthermore, eight inspections were conducted remotely.

Inspection work in the field can be broken down into 1,268 inspector.days in the NPPs (428 on-site inspections), 777 inspector.days in the other BNIs (311 on-site inspections), that is mainly the “fuel cycle” facilities, research facilities and installations undergoing decommissioning, and 393 for NPE (139 on-site inspections).

The remote inspections can be broken down as follows: 5 inspections for the NPPs, none for the other BNIs and 3 inspections for NPE.

Two joint inspections were performed in 2024 on the Dampierre-en-Burly NPP, as well as on CEA's Saclay site, which corresponds to 58 inspector.days on-site.

The ASN labour inspectors also carried out 436 interventions during the 158 inspection days in the NPPs.

3.1.4 Inspection of radioactive substances transport

In 2024, 146 inspector.days were devoted by ASN to on-site inspection of transport activities, corresponding to 90 on-site inspections. Of these, 26% were unannounced. One remote-inspection was also carried out.

3.1.5 Inspection of small-scale nuclear activities

ASN organises its inspection activity so that it is proportionate to the radiological issues involved in the use of ionising radiation and consistent with the actions of the other inspection services.

In 2024, 1,405 inspector.days were devoted to on-site inspections of small-scale nuclear activities, corresponding to 761 inspections, 8% of which were unannounced, plus three remote inspections. This inspection work was notably distributed among the medical, industrial, veterinary, research or naturally occurring radioactivity fields.

3.1.6 Inspection of ASN approved organisations and laboratories

ASN carries out a second level of inspection on approved organisations and laboratories. In addition to reviewing the application file and issuing the approval, this comprises surveillance actions such as:

- approval audits (initial or renewal audit);
- checks to ensure that the organisation and operation of the entity concerned comply with the applicable requirements;
- supervisory checks, which are usually unannounced, to ensure that the organisation's staff work in satisfactory conditions.

In 2024, 127 inspector.days were devoted to checking approved organisations and laboratories, corresponding to 69 inspections, 29% of which were unannounced, plus 3 remote inspections.

3.1.7 Checks on exposure to Radon and Naturally Occurring Radioactive Materials

ASN also checks radiation protection in premises where the exposure of persons to naturally occurring radiation may be reinforced owing to the underlying geological context (radon in PABs and in the workplace).

Monitoring exposure to radon

Article R. 1333-33 of the Public Health Code states that the activity concentration of radon in PABs is measured either by IRSN, or by organisations approved by ASN. These measurements are to be taken between 15 September of a given year and 30 April of the following year.

Article R. 4451-44 of the Labour Code stipulates that, whenever required, the initial checks on the radon activity concentration in areas identified owing to the radon risk must be carried out by accredited organisations.

Monitoring natural radioactivity in water intended for human consumption

Monitoring the natural radioactivity in water intended for human consumption is the role of the ARS. The procedures for these checks take account of the recommendations issued by ASN and are taken up in the General Health Directorate Circular of 13 June 2007.

The results of the checks are jointly analysed and utilised by ASN and the services of the Ministry of Health.

3.2 Analysis of the demonstrations provided by the licensee

The purpose of the files supplied by the licensee is to demonstrate compliance with the objectives set by the general technical regulations, as well as those that it has set for itself. ASN is required to check the completeness of the data and the quality of the demonstration.

The review of these files may lead ASN to accept or to reject the licensee's proposals, to ask for additional information or studies or to ask for work to be done to bring the relevant items into conformity.

3.2.1 Analysing the files transmitted by BNI licensees

Reviewing the supporting documents produced by the licensees and the technical meetings organised with them are one of the forms of control carried out by ASN.

Whenever it considers it necessary, ASN requests an opinion from its technical support organisations, the most important of which is IRSN. The safety review implies cooperation by numerous specialists, as well as efficient coordination, in order to identify the essential points relating to safety and radiation protection.

The IRSN assessment is based on in-depth technical discussions with the licensee teams responsible for designing and operating the installations. It is also based on studies and R&D programmes focused on risk prevention and on improving our knowledge of accidents. For certain dossiers, ASN asks the competent Advisory Committee of Experts (GPE) for its opinion. For the others, IRSN examines the safety analyses and gives its opinion directly to ASN. ASN procedures for requesting the opinion of a technical

support organisation and, where required, of a GPE, are described in chapter 2.

At the design and construction stage, ASN – aided by its technical support organisation – assesses the safety analysis reports describing and justifying the design principles, equipment and system design calculations, utilisation rules and test procedures, and quality organisation provisions implemented by the prime contractor and its suppliers. It also analyses the facility's environmental impact assessment. ASN regulates and oversees the construction and manufacture of structures and equipment, in particular those of the main primary system and the main secondary systems of Pressurised Water Reactors (PWRs). In accordance with the same principles, it checks the packages intended for TSR.

Once the nuclear facility has been commissioned, following ASN authorisation, all changes to the facility or its operation made by the licensee that could affect security, public health and safety, or the protection of the environment, are reported to ASN or submitted to it for authorisation. Moreover, the licensee must perform periodic safety reviews to update the assessment of the facility, taking into account any changes in techniques and regulations, and experience feedback. The conclusions of these reviews are submitted by the licensee to ASN, which can issue new binding requirements for continued operation.

The other files submitted by BNI licensees

A large number of files concern specific topics such as fire protection, fuel management in PWRs, relations with the outside contractors, etc.

The licensee therefore also periodically provides activity reports as well as summaries of water intake, liquid and gaseous discharges and waste produced.

3.2.2 Review of the applications required by the Public Health Code

ASN is responsible for reviewing applications to possess and use ionising radiation sources in the medical and industrial sectors. ASN also deals with the specified procedures for the acquisition, distribution, import, export, transfer, recovery and disposal of radioactive sources. It in particular relies on the inspection reports from the approved organisations and the reports on the steps taken to remedy nonconformities detected during these inspections.

In addition to the verifications carried out under the responsibility of the facilities and the periodic checks required by the regulations, ASN carries out its own checks when examining the applications.

3.3 Lessons learned from significant events

3.3.1 Anomaly detection and analysis

Background

The international Conventions ratified by France (section VI of Article 19 of the Convention on Nuclear Safety of 20 September 1994; section V of Article 9 of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management of 5 September 1997) require that BNI licensees implement a reliable system for early detection and notification of any anomalies that may occur, such as equipment failures or errors in the application of operating rules. Ten years previously, the “Quality Order” of 10 August 1984 already required such a system in France.

ASN thus drafted three guides defining the principles and reiterating the obligations binding on the licensees with regard to notification of incidents and accidents:

- the Guide of 21 October 2005 contains the provisions applicable to BNI licensees. It concerns significant events relating to nuclear safety (ESS), radiation protection (ESRs) and environmental protection (ESEs), applicable to BNIs;
- Guide No. 11 of 7 October 2009, updated in July 2015, contains provisions applicable to those in charge of nuclear activities as defined in Article L. 1333-1 of the Public Health Code and to the heads of the facilities in which ionising radiation is used (medical, industrial and research activities using ionising radiation);
- Guide No. 31 describes the procedures for notification of radioactive substances transport events (see chapter 9). This Guide has been applicable since 1 July 2017.

These guides can be consulted on asn.fr.

What is a significant event?

Detection of events (deviations, anomalies, incidents, etc.) by those in charge of the activities using ionising radiation, and implementation of corrective measures decided on after analysis, play a fundamental role in accident prevention. For example, EDF detects and analyses several hundred anomalies every year for each reactor.

Prioritising the anomalies should enable the most important ones to be addressed first. The regulations have defined a category of anomalies called “significant events”. These are events which are sufficiently important in terms of safety, the environment or radiation protection to justify that ASN be rapidly informed of their occurrence and subsequently receive a fuller analysis. Significant events must be notified to it, as specified in the Order

of 7 February 2012 (Article 2.6.4), the Public Health Code (Articles L. 1333-13, R. 1333-21 and R. 1333-22), the Labour Code (Article R. 4451-74) and the regulatory texts applicable to TSR (for instance, the European agreement on the carriage of Dangerous goods by Road).

The criteria for notifying the public authorities of events considered to be “significant” take account of the following:

- the actual or potential consequences for the workers, the general public, patients or the environment, of events which could involve safety or radiation protection;
- the main technical, human or organisational causes that led to the occurrence of such an event.

This notification process is part of an approach to continuously improve safety and radiation protection. It requires the active participation of all players (users of ionising radiation, carriers, etc.) in the detection and analysis of deviations.

It enables the authorities:

- to ensure that the licensee has suitably analysed the event and taken appropriate measures to remedy the situation and prevent it from happening again;
- to ensure that other parties responsible for similar activities benefit from OEF about the event.

The purpose of this system is not to identify or penalise any individual person or party.

Moreover, the number and the rating on the INES scale (International Nuclear and Radiological Event Scale) of the significant events which have occurred in a nuclear facility are not on their own indicators of the facility’s level of safety.

On the one hand, a given rating level is an over-simplification and is unable to reflect the complexity of an event and, on the other, the number of events listed depends on the level of notification compliance. The trend in the number of events does not therefore reflect any real trend in safety levels.

3.3.2 Implementation of the approach

Event notification

The licensee of a BNI or the person responsible for TSR is obliged to notify ASN and, as applicable, the administrative authority, without delay, of any accidents or incidents that occur on account of the operation of that installation or the transport activity and which could significantly prejudice the interests mentioned in Article L. 593-1 of the Environment Code.

Similarly, the RNA must report any event which could lead to accidental or unintentional exposure of persons to

ionising radiation and liable to significantly prejudice the protected interests.

According to the provisions of the Labour Code, employers are obliged to report significant events affecting their workers. When the head of a company carrying out a nuclear activity calls in an external contractor or non-salaried worker, the significant events concerning the workers are reported in accordance with the prevention plans and the agreements concluded pursuant to the provisions of Article R. 4451-35 of the Labour Code.

The reporting party assesses the urgency of notification in the light of the confirmed or potential seriousness of the event and the speed of reaction needed to avoid an aggravation of the situation or to mitigate the consequences of the event. The reporting time of two working days (four days for significant TSR events), mentioned in the ASN notification guides, does not apply when the consequences of the event require intervention by the public authorities.

When a given event potentially concerns several facilities, it is referred to as “generic”. The most common example is a fault in an equipment item installed on several nuclear reactors (see chapter 10). In this case, ASN analyses the event as a single event, with the response being essentially common to all the facilities affected. This process follows the IAEA recommendations, which specify that a single notification may be appropriate in the case of an event affecting “Defence in Depth” and concerning several similar facilities.

ASN analysis of the notification

ASN analyses the initial notification to check the implementation of immediate corrective measures, to decide whether to conduct an on-site inspection to analyse the event in depth, and to prepare for informing the public if necessary.

Within two months of the notification, it is followed by a report indicating the conclusions the licensee has drawn from analysis of the events and the steps it intends to take to improve safety or radiation protection and prevent the event from happening again. This information is taken into account by ASN and its technical support organisation, IRSN, in the drafting of the inspection programme and when performing the BNI periodic safety reviews.

ASN ensures that the licensee has analysed the event pertinently, has taken appropriate steps to remedy the situation and prevent it from recurring, and has circulated the OEF.

The ASN review focuses on compliance with the applicable rules for detecting and notifying significant events, the immediate technical, organisational or

TABLE 6 Number of significant events rated on the INES scale between 2019 and 2024

		2019	2020	2021	2022	2023	2024
Basic Nuclear Installations	Level 0	1,057	1,033	1,068	985	1,010	1,047
	Level 1	112	107	103	97	86	75
	Level 2	3	2	1	0	2	2
	Level 3 and +	0	0	0	0	0	0
	Total	1,172	1,142	1,172	1,082	1,098	1,124
Small-scale nuclear activities (medical and industry)	Level 0	142	135	177	163	176	210
	Level 1	35	24	33	37	25	21
	Level 2	2	1	0	2	0	0
	Level 3 and +	0	0	0	0	0	0
	Total	179	160	210	202	201	231
Transport of radioactive substances	Level 0	85	71	80	76	84	100
	Level 1	4	4	4	12	2	3
	Level 2	0	0	0	0	0	0
	Level 3 and +	0	0	0	0	0	0
	Total	89	75	84	88	86	103
Grand Total		1,440	1,377	1,466	1,372	1,385	1,458

* Only the data concerning significant events rated level 1 and higher on the INES scale were updated (following the re-ratings carried out in the year following that of reporting).

human measures taken by the licensee to maintain or bring the installation to a safe condition, and the pertinence of the submitted analysis.

ASN and IRSN also carry out a more wide-ranging examination of the operating feedback from the events. The significant event reports and the periodic reviews sent by the licensees, as well as the assessment by ASN and IRSN, constitute the basis of OEF. The examination of OEF may lead to ASN requests for improvements to the condition of the facilities and the organisation adopted by the licensee, but also to changes to the regulations.

OEF comprises the events which occur in France and abroad in nuclear facilities or in those presenting non-radiological hazards, if it is pertinent to take them into account in order to reinforce nuclear safety or radiation protection.

3.3.3 Technical inquiries held in the event of an incident or accident concerning a nuclear activity

ASN has the authority to carry out an immediate technical inquiry in the event of an incident or accident in a nuclear activity. This inquiry consists in collecting and analysing all useful information, without prejudice to any judicial inquiry, in order to determine the circumstances and the identified or possible causes of the event, and draw up the appropriate recommendations if necessary. Articles L. 592-35 *et seq.* of the Environment Code give ASN powers to set up a board of inquiry,

determine its composition (ASN staff and people from outside ASN), define the subject and scope of the investigations and gain access to all necessary elements in the event of a judicial inquiry.

Decree 2007-1572 of 6 November 2007 on technical inquiries into accidents or incidents concerning a nuclear activity specifies the procedure to be followed. It is based on practices defined by the other boards of inquiry and takes account of aspects specific to ASN, notably its independence, its own roles, its ability to impose binding requirements or sanctions.

3.3.4 Statistical summary of events

In 2024, 2,260 significant events were reported to ASN (see Table 6 above):

- 1,200 significant events concerning nuclear safety, radiation protection, the environment and the on-site transport of hazardous materials within BNIs, 1,124 of which are rated on the INES scale (75 level 1 events and two level 2 events). Of these events, 16 significant events were rated as “generic events”, in other words concerning several reactors, including one at level 2 on the INES scale;
- 103 significant events concerning TSR on the public highway (three events rated level 1 on the INES scale);
- 956 ESR for small-scale nuclear activities, including 210 rated on the INES scale (21 level 1 events).

Graphs 1 to 6 (see next pages) describe in detail the significant events reported to ASN in 2024, differentiating between them

according to the various notification criteria for each field of activity.

In 2024, two events were rated level 2 on the INES scale.

The rise in the number of nuclear activity significant events notified cannot be ascribed to any particular area or any specific cause. The details of the statistical analysis of these events are given in chapters 7 and following.

The two level 2 events concern the external contamination of two workers in the Tricastin and Saint-Laurent-des-Eaux NPPs. They are presented in a box in chapter 10 (see page 316).

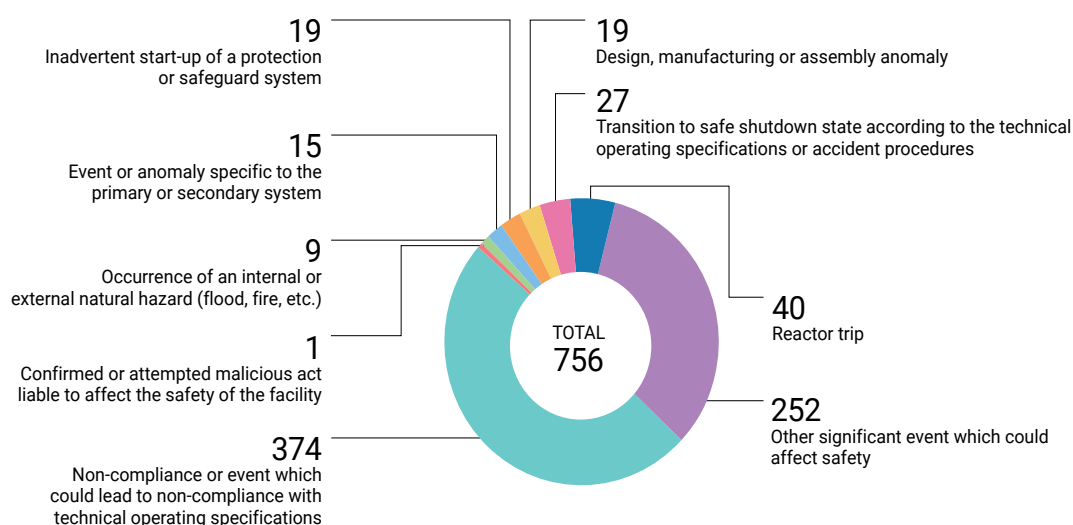
As indicated earlier, these data must be used with caution: they do not in themselves constitute a safety indicator. ASN encourages the licensees to report incidents, which contributes to transparency and the sharing of experience.

The breakdown of significant events rated on the INES scale is specified in Table 6 (see above). As the INES scale does not apply to significant events concerning patients, the rating of significant events affecting one or more patients in radiotherapy on the ASN-SFRO scale⁽²⁾ is specified in chapter 7.

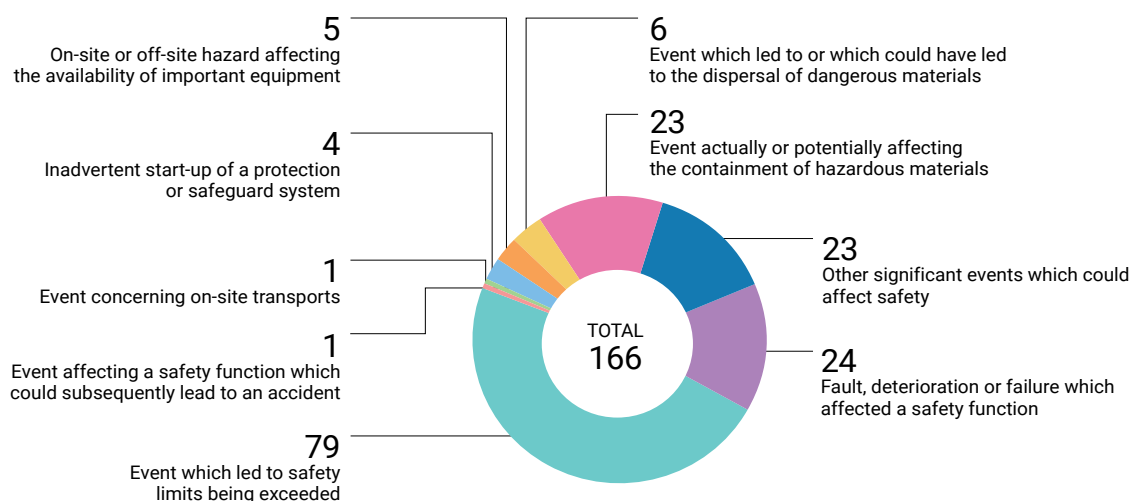
Similarly, significant events concerning the environment but involving non-radiological substances are not covered by the INES scale. They are classified as “out of INES scale” events.

2. This scale is designed for communication with the public in comprehensible, explicit terms, concerning radiation protection events leading to unexpected or unforeseeable effects affecting patients undergoing a radiotherapy medical procedure.

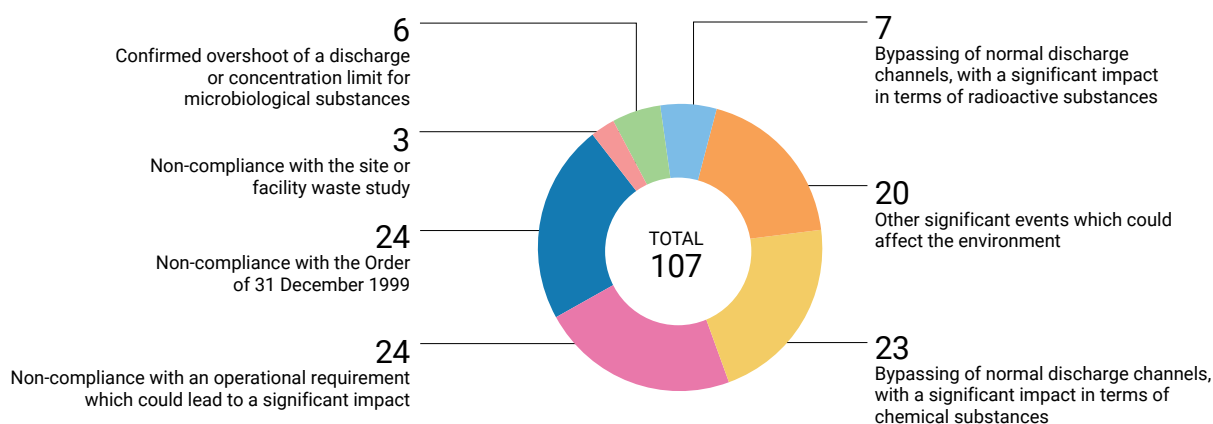
GRAPH 1 Events involving safety in the NPPs notified in 2024

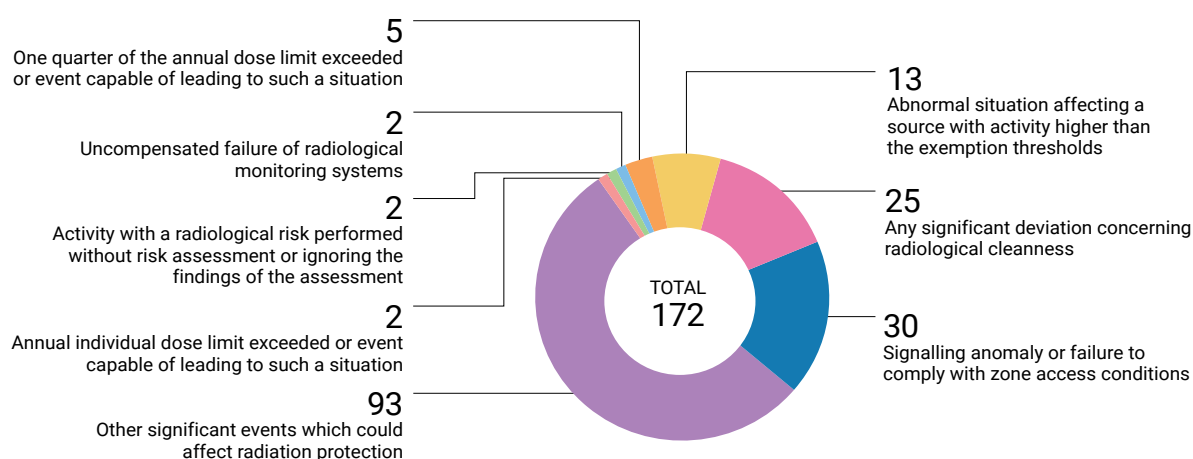
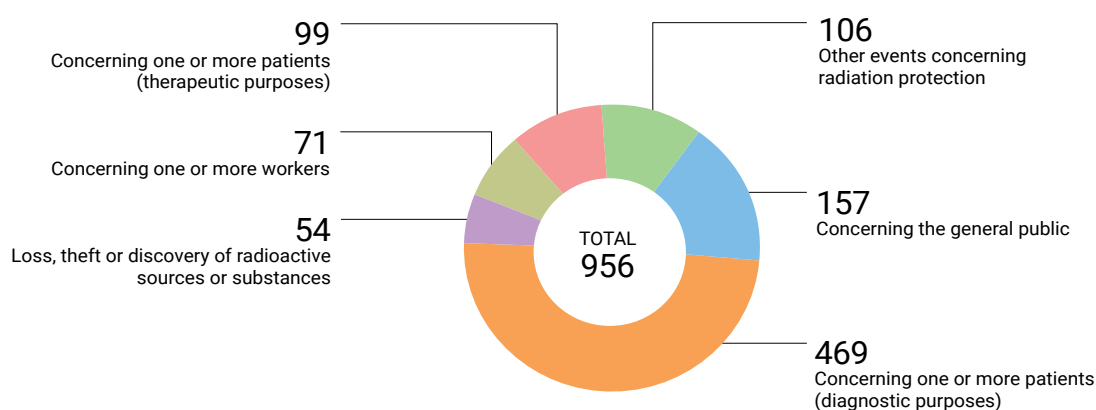
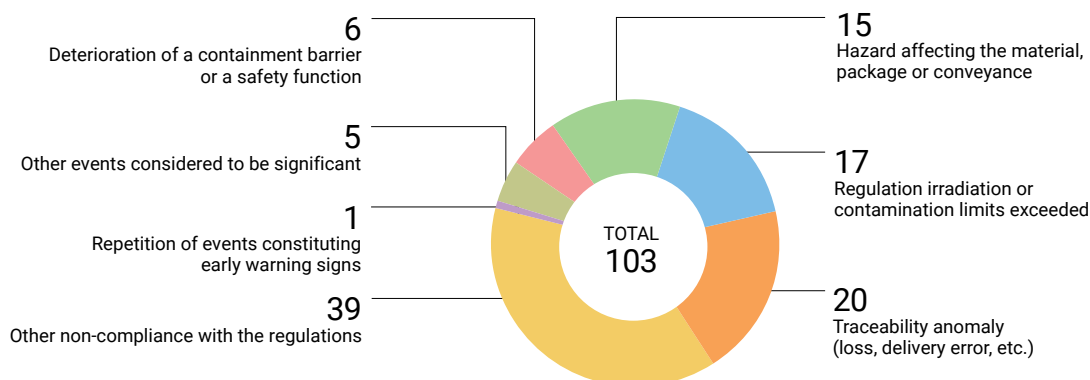


GRAPH 2 Events involving safety in BNIs other than NPPs notified in 2024



GRAPH 3 Significant environmental events in the BNIs notified in 2024



GRAPH 4 Events involving radiation protection in BNIs notified in 2024**GRAPH 5** Events involving radiation protection (other than BNIs and TSR) notified in 2024**GRAPH 6** Events involving the transport of radioactive substances reported in 2024

3.4 Raising the awareness of professionals and cooperating with the other administrations

Regulation is supplemented by awareness-raising programmes designed to ensure familiarity with the regulations and their application in practical terms appropriate to the various professions. ASN aims to encourage and support initiatives by the professional organisations that implement this approach by issuing best practices and professional information guides.

ASN issues the “Avoiding accidents” data sheets in the field of BNIs and transport, “Operating Experience Feedback” sheets, or “Patient safety” bulletins in the medical field, with the aim of sharing its OEF analyses.

Awareness-raising also involves joint actions with other administrations and organisations which oversee the same facilities, but with different prerogatives. One could here mention the labour inspectorate, the medical devices inspectorate work by the ANSM, the medical activities inspectorate work entrusted to the technical services of the Ministry of Health, or the oversight of small-scale nuclear activities at the Ministry of Defence entrusted to the Armed Forces General Inspectorate.

3.5 Information about ASN's regulatory activity

ASN attaches importance to coordinating Government departments and informs the other administration departments concerned of its inspection programme,

the follow-up to its inspections, the penalties imposed on the licensees and any significant events.

To ensure that its inspection work is transparent, ASN informs the public by placing the following on its website *asn.fr*:

- its resolutions and decisions;
- inspection follow-up letters for all the activities it inspects;
- approvals and accreditations it issues or rejects;
- incident notices;
- the results of reactor outages;
- its thematic publications on specific subjects.

4 — Monitoring the impact of nuclear activities and radioactivity in the environment

4.1 Monitoring discharges and the environmental and health impact of nuclear activities

4.1.1 Monitoring of discharges

The BNI Order of 7 February 2012 and amended ASN resolution 2013-DC-0360 of 16 July 2013, set the general requirements applicable to any BNI with regard to their water intake and their discharges of radioactive or chemical substances. In addition to these provisions, in its resolution 2017-DC-0588 of 6 April 2017, ASN defined the conditions for water intake and consumption, effluent discharge and environmental monitoring applicable more specifically to PWRs. This resolution was approved by the Minister for Ecological and Solidarity-based Transition in an Order of 14 June 2017.

Apart from the above-mentioned general provisions, ASN resolutions set specific requirements for each facility, more particularly the limits for water intake and discharge of radioactive or chemical substances.

Monitoring discharges from BNIs

The monitoring of discharges from an installation is essentially the responsibility of the licensee. The ASN requirements regulating discharges stipulate the minimum checks that the licensee is required to carry out. This monitoring focuses on the liquid or gaseous effluents (monitoring of the activity of discharges or concentrations and flows of chemical substances discharged, characterisation of certain effluents prior to discharge, etc.)

and on the environment around the facility (checks during discharge, samples of air, water, milk, grass, etc.) with regard to all pertinent parameters for characterising the impact of the facility on humans and the environment. The results of this monitoring are recorded in registers transmitted to ASN every month.

The BNI licensees also regularly transmit a certain number of discharge samples to an independent laboratory for cross-analysis. The results of these “cross-analyses” are sent to ASN. This programme of cross-analyses defined by ASN is a way of ensuring that the accuracy of the measurements taken by the licensee laboratories is maintained over time.

The inspections carried out by ASN

Through dedicated inspections, ASN ensures that the licensees actually comply with the regulations binding upon them with regard to the management of discharges and the environmental and health impact of their facilities. Every year, it carries out about 90 inspections of this type, split among the following three topics:

- prevention of pollution and management of detrimental effects and non-radiological hazards;
- water intake and effluent discharge, monitoring of discharges and the environment;
- waste management.

Each of these topics covers both radiological and non-radiological aspects.

Every year, ASN carries out 10 to 20 inspections with sampling and measurement. They are generally unannounced and are run with the support of specialist, independent laboratories appointed by ASN. Effluent and environmental samples are

taken for radiological and chemical analyses. Finally, every year, ASN carries out several reinforced inspections which aim to check the organisation put into place by the licensee to protect the environment; the scope of the inspection is then broadened to cover all of the above-mentioned topics. Within this context, situational exercises can be carried out to test the organisation implemented for pollution management (*see chapter 10*).

Accounting of BNI discharges

The rules for accounting of discharges, both radioactive and chemical, are set in the general regulations by amended ASN resolution 2013-DC-0360 of 16 July 2013 relative to control of the detrimental effects and the impact of BNIs on health and the environment. These rules were set so as to guarantee that the discharge values declared by the licensees, notably those considered in the impact calculations, will in no case be under-estimated.

For discharges of radioactive substances, accounting is not based on overall measurements, but on an analysis per radionuclide, introducing the notion of a “reference spectrum”, listing the radionuclides specific to the type of discharge in question.

The principles underlying the accounting rules are as follows:

- radionuclides for which the measured activity exceeds the decision threshold for the measurement technique are all counted;
- the radionuclides of the “reference spectrum” for which the measured activity is below the decision threshold (*see box next page*) are counted at the decision threshold level.

With regard to measurements

- **The Decision Threshold (SD)** is the value above which it is possible with a high degree of confidence to conclude that a radionuclide is present in the sample.
- **The Detection Limit (LD)** is the value as of which the measurement technique is able to quantify a radionuclide with a reasonable degree of uncertainty (the uncertainty is about 50% at the LD).

More simply, $LD \approx 2 \times SD$.

For the measurement results on chemical substances, the Quantification Limit is equivalent to the Detection Limit used to measure radioactivity.

Reference spectra

For the NPPs, the reference spectra of discharges comprise the following radionuclides:

- **Liquid discharges:** tritium, carbon-14, iodine-131, other fission and activation products (manganese-54, cobalt-58, cobalt-60, nickel-63, silver-110m, tellurium-123m, antimony-124, antimony-125, caesium-134, caesium-137);
- **Gaseous discharges:** tritium, carbon-14, iodines (iodine-131, iodine-133), other fission and activation products (cobalt-58, cobalt-60, caesium-134, caesium-137), noble gases: xenon-133 (permanent discharges from ventilation networks, when draining "RS" effluent storage tanks and at decompression of reactor buildings), xenon-135 (permanent discharges from ventilation networks and at decompression of reactor buildings), xenon-131m (when draining "RS" tanks), krypton-85 (when draining "RS" tanks), argon-41 (at decompression of reactor buildings).

For discharges of chemical substances with an emission limit value set by an ASN binding requirement, when the concentration values measured are below the quantification limit, the licensee is required by convention to declare a value equal to half the quantification limit concerned.

Per- and polyfluoroalkyl substances

Per- et Polyfluoroalkyl Substances (PFAS) are substances which degrade very slowly and are highly persistent in the environment, which poses many questions regarding their toxicity, both for human health and for the environment.

Following the action plan initiated by the Government in January 2023 to reduce PFAS-related hazards and improve the awareness of the population regarding exposure to these substances, ASN asked the BNI licensees whose activities are liable to be the cause of PFAS emissions to draw up a list of the PFAS used, produced, processed or discharged by their facility and then to carry out a campaign to search for and quantify their presence in the aqueous discharges from their facility.

Although the industrial processes employed in the BNIs do not use any PFAS, certain equipment (seals, mechanical packings, fire-fighting foam) present in the BNIs is liable to contain them. In 2024, the licensees of the BNIs concerned therefore carried out measurement campaigns, first of all on samples taken from the non-radioactive liquid discharge networks in their installations. These initial results confirm the absence of PFAS in the discharges in the majority of cases. Some facilities undertook to supplement their campaign by one or more measurements when the occasional presence of PFAS was detected. The results of additional campaigns to be performed on radioactive discharges are also expected by the end of 2026.

Following these campaigns, and if PFAS are confirmed as being present in BNI discharges, ASN could issue prescriptive requirements to regulate these discharges by setting emission limits and appropriate monitoring procedures.

Monitoring of discharges in the field of small-scale nuclear activities

Pursuant to ASN resolution 2008-DC-0095 of 29 January 2008, radioactivity measurements are taken on the effluents coming from the facilities that produce them.

In hospitals that have a nuclear medicine department, these measurements chiefly concern iodine-131 and technetium-99m (see chapter 7).

In the small-scale industrial nuclear sector, few facilities discharge radioactive effluents apart from cyclotrons (see chapter 8). The discharge permits stipulate requirements for the discharges and their monitoring, which are subject to particular scrutiny during inspections.

For nuclear medicine units and research laboratories, IRSN proposes a graded approach to monitoring of radioactive discharges into the public sewer system. This approach could consist of sampling and measurement protocols, as well as guideline levels to be compared with the results of these measurements in order to decide whether any corrective measures are needed.

4.1.2 Evaluating the radiological impact of nuclear activities

The radiological impact of effluents produced by medical activities and small-scale nuclear activities

The impact of radioactive discharges on sanitation workers (sewerage workers and wastewater treatment plant workers) and on workers responsible for removing and spreading wastewater treatment sludge

can, since 2019, be evaluated using the CIDRRE tool (Calculation of impact of radioactive discharges into the networks), developed by IRSN.

The final result is a prudent over-estimation, which gives an approximate idea of the doses liable to be received per category of sanitation workers, according to the facility which carries out the discharge, the collection system receiving it and the plant which treats the wastewater. CIDRRE is a means of ensuring that the annual dose received by the sanitation workers remains below 1 millisievert (mSv).

For the population, the estimated radiological impact linked to radioactive discharges from nuclear medicine units and research laboratories into the sewerage systems would appear to be below 300 microsieverts per year ($\mu\text{Sv}/\text{year}$) in all the studies, even in worst-case scenarios considering all the radionuclides detected in the sanitation systems. This impact is estimated to be lower than 1 $\mu\text{Sv}/\text{year}$ when the radionuclides used in nuclear medicine are not taken into account, with realistic hypotheses (IRSN data).

The radiological impact of BNIs

In accordance with the optimisation principle, the licensee must reduce the radiological impact of its facility to values that are as low as possible under economically acceptable conditions.

The licensee is required to assess the dosimetric impact of its activity. As applicable, this obligation is the result of Article L. 1333-8 of the Public Health Code, or the regulations concerning BNI discharges (Article 5.3.2 of amended ASN resolution 2013-DC-0360 of 16 July 2013 concerning control of detrimental effects and the impact of BNIs on health and the environment). The result is to be assessed considering the allowable annual dose limit for the public (1 millisievert per year – mSv/year) defined in Article R. 1333-11 of the Public Health Code, which corresponds to the sum of effective doses received by the public as a result of nuclear activities.

In practice, only traces of artificial radioactivity are detectable in the vicinity of the nuclear facilities; most measurements taken during routine surveillance are below the decision threshold or reflect the natural radioactivity. As these measurements cannot be used for dose estimations, models for the transfer of radioactivity to humans must be used, on the basis of measurements of discharges from the installation. These models are specific to each licensee and are detailed in the facility's impact assessment. During its assessment, ASN devotes efforts to verifying that these models are conservative, in order to ensure that the impact assessments are not underestimated.

In addition to the impact assessments produced on the basis of discharges from the facilities, the licensees are required to carry out environmental radioactivity monitoring programmes (aquatic environments, air, earth, milk, grass, agricultural produce, etc.), more specifically to verify compliance with the hypotheses used in the impact assessment and to monitor changes in the radioactivity level in the various compartments of the environment around the facilities (*see point 4.1.1*).

The doses from BNIs for a given year are estimated on the basis of the actual discharges from each installation accounted for the year in question. This assessment takes account of discharges from the identified outlets (stack, river or sea discharge pipe), the diffuse emissions not channelled to the outlets (for example tank vent) and the sources of radiological exposure to ionising radiation present in the installation.

In accordance with the provisions of Articles R.1333-23 and R.1333-24 of the Public Health Code, the estimation is calculated for a “person representative” of the persons most exposed within the population, except for those with extreme or rare habits and according to scenarios that are as realistic as possible. These scenarios take account of parameters specific to each site: distance from the site, meteorological data, etc. The differences observed from one site to another and from one year to another can to a large extent be explained by the use of these specific parameters.

The Table entitled “Radiological impact of BNIs since 2018” in chapter 1 presents an assessment of the doses due to BNIs calculated by the licensees.

For each of the nuclear sites presented, the radiological impact remains far below, or at most represents about 1% of the limit for the public, this limit being 1 mSv/year. Therefore in France, the discharges produced by the nuclear industry have an extremely small radiological impact.

4.1.3 Monitoring within the European framework

Article 35 of the EURATOM Treaty requires that the Member States establish the facilities needed to carry out continuous monitoring of the level of radioactivity in the air, water and soil and to ensure compliance with the basic standards of health protection for the general public and workers against the hazards of ionising radiation.

All Member States, whether or not they have nuclear facilities, are therefore required to implement environmental monitoring arrangements throughout their territory.

Article 35 also states that the European Commission (EC) may access the monitoring facilities to verify their operation and their effectiveness. During its verifications, it gives an opinion on the means implemented by the member states to monitor radioactive discharges into the environment and the levels of radioactivity in the environment around nuclear sites and over the national territory. It notably gives its assessment of the monitoring equipment and methodologies used and of the organisational setup.

Since 1994, the EC has carried out about ten verification visits to different types of nuclear facilities in France (nuclear power plants, “fuel cycle” plants, research centres, former uranium mines).

4.2 Environmental monitoring

4.2.1 The French National Network for Environmental Radioactivity Monitoring

In France, many parties are involved in environmental radioactivity monitoring:

- the nuclear facility licensees, who perform monitoring around their sites;
- ASN, IRSN (whose duties as defined by Decree 2016-283 of 10 March 2016 include participation in radiological monitoring of the environment), the Ministries (General Directorate for Health, General Directorate for Food, General Directorate for Competition Policy, Consumer Affairs and Fraud control, etc.), the services of the State and other public players carrying out monitoring duties across the national territory or in particular sectors (foodstuffs controlled by the General Directorate for Competition Policy, Consumer Affairs and Fraud control, for example);
- the approved air quality monitoring associations (local authorities), environmental protection associations and Local Information Committees (CLIs).

The French National Network of Environmental Radioactivity Measurements (RNM) federates all these players. Its primary aim is to collect and make available to the public, by means of a dedicated website (*mesure-radioactivite.fr*) all the regulation environmental measurements taken on French territory. The quality of these measurements is guaranteed by a laboratories approval procedure (*see point 4.3*).

The RNM guidelines (for example, the new types of measurements to be integrated into the RNM) are decided by a network steering committee made up of representatives from all the stakeholders in the network: ministerial departments, ARS, representatives of nuclear licensee or association laboratories, CLI members, IRSN, ASN, etc. The ASN Chairman’s

resolution CODEP-DEU-2023-053424 of 29 November 2023 enshrined the expansion of the composition of the RNM steering committee, notably by appointing representatives of the Dreal as members of the committee.

After the RNM website was launched in 2009 and overhauled for the first time in 2016, ASN and IRSN undertook work to modernise the tool in 2022 so that it was more in line with the needs of web users, whether the general public or more informed visitors.

A pluralistic working group consisting of the main nuclear licensees, representatives of civil society, ministers, IRSN and ASN, therefore met between 2022 and 2023 in order to identify areas for improvement and propose a number of changes to the site. Some have already been made, such as improving the function for performing searches around the sites. Modernisation of the website will continue in 2025.

4.2.2 The purpose of environmental monitoring

The licensees are responsible for monitoring the environment around their facilities. The content of the monitoring programmes to be implemented in this respect (measurements to be taken and frequency) is defined in amended ASN resolution 2013-DC-0360 of 16 July 2013, and in the individual requirements applicable to each installation (Creation Authorisation Decrees or ASN resolutions regulating water intake and discharges), independently of the additional measures that can be taken by the licensees for the purposes of their own monitoring.

This environmental monitoring:

- contributes to understanding the radiological and radio-ecological state of the facility’s environment through measurements of parameters and substances regulated in the requirements, in the various environmental compartments (air, water, soil) as well as in the biotopes and food-chain (milk, plants, etc.); a datum is determined before the facility is created and monitoring the environment throughout the lifetime of the facility enables any changes in this datum to be followed;
- helps verify that the impact of the facility on health and the environment is in conformity with the impact assessment;
- detects any abnormal increase in radioactivity as early as possible;
- ensures that the licensees comply with the regulations and that there are no facility malfunctions, notably by analysing the ground water;
- contributes to transparency and information of the public through the transmission of monitoring data to the RNM.

TABLE 7 Examples of radiological monitoring of the environment around BNIs

Environment monitored or type of inspection	Cattenom NPP (ASN resolution 2014-DC-0415 of 16 January 2014)	Orano plant at La Hague (amended ASN resolution 2015-DC-0535 of 22 December 2015)
Air at ground level	4 stations continuously sampling atmospheric dust on a fixed filter with daily measurements of total β activity (βG). γ spectrometry if $\beta G > 2 \text{ mBq/m}^3$ - Monthly γ spectrometry on groups of filters per station 1 continuous sampling station downwind of the prevailing winds, with weekly measurement of atmospheric ^3H	5 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the total α activity (αG) and total β activity (βG). γ spectrometry if αG or $\beta G > 1 \text{ mBq/m}^3$ - Monthly α (Pu) spectrometry on grouped filters per station 5 continuous sampling stations for halogens on specific adsorbent with weekly γ spectrometry to measure iodines 5 continuous sampling stations with weekly measurement of atmospheric ^3H 5 continuous sampling stations with bi-monthly measurement of atmospheric ^{14}C 5 continuous measurement stations for ^{85}Kr activity in the air
Ambient γ radiation	- Continuous measurement with recording: 4 radiation monitors at 1 km 10 radiation monitors on the site boundary 4 radiation monitors at 5 km	5 detectors with continuous measurement and recording 11 detectors with continuous measurement at the site fencing
Rain	1 continuous sampling station under the prevailing winds with bi-monthly measurement of βG and ^3H	2 continuous sampling stations including one under the prevailing winds with weekly measurement of αG, βG and ^3H γ spectrometry if significant αG or βG
Receiving environment liquid discharge	- Sampling from the river upstream of the discharge point and in the good mixing area for each discharge - Measurement of βG, potassium (K)* and ^3H - Continuous sampling in the river at the good mixing point ^3H measurement (average daily mixture) - Annual sampling in aquatic sediments, fauna and flora upstream and downstream of the discharge point with γ spectrometry, free ^3H measurement and, on fish, organically bound ^{14}C and ^3H - Periodic sampling from a stream and in the dam adjoining the site with measurements of βG, K, ^3H	- Daily seawater samples from 2 points on the coast, with daily measurements (γ spectrometry, ^3H) at one of these points and for each of the 2 points, α and γ spectrometry and βG, K, ^3H and ^{90}Sr measurements - Quarterly seawater samples at 3 points offshore with γ spectrometry and βG, K, ^3H measurements - Quarterly samples of beach sand, seaweed and limpets at 13 points with γ spectrometry + ^{14}C measurements and α spectrometry for the seaweed and limpets at 6 points - Sampling of fish, crustaceans, shellfish and molluscs in 3 coastal zones of the Cotentin with α and γ spectrometry and ^{14}C measurement - Quarterly sampling of offshore marine sediments at 8 points with α and γ spectrometry and ^{90}Sr measurement - Weekly to six-monthly samples of water from 19 streams around the site, with αG, βG, K and ^3H measurements - Quarterly sampling of sediments from the 4 main streams adjacent to the site, with γ and α spectrometry - Quarterly samples of aquatic plants in 3 streams in the vicinity of the site with γ spectrometry and ^3H measurement
Groundwaters	Monthly sampling at 4 points, bi-monthly at 1 point and quarterly at 4 points with βG, K and ^3H measurement	5 sampling points (monthly check) with αG, βG, K and ^3H measurement
Water for consumption	Annual sampling of water intended for human consumption, with βG, K and ^3H measurements	Periodic sampling of water intended for human consumption at 15 points, with αG, βG, K and ^3H measurements
Soil	1 annual sample of the topsoil with γ spectrometry	Quarterly samples at 7 points with γ spectrometry and ^{14}C measurement
Vegetation	2 grass sampling points, including one under the prevailing winds, monthly γ spectrometry and quarterly ^{14}C and C measurements - Annual campaign for the main agricultural crops, with γ spectrometry, ^3H and ^{14}C measurements	- Monthly grass sampling at 5 points and quarterly at 5 other points with γ spectrometry and ^3H and ^{14}C measurements, - Annual α spectrometry at each point - Annual campaign for the main agricultural crops, with α and γ spectrometry, ^3H, ^{14}C and ^{90}Sr measurements
Milk	2 sampling points situated at 0 to 10 km from the installation, including one under the prevailing winds, with monthly γ spectrometry, quarterly ^{14}C measurement and annual ^{90}Sr and ^3H measurement	5 sampling points (monthly check) with γ spectrometry, K, ^3H, ^{14}C and ^{90}Sr measurement

 αG = α total; βG = β total(*) Measurements of total concentration of potassium by spectrometry for ^{40}K .

4.2.3 Content of monitoring

All the nuclear sites in France that produce discharges are subject to systematic environmental monitoring. This monitoring uses a graded approach to the environmental risks or detrimental effects of the facility, as presented in the authorisation file, particularly the impact assessment.

The regulation monitoring of the environment of BNIs is tailored to each type of facility, depending on whether it is a nuclear power reactor, a plant, a research facility, a waste disposal centre, and so on. The minimum contents of this monitoring are defined by the amended Order of 7 February 2012 setting the general rules for BNIs and by the above-mentioned modified resolution of 16 July 2013. This resolution obliges BNI licensees to have approved laboratories take the environmental radioactivity measurements required by the regulations.

Depending on specific local features, monitoring may vary from one site to another. Table 7 (*see previous page*) gives examples of the monitoring performed by the licensee of an NPP and of a “fuel cycle” plant.

When several facilities (whether or not BNIs) are present on the same site, joint monitoring of all these installations is possible, as has been the case, for example, on the Cadarache and Tricastin sites since 2006.

These monitoring principles are supplemented in the individual requirements applicable to the facilities by monitoring measures specific to the risks inherent in the industrial processes they use.

Each year, in addition to sending ASN the monitoring results required by the regulations, the licensees transmit nearly 120,000 measurements to the RNM.

4.2.4 Environmental monitoring nationwide by IRSN

IRSN’s nationwide environmental monitoring is carried out by means of measurement and sampling networks dedicated to:

- air monitoring (aerosols, rainwater, ambient gamma activity);
- monitoring of surface water (watercourses) and groundwater (aquifers);
- monitoring of the human food chain (milk, cereals, fish, etc.);
- terrestrial continental monitoring (reference stations located far from all industrial facilities).

This monitoring is based on:

- continuous on-site monitoring using independent systems (remote-monitoring networks) providing real-time transmission of results. This includes:
 - the *Téléray* network (ambient gamma radioactivity in the air) which uses a system of continuous measurement monitors around the whole country. The density of this network is being increased around nuclear sites within a radius of 10 to 30 kilometres around BNIs;

- the *Hydrotéléray* network (monitoring of the main watercourses downstream of all nuclear facilities and before they cross national boundaries);

- continuous sampling networks with laboratory measurement, for example the atmospheric aerosols radioactivity monitoring network;
- laboratory processing and measurement of samples taken from the various compartments of the environment, whether or not close to facilities liable to discharge radionuclides.

Every year, IRSN takes more than 25,000 samples in all compartments of the environment (excluding the remote-measurement networks).

The artificial radioactivity levels measured in France are stable and situated at very low levels, generally at the detection sensitivity threshold of the measuring instruments. The artificial radioactivity detected in the environment results essentially from fallout from the atmospheric tests of nuclear weapons carried out in the 1960s, and from the Chernobyl (Ukraine) accident. Traces of artificial radioactivity associated with discharges can sometimes be detected near installations. To this can be added very local contaminations resulting from incidents or past industrial activities, and which do not represent a health risk.

On the basis of the nationwide radioactivity monitoring results published in the RNM and in accordance with the provisions of ASN resolution 2008-DC-0099 of 29 April 2008, as amended, IRSN regularly publishes a detailed *Summary of the radiological state of the French environment*. The fifth edition of this summary, for the period 2021-2023, was published in December 2024.

4.3 Laboratories approved by ASN to guarantee measurement quality

Articles R.1333-25 and R.1333-26 of the Public Health Code require the creation of an RNM and a procedure to have the radioactivity measurement laboratories approved by ASN. The RNM working methods are defined by the above-mentioned amended ASN resolution 2008-DC-0099 of 29 April 2008.

This network is being deployed for two main reasons:

- to pursue the implementation of a quality assurance policy for environmental radioactivity measurements by setting up a system of laboratory approvals granted by ASN resolution;
- to ensure transparency by making the results of this environmental monitoring and information about the radiological impact of nuclear activities in France available to the public on the RNM website (*see point 4.2.1*).

The approvals cover all environmental matrices for which regulatory oversight is imposed on the licensees: water, soil or sediment, biological matrices (fauna, flora, milk), aerosols and atmospheric gases. The measurements concern the main artificial or natural gamma, beta or alpha emitting radionuclides, as well as the ambient gamma dosimetry. The list of the types of measurements covered by an approval is set by the above-mentioned amended ASN resolution 2008-DC-0099 of 29 April 2008.

In total, the approvals cover about fifty measurements, for which there are as many Inter-laboratory Comparison Tests (ILTs). These tests are organised by IRSN in a 5-year cycle, which corresponds to the maximum approval validity period.

4.3.1 Laboratory approval procedure

The above-mentioned amended ASN resolution 2008-DC-0099 of 29 April 2008 specifies the organisation of the national network and sets the approval arrangements for the environmental radioactivity measurement laboratories.

The approval procedure notably includes:

- presentation of an application file by the laboratory concerned, after participation in an ILT;
- review of it by ASN;
- examination of the application files – which are made anonymous – by a pluralistic approval commission which delivers an opinion on them.

The laboratories are approved by ASN resolution published in its *Official Bulletin*. The list of approved laboratories is updated every six months and published on *asn.fr*.

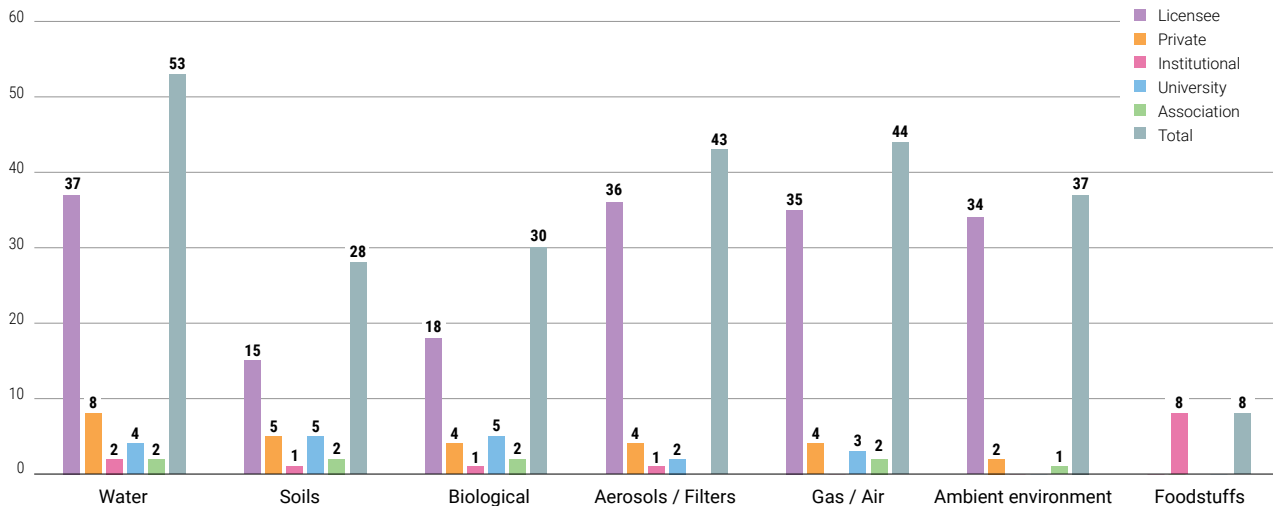
4.3.2 The approval commission

The approval commission is tasked with ensuring that the measurement laboratories have the organisational and technical competence to provide the RNM with high-quality measurement results.

The commission is authorised to propose approval, rejection, revocation or suspension of approval to ASN. It issues a decision on the basis of an application file submitted by the candidate laboratory and its results in the ILTs organised by IRSN. It meets every six months.

The commission, chaired by ASN, comprises qualified persons and representatives of the State services, laboratories, standardising authorities and IRSN.

In 2023, ASN renewed the composition of the approval commission in ASN Chairman’s resolution CODEP-DEU-2023-052098 of 13 October 2023, concerning nominations to the approvals commission for environmental radioactivity measurement laboratories.

GRAPH 7 Approved laboratories per type of matrix as at 1 January 2025

4.3.3 Approval conditions

Laboratories seeking approval must set up an organisation meeting the requirements of standard NF EN ISO/IEC 17025 concerning the general requirements for the competence of calibration and test laboratories.

In order to demonstrate their technical competence, they must take part in ILTs organised by IRSN. The five-year programme for these tests is updated annually. It is reviewed by the approval commission and published on the RNM's website. Up to 70 laboratories sign up for a type of test, including a number of laboratories from other countries.

The approval commission defines the evaluation criteria used for analysis of the

ILTs. When the result obtained in an ILT by a laboratory is not conclusive enough, ASN may, on the advice of the approval commission, issue an approval for a trial period of one to two years for example, or make issue of the approval dependent on the provision of additional data, or even the participation in a further corroborating test.

In 2024, IRSN organised five ILT and four corroborating tests. Since 2003, 115 ILTs have been carried out, covering 60 types of approval. The largest number of approved laboratories is for monitoring of radioactivity in water, with 53 laboratories. Between 30 and 44 laboratories are approved for measurement of biological matrices (fauna, flora, milk), atmospheric dust, air, or ambient gamma dosimetry. There are

28 approved laboratories for soils and sediments. Although most laboratories are competent to measure gamma emitters in all environmental matrices, between 10 and 20 of them are approved to measure carbon-14, transuranic elements or radionuclides of the natural chains of uranium and thorium in water, soil and sediments and the biological matrices (grass, plant crops or livestock, milk, aquatic fauna and flora, etc.).

In 2024, ASN issued 351 approvals or approval renewals. As at 31 December 2024, the total number of approved laboratories stood at 67, which represents 961 approvals of all types currently valid on 1 January 2025.

The detailed list of approved laboratories and their scope of technical competence is available on asn.fr.

5 — Inspections concerning counterfeit, falsifications and suspected fraud, and processing of reported cases

5.1 Inspections concerning counterfeit, falsifications and suspected fraud

Since 2015, several cases of irregularities that could be considered to be falsifications have been brought to light at known manufacturers, suppliers or organisations who have been working for many years on behalf of the French nuclear industry. Confirmed cases of counterfeit or falsification have also been encountered in a number of other countries in recent years. The term of irregularity was initially employed by ASN to cover any intentional modification, alteration or omission of certain information or data. ASN is gradually adopting the term of "Counterfeit, Falsification or Suspected Fraud" (CFS), which is better suited to the issue as it is more in line with the term usually

employed internationally: Counterfeit, Fraudulent and Suspect Items (CFSI). A CFS detected by ASN can be characterised by a judge in a case of criminal fraud.

The number of confirmed or suspected cases remains few in number but they do exist, despite the high level of quality demanded in the nuclear industry and the robustness of the monitoring and inspection chain, the key links of which are the manufacturers, suppliers and licensees. The licensees have improved their monitoring and therefore the detection of CFS. They must however maintain their efforts to adapt their monitoring methods more adequately to the prevention, detection, analysis and processing of cases of CFS.

In 2016, ASN began to look at adapting BNI inspection methods in an irregularity context. In so doing, it questioned other

regulation and oversight administrations, its foreign counterparts and the licensees with regard to their practices, in order to learn the pertinent lessons. This particular risk gave rise to changes to ASN's oversight methods (specific checkpoints, dedicated governance bodies, development of awareness of licensees and suppliers, etc.). The existing framework is used for processing.

In 2018, ASN also reminded the BNI licensees and the main manufacturers of nuclear equipment that a CFS is a deviation as defined by the BNI Order. The requirements of the Order therefore apply to the prevention, detection and processing of cases of CFS. More generally, the regulatory requirements concerning the safety and protection of persons against the risks related to ionising radiation also apply. For example, applying a signature to certify that an activity has been correctly

carried out, whereas in reality it has not, could – depending on the circumstances – be a breach of the rules of organisation, technical inspection of activities, skills management, etc.

For a number of years now the CFS search has become one of the usual inspection practices and specific internal tools have been made available to the inspectors.

Incorporating CFS into inspections corresponds to three contexts:

- inspections further to known subjects, resulting from CFS discovered in other facilities, or to monitor the processing of a case previously detected;
- inspections including an in-depth search for proof in the performance of activities, for example with verification of the actual presence of a person who certified that they had carried out an activity on a given date, or the examination of inspection registration source data;
- inspections with the purpose of raising awareness concerning the risks of CFS, notably during supplier inspections, where the risk of CFS in the subcontracting chain is dealt with.

This is a priority subject of inspection for ASN. An inspection campaign on all the BNIs was launched in 2024 and will continue in 2025. It concerns the organisations in place in the installations to prevent and process CFS. The inspections of this campaign, focusing on organisational and human factors, include numerous interviews with the various stakeholders in the life of the installations, from the hierarchy responsible for CFS aspects down to the operatives performing various works in the installations.

More than 70 inspections of this type were carried out in 2024. They mainly took place on the nuclear sites and at the manufacturers of equipment intended for use there. Inspections devoted to this topic were also carried out in the head office departments of the main nuclear licensees.

The cases detected are first of all dealt with as deviations from the regulatory requirements. They are also the subject of discussions with the site management and the head office departments of the licensees, so that preventive action can be taken. Depending on the potential implications of the deviation, a violation report can be drafted or, in the event of a misdemeanour, the Public Prosecutor's Office is notified and they are then responsible for determining whether or not to prosecute (Article 40 of the Penal Procedure Code).

In 2024, ASN issued three reports. When the Public Prosecutor initiates investigations, ASN provides support for the investigators appointed by the legal authorities for technical analysis of documents and to facilitate dealings with the nuclear licensees.

In addition, the question of data integrity – that is ensuring that data have not been

modified or destroyed without authorisation – linked to the risk of CFS, given that shortcomings in traceability can facilitate irregularities, continued to be frequently addressed since 2023 and formed the subject of requirements in several inspection follow-up letters.

New CFS are still being detected, both by the licensees, within the context of their monitoring and internal checks, and by the ASN inspectors. In 2024, 104 were examined by ASN, whether suspected cases, proven cases or cases finally cleared after analysis. This significant increase in the number of cases identified by comparison with 2023 can be explained by three main factors:

- the licensees, EDF in particular, continued to implement their CFS prevention, detection and processing actions. The inspections they carried out resulted in higher levels of detection;
- ASN's CFS inspection campaign mentioned above enabled the inspectors to detect CFS but also to collect more information from the licensees;
- greater publicity concerning the ASN whistle-blower system (see point 5.2) leads to new cases being identified.

CFS cases are being followed-up and processed in close collaboration with the licensees and manufacturers.

The CFS typology can be presented as follows:

- 80 concern cases specific to a facility, with no potential generic component (action signed off as done but absence in controlled area, falsification of performance of an activity or qualification of welders, etc.);
- 15 cases concern suppliers for which investigations were needed to check the absence of CFS, expanded to several licensees or suppliers (untraced or hidden weld repairs, supply of parts outside traceability circuit by "brokers", etc.). These cases led ASN to ask the licensees and manufacturer to check whether they were concerned (3 letters sent);
- 6 cases illustrate the potential of finding CFS in a related area such as approved or certified organisations: falsification of RPO certification, addition to an RPE-O appointment document without new signature, service provided as an approved organisation for radon measurements but without approval;
- 3 are cases found by ASN staff monitoring of news from abroad. Most of them lead to discussions with the licensees and manufacturers.

Finally, on 26 February 2024, the ASN Commission held a hearing of the EDF CEO on the subject of counterfeit, falsification and suspected fraud in the nuclear field. More details are given in the box in chapter 10.

ASN's actions to prevent, detect and process CFS are not limited just to the inspections. For example, ASN informs the main

licensees and manufacturers of the cases detected and analyses their responses. It holds bilateral discussions or inspection cross-observations with foreign safety regulators, through an international exchange channel that it actively helped to set up. In addition, ASN is making the suppliers aware of this. A specific informative guide (available in English and French) intended for the nuclear sector suppliers was published in 2024. One part of it is devoted to CFS.

Communication regarding cases of CFS dealt with by ASN could compromise other secret information protected by law, notably guarantees of strict confidentiality surrounding the authors of cases reported, the persons or companies involved, any third party mentioned and information collected by all recipients. ASN thus handles all these subjects confidentially and communicates no details.

5.2 Processing of reported cases

At the end of November 2018, ASN set up a portal to enable anyone wishing to notify it of irregularities potentially affecting the protection of persons and the environment (whistle-blower) to do so.

Act 2022-401 of 21 March 2022 aiming to improve whistle-blower protection, which modifies the system created by the "Sapin 2" Act of 9 December 2016, entered into force on 1 September 2022. It is supplemented by Constitutional Act 2022-400 of the same date, which aims to reinforce the role of the Defender of whistle-blower rights. These two Acts reinforce the whistle-blower protection system. They transpose Directive (EU) 2019/1937 of 23 October 2019 defining a common framework for this protection and take it even further.

A broader definition of whistle-blower, simplification of the alert procedures, reinforcement of the whistle-blower protections, a new status for the entourage of the whistle-blower and an expansion of the roles of the Defender of Rights with regard to whistleblowing are the main contributions of these Acts. Furthermore, Decree 2022-1284 of 3 October 2022 relative to the procedures for collecting and processing alerts submitted by whistle-blowers and setting out the list of external authorities instituted by the above-mentioned Act 2022-401 supplements these provisions by detailing the whistle-blowing report processing mechanisms. This Decree designated ASN as having competence to process whistle-blower alerts regarding radiation protection and nuclear safety. The system set up by ASN, which was originally voluntary, has been added to and meets these obligations.

By means of a system of pseudonyms for the reports received, ASN guarantees the confidentiality of anyone sending it

a report. Only a request from a judicial authority could override this confidentiality, something which has never yet happened.

It is however preferable for the person sending in the notification to leave their contact details so that ASN can:

- acknowledge receipt of the notification;
- contact them if clarification is required (this is frequently the case);
- inform them if action has been taken following their alert.

In 2024, 74 reports were sent to ASN: two-thirds (46) via the whistle-blower portal, the others by alternative means of transmission, mainly (15 reports) by direct contact with the ASN division geographically competent or the technical department in charge of the subject. The reports received vary:

- in the field concerned: about one third concern BNIs, one third the medical field;
- in their content: they can report CFS in the manufacturing plants, deterioration in the organisation of the entity which could affect radiation protection, poorly performed work, etc.

After a constant number of reports received in recent years, a significant rise was observed in 2024 (about +50%), despite a reduction in the reports outside the scope of ASN's oversight competence. A rising number of reports led to one or more in-depth interviews with their author.

With regard to reactors, this increase can be explained by:

- the performance of supplier inspections, a programme which continued to expand (*see point 6*). During these inspections, the subject of whistle-blower reports is covered. The suppliers are thus made more aware of this possible means of informing ASN;
- the June 2024 publication of the practical guide for the quality of equipment intended for nuclear installations, which includes a section on the whistle-blowing system;
- the 2024 ASN inspection campaign on CFS and human factors. The inspectors systematically ask the parties questioned whether they have access to a whistle-blowing system;
- implementation of the EDF action plan for CFS prevention and processing, the deployment of which was accelerated in 2024.

The fluctuation concerning the medical field cannot be explained by ASN's actions. Two factors could be a part of the explanation:

- the deployment of whistle-blowing arrangements by the health care professionals (doctors, nurses, dental surgeons, etc.) who are also designated by the above-mentioned Decree as competent to receive alerts and some of whom had deployed their own systems more belatedly than ASN. Whistle-blowing

reports could have followed different paths between 2023 and 2024 (transmission to the Order of Physicians rather than to ASN for example);

- the general publicity concerning the protection of whistle-blowers by the Defender of Whistle-blower Rights increased, notably with the publication of its first two-yearly report on whistle-blowers, to which ASN made a contribution.

Some reports are forwarded by ASN to other administrations when it is not competent to deal with them. These could also be foreign safety regulators. Three reports were thus transferred to ASN's foreign counterparts in 2024, as they involved installations in other countries.

All reports are examined and dealt with. This can lead to an inspection, a technical analysis, a request for information from a party responsible for a nuclear activity, etc. It could for example concern information regarding the security of a BNI, which must be addressed by the High Defence and Security Official at the Ministry for Energy.

Fifteen reports received in 2024 were verified during the course of inspections. The follow-up to these inspections is dealt with in the same framework as routine inspections.

6 — Inspection of the nuclear installations supply chain

The quality of manufacturing of the safety-important equipment for nuclear facilities is an essential factor in the safety of these facilities. The observed failures in compliance with the specified requirements for certain nuclear equipment, as well as the irregularities discovered in the industry, led ASN to reinforce its regulatory checks on the nuclear industry supply chain. In addition, at a time of considerable activity in the nuclear sector, controlling the supply chain is a particularly important challenge for the safety of the nuclear installations in service, as well as those being planned.

These checks take the form of inspections and can concern a variety of fields such as forges, foundries, piping manufacturers, but also manufacturers of generators, diesels, sensors, PLCs, I&C, pumps, etc. These inspections, both in France and abroad, can target companies of varying sizes. The inspections are a means of ensuring the pertinence of the monitoring of the subcontractor supply chain put into place by the licensees and manufacturers and, more particularly for the NPE, of checking the quality of manufacturing at the regulated manufacturers and their subcontractors. On the specific page of its website, ASN

publishes all the letters sent following up its inspections, and provides an annual summary (*see close-up in chapter 10*).

ASN also holds regular discussions with the nuclear industry representatives in order to explain the regulations, to develop changes made to the technical baseline requirements of the ordering parties, and share best practices and the ways of improving safety. ASN in particular wishes to see improvements in supplier and subcontractor knowledge of the regulatory requirements and of the need for traceability of activities important for the manufacture of equipment important for the protection of interests. This traceability is notably based on improved computerisation of manufacturing monitoring, which is insufficiently developed among certain companies in the sector. These discussions were in particular held with representatives of the sector within the French Nuclear Energy Industry Players Group (GIFEN).

In 2024, ASN published a practical guide in French and English, intended for the suppliers of equipment for nuclear facilities, and their subcontractors. The purpose of this practical guide is to make the

regulations and their objectives more accessible. It explains the design and manufacturing requirements for safety-important equipment, as well as the industrial practices that ASN considers to be satisfactory. The principles described are illustrated by industrial examples, with a resolutely practical approach. To draft it, in-depth technical exchanges were held with the GIFEN.

ASN is continuing with its international commitments regarding supplier oversight, within the Committee on Nuclear Regulatory Activities (CNRA) of the Nuclear Energy Agency (NEA). This commitment entails active participation in the Working Group on Supply Chain (WGSUP) involving the nuclear safety regulators, chaired by ASN. Within this working group, ASN shares and facilitates the adoption of best inspection practices among regulators, draws the attention of the regulators, licensees and suppliers to the most high-risk areas, and takes part in joint inspections.

7 – Identifying and correcting deviations

ASN implements enforcement measures, making it possible to oblige a licensee or RNA to restore compliance with the regulations, along with penalties.

In certain situations in which the actions of the licensee or RNA fail to comply with the regulations in force, or when it is important that appropriate action be taken by it to remedy the most serious risks without delay, ASN may resort to enforcement measures and impose the penalties provided for by law. The principles of ASN actions in this respect are:

- actions that are impartial, justified and appropriate to the level of risk presented by the situation concerned. Their scale is proportionate to the nuclear safety, public health and environmental risks associated with the deviation identified and also take account of factors relating to the licensee (past history, behaviour, repeated nature), the context of the deviation and the nature of the requirements contravened (regulations, standards, “rules of good practice”, etc.);

- administrative measures initiated on proposals from the inspectors and decided on by ASN or the administrative enforcement committee, in order to remedy risk situations and non-compliance with the legislative and regulatory requirements as observed during its inspections.

Moreover, criminal infringement reports (violation, misdemeanour) can be issued by the ASN inspectors and transmitted to the competent local Public Prosecutor’s Office, which will assess whether or not to prosecute.

7.1 Enforcement measures and administrative sanctions

ASN has a range of tools at its disposal regarding an RNA or a licensee, more particularly:

- the inspector’s observations;
- the official letter from the ASN departments (inspection follow-up letter);
- formal notice from ASN to regularise the administrative situation or to comply with the regulations in force, within a time-frame determined by itself;
- enforcement measures or administrative sanctions, applied after non-compliance with the formal notice served.

These measures, as set out in law, are as follows:

- deposit in the hands of a public accountant of a sum covering the total cost of the work to be performed;
- the automatic completion of the work at the expense of the licensee or the RNA (the sums previously deposited may be used to pay for the work concerned);
- suspension of the operation of the facility or of the transport operation until conformity is restored, or suspension of the activity until complete performance of the conditions imposed and the adoption of interim measures at the expense of the person served formal notice, in particular in the event of urgent measures to protect human safety;
- a daily fine (an amount set per day, to be paid by the licensee or the party responsible until full compliance with the requirements of the formal notice has been achieved);
- administrative fine.

It should be noted that these last two measures are proportionate to the gravity of the infringements observed. With regard to administrative sanctions, the administrative enforcement Committee, when referred to by the ASN Commission, may hand down the administrative fine set out in 4° of II of Article L. 171-8 of the Environment Code, when a formal notice decision, issued beforehand by ASN against a licensee or party responsible for the nuclear activity to require compliance of the activity with the regulations in force, has not been met by the latter.

The administrative enforcement Committee, for which the kick-off meeting was held on 19 October 2021, met again at its annual information meeting on 8 January 2024.

The law also makes provision for interim measures to safeguard security and public health and safety or protect the environment. ASN can therefore:

- provisionally suspend operation of a BNI, immediately notifying the Ministers responsible for nuclear safety, in the event of any serious and imminent risk;
- at all times require assessments and implementation of the necessary measures in the event of a threat to the abovementioned interests;

- take decisions to temporarily or definitively revoke the administrative title (authorisation and soon registration) issued to the RNA, after having informed the party concerned that it is entitled to submit observations within a given time, in order to comply with the exchange of views procedure.

In 2024, ASN sent out formal notice on three occasions: two for BNIs and one for small-scale nuclear activities.

ASN also decided to suspend a PE compliance certificate, a decision that was then lifted after reviewing the justifications of its compliance with the essential safety requirements.

7.2 The action taken following criminal violations

The texts also make provision for criminal infringements, misdemeanours or breaches. This will for example be non-compliance with the provisions concerning the protection of workers exposed to ionising radiation, non-compliance with formal notice served by ASN, performance of a nuclear activity without the required administrative title, non-compliance with the provisions of ASN resolutions or decisions, or irregular management of radioactive waste.

Any violations observed are written up in reports by the nuclear safety or radiation protection inspectors and transmitted to the Public Prosecutor’s Office, which decides on whether or not to prosecute.

The Environment Code makes provision for criminal penalties, a fine or even a term of imprisonment (up to €150,000 and three years in prison), depending on the nature of the violation. For legal persons found to be criminally liable, the amount of the fine can reach €10M, depending on the infringement in question and the actual prejudice to the interests mentioned in Article L. 593-1.

The Public Health Code also makes provision for criminal penalties, consisting of a fine of from €3,750 to €15,000 and a term of imprisonment of six months to one year.

TABLE 8 Number of violation reports transmitted by the ASN inspectors between 2018 and 2024

	2018	2019	2020	2021	2022	2023	2024
Report excluding labour inspection in the NPPs	14	8	4	2	3	4	4
Labour inspection report in the NPPs	2	4	8	0	2	2	3

Depending on the gravity of the offence, additional sentences may be applied to legal persons.

Class five penalties (fines) are stipulated in the field of nuclear safety for infringements mentioned in Article R. 596-16 of the Environment Code, as well as in the field of radiation protection for infringements mentioned in Articles R. 1337-14-2 to 5 of the Public Health Code, for example with regard to non-compliance with the requirements for notification of a significant event, to the administrative system (transmission of the title application file, compliance with general requirements, information concerning changes to the RPA.

With regard to pressure equipment, the provisions of Chapter VII of Title V of Book V of the Environment Code, which apply to products and equipment representing a risk, which covers pressure equipment, including that installed in BNIs, may notably order the payment of a fine, plus a daily penalty payment as applicable, until compliance with the formal notice served on the licensees. This Chapter also includes provisions applicable to the manufacturers, importers and distributors of such equipment, aiming to ban the marketing, commissioning or continued operation of an equipment item and to serve the licensee with formal notice to take all steps necessary to ensure conformity with the legislative and regulatory provisions applicable to its activity.

In the performance of their duties in NPPs, the ASN labour inspectors have at their disposal all the inspection, decision-making and enforcement resources of ordinary law inspectors (pursuant to Article R. 8111-11 of the Labour Code). Observation, formal notice, administrative sanction, report, injunction (to obtain immediate cessation of the risks) or even stoppage of the works, offer the ASN labour inspectors a broad range of incentive and constraining measures.

Finally, the inspector may record offences which do not fall within their scope of competence, such as an irregularity comparable to fraud (*see point 5.1*). In this case – and in the event of a misdemeanour this is mandatory – a report is sent to the Public Prosecutor's Office.

In 2024, seven violation reports were drawn up by the ASN inspectors. Table 8 (*see previous page*) shows the number of Violation Reports (PV) drawn up by the ASN inspectors between 2018 and 2023.

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AP

04

**Radiological
emergency and
post-accident
situations**



1

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Nuclear activities are carried out within a framework which aims to prevent accidents but also to mitigate their consequences. Despite all the precautions taken, an accident can never be completely ruled out and the necessary provisions for managing a radiological emergency situation must be planned for and regularly tested and revised.

Radiological emergency situations, resulting from an incident or accident liable to lead to an emission of radioactive substances or to a level of radioactivity potentially jeopardising public health, include:

- emergency situations arising on Basic Nuclear Installations (BNIs);
- accidents involving the transport of radioactive substances;
- emergency situations occurring in the field of small-scale nuclear activities.

Emergency situations affecting nuclear activities can also comprise non-radiological risks, such as fire, explosion or the release of toxic substances.

These emergency situations are covered by specific material and organisational arrangements, which include the contingency plans and involve both the licensee or party responsible for the activity and the public authorities.

The French Nuclear Safety Authority (ASN) is involved in managing these situations, with regard to questions concerning the regulation of nuclear safety and radiation protection and, backed more particularly by the expertise of its technical support organisation, the Institute for Radiation Protection and Nuclear Safety (IRSN), it has the following four key duties:

- check the steps taken by the licensee and ensure that they are pertinent;
- advise the authorities on population protection measures;
- take part in the dissemination of information to the population and media;
- act as Competent Authority within the framework of the international Conventions on Early Notification and Assistance.

In 2005, at the request of the Prime Minister, ASN also set up a Steering Committee for the Management of the Post-Accident Phase (Codirpa) so that, following on from the management of a radiological emergency, preparations can be made for the post-accident phase.

This pluralistic Committee notably comprises experts, representatives of the State's services, local elected officials, Local Information Committees (CLIs), associations, etc.

In 2022, this Committee published its latest recommendations to the Government. These aim notably to include the lessons learned from the accident at the Fukushima Daiichi Nuclear Power Plant (NPP – Japan) and the national emergency exercises on the national strategy for post-accident management of the consequences of a nuclear accident.

1 — Planning ahead

Four main principles underpin the protection of the general public against BNI risks:

- risk reduction at source, wherein the licensee must take all steps to reduce the risks to a level that is as low as possible in acceptable economic conditions;
- the emergency and contingency plans, designed to prevent and mitigate the consequences of an accident;
- controlling urban development around BNIs;
- informing the general public.

1.1 Looking ahead and planning

1.1.1 The Basic Nuclear Installation site emergency and contingency plans

The emergency and contingency plans relative to accidents occurring at a BNI define the measures necessary to protect the site personnel, the general public and the environment, and to control the accident.

a) Major Nuclear or Radiological Accident National Response Plan

ASN took part in drafting the Major Nuclear or Radiological Accident National Response Plan (PNRANRM), which was published by the Government in February 2014. The Plan incorporates the lessons learned from the Fukushima Daiichi NPP accident and the post-accident doctrine drawn up by the Codirpa in 2012. It specifies the national response to a nuclear accident, the strategy to be applied and

Rapid data feedback for more efficient emergency management

Under the aegis of the General Secretariat for Defence and National Security (SGDSN), ASN and IRSN have for several years been working with the licensees of nuclear installations other than the EDF reactors (for which there is also a system for feedback of technical information in the event of an emergency), in order to secure and optimise the transmission to IRSN and ASN of the information needed for emergency management, in an accident situation.

Many months of work and considerable commitment by the teams at IRSN and the licensees led to the first links between

the Orano facilities and the IRSN Emergency Centre being implemented in 2024. In an emergency situation, these links allow automatic and real-time transmission to the IRSN Emergency Centre of radioactive measurement data concerning the outlets from the facilities. These data will be rapidly available and are essential for assessing any radioactive releases into the environment in an accident situation, along with the possible consequences outside the facility. A local exercise conducted in 2024 on an Orano site demonstrated the pertinence of this approach.

the main actions to be taken. It includes the international nature of emergencies and the mutual assistance possibilities in the case of an event.

This plan is currently being revised by the SGDSN and ASN is involved in this revision work.

b) Off-site Emergency Plans

In the vicinity of the facility, the Off-site Emergency Plan (PPI) is established by the Prefect of the *département* concerned pursuant to Articles L. 741-6, R.741-18 *et seq.* of the Domestic Security Code, “to protect the populations, property and the environment, and to cope with the specific risks associated with the existence of structures and facilities whose perimeter is localised and fixed. The PPI implements the orientations of civil protection policy in terms of mobilisation of resources, information, alert, exercises and training”. These Articles also stipulate the characteristics of the facilities or structures for which the Prefect is required to define a PPI.

The PPI specifies the initial actions to be taken to protect the general public, the roles of the various services concerned, the systems for giving the alert, and the human and material resources likely to be engaged in order to protect the general public.

The PPI falls within the framework of the Disaster and Emergency Response Organisation (Orsec) which describes the protective measures decided on by the public authorities in large-scale emergencies. Therefore, beyond the application perimeter of the PPI, the *département* or zone Orsec plan is activated. ASN assists the Prefect, who is responsible for the drafting and approval of the PPI, by analysing the various aspects with its technical support organisation, IRSN, including those concerning the nature and scale of the radiological consequences of an accident.

The PPIs currently make it possible to plan the public authorities’ response in the first hours of the accident in order to protect the population living within a 20 km radius around the affected installation. The PPI

comprise a “reflex” phase, in which the licensee immediately issues an alert to the populations situated within a radius of from a few hundred metres up to 2 km (for electricity generating reactors). Once alerted by activation of the “PPI” sirens, the populations situated within this radius must take shelter and listen to the media. The PPI are also able to prepare for an “immediate evacuation” response from a distance of a few hundred metres up to 5 km (for electricity generating reactors). Finally, within a radius of up to 20 km around the installations, the PPI provide for the preventive distribution of stable iodine tablets for certain installations (reactors in particular), the adoption of measures to restrict consumption in the event of an accident, plus reinforced information of the populations regarding the risks from the installation and the appropriate behaviour to be followed.

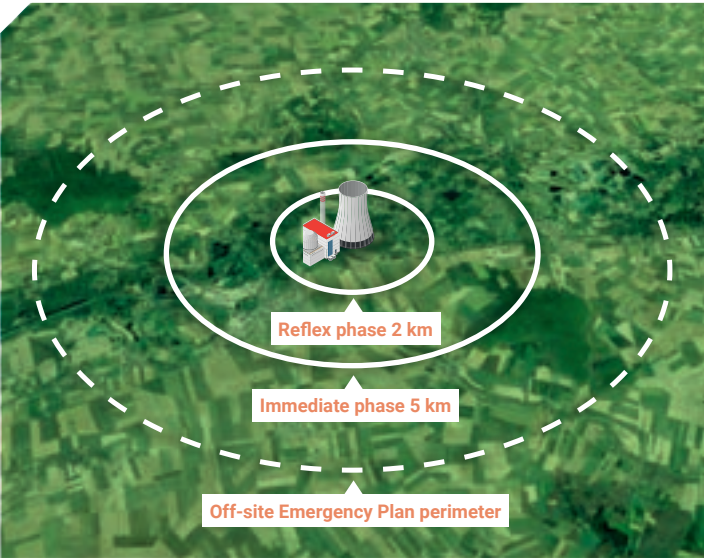
The additional measures to be taken beyond the zone covered by the PPI are specified, as applicable, through a joint approach which can be based on the Orsec arrangements, taking account of the characteristics of the accident and the weather conditions.

c) On-site Emergency Plan

As part of the BNI commissioning authorisation procedures, ASN examines and approves the On-site Emergency Plans (PUI) and their updates (Article R. 593-31 of the Environment Code).

The PUI, prepared by the licensee, is designed to restore the plant to a controlled and stable condition and mitigate the consequences of an event. It defines the organisational actions and the resources to be implemented on the site. It also includes the provisions for rapidly informing the public authorities.

DIAGRAM 1 Major Nuclear or Radiological Accident National Response Plan



Nationwide: Application of the “Major Nuclear or Radiological Accident National Response Plan”		
Reflex phase	Situation 1 of the Plan: immediate and short-duration release	- Shelter and await instructions over 2 km - Consumption restrictions
Immediate phase	Situation 2 of the Plan: immediate and long-duration release	- Shelter and await instructions over 2 km, then evacuation over 5 km - Consumption restrictions
Joint response	Other situation	Population protection measures based on dose forecasts and taking account of the local context

The obligations of the licensee relative to the preparation for and management of emergency situations are defined in Title VII of the Order of 7 February 2012 setting the general rules for BNIs. The associated provisions were stipulated in ASN resolution 2017-DC-0592 of 13 June 2017 concerning the obligations of BNI licensees in terms of preparedness for and management of emergency situations and the content of the PUI, known as the “emergency” resolution, approved by the Order of 28 August 2017.

1.1.2 Response plans for radioactive substance transport accidents

The transport of radioactive substances represents nearly a million packages carried in France every year. The dimensions, weight, radiological activity and corresponding safety implications can vary widely from one package to another.

ASN examines and approves the management plans for events linked to the transport of radioactive substances drawn up by the stakeholders for the transport of such substances pursuant to the international regulations for the carriage of dangerous goods. These plans describe the steps to be taken, depending on the nature and scale of the foreseeable hazards, in order to avoid damage or, as necessary, mitigate the effects. The content of these plans is defined in ASN Guide No. 17.

To deal with the possibility of a radioactive substances transport accident, each *département* Prefect must include in their implementation of the PNRANRM a part devoted to this type of accident, the Orsec-TMR (Transport of Radioactive Materials) plan. Faced with the diversity of possible types of transport operations, this part of the plan defines the criteria and simple measures enabling the first respondents (Departmental Fire and Emergency Service – SDIS – and law enforcement services in particular) to initiate the first reflex response measures to protect the general public and sound the alert, based on their findings on the site of the accident.

1.1.3 The response to other radiological emergency situations

Apart from the incidents or accidents which could affect nuclear installations or radioactive substances transport operations, radiological emergency situations can also occur:

- during performance of a nuclear activity for medical, research or industrial purposes;
- in the event of intentional or inadvertent dispersal of radioactive substances into the environment;
- if radioactive sources are discovered in places where they are not supposed to be.

In such cases, intervention is necessary to limit the risk of human exposure to ionising radiation. Together with the Ministries and the parties concerned, ASN therefore drafted Circular DGSNR/DHOS/DDSC 2005/1390 of 23 December 2005 relative to the principles of intervention in the case of an event that could lead to a radiological emergency, other than situations covered by a contingency plan or an emergency response plan. This Circular supplements the provisions of the Interministerial Directive of 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation presented in point 1.3 and defines the methods for the organisation of the State services in these situations.

Given the large number of potential originators of an alert and the corresponding alert circuits, all the alerts are centralised in a single location, which then distributes them to all the stakeholders: the centralising body is the fire brigade’s centralised alert processing centre CODIS-CTA (*Département* Operational Fire and Emergency Centre – Alert Processing Centre), that can be reached by calling 18 or 112.

The management of accidents of malicious origin occurring outside BNIs is not covered by this Circular, but by the Government’s NRBC (Nuclear, Radiological, Biological and Chemical) plan.

1.1.4 Controlling urban development around nuclear sites

The aim of controlling urban development is to limit the consequences of an accident for the population and property. An approach of this type has been in place since 1987 around non-nuclear industrial facilities and was reinforced following the AZF plant accident in Toulouse in 2001. Act 2006-686 of 13 June 2006 concerning transparency and security on nuclear matters (TSN Act, now codified in Books I and V of the Environment Code), enables the public authorities to control urban development around BNIs, by implementing institutional controls limiting or prohibiting new constructions in the vicinity of these facilities.

The actions to control urban development entail a division of responsibilities between the licensee, the mayors and the State:

- The licensee is responsible for its activities and the related risks.
- The mayor is responsible for producing the town planning documents and issuing building permits.
- The Prefect informs the mayors of the existing risks, verifies the legality of the steps taken by the local authorities and may impose institutional controls as necessary.

ASN supplies technical data in order to characterise the risk, and offers the Prefect its assistance in the urban development control process.

The current approach to controlling activities around nuclear facilities exclusively concerns those subject to a PPI and primarily aims to preserve the operational nature of the contingency plans, in particular for sheltering and evacuation, while limiting the population numbers concerned as far as possible. It focuses on the PPI “reflex” zone, determined by the Circular of 10 March 2000 revising the PPIs for BNIs, the pertinence of which was confirmed by the instruction of 3 October 2016.

In this “reflex” zone, immediate steps to protect the population are taken in the event of a rapidly developing accident (see point 1.1.1 b).

A 17 February 2010 Circular from the Ministry responsible for the environment concerning the control of activities in the vicinity of BNIs liable to present dangers off the site asked the Prefects to exercise increased vigilance with regard to urban development in the vicinity of nuclear facilities. This Circular states that the greatest possible attention must be paid to projects that are sensitive owing to their size, their purpose, or the difficulties they could entail in terms of protection of the general public in the “reflex” zone.

ASN is consulted on construction or urban development projects situated within this zone. The opinions issued are based on the principles explained in ASN Guide No. 15 on the control of activities around BNIs published in 2016. This Guide, drawn up by a pluralistic working group jointly overseen by ASN and the General Directorate for Risk Prevention (DGPR), comprising elected officials and the National Association of Local Information Committees and Commissions (Anccli), has the following basic objectives:

- preserve the operational nature of the contingency plans;
- give priority to regional development outside the “reflex” zone;
- allow controlled development that meets the needs of the resident population.

1.2 The emergency situation stakeholders

The response by the public authorities to a major nuclear or radiological accident is determined by a number of texts concerning nuclear safety, radiation protection, public order and civil protection, as well as by the emergency plans.

Act 2004-811 of 13 August 2004 on the Modernisation of Civil Protection, makes provision for an updated inventory of risks, an overhaul of operational planning, performance of exercises involving the general public, information and training

of the general public, an operational watching brief and alert procedures. Several Decrees implementing this Act, codified in Articles L. 741-1 to L. 741-32 of the Domestic Security Code, more specifically concerning the Orsec plans and PPIs, clarified it in 2005.

How radiological emergency situations are dealt with is specified in the interministerial directive of 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation (see Diagram 1).

Thus, at the national level, ASN is an active participant in interministerial work on nuclear emergency management.

The Fukushima Daiichi NPP accident showed that it was necessary to improve preparation for the occurrence of a multifaceted accident (natural disaster, accident affecting several facilities simultaneously). The response organisations thus put into place must be robust and capable of managing a large-scale emergency over a long period of time. Better advance planning must be carried out for work done under ionising radiation and, in order to provide effective support for the country affected, international relations must be improved.

1.2.1 Local response organisation

In an emergency situation, several parties have the authority to take decisions:

- The licensee of the affected nuclear facilities deploys the response organisation and the resources defined in its PUI (see point 1.1.1).

- ASN has a duty to monitor the licensee's actions in terms of nuclear safety and radiation protection. In an emergency situation, it calls on assessments by IRSN and can at any time ask the licensee to perform any assessments and take any actions it deems necessary.

- The Prefect of the *département* in which the installation is located takes the necessary decisions to protect the population, the environment and the property threatened by the accident. Within the framework of the PPI, this comprises the Orsec plans or the Off-site Protection Plan (PPE) in the event of a malicious act. The Prefect is thus responsible for coordinating the resources – both public and private, human and material – deployed in the PPI. He/she keeps the population and the mayors informed of events. ASN advises the prefect regarding population protection measures.

- The Prefect of the defence and security zone is responsible for coordinating reinforcements and the support needed by the Prefect of the *département*, for ensuring that the steps taken between *départements* are consistent, and for coordinating regional and national communications.

- Owing to his or her role in the local community, the mayor has an important part to play in anticipating and supporting the measures to protect the population. To this end, the mayor of a municipality

included within the scope of application of a PPI must draw up and implement a local safeguard plan to provide for, organise and structure the measures to accompany the Prefect's decisions. The mayor also plays a role in relaying the information and heightening population awareness, more particularly during iodine tablet distribution campaigns.

1.2.2 National response organisation

In a radiological emergency situation, each Ministry – together with the decentralised State services – is responsible for preparing and executing national level measures within their field of competence.

In the event of a major crisis requiring the coordination of numerous players, a governmental crisis organisation is set up, under the supervision of the Prime Minister, with activation of the Interministerial Crisis Committee (CIC). The purpose of this Committee is to centralise and analyse information in order to prepare the strategic decisions and coordinate their implementation at interministerial level. It comprises:

- all the Ministries concerned;
- the competent safety Authority and its technical support organisation (IRSN);
- representatives of the licensee;
- administrations or public institutions providing assistance, such as *Météo-France* (national weather service).

1.3 Protecting the population

The steps to protect the populations during the emergency phase, as well as the initial actions as part of the post-accident phase, aim to protect the population from exposure to ionising radiation and to any chemical and toxic substances that may be present in the releases. These measures are mentioned in the PPIs.

1.3.1 General protection measures

In the event of a major nuclear or radiological accident, a number of measures can be envisaged by the Prefect in order to protect the population:

- Sheltering and awaiting instructions: the individuals concerned, alerted by a siren or by FR-Alert (cell phone alert system), take shelter at home or in a building, with all openings closed, and wait for instructions from the Prefect broadcast by the media.
- Ingesting stable iodine tablets (only in the event of an accident involving radioactive iodine releases): when ordered by the Prefect, the individuals liable to be exposed to releases of radioactive iodine are urged to take the prescribed dose of iodine tablets.

- Evacuation: in the event of a risk of large-scale radioactive releases, the Prefect may order evacuation. The populations concerned are asked to prepare a bag

of essential personal effects, secure and leave their homes and go to the nearest assembly point.

Taking stable iodine tablets is a means of saturating the thyroid gland and protecting it from the carcinogenic effects of radioactive iodines.

Circular NOR INTE 1824870J of 13 September 2018 relative to the procedures for implementing iodine distribution campaigns within the PPI perimeters defines the principles governing the respective responsibilities of a BNI licensee and of the State with regard to the distribution of iodine tablets.

This Circular stipulates that the nuclear licensee – under the supervision of the State – shall be responsible for financing and distributing stable iodine tablets within the radius of the PPIs of its installation liable to release radioactive iodine in the event of an accident.

The previous information and iodine tablets distribution campaign within a radius of 0 to 10 km around the NPPs was carried out in 2016-2017, supplemented in 2019-2021 by a campaign in the 10-20 km zone following extension of the PPIs.

A campaign for renewal of the tablets distributed in 2016-2017 within the 0-10 km zone around the NPPs began in September 2024 and is currently in progress. A distribution campaign also started at the beginning of January 2025 around military ports.

Outside the zone covered by a PPI, tablets are stockpiled to cover the rest of the country. In this respect, the Ministries responsible for health and for the interior decided to constitute the stocks of iodine tablets which are put in place and managed by *Santé publique France* (Public Health France). Each Prefect defines the procedures for distribution to the population by means of a specific Orsec Iodine system, in compliance with the Circular of 11 July 2011. For its implementation, it relies on the local authorities (municipalities, public inter-municipal cooperation bodies – EPCI, etc.) and the services of the State responsible for emergency management. Specific exercises can be held on this topic.

The Prefect may also take measures to ban the consumption of foodstuffs liable to have been contaminated by radioactive substances as of the emergency phase (until the facility has been restored to a controlled and stable state).

The purpose of these measures, taken before the releases cease, is to facilitate management of the post-accident phase. Once the releases are over and the facility has returned to a stable state, further population protection steps are decided on, according to the deposition of radioactive materials in the environment. Depending on the ambient radioactivity level, this could involve:

- evacuating the population for a variable length of time;
- restrictions on the self-consumption of foodstuffs produced locally;
- checks on foodstuffs prior to marketing, in accordance with the maximum allowable levels of radioactive contamination defined at European level for the sale of foodstuffs.

1.3.2 Care and treatment of exposed persons

In the event of a radiological emergency situation, a significant number of people could be contaminated by radionuclides. These persons shall be cared for by the emergency response teams duly trained and equipped for this type of operation.

The Circular of 18 February 2011 regarding national doctrine for the use of emergency resources and care to deal with an act of terrorism using radioactive substances, specifies the provisions which also apply to a nuclear or radiological accident, and which aim to implement a unified nationwide methodology for the use of resources, in order to optimise efficiency.

The *Medical intervention following a nuclear or radiological event Guide*, the first version of which was published in 2018, and the drafting of which was coordinated by ASN, accompanies Circular DHOS/HFD/DGSR No. 2002/277 of 2 May 2002 concerning the organisation of medical care in the event of a nuclear or radiological accident, giving all the information of use for the medical response teams in charge of collecting and transporting the injured, as well as for the hospital staff. Under the auspices of ASN, a new version of this Guide including the organisational changes made since 2008 and the new protocols and methods for treating contamination, was published in June 2023.

1.4 Understanding the long-term consequences

The post-accident phase concerns the handling over a period of time of the consequences of long-term contamination of the environment by radioactive substances following a nuclear accident.

It covers the handling of consequences that are varied (economic, health, environmental and social), by their nature complex and that need to be dealt with in the short, medium or even long term, with a view to returning to a situation considered to be acceptable.

The procedure followed by the Codirpa, set up by ASN in 2005 at the request of the Prime Minister, led to the development of constituents of a first national doctrine for the post-accident management of a moderate scale nuclear accident leading to short-duration releases (less than 24 hours), published in 2012.

Following the work done by Codirpa to take better account of the lessons learned from the accident at the Fukushima Daiichi NPP, Operating Experience Feedback (OEF) from emergency exercises, changes to the regulations and to the international recommendations, a new version of the recommendations for post-accident management of a nuclear accident was published in 2022.

This document today constitutes the basis for post-accident management of a nuclear accident in France. It is intended for the local and national stakeholders concerned. Its purpose is to both incite these bodies to reflect upon the preparation for such a situation and guide them in the management of a real emergency.

The work of Codirpa is continuing in order to supplement these recommendations, notably to take better account of accidents not involving nuclear reactors which could notably involve alpha radioactivity. The work currently being done by the Committee is also aiming to define strategies to reduce the contamination of an area affected by a radiological or nuclear accident related to management of the associated waste, while taking account of the implications for the various types of environments affected (urban, agricultural, forest, etc.). In addition and in accordance with the mandate from the Prime Minister dated 18 June 2020, the examination of the pertinence of the post-accident management doctrine in the event of releases

of radioactive substances into aquatic environments, whether the sea, lakes or rivers, was started at the beginning of 2023.

Continuing its approach which is to include the population in the drafting of Codirpa's recommendations, ASN organised three citizen panel meetings in order to assess the understanding and acceptability of the protection measures and is collecting proposals from the populations concerned regarding Codirpa's proposals with respect to management of the consequences of a nuclear accident. On 11 September and 2 October 2024, the population living around the Paluel and Penly NPPs were invited to participate in a discussion with ASN regarding management of the marine environment following a nuclear accident (*see box below*). On 2 December, with the support and participation of the Anccli and the CLIs of Cadarache, Marcoule and La Hague, video-conference discussions were organised on the consideration of accidents with releases of alpha emitters in the recommendations for the post-accident management of a nuclear accident, published in 2022.

On these two subjects, and regardless of the form of the meeting (face to face or video-conference), feedback is positive for all the players: ASN receives feedback on the Codirpa's proposals while raising the population's awareness of the risk, and the public improves its knowledge and its emergency preparedness.



Citizen panels on the consequences of a nuclear accident on the marine environment

Consequences of a nuclear accident on the marine environment: ASN meets the public

To improve the population protection strategy in the wake of a nuclear accident, ASN wished to involve the stakeholders in Codirpa's work, to ensure that it is understood and accepted.

ASN and the Paluel-Penly Nuclear Local Information Committee (CLIN) thus organised two new citizen panels, on 11 September 2024 in Cany-Barville and 2 October 2024 in Petit-Caux, in order to collect the perceptions and expectations of the public living near a coastal nuclear installation.

These discussions lasted 3 hours and enabled about 25 local residents to express their opinion on the post-accident management of a nuclear accident concerning the marine environment (applicability and acceptability of the terrestrial post-accident zoning for the marine environment, difficulties linked to shifting contamination and fish, etc.).

The discussions were intense and will contribute to the drafting of Codirpa recommendations for the Government.

2 – ASN's role in an emergency and post-accident situation

2.1 The four key duties of ASN

In an emergency situation, the responsibilities of ASN, with the support of IRSN, are as follows:

- check the steps taken by the licensee and ensure that they are pertinent;
- advise the authorities on population protection measures;
- take part in the dissemination of information to the population and media;
- act as Competent Authority within the framework of the international Conventions on Early Notification and on Assistance.

Checking the steps taken by the licensee

In the same way as in a normal situation, ASN acts as the regulatory authority in an accident situation. In this particular context, ASN ensures that the licensee exercises in full its responsibility for keeping the accident under control, mitigating the consequences, and rapidly and regularly informing the public authorities. It draws on IRSN's expertise and assessments and can at any time ask the licensee to perform appraisals and take the necessary actions, without however taking the place of the licensee in the technical operations.

Advising the *département* and zone Prefects and the Government

The decision by the Prefect concerning the general public protection measures to be taken in radiological emergency and post-accident situations depends on the actual or foreseeable consequences of the accident around the site. The law states that it is up to ASN to make recommendations to the Prefect and the Government, incorporating the analysis carried out by

IRSN. This analysis covers both a diagnosis of the situation (understanding of the situation of the installation affected, analysis of the consequences for humans and the environment) and a prognosis (assessment of possible developments, notably radioactive releases). These recommendations more specifically concern the steps to be taken to protect the population in the emergency and post-accident phases.

Circulation of information

ASN is involved in informing:

- the media and the public: publication of press releases and organisation of press conferences; it is important that this action be coordinated with the other entities required to communicate (Prefects, licensees at both local and national levels, etc.);
- institutional and associative stakeholders: local authorities, ministries, Prefectures, political authorities, general directorates of administrations, CLI, etc.;
- foreign nuclear safety regulators.

Function of Competent Authority as defined by International Conventions

The Environment Code provides for ASN to fulfil the role of Competent Authority under the 1986 International Conventions on Early Notification and Assistance. As such, it collates and summarises information for the purpose of sending or receiving notifications and for transmitting the information required by these Conventions to the international organisations (International Atomic Energy Agency – IAEA – and European Union) and to the countries affected by the possible consequences on their own territory, jointly with the Ministry for Foreign Affairs.

2.2 Organisation in the event of a major accident

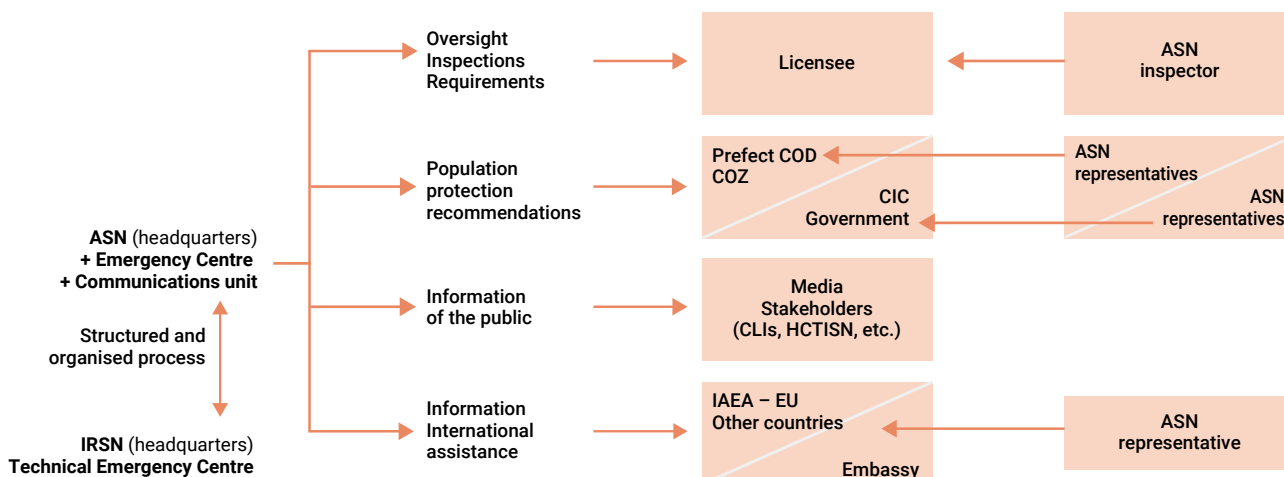
The ASN emergency response organisation set up to deal with a major accident more specifically comprises:

- the participation of ASN staff in the various units of the CIC;
- the creation of a national Emergency Centre in Montrouge (Île-de-France region) organised around an emergency director and various specialised units:
 - an “information management and coordination” unit, in charge of supporting the emergency director;
 - a logistics unit;
 - a “safety” unit in charge of understanding and assessing the ongoing event;
 - a “protection of persons, the environment and property” unit, notably in charge of proposing population protection actions;
 - an “internal and external communication” unit;
 - an “international relations” unit;
 - a “forward planning” unit.

The working of the Emergency Centre is regularly tested during national emergency exercises. The Centre is activated on the occasion of incidents or accidents. At the local level, ASN representatives visit the *département* and zone Prefects to help them with their decisions and their communication actions. ASN inspectors may also go to the site affected; others take part in emergency management at the headquarters of the regional division involved.

In 2024, the ASN Emergency Centre was activated on 10 occasions for 7 national exercises, 3 international exercises (1 of which was a “tabletop” exercise without actual activation of the Emergency Centre) and 1 actual situation.

DIAGRAM 2 The role of ASN in a nuclear emergency situation



COD: Departmental Operations Centre – COZ: Zone Operations Centre – CIC: Interministerial Crisis Committee – CICNR: Interministerial Committee for Nuclear or Radiological Emergencies
 – CLI: Local Information Committee – HCTISN: High Committee for Transparency and Information on Nuclear Safety.

TABLE 1 Positions of the various stakeholders in a radiological emergency situation

	Decision	Expert appraisal	Intervention	Communication
Public authorities	Government (CIC) Prefecture (COD, COZ)	–	Prefecture Civil protection	Government (CIC) Prefecture (COD)
	ASN (CU)	IRSN (CTC) <i>Météo-France</i>	IRSN (mobile units)	ASN IRSN
Licensees	National and local levels	National and local levels	Local level	National and local levels

CIC: Interministerial Crisis Committee - COD: Departmental Operations Centre – COZ: Zone Operations Centre - CTC: Emergency Technical Centre – CU: Emergency Centre

The ASN emergency organisation was called on several times in 2024, following triggering of the PUI on nuclear installations.

In 2024, three NPPs triggered their PUI following an outbreak of fire in an area situated outside the controlled area (in other words, outside the nuclear area): the Chinon NPP in February (transformer fire), the Paluel NPP in May (transformer fire) and the Cattenom NPP in June (fire in a ventilation room). In each case, the on-call team was activated in order to monitor the development of the situation and prepare to activate the Emergency Centre if necessary. These three situations were rapidly brought under control by the EDF teams, leading to no consequences for the safety of the installations. Each time, ASN authorised lifting of the PUI a few hours after it was triggered.

On 10 April 2024 at 18h30, ASN was informed by the Apave company that a radioactive source had become blocked during radiographic inspections by Apave NDT on the site of the ADF company in Colmar (Haut-Rhin *département*). The ASN on-call team, along with the ASN Strasbourg division, monitored the event so that they could assist the public authorities in managing it (*see chapter 8*).

On 11 December 2024 at 13h21, the ASN on-call team decided to activate its Montrouge Emergency Centre after being alerted regarding a fire on the Orano site in Bessines-sur-Gartempe. ASN monitored the situation jointly with the prefecture of the Haute-Vienne *département*, the licensee and IRSN. The situation was brought under

control by the Orano teams on the site in mid-afternoon and the ASN Emergency Centre was deactivated at 16h30. The IRSN sent its environmental monitoring resources to the site, which confirmed that there were no radioactive releases.

During exercises, or in the event of a real emergency, ASN is supported by a team of analysts working in IRSN's Technical Emergency Centre.

ASN's alert system allows mobilisation of its Emergency Centre staff and those of IRSN. This automatic system sends an alert signal to the staff equipped with appropriate reception devices, as soon as it is remotely triggered by the BNI licensee originating the alert. It also sends the alert to the staff of the SGDSN, the General Directorate for Civil Security and Emergency Management (DGSCGC), the Interministerial Emergency Management Operations Centre, *Météo-France* and the Ministerial operational monitoring and alert centre (CMVOA) of the Ministries for Regional Planning and for Ecological Transition.

A radiological emergency toll-free number also enables ASN to receive calls reporting events involving sources of ionising radiation used outside BNIs or during the transport of radioactive substances. It is accessible 24/7. This number is reserved for companies holding a licence to possess radioactive sources issued by ASN in accordance with the Public Health Code and for companies transporting radioactive materials. Depending on the severity of the event, ASN may activate its Montrouge Emergency Centre by triggering the alert system. If not, only the ASN

local level (regional division concerned) intervenes to perform its Prefect support and communication duties, if necessary, calling on the expertise of the national departments. In order to enhance the graded nature of the ASN response and organisation in the event of an emergency, for situations not warranting activation of the Emergency Centre, the on-call team provides assistance to support the regional division concerned.

Since 2018, an on-call duty system reinforces the robustness and the mobilisation and intervention reactivity of the ASN staff.

Diagram 2 (*see previous page*) summarises the role of ASN in a nuclear emergency situation. This functional diagram illustrates the importance of the ASN representative to the Prefect, who relays and explains the recommendations coming from the ASN Emergency Centre.

Table 1 shows the positions of the public authorities (Government, ASN and technical experts) and the licensees in a radiological emergency situation. These players each operate in their respective fields of competence with regard to assessment, decision-making, intervention and communication, for which regular audio-conferences are held. The exchanges between the players lead to decisions and orientations concerning the safety of the facility and the protection of the general public. Similarly, relations between the communication units and the spokespersons of the emergency centres ensure that the public and media are given coherent information.

3 — Learning from experience

3.1 Carrying out exercises

The main aim of these nuclear and radiological emergency exercises is to test the planned response in the event of a radiological emergency, in order:

- to measure the level of preparedness of all the entities involved (safety Authorities, technical experts, licensees);
- to ensure that the plans are kept up to date, that they are well-known to those in charge and to the participants at all levels and that the alert and coordination procedures they contain are effective;

- to train those who would be involved in such a situation;
- to implement the various aspects of the organisation and the procedures set out in the Interministerial Directives: the emergency plans, the contingency plans, the local safeguard plans and the various conventions;
- to contribute to informing the media and to develop a general public information approach so that everyone can, through their own individual behaviour, contribute to civil protection;
- to build on emergency situation management knowledge and experience.

These exercises, which are scheduled by an annual interministerial instruction, involve the licensee, the Ministries, the offices of the Prefects and services of the *départements*, ASN, the Defence Nuclear Safety Authority (ASND), IRSN and *Météo-France*, which can represent up to 300 people when resources are deployed in the field. They aim to test the effectiveness of the provisions made for assessing the situation, the ability to bring the installation or the package to a safe condition, to take appropriate measures to protect the general public and to ensure satisfactory communication with the media and the populations concerned.

3.1.1 National nuclear and radiological emergency exercises

In the same way as in previous years, and together with the SGDSN, the DGSCGC and the ASND, ASN prepared a programme of national nuclear and radiological emergency exercises for 2024, concerning BNIs and the transport of radioactive substances.

This programme was announced to the Prefects in the interministerial instruction of 24 January 2024.

Generally speaking, these exercises enable the highest-level decision-making circles to be tested, along with the ability of the leading players to communicate, sometimes with simulated media pressure on them.

Table 2 describes the key characteristics of the national exercises conducted in 2024.

In addition to the national exercises, the Prefects are asked to conduct local exercises for the sites in their *département*, in order to improve preparedness for radiological emergency situations and more specifically to test the time needed to mobilise all the parties concerned.

The performance of a national nuclear and radiological emergency exercise, at maximum intervals of five years on the nuclear sites covered by a PPI, and at least one annual exercise concerning the transport of radioactive substances, would seem to be a fair compromise between the training of individuals and the time needed to effect changes to organisations.

In 2024, in addition to the general objectives of the exercises listed in Table 2, additional objectives were introduced into the schedule, taking account of lessons learned and the results of the exercises and experimental training carried out in 2023.

ASN is also heavily involved in the preparation and performance of other emergency exercises that have a nuclear safety component and are organised by other players such as:

- its counterparts for nuclear security (HFDS – Defence and Security High Official reporting to the Minister in charge of energy) or for Defence-related facilities (ASND);
- the international bodies (IAEA, European Commission, Nuclear Energy Agency – NEA);
- the Ministries for Health, the Interior, etc.

The experience acquired during these exercises should enable the ASN personnel to respond more effectively in real emergency situations.

3.2 Assessing with a view to improvement

Assessment meetings are organised immediately after each exercise in each Emergency Centre and at ASN a few weeks after the exercise. ASN, along with the other players, endeavours to identify best practices and the areas for improvement brought to light during these exercises.

These assessment meetings enable the players to share their experience through a participative approach. They more specifically revealed:

- the importance of having scenarios that were as realistic as possible, in real meteorological conditions and that were technically complex enough to be able to provide useful experience feedback;
- the importance of communication in an emergency situation, in particular to inform the public and foreign authorities as rapidly as possible and avoid the spread of rumours liable to hamper good emergency management, in France and in other countries;
- the importance of providing the decision-makers with a clear view of the radiological impacts in the form of maps: the tool called “Criter” developed by IRSN gives a representation of the results of environmental radioactivity measurements.



Exercises to ensure the system is fully operational by 1 January 2025

Act 2024-450 of 21 May 2024, relative to the organisation of nuclear safety and radiation protection governance, in order to address the challenges of the nuclear industry's renewal, provides for the creation of the Authority for Nuclear Safety and Radiation Protection (ASNR) through a merger of ASN and IRSN. Since 1 January 2025, ASNR has thus taken over the duties currently performed by ASN and IRSN in an emergency situation. As of the publication of this Act, ASN and IRSN reinforced their collaboration to ensure the ASNR has an operational emergency response organisation by 1 January 2025. This emergency response organisation was tested on several occasions between September and December 2024, both during national emergency exercises (see *Table 2 of 2024 national exercises*), but also during “local” exercises organised by the nuclear licensees at the local level.

Thus on Tuesday 17 September 2024, the ASN and IRSN teams met at the IRSN Emergency Centre in Fontenay-aux-Roses

(the future site of the ASNR Emergency Centre) to take part in an emergency exercise organised by EDF on the Flamanville site, in ASNR operational mode for the first time. About thirty IRSN and ASN emergency team members took part in this exercise, which started at 9h20 with the triggering of the PUI on the Flamanville site. A large number of observers were also present, in order to familiarise themselves with the new organisation and prepare their feedback.

This grouping in a single Emergency Centre was much appreciated by the participants and led to more fluid interactions between the various stakeholders, thus facilitating the production of recommendations and data used to assess the situation and intended for the public authorities.

This exercise produced joint ASN-IRSN feedback for use by the working group in charge of implementing the ASNR emergency response organisation on 1 January 2025.



TABLE 2 National nuclear and radiological emergency exercises conducted in 2024

Nuclear site	Dates of exercise	Main characteristics
EDF Civaux NPP (86)	24 and 25 January	- Decision-making process and simulated media pressure - Test of bilateral information exchanges with Luxembourg and Germany
INEX 6 exercise (NEA)	7 February	- Tabletop exercise - Post-accident management regarding different aspects: foodstuffs, decontamination work and management of the corresponding waste
Bugey NPP (01)	28 February	Decision-making process and simulated media pressure
Transport of radioactive substances (88)	27 June	- Feedback from the field to the national Emergency Centre - Decision-making process
ConvEx-2b (IAEA)	3 et 4 September	Test of the mechanisms for offering assistance to a country affected by an accident
ECUREX (European Commission)	25 September	Test of European mechanisms for information feedback in the event of an accident in a European country
Cherbourg Naval Base (50)	14 and 15 November	Test of the new ASNR emergency organisation and coordination with ASDN
EDF Belleville-sur-Loire NPP (18)	21 and 22 November	- Decision-making process - ASN inspectors dispatched to the affected site
EDF Tricastin NPP (26)	28 November	Test of the new ASNR emergency organisation
Transport of radioactive substances (60)	12 december	- Feedback from the field to the national Emergency Centre - Test of the new ASNR emergency organisation

4 — Outlook

In 2024, ASN continued its activities in the field of emergency management and took part in numerous national and international exercises, organising a large number of inspections to allow testing of the operational nature of emergency management at the licensees, by means of simulations.

With regard to post-accident management, 2024 is the last year of Codirpa's current mandate.

In 2025, ASNR will be consolidating its emergency response by taking advantage of the creation of the ASNR Emergency Centre which brings together the decision-making bodies of the former ASN and the expert assessment skills of the former IRSN within

the same organisation. This new Emergency Centre, which has been operational since 1 January 2025, is the fruit of preparatory work performed throughout 2024. ASNR will carry out specific inspections on the emergency management topic, will take part in national emergency exercises and will work on relations with its border counterparts in order to improve the consistency of emergency management with them.

In the post-accident field, the reports on completion of the work done to take account of accidents other than those in the NPPs and on marine environment management in the post-accident phase will be published in early 2025.

Finally, ASNR will submit proposals to the Prime Minister regarding the follow-up to Codirpa's work, with a view to a new mandate.

05

**Informing
and involving the
various audiences**



1

Developing relations with the various audiences p. 185**1.1 The general public**

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- 2.3.1 Consultation of the public on draft ASN regulations
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- 2.3.3 Consultation of particular bodies
- 2.3.4 Consultation: for ever wider and more varied participation of the various audiences

2.4 The information actors

- 2.4.1 High Committee for Transparency and Information on Nuclear Safety
- 2.4.2 Institute for Radiation Protection and Nuclear Safety
- 2.4.3 Local Information or Monitoring Committees
- 2.4.4 National Association of Local Information Committees and Commissions



The Act of 13 June 2006 on Transparency and Security in the Nuclear Field defined not only the public's right to be informed but also the nuclear players' duty of transparency. To fulfil this duty, ASN – the French Nuclear Safety Authority – deploys its efforts in two directions:

- ASN uses a wide range of means of involving its various audiences to fulfil its duty to inform and its goal of contributing to enlightened societal choices with regard to nuclear safety and radiation protection. Through this proactive and continuous approach, ASN is working to improve the understanding of the challenges and enriching its decision-making process by enhancing the participation of the stakeholders, as well as reinforcing the nuclear safety and radiation protection culture. ASN also conducts specific actions aimed at the professionals (publication of guides, organisation of conferences and seminars) to inform them of the regulations and enhance their awareness of safety and radiation protection issues.
- ASN also replies to the many queries from the stakeholders, such as environmental associations, professionals, local authorities, etc. The ASN spokespersons also respond to numerous queries from the media.

Each year, ASN is given a hearing before the Parliament on its activities and high-stake issues. It also contributes to the work of the Local Information Committees (CLIs).

1 — Developing relations with the various audiences

1.1 The general public

ASN works to ensure that citizens have reliable information on the nuclear risks and that they develop the appropriate radiation protection reflexes in all circumstances (particularly with respect to the risks of exposure of medical personnel and patients during medical activities involving ionising radiation, but also for people living close to nuclear installations). To this end, ASN develops relations with its stakeholders and uses diverse vectors: printed or digital publications, website, social networks, events communication, etc.

Since 2022, ASN has participated in National resilience day (13 October) which aims to raise citizen awareness to natural and industrial risks. This national day brings together several nuclear sector actors (the National Association of Local Information Committees and Commissions – Anccli, EDF and the Institute for Radiation Protection and Nuclear Safety– IRSN) in order to raise public awareness of the nuclear risks and what to do in the event of a nuclear alert. In 2024, ASN mobilised six of its regional divisions which organised various actions (conferences, events, workshops). ASN participated more specifically in the “resilience village” in Belleville-sur-Loire (Cher département) which received nearly 900 visitors (see box next page).

In its youth-focused work, ASN renewed its support for the “International High School Radiation Protection Meetings”, where French and foreign high school pupils can share the research work they have carried out during the academic year. On 3 and 4 April 2024, 110 high school pupils and their teachers gave a presentation at IRSN's Fontenay-aux-Roses site of their work on protection against radiological risks.

The *Cahiers de l'ASN* publications aim to provide an informative overview of major subjects relating to nuclear safety. With numerous illustrations (diagrams, photos, computer graphics) and short and airy texts, they are designed to make for easy reading. The *Cahiers de l'ASN* are distributed to nearly 6,000 subscribers and are available at asn.fr.

Two new issues of the *Cahiers de l'ASN* were published in 2024:

- *Cahier #05 – 1,300 MWe nuclear reactors – Operation beyond 40 years: the issues of the 4th periodic safety review;*
- *Cahier #06 – Radioactive waste: how to implement lasting solutions to protect human health and the environment?*

They supplement the existing collection of *Cahiers*:

- *Cahier #01 – Nuclear power plants going beyond 40 years: the issues of the 4th periodic safety review of the 900 MWe nuclear power reactors;*

- *Cahier #02 – Nuclear power plants going beyond 40 years: what are the conditions for the continued operation of EDF's 900 MWe reactors?;*
- *Cahier #03 – 10 years after Fukushima: what safety improvements for nuclear facilities in France?;*
- *Cahier #04 – The decommissioning challenges: ensuring the correct performance of this final phase in the life of a nuclear facility.*

In 2025, the collection will be renamed *Cahiers de l'ASNR*. A new cahier will be devoted to the conditions of continued operation of the 1,300 MWe nuclear reactors beyond 40 years.

Furthermore, in 2023 ASN published a *Cahier Histoire de l'ASN*, devoted to nuclear accidents and developments in nuclear safety and radiation protection.

ASN sends its two-monthly *Lettre de l'Autorité de sûreté nucléaire* (Nuclear Safety Authority Newsletter) to more than 5,000 subscribers. This publication provides a summary of the most noteworthy topical issues and information relative to ASN resolutions and actions. To receive the ASN newsletter free of charge, simply register on asn.fr.

1.1.1 The website *asn.fr*

With more than 850,000 visits in 2024, the *asn.fr* website is at the heart of ASN's information organisation. It posts the draft opinions and resolutions that represent the most important issues for public consultation.

The website is also a reference source of information for the more informed audiences: citizen experts, professionals, members of environmental associations. In all, nearly 3.5 million pages of the website were viewed in 2024.

The aim of the website is to facilitate access to its 25,000-odd pages devoted to the oversight of nuclear safety and radiation protection, the regulations, and ASN's actions in the areas of health, industry and nuclear research. Content and functionalities are available under the same conditions whatever the medium used (computer, telephone, tablet), in accordance with the accessibility standards in effect and the requirements of the Act for a Digital Republic.

A high-performance search engine and a map of the facilities (nuclear power, industrial and medical) provide for fast and precise browsing.

The website endeavours to facilitate access to the desired information according to the audiences:

- workers in the sectors subject to ASN oversight and regulation (for the on-line services and forms in particular), technical experts, lawyers, people living near nuclear facilities, patients and medical practitioners, elected officials and journalists can access the news of the sites or the inspection documents that interest them: inspection follow-up letters, significant event notices, etc.;
- citizens interested in the safety issues and wishing to be involved in the decision-making process. Educational content (videos, computer graphics, topical files) is available and the "public consultation" module has been improved.

ASN has stepped up the fraud prevention and detection measures following the discovery of irregularities in the Creusot Forge plant in 2016, with the organisation in 2024 of a webinar on the subject in collaboration with Anccli, and the publication of a dedicated guide (see box next page). The *asn.fr* website has a secured form for reporting cases of fraud in the nuclear sector. This application guarantees the protection of whistle-blowers and confidential treatment of the information received. Of the 74 reports ASN received in 2024, 46 were made via the on-line reporting portal of *asn.fr*.

"National resilience day": raising public awareness at the "resilience village" event in Belleville-sur-Loire (Cher département)

On 6, 7 and 8 November 2024, Belleville-sur-Loire hosted the "Atom'Investigation" village, an event to raise awareness to nuclear risks baptised "National resilience day". On this occasion, ASN organised two events which were attended by nearly 900 visitors.

The organisation of the "Atom'Investigation" resilience village is the result of a collective effort (26 partner entities) coordinated by the Prefecture of the Cher département. Bringing together nuclear and radiological risk actors (ASN, IRSN, Anccli, French National Agency for Radioactive Waste Management – Andra, EDF, Departmental Fire and Emergency Services – SDIS, CLIs, French Institute of Instructors-Major Risks and Environmental Protection – Iffo-RME, etc.), the village was inaugurated on 6 November by the Prefect of the Cher département in the presence of Géraldine Pina, ASN Commissioner.

Scheduled between the campaign of preventive distribution of stable iodine tablets (launched on 15 September) and the emergency exercise at Belleville-sur-Loire (21 and 22 November), "Atom'Investigation" aimed to develop knowledge of the nuclear risk, prepare the public for a nuclear accident and develop collective resilience.

ASN proposed two events: one entitled "Returning to your home after a nuclear accident" was based on a role game on the post-accident theme (see below); the other devoted to nuclear safety used the display boards of the ASN-IRSN exhibition.

These events were attended by nearly 700 pupils (32 classes), 52 accompanying adults and about a hundred local residents, who used the opportunity to ask any questions they had. This positive experience feedback will be useful to ASNR



in what, since 1 January 2025, constitutes one of its new duties, namely "to contribute to the development of a radiation protection culture in the citizens" (Article 1 of Act 2024-450 of 21 May 2024).

The role game "Returning to your home after a nuclear accident"

Developed by ASN with the support of Iffo-RME, this role game is based on the use of a play mat representing an area close to an accident-stricken nuclear facility. Magnets to be positioned on the play mat prompt the players to reflect upon what will become of an area contaminated by radioactivity.

The objective is to avoid a number of misrepresentations and to explain, for example, the difference between contamination and irradiation, or to understand that an accident at a nuclear power plant in France would not result in a nuclear explosion. This is a prerequisite for presenting the approach for winning back an area after an accident. This approach is addressed through the presentation of decontamination techniques, prioritisation of the objectives (what should you decontaminated first?), and the benefits for citizens of measuring the radioactivity in their environment.

As of 1 January 2025, the website of the French Authority for Nuclear Safety and Radiation Protection (ASNR) *asn.fr* provides access to the information and services available on the previous websites of ASN and IRSN.

1.1.2 The social networks

The website content, which can be consulted on smartphones or tablets, is also shared on the main social media (primarily X, Facebook, YouTube and LinkedIn). The news feeds of the ASN social media accounts convey the main position statements. The major events in which ASN participates (parliamentary hearings, public meetings) are announced and can be followed in real time on the social networks. ASN's social media

accounts would also be used to inform the public in an emergency situation.

ASN's news was followed and passed on in 2024 by more than 17,500 subscribers on X, more than 55,000 on LinkedIn and 4,900 on Facebook.

In 2025, the ASN and IRSN accounts are replaced by those of ASNR on X, LinkedIn, YouTube, Facebook and Instagram.

1.1.3 The ASN/IRSN exhibition

As part of their duty to inform the public, ASN and IRSN have created educational content intended for high school pupils, students, employees, hospital personnel, patients, etc., and for the citizens in general. Comprising more than 80 display boards covering eleven themes, the exhibition, entitled "Radioactivité – découvrir et comprendre" (Learning about and



understanding radioactivity) is designed to provide information on radioactivity – whether natural or artificial – its uses, its implications and its effects on human health and the environment. A set of question-and-answer cards was created in 2024 as a teaching aid to be used with the exhibition.

The exhibition was hosted in 35 places in 2024: high schools, CLIs, healthcare facilities, regional authorities, etc.

This exhibition is made available on request, free of charge. It can be integrated into numerous events and meet the needs of varied situations (*see next page*).

The exhibition can also be viewed on line. The website (<https://expo-radioactivite.irs.fr>) was revamped in 2024, with more attractive images and more fluid and intuitive browsing.

1.1.4 The ASN Information Centre

Any citizen can address information requests to ASN, either on-line, by letter or by phone. In 2024, the on-line information centre responded to 663 requests on diverse subjects (technical questions, requests for transmission of administrative documents, information relative to the environment, publications, documentary searches, etc.).

As of 2025, on-line information requests are to be made at info@asn.fr.

1.2 The professionals

ASN produces specific publications, organises and takes part in numerous symposia and seminars to make known the regulations, to raise professionals' awareness of their responsibilities and the implications of nuclear safety and radiation protection, and lastly to encourage the reporting of significant events.

1.2.1 Making known the regulations and enhancing the radiation protection culture

ASN considers that having clear regulations based on the best safety standards is an important factor for improving nuclear safety and radiation protection. Over the last few years it has thus undertaken a major overhaul of the technical and general regulations applicable to Basic Nuclear

Installations (BNIs), while always being attentive to the clarity and completeness of the information delivered to the professionals concerning these regulations. The same goes for radiation protection of workers and patients in the medical and industry sectors: ASN makes guides, practical sheets and reference manuals available to everyone.

A space for the professionals on asn.fr

The professionals have a dedicated space on the ASN website where they can find forms and regulatory texts, along with publications aiming to provide explanations or assistance in the application of the regulations. As of 1 January 2025, this content is available via the heading "Regulations" on asn.fr.

Practical tools for concrete application of the regulations

Radiation protection regulations have undergone major changes in the Public Health Code and the Labour Code alike.

The ASN Guides give recommendations, present the means ASN considers appropriate for achieving the objectives set by the regulations, and share the methods and good practices resulting from lessons learned from significant events.

ASN has published a practical guide for nuclear component suppliers and manufacturers (*see box below*). It is available in both French and English via a dedicated page in the professional space of the asn.fr website. In this space, nuclear

Guaranteeing the quality of equipment intended for nuclear facilities



1,200 plants design and manufacture equipment for nuclear facilities, either as 1st-tier suppliers or as subcontractors. The industry players have expressed their need to better understand the specific requirements associated with the nuclear sector.

After two years of work and interchanges with stakeholders, ASN published in June 2024 a practical guide that is tailored to meet their concerns. Each topic is illustrated by examples from industry and answers the questions addressed to ASN.

This guide places the emphasis on a number of fundamentals:

- ensuring that subcontractors are properly informed of the safety requirements;
- identifying and ensuring the traceability of all manufacturing activities that could affect the safety of the nuclear facility;
- preventing and detecting the risks of fraud.

The guide was distributed at the "Outlook Days" of the French Nuclear Energy Industry Group (GIFEN), as well as to the nuclear licensees.

Objective: jointly ensure the quality of the equipment important for nuclear safety and improve the transmission of the design and manufacturing requirements along the entire subcontracting chain.

? RADIOACTIVITÉ

DÉCOUVRIR & COMPRENDRE

11
Sequences

85
Display boards



Radioactivity, what is it?



Radioactivity around us



The radon in our homes



The effects of radioactivity on the body



Treating illness with radiation



Little-known uses of radiation



Are nuclear power plants safe?



The nuclear accident



The "fuel cycle"



What do we do about radioactive waste?



The nuclear players

An exhibition to raise public awareness

The ASN-IRSN exhibition "Discovering and understanding radioactivity" intends to disseminate clear and objective information, without taboos or biases, on radioactivity, its uses, its risks, and its effects on health and the environment.

Each display board features computer graphics along with precise explanations, a "debate" section setting out the diversity of opinions and a popularised presentation of the subject for the younger audiences.

Organise the exhibition to meet your specific need

You can set up the exhibition that will best meet the needs of your audience. It can be consulted on line to choose the appropriate display boards.

■ Easy to set up

The exhibition takes the form of lightweight roll-up display boards that are easy to set up and take down. It can be adapted to the surface area and the layout of the hosting site.



It can be set up by one person without assistance. It takes about 30 minutes to set up fifteen display boards and 15 minutes to take them down.

■ Provided free of charge

ASN and IRSN make the exhibition available to town councils, teachers, local information committees, heads of associations and companies, health professionals, etc.

It can be integrated into numerous events and meet the needs of varied situations: emergency exercises, science fairs, open days, Day of resilience, educational projects, etc.



To borrow the exhibition, go to:

<https://www.asnr.fr/information/exposition-pedagogique-de-lasnr>



licensee suppliers and their subcontractors can find informative documents, follow-up letters to the inspections conducted by ASN on suppliers' premises and the ASN position statement letters.

The guide entitled *Main regulatory radiation protection provisions applicable in medical and dental radiology* was entirely updated in October 2024.

ASN met the radiology professionals at the French radiology days (JFR) in Paris in October, and the radiation protection professionals at the congress of the French Society for Radiation Protection (SFRP) in Lyon in November. Focusing this year on the theme of "Sharing know-how", the event provided the opportunity to widen and update knowledge in the area of radiation protection: regulatory changes, technical progress, experience feedback and practical cases.

1.2.2 A platform to facilitate on-line procedures

The regulatory procedures are gradually undergoing their digital transformation on the on-line services portal at *asn.fr*. ASN thus aims to facilitate the procedures for professionals, which helps to promote safety culture. Eleven declaration forms (including forms for declaring the possession of radioactive devices and sources and reporting dangerous goods transport events) and seven registration application forms (proposed to those responsible for nuclear activities in the industrial, medical, veterinary and research domains) are available.

1.2.3 Media for sharing good practices

The *Patient safety – Paving the way for progress bulletin* was created in March 2011 to disseminate the lessons learned from significant radiation protection events to medical professionals.

Since July 2019, it alternates between subjects devoted to radiotherapy, diagnostic medical imaging (conventional, computed tomography scanning and nuclear medicine) and Fluoroscopy-guided Interventional Practices (FGIPs). Produced by multidisciplinary working groups coordinated by ASN, the bulletin offers a thematic presentation, good practices and

recommendations developed by the professional organisations of the discipline concerned and the health and radiation protection institutions.

A "Learning from experience" sheet for the medical sector was published in April 2024. It alerts medical imaging centres to the risk of accidental changing of the exposure settings when restarting a mobile radiology device, a problem that caused additional exposures in children.

These publications are available on *asn.fr*.

1.3 The media

ASN maintains regular relations with the regional, national and foreign media throughout the year. Each year, the ASN spokespersons respond to more than 500 press requests and give some twenty local and national press conferences.

The news in 2024 was largely dominated by the debates concerning the reorganisation of the oversight of nuclear safety and radiation protection, the commissioning of the Flamanville EPR, the new nuclear programme with the announcement of several reactor construction projects and the development of Small Modular Reactors (SMRs), as well as the continued operation of the existing reactors beyond 50 years.

The regional conferences provided local information for the media on the latest news of the oversight of the facilities, the risk culture and how it is integrated by the population. ASN also maintains relations with the medical press on the subjects of patient and medical personnel radiation protection.

Each year at the time of the publication of its annual *Report on the situation of nuclear safety and radiation protection in France*, ASN meets regional press journalists. Ten regional conferences were held in 2024 from 10 to 24 September, bringing together 70 media representatives.

At these meetings, the ASN regional divisions report on ASN's assessment of the safety of the facilities in the regions. The current regional news in the area of radiation protection is addressed, whether it concerns the medical and industrial sectors, sites contaminated by radioactive substances, population exposure to radon, or former mining sites, etc.

Lastly, ASN has a duty to inform the public in the event of an emergency situation⁽¹⁾. In order to prepare for this, ASN staff receive specific training and take part in exercises. Emergency exercises are held each year, with simulated media pressure from journalists designed to test ASN's responsiveness to the media, as well as the consistency and quality of the messages put across by the various players, both nationally and locally (see chapter 4). The social networks have been integrated in these simulations since 2011.

1.4 Elected officials and institutional bodies

Each year, ASN presents its annual *Report on the situation of nuclear safety and radiation protection in France* to the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST).

This report, which constitutes the reference document on the state of the activities regulated by ASN, is also submitted to the President of the Republic, to the Government and to Parliament. It is sent out to more than 2,000 addressees: heads of administrative authorities, elected officials, licensees and persons/entities in charge of regulated activities or installations, associations, professional unions and organisations, etc.

Each year ASN is given about ten hearings before Parliament on its activity, on subjects relating to nuclear safety and radiation protection and in the context of the budget bill. ASN also maintains regular relations with national and local elected officials on the subjects of nuclear safety and radiation protection

1.5 International cooperation

ASN invests itself at international level to foster the sharing of best practices with regard to informing the public. It takes part in the transparency working group of the European Nuclear Safety Regulators Group (ENSREG); it participates in the work of the International Atomic Energy Agency (IAEA) and the Working Group on Public Communication of the Nuclear Energy Agency (NEA).

1. According to Article L. 592-32 of the Environment Code.

2 — Reinforcing the right to information and participation of the public

In 2024, ASN created a section on its website presenting the range of methods of associating the various audiences that it uses as the basis for fulfilling its duty to inform and involve the public.

ASN is extremely vigilant in the application of all the legislative and regulatory provisions relative to transparency and access of the various audiences to information. It ensures that they are applied by the licensees that are subject to its oversight. It also initiates voluntary actions to supplement the legislative and regulatory system for involving the public in developing public decisions. The aim is to record the expectations, worries, requirements and subjects of concern of the various stakeholders.

2.1 Information provided by the licensees

The main nuclear activity licensees implement a proactive public information policy. They are also subject to a number of legal obligations, either general, such as the environmental report required by the Commercial Code for joint stock companies, or specific to the nuclear sector as detailed below.

The annual public information report drawn up by the BNI licensees

All BNI licensees must establish an annual report concerning more specifically their situation and the steps they take with regard to the prevention of risks for public health and the environment, in accordance with Article L. 125-15 of the Environment Code. These reports are made public and transmitted to the CLI for the installation concerned and to the French High Committee for Transparency and Information on Nuclear Safety (HCTISN – Article L. 125-16).

Access to information in the possession of the licensees

The nuclear sector has a system that fosters public access to information. In application of Article L. 125-10 of the Environment Code, licensees must communicate to any person who so requests, the information they hold on the risks their activity presents for public health and the environment and on the measures taken to prevent or reduce these risks. This right to information on the risks also concerns those responsible for the transport of radioactive substances when the quantities involved exceed the thresholds set by law.

The Commission for Access to Administrative Documents

If a licensee refuses to communicate a document, the requesting party can refer the issue to the Commission for Access to Administrative Documents (CADA), an

independent administrative Authority. If the opinion of the CADA is not followed, the dispute may be taken before the administrative jurisdiction which will rule on whether or not the information in question can be communicated. ASN is particularly attentive to the application of this right to information, in compliance with the protection of interests provided for in law. Communication of the requested information must in particular not jeopardise national defence secrecy, State security, public safety, research and prevention of violations of any sort by the competent services, or business secrecy, which includes the secrecy of processes, economic and financial information and commercial or industrial strategies.

2.2 Information given to people living in the vicinity of Basic Nuclear installations

Article L. 125-16-1 of the Environment Code makes it obligatory to regularly inform the population in the neighbourhood of a BNI (people residing or working within the perimeter of an Off-Site Emergency Plan – PPI) of the nature of the risks of an accident linked to this installation, on the potential consequences of such accidents, on the planned safety measures and the action to take in the event of an accident. This information is provided at the expense of the licensee.

2.3 Consultation of the public on draft opinions, guides and resolutions

Article 7 of the Environment Charter embodies the right for any person to participate in the development of public decisions having an impact on the environment. French law accordingly provides for a number of public participation instruments (public inquiries or on-line consultations).

On this account, a large number of draft texts (ASN regulations or individual resolutions) subject to ASN opinion or produced by ASN, are subject to public participation. ASN has developed a policy that is highly favourable to public participation and it also consults the public on certain draft opinions or guides.

2.3.1 Consultation of the public on draft ASN resolutions

Article L. 123-19-1 of the Environment Code provides for a procedure of public consultation *via* the Internet on draft resolutions other than individual resolutions

having an impact on the environment. ASN has decided to apply this widely. Consequently, all draft ASN regulations concerning BNIs, including those relating to nuclear pressure equipment, are subject to public participation. The same approach is applied for the ASN regulations relative to the transport of radioactive substances.

ASN's regulations relating to radiation protection are also submitted to public participation if they concern activities involving significant discharges into the environment, producing a significant quantity of waste, causing significant nuisance for the neighbourhood or representing a risk for the people living nearby and the surrounding environments in the event of an accident.

Lastly, ASN applies the same procedure to certain draft guides and draft opinions, even though they do not constitute ASN regulations within the meaning of Article L. 123-19-1. Two consultations held in 2024 concerned draft ASN regulations.

The consultation for ASN regulations relating to radiation protection can be conducted on the basis of Article R*. 132-10 of the Code of Relations between the Public and the Administration when these regulations do not come under Article L. 123-19-1 of the Environment Code.

Consultations, what they involve



The public participation procedure consists in posting the draft ASN regulations on the ASN website (accessible *via asnr.fr* as of 1 January 2025) for at least 21 days in order to give people time to make their comments.

A synthesis of the remarks received, indicating how they were taken into account and a document setting out the reasons for the regulation are published on *asn.fr* at the latest on the date of publication of the regulation.

An indicative list of the scheduled consultations on draft ASN regulations and guides having an impact on the environment is updated every three months on *asn.fr*.

For the individual resolutions:

- it is the application file that is made available to the public if the resolution concerns an application;
- documents are available for consultation for fifteen days at least.



Fourth periodic safety review of the 1,300 MWe reactors: 9 months of consultation

The consultation prior to the future ASNR resolution on the conditions of the 4th periodic safety review of the 1,300 MWe nuclear reactors began in January 2024. Organised on the initiative of the HCTISN, this voluntary consultation ended in September 2024. Its objective was to inform the public about the process and the challenges of the 4th periodic safety review of the 20 nuclear reactors in operation and to inventory the citizens' questions on the conditions of continued operation of these reactors.

As was the case with the 900 MWe reactors, a digital platform was opened first as of autumn 2023. The website *concertation.suretenucleaire.fr* gives access to the relevant documents (those of the licensee, IRSN and ASN) and gives Internet users the possibility of asking questions and expressing opinions on the subject. Website visitors thus submitted more than 300 contributions on the subjects relating to the 4th safety review and, more broadly, on the continued operation of the nuclear reactors.

The platform also allowed the identification, through an on-line survey, of the subjects deemed the most important in the eyes of the public, so that the various actors could take them into account and provide answers via webinars. Five discussion webinars thus served to answer the questions of the public on the

security of the facilities, the consequences of climate change for the facilities or on the phenomena of ageing of the nuclear power plant components.

Alongside these methods of remote interchange, the HCTISN coordinated several face-to-face meetings with the public: eight meetings were thus held around the power plants concerned by the safety review, in addition to three workshops conducted near the Saint-Alban nuclear site. Organised with the support of the CLIs and Anccli at Cattenom, Belleville-sur-Loire and Golfech, for example, these meetings were attended by nearly one hundred people and enabled the local residents, elected officials and members of associations to put their questions to EDF, ASN and IRSN. Two guarantors chosen from the list of the National Public Debate Commission (CNDP) were mandated by the HCTISN to ensure that the information was clear and understandable.

The consultation ended on 30 September; the lessons learned and the public's comments on its draft resolution which will be collected between May and June 2025, will be taken into account by ASNR in its resolution on the conditions of the 4th period safety review of the 1,300 MWe reactors, expected to be issued in summer 2025.

2.3.2 Consultation of the public on draft individual resolutions

The individual resolutions⁽²⁾ concerning nuclear safety and radiation protection can form the subject of several public consultation procedures which are presented below.

The public inquiry

In application of the Environment Code, the BNI creation authorisation and decommissioning applications form the subject of a Public inquiry⁽³⁾. The file that undergoes the public inquiry contains the impact analysis and the risk control analysis, among other things. The impact analysis and the risk control analysis provide a clearly understandable

inventory of the risks that the projected installation represents and an analysis of the measures taken to prevent these risks. This analysis also includes a non-technical summary intended to facilitate the general public's understanding of the information it contains.

Since 2017, the public inquiry file can be consulted on line throughout the duration of the inquiry, and is provided in printed format in one or more predetermined places as soon as the public inquiry opens. The preliminary safety report (a more technical document) is not included in the public inquiry file but can be consulted throughout the inquiry period under

the conditions set by the order governing the inquiry.

Article L. 593-19 of the Environment Code requires the review report submitted by the licensee following the periodic safety reviews beyond the 35th year of operation of a nuclear power reactor to be subject to public inquiry. This system is particular insofar as the public inquiry in this case does not concern a project subject to an administrative authorization but a safety review report drawn up by the licensee. Articles R. 593-62-2 to R. 593-62-9 of the Environment Code set the conditions necessary for holding this public inquiry, notably to foster the effectiveness of public participation by enabling the public to assess the safety improvements already implemented and planned by the licensee in the context of the continued operation of its installation. ASN must take account of the results of this public inquiry in the resolution it may be obliged to issue to set complementary requirements.

Posting the draft documents on *asn.fr*

The individual resolutions that are not subject to public inquiry and which could have a significant effect on the environment (such as the draft resolutions relative to water intakes or discharges) are made available for consultation on the Internet in application of Article L. 123-19-2 of the Environment Code. If III of Article L. 122-1-1 of the Environment Code is applied, some BNI commissioning resolutions are subject to on-line public participation provided for in Article L. 123-19 of the Environment Code. During the year 2024, 82 consultations concerned draft individual resolutions.

The on-line consultation system remains available in 2025 on *asn.fr*.

2.3.3 Consultation of particular bodies

The BNI authorisation procedures also provide for consultation of the environmental Authority, the regional authorities and their groupings concerned by the project, and the CLIs (see point 2.4.3). The CLIs also have the possibility of being heard by the ASN Commission before it issues its opinion on the draft decrees, such as the Draft Authorisation Decree which is submitted to ASN by the Minister responsible for nuclear safety.

The CLI is consulted on the draft ASN requirements concerning water intakes, effluent discharges into the surrounding environment and the prevention or mitigation of detrimental effects of the installation for the public and the environment.

2. Resolutions that apply to a licensee for a given installation.

3. In application of the provisions of Article L. 593-8 or L. 593-28 of the Environment Code.

The Prefect forwards, for information, the draft requirements and the presentation report to the Departmental Council for the Environment and for Health and Technological Risks (Coderst).

It can also ask this Council for its opinion on the draft requirements.

2.3.4 Consultation: for ever wider and more varied participation of the various audiences

ASN ensures that these consultations allow the public and the associations concerned to contribute, in particular by verifying the quality of the licensee's files and by trying to develop the CLI's resources so that they can express an opinion on these files.

Digital technologies and citizen participation practices are bringing ASN to change the public consultation framework to ensure effective participation of the public in the decision-making process.

2.4 The information actors

2.4.1 High Committee for Transparency and Information on Nuclear Safety

The High Committee for Transparency and Information on Nuclear Safety (HCTISN), created by the TSN Act, is a body that informs, discusses and debates on nuclear activities, their safety and their impact on human health and the environment.

It can also deal with any issue concerning the accessibility of nuclear security information and propose any measures such as to guarantee or improve transparency.

The HCTISN develops opinions and makes them public. It organises four plenary meetings per year, at which major topical subjects are presented and discussed: all the presentations are available at hctisn.fr. The ASN Chairman is a member of the High Committee; ASN sits on the board of the HCTISN in an advisory capacity, takes part in its various working groups and regularly provides information on the subjects on plenary session agendas.

The two HCTISN groups, one devoted to the consultation on the fourth periodic safety review of the 900 and 1,300 MWe nuclear power reactors, the other to the consultation for the Cigéo project, continued their work in 2024.

2.4.2 Institute for Radiation Protection and Nuclear Safety

The Institute for Radiation Protection and Nuclear Safety (IRSN) implements a policy of information and communication that is consistent with the objectives agreement signed with the State.

The Energy Transition for Green Growth Act (called the "TECV Act") has obliged IRSN to render public the opinions it issues to the authorities who refer matters to it. Thus, since March 2016, IRSN publishes twice monthly on its website

all the opinions it issues at the request of ASN. These opinions are the synthesis of the expert assessment carried out by IRSN in response to ASN's referral.

On subjects that prompt questions on the part of the public or the public actors, ASN and IRSN ensure that their statements are properly coordinated in order to guarantee coherent, clear and consistent information. Since 1 January 2025, these two bodies have been merged to form a single entity, ASNR.

2.4.3 Local Information or Monitoring Committees

The Local Information or Monitoring Committees (CLIs) have a general mandate of monitoring, informing and consultation with regard to nuclear safety and radiation protection. They analyse the impacts of nuclear activities on the people and the environment within their scopes⁽⁴⁾.

ASN considers that the smooth functioning of the CLIs contributes to safety and it maintains a meaningful dialogue with them. It is attentive to ensuring that the CLIs are as fully informed as possible, including by attending their public meetings. In partnership with Anccli (see point 2.4.4), ASN fosters the networking of the CLI special advisors and gives the CLIs the necessary tools and assistance for them to provide reliable information to "layman" audiences. ASN assisted the CLIs at their request: on technical issues through its inspectors, and on questions of dissemination of information through its communication supervisors. The ASN-IRSN exhibition is regularly made available to the CLIs.

The ASN inspectors can also give the CLI representatives the opportunity to take part in inspections⁽⁵⁾. They motivate the BNI licensees to facilitate CLI access to files of the procedures in which their opinion will be required, and encourage involving the CLIs in the preparation of emergency exercises.

ASN considers that the development of a diversified range of expertise in the nuclear field is essential to enable the CLIs to base their opinions on expert assessments other than those carried out for the licensee or ASN itself. Anccli assists and supports the CLIs through its group of scientific experts.

Some CLIs call upon external service providers to advise them concerning technical files on which they wish to take a stance.

Consultation in the context of the Cigéo project review procedure

In order to meet the expectations of societal participation in the Cigéo project, and consistently with the measures planned on this account by the 5th PNGMDR (French National Radioactive Materials and Waste Management Plan), ASN has deployed an unprecedented consultation method for the technical review process.

Various stakeholders (about twenty organisations, including CLIs, Anccli and environmental protection associations) were thus consulted as part of IRSN's review of the Cigéo creation authorisation application, with the aim of identifying their expectations relating to nuclear safety and radiation protection, so that they could be taken into account when framing the assessment of the file. Following this exercise, the IRSN referral project was

modified, for example, to incorporate aspects related to addressing climate change issues.

To guarantee the continuity of participation by society throughout the technical review process, consultation measures will also be taken when drafting the Advisory Committees of Experts (GPEs) referrals on the three previously mentioned topics, and the public will be regularly informed, notably after each meeting of these GPEs. This information will provide some answers to the expectations and question that will have been integrated in it.

In keeping with this method, ASNR will organise a consultation on the preparation of the GPE referral with a view to its third meeting, scheduled for mid-2025.

4. The operating framework for the CLIs is defined by Articles L. 125-17 to L. 125-33 of the Environment Code and by Decree 2008-251 of 12 March 2008 relative to the CLIs for the BNIs, and by Decree 2019-190 of 14 March 2019 codifying the provisions applicable to BNIs, to the transport of radioactive substances and to transparency in the nuclear field.

5. In the current situation, only the ASN inspectors and the experts accompanying them have an enforceable right of access to the licensee's facilities. This means that the consent of the licensee is necessary for observers from CLIs to participate in inspections.

Meeting the information expectations of people living in the vicinity of nuclear power plants



ASN and Anccli conducted a qualitative survey in 2024 with Verian, a polling organisation, on the information expectations of people living near nuclear power plants. This study revealed that although the local residents feel they are poorly informed about the power plant, they manifest little interest in being better informed. Four factors would seem to explain this: people distancing themselves from the risk; a subject that is considered too complex; information that is available

but the formats and content of which do not seem appropriate for the uses and needs of the local populations; an ecosystem of nuclear players that is poorly known and complex. Several action levers have been identified, such as the development of simple and repeated communication on the action to take in the event of an alert, the transmission of personalised information, and the development of communication with the municipalities.

The CLIs and informing the various audiences

The CLIs organise plenary meetings and set up specialist commissions. The TECV Act obliges each CLI to hold at least one public meeting per year.

ASN promotes exchanges of good practices in order to make these public meetings moments of worthwhile discussion and opportunities to contribute to having a well-informed population.

The majority of the CLIs have a website or have pages on the website of the local authority that supports them; some twenty CLIs publish a newsletter (sometimes as inserts in the news bulletin of a local authority).

The 36th CLI conference

The 36th CLI conference, organised on the initiative of ASN in partnership with Anccli, was held in Montrouge on 8 October 2024 and attended by more than 150 participants.

The morning session was devoted to topical subjects: the ASN – CLI/Anccli partnership to develop the radiation protection culture, the results of the consultation of the 4th periodic safety review of the 1,300 MWe reactors and the preventive distribution of stable iodine tablets.

The afternoon session began with the challenges of informing the people living in the vicinity of nuclear power plants. After a joint presentation by ASN and Anccli of the lessons learned from an opinion poll concerning the perception of the nuclear sector, the contributors from Centre for studies and expert assessments of risks, the environment, mobility and development (Cerema), from ASN and

from the Permanent secretariat for the prevention of industrial pollution of the Provence-Alpes-Côte d'Azur region, put forward possible avenues for stimulating commitment in the regions.

The second round table explored levers for involving the stakeholders: in the public debate, with testimonials from the CNDP and a participant in the French Citizens' Convention on Climate; in the development of the Winter Medication Plan with the French Health Products Safety Agency (ANSM); and lastly in expert assessments and research with the public institutions having signed the Charter on Openness to Society.

The conference was illustrated by a graphic facilitator to promote the sharing of interchanges within the CLIs.

2.4.4 National Association of Local Information Committees and Commissions

Article L. 125-32 of the Environment Code provides for the setting up of an association of CLIs (see point 2.4.3), and the Decree of 12 March 2008 details the mandate of this federation.

Anccli brings together the 35 French CLIs and the 34 committees put in place for the defence-related installations. Anccli has a scientific committee and has set up five thematic advisory groups ("Radioactive materials and waste", "Post-accident – territories", "Safety", "Decommissioning" and "Health"). It is also heavily involved in the discussion and interchange bodies set up by its partners (HCTISN, ASN, IRSN, etc.).

Partnership with ASN

Anccli takes part in various GPEs or *ad hoc* working groups set up by ASN on topics such as environmental monitoring, waste, post-accident situations, and social, organisational and human factors. Thanks to the presence of Anccli, the viewpoint of civil society can be heard.

Anccli maintains a technical dialogue with ASN and IRSN on the high-stake issues and takes part in the public consultations on nuclear questions. In 2024, ASN and Anccli jointly organised three webinars to answer the CLIs' questions on "counterfeiting, falsifications and suspicions of fraud in nuclear facilities" (June); on "small modular reactors" (September); and to clarify the issues concerning the "5th periodic safety review of the 900 MWe reactors" at the kick-off of the public consultation (October) on ASN's draft position statement concerning EDF's approaches for the generic phase.

Each year, ASN organises the national conference of CLIs in cooperation with Anccli.

The ASN Commissioners meet annually with the members of the Anccli Board of Directors, and ASN is invited to take part in the Anccli general meeting. Over time, these various interchanges have led to a relationship of trust and partnership between Anccli and ASN, over and beyond the multi-year agreement that binds the two institutions.

The activity of Anccli

Anccli runs the network of CLIs that it represents. By ensuring regular monitoring and issuing clarifications and information that can be readily understood by the general public, Anccli helps give the CLIs the means to fulfil their public information duties. Attentive to the concerns of the CLIs and in relation with diverse sources of expertise, Anccli conducts national reflections on nuclear safety issues and widely passes on the results of this work (Anccli positions) to the national and European bodies and to local elected officials and CLI audiences.

06

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Through a range of bilateral, European and multilateral cooperation frameworks, in which it participates, the French Nuclear Safety Authority (ASN) aims to promote the establishment of ambitious international baseline requirements. Within these frameworks, ASN also ensures that the French positions and doctrines are made known and that international best practices are adopted to achieve progress in nuclear safety and radiation protection in France and worldwide.

ASN also submits proposals to the Government regarding France's positions in international negotiations within its field of competence, and represents France in the relevant international and community bodies.

1 — ASN's objectives regarding international relations

The international arena is a strategic challenge to which ASN devotes particular attention and resources. ASN's actions in this field aim for continuous improvement in safety, based on changing knowledge and sharing of practices, in particular in terms of regulation and oversight. This action also aims to ensure ambitious harmonisation of international requirements regarding nuclear safety and radiation protection.

At a time of major changes in the international situation and of new challenges in the nuclear field, ASN's strategic goals are on the one hand to influence the establishment of international standards and practices and, on the other, to make the most of international feedback and collaborations. ASN's objectives are thus organised around four main points:

- to promote the creation of ambitious international baseline requirements;
- to make the French and European positions and regulations known to its counterparts;
- to encourage international work on the priority technical issues identified by ASN;
- to benefit from the best international practices to achieve progress in nuclear safety and radiation protection in France.

To achieve these goals, ASN maintains close bilateral relations with numerous countries. It also takes part in numerous multilateral exchanges within bodies and organisations with different statuses,

whether at European level with the European Nuclear Safety Regulators Group (ENSREG), the Western European Nuclear Regulators Association (WENRA) and the Heads of the European Radiological Protection Competent Authorities (HERCA) or at the international level, more particularly with the International Atomic Energy Agency (IAEA) or the Nuclear Energy Agency (NEA) of the Organisation for Economic Cooperation and Development (OECD).

Through its bilateral relations, ASN has direct and fruitful exchanges with its counterparts on topical subjects or on particular points regarding regulation or oversight.

These exchanges are an opportunity for ASN to share its experience and compare its positions and practices. They also cast an outside light on position statements, technical questions or societal acceptability, thereby enriching the national debates and consolidating decisions and resolutions. They also enable ASN to be directly informed of the nuclear safety and radiation protection situation in other countries. In this respect, ASN's relations with its counterparts in neighbouring countries are of particular interest. These exchanges are also essential in the management of radiological emergency situations.

Europe is one of the priority areas for ASN's international actions. Its goal is to contribute to the sharing, harmonisation

and improvement of nuclear safety and radiation protection. ASN shares its vision of the priority issues, compares its analyses and discusses the nuclear safety and radiation protection practices of its counterparts. Its ambition is to help establish a high level of stringency in this field at the European level, that can rely on harmonised baseline requirements and doctrines drawn up in a collaborative manner.

ASN is also working to develop the sharing of France's good practices and regulations in nuclear safety and radiation protection outside Europe. On this point, it aims to ensure that European doctrine, which promotes the highest levels of stringency, constitutes a benchmark worldwide, notably for countries adopting new reactor models and countries gaining access to nuclear energy for the first time. These international exchanges, which take place in a variety of circles, also enable ASN to benefit from international best practices and experience, thus helping to advance nuclear safety and radiation protection in France.

ASN is therefore active at three levels of international cooperation. It aims to ensure that a constant and balanced presence is maintained within each one, considering that each one is specific and that the complementarity between them contributes to the target of harmonisation and continuous improvement of nuclear safety and radiation protection.

2 — The European framework for ASN's international relations

European harmonisation of nuclear safety and radiation protection principles and standards has always been a priority for ASN. In this context, ASN participates actively in exchanges between the national nuclear safety and radiation protection authorities of the Member States.

2.1 The EURATOM Treaty and its working groups

The Treaty instituting the European Atomic Energy Community (EURATOM) was signed on 25 March 1957 and constitutes the primary source of law in the field. It allowed the harmonised development of provisions allowing a strict regime of oversight for nuclear safety and security and radiation protection. In 2002, in its jurisprudence C-29/99, the Court of Justice of the European Union (EU) recognised that the Euratom Community shared competences with the Member States in the field of nuclear safety, going beyond simply the fields of radiation protection and information about emergency situations.

ASN experts participate in the work of the EURATOM Treaty Committees and working groups in the following areas:

- Radiation Protection Basic Standards (Article 31);
- verification and monitoring of environmental radioactivity (Article 35);
- information concerning the monitoring of radioactivity in the environment (Article 36);
- notifications relative to radioactive effluent discharges (Article 37).

The Article 31 expert group met twice in June and November 2024. It was informed of and consulted on the work of the European Commission (EC) notably with regard to:

- the SAMIRA strategy (Strategic Agenda for Medical Ionising Radiation Application) and in particular the EU-JUST-CT projects, with the publication of RP 205 (EC Radiation Protection Guide No. 205), SIMPLERAD (study on implementation of the legal bases of Euratom and the EU with regard to the therapeutic uses of radiopharmaceuticals), MARLIN (Harmonising Incident Learning Systems for Enhanced Patient Safety in Radiology), Equipment Study (requirements applicable to medical equipment with respect to oversight and monitoring of patient exposure to ionising radiation);
- the report drawn up on the checks performed on the obligations linked to radioactive sources;
- EC work on construction materials.

The expert group also issued an opinion on the clinical peer reviews on the basis of which the Commission published recommendations in April 2024 (2024/1112/Euratom). The Commission also published recommendations on the radon dose coefficients (2024/440/Euratom of 2 February 2024) based on the opinion of the expert group consulted in 2023.

The expert group also organised a workshop in November 2024 on the practical use of the new radon coefficients, at which France was able to share its experience.

A scientific seminar was also organised in November 2024 to review progress and experiences in the justification, optimisation, implementation and evaluation of health screening using ionising radiation. At the seminar, ASN presented its work on digital mammography and on the place of tomosynthesis in breast cancer screening.

2.2 The European Euratom Directive on the Safety of Nuclear Facilities

The Council 2009/71/Euratom Directive of 25 June 2009, revised in 2014 following the accident at the Fukushima Daiichi NPP (Japan), establishes a Community framework to ensure nuclear safety within the European Atomic Energy Community and to encourage the Member States to guarantee a high level of nuclear safety (see "Regulation" section on *asn.fr*).

It notably makes provision for greater powers and independence for the national safety regulators, reinforces requirements regarding transparency, sets an ambitious safety objective for all Member States (derived from the baseline safety requirements produced by WENRA), establishes a European peer review system for safety topics and requires periodic safety reviews every 10 years. It also reinforces provisions concerning education and training.

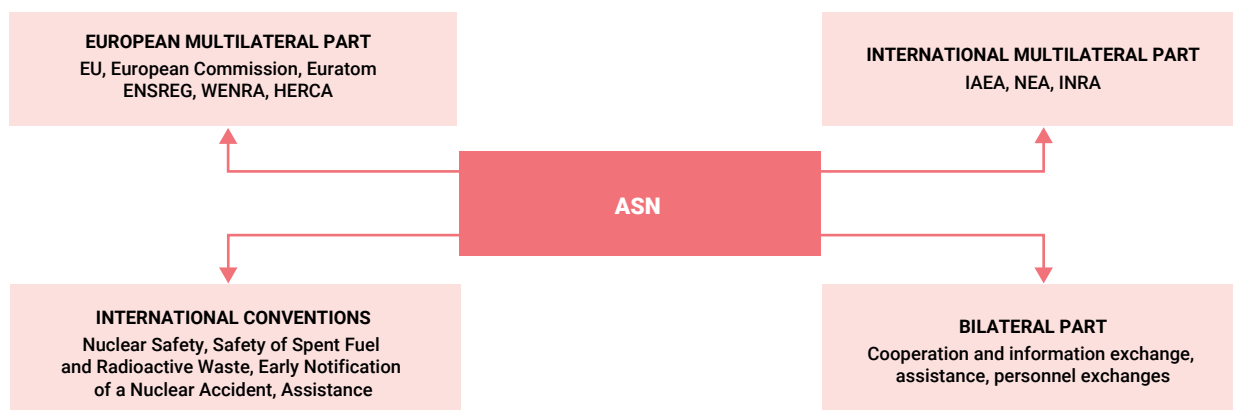
This Directive is transposed into French law.

It should however be noted that European legislation does not yet enshrine in law the institutional independence of the safety regulators.

2.3 The European Euratom Directive on the Management of Spent Fuel and Radioactive Waste

On 19 July 2011, the Council of the EU adopted a Directive establishing a community framework for the responsible and safe management of spent fuel and radioactive waste (Directive 2011/70/Euratom).

ASN action on the international stage



The adoption of this Directive contributes to reinforcing nuclear safety within the EU, by making the Member States more accountable for the management of their spent fuels and their radioactive waste.

This Directive is legally binding and covers all the aspects of spent fuel and radioactive waste management, from production through to long-term disposal.

It reiterates the prime responsibility of the producers and the ultimate responsibility of each Member State to ensure the management of the waste produced on its territory, making sure that the necessary measures are taken to guarantee a high level of safety and to protect workers and the general public against the dangers of ionising radiation.

It clearly defines the obligations regarding the safe management of spent fuel and radioactive waste and requires that each Member State adopt a legal framework for safety issues, making provision for the creation of:

- a competent regulatory authority with a status that guarantees its independence from the waste producers;
- authorisation procedures involving authorisation applications examined on the basis of the safety cases required from the licensees.

The Directive regulates the drafting of national spent fuel and radioactive waste management policies to be implemented by each Member State. More specifically, it requires each Member State to establish a legislative and regulatory framework designed to set up national programmes for the management of spent fuel and radioactive waste.

The Directive also contains provisions concerning transparency and participation of the public, the financial resources for management of spent fuel and radioactive waste, training, as well as obligations for self-assessment and regular peer reviews of the national framework and the competent regulatory authority. These aspects constitute major advances in reinforcing the safety and accountability of spent fuel and radioactive waste management in the EU. The Energy Transition for Green Growth Act of 2015 and the Ordinance of 10 February 2016 ensured that the provisions of the Directive were transposed into French law.

2.4 The European Euratom Directive on Radiation Protection "Basic Standards"

Directive 2013/59/Euratom of 5 December 2013 on Radiation Protection Basic Standards applies to the justification, optimisation and limitation of doses, regulatory control, preparedness for emergency situations, training and other related fields (for example the radon risk, naturally occurring

radioactive substances and construction materials). The modifications made in 2016 and 2018 to the Defence, Environment, Public Health and Labour Codes, allowed its transposition into French law.

2.5 The European Nuclear Safety Regulators Group (ENSREG)

ENSREG – the European Nuclear Safety Regulators Group – was created in 2008 and brings together experts delegated by the Member States of the EU, with the aim of supporting the EC in its legislative initiatives in the field of nuclear safety and radiation protection.

ENSREG helped bring about a political consensus in the drafting of European Directives on nuclear safety and the management of spent fuel and waste. ENSREG also took part in the process to revise the Nuclear Safety Directive, following on from the assessment and analysis of the Fukushima Daiichi NPP accident.

The activities of ENSREG are underpinned by three working groups, devoted to installations safety and international cooperation (WG1), the safe management of radioactive wastes and spent fuels (WG2) and transparency in the nuclear field (WG3) respectively. ASN contributes to the work done by each of them.

In accordance with the Safety Directive of 2014, ENSREG organises European thematic peer reviews. The first of these exercises, which began in 2017, concerned the management of nuclear reactor ageing and, with regard to France, ended with the publication of the closing report in 2021.

Work on the second thematic peer review concerning the protection of nuclear facilities against fire risks continued in 2024, with peer review of the national assessment reports, including that from France. Two seminars, held in Luxembourg, were a forum for discussions on best practices and identifying areas for improvement in each country. The peer review will come to an end in 2025 with the drafting of reports (Summary Report and Country Review Report) which will enable each country to draw up its national action plan.

2.6 The European Community Urgent Radiological Information Exchange system (ECURIE)

ECURIE, the European Community Urgent Radiological Information Exchange system, is one of the rapid action systems set up by the EC, which has an information exchange network for receiving and triggering an alert and thus for rapidly circulating information within the EU in the event of a radiological emergency.

This system was put into place by a Decision of the EU Council of 14 December 1987, notably in the wake of the Chernobyl (Ukraine) NPP accident in 1986. This Decision was ratified by all the EU Member States and a certain number of third-party countries, such as Switzerland and Turkey. Within this context, ASN takes part in the "ECUREX" exercises organised by the EC. In 2024, ASN took part in one exercise of this type (see chapter 4).

2.7 The Western European Nuclear Regulators' Association (WENRA)

The Western European Nuclear Regulators' Association (WENRA) was created in 1999 at the initiative of ASN and its current members are the 19 heads of the safety regulators of the European countries with experience in electricity generating reactors. It is open to 13 other countries with associate member (3 regulators) or observer (10 regulators) status.

After being chaired from 2019 to 2023 by Olivier Gupta, ASN Director General, WENRA is now chaired by Mark Foy, Director General and Chief Nuclear Inspector of the Office for Nuclear Regulation (ONR), the United Kingdom's nuclear safety regulator.

Considering that the national safety regulators, in the light of their experience and their practical familiarity with the installations, are better placed than the EC to set the technical rules applicable to the nuclear installations in Europe, WENRA defined as its primary mission the voluntary harmonisation of the national regulations of its members, aiming for the highest level of safety that is reasonably achievable. To achieve this, WENRA developed "safety reference levels" for each technical topic, based on the most recent IAEA safety standards. Subject to peer review, the WENRA members then examine whether these reference levels are indeed included in the regulations of their country, and modify them if not. Work has also been started to compare the procedures for actually implementing these reference levels in the nuclear installations. This voluntary harmonisation approach is the only one of its kind internationally and constitutes one of the specificities of WENRA within the international organisations.

To carry out its work, WENRA draws on three working groups, each with competence in a field of nuclear safety:

- the Reactor Harmonisation Working Group (RHWG);
- the Working Group on Radioactive Waste and Decommissioning (WGWD);
- the Working Group on Research Reactors (WGRR).



WENRA plenary meeting in Warsaw (Poland) – November 2024

In 2024:

- WENRA celebrated its 25 years in Poland during the association's plenary meeting in November. This event was the opportunity for WENRA to confirm the importance of its publications and its work, as well as its unique place in the landscape of international organisations;
- in-depth exchanges were held with various international bodies, including IAEA, ENSREG, ETSO (European Technical Safety Organisations Network) and ENISS (European Nuclear Installations Safety Standards) in order to identify the possible areas for future cooperation and avoid duplication of activities, in line with WENRA's new strategy;
- on the basis of the latest work of the RHWG, WENRA considered that the reference safety levels currently applicable to nuclear reactors will remain valid for the next ten years, barring any urgent need to update them;
- WENRA continued its work on the safety objectives applicable to Small Modular Reactors (SMRs);
- WENRA has started work to reach a joint position on the important subject of the long-term operation of the existing reactors, by defining criteria to be taken into

account by its members when reviewing the corresponding authorisation applications;

- in its additional analysis concerning the notion of accident-tolerant fuels, as mentioned by the EC in the additional delegated act passed within the framework of the European regulation on taxonomy⁽¹⁾, WENRA considered that it would be unrealistic to attempt to define an accident-tolerant fuel and that it is up to the national safety regulators to issue the necessary authorisations for use of a fuel in the reactor, on the basis of their regulations;
- the WGWD published an update of its 2014 and 2018 reports, reviewing the implementation in the national regulations of the WENRA member countries of some 300 reference safety levels applicable to the field of radioactive waste and decommissioning;
- the working groups increased their exchanges to identify subjects of a cross-cutting nature, for which cooperation could be beneficial;
- PAA (*Państwowa Agencja Atomistyki*), the Polish safety regulator, which hitherto had observer status, joined WENRA as a permanent member in the light of its past involvement in and contributions to the association, its current missions in the

development of the Polish nuclear programme and Poland's status as an EU member;

- NRA (Nuclear Regulation Authority), the Japanese nuclear safety regulator, which hitherto had observer status, joined WENRA as an associated member in the light of its involvement in and contributions to the association, in particular with respect to implementation of the reference safety levels in the Japanese regulation.

In addition, with respect to the war in Ukraine, WENRA maintained its exchanges with the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU) so that it could provide it with any support necessary.

2.8 The association of the Heads of European Radiological Protection Competent Authorities (HERCA)

In the field of radiation protection, HERCA, founded in 2007, also at the instigation of ASN, is an association of the Heads of the European radiological protection competent authorities. Its aim is to reinforce European cooperation in radiation protection and to harmonise national practices.

HERCA now comprises 56 authorities from 32 European countries, comprising the 27 members of the EU, Iceland, Norway, the United Kingdom, Serbia and Switzerland. Since June 2023, Jean-Luc Lachaume, an ASN Commissioner, has chaired HERCA with the support of two vice-chairs, one from the Swiss Federal Office of Public Health (OFSP) and the other a Commissioner of the Spanish nuclear safety regulator (*Consejo de Seguridad Nuclear – CSN*).

Six expert groups are currently working on the following themes:

- practices and sources in the industrial and research fields;
- medical applications of ionising radiation;
- preparedness for and management of emergency situations;
- veterinary applications;
- natural radiation sources;
- education and training.

HERCA also hosts a network of experts which collaborate at several levels: collection, registration and reporting of occupational doses.



HERCA meeting in Brussels (Belgium)

1. The European "Taxonomy" regulation designates the classification of economic activities with a favourable environmental impact. Its aim is to steer investments towards "environmentally sustainable" or "green" activities favourable to the energy and ecological transition, notably those contributing to the fight against climate change.

In 2024, the association met in Madrid in May and then in Brussels in December.

The undertakings made by the new Chair concern the concrete implementation of HERCA's strategy, with ASN making a significant contribution to its definition. The main areas for focus in 2024 are the following:

- reinforcing HERCA communications and visibility in order to improve the accessibility of its technical documentation and its positions by its stakeholders and the public;
- continued active participation in the project to overhaul the recommendations of the International Commission on Radiological Protection (ICRP);
- holding of a seminar in May 2024, with the participation of the EC, dedicated to implementing Council Directive 2013/59/Euratom of 5 December 2013 by its member countries.

In 2024, HERCA signed a Memorandum of Understanding with the European Association of Nuclear Medicine (EANM). HERCA also took part in several international events, including those organised by the EC (Article 31 of the EURATOM Treaty), the IAEA (Radiation Safety

Standards Committee – RASSC), or the ICRP (meeting of Special Liaison Officers).

Finally, HERCA published the “country data sheets” of its members regarding the designation of radiation protection experts and officers required by Directive 2013/59/Euratom.

2.9 The European Commission's assistance programmes

At the European level, through the Instrument for Cooperation on Nuclear Safety (ICNS) it created in 2007, the EC enables nuclear safety regulators in emerging countries to benefit from assistance missions to help them set up or reinforce their regulatory framework and practices in the field of nuclear safety and radiation protection.

In 2021, the European Parliament approved a budget of 300 million euros for the period 2021-2027. This budget allows funding of activities carried out by the nuclear safety regulators of the Member States, their technical support organisations and other organisations, as applicable, on behalf of the beneficiary countries.

In 2024, ASN thus coordinated the creation of a consortium to support the development of nuclear safety culture in several African countries. The purpose of this programme is to help the nuclear safety regulators in the beneficiary countries to implement a regulatory framework based on the strictest nuclear safety and radiation protection standards.

This project, for which the EC intends to allocate a budget of 4.8 million euros, includes Expertise France and Several European safety regulators and technical support organisations in the consortium, including the French Institute for Radiation Protection and Nuclear Safety (IRSN). The contract was signed in December 2024 and the project is scheduled to last 48 months.

The European Instrument for Nuclear Safety (EINS) is supplemented by other international technical assistance programmes in response to resolutions taken by the G8 or by IAEA to improve nuclear safety in third-party countries and which are financed by contributions from donor States and from the EU.

3 — The multilateral framework for ASN's international relations

At the multilateral level, cooperation takes place notably within the framework of the IAEA, a United Nations agency founded in 1957, and the NEA, created in 1958. These agencies are the two most important intergovernmental organisations in the field of nuclear safety and radiation protection.

3.1 The International Atomic Energy Agency (IAEA)

The IAEA is a United Nations organisation based in Vienna and comprises 177 Member States. IAEA's activities are focused on two main areas: one of them concerns the control of nuclear materials and non-proliferation and the other concerns all activities related to the peaceful uses of nuclear energy. In this latter field, two IAEA departments are tasked with developing and promoting nuclear energy respectively on the one hand and the safety and security of nuclear facilities and activities, on the other.

Following on from the action plan approved by the IAEA Board of Governors in September 2011 and with the aim of reinforcing safety worldwide by learning the lessons from the Fukushima Daiichi NPP accident, the IAEA is in particular focusing its work on the following

fields: safety standards and peer review missions.

Safety standards

The IAEA Safety Standards describe the safety principles and practices that the vast majority of Member States use as the basis for their national regulations. This activity is supervised by the IAEA's Commission on Safety Standards (CSS), set up in 1996. The CSS comprises 24 highest level representatives from the national safety regulators, appointed for a term of four years. One ASN Commissioner sits on this Commission. It coordinates the work of five committees tasked with drafting documents in their respective fields: NUSSC (Nuclear Safety Standards Committee) for the safety of reactors, RASSC for radiation protection, TRANSSC (Transport Safety Standards Committee) for the safety of radioactive substances transport, WASSC (Waste Safety Standards Committee) for the safe management of radioactive waste and EPRESC (Emergency Preparedness and Response Standards Committee) for preparedness and coordination in a radiological emergency situation. France, represented by ASN, is present on each of these committees, which meet twice every year. Representatives of the various French organisations concerned also take part in the technical groups which draft these documents.

2024 was marked by the start of the 6th CSS mandate chaired by the Director General of the Swiss nuclear safety regulator (*Inspection fédérale de la sécurité nucléaire – IFSN*), Mark Kenzelmann. The drafting of the long-term plan for the coming fifteen to twenty years is continuing.

Peer review missions

IAEA proposes several types of review missions for those Member States which so request. These missions are carried out by teams of experts on particular topics in the countries which so request. Each team of auditors consists of experts from Member States and from the IAEA. The audits are produced on the basis of the IAEA's baseline Safety Standards. Several types of audit are proposed, notably the IRRS (Integrated Regulatory Review Service) missions devoted to the national regulatory framework for nuclear safety and the working of the safety regulator, the OSART (Operational Safety Review Team) missions, devoted to the safety of NPPs in operation, or the ARTEMIS (Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation) missions, devoted to national radioactive waste and spent fuel management programmes. The audit results are written up in a report transmitted to the requesting country and may comprise various levels of recommendations while also recognising good practices. It is up to the

requesting country to take account of the recommendations issued by the experts. A follow-up mission, the purpose of which is to verify the progress made in taking account of the recommendations, is held between 18 months and 4 years after the initial mission, depending on the type of audit. ASN's situation regarding these missions is presented below.

IRRS Missions

The IRRS missions are devoted to analysing all aspects of the framework governing nuclear safety and the activity of a safety regulator. ASN is in favour of holding these peer reviews on a regular basis, and incorporates their results into its continuous improvement approach. It should be noted that, pursuant to the provisions of the 2009/71/Euratom Directive amended in 2014, the Member States of the EU are already subject to periodic and mandatory peer reviews of their general nuclear safety and radiation protection oversight organisation. The IRRS missions are a means of meeting this obligation.

In 2024, a number of ASN staff members took part in IRRS missions in the United Kingdom, Canada, South Korea, Bulgaria and Ghana.

OSART Missions

In France, it is ASN that asks the IAEA to organise OSART missions devoted to the safety of NPP operation, in coordination with EDF, the licensee of the NPPs.

In 2024, an OSART mission took place in France in the Nogent-sur-Seine NPP.

NHSI Initiative

In 2024, ASN continued its commitment to the work of the Nuclear Harmonisation and Standardisation Initiative (NHSI), a wide-ranging project initiated by the IAEA in 2022 to support the large-scale development of SMRs.

Phase I, which ended in 2024, notably required that the nuclear safety authorities propose a collaboration method for a joint evaluation of this type of reactor models, during the phase prior to the review phase required by the regulations.

The purpose of Phase II is notably to share the experience of the authorities who had already jointly carried out this type of collaboration.

The regional training and assistance missions

ASN responds to requests from the IAEA secretariat, in particular to take part in regional radiation protection training and in assistance missions. The beneficiaries are often countries of the French-speaking community.

In addition, and still under the supervision of IAEA, ASN also participated in the Regulatory Cooperation Forum (RCF). This Forum, created in 2010, aims to establish contacts between the safety regulators of countries adopting nuclear energy for the first time and the safety regulators of the leading nuclear countries, in order

to identify their needs and coordinate the support to be provided, while ensuring that the fundamental principles of nuclear safety are met (independence of the regulator, appropriate legal and regulatory framework, and so on).

In 2024, in addition to preparing assistance for the nuclear safety regulators of Ghana and Poland, the RCF continued to reinforce its cooperation with the EU (EINS) and with regional safety regulator forums.

Management of nuclear and radiological emergency situations

ASN takes part in the IAEA's work to improve notification and information exchanges in radiological emergency situations.

On this subject, ASN takes part in the exercises organised by the IAEA to test the operational provisions of the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency, called "convention exercises" or "ConvEx exercises". These exercises, which are more specifically designed to enable the participants to acquire practical experience and understand the procedures involved in preparing and running these interventions, are of three types:

- the ConvEx-1 exercises, more specifically designed to test the emergency lines of communication established with the points of contact in the Member States;
- the ConvEx-2 exercises, designed to test particular aspects of the international framework for the preparation and performance of emergency interventions and the assessment and prognosis provisions and tools for emergency situations;
- the ConvEx-3 exercises, aimed at assessing the emergency intervention provisions and the resources in place to deal with a severe emergency for several days.

In 2024, ASN took part in one "ConvEx" exercise (see chapter 4).

ASN also takes part in defining international assistance strategy, requirements and means and in developing the Response Assistance Network (RANET) within the IAEA. This network was mobilised in 2022 to address the needs for individual protection and radiation protection resources expressed by Ukraine.

3.2 The Nuclear Energy Agency (NEA) of the OECD

Created in 1958, the NEA today comprises 38 member countries from among the most industrially developed states. Its main goal is to help the member countries maintain and expand the scientific, technological and legal bases essential to the safe, environmentally-friendly and economical use of nuclear energy. Owing to the war in Ukraine, Russia's membership of the NEA was suspended on 2 April 2022.

Within the NEA, ASN is more particularly involved in the work of the Committee on Nuclear Regulatory Activities (CNRA). It also takes part in the Committee on Radiological Protection and Public Health, the Radioactive Waste Management Committee, the Committee on Decommissioning of Nuclear installations and Legacy Management, as well as several working groups of the Committee on the Safety of Nuclear Installations, including the Working Group on Human and Organisational Factors (WGHO).

The various NEA committees coordinate working groups involving experts from the member countries. Five working groups, two expert groups and an information exchange forum underpin the activities of the Committee. ASN is involved in each of them and in particular chairs the working group on the nuclear procurement chain and the working group on reactor surveillance, and is vice-chair of the expert group on sharing operational experience feedback.

In 2024, ASN took part in an NEA emergency exercise (INEX-6). Modules 2, "Food safety", and 4, "Radioactive waste management", were run.

3.3 The International Nuclear Regulators' Association (INRA)

The International Nuclear Regulators Association (INRA) comprises the heads of the regulators of Canada, France, Germany, Japan, South Korea, Spain, Sweden, the United Kingdom and the United States. This association is a forum for regular and informal discussions concerning topical matters in these various countries and the positions adopted on common international issues. It meets twice a year in the country holding the Presidency, with each country acting as president for one year in turn.

Two meetings were held in 2024. The first, in Germany, discussed the situation of the nuclear facilities in Ukraine, topical matters from the association's members, the decommissioning of nuclear facilities, the rising number of SMR projects and the service life extension of the existing NPPs. Following the meeting, the chairmanship of INRA was entrusted for one year to the ASN Chairman. The second meeting, held in Vienna in the margins of the IAEA General Conference, was notably an opportunity for the association to approve the revision of its terms of reference. A thematic session also looked at the implications of the growing use of Artificial Intelligence (AI) in the nuclear field. These exchanges confirmed the need for more in-depth discussions, notably to share experience and visions on how the reliability of the data used by AI can be guaranteed, the conditions in which a final decision may or may not be delegated to an AI system, and cybersecurity.



INRA meeting in Vienna (Austria) in 2024

4 — International Conventions

ASN is the national point of contact and the Competent Authority for the two nuclear safety conventions which deal with NPPs (Convention on Nuclear Safety) and spent fuel and radioactive waste (Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management) respectively. ASN is also the Competent Authority for the two Conventions dedicated to the transboundary management of the possible consequences of accidents (the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency).

4.1 Convention on Nuclear Safety

The Convention on Nuclear Safety was one of the results of international discussions initiated in 1992 in order to contribute to maintaining a high level of nuclear safety worldwide.

The Convention on Nuclear Safety was signed by France in 1994 and entered into force on 24 October 1996. In September 2024, it had 96 contracting parties.

The objectives of the Convention are to attain and maintain a high level of nuclear safety worldwide, to establish and maintain effective defences in nuclear facilities against potential radiological risks and to prevent accidents which could have radiological consequences and mitigate their consequences should they occur. The areas covered by the Convention have long been part of the French approach to nuclear safety.

In 2015, the contracting parties to the Convention, taking account of the lessons learned from the Fukushima-Daiichi NPP accident, adopted the Vienna Declaration on nuclear safety. This Declaration, which extensively incorporates the principles of

the European Directive on the safety of nuclear facilities, sets ambitious nuclear safety objectives aiming to prevent nuclear accidents worldwide and to mitigate the radiological consequences if one were to occur.

The Convention makes provision for review meetings by the contracting parties every three years, to develop cooperation and the exchange of experience.

As Competent Authority, ASN coordinates French participation in this three-yearly peer review exercise, in close collaboration with the institutional and industrial partners concerned. This coordination work concerns the drafting of the national report, analysis of the reports from the other contracting parties and participation in the review meetings.

In 2024, ASN actively participated in the meetings aiming to improve the effectiveness and efficiency of the Convention on Nuclear Safety, in preparation for the 10th review cycle, which will take place in April 2026 and for which the reports are expected in 2025.

4.2 The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management

The Joint Convention is the counterpart to the Convention on Nuclear Safety for the management of spent fuel and radioactive waste from civil nuclear activities. France signed it on 29 September 1997, and it entered into force on 18 June 2001. At the end of 2024, this Convention had 90 contracting parties. In the same way as the Convention on Nuclear Safety, it is founded on a peer review mechanism, with each contracting party submitting a 3-yearly national report to the other parties for review, along with a review meeting.

The review meeting will be held in March 2025. The French report, the drafting of which was coordinated by ASN, was submitted to the IAEA in August 2024.

4.3 The Convention on Early Notification of a Nuclear Accident

The Convention on Early Notification of a Nuclear Accident entered into force on 27 October 1986, six months after the Chernobyl accident and had 133 contracting parties at the end of 2024.

The contracting parties undertake to inform the international community as rapidly as possible of any accident leading to the uncontrolled release of radioactive substances into the environment and liable to affect a neighbouring State. For this purpose, the IAEA proposes a tool to the Member States for notification and assistance in the event of a radiological emergency.

ASN made an active contribution to the production of this tool, the USIE (Unified System for Information Exchange in Incidents and Emergencies), which is in use in ASN's emergency centre and is tested on the occasion of each exercise.

The Interministerial Directive of 30 May 2005 specifies the conditions of application of this text in France and mandates ASN as the Competent National Authority. It is therefore up to ASN to report the events to the international institutions without delay, to rapidly provide pertinent information about the situation, in particular to border countries, so that they can take the necessary population protection measures and, finally, to provide the ministers concerned with a copy of the notifications and the information transmitted or received.

4.4 Convention on Assistance in the Event of a Nuclear Accident or Radiological Emergency

The Convention on Assistance in the event of a Nuclear Accident or Radiological

Emergency entered into force on 26 February 1987 and had 123 contracting parties at the end of 2024.

Its aim is to facilitate cooperation between countries should one of them be affected by an accident having radiological consequences. This Convention has already

been activated on several occasions as a result of irradiation accidents caused by abandoned radioactive sources. More specifically, France's specialised medical services regularly provide treatment for the victims of such accidents.

5 — The bilateral framework for ASN's international relations

ASN collaborates with about twenty foreign safety regulators under bilateral agreements. These agreements are general information exchange protocols between safety regulators. In certain cases, they can be part of broader Governmental agreements (case of Germany, Belgium, Luxembourg and Switzerland).

The countries with which ASN maintains particularly close relations are, on the one hand, neighbouring countries, especially those whose border is situated close to a French nuclear facility and, on the other, the major nuclear countries and the countries using French nuclear technologies.

These relations enable strategic information to be exchanged. This is notably the case during high-level meetings, at which points of doctrine and topical subjects for each authority (organisational and regulatory changes, events, feedback, etc.) are covered. They are also an opportunity for exchanges of technical and operational information. Practices can in particular be compared in detail during topical workshops or inspection cross-observations, in order to highlight practices from which ASN can draw inspiration.

Many topics were covered throughout the year by ASN and its counterparts, such as the new nuclear context, the reactors fourth periodic safety reviews, stress corrosion, decommissioning, radioactive waste management, the precautionary culture, small modular reactors, management of emergency situations and the transformation of the regulators.

5.1 Bilateral cooperation between ASN and its foreign counterparts

SOUTH AFRICA

In October 2024, as part of the technical exchanges between ASN and the South African National Nuclear Regulator (NNR), five NNR inspectors were welcomed to ASN's Lyon regional division. The mission concerned the fourth ten-yearly outages, extension of the service life of the reactors, inspection and oversight practices for reactor outages, and EDF's Nuclear Rapid Intervention Force (FARN). A remote bilateral meeting was also held between

the ASN and NNR managements and confirmed the principle of an equivalent mission at NNR's Cape Town regional division for ASN's Lyon regional division inspectors in about one year.

In November 2024, two ASN staff members took part in the national emergency exercise at the Koeberg NPP in Cape Town, in order to share ASN's expertise and know-how in planning and response to nuclear emergency situations.

GERMANY

The Franco-German Commission was created as an inter-governmental body and involves several competent authorities at both national and local levels. In addition to the Commission's plenary meetings, two working groups meet regularly, one to address the safety of NPPs in border areas, the other the management of emergency situations.

The 50th meeting of the Commission was held in Berlin and Wannsee on 19 and 20 June 2024. The discussions concerned topical subjects and the major issues affecting the two countries, preparedness for emergency situations, monitoring of NPPs close to the Franco-German border and the management of nuclear waste and the status of decommissioning projects. This meeting was also an opportunity for its participants to visit the Helmholtz Centre for materials and energy research in Berlin (*Helmholtz-Zentrum Berlin für Materialien und Energie* – HZB) based in Wannsee and more particularly its BER II light water research reactor (shut down), as well as its proton therapy centre.

On 17 and 18 September 2024, a German delegation went to ASN's Strasbourg regional division for the 58th meeting of the NPP safety working group. This meeting was an opportunity to review the current situation of the NPPs close to the border (Cattenom, Fessenheim, Neckarwestheim, Philippsburg) as well as significant events (trend for 2023 and recent noteworthy events) in France and Germany.

On 26 November 2024, the working group focusing on preparedness for emergency situations also held a remote meeting.

BELGIUM

The exchanges between ASN and its Belgian counterpart, the Federal Agency for Nuclear Regulation (*Agence fédérale de contrôle nucléaire* – AFCN), lead to national and local level cooperation actions, in particular with ASN's border regional divisions of Lille and Châlons-en-Champagne. These exchanges are coordinated by the Franco-Belgian steering committee, which met in Brussels on 27 November 2024. The two delegations, consisting of representatives from the regulators and their respective technical support organisations, IRSN and Bel V, notably discussed the results of the implementation of the Convention for the rapid exchange of information in the event of a nuclear emergency and the ASNR's future emergency response organisation. ASN also presented the latest situation at the Chooz and Gravelines NPPs.

CANADA

In June 2024, as part of the technical exchanges between ASN and the Canadian Nuclear Safety Commission (CNSC), a CNSC inspector was welcomed to the ASN Orleans regional division. The mission concerned inspection practices in nuclear facilities, with respect to management of safety, monitoring of suppliers and counterfeit, falsification or suspected fraud.

CHINA

A remote technical meeting between ASN and its Chinese counterpart (National Nuclear Safety Administration – NNSA) accompanied by their respective technical support organisations, IRSN and NSC (Nuclear and Radiation Safety Center) was held on 28 and 29 May 2024, concerning experience feedback from operation of the world's first two EPR reactors to be have been commissioned, on the Taishan site.

SPAIN

In 2024, as part of the bilateral relations with the Spanish nuclear safety regulator (CSN), a CSN representative took part in ASN's public consultation actions on several occasions, concerning the Cigéo creation authorisation application file. She also held discussions with IRSN and the National Radioactive Waste Management Agency (Andra) regarding the follow-up of this file.



Visit to the Flamanville EPR by ASN representatives and Commissioner Caputo from the NRC (United States) – January 2024



Bilateral meeting between representatives of AERB (India) and ASN – March 2024

These exchanges led to a report, the conclusions of which notably indicate that France's experience with consultation of the public and the stakeholders is extensive and could be transposed to Spain to help CSN draw up recommendations *via* a future guide on consultation measures regarding disposal facilities in this country.

The ASN Bordeaux regional division hosted a technical visit by CSN inspectors from **16 to 18 October 2024**. Discussions concerned the regulation and oversight of industrial radiography activities. The Spanish delegation observed an unannounced inspection of a radiography work-site and visited a fixed facility.

UNITED STATES

In **January 2024**, a Commissioner from the NRC (Nuclear Regulatory Commission) met the ASN Commission in Montrouge to discuss the French approach to regulation of the "fuel cycle" and then, with the ASN Caen regional division, visited the Orano facilities at La Hague, as well as the EPR construction site in Flamanville.

In **February 2024**, ASN took part in an international seminar organised by NRC on Operating Experience Feedback (OEF) regarding the stress corrosion phenomenon affecting reactor piping.

FINLAND

ASN and the Finnish nuclear safety regulator (*Säteilyturvakeskus* – STUK) met in Montrouge from **2 to 4 April 2024**. During this meeting, ASN and STUK discussed a large number of subjects of common interest, such as the disposal of radioactive waste, the challenges raised by the emergence of innovative small modular reactor projects, EPR type reactors, and management of the ageing of the fleet of existing NPPs. Following technical discussions, a visit to Andra's Meuse/Haute-Marne centre was organised.

INDIA

An ASN delegation headed by its Chairman went to Mumbai from **5 to 7 March 2024** to meet its Indian counterpart, the AERB (Atomic Energy Regulatory Board). This meeting was organised as part of the cooperation agreement that has linked the two safety regulators for nearly 25 years now. The technical discussions in particular covered the service life extension of the NPPs, safety improvements to the reactors in service, emergency preparedness, the approaches adopted by the safety regulators to examine and evaluate new reactor technologies, notably SMRs. The AERB is also one of the rare nuclear safety regulators in the world to have its

own in-house nuclear safety and radiation protection research institute, and a specific session was devoted to this topic.

JAPAN

The annual bilateral meeting with the Japanese Nuclear Regulation Authority (NRA) was held from **19 to 21 November 2024** at the ASN headquarters. The subjects covered notably concerned the creation of the Authority for Nuclear Safety and Radiation Protection (ASNR), the regulation of the recycling of very low-level (VLL) metal waste, the stress corrosion phenomenon, cooperation between the two regulators in the field of inspection, monitoring of the digital technologies used in instrumentation and control systems, management of obsolescence during the periodic safety reviews, and the safety improvements made to mitigate the consequences of a severe accident. The highly fruitful exchanges identified several cooperation actions for the coming year. The meeting was also followed by a visit to the Flamanville NPP, in the presence of ASN's Caen regional division.

The exchanges on inspection practices resumed in 2024, with the visit to Japan by a team of inspectors from ASN's Lyon regional division, which led to technical meetings on service life extension, the decommissioning of sodium fast reactors and preparedness for emergency situations, as well as the observation of Japanese practices in the regulation and oversight of the safety of nuclear sites.

LUXEMBOURG

The Franco-Luxembourg joint commission on nuclear safety held its 22nd meeting on **10 June 2024** in Luxembourg. On this occasion, the Commission discussed recent developments in both countries in the fields of nuclear safety and radiation protection, including the 2023 results from the Cattenom NPP, the fourth periodic safety review of the 1,300 MWe reactors, the new organisation for the transboundary alert system and preparedness for emergency situations.

NETHERLANDS

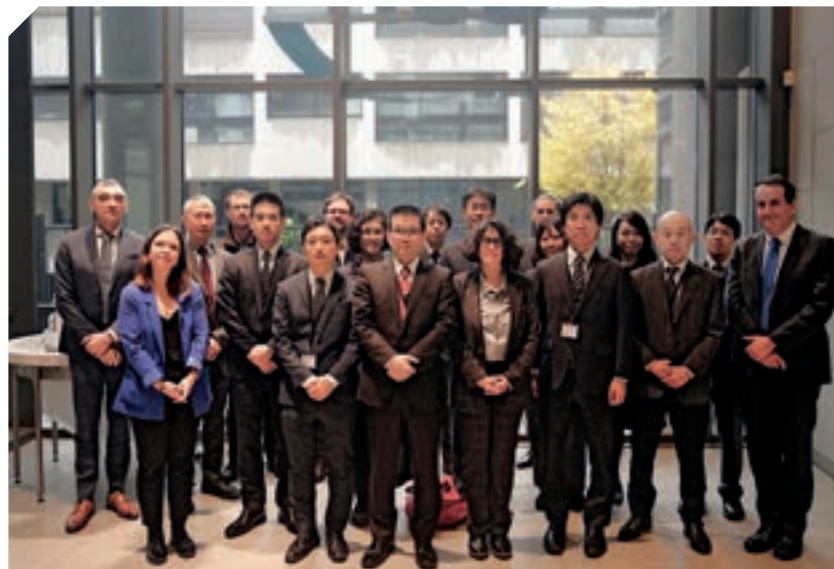
The second bilateral meeting between the Dutch nuclear safety regulator (*Autoriteit Nucleaire Veiligheid en Stralingsbescherming* – ANVS) and ASN was held in The Hague on **16 December 2024**. The meeting was an opportunity to discuss topical subjects in both countries, changes to French and Dutch policies and programmes, new reactor construction projects in France and the Netherlands and the plans for a joint evaluation of the Thorizon SMR project.

UNITED KINGDOM

In **February 2024**, the ONR organised the first technical meeting on climate change in London, with ASN (France), ANVS (Netherlands) and AFCN (Belgium).



Visit to Japan by a team of inspectors from ASN's Lyon regional division



Bilateral meeting between members of the NRA (Japan) and ASN, in the Montrouge headquarters – November 2024



Visit to the Orano plant at La Hague on the occasion of the annual bilateral meeting with the SSM (Sweden) – September 2024

This meeting was an opportunity to discuss the constraints surrounding adaptability to the foreseeable effects of climate change. This identified common problems such as rising water levels, the “extreme heat” plan, or the frequency and intensity of storms. Another meeting will be held in January 2025 with the participation of the Finnish regulator (STUK).

SWEDEN

A bilateral meeting was held with the Swedish nuclear safety regulator (*Strålsäkerhetsmyndigheten* – SSM) from **25 to 26 September 2024**. Several subjects of common interest were covered, such as the reuse of VLL metallic radioactive waste, international SMR initiatives, OEF from oversight of decommissioning of nuclear installations and managing and maintaining skills levels.

The ASN-SSM delegation then went to Cherbourg to visit Orano's waste reprocessing plant at La Hague.

A cycle of cross-inspections with the Swedish regulator was maintained in 2024. In March, ASN inspectors went to Sweden's Ringhals NPPs, to accompany the SSM during a fire inspection.

SWITZERLAND

The Franco-Swiss Commission (CFS) was created as an inter-governmental body and involves several competent authorities at both national and local levels. This Commission met on **16 May 2024** at Mont Terri in Switzerland.

With respect to ASN, the CFS involves both the head office departments and ASN's Lyon and Strasbourg regional divisions.

5.2 ASN assistance actions in a bilateral framework

ASN may be required to respond to assistance requests *via* bilateral actions with the safety regulator of the country concerned, in addition to the instruments, both European (INSC) and international (RCF). The purpose of this cooperation is to enable the beneficiary countries to acquire the safety culture and transparency that is essential for a national system of nuclear safety and radiation protection oversight. Nuclear safety oversight must be based on national competence and ASN consequently only provides support for the establishment of an adequate national framework, ensuring that the national safety regulator it advises retains full responsibility for its oversight of the nuclear facilities. It pays particular attention to countries acquiring technologies of which it has experience in France.



CFS meeting at Mont Terri (Switzerland) – May 2024

6 – Outlook

For ASN, the year 2024 was a busy one internationally. Numerous meetings with its counterparts enabled ASN to discuss its practices and share the challenges of the new nuclear context and the constant rise in the introduction of innovative technologies – such as AI – in the nuclear sector.

The question of the required level of safety, within a context of renewal of the nuclear sector in certain countries and their growing interest in SMRs, as well as the methods for collaboration between the nuclear safety regulators, were frequently debated. The challenges and issues linked to the potential service life extension of existing nuclear reactors beyond the initial design lifetime, were also extensively covered.

ASN's presence in the multilateral bodies in Europe (ENSREG, WENRA, HERCA) and internationally (IAEA, NEA) was also considerable, and ASN frequently promoted an innovative position and strong messages designed to guarantee that safety remains an absolute priority.

2025 will no doubt be a year of significant transition for the new ASNR. The foundations of ASNR are the combined expertise of ASN and IRSN and it will need to build its legitimacy and credibility in its new areas of competence expanded to include research, expert assessment and regulation. At the international level, its new international department, resulting from the merger of the ASN international relations department and the IRSN European and international affairs department, will have a central role to play, with both the ASNR Commission and its Executive Committee, regarding international strategy and positioning.

In this particular context, ASNR will have a major role to play in the various international bodies. In bilateral terms, ASN intends to welcome several of its counterparts, including the Chinese and Indian authorities. At the multilateral level, several important events are planned, including the Joint Convention review meeting in March, and various exchanges as part of Phase II of the NHSI which will begin in 2025.

In the particular field of SMRs, ASN will continue to promote its vision of the safety objectives within various international frameworks. Given that their inherent characteristics are liable to offer increased performance in terms of safety, and the fact that, depending on their purpose, these reactors could be built close to densely populated or industrial areas, ASN considers that the safety objectives applicable to SMRs must be more stringent than those applied to the Generation III and III plus reactors. Whenever necessary, it will share this position.

At the international level, 2025 promises to be a particular year for ASNR, which will have to consolidate its internal organisation on the one hand, and build new relationships on the other.

07

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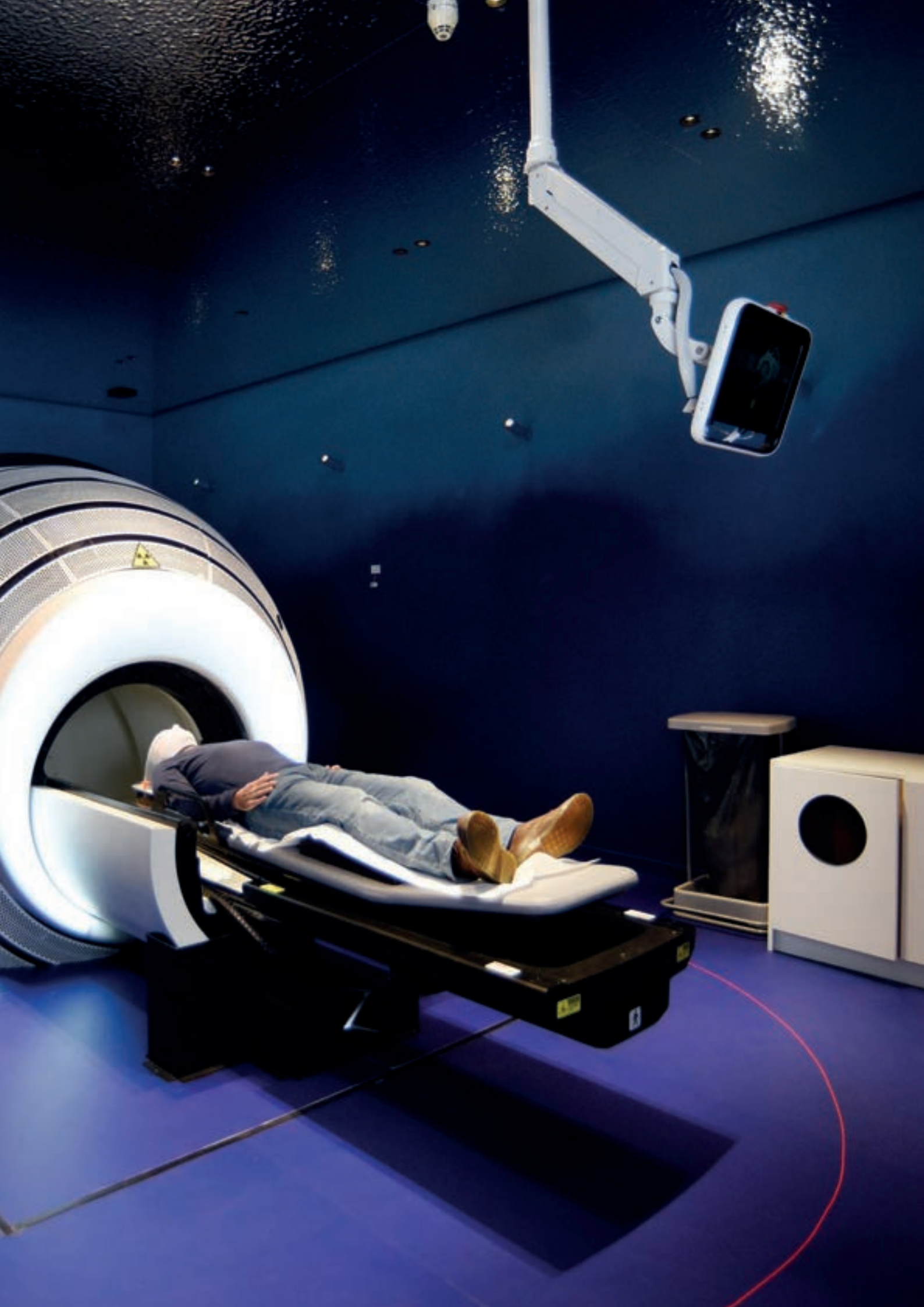
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For more than a century now, medicine has made use of ionising radiation produced either by electric generators or by radionuclides in sealed or unsealed sources for both diagnostic and therapeutic purposes. These techniques represent the second source of exposure of the population to ionising radiation (behind exposure to natural ionising radiation) and the leading source of artificial exposure (see chapter 1).

The exposure of patients to ionising radiation for diagnostic or therapeutic purposes is distinguished from the exposure of workers, the public and the environment, for which there is no direct benefit. The principle of dose limitation does not apply to patients due to the need to adapt the delivered dose to the diagnostic or therapeutic end-purpose. The principles of justification and optimisation are fundamental, even if the radiation protection risks differ according to the medical uses.

In radiotherapy (external-beam or brachytherapy) as in Internal Targeted Radiotherapy (ITR) which is developing strongly at present, the major risk is linked to the administered dose and, if applicable, the high dose rates used. There are specific risks linked to the use of sealed radionuclide sources (in brachytherapy, with high-activity sources) and unsealed sources (in nuclear medicine), associated in the latter case with the doses delivered to the patient's carers and family, as well as the management of waste and effluents. The ever-continuing expansion of Fluoroscopy-Guided Interventional Procedures (FGIPs) carried out using increasingly sophisticated devices can lead to significant exposure of the patient for whom the procedure brings health benefits, but also for the personnel in the immediate vicinity. Lastly, Computed Tomography (CT) examinations, although they do not present a major risk in terms of delivered dose or dose rate for an individual, contribute very significantly to population exposure resulting from medical diagnostic procedures due to their frequency of use, underlining the importance of justification for each procedure using ionising radiation.

1 — Radiation protection and medical uses of ionising radiation

1.1 The different activity categories

Medical nuclear activities can be divided into two broad categories, namely those for diagnostic purposes and those for therapeutic purposes. The medical diagnostic activities that use ionising radiation comprise radiology – which includes computed tomography, conventional radiology and dental radiology, and diagnostic nuclear medicine. Situated at the boundary between diagnostic and therapeutic activities are the Fluoroscopy-Guided Interventional Practices (FGIPs), which bring together various techniques used essentially for invasive medical or surgical procedures carried out for diagnostic, preventive or therapeutic purposes guided via an image obtained using X-rays. The majority of therapeutic activities such

as external-beam radiotherapy, radio-surgery, brachytherapy and therapeutic nuclear medicine (called “Internal Targeted Radiotherapy” – ITR⁽¹⁾) are devoted to the treatment of cancers.

These different activities and the techniques used are presented in sections 2.1 to 2.6.

1.2 Exposure situations in the medical sector

1.2.1 Exposure of health professionals

Medical professionals are subject in particular to the risk of external exposure created by the Medical Devices (MDs – devices containing radioactive sources, X-ray generators or particle accelerators)

or by sealed or unsealed sources. When using unsealed sources, the risk of contamination must also be taken into consideration in the risk assessment (in nuclear medicine and in the biology laboratory).

According to the data collected in 2023 by Institute for Radiation Protection and Nuclear Safety (IRSN), the medical and veterinary sectors account for the majority of the people monitored: 47%, i.e. 122,228 people, were subject to individual dosimetric monitoring. The monitored personnel headcount (classified and non-classified) has dropped by nearly 8% overall compared with 2022. This drop can be explained by the fact that employers are no longer obliged to register non-classified workers in the Ionising radiation exposure monitoring information system (Siseri). This trend should continue in the coming years.

1. Internal Targeted Radiotherapy aims to administer a RadioPharmaceutical Drug (RPD) or implant a radioactive medical device so that the ionising radiation delivers a high dose as close as possible to the organ that needs to be treated (also called the target organ) for curative or palliative purposes. The majority of these treatments are dispensed within nuclear medicine departments.

The average individual annual dose received is 0.31 millisievert (mSv) in the medical sector and 0.26 mSv in the dental sector. This figure remained relatively stable between 2015-2023, with the exception of 2020, when it dropped by 17% due to the Covid-19 pandemic (*see chapter 1*).

Among the health personnel liable to be exposed and therefore subject to dosimetry monitoring, those working in radiology (72% of the medical personnel monitored, in diagnostic radiology and intervention radiology alike) receive an average individual annual dose of 0.20 mSv. The nuclear medicine personnel, who represent 5% of the monitored health personnel, are exposed to an average individual annual whole body dose that is four times greater, estimated at 0.78 mSv.

It is also in the medical sector that the majority of situations of occupational exposure to the extremities (hands) occur. Consequently 15,403 medical professionals were subject to dosimetric monitoring of the extremities by ring or wrist dosimeter, which represents 60% of the workers monitored in this way and about 60% of the total dose to the extremities. The radiology sector has the largest number of monitored workers, with about 68% of the total headcount of medical personnel monitored by dosimetry at the extremities (49% for interventional radiology and 19% for diagnostic radiology), and accounts for 27% of the total exposure dose to the extremities in the medical field. The nuclear medicine sector represents 20% of the monitored personnel and accounts for 68% of the total dose in this area. One hundred and forty-four workers in the dental sector are subject to dosimetry monitoring at the extremities and represent less than 0.1% of the total dose to the extremities.

The contribution of interventional activities to the total dose is probably underestimated, particularly due to insufficient use of extremity dosimeters by staff in the operating theatre.

Lastly, nearly 84% of the personnel monitored for exposure to the lens of the eye work in medical activities, representing 4,756 workers accounting for 56% of the total dose to the lens of the eye. The average individual dose for medical activities (dental activities excluded) in 2023 was 1.38 mSv. Nearly two-thirds of the personnel monitored for lens of the eye dosimetry work in the FGIP sector which accounts for 70% of the total dose in the medical sector. Two cases of exceeding limit exposure values were registered by the occupational physician in the medical sector: one in effective dose in the dental sector and one in dose to the extremities in interventional radiology (*see chapter 1*).

1.2.2 Exposure of patients

In medical applications for diagnostic purposes, the aim of optimising exposure to ionising radiation is to deliver the minimum dose that produces an image of sufficient quality to obtain the relevant diagnostic information or allows performance of the planned interventional procedure. For therapeutic applications, the dose delivered must be much higher than in diagnostic applications in order to destroy the targeted cells while preserving the surrounding healthy tissue as best possible. As the principle of limitation does not apply to patients, the principles of justification and optimisation (*see point 1.3*) must be applied all the more rigorously.

In medical imaging, the principles of optimisation and justification (avoiding unnecessary examinations, or those whose result can be obtained using non-irradiating techniques that give an equivalent diagnostic level when available) are at the centre of the action plans for controlling doses delivered to patients. These action plans were developed by ASN in 2011 and 2018 in collaboration with the services of the Ministry of Solidarity and Health and the health professionals. The action plan of 2018 will be updated after finalising the situation assessment carried out with all the stakeholders.

The optimisation principle, defined by Article L. 1333-2 of the Public Health Code (*see chapter 2*), known as the ALARA⁽²⁾ principle, has led to the introduction, in the area of medical imaging using ionising radiation, of the concept of “Diagnostic Reference Levels” (DRLs).

These DRLs, which must not be considered to be “dose limits” or “optimum doses”, are established for standard examinations and typical patients. The DRLs are thus dosimetric indicators used to assess the quality of practices.

The comparison of a DRL value with a dose received during an individual examination is not relevant for a given individual, because in certain situations the conditions of the examination can justify a higher value (to take into account the patient’s morphology for example, or other factors that do not call into question the benefit/risk of the procedure). The optimisation principle should lead the persons/entities Responsible for a Nuclear Activity (RNAs) that use imaging by ionising radiation to compile their own Local Dose Reference Levels (LDRLs) to continue optimising their practices if this is compatible with obtaining a diagnostic quality image. ASN encourages such practices and wants the medical professionals to generalise them in the interest of the patients. ASN resolution 2019-DC-0667

of 18 April 2019 sets the DRL values and requires heads of radiology and nuclear medicine departments to carry out (or have others carry out) periodic dosimetric evaluations and to send the results to IRSN. The data collected by IRSN are analysed with a view to updating the DRLs. This resolution will be amended in 2025 to introduce new DRL values for Digital Radiography (DR) mammography and tomosynthesis (3D) mammography, and new DRL values for dental Cone Beam Computed Tomography (CBCT).

The last “ExPRI” study, which analyses exposure of the French population to ionising radiation due to medical imaging examinations, was published by IRSN in late 2020. It presents the data for 2017, which are compared with those of 2012 to show how they have evolved. These analyses are carried out using diagnostic imaging procedures drawn from a representative sample of beneficiaries of the French health insurance system, by method of imaging (conventional, interventional and dental radiology, CT scans and nuclear medicine), by explored anatomical region, by age and by sex. The analyses reveal stability of exposure on average (*see chapter 1, point 3.3*).

1.2.3 Exposure of the public

The impact of medical applications of ionising radiation is likely to concern:

- members of the public who live near facilities that emit ionising radiation and the persons working in these facilities who are not workers classified in application of the Labour Code with regard to the radiological risk;
- embryos or fetuses exposed in utero when pregnant women are exposed for medical purposes;
- the personnel of the sewage networks and wastewater treatment plants who could be exposed to effluents produced by nuclear medicine departments, and in the event of non-compliance with waste management procedures, the personnel working in waste treatment facilities who could be exposed to waste produced by nuclear medicine departments or by patients at home having received therapeutic nuclear medicine treatment;
- carers and comforters of patients having received therapeutic nuclear medicine treatment and healthy volunteers participating in biomedical research involving exposure to ionising radiation. The regulatory obligations applicable to these exposures are those that apply to medical exposures. These exposures are therefore not subject to the dose limits for the public but must comply with dose constraints (*see below and point 1.3.4*).

2. The ALARA (As Low As Reasonably Achievable) principle appeared for the first time in Publication 26 of the International Commission on Radiological Protection (ICRP) in 1977. It was the culmination of a reflection on the principle of radiation protection optimisation. Acceptance and implementation of the ALARA principle have evolved significantly in Europe over the last thirty years, with close involvement of the European Commission which resulted in the creation of a European ALARA network in 1991.

The estimated doses for the public (people external to the health facility) resulting from discharges from nuclear medicine departments are a few tens of microsieverts (µSv) per year for the most exposed people, primarily the personnel working in sewage networks and wastewater treatment plants (IRSN studies, 2005 and 2014). In 2015, IRSN developed an aid baptised CIDRRE (French acronym for “Calculation of the impact of radioactive discharges into wastewater networks”). This aid enables nuclear medicine departments to estimate, with reasonably penalising assumptions, conservative dose values for the sewage system workers based on the activities they administer to patients or use in their research work. Situations of exposure of waste treatment personnel associated with the handling of radioactive waste from nuclear medicine departments or healthcare services or produced by patients at home are exceptional and of very limited scale, even if radiation portal monitors do get activated from time to time at the entrance to waste treatment facilities, in which case complex operations are required (sorting, characterisation, etc. – see point 2.3.3.4).

The number of exposures of pregnant women unaware of their pregnancy notified to ASN decreased by 7% in 2024 compared with 2023. This represents 17% of the Significant Radiation Protection Event (ESR) notifications in 2024 (see point 2.7) compared with 26% on average over the previous 10 years. This figure, which fluctuates regularly, has been following a downward trend since 2021. At the end of 2021, ASN published a “Patient Safety” bulletin entitled *Ionising radiation: limiting exposures of women unaware of their pregnancy* which is gradually bearing fruit. These events occur primarily in computed tomography (60% of events in 2024), illustrating the benefit of developing the systematic adoption of pregnancy screening tests in these imaging centres. It should also be pointed out that the number of notifications of accidental in utero exposures of embryos or fetuses in nuclear medicine almost doubled in 2024 compared with 2023. This is the first time the number of notifications in this speciality exceeds that for conventional radiology. The doses delivered to the uterus in these imaging examinations are less than 100 milligrays (mGy). This value is below the value for which no increase in malformations or reduction in intellectual quotient has been detected to date in comparison with spontaneous risks (estimated at 3%)³. The exposure of pregnant women unaware of their pregnancy during therapeutic treatments using ionising radiation could, given the higher doses than in diagnostic imaging,

exceed 100 mGy depending on the zone treated. The exposure of a foetus to more than 100 mSv may lead the patient to decide to have an abortion.

In nuclear medicine the administration of a RadioPharmaceutical Drug (RPD) also exposes the medical professionals who are involved in dispensing and/or monitoring the treatment (who are subject to monitoring as mentioned earlier in point 1.2.1) and can potentially expose the patient’s family and comforters. The regulations have introduced the notion of “dose constraints” for the patient’s family circle in order to control such exposure. To verify compliance with these dose constraints with respect to the patient’s family circle, equivalent ambient dose rate measurements can be taken before discharging a patient who has undergone a nuclear medicine procedure. In clinical practice, nuclear medicine departments make the discharging of patients having received a high activity (therapeutic application) conditional on an equivalent dose rate of about 20 microsieverts per hour (µSv/h) at a distance of 1 m (recommendations of the GPRP in Medical Applications – October 2017. It is usually necessary to hospitalise the patient in a radiation-proof room while waiting for the activity to decay. The introduction of new RPDs will lead to the updating of the instructions for the carers and family circle. The working group tasked with patient radiation protection (GT RPP) is working to establish recommendations for harmonising practices in nuclear medicine departments and the information to give to patients’ carers and family circle (see chapter 2).

1.2.4 The environmental impact

In nuclear medicine, the radioactive sources administered to the patients will undergo physical decay (period of time stemming from their physical-chemical properties) but also biological elimination (resulting from the biological metabolism, as with any medication). Patients having received an injection eliminate part of the administered radioactivity, mainly via the urinary tract. Nuclear medicine departments are designed and organised for the collection, storage and disposal of the radioactive waste and effluents produced in the facility, particularly the radionuclides contained in patients’ urine (see point 2.3.2), and are required to draw up an Effluents and Waste Management Plan (EWMP) detailing the collection, management and disposal arrangements. In addition, a discharge monitoring system must be put in place.

The environmental impact of using ionising radiation for medical purposes is

measured by the environmental radiological monitoring ensured by IRSN (see chapter 3). The measurement results are approximately equivalent to the background radiation. Radioactivity measurements in major rivers or wastewater treatment plants of large towns occasionally reveal the presence of artificial radionuclides used in nuclear medicine (iodine-131, for example; assessment of the radiological condition of the French environment from 2018 to 2020). However, no trace of these radionuclides has been detected in water intended for human consumption (see chapter 1). Furthermore, the bibliographic study conducted by IRSN⁴ in 2021 reveals a low radiological impact on the public of the radioactive discharges from nuclear medicine departments into the sewage systems (from its analysis of two French studies, IRSN estimates that the exposure of people living near wastewater treatment plants is less than 1 microsievert per year – µSv/year).

1.3 Regulations

1.3.1 General regulations

Protection of the personnel working in facilities that use ionising radiation for medical purposes is governed by the provisions of the Labour Code (Articles R. 4451-1 to R. 4451-146).

In order to protect the public and the workers, the facilities that use MDs emitting ionising radiation must also satisfy the technical rules defined in the ASN resolutions (see *technical rules described in points 2.1.2, 2.2.2, 2.3.2, 2.4.2, 2.5.2 and 2.6.2 of this chapter*).

The monitoring of sources (radioactive sources including RPDs, devices emitting ionising radiation, particle accelerators) is subject to specific rules figuring in the Public Health Code (Articles R. 1333-152 to R. 1333-164). These rules concern the acquisition, distribution, import, export, sale, transfer, recovery and disposal of the sources. If the sources are not exempted, they must be notified, registered or licensed, depending on their nature. The sources are inventoried and then taken back when expired, and they can be subject to financial guarantees to ensure their recovery by the supplier.

1.3.2 Radiopharmaceutical drugs and medical devices

The radionuclides used in nuclear medicine can be classified in two categories:

- the RPDs, which like all medicinal drugs are subject to obtaining a Marketing Authorisation (MA), issued by either the French Health Products Safety Agency

3. ICRP Publication 84. Ann. ICRP 30. ICRP Supporting Guidance 2. Ann. ICRP 31. ICRP Publication 90. Ann. ICRP 33. ICRP Publication 103. Ann. ICRP 37, ICRP Publication 105. Ann. ICRP 37.

4. IRSN Report No.2021-00848 on the estimation of the impact on the public of effluents containing radionuclides coming from nuclear medicine departments and research laboratories.

(ANSM) or the European Medicines Agency (EMA) before they can be used in accordance with the manufacturer's recommendations;

- active implantable MDs (such as microspheres labelled with yttrium-90) also require their manufacturer to apply the "CE" marking in order to be placed on the market in the member states or parties to the agreement with the European Economic Community in application of Directive 90/385/EEC transposed into the French Public Health Code in Articles R. 5211-1 to R. 5211-73.

Pending the obtaining of an MA, and to allow early access to medicines for patients suffering from serious or rare diseases, derogation processes have proliferated in France over the last twenty years. In order to simplify and harmonise these different processes, a reform of the access to medicines by derogation was implemented on 1 July 2021 (Decree 2021-869 of 30 June 2021). This reform, which aims to *"allow even faster access to these medicines for patients at a therapeutic dead-end"*, replaces the six authorisation systems by two conditions of access, namely compassionate access and early access.

The MDs emitting ionising radiation (electrical X-ray generators and particle accelerators, microspheres labelled with yttrium-90) used in nuclear-based medical activities must meet the essential requirements defined in the Public Health Code (Articles R. 5211-23 and R. 5211-23-1 for active implantable medical devices and R. 5211-22 for the other medical devices). The "CE" marking, which certifies conformity with these essential requirements, is mandatory. Further to technological developments, the Order of 15 March 2010 laying down the essential requirements applicable to MDs other than active implantable devices (microspheres labelled with yttrium-90), was amended on 4 October 2019 to reinforce the provisions concerning the display of the dose during imaging procedures.

Furthermore, European regulation EU 2017/745 of 5 April 2017 came into force on 26 May 2021. It has been amended by European regulation EU 2023/607 of 15 March 2023 which prolongs temporary provisions. Due in particular to the effects of the Covid-19 pandemic on companies and the as yet small number of organisations notified under the abovementioned regulation, these new provisions allow manufacturers who began a process for assessing the conformity of their MDs before 26 May 2024 under Regulation (EU) 2017/745 to continue, under certain conditions, putting these MDs on the market in accordance with Directive 90/385/EEC or Directive 93/42/EEC. The date beyond which it will no longer be possible to put

on the market or put into service MDs emitting ionising radiation which do not comply with the abovementioned directives is set at 31 December 2028 at the latest, with the exception more specifically of iodine-125 seeds used in brachytherapy and yttrium-90-labelled microspheres mentioned above which must comply with Regulation (EU) 2017/745 by 31 December 2027 at the latest. This new European regulation reinforces patient safety on the one hand through a better clinical assessment of the MDs, and transparency on the other, thanks to the European Database on Medical Devices (EUDAMED). This database is accessible to the manufacturers and the competent authorities responsible for monitoring the MD market; the general public has partial access to it. The aim of giving access to the information in this database is:

- to help to improve the collaboration between:
 - the manufacturers or their representative and the competent authority of the country in which the MDs are manufactured/sold/installed,
 - the competent European authorities responsible for monitoring the MD market;
- to ensure greater public transparency, in particular by making available to the public the summary of the safety and clinical performance characteristic of each MD. To facilitate early access of patients to innovative and useful technologies which do not yet have the "CE" marking, the French National Authority for Health (HAS) has instituted an "innovation pass". This innovation pass is a derogation and temporary mechanism put in place to facilitate early access of patients to innovative technologies (MDs) which are in the early phase of clinical development. The clinical study is conducted with the aim of confirming the human health benefit of the new technology.

The clinical assessments conducted in order to put on the market MDs, RPDs, or for derogation processes allowing patients to receive an innovative treatment, are determining factors in the application of the justification principle (see point 1.3.4).

To anticipate the radiation protection issues associated with the introduction of new techniques and emerging practices, the Committee for the Analysis of New Techniques and Practices using Ionising Radiation (Canpri – see chapter 2) was called upon in 2020 to work on the ZAP-X® gyroscopic stereotactic intracranial radiosurgery and radiotherapy platform. Canpri issued its opinion in 2023 on the radiation protection of patients, workers, the fitting out of the rooms and the management of waste after use. Its opinion includes recommendations intended for future users, manufacturers and institutions (Ministry

of Health, HAS, ANSM, ASN, professional organisations, etc.). ASN issued a position statement on this basis on 22 October 2024 and published its opinion on its website (opinion 2024-AV-0447 of 22 October 2024).

Canpri has also undertaken work on flash radiotherapy at the request of ASN since 2022. Its opinion is expected in 2025.

1.3.3 Administrative system

As part of the recasting of the classification of the different nuclear activities introduced by Decree 2018-434 of 4 June 2018 stipulating diverse provisions in the nuclear field, ASN wanted to implement a more graded and proportionate approach to the risks.

Three authorisation systems are now in place, namely licensing, notification and, since 1 July 2021, a simplified system called "registration". Notification is a simple procedure which does not require the submission of any supporting documents. It is suited to the nuclear activities that present the lowest risks for workers, the public, patients and the environment. Licensing serves to regulate the activities presenting the greatest risks, for which ASN checks, when examining the application file, that these risks have effectively been identified by the applicant and that the barriers intended to mitigate their effects are appropriate. This system is applicable to radiotherapy (including radiosurgery), brachytherapy and nuclear medicine for diagnostic and therapeutic purposes. Registration also involves the submission of documents for examination, but fewer in number.

Since 1 July 2021, the ASN on-line services portal allows RNAs to register their activities. The list of medical activities subject to registration has been defined on the basis of the radiation protection risks (see Table 1) by ASN resolution 2021-DC-0704 of 4 February 2021. This system is applicable to computed tomography and to FGIPs, activities with radiation protection implications. Owing to the diversity of the "CBCT" devices and the particular radiation protection conditions associated with their use, these devices have also been placed under the registration administrative system in order to guarantee, in principle, better oversight of the radiation protection rules. Conventional radiology and dental radiology will continue to come under the notification system.

The French healthcare licensing system came into effect in June 2023. Projects concerning the creation of any healthcare facility, the creation, conversion and grouping of healthcare activities, including in alternative forms to hospitalisation, and the installation of large medical devices are subject to the authorisation of the Regional Health Agencies (ARS). The healthcare activities licence is a constituent of the application

TABLE 1 Classification of nuclear-based medical activities according to the radiation exposure risks

Activities	Patients	Professionals	Public and environment
External-beam radiotherapy	3	1	1
Brachytherapy	2	2	2
Internal targeted radiotherapy	3	2	3
Fluoroscopy-guided interventional practices	2 to 3 depending on the procedures	2 to 3 depending on the procedures	1
Diagnostic nuclear medicine	1 to 2 depending on the procedures	2 to 3 depending on the procedures	2
Computed tomography	2	1	1
Fluoroscopy-guided procedures on remotely controlled table in radiology department	1	1	1
Conventional radiology	1	1	1
Dental radiology	1	1	1

1: No risk or low risk – 2: Moderate risk – 3: High risk

for a licence to possess and use a radioactive source or a device emitting ionising radiation. Among the changes stemming from the reform is the introduction of new healthcare activities, including interventional radiology and nuclear medicine and the reinforcing of the quality and safety approach with extension of the enforceability of the technical operating conditions of radiotherapy to neurosurgery departments. The healthcare activities and major medical equipment items will have to comply with the Installation Conditions (ICs – they detail the levels of the procedures in particular) set for each of them by the provisions of Chapter III of Title III of Book I of the 6th Part of the Public Health Code (Articles R. 6123-1 to R. 6123-212). These ICs are also associated with Technical Operating Conditions (TOCs – they include for example requirements concerning the composition of the teams, qualification of the personnel, fitting out of the rooms, patient follow-up methods, recourse to certain treatment methods, etc.). These TOCs are detailed by the provisions of Chapter IV of Title II of Book I of the 6th Part of the Public Health Code (Articles D. 6124-1 to D. 6124-501). The implementation of this reform will continue to modify the organisational structures in place, notably by encouraging cooperation between healthcare organisations. These groupings can lead the holder of a nuclear activity or activities licence to ask ASN to modify or even to revoke the license (change of RNA, development or change of agreements, etc.). For example, in nuclear medicine certain devices may be shared between healthcare facilities; in external-beam radiotherapy, the radiosurgery activity may be attached to a neurosurgery department and no longer to a radiotherapy department. Nuclear medicine departments are divided into two categories: category A departments which do not perform therapeutic procedures and category B departments which do perform therapeutic procedures among others.

ASN is attentive to the impact of this reform on the nuclear activity licences and on radiation protection conditions because of these organisational changes.

1.3.4 The particularities of radiation protection of patients

Justification and optimisation – The protection of patients undergoing medical imaging examinations or therapeutic procedures using ionising radiation is regulated by specific provisions of the Public Health Code (Articles R. 1333-45 to R. 1333-80). The principles of justification of the procedures and optimisation of the delivered doses constitute the cornerstone of this regulation. The principle of dose limitation does not apply to patients due to the need to adapt the delivered dose to the diagnostic or therapeutic end-purpose for each patient. ASN ensures that this regulatory framework is updated through specific provisions with regard to optimisation, quality assurance, training and qualification as described below.

The required qualifications – The use of ionising radiation on the human body is restricted to physicians and dental surgeons having the necessary skills to perform these procedures (Article R. 1333-68 of the Public Health Code). To adapt the regulatory provisions to the technical changes and conditions of professional practice, ASN published resolution 2020-DC-0694 of 8 October 2020, approved by the Order of 5 July 2021, which came into effect in July 2021. It repeals the resolution of 23 August 2011 (2011-DC-0238) and updates the qualifications required for physicians and dental surgeons who perform procedures using ionising radiation for medical purposes or human subject research. It also sets the requirements for designating physicians coordinating a medical nuclear activity and to apply for a license or registration as a natural person.

The quality assurance obligations – To control the doses delivered to patients and thereby contribute to improved treatment safety, the obligations of the RNAs with regard to quality assurance for all medical activities involving ionising radiation are now governed by two ASN resolutions:

- resolution 2019-DC-0660 of 15 January 2019 in medical imaging, that is to say in nuclear medicine for diagnostic purposes, in dental and conventional radiography, in computed tomography and for FGIPs;
- resolution 2021-DC-0708 of 6 April 2021 for therapeutic procedures, that is to say external-beam radiotherapy, including contact therapy and intraoperative radiotherapy, brachytherapy, nuclear medicine for therapeutic purposes (ITR) and radiosurgery.

These resolutions oblige the RNA, with requirements proportionate to the radiation protection risks, to formalise the work instructions associated with the operational implementation of the two general principles of radiation protection (justification for the procedures and dose optimisation), and those concerning Learning From Experience (LFE), the training and authorisation of professionals and, for therapeutic procedures, the prospective risk analysis. The above-mentioned resolution 2021-DC-0708 of 6 April 2021 updates and tightens the quality assurance requirements, particularly when there is an organisational or technical change, and when services are outsourced.

A clinical peer review figures among the quality assurance obligations.

The principle of the clinical peer review has been written into Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. Transposed into French law in Article R. 1333-70 of the Public Health Code, the clinical peer review, which is included in the quality assurance system provided for in Article L. 1333-19 of the Public Health Code, is the “assessment method which, in view of the criteria determined by the quality assurance baseline, gives the patient guarantees regarding the competence of the medical and healthcare team, the quality of care and the safety of the procedures, which includes patient radiation protection”.

The clinical peer reviews have been introduced progressively since 2023 on the initiative of the General Directorate for Health (DGS) in the areas of imaging and radiotherapy initially, with the backing of the professional organisations and national councils concerned. ASN participates in the steering committees set up by the DGS to monitor implementation

of these clinical peer reviews. The review grids have been finalised and the recruitment and training of reviewers (physicians, medical physicists and radiographers) has been completed, as has the identification of volunteer centres to test the process. The pilot phase for testing the review process as a whole (organisation, documentation, etc.), and the appropriateness of the said grids for the two areas was initiated late 2023. The assessment conducted at the end of 2024 on about ten volunteer radiotherapy centres is broadly positive as regards review preparation on the part of the reviewers, the reviewed centres and the subjects addressed during the reviews, such as justification of the procedure (patient radiation protection). Deployment of the pilot phase in radiotherapy will continue in 2025. In radiology, some thirty imaging facilities out of the 70 candidacies received by National Professional Council (CNP) for radiology had been reviewed by the end of July 2024. The medical imaging reviews held in the first year of operation will undergo an assessment. The reviews will continue on a voluntary basis in 2025.

At the end of these experimental phases, a national assessment will be carried out by the Ministry responsible for health in order to extend these clinical reviews to the national scale, with conditions of performance and the frequency of the reviews being specified in an Order. ASN encourages the deployment of these reviews in the sectors with high radiation protection risks which are not covered at present, namely radiosurgery and therapeutic nuclear medicine and, in particular, it encourages the professional organisations to start working on the review baseline requirements as of now.

Training in patient radiation protection

The obligations for continuous training in patient radiation protection are set in Articles L. 1333-19, R. 1333-68 and R. 1333-69 of the Public Health Code. The system as a whole was revised in ASN resolution 2019-DC-0669 of 11 June 2019 amending resolution 2017-DC-0585 of 8 January 2015, further to discussions with all the CNPs concerned. This resolution aims to clarify and enhance the teaching objectives concerning justification, to integrate new actors and to foster interfacing with the other continuous training systems. Pursuant to this resolution, 18 professional guides have been produced by the professional organisations, validated by ASN and put on line on asn.fr⁽⁵⁾. To monitor the practical implementation of this new regulatory framework,

a qualitative and quantitative assessment involving all the professions was carried out in 2022. An inventory of the training offerings has been drawn up to identify the main players (health facilities, professional organisations, continuous training organisations). For the guide for radiotherapy professionals and the guide for radiographers working in imaging, a specific assessment has been conducted by the Centre of Studies on the Evaluation of Protection in the Nuclear Field (CEPN) at the request of ASN, on the number and content of these two training courses. This assessment focused on compliance with the regulations, the organisation of the training courses, their teaching methods and the level of satisfaction of the professionals who have followed the courses. The first results show that the training guides are broadly followed by the training organisations (whether public or private). This work was presented in 2023 to the committee that monitors the national plan for controlling imaging doses and to the Advisory Committee of Experts for Radiation Protection – GPRP (see chapter 2) and continued in 2024 with, in particular, a presentation of the results to the organisations providing training in patient radiation protection.

1.4 The risks and oversight priorities

In order to establish its oversight priorities, ASN has classified the nuclear-based medical activities according to the risks for the patients, the personnel, the public and the environment. This classification takes particular account of the doses delivered or administered to the patients, individually or collectively, the fitting out of the premises and the conditions of use of sources of ionising radiation by the medical professionals, the production of waste and effluents contaminated by radionuclides, the source security risks (high activity sealed sources), lessons learned from significant events notified to ASN and the radiation protection situation in the institutions exercising these activities.

On the basis of this classification (see point 1.3.3, Table 1), ASN considers that its inspection priorities must focus in priority on external-beam radiotherapy – including radiosurgery, brachytherapy, nuclear medicine and FGIPs. The inspection frequencies, based on an approach graded according to the radiation protection risks (see Table 2), enable all the safety-significant activities to be inspected over a period of three to five years, depending

on the sectors. These frequencies are increased when vulnerabilities that could have an impact on radiation protection are identified (difficulties linked to human resources, technical or organisational changes, quality management or insufficient control of risks – lateness in formalising practises, absence of risk assessments, lack of risk culture –, particular risks associated with certain techniques, etc.). This can lead ASN to place certain centres under tightened surveillance, when significant persistent malfunctions have been found, and to inspect them at least annually (see chapter 3). The inspection frequency for FGIPs can be reduced by ASN depending on the knowledge of the radiation protection situation of the facilities, on the basis in particular of the inspections carried out when issuing a registration.

In 2018, ASN defined a list of systematic inspection points concerning the radiation protection of workers, patients and the public, the management of sources, waste and effluents, and the security of sources. These inspections, associated with indicators, enable regional and national assessments to be carried out and the developments to be measured over time. Some indicators are common to all the inspected activities, such as the organisation of radiation protection and of medical physics, and training in radiation protection of workers and patients. Others are specific to a given activity, such as the management of waste and effluents in nuclear medicine or the security of sources in brachytherapy. These indicators serve in particular as the basis for assessing the radiation protection situation in the medical sector (see point 2). These systematic checks are complemented by investigations on specific themes defined in an annual or multi-annual framework and adapted to the particular situations encountered in the inspections.

The main themes chosen in 2024 were:

- in radiotherapy – including radiosurgery, and brachytherapy: risk management and in particular learning lessons from ESRs, management of skills and training, mastery of the equipment and more particularly the accelerator calibration process and the security of high-activity sealed sources;
- in nuclear medicine: the management of adverse events relating to the administration of RPDs, implementation of the verifications to ensure there is no surface or atmospheric contamination;
- in FGIPs: implementation of the optimisation approach and training practitioners in patient radiation protection.

5. asn.fr/espace-professionnels/activites-medicales/guides-professionnels-de-formation-continue-a-la-radioprotection

TABLE 2 Inspection frequency by nuclear-based medical activity

Nuclear-based medical activity	Routine frequency
External-beam radiotherapy	Every 4 years
Brachytherapy	Every 4 years
Diagnostic nuclear medicine	Every 5 years
Therapeutic nuclear medicine on out-patient basis (e.g. iodine < 800 Megabecquerels – MBq, synoviortheses, etc.)	Every 4 years
Therapeutic nuclear medicine with complex therapies using iodine >800 MBq, lutetium-177, yttrium-90 and hospitalisation	Every 3 years
Fluoroscopy-guided interventional practices with risks	Every 5 years approximately ^(*)
Computed tomography (emergencies or paediatrics with radiation protection risks)	Sampling: about twenty facilities per year

* Depending on ASN's knowledge of the radiation protection situation in the facilities, based in particular on the inspections carried out when issuing a registration.

Although the RNAs are given advance notice of the majority of routine inspections (see chapter 3), unannounced inspections may be carried out. Six unannounced inspections were thus carried out in 2024 covering all the inspected activities (two in FGIPs, two in nuclear medicine, one in radiotherapy and one in computed tomography – see point 2.1.3). Furthermore, inspections may be carried out in the commissioning context when installing new MDs or for new facilities, and when investigating ESRs.

1.5 Significant radiation protection events

It is mandatory for ASN to be notified of ESRs pursuant to the Public Health Code (Articles L. 1333-13, R. 1333-21 and 22) and the Labour Code (Article R. 4451-74 – see chapter 3, point 3.3). In the medical field, ESRs have been notified to ASN since 2007. Notifying these events makes it possible, after analysing them, to give feedback to the medical professionals with a view to continuous improvement of radiation protection.

An on-line services portal has been provided at teleservices.asn.fr to enable all the medical professionals to file their

notifications on line. This portal is integrated in the adverse public health events reporting portal managed by the Ministry responsible for health. Depending on the type of event reported, the notification is sent automatically to ASN (regional division and Department of ionising radiation and health – DIS), to the ARS for all events concerning the patient and to the ANSM for events relating to medical devices vigilance or drug safety monitoring.

The methods of notification and of codifying the significant events notification criteria defined in ASN Guide No. 11 are soon to be updated. The ASN-SFRO scale for rating events concerning patients undergoing radiotherapy or brachytherapy treatment remains unchanged. The aim of this scale, developed in collaboration with the French Society for Radiation Oncology (SFRO), is to inform the public about radiation protection events affecting patients in the course of a radiotherapy or brachytherapy treatment, taking into account, in addition to the confirmed consequences, the potential effects of the event and the number of patients exposed (see chapter 3).

In addition to this, the incident notices are published on asn.fr.

To meet its obligation to inform health professionals of the lessons learned from the analysis of events that could affect the health of the persons mentioned in Article L. 1333-13, when these events have relevance from the patient radiation protection viewpoint (Article R. 1333-74 of the Public Health Code), ASN regularly produces information media:

- “Learning from experience” sheets further to an ESR to rapidly inform the medical professionals potentially concerned in order to prevent the event from occurring in another centre;
- “Patient safety - Paving the way for progress” bulletins, published since March 2011. The “Patient safety” bulletin offers a thematic presentation of the good practices of medical departments and the recommendations developed by the professional organisations of the discipline concerned and the health and radiation protection institutions;
- circular letters addressed to the RNAs to draw their attention to particular points that have caused ESRs, to disseminate the lessons learned from these events and/or to make known its recommendations on the subject.

To produce the first two types of information media, ASN is assisted by two multidisciplinary Working Groups (WGs) in the fields of radiotherapy and imaging respectively. Documents of this type are published on the ASN website in the section “Espace professionnels”, sub-section “Retour d'expérience”. The circulars are published in the sections devoted to each medical activity, under the sub-section “Lettres circulaires”.

All of these communication media, over and beyond fulfilling ASN's obligation, are produced with particular care in order to stimulate the interest of the medical professionals and encourage the sharing of lessons learned from experience.

Refer to point 2.7 below for further information on the work of these WGs.

2 — Nuclear-based medical activities

2.1 External-beam radiotherapy

Radiotherapy, along with surgery and chemotherapy, is one of the key techniques employed to treat cancerous tumours. Radiotherapy uses ionising radiation to destroy malignant cells and also dysfunctional non-malignant cells. We distinguish external-beam radiotherapy, where the source of radiation (particle accelerator

or a sealed radioactive source in the case of Gamma knife®) is external to the patient, from brachytherapy, where a sealed radioactive source is placed as close as possible to the cancerous lesion, either via the natural cavities or by catheters (see point 2.2).

The radiation sessions are always preceded by the preparation of a treatment plan which serves to set the conditions for achieving a high dose in the target volume

while preserving the surrounding healthy tissues. The treatment plan defines the dose to deliver, the target volume(s) to treat, the organs at risk to be protected, the ballistics of the radiation beams and the predicted dose distribution (dosimetry). Preparation of the treatment plan requires close cooperation between the radiation oncologist, the medical physicist and, if necessary, the dosimetrists.

The main radiation protection risk is linked to the dose delivered to the patient; the change of treatment techniques with the development of hypofractionated radiotherapy (see point 2.1.1), which consists in delivering higher doses during a given session, makes it all the more crucial to control delivery of the dose.

This is why ASN's oversight focuses on both the ability of the centres to control delivery of the dose to the patient and to learn lessons from the malfunctions that have occurred or could occur. Implementation of the treatment Quality and Safety Management System (QSMS), skills management, mastery of the equipment, the culture of reporting adverse events, including ESRs, and the ability to analyse them, are the focal points of the ASN inspections. As technical, organisational and human changes are potential risk-generating situations, particular attention is also given to change management during the inspections.

2.1.1 Description of the techniques

Several external-beam therapy techniques are currently used in France.

The SFRO considers **three-dimension conformal radiotherapy** to be the basic technique in its *Guide to recommendations for the practise of external-beam radiotherapy and brachytherapy* (Recorad), updated in February 2022. This technique uses three-dimensional images of the target volumes and neighbouring organs obtained with a CT scanner, sometimes in conjunction with other imaging examinations (Positron Emission Tomography – PET, Magnetic Resonance Imaging – MRI, etc.). For several years now, however, the proportion of treatments performed using this technique is decreasing in favour of **Intensity-modulated radiotherapy (IMRT)**, which saw the day in France in the early 2000s and allows better adaptation to complex tumoral volumes and better protection of neighbouring organs at risk, thanks to modulation of the intensity of the beams during irradiation.

Following on from IMRT, **Intensity-modulated Volumetric Arc Therapy (IMVAT)** is now being used increasingly frequently in France and is the reference technique for prostate and head and neck cancers. This technique consists in irradiating a target volume while continuously varying several parameters during treatment: the shape and intensity of the beams, the position and speed of rotation of the accelerator around the target volume and therefore around the patient.

Helical radiotherapy, or tomotherapy, enables radiation treatment to be delivered by combining the continuous rotation of an accelerator with the longitudinal movement of the patient during the treatment. The possibility of modulating radiation intensity allows equally well the irradiation of large complex-shaped volumes as of highly-localised lesions, if necessary in mutually independent anatomical regions. The system requires the acquisition of images under the treatment conditions of each session for comparison with reference computed tomography images in order to reposition the patient.

Stereotactic radiotherapy is a treatment method that aims at delivering high-dose radiation to intra- or extracranial lesions (whether cancerous or not) with sub-millimetric accuracy through multiple mini-beams which converge at the centre of the target. The total dose is delivered either in a single session or in a hypofractionated manner, depending on the disease being treated. This technique demands great precision in defining the target volume to irradiate and uses specific identification techniques in order to localise the lesions with millimetric accuracy. The increase in doses per treatment session usually implies, with linear accelerators, the use of Flattening-Filter-Free (FFF) beams which allow the dose rate and therefore the dose per session to be increased.

This therapeutic technique essentially uses three specific types of equipment, such as:

- Gamma Knife®, which uses more than 190 cobalt-60 sources, that is to say more than 190 non-coplanar beams centred on the tumour. The movement of the table on which the patient is positioned enables the desired dose to be delivered to the entire tumour with great precision.

- CyberKnife® is a miniaturised linear accelerator mounted on a robotic arm, providing nearly 2,000 non-coplanar beam entry points around the patient. This machine also allows tumour position tracking during irradiation.
- Multi-purpose linear accelerators equipped with additional collimation means (mini-collimators, localisers that can produce mini-beams), ensuring appropriate mechanical precision and equipped with a table with 6 degrees of freedom (allowing non-coplanar treatments and better positioning, among other things).

A new mono-energy radiotherapy accelerator, a self-shielded gyroscopic platform called “ZAP-X®” (ZAP Surgical, 3 MV, FFF mode) was authorised in March 2023 for use in France for stereotactic intracranial radiotherapy and radiosurgery (see *Canpri opinion* in points 1.2.2 and 1.3.2 above).

Since 2018, the combination of a **linear accelerator for radiotherapy coupled with an MRI scanner** has been developing.

Contact therapy or contact radiotherapy is an external-beam radiotherapy technique. The treatments are delivered by specific devices using low-energy photon beams with the radiation source placed in contact with the lesion to irradiate (superficial lesions such as skin cancers, endocavitary lesions such as cancer of the rectum, sometimes in contact with the surgical field after removing the tumour, as might be the case with cancer of the pancreas or liver, etc.).

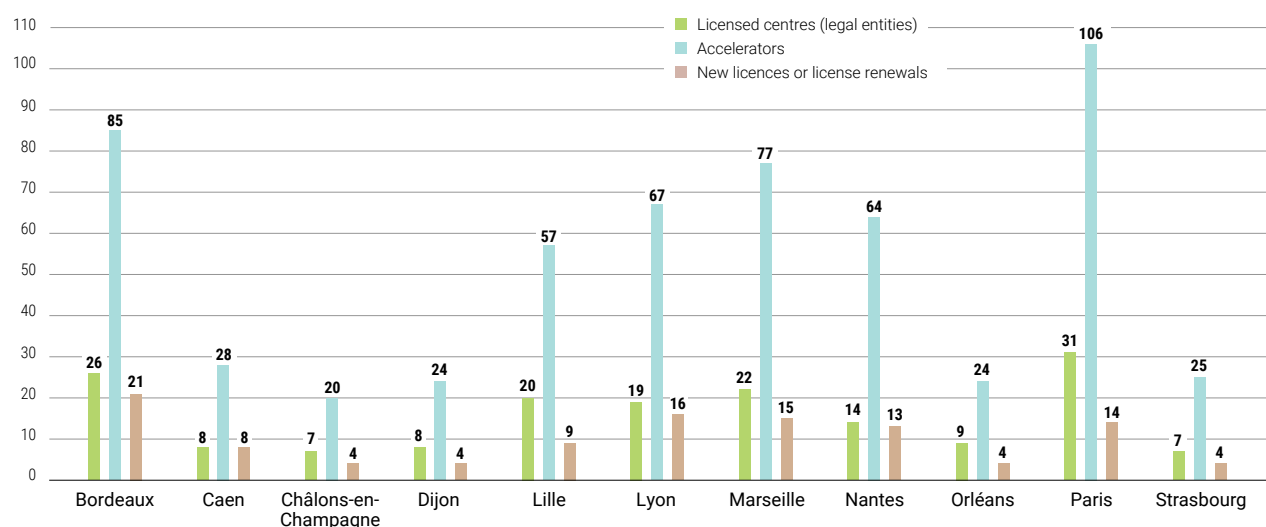
Intraoperative electron radiotherapy is based on applying a beam of electrons (energy up to 12 Megaelectronvolt – MeV) directly to the surgical field using mobile electron accelerators featuring the “CE” marking and with built-in shielding to allow them to be used directly in the operating theatre. They allow optimal irradiation of the tumour (dose in a single very high fraction) while preserving the surrounding healthy tissues to the maximum extent possible. This technique is used primarily as a complement to secondary external-beam radiotherapy for treating non-removable tumours (sarcomas, pancreas, etc.).

Hadron therapy is a treatment technique based on the use of beams of charged particles (hadrons comprising protons and carbon ions), which can deliver the dose in a highly localised manner during treatments, thereby drastically reducing the volume of healthy tissue irradiated. In France, only proton therapy is used for clinical purposes. According to its advocates, hadron therapy with carbon ions is more suited to the treatment of the most radiation-resistant tumours and could result in several hundred additional cancer cases being cured each year.

Adaptive radiotherapy is a radiotherapy technique that takes into account the movements and deformations of the organs and the tumour during the treatment. The treatment planning system recalculates the dose distribution before each delivery of the treatment fraction of the day, this new dose distribution is either accepted or not by the radiation oncologist. Two types of machine can deliver such adaptive treatments at present:

- Ethos®, which uses 3D imaging obtained by the imager integrated in the accelerator (CBCT) to recalculate the dose distribution;
- linear accelerators coupled to a MRI machine, referred to as “MRI-Linac”, which uses MRI imaging to recalculate the dose distribution. Thanks to MRI, it is also possible to associate real-time monitoring (gating) of the target volume during delivery of the treatment.

GRAPH 1 Breakdown, by ASN regional division, of the number of centres and external-beam radiotherapy accelerators inspected and the number of new licences or license renewals issued by ASN in 2024



Given this context, ASN wanted to encourage an initiative to assess this new technique. To this end, in late 2023 it initiated a study with the SFRO and the National Council of Radiation Oncologists (CNPO) to collect the data necessary for a large-scale assessment before the technique becomes widely adopted in France. A steering committee in which participate the HAS, the DGS, the General Directorate of the Healthcare Offering (DGOS), the National Cancer Institute (INCa), IRSN, the SFRO and the CNP, has been set up by ASN to conduct and follow-up this study in compliance with the rules of good assessment practice. All the centres with an adaptive radiotherapy machine expressed their interest in participating in the project, for which the assessment methodology was finalised at the end of 2024. The MRI-Linac and CBCT-Linac techniques are to be assessed separately, by assessing a tumoral location of interest for each technique: unresectable pancreatic cancers on the MRI-Linac machines and urothelial carcinomas (bladder cancer) on the CBCT-Linac machines.

2.1.2 Technical rules applicable to external-beam radiotherapy facilities

On account of the high dose rate and high energy of the beams when delivering the dose to the patient, the devices must be installed in rooms specially designed to guarantee radiation protection of the staff, turning them into veritable bunkers in which the wall thickness can vary from 1 to 2.5 metres of ordinary concrete.

A radiotherapy installation comprises a treatment room including a technical area containing the treatment device, a control station outside the room and, for some accelerators, auxiliary technical premises.

The protection of the premises, in particular the treatment room, must be determined in order to respect the annual exposure limits for the workers and/or the public around the premises. The current conditions of design of these rooms were reviewed in 2019. A specific study must be carried out for each installation by the machine supplier, together with the medical physicist and the Radiation Protection Advisor (RPA). This study defines the thicknesses and nature of the various protections required, which are determined according to the conditions of use of the device, the characteristics of the radiation beam and the use of the adjacent rooms, including those vertically above or below the treatment room. This study must be included in the file submitted to ASN to support the application for a license to use a radiotherapy installation.

In addition, a set of safety systems informs the operator of the machine operating status (exposure in progress or not) and switches off the beam in an emergency or if the door to the irradiation room is opened.

The bunker with shielding baffle remains the reference insofar as it reduces the shielding required at the ventilation duct and electrical duct inlets and provides greater security in the event of failure of the door motorisation system or if anyone gets accidentally locked inside. However, if the space available to the licensee is limited, which compromises the installation of the accelerator, a smaller shielding baffle, or even none at all, can be envisaged under certain restrictive conditions. Moreover, the arrival of self-shielded MDs such as the ZAP-X® platform could make it possible to consider having an installation with fewer architectural constraints (no bunker), and to meet the healthcare offering needs of certain regions more directly. In its opinion 2024-AV-0447 of

22 October 2024, ASN recommends that medical-economic studies be carried out to confirm the justification of this MD compared with the other existing devices used in France. Furthermore, the conditions of installation and use of this platform should enable the level of ionising radiation exposure of the personnel working on this platform and in adjacent rooms to be optimised. ASN considers that the ionising radiation exposure levels of these professionals should not be higher than those found at present when using medical particle accelerators installed in bunkers.

2.1.3 Radiation protection situation in external-beam radiotherapy

The installed base of external-beam radiotherapy facilities in 2024 comprises 577 particle accelerators installed in 171 radiotherapy centres subject to ASN licensing (see Graph 1).

More than 220,000 patients⁽⁶⁾ are treated each year, which represents 4.12 million radiation sessions (in 2023). The French Radiotherapy Observatory (INCa) lists 953 radiotherapists (headcount in 2023). ASN issued 112 licences in 2024, slightly fewer than in 2023 (121). ASN nevertheless notes the maintaining of a drive to modernise and enlarge the radiotherapy centres (relocation, increase in the number of bunkers, replacement of accelerators, etc.). Given the significant number of accelerators aged over 10 years (20 to 30% of the installed base in some regions), accelerator replacement requests could increase in the next few years.

Furthermore, the rise in the number of stereotactic treatments in radiotherapy departments across the country is continuing, with an increase in extra-cranial stereotactic indications (lung, liver, spine,

6. In 2021, 214,000 cancer patients were treated by radiotherapy with 4.3 million treatment sessions (source: INCa Observatory).

bones, ENT). This activity presents radiation protection risks and requires skills of a high standard and greater control of the doses delivered. It also takes up more medical and medical physics time and requires work organisation adaptations. Furthermore, the reform of care authorisations (*see point 1.3.3*) is likely to lead to changes in the porting of nuclear activity authorisations (for radiosurgery for example), and organisational changes. ASN is extremely attentive to the impact of these changes on radiation protection, and in particular to the adequacy of the planned resources for implementing treatments of this type.

The safety of radiotherapy treatments has been a priority area of ASN oversight since 2007 on account of the high doses delivered to the patient. Since 2019, the four-yearly inspection programmes have placed the emphasis on the ability of the centres to deploy a risk management approach. Skills management, the implementation of new techniques or practices and the mastery of the equipment are also examined in depth, depending on the centres.

ASN has continued its graded inspection approach:

- by reducing, in the light of the progress made in the control of treatment safety, the average frequency of inspections, which since 2020 has been reduced to once every four years (instead of the previous three-yearly frequency), enabling all the centres to be inspected every four years;
- by maintaining a higher frequency for the centres presenting vulnerabilities or risks, particularly for some centres having necessitated tightened inspections.

ASN conducted 66 inspections in 2024, representing 39% of the French centres. These 66 inspections include the routine inspections, commissioning inspections, inspections further to ESRs and unannounced inspections if any (one in 2024).

In 2024, ASN again observed difficulties in recruiting radiographers, medical physicists and radiation oncologists, irrespective of the region. This lack of personnel has impacts on the activity, the organisational set-ups and the working conditions of the medical staff (reduction in treatment slots, overstretched personnel, tensions in the teams, etc.). Holding interviews with the medical and paramedical teams and medical physicists during the inspections brings to light situations of tension and malfunctioning, which are sources of risks for the patients despite a highly formalised reference framework. Holding interviews with senior management enables these risk situations to be discussed with a view to helping the department identify technical, human and organisational lines for improvement.

These inspections focusing on Human and Organisational Factors (HOFs) are conducted regularly by ASN in the area of radiotherapy; they sometimes detect situations representing a risk for patient safety that would not be found during a conventional inspection.

2.1.3.1 Radiation protection of external-beam radiotherapy professionals

When the radiotherapy facilities are designed in accordance with the rules in force, the radiation protection risks for the medical staff are limited due to the protection provided by the facility.

The results of the inspections conducted in 2024 reveal no difficulties in this sector: Radiation Protection Experts (RPEs) have been effectively appointed in all the inspected centres; the technical radiation protection verifications have all been carried out at the required statutory frequency.

2.1.3.2 Radiation protection of external-beam radiotherapy patients

The assessment of the radiation protection of radiotherapy patients is based on the inspections focusing on implementation of the treatment QSMS, made compulsory by ASN resolution 2021-DC-0708 of 6 April 2021. Since 2016, in the course of its inspections ASN verifies the adequacy of the human resources, particularly in medical physics. Emphasis is also placed on the internal organisation methods to guarantee a culture of reporting significant event (or near miss), ensuring their follow-up and systematically analysing them when necessary.

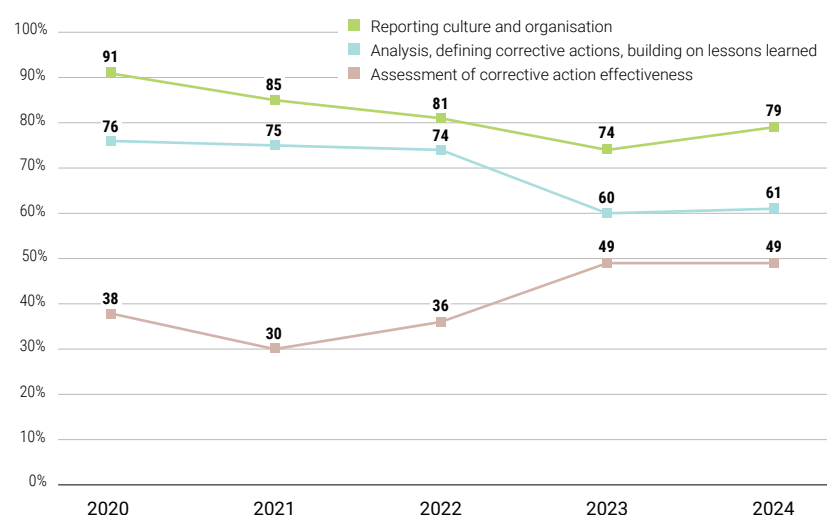
ASN notes that the requirements concerning the medical physics organisation and the presence of a medical physicist during the treatments are satisfied in all the centres, even if there may be personnel shortages from time to time.

The ASN inspectors observe that deployment of the authorisation process is continuing, still with disparities between the medical and paramedical personnel given that it is applied mostly for the paramedical staff.

Furthermore, the analysis of compliance with regulatory requirements concerning the management of events over the 2020-2024 period shows a constant proportion of departments complying with the regulations, with significant disparities depending on the requirements concerned (*see Graph 2*):

- The detection of adverse events, their reporting (internally or to ASN) and their recording are deemed satisfactory on the whole, with rates varying between 74% and 91% over the period in question, with better results observed in 2024 (79%) compared with 2023 (74%).
- The analysis of these adverse events, the defining of corrective actions and building on the lessons learned, after an initial phase of progress followed by stabilisation in 2021 and 2022 at around 75%, is dropping in 2023 and 2024 with about 60% of the inspected centres carrying out these steps satisfactorily.
- The improvement in practices resulting from Incident Learning Systems (ILS) and assessing the effectiveness of the corrective actions still represent the weak spot of these events analysis procedures, with the situation being deemed satisfactory in only 30% (2021) and 49% (2023 and 2024)

GRAPH 2 Change in the percentage of conformity of external-beam radiotherapy facilities in the management of events giving rise to corrective actions over the 2020-2024 period



ASN has analysed the significant radiation protection events involving laterality errors occurring in external-beam radiotherapy in 2023-2024 from the human and organisational factors aspect

The notification of several ESRs involving laterality errors in 2023-2024 led ASN to analyse them from the HOF aspect using the significant event reports transmitted by the centres. The results of this analysis were compared with the data in "Patient safety" bulletin No. 6 (May 2014) to understand how they are evolving.

The results of the analysis show firstly that six of the seven laterality errors that occurred in 2023-2024 were due to errors at the medical prescription stage (prescription errors, conflicting information in the associated documents), whereas in the 2010s, delineation errors^(*) were the main cause of laterality errors. The numerous checks implemented at the simulation, delineation and dosimetry stages did not detect the laterality error made at the medical prescription stage, in particular because the medical staff involved (radiographer, dosimetrist, medical physicist) use the documents containing the error (prescription and associated documents) to carry out their checks.

Laterality errors are explained in particular by four types of root causes, the first three of which concern the medical prescription stage: **missing elements** (target volume not visible due to the surgical procedure, patient's file incomplete, no team review of the file, disappearance of anatomical landmarks with the technological and surgical developments, etc.), elements leading to confusion (previous history of multiple left / right cancer, automatic contouring of both organs in paired organs, reworked area on the image, surgical staples, calcification or nodule on the contralateral organ, zoomed images, etc.), **potential laterality problems** (16% of adults have difficulty distinguishing right from left) and the deterioration of the work conditions for all the personnel (staff shortages, excessive workload, interruptions, etc. figure in the ESR reports transmitted by the centres).

In addition, the **level of severity of these ESRs is higher**. As the significant event reports lacked data on the doses received by the patients, two criteria were studied: the level of severity declared on the ASN-SFRO scale and the number

of sessions concerned by the laterality error. The seven ESRs studied in 2023-2024 were rated level 2 on the ASN-SFRO scale, whereas in the 2010s, the majority were rated level 1. The number of sessions targeting the "wrong side" is higher in the 2020s than in the 2010s. They can now concern the entire treatment due to late detection of the error (post-treatment follow-up consultation).

This analysis was presented to the SFRO in October 2024. The findings put forward by ASN during the presentation were confirmed and supplemented: making out the medical prescription is identified as a risk-prone stage. These ESRs occur essentially after a surgical procedure which has rendered the tumour undetectable and/or following several cancers affecting or having affected both sides. The prescription error can arise at earlier stages, such as during the multidisciplinary consultation meeting or when entering the laterality in the patient's file. The means of detecting a laterality error can be diminished when the tumour is no longer detectable, particularly in post-surgical situations (post-operative, surgical progress), in the case of a bilateral disease or when the irradiation technique no longer allows the treatment fields to be viewed on the skin (VMAT). The checks put in place to prevent laterality errors when performing the procedure are not appropriate to allow such prescription errors to be detected before performing the procedure. Beyond the actions proposed by the SFRO (check-list, questioning the patient about the laterality, meetings between interns and senior radiotherapist after the centring CT scan), ASN underlines the benefit of analysing the medical prescription activity in order to better understand it, and in particular the constraints encountered and the action levers to put in place to prevent similar events from occurring.

The Authority for Nuclear Safety and Radiation Protection (ASNR) will publish a "Treatment safety" sheet on the subject in the first quarter and will be associated with the WG set up by the SFRO on laterality and re-irradiation errors.

* Action of marking the contour of an organ on a medical image.

of the centres inspected. ASN nevertheless notes a boost in progress in 2024 with 49% of the centres deploying the procedures satisfactorily, compared with 36% in 2022 (see Graph 2). ASN also observes an increase in the participation of radiotherapists in these procedures in the inspected centres over the last two years. Furthermore, regular assessment of the corrective actions implemented and updating of the prospective risks analysis on the basis of the lessons learned from the events reported

internally, which is obligatory pursuant to the abovementioned ASN resolution 2021-DC-0708 of 6 April 2021, are vital in order to improve treatment quality and safety.

The ability of a centre to deploy a risk management procedure was again subject to specific investigations in 2024. These investigations reveal that:

- Although the requirements for quality and safety management in radiotherapy departments are satisfied in the majority

Inspection of a centre after two level-2 ESRs were notified in the space of one month

An inspection was organised following the occurrence of two level-2 ESRs in a short space of time in the same radiotherapy centre, notified to ASN on 25 March and 25 April 2024 respectively.

The first ESR concerned a laterality error (right-left reversal) that occurred during treatment preparation, when selecting the target organ at the delineation stage. The second ESR concerned an error resulting from failure to take into account the overlapping of treatment planes. It occurred during the treatment of a patient undergoing stereotactic treatment on three locations simultaneously.

These ESRs were rated level 2 on the ASN-SFRO scale. They occurred in a context of sustained activity with a very significant increase in use of the stereotactic technique spanning several months now, an ongoing change of accelerator and a shortage of radiographers. The impact of these situations or developments had not been sufficiently grasped in the prospective risk analysis.

The inspection moreover highlighted the deficiencies in the management of the treatment preparation process, with a large percentage of patient files being finalised on the very day the treatments started, and well as shortcomings in assessing the human resources required for the level of activity of the centre.

Lastly, the inspection revealed the need to analyse the events in greater depth, involving all the stakeholders in deciding on the corrective actions and assessing the robustness of the safety barriers put in place.

of cases, there are still disparities between centres. Nearly two-thirds of the departments have updated their prospective risks analyses (63%). The situations considered to be unsatisfactory concern the departments whose prospective risk analyses have not taken into account the lessons learned from internal or external events (those from other centres for example, disseminated by the ASN publications such as the "Patient safety" bulletins and "Learning from experience" sheets, the deployment of new practices or organisational changes when the technical platforms evolve. The impact of an organisational or technical change on the operators' activity is effectively not always analysed, yet these changes are potential sources of disruption, particularly in the organisation of treatments and work practices and can weaken the existing lines of defence.

• The risk management approach is coordinated satisfactorily in 59% of the centres inspected. These are the centres in which management is involved in the approach and has defined a policy with shared, assessable and assessed operational objectives, has allocated the necessary resources, in particular to the operational quality manager and communicated on the results of this policy. Conversely, these procedures stand still or regress when senior management does not sustainably grant sufficient means to the operational quality manager or when s/he does not have sufficient authority to deploy them.

The procedures to formalise the change management process are being increasingly deployed. They are deemed satisfactory in slightly over half the centres (53%) inspected in 2024, whereas over the 2021-2023 period they were satisfactory in 40% of the centres. To help them to better adopt material and/or technical changes, IRSN has published, in partnership with the radiotherapy professionals and at the request of ASN, a *Guide to the adoption of a material or physical change in radiotherapy*.

In a persistent context of medical staff shortages, organisational changes due to the reform of the healthcare licences or healthcare facility buy-out operations, ASN continues to urge the decision makers, RNAs and medical professionals to be vigilant regarding the need to assess the impact of these changes insofar as these projects demand significant investment on the part of the personnel, adding to their existing workload.

2.1.3.3 Significant events in external-beam radiotherapy

In 2024, 95 ESRs were notified in radiotherapy. The majority of the events concern patient radiation protection, with 79 ESRs notified under criterion 2.1 (exposure of patients for therapeutic purposes). Most of the events have no expected clinical consequences.

Among these events, 45 were rated level 1 on the ASN-SFRO scale, i.e. 57% of the total, and five were rated level 2. One ESR was rated level 4.

The level-2 ESRs concern:

- three cases of laterality errors (*see box previous page*), all three concerning treatment of a breast cancer; in one case, the entire treatment was delivered to the wrong side in 20 sessions; in the other two cases, the treatment was delivered to the wrong side for 8 of the 25 planned sessions and 6 of the 15 planned sessions respectively;
- a dose protraction / fractionation error in a treatment of a cancer of the right breast using the Vmat technique that induced a 20% excess dose to the target volume;
- an error linked to the failure to take into account the overlapping of treatment plans, which occurred in the treatment of a patient undergoing stereotactic treatment on three locations simultaneously.

Two of the above-mentioned ESRs were notified by the same centre in the space of one month and triggered an ASN inspection (*see boxes previous page and below*). The ESR of level 4 on the ASN-SFRO scale occurred in 2023 but was notified in 2024.

It resulted from the failure to take into account, in the medical prescription, a previous treatment delivered in 2013 to the same anatomical area and which led to over-irradiation of the pelvic region and exceeding of the dose constraint to the rectum (*see box below*).

In addition, two ESRs rated level 1 on the ASN-SFRO scale concern cohorts of patients and are linked to:

- a contouring error concerning 127 patients: absence of contouring at the junction between the spinal cord and the cerebral trunk over several anatomical sections;
- a positioning error that concerned 6 patients following the non-functioning of automatic KV repositioning of the table on three accelerators.

As in the preceding years, these events highlight organisational weaknesses concerning:

- the keeping of the patients' medical files, which provide an overall picture and give access to the required information at the right time; the earlier the error is committed in the treatment process (e.g. wrong side), particularly in the initial consultation and prescription elaboration phase, the less the laterality information is called into question in the subsequent stages of the patient care pathway; it is therefore essential to test the barriers in place at these stages of the process;
- validation steps in which the parameters to verify are not sufficiently explicit (what check? At what stage of the process? By which operator?);
- the management of the patients' medical file movements which, if it is not optimised, creates constraints on the work

Significant radiation protection event rated level 4 on the ASN-SFRO scale



ASN was informed on 20 June 2024 of an ESR that occurred during external-beam radiotherapy treatment of a patient with a relapse of a cancer of the pelvic region.

The treatment, which was delivered in summer 2023, did not take into account a previous treatment of the same anatomical region by external-beam radiotherapy in 2013. A complete treatment (i.e. 38 sessions of 2 grays – Gy) was thus delivered in 2023, leading to over-irradiation of the organs at risk given the radiotherapy treatment of 2013. Several months after the end of the treatment, major lesions necessitating surgical treatment appeared, revealing the over-irradiation.

This ESR was rated level 4 on the ASN-SFRO scale in view of the appearance of serious late effects in the patient with a major deterioration in quality of life.

An incident notification was published on the ASN website on 12 July 2024. ASN pointed out that these re-irradiation situations represent high risks, particularly when the treated areas are identical or

adjacent to those treated previously. In effect, if each treatment is subject to planning with the aim of preserving the healthy tissues around the tumour, said to be "at risk", by limiting their irradiation as much as possible, the accumulation of several treatments on a given zone can lead to significant irradiation of these organs at risk. Consequently, the radiotherapy treatment prescription and planning must take account of any previous treatments and the cumulative effect of the irradiations in order not to deliver excessive cumulative doses to the organs at risk.

ASN has drawn the attention of the medical professionals and all the radiotherapy centres to this growing problem and the need to put safety barriers in place and to assess them regularly. These particular risks led ASN to devote a "Patient safety" bulletin to prior radiotherapy treatments in June 2020. This bulletin underlines the significant clinical risks associated with the treatment of patients who have received several radiotherapy treatments in the course of their life and identifies areas for improvement.

An inspection conducted by ASN on 23 August 2024 gave a better understanding of the occurrence context of this ESR, notably through consultation of the information recorded in the patient's medical file (follow-up consultation report, nuclear medicine report, date of validation, etc.) and of the quality unit's analysis.

The established action plan was examined and considered on the whole appropriate to counter the observed deficiencies. The inspectors observe that the delivery of an external-beam radiotherapy treatment without a formal decision in a multidisciplinary consultation meeting (obligatory under Article R. 6123-91-1 of the Public Health Code) and the absence of any record of follow-up consultations during the two months of the treatment (obligatory under Article R. 6123-93 of the Public Health Code) constitute major nonconformities in the medical organisation of the centre.

Furthermore, the event was not notified until 20 June 2024 which is considered too late, given that the medical reports of December 2023 mention radiation-induced symptoms.

activity of the medical staff, fostering the weakening of certain control barriers.

Furthermore, the increase in complex treatments with several locations to treat and situations of prior radiotherapy history should lead the centres to question the robustness of the safety barriers for these situations.

Moreover, the WG on lessons learned by radiotherapy professionals led by ASN has worked on the development of new sheets entitled "treatment safety". The first two sheets detailing good practices to apply to avoid ESRs relating to identity monitoring and laterality errors shall be published in the first quarter of 2025.

The number of ESRs in radiotherapy has been dropping continually and significantly since 2015 (see point 2.7, Graph 14 page 242), and by about 13% since 2021. If this drop can be attributed in part to a better control of the risks (application of strict quality assurance procedures, complete dematerialisation with lists of "record and verify" tasks, harmonisation of medical protocols, contour delineation

assistance software, automatic application of dosimetry shifts, monitoring of preparation times, etc.), the ASN inspectors observe, as in 2023, a reduction in the number of adverse events registered and analysed internally and fewer meetings of the experience feedback committees. The root causes of these events are still not sufficiently investigated and the lessons learned from the events notified at national level are poorly integrated.

Lastly, in 2024, following a national seminar organised in 2023 entitled "Quality-safety approach in radiotherapy: what lessons have been learned after more than 15 years?", ASN conducted a reflection on ways of developing its oversight. This reflection led it to hear all the stakeholders (professional organisations, health authorities) and other oversight authorities and to draw the lessons from a seminar on radiotherapy inspection practices organised by Heads of the European Radiological Protection Competent Authorities (HERCA). The new inspection guidelines of ASNR will be communicated to all the radiotherapy actors in early 2025.

SUMMARY

In radiotherapy, the inspections carried out by ASN over the period 2021-2024 and covering all the installed base, confirm that the safety fundamentals are in place: organisation of medical physics, equipment verifications, training in patient radiation protection and deployment of quality assurance procedures.

ASN also underlines the progress in the area of clinical reviews with the setting up of experiments which will continue in 2025 before going into widespread application, and encourages the rapid extension of these reviews to radiosurgery. It also encourages the departments using new practices to assess them by putting in place procedures similar to the one developed on ASN's initiative for adaptive radiotherapy.

The analysis of the 2021-2024 period also confirms that the departments are struggling to maintain learning from experience procedures, with fewer meetings of experience feedback committees, insufficiently detailed ESR analyses and persistent difficulties in assessing the robustness of corrective actions. Although the continuing significant drop since 2015 in the number of ESRs notified to ASN can presumably be attributed in part to greater treatment safety, it also results from the departments' difficulty in maintaining collective momentum. In addition, the prospective risk analyses are still insufficiently updated prior to organisational or technical changes or after analysing the lessons learned from events.

The occurrence of events such as laterality and positioning errors, delineation of organs at risk and/or target organs still reveals organisational weaknesses and the need to regularly assess practices. Events resulting from failure to take earlier treatments into account remain an inspection priority for ASN, given their potential seriousness and the increase in the number of re-irradiations.

ASN remains particularly attentive to the deployment of new techniques and practices in radiotherapy. After having encouraged the assessment of adaptive radiotherapy, ASN will continue its work in cooperation with the various institutional actors in the health sector, the professional organisations and assisted by its groups of experts, particularly Canpri, notably concerning flash radiotherapy.

Lastly, in 2024, in a context of increasing complexity, fewer resources, extensive innovation and organisational changes, ASN defined the directions of its next four-yearly inspection programme in collaboration with the stakeholders and drawing the lessons from the inspection practices of its counterparts and other authorities in charge of activities involving risks. ASNR will communicate them to all the RNAs in early 2025.

2.2 Brachytherapy

Brachytherapy can be used to treat certain pathologies and cancerous tumours in particular either specifically or as a complement to another treatment technique.

This technique consists in placing radionuclide sources, in the form of sealed sources, either in contact with or inside the solid tumours to be treated. The main radionuclides used in brachytherapy are iridium-192 and iodine-125.

Brachytherapy uses three techniques (detailed below), which differ more specifically in the dose rate applied according to the indications.

As with radiotherapy, the radiation protection issues are linked to the intensity of the dose delivered to the patient and, if applicable, the high dose rates and the mastery of the equipment. Furthermore, as high-activity sources are involved, the management of emergency situations in the event of source jamming, as illustrated by the feedback from events notified to ASN, and the security of the sources, constitute specific risks of brachytherapy. That is why the ASN checks focus on the management of source security in addition to those on external-beam radiotherapy.

2.2.1 Description of the techniques

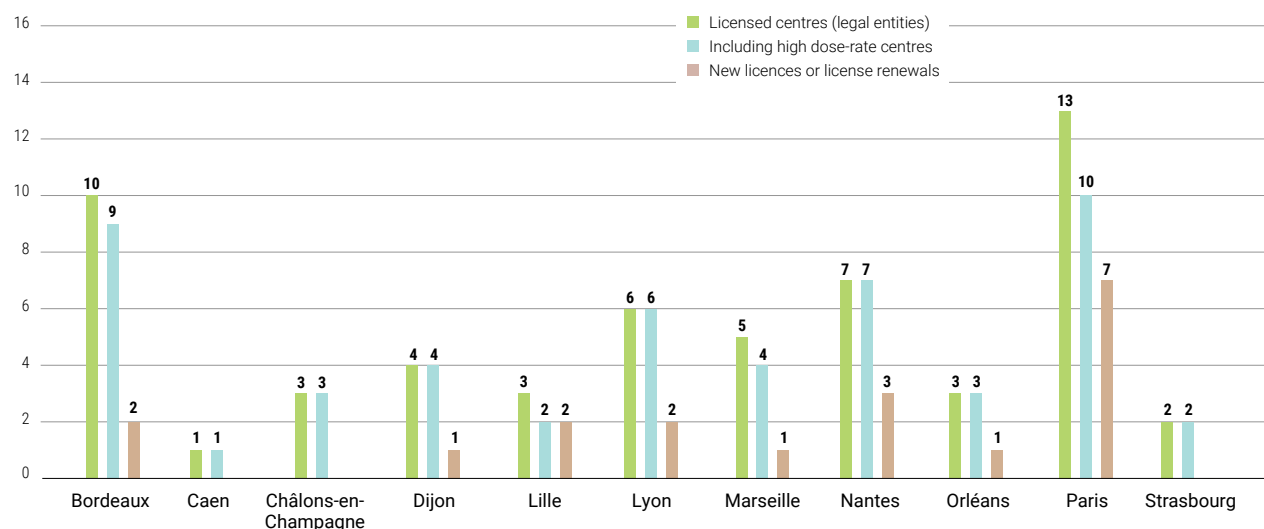
The radiation protection risks in brachytherapy, apart from the problem of managing sealed sources, depend on the dose rate associated with the technique, the method of delivering the radiation to the tumour (permanent or temporary implantation, or temporary application).

The use where necessary of source afterloaders means that the medical personnel do not have to handle the sources and allows the patient to be treated without irradiating the personnel. On the other hand, it is necessary to make provisions for accident situations associated with malfunctioning of the source afterloader and the high dose-rate delivered by the sources used.

Low Dose-Rate (LDR) brachytherapy is carried out at present using sealed sources of iodine-125 in the form of permanently implanted seeds, or caesium-137 applied temporarily. The dose rates are between 0.4 and 2 grays per hour (Gy/h).

A new medical technique called "DaRT" (Diffusing alpha emitters Radiation Therapy) is currently being tested in a clinical investigation into the treatment of skin cancers. This technique consists in implanting sealed radium-224 sources which emit alpha particles in the tumour using an afterloader; the sources are left in the tumour for 15 to 20 days.

GRAPH 3 Breakdown, by ASN regional division, of the number of brachytherapy centres, of high dose-rate brachytherapy centres and the number of new licenses or license renewals in 2024



Pulsed Dose-Rate (PDR) brachytherapy delivers dose rates of between 2 and 12 Gy/h and uses sources of iridium-192 with a maximum activity of 18.5 Giga-becquerels (GBq), which are applied with a specific source afterloader. It is based on the use of a single radioactive source which moves in steps, and stops in predetermined positions for predetermined times. The doses are delivered in sequences of 5 to 20 minutes, sometimes even 50 minutes, every hour for the entire duration of the treatment, hence the name pulsed dose-rate brachytherapy.

High Dose-Rate (HDR) is carried out using high-activity (about 370 and 91 GBq respectively) sealed sources of iridium-192 or cobalt-60. The dose rates are higher than 12 Gy/h. Positioning is done using an afterloader containing the source. The treatments are delivered on an out-patient basis, in one or more sessions of a few minutes, spread over several days if necessary.

2.2.2 Technical rules applicable to brachytherapy facilities

The rules for radioactive source management in brachytherapy are comparable to those defined for all sealed sources, regardless of their use (see point 1.3.1).

In cases where permanent implant techniques are used (LDR), the applications are carried out in the operating theatre with ultrasonography monitoring, and do not require hospitalisation in a room with radiation protection. The PDR technique, which uses source afterloaders (usually 18.5 GBq of iridium-192), necessitates hospitalisation of the patient for several days in a room with radiological protection appropriate for the maximum activity of the radioactive source used. Lastly, with the HDR sources, as the maximum activity used in the source afterloaders is

high (370 GBq of iridium-192 or 91 GBq of cobalt-60), the irradiations can only be carried out in a room with a configuration comparable to that of an external-beam radiotherapy room in terms of collective protection because of the high dose level used.

The Order of 29 November 2019 sets the obligations concerning the protection of ionising radiation sources and batches of radioactive sources of categories A, B, C and D against malicious acts. The requirements concerning the protection barriers and their resistance time for category A, B and C sources are enforceable since 1 July 2022 (see chapter 8, point 2.3.2).

As some centres could not enlarge their premises or build new bunkers, ASN licensed two centres with “mixed-purpose” bunkers for joint external-beam radiotherapy and HDR brachytherapy practices on the basis of an expert assessment by IRSN concerning the design rules for premises housing both medical linear electron accelerators and HDR source projectors. The regulatory provisions to protect high-activity sources against malicious acts have been taken into account.

ASN was particularly attentive to the analysis of the licensee’s provisions regarding the following main points:

- organisation of the alternations between the different treatments and the quality control time slots (number of patients treated, organisation of the schedules, time slots for MD quality controls, time slots for treatments, etc.);
- patient positioning that facilitates their evacuation in case of emergency;
- specific safety systems preventing the simultaneous operation of two devices;
- separate and clearly identified indicator lights and emergency stop controls for the two systems;

- double zoning plan displayed at the entrance;
- procedure if personnel get shut inside, for both devices.

2.2.3 Radiation protection situation in brachytherapy

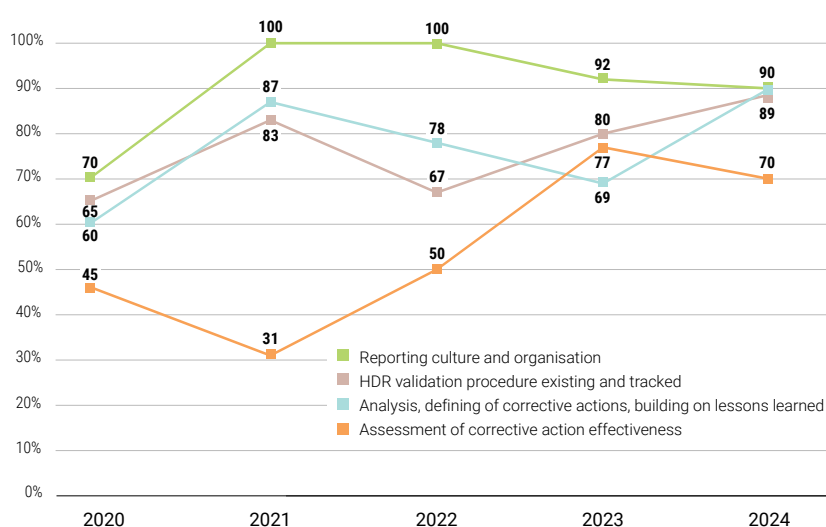
ASN has licensed 57 brachytherapy centres, 51 of which use the HDR technique. Nineteen licences were issued in 2024 (see Graph 3). The brachytherapy activity is stable, with HDR brachytherapy still representing the majority of treatments. ASN observes that some brachytherapy centres have difficulties in maintaining certain activities due to a lack of medical staff trained in brachytherapy techniques, even if they wish to maintain these activities in order to offer the patients the most appropriate treatments for their pathology.

The INCa Observatory records 600 to 700 LDR treatments, 700 to 750 PDR treatments for gynaecological cancers and between 4,500 and 5,000 HDR treatments.

In the same way as for external-beam radiotherapy, the safety of brachytherapy treatments has been a priority area of ASN oversight since 2007, because of the intensity of the doses delivered and, where applicable, the high dose rates. As brachytherapy is carried out within the radiotherapy departments, the inspection programme for the 2021-2024 period is identical to that for external-beam radiotherapy, with a four-yearly frequency and checks similar to those applied in external-beam radiotherapy (see point 2.1.3.2).

On account of the use of high activity sources, specific checks focus on medical staff training, such as knowledge of the action to take in the event of an emergency (source jamming), and the security of these sources (organisation in place for

GRAPH 4 Change in the percentage of conformity of brachytherapy facilities in the management of events giving rise to corrective actions over the 2020-2024 period



source management, appropriate measures to prevent unauthorised access to the sources, source inventory, protection against malicious acts and management of sensitive information).

In 2024, 16 inspections were carried out on the theme of radiation protection, representing 28% of the licensed departments.

2.2.3.1 Management of sources

The organisational set-ups enable the category of each source or batch of sources to be identified in 80% of the centres inspected, a level similar to that of industry and the findings of the previous years. This is the indicator that obtains the highest score of conformity and the number of sites that have not yet classified their sources is very small.

The nominative authorisations delivered by the RNA to allow access to the sources, their carriage, or access to the information relating to the means or measures that protect them raise no comments in slightly less than half the situations. This result is also comparable with the industrial sector, even though it would in principle seem more difficult to comply on this point given the number of persons concerned and the nature of the medical facilities whose function is to receive the public. No critical situation (absence of license) was found in the medical sector.

Half the inspections in 2024 concluded that the policy for protection against malicious acts was satisfactory, as were the measures implemented for the identification and control of sensitive information. This is a great improvement compared with the last three years.

A substantial improvement is required in the identification of the barriers to protect, for which the indicator remains mediocre: in 2024, one inspected facility in four had correctly defined its barriers; the figure in 2023 was one in five.

One third of the facilities inspected in 2024 has a maintenance plan for the technical protection systems that is correctly applied. Here too an improvement is necessary, as shortcomings had already been found in this respect in the preceding years.

The results are detailed in chapter 8.

ASN notes that progressive deployment of the new requirements relative to protecting access to high-activity sources is continuing. This situation is gradually improving but cannot yet be considered compliant.

2.2.3.2 Emergency situations and management of malfunctions

The malfunctions of brachytherapy devices which can result in jams or incorrect positioning of the source can lead to overexposure of staff or patients, sometimes with serious consequences (radiation necrosis). Consequently, this type of event underlines the need to comply with the technical requirements concerning the use of these devices, and the obligations to provide training in emergency situation management and to conduct exercises.

2.2.3.3 Radiation protection of medical professionals

The occupational radiation protection measures deployed in 2024 by the brachytherapy departments were considered satisfactory in three quarters of the departments compared with just half in 2023. Of the 16 centres possessing high-activity sources inspected in 2024, 80% have put in place enhanced training in emergency situations and have organised situational exercises, particularly for managing situations linked to source jamming whereas only 46% had done so in 2023. ASN thus finds that the situation is better in 2024, but reiterates the importance of providing radiation protection training for the professionals when high-activity sources are possessed in order to be capable of managing jammed source situations.

2.2.3.4 Radiation protection of patients

As with external-beam radiotherapy, the radiation protection of brachytherapy patients is assessed from the inspections concerning the implementation of the treatment QSMS and the medical physics organisation.

ASN notes that the requirements concerning the medical physics organisation and the presence of a medical physicist during the treatments are satisfied in all the inspected centres.

2.2.3.5 The treatment quality and safety management system

The qualitative result of the inspections carried out in 2024 has shown that the majority of brachytherapy departments inspected have deployed a QSMS, with the support of the external-beam radiotherapy departments (see Graph 4).

A review of the inspections carried out over the 2021-2024 period and covering all the departments reveals the following trends:

- The notification culture and the organisation for managing the reports are considered satisfactory for all the departments inspected in recent years, with ratings of 100% in 2021 and 2022, 92% in 2023 and 90% in 2024.
- The analysis, defining of corrective actions and building on lessons learned are considered satisfactory in more than two-thirds of the departments, with a better situation in 2024 (90%).
- The assessment of corrective action effectiveness has been progressing since 2021. Thus, while only a third of the departments assessed the effectiveness of corrective actions in 2021, 70% of the inspected centres did so in 2024.
- Ninety percent (90%) of the departments inspected in 2024 have a validation procedure for HDR treatments, whereas the figures for the 2021-2024 period ranged from two thirds to 89%.
- The authorisation process is being deployed, but there are still disparities between the medical and paramedical personnel, given that it is applied mostly for the paramedical staff.

Maintenance and quality controls – The majority of the centres have an inventory of the MDs and a register for recording maintenance operations and quality controls. In the absence of regulatory baseline requirements for the quality controls of brachytherapy devices, the quality controls implemented are based on the recommendations of the manufacturers or professional organisations. Guide of the European Society for Radiation Oncology (ESTRO) – Booklet No. 81 and Guide No. 36 of the French Society of Medical Physics (SFPM).

Maintenance of the afterloaders (for HDR and PDR applications) – This is ensured by the manufacturers, particularly when replacing sources. The brachytherapy departments rely on these verifications to guarantee correct operation of the devices. The source activity is verified at each delivery, and verifications are also carried out on source removal.

ASN notes that the verifications performed by the departments can sometimes prove insufficient when a new device is received, and draws attention to the need to clearly define these verifications taking into account the manufacturer's requirements, particularly for HDR brachytherapy. As the doses delivered at each brachytherapy session are about 4 to 10 Gy, errors in treatment delivery can have serious consequences for the health of the patient.

2.2.3.6 Significant events notified in brachytherapy

In 2024, 11 ESRs were notified in brachytherapy, 8 of which were under criterion 2.1 (exposure of patients for therapeutic purposes). Six are rated level 1 and two rated level 0 on the ASN-SFRO scale.

One ESR in brachytherapy notified by several healthcare centres in 2023 and early 2024, rated level 1 on the ASN-SFRO scale, concerned a cohort of patients in three different centres. The event was notified after the manufacturer informed the centres of a value rounding error in the software causing inaccuracy in the space between the computed tomography sections imported for the dosimetric planning of treatments. This event also led to a medical device vigilance notification to the ANSM. This inaccuracy

could have resulted in a dose error of about 5 to 10% on each brachytherapy treatment fraction in certain conditions of use. The manufacturer proposed corrective measures involving the software parameter settings. In one of the centres which made its report in 2024, 136 patients were concerned, *i.e.* nearly half the cases in the cohort, and all the medical files were verified in order to calculate the errors in dose delivered to the target volumes, which were less than 5%. This centre decided to change the HDR afterloader.

One event concerned the loss of a container of iodine-125 seeds. After treating a prostate cancer patient by brachytherapy in the operating theatre, one of two unused containers of iodine seeds could not be found. This treatment consists in placing radioactive seeds of iodine-125 in the patient's prostate gland to irradiate the zone of the tumour. The iodine-125 seeds ordered for an intervention are not always implanted in their totality. The iodine-125 seeds not used are recovered to be returned to the supplier in a lead-lined steel container. At the end of the intervention of 1 October 2024, the box holding a container of a cartridge of 15 iodine-125 seeds that were not used for the treatment was disposed of *via* the domestic waste channel. This ESR illustrates the importance of having full knowledge of the management and traceability procedures for unused sources. Considering the failure of the monitoring provisions that resulted in the loss of this radioactive source, ASN rated the event level 1 on the INES scale (International Nuclear and Radiological Event Scale, graded from 0 to 7 in increasing order of severity).

Furthermore, the reform of healthcare licences (*see point 1.3.3*) has introduced two licensing "levels" for nuclear medicine (levels A and B) in application of Decree 2021-1930 concerning the conditions of installation of nuclear medicine departments. Level A concerns the diagnostic or therapeutic activities other than the treatment of cancerous pathologies, carried out by administering RPDs that are ready to use or are prepared using an aseptic process in a closed system. Level B is attributed when the activity includes, in addition to the procedures covered by level A, the following procedures:

- procedures with the administration of an RPD prepared using an aseptic process in an open environment;
- diagnostic procedures carried out for explorations of cellular marking (labelling) of the formed elements of the blood by one or more radionuclides;
- therapeutic procedures carried by the administration of active implantable MDs;
- therapeutic procedures for cancerous pathologies performed by administering RPDs.

The healthcare activity licence for nuclear medicine is now granted by geographical site on condition that the provisions concerning the number of Single Photon Emission Computed Tomography (SPECT) and PET devices are observed (*see point 2.3.1*). The facilities will have to regularise their situation and submit applications to install new devices in already authorised sites or for the creation of new sites with the ARS. The licenses to possess and use a radioactive source or a device emitting ionising radiation issued by ASN shall be updated according to the nature of these changes (change of holder, site, device, sharing of devices, etc.).

Nuclear medicine is included in ASN's inspection priorities. The main radiation protection risks are linked to the use of unsealed sources, which generate radioactive waste and effluents and can lead to contaminations. Nuclear medicine is moreover the main contributor to doses at the extremities of professionals in the nuclear sector (*see point 1.2.1*). During inspections, particular attention is focused on management of the sources, waste and effluents, occupational radiation protection, control of drug dispensing, through quality assurance obligations and the experience feedback process.

2.3.1 Description of the techniques

In vivo diagnostic nuclear medicine allows the production of functional imaging which is complementary to the purely morphological imaging obtained by the other imaging techniques. This technique consists in examining a function of the organism by administering a specific

SUMMARY

In brachytherapy, the inspections carried out in 2024 in nearly a quarter of the departments, considered alongside those carried out over the 2021-2024 period, enabling all the departments to be covered, confirm that the radiation protection rules are properly applied. ASN observes in 2024 that the gradual deployment of the new requirements relative to the protection of high-activity sources against malicious acts is continuing, particularly as regards putting in place a protection policy, measures for preventing unauthorised access to these sources and the identification and control of sensitive information. This situation is gradually improving but cannot yet be considered compliant. Some centres are still faced with difficulties when bringing into compliance necessitates major works. Moreover, ASN observes that the procedures for learning lessons from malfunctions are progressing and draws the departments' attention to the need to have full knowledge of the management and traceability procedures for surplus iodine-125 seeds not used in prostate gland brachytherapy treatments.

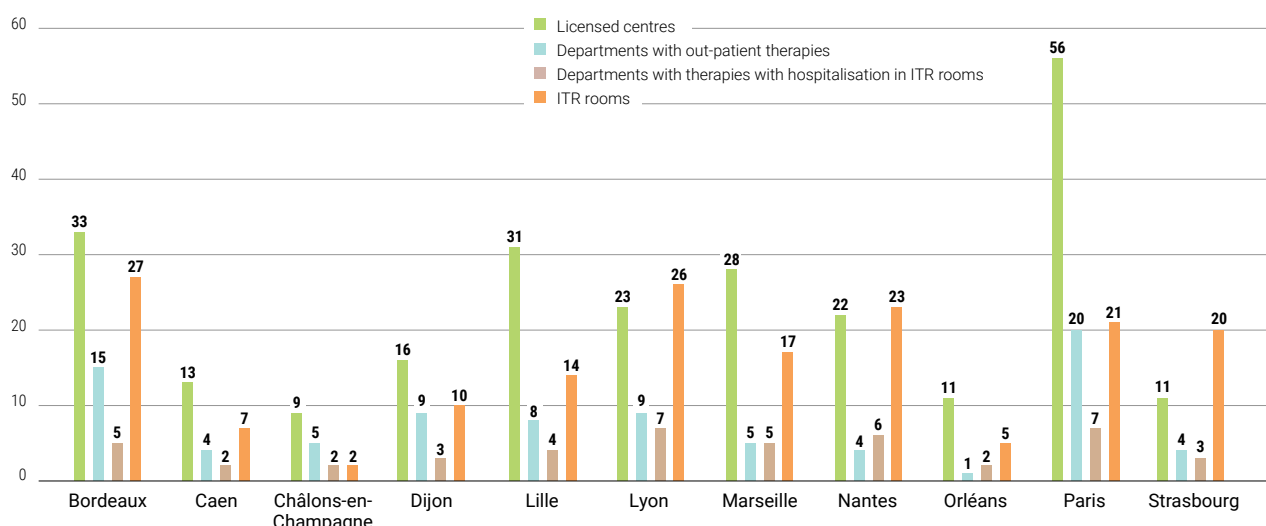
Lastly, maintaining a brachytherapy activity still represents a challenge for the years to come given the resources and skill that will be required.

Thanks to the increase in new radionuclides and vectors, nuclear medicine has developed strongly over the last few years, for diagnostic and therapeutic purposes alike.

2.3 Nuclear medicine

Nuclear medicine is a medical discipline that uses radionuclides in unsealed sources for diagnostic purposes (functional imaging *in vivo* or medical biology *in vitro*) or therapeutic purposes (ITR).

GRAPH 5 Overview of the national nuclear medicine base in 2024



radioactive substance – an RPD – to the patient. The choice of RPD depends on the studied organ or function. The RPD conventionally consists of a radionuclide which can be used alone (in this case the radionuclide constitutes the RPD) or be attached to a vector (molecule, hormone, antibody, etc.). In the latter case, it is the specific attachment of the vector that determines the studied function. Table 3 presents some of the principal radionuclides used in various explorations.

It is by detecting the ionising radiation emitted from the radionuclide by using a specific detector that the RPD can be located in the organism and images of the functioning of the explored tissues or organs can be obtained. The majority of detection devices allow tomographic acquisitions and cross-sectional imaging and a three-dimensional reconstruction of the organs. Depending on the type of radionuclide used, the term SPECT, still called “gamma-camera”, is used for radionuclides emitting gamma radiation and PET for radionuclides emitting positons.

In order to make it easier to merge functional and morphological images, hybrid appliances have been developed. They combine PET cameras or gamma cameras

with a CT scanner (PET-CT or SPECT-CT). A PET camera can also be coupled with an MRI scanner, but this is rarer.

In vitro diagnostic nuclear medicine is a medical biology technique used to assay certain compounds contained in the biological fluids sampled beforehand from the patient (e.g. hormones, tumoral markers, etc.); it is used frequently because it has the highest detection sensitivity of the techniques using ionising radiation. This technique uses assaying methods based on immunological reactions (reactions between antigens and antibodies labelled with iodine-125), hence the name Radio Immunology Assay or radioimmunoassay – RIA). However, the number of *in vitro* diagnostic laboratories is decreasing due to the use of techniques offering greater detection sensitivity, such as immunoenzymology or chemiluminescence.

Nuclear medicine for therapeutic purposes, or ITR, uses the administration of the RPDs to deliver a high dose of ionising radiation to a target organ for curative or palliative purposes. Two areas of therapeutic application of nuclear medicine can be identified: oncology and non-oncological diseases.

Human Subject Research (HSR) in nuclear medicine has been particularly dynamic in recent years, primarily in the field of oncology therapy with the emergence of new vectors and radionuclides. This research is leading to the gradual introduction of new treatments which are intended to be proposed to a growing number of patients in the coming years, raising radiation protection issues which are currently being examined by ASN.

ITR treatments can be administered either by mouth (e.g. capsule of iodine-131) or by systemic route (intravenous injection or via a catheter).

Some treatments – depending on the administered activity or the nature of the radionuclide used – require patients to be hospitalised for several days in specially fitted-out rooms in the nuclear medicine department to ensure the radiation protection of the personnel, of people visiting the patients and of the environment. The radiological protection of these rooms is adapted to the nature of the radiation emitted by the radionuclides, and the contaminated urine of the patients is collected in tanks. When treatments are administered on an out-patient basis or in hospital rooms external to the nuclear medicine department, a circuit must also be provided to channel the patients’ urine to decay tanks, knowing that ASN’s circular letter of 12 June 2020 provides for, in the case of treatments based on lutetium-177, provisional derogation measures to give departments without these tanks time to install them. Out-patient treatment also implies, in certain cases, decay management of the waste produced by the patients in their home prior to disposal via the household waste route.

Forty-five (45) nuclear medicine departments have a combined total of 170 ITR rooms for therapeutic purposes (see Graph 5).

TABLE 3 Main radionuclides used in diverse *in vivo* nuclear medicine explorations

Type of examination	Radionuclides used
Thyroid metabolism	Iodine-123, technetium-99m
Myocardial perfusion	Rubidium-82, technetium-99m, thallium-201
Lung perfusion	Technetium-99m
Lung ventilation	Krypton-81m, technetium-99m
Osteoarticular process	Fluor-18, technetium-99m
Renal exploration	Technetium-99m
Oncology – search for metastases	Fluor-18, gallium-68, technetium-99m
Neurology	Fluor-18, technetium-99m

Medical dispensaries

On account of the ongoing reform of healthcare authorisations (*see point 2.3*), the authorisation for level A holders requires that a radiopharmacist be attached to the medical dispensary if the nuclear medicine department is located in a site that has a dispensary. For the holders of level B, the radiopharmacist duties are ensured and organised within the medical dispensary of the site and the RPD preparation room within the nuclear medicine department, called the “nuclear pharmacy”, forms part of the medical dispensary. In 2020, there were 105 nuclear pharmacies in the nuclear medicine departments in public healthcare institutions and non-profit private healthcare institutions, such as the cancer centres. The radiopharmacist is primarily responsible for managing the RPD circuit (procurement, possession, preparation, control, dispensing and traceability) and the quality of preparation. The ANSM published a guide to *Good preparation practices* on 20 September 2023, replacing the guide dating from 2007.

The equipment

In addition to the cameras installed in the nuclear medicine departments, radiation-proof enclosures are installed in the departments to permit safe handling of unsealed sources.

Automated or semi-automated devices are also used in the preparation and injection of RPDs labelled with fluorine-18 and gallium-68.

2.3.2 Technical rules applicable to nuclear medicine facilities

The radiation protection constraints specific to nuclear medicine are linked to the use of radionuclides in unsealed sources. The departments are designed and organised for the reception, storage and handling of these unsealed radioactive sources with a view to their administration to patients or in the laboratory (in the case of radioimmunology). Provision is also made for the collection, storage and disposal of radioactive wastes and effluents produced in the facility, particularly the radionuclides contained in patients' urine.

Compliance with the technical design, operating and maintenance rules of nuclear medicine departments

Nuclear medicine departments must satisfy the rules prescribed by ASN resolution 2014-DC-0463 of 23 October 2014 relative to the minimum technical rules of design, operation and maintenance to be satisfied by *in vivo* nuclear medicine facilities.

This resolution details in particular the rules for the ventilation of nuclear medicine department premises and the rooms accommodating patients receiving, for example, treatment for thyroid cancer with iodine-131. Guide No. 32 detailing certain aspects of this resolution was published by ASN in May 2017 and was updated in February 2020.

In addition, facilities equipped with a CT scanner coupled with a gamma-camera or a PET camera must comply with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017 laying down the minimum technical design rules to be satisfied by premises in which electrical devices emitting X-rays are used.

Management of waste and effluents from nuclear medicine departments

The management of waste and effluents potentially contaminated by radionuclides must be described in a management plan which includes, more specifically, the conditions of monitoring of discharged effluents in accordance with Article R. 1333-16 of the Public Health Code and ASN resolution 2008-DC-0095 of 29 January 2008. Premises must be dedicated to these activities, as must specific equipment for monitoring the conditions of effluent discharges (tank filling levels, leakage alarm systems, etc.). The compliance of the facilities for collecting the effluents and wastes produced by nuclear medicine departments must be verified regularly. Revision of this resolution began at the end of 2020 and will also lead to an update of ASN Technical Guide No. 18 of 26 January 2012.

One of the 15 recommendations of the Working Group report “Discharging of effluents containing radionuclides from nuclear medicine units and research laboratories into the sewage network” published in June 2019 on *asn.fr* introduces the notion of setting “contractual” or “management”

Inspections on the theme of contamination verifications

Three inspections carried out in nuclear medicine departments during 2024 included a part dedicated to the verification of non-contamination using IRSN's measuring means. The atmospheric and surface contamination measurements were taken using air samplers and contamination meters and by laboratory analysis of smear samples. The measurement and sampling points were determined by the IRSN experts based on the plans of the department and its activities on the day the measurements were taken. They concerned both key places in the department and measurement points in adjacent rooms (pre-injection waiting room, corridor in a non-restricted area, etc.). The first returns from these measurement campaigns indicate generally good control of the contamination risk in the departments inspected. The analysis reports are then communicated to the RNA so that they can be taken into account when defining measurement points that will be subject to statutory verifications. This initiative will be applied in several other nuclear medicine departments in 2025.

guidance levels, if applicable, in the discharge license mentioned in Article L. 1331-10 of the Public Health Code. These guidance levels, whose value would be specific to each centre, are management levels which, in the event of a drift in the measurement results, must trigger an investigation and, if necessary, corrections in the centre's effluents collection and disposal system. ASN has asked IRSN⁽⁷⁾ to propose a measurement protocol and provide the centres with a method to use the results to define their own “local” guidance levels, which could figure in the discharge licenses between the centre producing these discharges and the sewage network administration managers.

IRSN submitted its reports⁽⁸⁾ to ASN in 2023; the IRSN recommendations shall be analysed as part of the revision of ASN resolution 2008-DC-0095 of 29 January 2008 (*see point 2.3.3.3*).

7. Referral CODEP-DIS-2020-013834 – Request for expert assessment concerning the definition of a measurement protocol and a method of utilising the results in order to establish local guide levels for environmental discharges containing radionuclides coming from nuclear medicine departments and research laboratories.

8. IRSN Report No. 2023-00061 – Guide levels for the discharge of radionuclides concerning the defining of a measurement protocol and a method of utilising results in order to establish local guide levels for environmental discharges containing radionuclides coming from nuclear medicine departments: situation analysis and proposals.

IRSN Report No. 2023-00241 – Guide levels for the discharge of radionuclides concerning the defining of a measurement protocol and a method of utilising results in order to establish local guide levels for environmental discharges containing radionuclides coming from research laboratories: situation analysis and proposals.

2.3.3 Radiation protection situation in nuclear medicine

The nuclear medicine facilities installed base in 2024 comprises 253 licensed nuclear medicine departments, of which 109 practice exclusively a diagnostic activity. Among the departments involved in therapy, 46 have the capacities to practice high-activity ITR requiring hospitalisation in a radiation-proof room, whereas the other departments practice exclusively ITR therapy in non-radiation-proof rooms, mainly on an out-patient basis, whether for treatments with moderate-activity iodine-131 or for certain treatments with lutetium-177.

During 2024, 139 nuclear medicine licences were issued, including: equipment changes or commissioning (PET scanners in particular), increases in the activity of radioisotopes already used, license extensions to allow the use of new radionuclides, and licences to perform clinical studies with new RPDs (such as actinium-225 and holmium-166).

ASN inspections in nuclear medicine are scheduled applying a graded approach that takes into account the breakdown of the types of procedures performed in the departments, with risks that differ depending on whether they concern diagnostic or therapeutic procedures. In this context, the inspection frequency is five-yearly for departments that only perform diagnostic examinations, four-yearly for departments performing diagnostic examinations and out-patient therapeutic procedures (delivery of iodine with activities below 800 MBq, synoviortheses, etc.) and three-yearly for the departments performing complex therapies using iodine with delivered activities exceeding 800 MBq, lutetium-177, yttrium-90 (with hospitalisation in a room that may or may not be radiation-proof). This means that about a quarter of the national installed base is inspected each year. These frequencies will change as from 2025 to take into account the reform of healthcare licenses, which has separated nuclear medicine departments into two categories (level A and level B) on the basis of their risks. Consequently, level-B nuclear medicine departments will be inspected every three years whereas level-A departments will be inspected every five years (see point 1.3.3).

With regard to the radiation protection risks, the ASN inspections focus on radiation protection of workers (organisation of radiation protection, delimiting restricted areas, ambient dosimetry, staff dosimetry) and patients (analysis of DRLs, quality control of medical devices, control of dispensing of RPDs,) and source management (circuit followed by unsealed sources, from delivery to disposal, such as the delivery reception premises, storage tanks and effluent discharges).

In 2024, 69 nuclear medicine departments were inspected, representing 27% of the facilities. During these inspections the centres mentioned staffing problems, particularly with radiographers (recruitment difficulties, high turnover), and difficulties in recruiting practitioners in certain regions. The progressive reform of the healthcare licences also raises the question of whether there are enough radiopharmacists, as they must now assist the level-A nuclear medicine departments. Given the development of ITR, the number of medical physicists is also a focus of attention. ASN endeavours to question the centres about the adequacy of their resources, particularly when new projects are underway and in a context of increasing activity.

ASN conducted inspections in 2024 with experts from IRSN using measuring equipment to check control of the contamination risk by the RNAs (see box previous page).

2.3.3.1 Radiation protection of nuclear medicine professionals

From the radiological viewpoint, the personnel are subjected to a risk of external exposure – in particular on the fingers – due to the handling of certain radionuclides (case with fluorine-18, iodine-131, gallium-68 or yttrium-90) when preparing and injecting RPDs, and a risk of internal exposure through accidental intake of radioactive substances.

The inspections carried out in 2024 give mixed results regarding the way occupational radiation protection requirements are taken into account, compared with the previous years (see Graph 6).

The monitoring and analysis of occupational exposures are stagnating in the inspected departments whereas progress was observed in the preceding years (77% of the inspected departments comply with these measures as opposed to over 90% in the previous years). The other deviations observed concern deficiencies in the verification of the risk of atmospheric contamination or checks for contamination in areas adjacent to places in which radionuclides are handled, in the application of measures concerning the marking out of regulated zones in keeping with workplace verifications, and the verifications of work equipment and sealed sources. The distinct drop in conformity observed in the latter verifications in 2023 persists, with only 64% of the departments inspected being able to prove that the verifications were carried out at the required statutory frequency for the all the sources and equipment items. Furthermore, only 38% of the departments inspected had carried out compliance work further to the nonconformities found at the last verifications. Lastly, a recurrent area for improvement is still the coordination of the prevention measures with outside contractors, with only slightly more than

one-third of the nuclear medicine departments having drawn up a prevention plan with all their outside contractors.

On the other hand, the requirement to designate a Radiation Protection Expert-Officer (RPE-O) dedicated to nuclear medicine is well respected (valid certificate issued by the employer in all the departments inspected), and the refreshing of radiation protection training of the medical professionals has distinctly improved in 2024 after the decline observed in the last few years (in 78% of the departments inspected, the training of all the medical staff concerned dates back less than three years, compared with 59% in 2023).

2.3.3.2 Radiation protection of nuclear medicine patients

The ASN inspectors note a clear improvement in the optimisation approach, with 82% of the departments deploying a complete DRL management system, compared with 68% in 2023 (see Graph 7), even if difficulties are still observed from time to time, to the extent that some departments have no optimisation approach whatsoever.

Management of the third-party quality controls of MDs has returned to a satisfactory level following the regression observed in 2023, since 89% of the inspected departments had carried out the quality controls on all their MDs at the required regulatory frequency (see Graph 7).

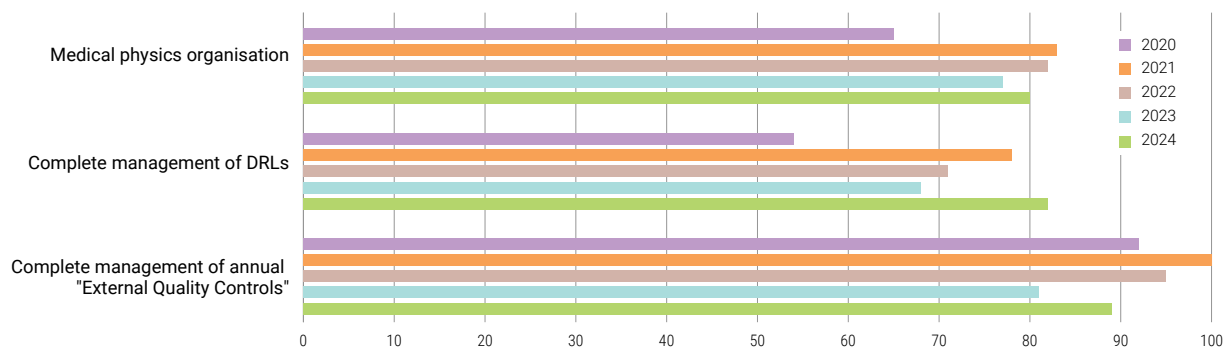
The organisation put in place to integrate medical physicists, identify their duties and quantify their time of presence on site is satisfactory in 80% of the departments (see Graph 7). This organisation can still be improved however in some departments inspected in 2024, where the Medical Physics Organisation Plan (POPM) is incomplete and the medical physics organisation described in the POPM is considered inadequate.

Lastly, following the publication of two ASN resolutions 2019-DC-0660 and 2021-DC-0708, laying down the quality assurance obligations in medical imaging and for therapeutic procedures respectively, ASN notes a strong commitment and significant investment on the part of the medical departments in the deployment of the QMS's. Deployment of the authorisation process is continuing, even if this year ASN still observes disparities between the medical and paramedical personnel, given that it is applied mostly for the paramedical staff. Although the events notification culture exists in a large proportion of the departments inspected, it must be improved and even reinforced, particularly regarding the analysis of events. ASN once again observed this year that ESRs had not been notified by some centres.

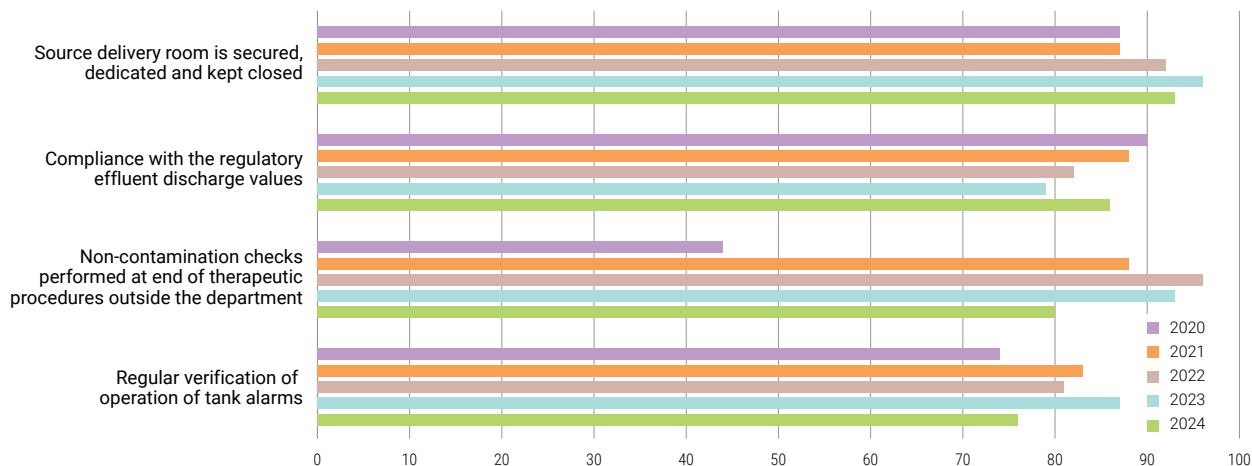
GRAPH 6 Development of nuclear medicine department compliance with occupational radiation protection regulations over the 2020-2024 period

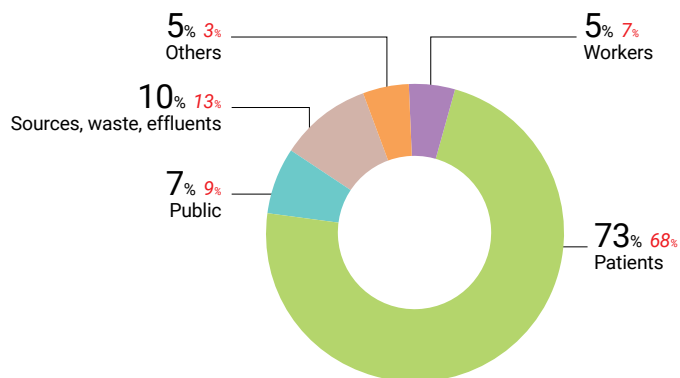


GRAPH 7 Development of nuclear medicine department compliance with patient radiation protection regulations over the 2020-2024 period



GRAPH 8 Development of nuclear medicine department compliance with protection of the public and the environment over the 2020-2024 period



GRAPH 9 Breakdown (in %) of ESRs in nuclear medicine in 2024

In red: average of the number of ESRs notified during the 10 preceding years.

2.3.3.3 Protection of the public and the environment

More than 90% of the departments inspected over the 2019-2024 period (93% in 2024) have a dedicated and protected delivery room in compliance with the requirements of ASN resolution 2014-DC-0463 of 23 October 2014, and 86% of these departments have no particular difficulties in complying with the statutory effluent discharge limits (10 becquerels per litre – Bq/L – for the contaminated effluents after interim storage, or 100 Bq/L for effluents from the rooms of patients treated with iodine-131) set for the activity concentration of effluents discharged after radioactive decay (see Graph 8).

However, two points which had improved over the last three years regressed slightly in 2024. The first concerns the contamination checks at the end of procedures performed outside the department (activities such as looking for sentinel lymph nodes in the operating theatre), which are still not performed systematically in 20% of the departments inspected, while pointing out that the small number of departments concerned (10) out of those inspected in 2024 may explain this figure. The second point concerns the obligation to verify the storage tank leak detectors in the retention trays which is carried out to a lesser extent than last year (76% of the departments inspected were compliant compared with 87% in 2023). Regarding this latter point it has been observed that the transfer of alarms to an entity external to the nuclear medicine department outside working hours, although judicious in principle, is not always adequately addressed. The inspections have also revealed that the Effluent and Waste Management Plans (EWMPs) do not always contain all the required elements such as the discharge authorisation, often signed tardily with the manager of the public wastewater

drainage network, and the setting of a maximum permissible value at the outlet of the centre.

ASN also notes that the RNAs have difficulties in implementing the new regulations concerning the verifications to be carried out under the Public Health Code which are applicable since 1 January 2023. The main difficulty is linked to the definition of the requirements (scope of the verification action) of the Order, for the approved organisations and healthcare centres alike.

2.3.3.4 Significant events notified in nuclear medicine

Out of the 69 departments inspected, most of them have a system for recording adverse events. For the majority of events notified to ASN, the proposed action plan is appropriate but shortcomings are sometimes observed in the analysis of their root causes. On the other hand, several inspected departments had not notified certain ESRs to ASN, primarily due to the personnel's lack of awareness of events notification.

The number of ESRs notified in 2024 totals 324, a great increase compared with 2023 (+61%) and double the number notified in 2019 (see point 2.7). This change results very probably from an increase in the number of procedures in nuclear medicine, a discipline that developing strongly, whether for diagnostic purposes – with PET scans in particular – or therapeutic purposes, but can also be explained by greater adoption of the quality assurance approach by the centres, which integrates the notification of ESRs. This trend must not mask the fact that failures tonotify events are still observed occasionally.

As in the preceding years, the majority of the reported events (73%) concern patients (see Graph 9).

Contamination of a nuclear medicine department employee

On 20 December 2024, when a preparation technician was manipulating a syringe containing technetium-99m, the needle came off the syringe causing a few drops to be projected onto the technician's arm resulting in cutaneous contamination. A contamination check and a decontamination procedure were implemented by the centre's RPE-O. The dosimetric evaluation carried out considering the worst-case assumptions led to a dose exceeding one quarter of the maximum annual dose to the extremities for a worker. ASN therefore rated this event level 1 on the INES scale, as specified in the incident notification it published on its website. The centre's analysis of the event enabled corrective actions to be defined (fitting all the syringes with special connectors, drafting of a procedure for treating a medical professional contaminated during the injection process, and systematic wearing of anti-spray protective glasses during injection), the implementation of which shall be verified by ASN during its inspections.

Significant events concerning patients (237 ESRs, i.e. 73% of the notified ESRs)

The large majority of ESRs concerning nuclear medicine patients occur in the course of diagnostic procedures (70%). Most of these ESRs have no expected clinical consequences, in view of the activities injected. They result mainly from drug preparation or administration errors leading to injection of the wrong RPD or an inappropriate RPD activity (53% of the ESRs concerning patients, a figure that is stable compared with 2023). They result from organisational and human malfunctions, usually in high workload situations. Seven of these ESRs in 2024 concerned children and also resulted from preparation and injection errors. The other ESRs which occurred during diagnostic procedures are most often linked to an error in the examination requests, in the physician's prescription or their treatment (16%) or a problem that arose during image acquisition (16%) (failure, incorrect protocol, etc.). One ESR received particular attention given the number of patients concerned (70) and led to the publication of an incident notification on the ASN website. It involved the delivery of higher-than-planned doses in scintigraphy examinations due to incorrect utilisation of the dose calibrator used to measure the activities to be injected into the patients.



Non-compliant disposal of radionuclide-contaminated waste from nuclear medicine departments

An ESR was notified to ASN in early August 2024 following triggering of the radiation portal monitor on a waste disposal site receiving waste from one of the centres of a hospital group. This ESR follows on from a series of other reports of radiation portal monitor triggering on reception of waste from centres of this same hospital group. Altogether, five containers of waste contaminated by radionuclides used in nuclear medicine were sent to the waste treatment sites without the regulatory waste management by decay requirements having been observed. The nuclear medicine departments that use radioactive preparations for diagnostic or therapeutic purposes routinely produce waste contaminated by radioactive elements. Due to their rapid radioactive decay, these elements lose their radioactivity in a time ranging from a few hours to a few days; consequently, they can only be disposed of in the waste treatment routes after a period of radioactive decay, which is the natural phenomenon of disintegration of the radioactive atoms over time whereby the radioactivity is gradually reduced until it becomes equivalent to the background radiation. Disposal of this waste remains conditional on the results of checks, one of which uses an on-site fixed radiation portal monitor, as defined by ASN resolution 2008-DC-0095 (Articles 15 and 16). The waste treatment centres, pursuant to the regulations relative to Installations

Classified for Protection of the Environment, are equipped with radiation portal monitors enabling them to detect any contamination of the waste they receive immediately on reception and to take the necessary measures where applicable for the said waste to be treated via appropriate routes.

The analysis of these events revealed firstly a malfunction of the fixed detection system of one centre, and secondly deviations in the disposal procedures, as one container of waste contaminated by radionuclides triggered the detection system of the waste sorting area without having been placed in the radioactive decay area prior to its disposal. ASN rated the last event in the series level 1 on the INES scale due to the repeated nature of the events over a short time frame (4 ESRs in less than three months) and reiterated in the incident notification published on its website the importance of keeping the radiation portal monitors of the areas for sorting waste contaminated by radionuclides in the healthcare centres in good working order, along with the importance of training the operators responsible for sorting this waste in the instructions applicable in the centre.

This type of radiation portal monitor triggering event can also occur on reception of radiation-contaminated waste produced by patients in their home after an ITR medical procedure if this waste is disposed of with the household waste without having

observed the required decay period, or if the waste contains radionuclides with a longer half-life, as is the case with the metastable lutetium-177 that is sometimes present as an impurity in lutetium-177-based radiopharmaceutical preparations. In view of the large increase in patients receiving ITR treatments, the preference given to out-patient treatment methods and the difficulty in making provisions for the retention and collection of radiation-contaminated waste produced by certain patients in their home, the frequency of these events is tending to increase.

The management of such events mobilises considerable resources (intervention of the fire brigade or specialised personnel, additional waste sorting, radiological characterisations, separate management, etc.) and can have highly penalising operational consequences for the household waste collection and management system: in some cases waste collection strikes or refusals to accept waste have been observed, illustrating the major and specific impact that an incident can have from the moment it has a radiological dimension. ASN urges all the actors concerned (promoters, departments, healthcare centres, professional organisations, local authorities, etc.) to make every effort to put in place the necessary means to reliably prevent the occurrence of these incidents, in a context where a significant increase in ITR treatments is expected in the coming years.

In 2024, nine events that occurred during therapeutic procedures were notified, five linked to complications associated with either the use of yttrium-90 microspheres (3 ESRs), or cases of extravasation⁹ with lutetium-177 (2 ESRs). One “Experience feedback” sheet concerning complications during a liver cancer treatment by radioembolisation using yttrium-90 was drawn up in 2024 in order to share good practices to limit the frequency of occurrence of such events. The other ESRs concern errors in the handling or injection of RPDs (two ESRs with lutetium-177 and two with iodine-131). ASN alerts nuclear medicine departments to the risk of extravasation during therapy with lutetium-177 PSMA which can lead to local exposure to the skin of several grays and necessitate a special medical response. In 2025, ASN will establish, jointly with the medical professionals, the lessons learned from the notified ESRs.

Significant events concerning medical professionals (14 ESRs, i.e. 5% of the notified ESRs)

Fourteen events concerning nuclear medicine professionals were notified in 2024. They result from contaminations that led to internal or external exposures (surface contaminations as a result of handling errors or reception of a broken vial). None of these ESRs led to exceeding of the regulatory dose limit for the workers concerned, but one was rated level 1 on the INES scale because it led to exposure exceeding, on a one-off basis, a quarter of the regulatory limit for exposure to the extremities. This ESR led to the publication of an incident notification on the ASN website (see box previous page).

Significant events concerning the public (19 ESRs, i.e. 7% of the notified ESRs)

Eighteen ESRs result from exposure of the foetus in women who were unaware of their pregnancy. The doses received had no consequences for the unborn child. A

“Patient safety” bulletin published in 2021 was devoted to this type of event. The 19th ESR concerns a high dose rate (hot spot) detected in a corridor and caused by pipes displaying a high level of crystallisation necessitating specific servicing work to remove the source of exposure.

Significant events concerning radioactive sources, waste and effluents (31 ESRs, i.e. 10% of the notified ESRs)

These ESRs are mostly related to source losses/discoveries, the dispersion of radionuclides (resulting from overflows of radioactive effluent tanks or leaks in the effluent evacuation circuit), deliveries that do not comply with the licenses and unauthorised discharges of effluents into the environment (emptying of tanks, etc.).

Difficulties have recently emerged in the management of the solid waste produced in the ITR treatments of certain prostate cancers with RPDs using lutetium-177, leading notably to the triggering of radiation

9. Extravasation is an inappropriate accidental and unintentional injection or leakage of drugs into the perivascular or subcutaneous spaces rather than into the target vascular compartment.

portal monitors in the sorting centres for waste coming from hospitals (*see box previous page*) or private individuals. The patient is given instructions on leaving the nuclear medicine department regarding the management of the waste produced at home (sanitary protections, for example) in the days following treatment, including storage of their waste in the home for several weeks. At present these instructions are not harmonised nationally. Storage of this type of waste in the home can be difficult (lack of space or a suitable area). Consequently, it can happen that waste arrives at the waste treatment facilities before the time indicated in the patient's discharge instructions has lapsed, triggering the radiation portal monitors. Solutions have been proposed by domestic waste treatment centres, such as providing patients with larger-volume

collectors and having them picked up by a door-to-door service, while at the same time enhancing patient awareness. Further to an increase in the triggering of radiation portal monitors at the entrance to waste treatment centres, linked to the introduction of new RPDs (especially those containing lutetium-177), ASN initiated studies in 2024, assisted in particular by the GPRP and a WG comprising representative of the French Society of Nuclear Medicine and Molecular Imaging (SFMN), IRSN, DGS, DGOS, ANSM, the General Directorate for Risk Prevention (DGPR) and Departmental Fire and Emergency Services (SDIS). The aim of these studies is to identify areas for improvement to better manage these situations and to propose information to enhance communication, particularly with the waste management professionals.

SUMMARY

The inspections carried out in 2024 in a quarter of the nuclear medicine departments, considered alongside those carried out over the 2020-2024 period, enabling all the departments to be covered, reveal – despite progress in the training of the medical professionals – a less satisfactory occupational radiation protection situation in 2024, particularly in the monitoring and analysis of exposure of the professionals, in the workplace verifications and the equipment and sealed sources. Three inspections conducted with IRSN experts during which measurements were taken indicate good overall control of the contamination risk in the inspected departments.

The inspections in 2024 confirm, as in the preceding years, that particular attention must be paid to observance of the statutory provisions concerning effluent management (particularly the verification of the decay tank alarms and their transfer outside working hours) and of the waste produced by the patients, associated with the introduction of new radiopharmaceutical drugs which can cause triggering of radiation portal monitors at the entrance to waste treatment facilities.

With regard to patient radiation protection, implementation of the principle of optimisation with the collection and analysis of DRLs has improved. Further progress is needed in the deployment of the QMS's and in the quality of the ESR analyses. The ESRs reveal that the drug preparation and administration processes, particularly the utilisation of the dose calibrator, must be regularly assessed in order to control the medication circuit (*see Patient safety bulletin "Safeguarding the medication circuit in nuclear medicine"*). In addition, measures to prevent the risk of extravasation and to treat patients if such a situation arises, must be defined in all the departments because these situations can lead to significant exposure at the injection site.

The growing emergence of clinical trials involving new vectors and new radionuclides (lutetium-177, actinium-225, holmium-166, etc.) makes it necessary to deepen knowledge of the associated radiation protection risks, not only for the patients and their family circles, but also for the medical professionals, the public and the environment. ASN will publish an opinion in 2025 based on the opinions of the experts it has consulted and the work undertaken with all the actors concerned. The commitment and collaboration of all the stakeholders – inspection agencies, manufacturers, promoters, investigators, healthcare service providers and professional associations – is essential to allow the development of innovation in a safe environment for the benefit of the patients.

Lastly, ASN will adapt the frequency of its inspection in 2025, to five years for departments performing diagnostic procedures only and three years for departments performing therapeutic procedures, and will continue the inspections with measurement campaigns to assess the control of the contamination risk in nuclear medicine departments.

2.4 Fluoroscopy-guided interventional practices

Fluoroscopy-Guided Interventional Practices (FGIPs) group all the imaging techniques using ionising radiation for the purpose of imaging, guidance or verification, for performing invasive medical or surgical procedures for diagnostic, preventive or therapeutic purposes. The practices are therefore based on the use of real-time radiological imaging to guide precise and mini-invasive medical operations. Today it is possible to treat patients previously considered inoperable or who required major surgical operations. The patients thus benefit from less traumatic procedures with shorter recovery times and lower risks of complications.

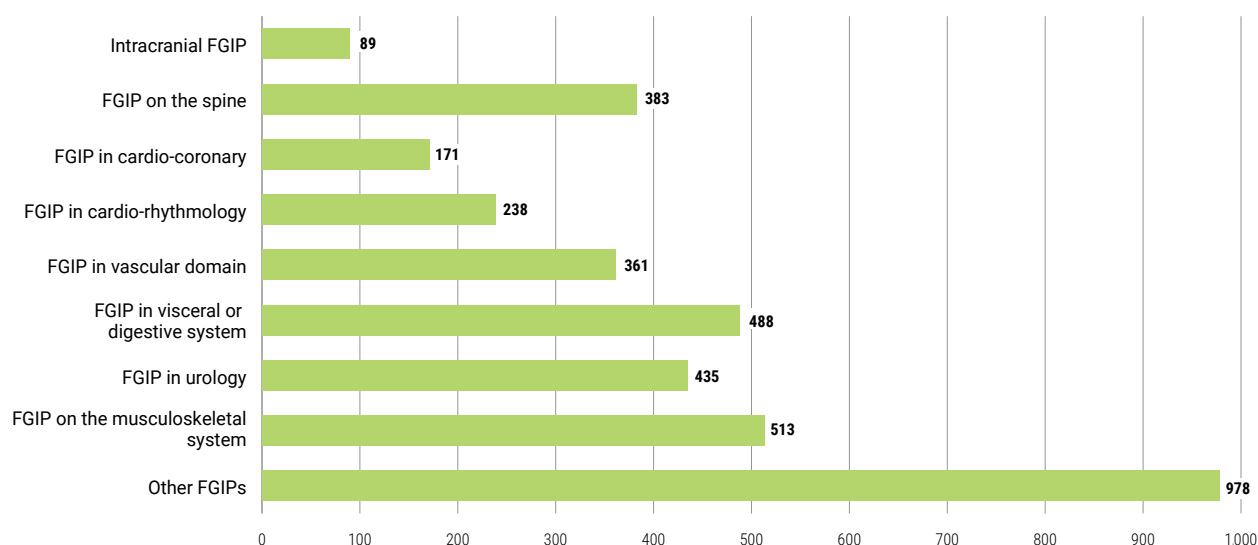
These medical practices have been evolving constantly for several years now, and are used for an ever-increasing number of pathologies, providing opportunities for new therapeutic and diagnostic possibilities. Due to their interventional nature, these procedures are carried out in two separate environments – either operating theatres or interventional imaging departments – depending on the target and the pathology. Fixed interventional radiology rooms have been designed and fitted out taking into account the utilisation of ionising radiation. This is not the case for all operating theatres, which are gradually being brought into compliance.

On account of the exposure levels involved, as much for the patients as for the professionals who can be obliged to work close to the radiation sources, and the increase in the number of procedures performed using ionising radiation, FGIPs and operating theatres in particular, due to a less well-developed radiation protection culture, are part of ASN's national inspection priorities.

2.4.1 Description of the techniques

The healthcare centres

According to the codes of the common classification of medical procedures and the activity data notified by the healthcare centres to the Agency for Information on Hospital Care (AIHC), about 900 centres perform FGIPs involving risks with regard to radiation protection in one or more disciplines. The risk-prone FGIPs include cardiology (implanting pacemakers and defibrillators, angioplasty, etc.), interventional neurology (embolization of arteriovenous malformation), vascular radiology (embolization of the coeliac artery), or uterine embolization. Graph 10 shows the breakdown of the number of centres by FGIP category for the centres

GRAPH 10 Breakdown of the number of centres by category of fluoroscopy-guided interventional practices in 2024

having declared the FGIPs⁽¹⁰⁾ they practice. Based on available information, the most widely practised procedures in the centres are those performed on the digestive and visceral system, in urology, and on the musculoskeletal system (some 450 centres concerned).

The equipment

The equipment items used in FGIPs are either fixed C-arm devices installed in the interventional imaging departments in which vascular specialities (neuroradiology, cardiology, etc.) are carried out, or mobile C-arm radiology devices used chiefly in operating theatres in several surgical specialities such as vascular surgery, gastroenterology, orthopaedics and urology. More and more medical techniques are using the characteristics of these mobile C-arm radiology devices to guarantee the patients an optimal treatment offering. To give an example, a mobile C-arm radiology device coupled with a shock wave generator can be used in the operating theatre to perform “lithotripsy”, a procedure which breaks up kidney stones into small fragments which can then be eliminated naturally via the urinary system.

The detectors present on the devices with C-arms are image intensifiers or flat panel detectors. These devices employ techniques that use fluoroscopy and dynamic radiography (called “photo fluorography”, or “cineradiography”) intended to produce images with high spatial and temporal resolution. Practitioners can also use the subtraction method to obtain images, after injecting a contrast agent. A growing number of manufacturers are developing new innovative technologies with increasing use of Artificial Intelligence (AI). The

centres practising FGIPs are equipped with ever-more efficient and sophisticated medical devices. “Hybrid” operating room facilities, which combine the characteristics of a conventional operating theatre with those of an interventional imaging room, are continuing to develop. These operating rooms contain fixed or mobile C-arm units and fixed or mobile scanners. This combination enables the surgeon to perform “mini-invasive” surgery with 2D and 3D imaging. Given that the delivered dose levels are higher than in other interventional procedures, practices must be optimised in order to reduce the exposure doses for both the patients and the operators, who often work in the immediate proximity of the patient. ASN also observes the use of CBCT devices in the departments performing FGIPs.

2.4.2 Technical rules for the fitting out of medical rooms

The rooms in which FGIPs are carried out, operating theatres and interventional imaging rooms, must be organised in accordance with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017 laying down the technical design rules to be satisfied by rooms in which electrical devices emitting X-rays are used.

The design rules for the rooms, set by the above resolution, aim to protect the workers by limiting their exposure to ionising radiation. The arrangements must make it possible for any member of personnel entering a room in which an electrical device emitting X-rays is present and used, to assess the risk in order to take appropriate radiation protection measures on

entering or when inside the room. With regard to signalling systems, they are obligatory at the point of access to the operating rooms and inside the rooms when a device is present and to signal the emission of radiation. It is important to point out that many medical and non-medical staff members intervene in the operating theatre. Simple and practicable instructions must be favoured in a context of multiple risks and a complex environment. The signalling systems moreover count among the most effective prevention measures, as does the wearing of appropriate personal protective equipment and dosimeters by each operator, from the moment a restricted area is delimited due to the risk of exposure to ionising radiation.

Some centres are equipped with operating halls that constitute technical platforms allowing procedures to be performed simultaneously with the sharing of certain members of staff. Compliance with the regulatory requirements, particularly those concerning signalling, can be more complicated in these halls.

2.4.3 Radiation protection situation in fluoroscopy-guided interventional practices

For some years now ASN has been receiving regular reports on ESRs in the area of FGIPs, but their number remains low for the number of procedures performed. In the course of its inspections, ASN still finds that the medical professionals lack knowledge of the criteria for reporting significant events, even though the doses administered in some centres are high and sometimes exceed the dose

10. Form that the centres had to fill out with the information requested in paragraph 1 of article 12 of ASN resolution 2021-DC-0704 relative to the registration system in the medical field «For fluoroscopy-guided interventional practices having been notified to ASN, a description of the types of procedures performed in accordance with the list figuring in article 1 (of the resolution), and the references of the notification concerned, must be submitted within twelve months following entry into effect of this resolution (before 1 July 2022).

thresholds beyond which tissue damage occurs (radiodermatitis, necrosis) in patients having undergone particularly long and complex interventional procedures. In addition to these events, which underline the major radiation exposure risks for the patients, are those concerning professionals, whose exposure can lead to the exceeding of regulatory dose limits, particularly at the extremities (fingers) and the lens of the eye.

Ever more efficient and sophisticated techniques are developing in environments with little experience of the radiological risk. In this context, it is essential to optimise the doses, as much for the patients as for the personnel. This is why ASN's inspections focus in particular on the rules for the fitting out of premises, the delimiting and signalling of restricted areas, dosimetric and medical monitoring of the personnel, the provision of Personal Protective Equipment (PPE). Concerning patients, particular attention is paid to the optimisation of doses delivered to the patient (putting in place DRLs and dose analysis), personnel training in patient radiation protection and the use of the MDs. Application of ASN resolution 2019-DC-0660 of 15 January 2019 laying down the quality assurance obligations in medical imaging using ionising radiation helps the centres manage the risks arising from ionising radiation.

As FGIPs are numerous, varied, and performed in many different departments (neuroradiology, interventional cardiology, interventional radiology and operating theatres) within a given centre, the inspection programme is established so that all the departments performing radiation-risk procedures are inspected every five years. Nevertheless, the progress made in certain centres, the checks carried out when examining the FGIP registration applications, and the need to focus inspections more on the departments that are falling seriously behind in fulfilling the regulatory radiation protection obligations have led ASN to adjust the inspection frequency.

Inspection prioritisation is based on the number of procedures performed within a centre, the nature of the procedures which determine the radiation protection risks for the patients and medical staff, the condition of the facilities, (compliance with facility fitting out rules and persistence of nonconformities), the radiation protection culture of the teams and the situational factors (ESRs, vulnerabilities identified in previously inspected centres). This is why, since 2018, ASN prioritises its inspections in operating theatres, where the radiation protection culture is less firmly anchored than in interventional imaging departments.

In 2024, 171 centres were inspected corresponding to 115 departments. As in 2023, the operating theatre complexes of the university hospital centres and the largest hospital centres, represent 73% of the inspections, and the departments licensed by the ARS (licensed for treatments in cardiac rhythmology, interventional cardiology and neuroradiology) were prioritised. Furthermore, and for the first time, ASN conducted inspections in 2024 of employer private practitioners performing own-account procedures in operating theatres or interventional rooms. This is because these practitioners are responsible for the health and safety obligations with respect to the risk associated with ionising radiation for themselves and their employees. During the year 11 private practitioners were inspected by the various regional divisions of ASN.

During these inspections ASN finds differences between the procedures for which the structure is registered with ASN and those effectively practised. In effect, the FGIP offering in the inspected centres changes frequently because it depends on the specialists the centres are able to recruit (mobility, lack of personnel in certain specialities).

At present, only 65% of the interventional radiology departments and 44% of the operating theatres have rooms conforming to the requirements of the above-mentioned ASN resolution 2017-DC-0591 of 13 June 2017 setting the technical fitting out rules and have drawn up a conformity report. These percentages have varied little over the last five years. The centres still mention financial difficulties and technical difficulties in particular in meeting the signalling requirements in the restricted areas, particularly with the emergence of new technologies that make electrical network modifications necessary.

ASN observed moreover that several medical centres were using medical devices without a registration record. This situation renders the centres liable to legal penalties and compromises the traceability and safety of the devices. ASN reminds the RNAs of their obligation to submit registration applications at least six months before commissioning or renewing medical devices. This period is necessary to guarantee rigorous processing of the applications. Noting the absence of an administrative act authorising the exercise of its activities and recurrent failures to comply with the regulations, ASN served formal notice on one hospital to submit a registration application. The hospital has now taken action to regularise its situation.

2.4.3.1 Radiation protection of medical professionals

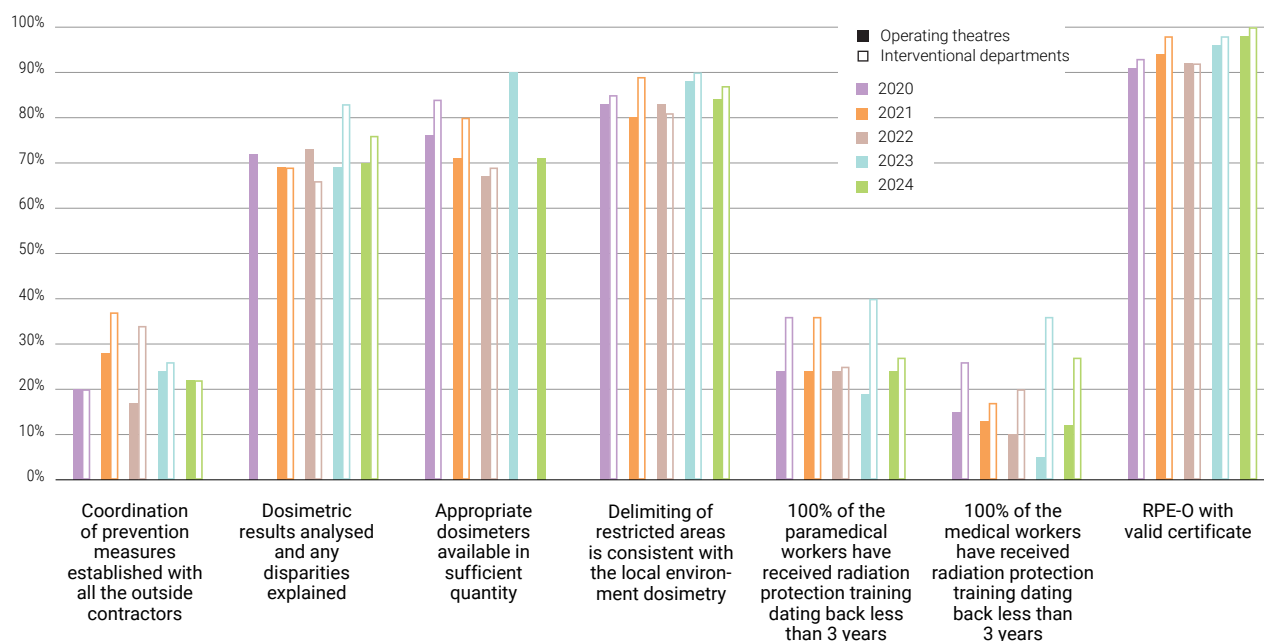
ASN considers the level of occupational radiation protection to be satisfactory, particular regarding the integration of the results of verifications for the delimitation of zones, with 84% of zones correctly delimited in the operating theatres and 87% in the interventional imaging department in 2024. These levels of conformity are nevertheless slightly lower than in 2023. Virtually all the centres inspected (99% of the departments inspected) have appointed an RPE.

The finding concerning the lack of training of the medical professionals in occupational radiation protection in 2024 is identical to the preceding years. This is a recurrent issue, particularly in operating theatres, where only 12% of the medical personnel (as opposed to 24% in interventional imaging departments) and 27% of the paramedical personnel (same percentage as in interventional imaging departments) are trained. Although this percentage is higher than in 2023, the level of training in occupational radiation protection remains a subject of concern to which the RNAs should devote particular attention.

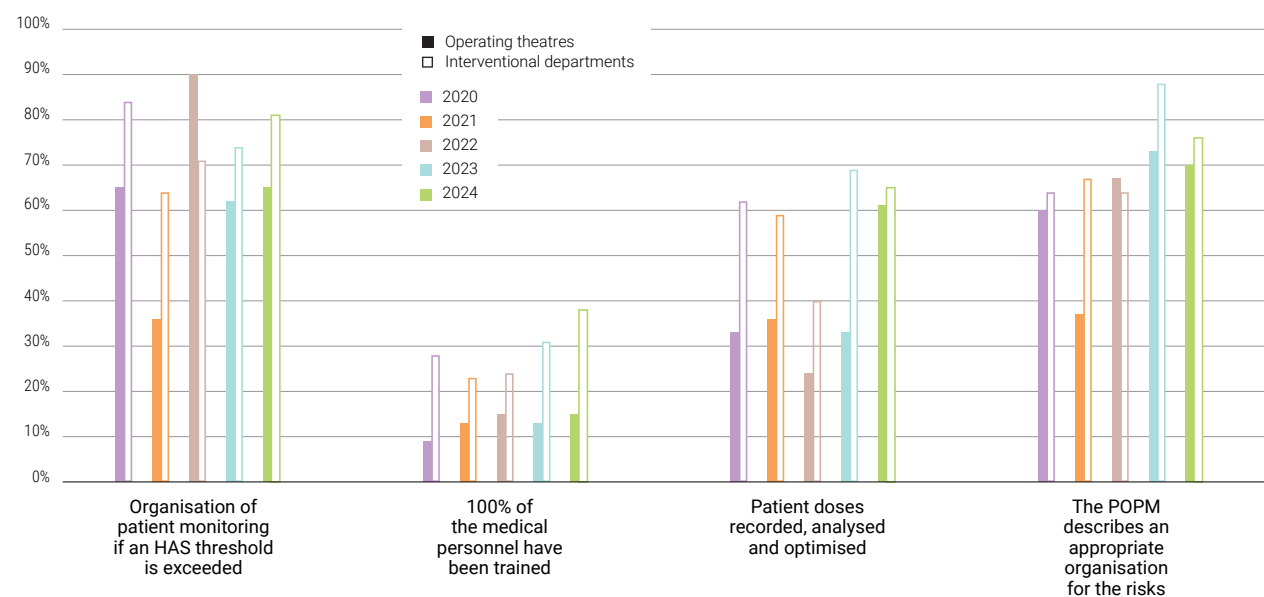
ASN observes in 2024, as in 2023, significant use of Radiation Protection Organisations (RPOs), either as a specialised contributor to assist an internal RPE-O, or as an RPE. The use of RPOs can partly explain the difficulties in training the personnel due to the lower organisational flexibility of outsourced training sessions. Furthermore, calling upon an RPO necessitates supervision of this service with strong internal mobilisation and an interlocutor who is capable of following through with the radiation protection questions, because the on-site presence of the RPO's personnel is often very limited. Without close involvement of the centres, the RPO's will use standard documents that ignore the departments' particularities. They are moreover often poorly known or unknown to the teams, who have difficulties in assimilating them. Yet compliance with and assimilation of the occupational radiation protection requirements is dependent on a high degree of involvement of the people who ensure in particular the correct implementation of radiological zoning, the radiation protection verifications and the occupational radiation protection training courses.

Coordinating prevention measures with outside contractors, including private practitioners, is also an area for progress in interventional imaging departments and operating theatres alike. The percentage of inspected departments having formalised

GRAPH 11 Change in the conformity of the FGI facilities inspected (in %) on the theme of medical staff radiation protection from 2020 to 2024 (operating theatres and interventional departments)



GRAPH 12 Change in the conformity (in %) of the FGI facilities inspected on the theme of patient radiation protection from 2020 to 2024 (operating theatres and interventional departments)



prevention measures with all their service providers through a prevention plan varies between 17 and 28% for the 2019-2024 period. In 2024, only 22% of the inspected centres had formalised these measures. Yet knowledge of the risks linked to ionising radiation and of the appropriate prevention measures for the situations encountered, particularly by private practitioners, is a prerequisite for ensuring their radiation protection and that of other professionals.

In 71% of the operating theatres inspected in 2024, the medical personnel have dosimetric monitoring devices available in

sufficient quantity and appropriate for their types of exposure. This situation has regressed since 2023, where 90% of the inspected centres provided appropriate dosimetry equipment.

ASN also observes that the analysis of the dosimetric results by the RPE-Os has slightly improved over the last five years, enabling the bad practices to be identified and corrected; the situation is better in the interventional imaging departments than in operating theatres, with 75% of the departments having analysed the dosimetric results in 2024 compared with 71%

in 2019, while the figures for the operating theatres stand at 70% in 2024 and 60% in 2019.

Lastly, the inspections of private practitioners revealed non-conformities concerning training, dosimetric monitoring and the assessment of occupational risks for these professionals and their employees. They provided the opportunity to remind the private practitioners of employers' obligations to prevent both their own and their employees' occupational risks linked to exposure to ionising radiation.

Radiation protection technical verifications

ASN notes that the verification programme for work equipment and radiation protection instrumentation is drawn up and implemented in 56% of the interventional imaging departments and 53% of the operating theatres. When nonconformities had been identified, they had been corrected or were in the course of being corrected on the date of inspection in 78% of the cases.

2.4.3.2 Radiation protection of patients

Of the departments performing FGIPs inspected in 2024, 74% call upon a medical physicist and have a POPM describing the organisation for involving a medical physicist, whose duties and times of presence on site are defined according to the centre's activities. This figure has remained relatively stable over the 2019-2024 period. Recourse to outside contractors for medical physics services continues to expand in private sector centres and public hospitals alike. The outsourcing of medical physics duties is largely delegated to special advisors who intervene on site as and when required. ASN points out that close collaboration between operators and the medical physicist and regular presence of the physicist in the departments lead to optimised use of the equipment, with the setting up of protocols adapted to the procedures, recording of delivered doses and evaluation with regard to the locally-defined dosimetric reference levels. ASN notes that the external medical physicists working under a service contract are rarely present on the sites, including when the presence of a medical physicist is required by the regulations, for example during medical device acceptance tests and the setting up of optimised protocols under article 10 of ASN resolution 2021-DC-0704 of 4 February 2021.

The training of physicians in patient radiation protection is a recurring weak spot: about 15% of the operating theatres have trained all the physicians. The medical personnel in the interventional imaging departments medical are trained to a greater extent, with 38% of the departments having trained all their medical personnel, an improvement compared with 2023 (31%).

Over the last five years, 60% of the interventional imaging departments on average have collected, analysed and optimised the doses. ASN notes a broadly stable situation in 2024, with 65% of the interventional imaging departments meeting these obligations compared with 69% of those inspected in 2023. On the other hand, only 36% of the operating theatres satisfied these optimisation requirements in 2024. ASN finds the same weakness in the application of the optimisation principle

in setting machine parameters and optimising the protocols used. The training time for the medical staff is insufficient and the recurrent shortage of paramedical personnel does not facilitate the scheduling and following of training courses. Nevertheless, reference levels for the most common examinations are being developed locally more and more often. This approach makes it possible, among other things, to set alert levels for triggering appropriate medical monitoring of the patient according to the dose levels delivered to the patient. Patient dose archiving and analysis systems are also deployed and facilitate the development of these reference levels and the programming (or adaptation) of local alert levels per machine and by type of procedure. These systems are an asset for tracking the doses previously received by the patient and for patient monitoring, and they contribute to the optimisation of the dose delivered.

ASN is regularly alerted by situations of noncompliance with the required qualifications in the operating theatre. The shortage of radiographers in operating theatres means that nurses are required to operate devices emitting ionising radiation under the responsibility of the physicians. ASN is also questioned about the scopes of intervention and the patient radiation protection training obligations of State-Registered Operating Theatre Nurses (SROTNS) and State-Registered Nurses (SRNs). ASN reiterates that devices emitting ionising radiation may only be operated by radiographers whose training in patient radiation protection is current and under the responsibility of a physician. With regard to SROTNS, they now have new prerogatives and can, under the responsibility of a surgeon, assist in certain interventional procedures (performed under mobile C-arm unit in the operating theatre, not requiring a protocol adjustment and delivering a dose of less than 10 grays per square centimetre – Gy/cm² (Dose Area Product – DAP – at end of procedure) without being authorised to operate or set the parameters of the medical device. They must also have a specific work tasks qualification and be current in their patient radiation protection training (ASN resolution approving the patient radiation protection continuous training guide for SROTNS). With regard to SRNs, they can only operate devices emitting ionising radiation under the responsibility of a physician in the context of a cooperation protocol approved by the ARS in accordance with the Article of Act 2019-774 of 24 July 2019 on the organisation and transformation of the health system or under the provisions of Decrees 2019-678 of 28 June 2019 and 2024-954 of 23 October 2024 relative to the conditions

of performance of certain professional procedures by nurses in the operating theatre.

Patient monitoring if the skin exposure threshold defined by the HAS⁽¹¹⁾ is exceeded is formalised to a greater extent in the interventional imaging departments (81%) inspected in 2024 than in the operating theatres (65%); interventional imaging departments are more frequently concerned by procedures leading to such exposure levels than the operating theatres.

Although the nonconformities detected during the external quality controls of the medical devices have been or are in the processing of being corrected, persistent situations of human resource shortages within several external quality control organisations have been reported. These difficulties have led to significant delays in the quality controls, sometimes compromising their regularity and effectiveness. Given this context, ASN calls for increased vigilance in order to guarantee the continuity and quality of these quality controls which are essential for patient safety and the correct functioning of the MDs.

2.4.3.3 Significant events notified in relation with fluoroscopy-guided interventional practices

An events recording system is in place in more than 69% of the inspected sites performing FGIPs. In 2024, 32 significant events were notified (compared with 26 in 2023) and concern:

- overexposures of patients (14 ESRs);
- exposures of medical staff (12 ESRs);
- one overexposure of patient and professionals (1 ESR);
- exposure of foetuses in women unaware of their pregnancy at the time of the procedure (5 ESRs).
- one malfunction of lighted signalling systems in an operating theatre (1 ESR).

In two of these ESRs, the amplifiers generated radiation without any external input, triggering the untimely emission of X-rays. These two incidents lasted 6 seconds (s) and 20 s respectively, the first being stopped by activation of the emergency stop control, the second highlighting the failure of the safety mechanisms that are supposed to prevent such untimely activations. These events underline the need for an in-depth analysis of the technical causes and a tightened verification of the built-in safety systems in order to prevent the recurrence of these anomalies with potential harmful consequences for the radiation protection of staff and patients. The majority of patient overexposures are due to long and complex procedures (in interventional neuroradiology, urology, digestive tract surgery, fitting Implantable Venous Access Devices – IVAD, also called implanted ports).

11. Improving patient monitoring in interventional radiology and fluoroscopy-guided procedures – reducing the risk of deterministic effects of 21 May 2014.

Another ESR was notified further to the use of X-rays with an extracorporeal lithotripsy device on a patient by a person external to the hospital who was neither a physician nor a radiographer. The utilisation of X-rays on the human body in this way breaches the provisions of Article R. 1333-68 of the Public Health Code. ASN conducted an inspection within the service provider company further to this event

Analysis of the events reveals diverse causes such as a lack of protocol optimisation, inappropriate utilisation of the devices by the operators revealing deficiencies in operator training and the importance of implementing a specific work task qualification procedure. These weak points constitute areas for improvement.

ASN reiterates the importance of the radiation protection culture and compliance with its rules, in particular the providing of all the tools allowing the optimisation of practices, the use of personal and collective protective equipment, and compliance with the rules concerning the wearing of passive and active dosimeters, including their stowage on the panels provided for this purpose, for exposure monitoring and reactive alert in the event of abnormal exposure.

Lastly, events were notified concerning accidental exposures of the foetus of pregnant women unaware of their pregnancy, who underwent a therapeutic procedure in the pelvic region. A “Patient safety” bulletin entitled *Ionising radiation: limiting the exposure of women who are unaware of their pregnancy* published in 2021 addressed the lessons learned specifically from this type of event.

SUMMARY

The inspections conducted in 2024 in the area of FGIPs, considered with those performed over the period 2019-2023, allowing coverage of all the facilities considered to have radiation protection risk implications, reveal the fact that radiation protection makes very little progress from one year to the next, with a situation that still remains better in the interventional imaging departments than in the operating theatres. In most facilities, the premises are slowly being brought into conformity to comply with the technical design rules, even though these modifications are essential in order to prevent the occupational risks. Even if the appointment of RPE-Os, the delimiting of restricted areas, the performance of technical verifications and quality controls of MDs are considered satisfactory, deviations from the regulations are still frequently observed, in the radiation protection of the professionals and patients alike, with unsatisfactory situations concerning training in occupational and patient radiation protection and the coordination of prevention measures during concomitant activities, particularly with private practitioners. The inspections of employer private practitioners highlighted nonconformities with regard to the occupational radiation protection obligations and the fact that they were poorly aware of their responsibility, as employers, with respect to the protection of themselves and their employees.

ASN found moreover that several medical centres were using MDs that were not registered and decided to take enforcement action by giving one hospital formal notice to submit a registration application immediately.

ASN observes that the trend noted in 2023 is developing and that the centres are turning increasingly to RPOs, either as specialised contributors to assist an internal RPE-O, or as an RPE and that this outsourcing, if it is not adequately managed, leads to a dilution of the responsibilities of the RNAs and poorer assimilation of, or even a deterioration in radiation protection. Although the use of medical physicists and formalising of the POPMs is gaining ground, further progress must be made in the implementation of the optimisation procedure, particularly in the operating theatres where doses are still insufficiently analysed and inappropriate or non-existent protocols are still observed. The reporting culture, however, has been spreading in the past five years, with the deployment of events recording systems. The notification of ESRs underlines that maintenance operations, which can have consequences on the delivered doses, must be correctly supervised and that the training of practitioners in the use of medical devices is crucial for control of the doses. Extensive work to raise the awareness of all the medical, paramedical and administrative staff in the centres is still necessary to give them a clearer perception of the risks, especially for operating theatre staff.

2.5 Medical and dental radiodiagnosis

2.5.1 Overview of the equipment

Medical radiodiagnosis is based on the principle of differential attenuation of X-rays in the organs and tissues of the human body. The information is collected on digital media allowing computer processing of the resulting images, and their transfer and filing.

Diagnostic X-ray imaging is one of the oldest medical applications of ionising radiation; it encompasses all the methods of morphological exploration of the human body using X-rays produced by electric generators. It occupies an important place in the field of medical imaging and comprises various techniques (conventional radiology, radiology associated with interventional practices, computed tomography, mammography) and a very wide variety of examinations (retroalveolar, radiography of the thorax, chest-abdomen-pelvis CT scan, etc.).

The request for a radiological examination by the physician must be part of a diagnostic strategy taking account of the patient's known medical history, the question posed, the expected benefit for the patient, the examination exposure level and the dose history and the possibilities offered by other non-irradiating investigative techniques. The French Society of Radiology and Medical Imaging issues a Guide for Radiology and Medical Imaging Examination Referrals (ADERIM) to enhance the relevance of the examinations requested by referring physicians.

If the dose delivered does not in itself represent a radiation protection health risk, it is the large number of examinations carried out among the population that contributes significantly to the collective dose of medical origin.

2.5.1.1 Medical radiodiagnosis

Conventional radiology

Conventional radiology (producing radiographic images, or radiographs), if considered by the number of procedures, represents the large majority of radiological examinations performed.

The examinations mainly concern the bones, the thorax and the abdomen. Conventional radiology can be carried out in fixed facilities reserved for diagnostic radiology or, in certain cases, using portable devices if justified by the clinical situation of the patient.

Angiography

This technique, used for exploring blood vessels, involves injecting a radio-opaque contrast agent into the vessels which enables the arterial (arteriography) or venous (venography) tree to be visualised. Angiography techniques benefit from computerised image processing (such as digital subtraction angiography).

Mammography

Given the composition of the mammary gland and the fineness of detail required, screening for breast cancer necessitates the use of mammography units, specific radiology devices providing high-definition and high-contrast images. Two complementary imaging techniques are currently available, planar imaging (2D) and tomosynthesis imaging (3D). At present, only planar imaging, which functions at a low voltage and gives high definition and high contrast images, is approved by the HAS for breast cancer screening. ASN participated in a working group coordinated by the HAS which has assessed the position of tomosynthesis mammography in the breast cancer screening strategy. In 2019, the HAS published a first report on the technical performance of tomosynthesis mammography in breast cancer screening of average-risk women. A second report on the evaluation of the performance and the position of tomosynthesis mammography in the French organised breast cancer screening programme was published by the HAS in April 2023. It recommends integrating tomosynthesis mammography (3D) in the organised screening programme, on condition that it is always associated with 2D synthetic image reconstruction (2Ds) in order to improve the screening performance without increasing the dose of ionising radiation.

The use of these devices is subject to quality controls defined by the ANSM. The 2D quality controls are defined by the ANSM resolution of 15 January 2020 which entered into effect on 15 January 2021. ASN was consulted in this context and gave a favourable opinion on the draft resolution relative to the internal and external quality controls of digital mammography facilities. This resolution is currently being updated. The future resolution will update the checks performed on 2D mammography units and will introduce external quality controls for the tomosynthesis devices.

ASN has asked the GPRP to update the collection methods and the DRLs for 2D-DR mammography and to establish them for tomosynthesis mammography. The opinion issued by the GPRP in June 2023 will allow the updating of ASN resolution 2019-DC-0667 of 18 April 2019 on the methods of evaluating the ionising radiation doses delivered to patients during radiology, FGIP or nuclear medicine procedures, and the updating of the associated DRLs.

Computed tomography

Computed Tomography (CT) scanners use a beam of X-rays emitted by a tube that rotates around the patient's body as the bed moves linearly, describing a helical scan. These scanners produce a three-dimensional reconstruction of the organs with very much better image quality than that of conventional radiology devices. An

examination can comprise multiphase image acquisitions on the same given anatomical location or on different anatomical regions.

This technique can, like MRI, be associated with functional imaging provided by nuclear medicine in order to obtain fusion images combining functional information with structural information.

The technologies developed over the last few years (such as multi-energy photon-counting CT scanners) have made examinations easier and faster to perform, and have led to an increase in exploration possibilities (example of dynamic volume acquisitions) and in the indications⁽¹²⁾. The placing of mobile CT systems on the market for intraoperative use is to be underlined, as is the increase in fluoroscopy-guided interventional CT procedures.

On the other hand, these technological developments have led to an increase in the number of examinations, resulting in an increase in the doses delivered to patients and thus reinforcing the need for strict application of the principles of justification and optimisation (see point 1.3.4). Technological advances nevertheless allow a new mode of image reconstruction thanks to iterative reconstruction and deep learning of AI. CT can thus provide consistent image quality at reduced doses. Strict application of the principles of justification of the procedures and optimisation of the protocols remains as topical as ever.

Teleradiology

Teleradiology is a medical procedure in its own right defined in the Public Health Code, performed at a distance from the patient by a radiologist who performs the procedure at the request of a referring physician. Essentially two methods are used:

- Telediagnosis, which is a remote radiological medical service for a patient when a radiologist is not present on site, either on a one-off basis in an emergency situation, or on a regular basis in non-emergency situations. The radiographer takes charge of the patient to perform the radiological or CT examination after receiving the instructions from the teleradiologist. At the end of the examination, the images are sent to the teleradiologist in order to formalise a results report in a manner comparable with what an on-site radiologist would have done.

- Tele-expertise is defined as having recourse to a second opinion. The radiologist on the scene who performed and validated the examination, or a referring physician, asks for a second opinion on the images produced.

Teleradiology is more than just a remote interpretation of images. Its development is becoming more widespread to allow continuity of out-of-hours service and to reduce

the waiting times before receiving medical care. The organisation of the practice, the way it interfaces with the personnel on site and the many responsibilities are specified by contract between the healthcare facility and the teleradiology service provider.

In May 2019 the HAS published a *Guide to good practices concerning the quality and safety of tele-imaging procedures*. Details are provided, with organisational, technical and operational recommendations. The French Professional Council of Radiology and Medical Imaging (G4) and the French Council of the Order of Physicians jointly published a teleradiology charter in February 2020, containing nine general recommendations. Lastly, the G4 also drafted baseline requirements for the profession and the skills of the radiologist in January 2023. It reinforces the position of teleradiology in the regional healthcare organisation and the availability, preferably in person, of the radiologist.

ASN very recently completed (late 2024) a study it conducted with the French Nuclear Protection Evaluation Centre (CEPN), to assess the situation of teleradiology practices in France by conducting a survey with the teleradiology users and the teleradiologists. The conclusions will be published in 2025.

2.5.1.2 Dental radiodiagnosis

Intra-oral radiography

Intra-oral radiography generators, which are usually mounted on an articulated arm, are used to take localised planar images of the teeth (the radiological detector is placed in the patient's mouth). They operate with low voltage and current and a very short exposure time, of a few hundredths of a second. This technique is usually associated with a digital system for processing and filing the radiographic image.

Panoramic dental radiography

Panoramic radiography (orthopantomography) gives a single picture showing both jaws in full, by rotating the radiation generating tube around the patient's head for a few seconds.

Cone-beam computed tomography

3D Cone-Beam Computed Tomography (CBCT) is developing very rapidly in all areas of dental radiology, due to the exceptional quality of the images produced (spatial resolution of about 100 microns – μm). The trade-off for this better diagnostic performance is that these devices deliver significantly higher doses than in conventional dental radiology. They must be used in accordance with the recommendations given by the HAS in 2009, the conclusions of which indicate that it should only be proposed in certain duly selected clinical indications and reiterate that whatever the case, the fundamental principles of justification and optimisation must be applied.

12. The term indication means a clinical sign, an illness or a situation affecting a patient which justifies the value of a medical treatment or a medical examination.

In this context, ASN has called upon the GTRPP to set up a WG to obtain its opinion on:

- IRSN's recommendations concerning DRLs in dental surgery;
- the information to be provided by the device manufacturers and suppliers;
- the need to update the Guide to radiological examination indications and procedures in odontostomatology, and more particularly in paediatrics;
- the means available to dental surgeons to optimise delivered doses;
- the initial and continuous training needs of the professionals involved in delivering the dose.

The IRSN report and the GPRP recommendations revealed that dental surgeons lacked knowledge of the machine and command of the settings and main functions proposed by the devices despite the training that is obligatory for this technique. This finding has led ASN to schedule an inspection campaign in 2025 targeting dental surgeons who use CBCT and to provide them with a self-assessment matrix to raise their awareness of dose optimisation in dental CBCT.

2.5.2 Technical layout rules for medical and dental radiodiagnosis facilities

Radiology facilities

A conventional radiological facility usually comprises a generator (high-voltage unit, X-ray tube), associated with a support (the stand) for moving the tube, a control unit and an examination table or chair.

Mobile facilities, but which are routinely used in the same room, such as the X-ray generators used in operating theatres, are to be considered as fixed facilities.

Radiological facilities must be fitted out in accordance with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017. This resolution applies to all medical radiology facilities, including CT and dental radiology. It does not however apply to X-ray generators that are used exclusively for bedside radiography and excluding any use in fluoroscopy mode. A technical report demonstrating conformity of the facility with the requirements of the ASN resolution must be drawn up by the RNA.

Portable electrical X-ray generating

ASN and the Dental Radiation Protection Commission published an information notice in May 2016 reiterating the rules associated with the possession and utilisation of portable X-ray generating devices: “The performance of radiological examinations outside a room fitted out for that purpose must remain the exception and be justified by vital medical needs, limited to intraoperative examinations or for patients who cannot be moved. Routine radiology practice in a dental surgery equipped with a compliant facility shall not be carried out using mobile or portable devices”.

This position is consolidated by that adopted by the HERCA, for which the use of such devices should be reserved for invalid patients, for the forensic medicine sector and for military personnel in the field of action (*Position statement on use of handheld portable dental X-ray equipment* – HERCA, June 2014).

ASN notes the emergence of a mobile radiology offering to meet specific health-care needs (treatment of cerebrovascular accidents – CVA [strokes], ageing population, etc.) or the needs of regions confronted with medical deserts, without at present having any visibility on how this trend will evolve. Consequently, trucks providing dental care circulate in rural areas to relieve congested emergency services (trucks in the Alsace region equipped with MDs capable of responding to emergencies) or to provide care to patients who cannot travel (acquisition of new portable dentistry devices for people in retirement homes, autistic patients, etc.). Experimentation is in progress as part of the ASPHALT project involving the Paris SAMU (Emergency Medical Assistance Service) and nine Paris hospitals, with CT scanners carried in ambulances to treat CVA victims.

2.5.3 Radiation protection situation: focus on the computed tomography scanner

In France, medical applications represent the primary source of artificial exposure of the public to ionising radiation, chiefly due to CT examinations (*see chapter 1*). Imaging examinations have proven their benefits for both diagnosis and treatment.

The issue at stake however is to avoid examinations that are not really necessary or that offer no real benefit for the patients, or the results of which could be obtained by other available, non-irradiating techniques. In order to control the increase in doses observed over these last few years, two successive dose control plans (*see chapter 1*) have been developed in recent years. Issued in this context, ASN resolution 2019-DC-660 of 15 January 2019 relative to quality assurance in medical imaging contributes to the control of doses by requiring operational implementation of the justification and optimisation principles. Each year, ASN conducts about twenty inspections in computed tomography, adopting a graded approach by targeting the Accident & Emergency (A&E) departments (most often shared with the radiology department) and the paediatric CT scanners because of the vulnerability of children. Numerous ESRs occur in CT examinations in the A&E departments and are caused by poor communication or organisation between the A&E staff and radiology. The inspections conducted by ASN focus in particular on the verification of proper application of the requirements defined by the abovementioned ASN resolution 2019-DC-0660 of

15 January 2019, especially the justification of the examinations and optimisation of the procedures.

ASN carried out 24 inspections in departments equipped with CT scanners in 2024. Half of the inspections revealed shortcomings in personnel training in both occupational radiation protection and patient radiation protection. These inspections highlight the departments' difficulties in implementing the specific work tasks qualification relating to use of the CT scanner. The qualification procedure is often initiated for the paramedical staff with the ongoing deployment of matrices, but is often incomplete for the medical staff.

Continued efforts are required in the application of the principle of optimising CT procedures. The methods of recording and analysing the doses with regard to the DRLs are not always formalised in the quality management system for the most common and the most irradiating procedures in order to define local reference levels, and the same goes for procedures for vulnerable people (pregnant women and paediatric activities).

A tendency to declassify certain personnel categories (radiographers, radiologists, private practice radiologists, stretcher-bearers) working with the scanner and likely to have access to the delimited areas is noted. The computed tomography inspections reveal cases where non-classified workers have not been issued authorisations to access the delimited areas, and the need to improve their radiological monitoring.

The use of teleradiology is continuing to increase, and in 2025 ASN will publish the results of a study it has initiated on this subject in order to identify the radiation protection risks. The inspections of the centres have revealed difficulties in appointing a coordinating radiologist physician in centres that no longer have salaried radiologists. Efforts must be maintained in the drawing up and validating of teleradiology examination protocols and subjecting them to strict quality assurance procedures.

ASN notes moreover that 31 ESRs out of the 253 ESRs notified in computed tomography (about 13.8%) occur in a teleradiology context and are linked to communication problems between the on-site and the remote medical professionals.

2.5.4 Significant events notified in medical and dental radiodiagnosis

In 2024, 365 ESRs were notified in medical and dental radiodiagnosis (+13% compared with 2023):

- 112 in conventional radiology, of which 26 concerned women unaware of their pregnancy;
- 253 in computed tomography, of which 87 concerned women unaware of their pregnancy;
- no ESR in dental radiology.

The ESRs mainly concern women who were unaware of their pregnancy (113 notifications). A slight decrease in the number of ESR notifications has been observed since 2021 (from 147 ESRs in 2021 to 113 in 2024), when a specific “Patient safety” bulletin was produced and issued in order to improve the organisational measures to reduce the number of events. The

analysis of the notified ESRs shows that checking for pregnancy when registering the appointment, checking-in and installing the patient can be further improved. The β -HCG level is not always assayed, and is sometimes incorrectly interpreted or not consulted. Urinary self-tests are little used. The other causes of ESRs are linked to shortcomings in the patient management

process (errors in identity monitoring, in the anatomical region exploration protocol, in examination scheduling).

Among the ESRs notified in 2024, one was particularly noteworthy in view of the size of the cohort of patients concerned nationally in several paediatric or neonatology departments (*see box below*).

SUMMARY

In CT, ASN’s oversight focuses essentially on compliance with the requirements of ASN resolution 2019-DC-660 of 15 January 2019, particularly concerning formalisation of the principle of justification and optimisation. The departments must still embrace the quality assurance procedures and the associated tools (formalisation of the justification and optimisation process, specific work tasks qualification, lessons learned from significant events, etc.). Efforts must also continue in the formalisation of the procedures by type of medical procedure, taking into account the persons at risk, and for the procedures performed remotely in the teleradiology context. The analysis of doses with regard to existing diagnostic reference levels and the procedures that are not subject to DRLs can be improved.

ASN notes that teleradiology is progressing constantly with technical and organisational constraints linked to communication and consultation issues that are underestimated by the centres (software interfaces, communication problems) which are liable to foster the occurrence of ESRs if the service is not managed properly.

In 2025, ASNR will publish the results of a study it has initiated on this subject in order to identify the radiation protection risks.

2.6 Human body product irradiators

2.6.1 Description

The irradiation of products from the human body is used in particular to prevent post-transfusion reactions in blood-transfusion patients. The blood bag is irradiated with a dose of about 20 to 25 grays.

Since 2009, irradiators with sources have been gradually replaced by X-ray generators which have been subject to notification to ASN since 2015. In 2023, the installed base of irradiators comprises 135 devices equipped with X-ray generators.

2.6.2 Technical rules applicable to facilities

A blood product irradiator must be installed in a dedicated room designed to provide physical protection (against fire, flooding, break-in, etc.). Access to the device, which must have a lockable control console, is limited to the persons authorised to use it.

The fitting out of premises accommodating irradiators equipped with X-ray generators must comply with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017.

2.7 Significant radiation protection events

The number of ESRs notified to ASN in the medical sector (827) in 2024 has risen by more than 20% compared with 2023 (655) (*see Graph 13 next page*). This significant increase is mainly accounted for by the number of ESRs notified in nuclear medicine. ASN reiterates the importance of notifying ESRs in order to establish shared learning from experience and improve radiation protection.

Accidental modification of exposure settings on a mobile radiology device

During a dosimetric study of bedside X-ray examinations of infants hospitalised in the Bordeaux University Hospital, the medical physics team detected exposures higher than those expected for this type of examination and in November 2023 notified an ESR to ASN in accordance with the regulations in effect. This ESR was the subject of an incident notification published on the ASN website in January 2024. The retrospective analysis of these doses recorded by the Dose Archiving and Communication System (DACS) showed that a cohort of nearly 250 children was concerned between 2022 and 2023. The exposures, which represented a few tens of microsieverts, induce no clinical consequences and require no particular monitoring.

They can be explained by the combination of a design particularity of the mobile radiology device (FDR Nano – Fujifilm) and inadequate knowledge of the steps for stopping and restarting this medical device. As a result, pulmonary X-ray constants for adults defined by the manufacturer (85 kilovolt – kV and 1,575 milliamperes-seconds – mAs) are selected automatically by default whereas the operators thought they were using paediatric X-ray constants. In effect, if the exposure conditions are defined while the tube power switch is in the off position, they are not transmitted and when the tube is switched on the default values take

effect. If the correspondence of the exposure parameters between the “image” console and the “X-ray controller” is not verified, the X-ray image is taken using the default parameters defined by the manufacturer. The dose received during this X-ray exposure is therefore not the appropriate dose.

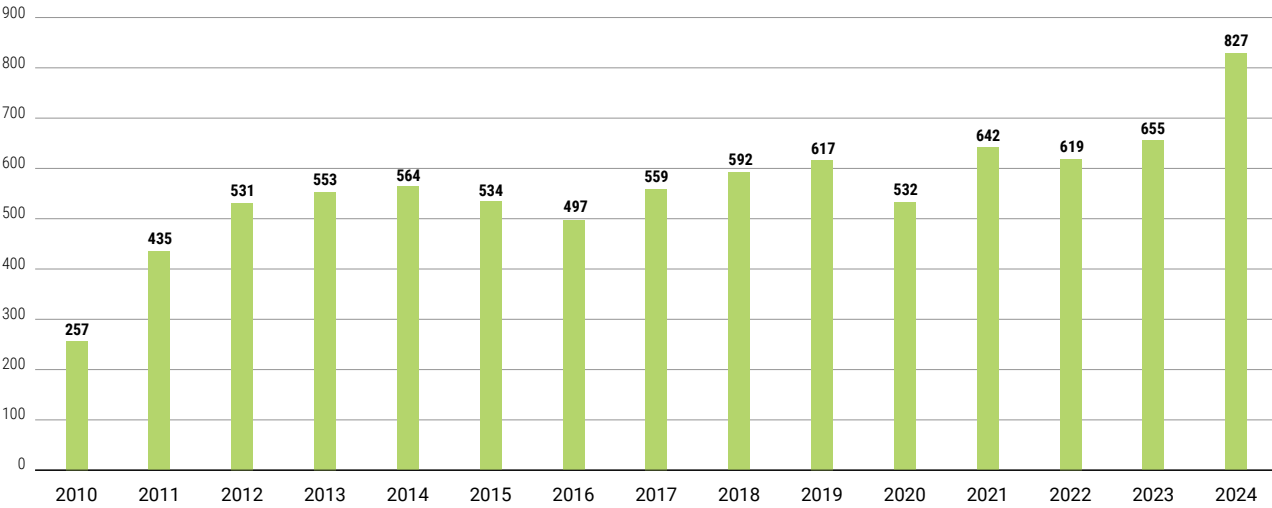
In the wake of the Bordeaux hospital incident, more than ten other hospital centres informed ASN that they were in the same situation with a cohort of children who had received inappropriate doses. These serial events led ASN to produce an “Experience feedback” sheet through its WG on lessons learned in imaging. It aims to draw the attention of the centres to the particular way this device functions, to the possible adverse effects if the instructions are not observed and to recommend possible measures to take pending correction by the manufacturer. This sheet was sent to more than 200 healthcare facilities and was published on the ASN website on 22 April 2024.

Moreover, the ANSM has urged the manufacturer to modify the device’s human-machine interface to prevent use of the default exposure parameters. The modifications were made in autumn 2024 and a new software version correcting this problem is currently being put in place in the entire French installed base.

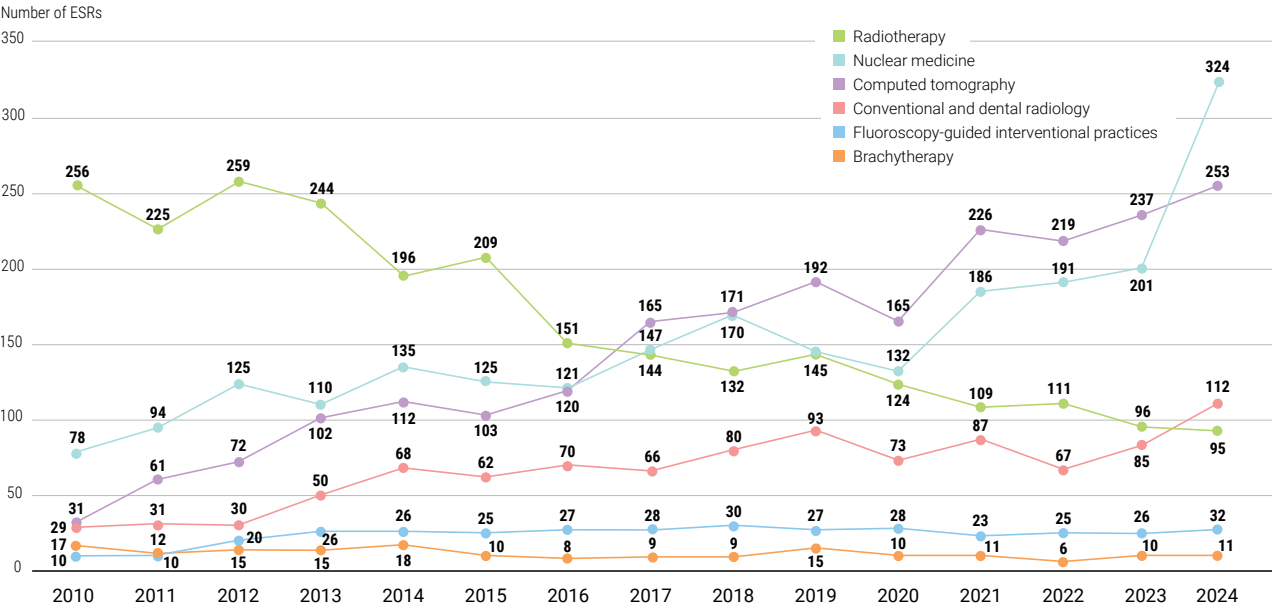
Graphs 13 and 14 illustrate how the number of ESRs has evolved by activity category since 2010. Graphs 15 and 16 illustrate the breakdown of the number of ESRs in 2024 by area of exposure (environmental impact,

exposure of the general public, exposure of patients, exposure of professionals) and by category of medical activity compared with the average number of ESRs over the preceding ten years.

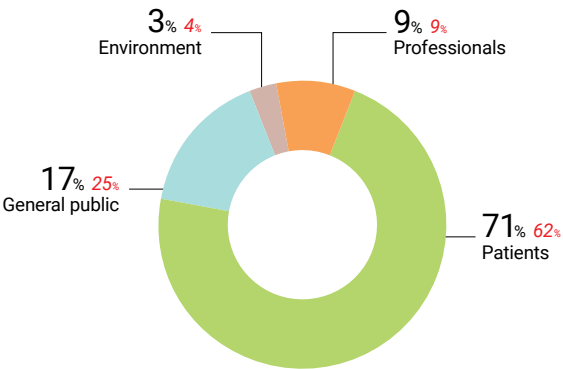
GRAPH 13 Development of the number of annual ESR reports from 2010 to 2024



GRAPH 14 Number of ESRs by activity category during the period 2010-2024

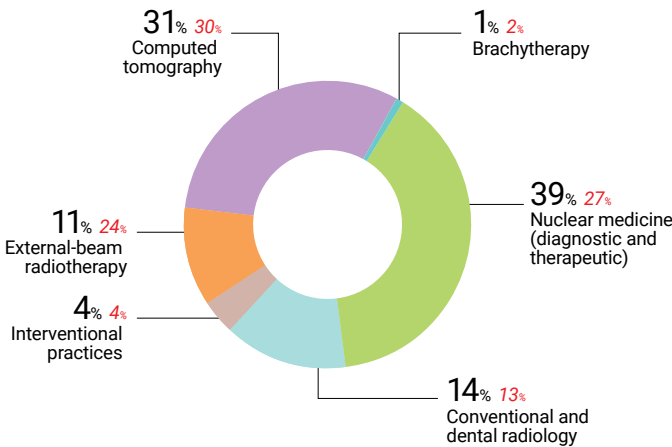


GRAPH 15 Breakdown (in %) of ESRs by exposure category in 2024



In red: average of the number of ESRs notified during the 10 preceding years.

GRAPH 16 Breakdown (in %) of ESRs by activity category concerned in 2024



Graph 15 shows that the number of ESRs concerning the medical professionals or the environment has remained stable while the number of ESRs concerning patients has risen. The number of ESRs notified has been increasing in conventional radiology and computed tomography since 2010, and even more so in nuclear medicine, where it exceeds the number of ESRs in computed tomography. This is the first year since ESR notification became obligatory that the number of ESRs in nuclear medicine exceeds the number of ESRs notified in the other activities. The number of ESRs in external-beam radiotherapy in 2024 remains stable with respect to 2023 but is nevertheless tending to decrease. On the other hand it is stable for interventional practices with about thirty ESRs in 2024.

Human factors are the cause of many significant events according to the notifiers. As a result, the training, the procedures, the working systems and the way in which they affect the performance of the personnel as regards decision making and execution of the key radiation protection measures are not sufficiently questioned.

ASN also notes that the relevance and effectiveness of the corrective actions defined after reporting an ESR to prevent its recurrence are not sufficiently assessed. The organisation of training and information sessions, reminders of instructions and the addition of check points are measures that are frequently mentioned in the experience feedback reports sent to ASN by the centres. Despite this, similar ESRs are still notified in some of these centres, indicating that the measures have not been sufficiently effective to prevent recurrence of the events. ASN thus underlines the importance of taking account of the lessons learned from previous events, whether internal or external, and assessing the effectiveness of the corrective measures taken. ASN also points out that the investigations must be conducted with a systemic approach, including the examination of the HOFs involved such as the training, the procedures, the work methods and the way in which they affect the performance of the personnel as regards decision making and execution of the main radiation protection measures. This incident management approach should result

in more effective corrective actions to prevent the recurrence of similar significant events in the future.

In 2024, ASN informed the health professionals of two lessons learned from the analysis of ESRs which are of interest for patient radiation protection. It convened its “imaging experience feedback” WG to produce two experience feedback sheets in the following specialities:

- one in conventional radiology: “Experience feedback” sheet on the accidental modification of the exposure settings of a mobile radiology device (*see box page 241*);
- the other in therapeutic nuclear medicine: “Experience feedback” sheet concerning extra-hepatic complications after using yttrium-90 microspheres to treat a liver cancer (*see point 2.3.3.4*).

Within the framework of radiotherapy experience feedback WG, ASN also worked on the preparation of two “Experience feedback” sheets on the radiotherapy treatment safety: the first focuses on identity monitoring and the second on laterality error prevention. These two sheets will be published in early 2025.

3 — Synthesis and prospects

On the basis of the inspections carried out in 2024 and an analysis of the period enabling the entire installed base of facilities with risks to be covered, ASN considers that the state of radiation protection in the medical sector remains at a satisfactory level, relatively comparable from one year to the next, although with a number of persistent shortcomings.

It notes that the experimental clinical review initiatives, which began at the end of 2023 exclusively in radiotherapy and radiology under the control of the Ministry responsible for health, are going well but need to be continued for longer before being put into widespread application. ASN encourages their extension to the highest-risk activities, prioritising radio-surgery and therapeutic nuclear medicine, and calls upon the CNPs to take action as of now to set up review matrices. ASN moreover also encourages radiotherapy departments to embrace procedures for assessing new practices, like the procedure put in place for adaptive radiotherapy.

It also encourages the CNPs to take into account the need to update the radiation protection guides they have produced, using as a basis the results of the evaluation of the new system for training in patient radiation protection that ASN published in 2024.

ASN draws attention to the fact that the signals identified in 2023 and reiterated below lead to a degradation of the radiation protection culture. They are identified as factors contributing to ESRs and noted in inspections as factors explaining poorer compliance with the regulations:

- a widespread finding of diminished resources with strained staffing levels for radiographers, medical practitioners and medical physicists, with the development of temporary work and tasks being performed by personnel without the required qualifications;

- in imaging, recourse to service providers (RPOs) over which the medical centres have insufficient control, to assist the RPE-Os and medical physicists, which could lead to a loss of radiation protection skills and a lack of the flexibility necessary for the implementation of the regulatory radiation protection requirements (training, verifications, etc.);
- constant expansion of teleradiology with technical and organisational constraints linked to this method of organisation that are underestimated by the centres (communication problem, software interfaces);
- ASN will publish in 2025 the lessons learned from a study it has conducted on this subject;
- the complexification of organisational structures, with resource sharing and the risk of diluting responsibilities, in a context of reforms in the healthcare authorisations and the buying out of centres.

Consequently, ASN maintains its request that decision makers be attentive to the need to assess the impact of these changes on the organisational set-ups and the work of those involved and to precisely define their roles and responsibilities so that the radiation protection requirements are satisfied.

In radiotherapy, although the safety fundamentals are in place, radiotherapy departments are struggling to maintain learning from experience procedures with fewer meetings of experience feedback committees, insufficiently detailed ESR analyses and persistent difficulties in assessing the robustness of corrective actions. The recurrence of wrong-target errors (laterality, delineation and positioning errors in particular), the multiplication of simultaneous treatments of several locations and re-irradiations, in a context where more and more patients are receiving several radiotherapy treatments in the course of their lifetime, underline the need firstly to regularly assess the barriers put in place by capitalising on national experience feedback, and secondly to update the prospective risks analyses on the basis of local and national experience feedback. These studies are still incompletely conducted prior to technical and organisational changes.

In brachytherapy, the inspections confirm that the radiation protection rules are duly taken into account. The challenges associated with maintaining the resources and skills necessary for this activity in the years to come subsist. The gradual deployment of the new requirements relative to the protection of high-activity sources against malicious acts is continuing, particularly as regards putting in place a protection policy, measures for preventing unauthorised access to these sources and the identification and control of sensitive information. This situation is gradually improving but cannot yet be considered compliant.

In nuclear medicine, the inspections find that patient radiation protection is duly taken into account as concerns application of the principle of optimisation with recording and analysis of the DRLs, while underlining that further progress is required in QMS deployment. The ESRs reveal that the administration processes must be regularly assessed to ensure control of the medication circuit, particularly the processes that can lead to errors affecting several patients (use of the dose calibrator). ASN alerts the RNAs to the risk of extravasation with lutetium-177, which can lead to significant exposures at the injection site, and is currently working in collaboration with the professionals to establish the lessons learned from the notified ESRs. It has moreover published an “Experience feedback” sheet on the complications that occurred during the treatment of a hepatic cancer by radioembolisation using yttrium-90. Furthermore, particular attention must be paid to management of the effluents (functioning of decay tank alarms) and the waste generated by the patients, linked to the introduction of new radiopharmaceuticals. Lastly, despite some progress in the training of professionals, the situation observed in 2024 concerning occupational radiation protection and monitoring of equipment and sources (dosimetry analysis, verifications, coordination of prevention measures during concomitant activities) is less satisfactory.

In the area of FGIPs and more particularly in the operating theatre, regulatory nonconformities persist over the years, concerning the technical rules for fitting out facilities, radiation protection training requirements (occupational and patient radiation protection training courses) and the coordination of prevention measures during concomitant activities. ASN observes that the centres are turning increasingly to RPOs and that this outsourcing, if it is not adequately managed, leads to a dilution of the responsibilities of the RNAs and poorer assimilation of, or even a deterioration in, radiation protection. Furthermore, the inspections of employer private practitioners reveal poor knowledge of the statutory radiation protection obligations of the Labour Code with respect to themselves and their employees. Lastly, ASN observed that several medical centres had not registered their radiation generating equipment and decided to take enforcement action against one hospital.

In 2025, ASNR will continue its inspections in the priority sectors, namely radiotherapy, radiosurgery, nuclear medicine, FGIPs and CT. In radiotherapy, after having led a reflection involving all the stakeholders, ASNR will update its inspection guidelines and launch its new four-yearly inspection programme in 2025. In nuclear medicine, it will adjust the inspection frequency to better integrate the radiation protection risks, particularly for the departments conducting clinical trials. In radiotherapy and nuclear medicine respectively it will continue its specific inspections on the command of the accelerator calibration process and the verification of non-contamination on the basis of the lessons learned from the ESRs notified in the last few years. Concerning the FGIPs, ASNR will continue to conduct targeted inspections of private practitioners with employer status. Lastly, having observed deficiencies in dental surgeons’ command of the utilisation of CBCT and the deployment of the optimisation approach during the work to update ASN resolution

2019-DC-0667 on the diagnostic reference levels, ASNR will initiate an inspection campaign in this area. As part of this campaign it will provide the RNAs with a self-assessment matrix for the dental surgeons.

On the regulatory front, in 2025 ASNR will revise ASN resolution 2019-DC-0667 of 18 April 2019 setting DRL values, to update the values for mammography and CBCT procedures. It will continue the preparatory work for the revision of ASN resolution 2008-DC-0095 of 29 January 2008 laying down the technical rules applicable to the disposal of effluents and waste contaminated by radionuclides. ASNR will also publish in 2025 the lessons learned from its teleradiology study.

Lastly, particular attention is still focused on the deployment of new therapy techniques and practices (radiotherapy, ITR). ASNR will continue its work in cooperation with the various institutional actors in the health sector, the professional organisations and assisted by its groups of experts, particularly the Canpri, particularly with regard to flash radiotherapy and the project group set up to define the adaptive radiotherapy evaluation methods which will be deployed as of 2025. In therapeutic nuclear medicine, the radiation protection risks for patients and their family circle, workers, and the management of effluents and waste are a priority in a context of introduction of new radiopharmaceuticals, projected increase in the number of patients eligible for these new treatments with limited infrastructure and the conditions of treatment on an out-patient basis. ASNR will give an opinion in early 2025 based on the work of IRSN and GPRP and the lessons learned from the European Commission’s SimpleRad project.

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**Sources of ionising
radiation and their
industrial, veterinary
and research
applications**



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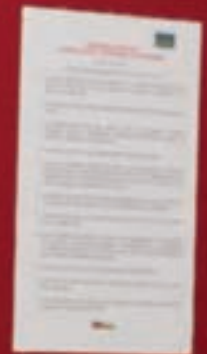
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The industrial and research sectors have been using sources of ionising radiation in a wide range of applications and locations for many years now. The purpose of the radiation protection regulations is to check that the safety of workers, the public and the environment is properly ensured. This protection involves more specifically ensuring proper management of the sources, which are often portable and used on worksites, and monitoring the conditions of possession, use and disposal, from fabrication through to end of life. It also involves monitoring the main stakeholders, that is to say the source manufacturers and suppliers, and enhancing their accountability.

The radiation sources used are either radionuclides – essentially artificial – in sealed or unsealed sources, or electrical devices generating ionising radiation. The applications presented in this chapter concern the manufacture and distribution of all sources, the industrial, research and veterinary uses (medical activities are presented in chapter 7) and activities not regulated under the Basic Nuclear Installations (BNIs) System (these are presented in chapters 10, 11 and 12).

The updating of the regulatory framework for nuclear activities established by the Public Health Code is leading to a tightening of the principle of justification, consideration of natural radionuclides, and the implementation of a more graded approach in the administrative systems and measures to protect sources against malicious acts. As of January 2019, the regulation of industrial, research and veterinary activities has been substantially modified by the extension of the notification system to certain nuclear activities that use radioactive sources. The continuation of the work to tailor the administrative systems to the radiation exposure risks involved in the various nuclear activities crossed a milestone in 2021 with the entry into force on 1 July of the new simplified authorisation system called “registration”.

Since 2022, the French Nuclear Safety Authority (ASN) has been continuing the work of revising the forms detailing the content of the authorisation application to be submitted by the licensees, in order to complete the comprehensive overhaul of the system regulating these nuclear activities.

1 — Industrial, research and veterinary uses of ionising radiation

1.1 Uses of sealed radioactive sources

Sealed radioactive sources are defined as sources whose structure or packaging, in normal use, prevents any dispersion of radioactive substances into the surrounding environment. Their main uses are presented below.

1.1.1 Verification of physical parameters

The operating principle of these physical parameter verification devices is the attenuation of the signal emitted: the difference between the emitted signal and the received signal can be used to assess the desired information.

The most commonly used radionuclides are carbon-14, cobalt-60, krypton-85, caesium-137, promethium-147 and americium-241. The source activities range from a few kilobecquerels (kBq) to a few gigabecquerels (GBq).

The sources are used for the purpose of:

- Atmospheric dust measurement: the air is permanently filtered through a tape placed between the source and detector and running at a controlled speed. The intensity of radiation received by the detector depends on the amount of dust on the filter, which enables this amount to be determined. The most frequently used sources are carbon-14 (with an activity of 3.5 megabecquerels – MBq) or promethium-147 (with an activity of 9 MBq). These measurements are used for air quality monitoring by verifying the dust content of discharges from industrial plants.

- Paper weight measurement: a beam of beta radiation passes through the paper and hits a detector situated opposite. The signal attenuation on this detector indicates the density of the paper, and therefore its weight per unit area. The sources used are generally krypton-85 or promethium-147, with activities of 3 GBq at the most.

- Liquid level measurement: a gamma radiation beam passes through the container holding the liquid. It hits a detector situated opposite. The signal attenuation measured on this detector indicates the filling level of the container and automatically triggers certain operations (stop/continue filling, alarm, etc.). The radionuclides used depend on the characteristics of the container and the content.

USE OF SEALED RADIOACTIVE SOURCES BY END-PURPOSE



- The sources generally used are americium-241 (with an activity of 1.7 GBq) or caesium-137 – barium-137m (with an activity of 37 MBq), as the case may be.
- Density measurement and weighing: the principle is the same as for the above two measurements. The sources used are generally americium-241 (with an activity

- of 2 GBq), caesium-137 – barium-137m (with an activity of 100 MBq) or cobalt-60 (with an activity of 30 GBq).
- Soil density and humidity measurement (gammadensimetry), particularly in agriculture and public works. These devices function with a source of caesium-137 and a pair of americium-beryllium sources.

- Diagraphy (logging), which enables the geological properties of the subsoil to be examined by inserting a measurement probe containing a source of cobalt-60, caesium-137, americium-241 or californium-252. Some sources used are high-activity sealed sources.

1.1.2 Neutron activation

Neutron activation consists in irradiating a sample with a flux of neutrons to activate the atoms in the sample, which renders the sample radioactive. The number and the energy of the gamma photons emitted by the sample in response to the neutrons received are analysed. The information collected is used to determine the concentration of atoms in the analysed material.

This technology is used in archaeology to characterise ancient objects, in geochemistry for mining prospecting and in industry (study of the composition of semiconductors, analysis of raw mixes in cement works).

Given the activation of the analysed material, this requires particular vigilance with regard to the nature of the objects analysed. Articles R.1333-2 and R.1333-3 of the Public Health Code prohibit the use of materials and waste originating from a nuclear activity for the manufacture of consumer goods and construction products if they are, or could be, contaminated by radionuclides, including by activation. Waivers may however be granted in a very limited number of cases (*see point 2.2.1*).

1.1.3 Other common applications

Sealed radioactive sources can also be used for:

- gamma radiography which is a non-destructive inspection method (*see point 3.3*);
- industrial irradiation, used for sterilisation in particular (*see point 3.2*);
- eliminating static electricity;
- calibrating radioactivity measurement devices (radiation metrology);
- practical teaching work concerning radioactivity phenomena;
- detection by electron capture. This technique uses sources of nickel-63 in gaseous phase chromatographs and can be used to detect and dose various chemical elements;

- ion mobility spectrometry used in devices that are often portable and used to detect explosives, drugs or toxic products;
- detection by X-ray fluorescence. This technique is used in particular for detecting lead in paint. The portable devices used today contain sources of cadmium-109 (half-life 464 days) or cobalt-57 (half-life of 270 days). The activity of these sources can range from 400 MBq to 1,500 MBq. This technique, which uses a large number of radioactive sources nationwide (nearly 4,000 sources), is the result of a legislative system designed to prevent lead poisoning in children by requiring a check on the lead concentration in paints used in residential buildings constructed before 1 January 1949 for any sale, new rental contract, or work significantly affecting the coatings in the common parts of the building.

Graphs 1A and 1B (*see previous page*) show the number of licensed, registered or notified facilities using sealed radioactive sources in the identified applications. They illustrate the diversity of these applications and their development over the last five years.

It should be noted that:

- a given facility may carry out several activities, and if it does, it appears in Graph 1 (A and B) and the following diagrams for each activity;
- the breakdown between the licensing, registration and notification system (radioactive sources and electrical devices emitting ionising radiation) for a given application is not yet stabilised, because the changes of administrative system concerning the nuclear activities subject to notification since 1 January 2019, are going to extend through to 1 July 2026 (*see point 2.4.2*) for those subject to registration since 1 July 2021.

1.2 Uses of unsealed radioactive sources

The main radionuclides used in the form of unsealed sources in non-medical applications are phosphorus-32 or 33, carbon-14, sulphur-35, chromium-51, iodine-125 and tritium. They are used in particular in research and in the pharmaceutical sector. They constitute a powerful investigative tool in cellular and molecular biology. Using radioactive tracers incorporated into molecules is common practice in biological research. There are also a number of industrial uses, for example as tracers or for calibration or teaching purposes. Unsealed sources are used as tracers for measuring wear, detecting leaks or friction spots, building hydrodynamic models and in hydrology.

As at 31 December 2024, 532 facilities were authorised to use unsealed radioactive sources (to which can be added 139 facilities covered by the registration system).

Graph 2 specifies the number of facilities licensed (or registered) to use unsealed radioactive sources, according to the various listed applications, in the last five years.

1.3 Uses of electrical devices emitting ionising radiation

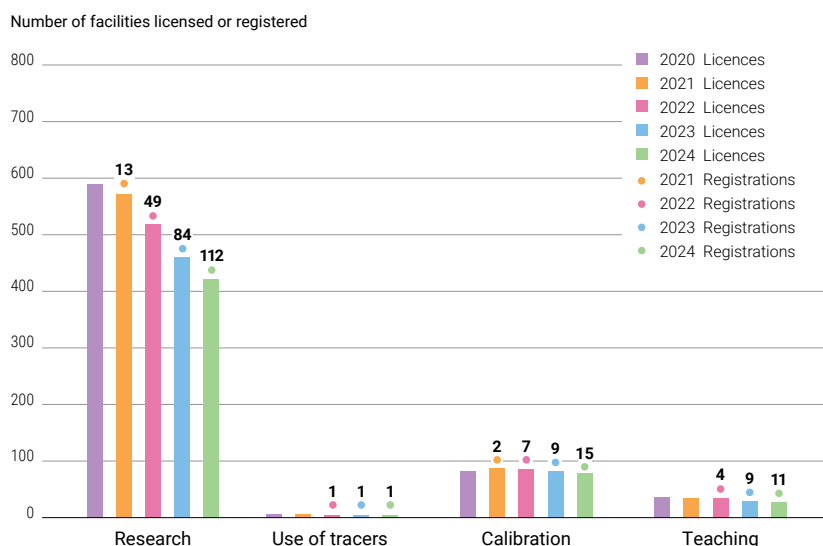
1.3.1 Main industrial applications

In industry, electrical devices emitting ionising radiation are used mainly in non-destructive testing, where they replace devices containing radioactive sources.

Graphs 3A and 3B (*see next page*) show the number of facilities using electrical devices generating ionising radiation in the listed applications under the licensing, registration or notification systems respectively. They illustrate the diversity of these applications and their development over the last five years. This development is closely related to the regulatory changes which have gradually created a new system of licensing or notification, and more recently registration (*see point 2.4.2*), concerning the use of these devices. At present, measures to bring the professionals concerned into compliance are very widely engaged in many activity sectors.

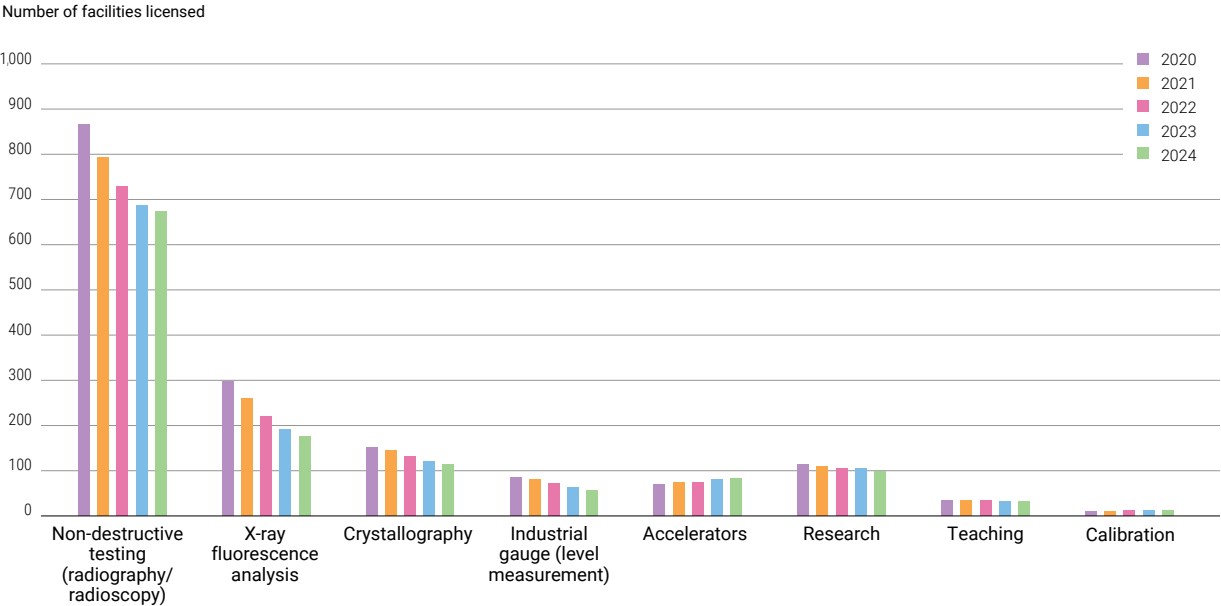
The electrical devices emitting ionising radiation are chiefly X-ray generators. They are used in industry for non-destructive structural analyses (analysis techniques such as tomography, diffractometry, also called X-ray crystallography, etc.), checking the quality of weld beads or inspecting materials for fatigue (in aeronautics in particular).

GRAPH 2 Use of unsealed radioactive sources by end-purpose

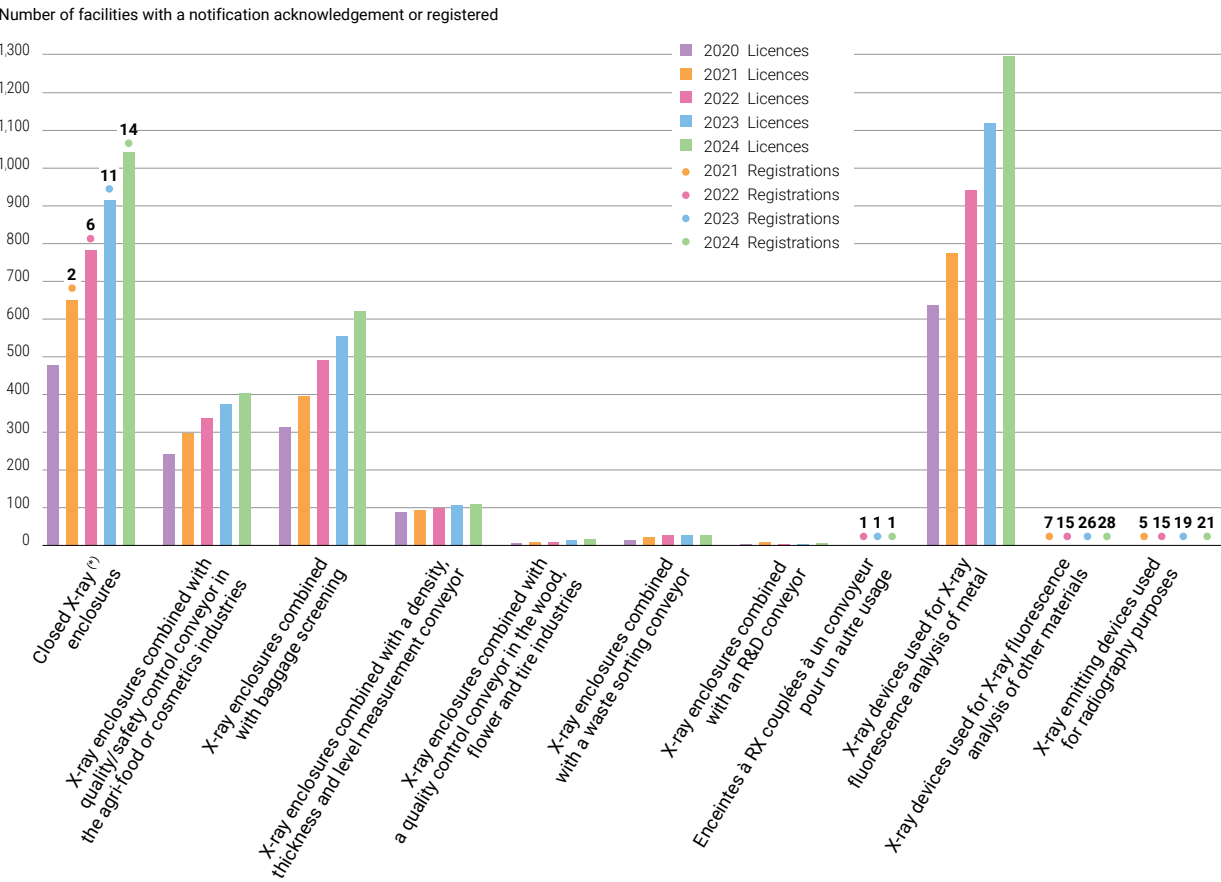


USE OF ELECTRICAL DEVICES EMITTING IONISING RADIATION
BY END-PURPOSE (VETERINARY SECTOR EXCLUDED)

GRAPH 3A Breakdown of licences for electrical devices emitting ionising radiation



GRAPH 3B Breakdown of notifications or registrations of electrical devices emitting ionising radiation



These devices, which function using the principle of X-ray attenuation, are used as industrial gauges (measurement of drum filling, thickness measurement, etc.), inspection of goods containers or luggage and also the detection of foreign bodies in foodstuffs.

The increase in the number of types of device available on the market can be explained more particularly by the fact that when possible, they replace devices containing radioactive sources. The advantages of this technology with regard to radiation protection are linked in particular to the total absence of ionising radiation when the equipment is not in use. Their utilisation does nevertheless lead to worker exposure levels that are comparable with those resulting from the use of devices containing radioactive sources.

Baggage inspection

Ionising radiation is used constantly in security screening checks, whether for the systematic verification of baggage or to determine the content of suspect packages. The smallest and most widely used devices are installed at the inspection and screening checkpoints in airports, in museums, at the entrance to certain buildings, etc.

The devices with the largest inspection tunnel areas are used for screening large baggage items and hold baggage in airports, as well as for air freight inspections. These devices are supplemented by tomographs, which give a series of series of cross-sectional images of the object being examined.

The irradiation zone inside these appliances is sometime delimited by doors, but most often simply by one or more lead curtains.

X-ray body scanners

This application is mentioned for information only, since the X-ray scanners are not currently used for security checks on people in France (in application of Article L. 1333-18 of the Public Health Code). Some experiments have been carried out in France using non-ionising imaging technologies (millimetre waves).

Inspection of consumer goods

The use of devices for detecting foreign bodies in certain consumer products has developed over the last few years, such as for detecting unwanted items in food products or cosmetics.

X-ray diffraction analysis

Research laboratories are making increasing use of small devices of this type, which are self-shielded. Experimental devices used for X-ray diffraction analysis can however be made up from parts obtained from various suppliers (goniometer, sample holder, tube, detector, high-voltage generator, control console, etc.) and assembled by the experimenters themselves.

X-ray fluorescence analysis

Portable X-ray fluorescence devices are used for the analysis of metals and alloys.

Measuring parameters

These devices, which operate on the principle of X-ray attenuation, are used as industrial gauges for measuring fluid levels in cylinders or drums, for detecting leaks, for measuring thicknesses or density, etc.

Irradiation treatment

More generally used for performing irradiations, the self-shielded devices exist in several models that sometimes differ only in the size of the self-shielded chamber, while the characteristics of the X-ray generator remain the same.

Radiography for checking the quality of weld beads or for the fatigue inspection of materials is detailed in point 3.1.1.

1.3.2 Veterinary diagnostic radiology

In 2024, the profession counted 21,494 veterinary surgeons, about 20,000 non-veterinarian employees and 6,641 veterinary facilities. These facilities increasingly belong to large groups, sometimes set up as a network grouping several hundred veterinary practices, thereby allowing the sharing of resources between facilities. This trend goes hand in hand with the tendency for veterinary surgeons to no longer necessarily want to own their own practice. Private practice facilities owned by veterinary surgeons nevertheless still exist, sometimes with special legal statuses allowing, for example, several veterinary surgeons exercising the profession on an individual basis to group together. Veterinary surgeons use diagnostic radiology devices for purposes similar to those used in human medicine. Veterinary diagnostic radiology activities essentially concern pets:

- some 5,000 veterinary facilities in France have at least one diagnostic radiology device;
- about 140 computed tomography scanners are used in veterinary applications;
- other practices drawn from the medical sector are also implemented in specialised centres: scintigraphy, brachytherapy, external-beam radiotherapy and interventional radiology.

The treatment of large animals (mainly horses) requires the use of more powerful devices installed in specially equipped premises (radiography of the pelvis, for example) and portable X-ray generators, used indoors – whether in dedicated premises or not – or outdoors.

In order to better ensure compliance with regulatory requirements, ASN introduced a notification system in 2009 for what were

termed “pet-care activities” involving less serious radiation risks (*see point 2.4.2*). This simplification has led to regularisation of the administrative situation of a growing number of veterinary facilities (*see Graph 4*).

To continue grading the regulatory requirements to the radiation exposure risks, all activities using electrical devices emitting X-rays used for veterinary diagnostic radiology come under the registration system (*see point 2.4.2*), with the exception of pet-care activities which remain eligible for the notification system). Consequently, only a few high-risk activities (brachytherapy, external-beam radiotherapy and interventional radiology) stemming from the medical sector are still subject to licensing.

The devices used in the veterinary sector are sometimes derived from the medical sector. However, the profession is increasingly adopting new devices specially developed to meet its own specific needs.

With regard to veterinary facilities, the administrative situation has been continuously improving for a number of years now. At the end of 2024, ASN counted nearly 6,000 notifications, registrations or licenses, that is to say virtually all of the veterinary facilities identified as using ionising radiation in France.

Among the veterinary activities, those performed on large animals (mainly horses) outside specialised veterinary practices (under “field” conditions), are considered to be those with the most significant radiation exposure risks, more specifically for persons external to the veterinary practice taking part in these procedures (horse owners and stable lads).

During its various oversight actions (carried out as and when required or during thematic campaigns) covering all veterinary activities involving ionising radiation, ASN has seen the results of the efforts the veterinary bodies have made in the last few years to comply with the regulations and has noted good field practices in the inspected veterinary facilities, including in particular:

- worker occupational exposure monitoring by passive dosimetry;
- the virtually systematic use of personal protective equipment;
- an optimisation approach to the associated operations in nearly all the facilities using ionising radiation for performing diagnostic radiology on large animals.

The profession must nevertheless remain attentive to the following points:

- the initial and periodic verifications of the radiation devices and the radiology premises;
- the radiological zoning, particularly when an operation area has to be set up;

- the radiation protection of people external to the veterinary facilities who may participate in the diagnostic procedures;
- the formalisation and traceability of the documents proving due compliance with the regulatory requirements relating to radiation protection.

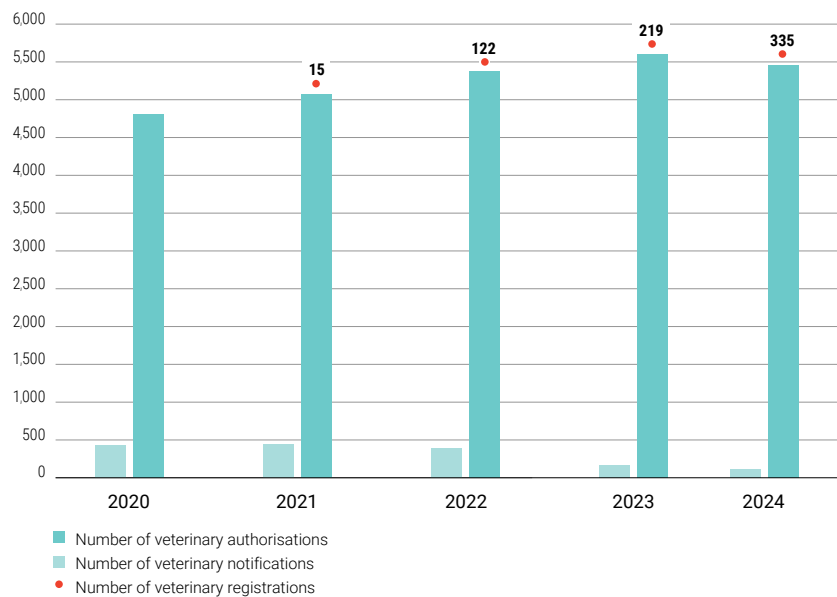
There are also some (rare) cases of veterinary facilities in which the radiation protection organisation is highly unsatisfactory. These shortcomings can lead ASN to take more stringent or even enforcement measures, if a “soft” approach has no effect.

Over the last few years ASN has also observed large-scale recourse to Radiation Protection Organisations (RPOs) external to the veterinary facilities to fulfil the function of Radiation Protection Expert (RPE) in these facilities. Such outsourcing is possible, but must not reduce the sense of responsibility of the veterinary surgeons, who retain prime responsibility for appropriate radiation protection in their facilities.

The strong nationwide commitment of the profession to harmonising practices, raising awareness, training student veterinary surgeons and drafting “framework documents” and guides is considered very positive by ASN, which has regular interchanges with the profession’s national bodies (more particularly the veterinary radiation protection commission).

These interchanges enable ASN to take the particularities of the veterinary environment into account when defining its policy. For example, in 2024 they led ASN to introduce an administrative simplification for non-salaried veterinary surgeons (private practice associate, locum or

GRAPH 4 Use of electrical devices generating ionising radiation for veterinary activities



consultant veterinary surgeon) who use the diagnostic devices provided by a veterinary facility. This simplification, which takes into account low radiation exposure risks, is therefore not applicable to activities that are subject to the licensing system and present substantial risks.

1.3.3 The other uses of electrical devices emitting ionising radiation

This category covers all the electrical devices emitting ionising radiation other than those mentioned above and which

are not concerned by the licensing, registration or notification exemption criteria set out in Article R. 1333-106 of the Public Health Code.

This category includes, for example, devices generating ionising radiation but not used for this property, namely ion implanters, electron-beam welding equipment, klystrons, certain lasers, certain electrical devices such as high-voltage fuse tests.

Lastly, some applications use particle accelerators (see point 3.3.1).

2 — The legislative and regulatory framework for industrial, research and veterinary activities

2.1 The authorities regulating the sources of ionising radiation

ASN is the Authority that grants the licenses, issues the registration decisions and receives the notifications, depending on the regulatory regime applicable to the nuclear activity concerned.

However, to simplify administrative procedures for licensees already licensed under another system, the Public Health Code makes specific provisions. This concerns more specifically:

- The radioactive sources held, manufactured and/or used in installations licensed under the Mining Code (Article L. 162-1) or, for unsealed radioactive sources, those held, manufactured and/or used in Installations Classified for Protection

of the Environment (ICPEs) which come under Articles L. 511-1 to L. 517-2 of the Environment Code, and have a licensing system. The Prefect is responsible for including, in the licenses he delivers, radiation protection requirements for the nuclear activities carried out on the site.

- The installations and activities relating to national defence, for which Defence Nuclear Safety Authority (ASND) is responsible for regulating the radiation protection aspects.

- The installations authorised under the BNI legal system. ASN regulates the radioactive sources and electrical devices emitting ionising radiation necessary for the operation of these installations under this system. Holding and using other sources within the bounds of the BNI remain subject to licensing pursuant to Article R. 1333-118 of the Public Health Code.

These provisions do not exempt the licensee from complying with the requirements of the Public Health Code, and in particular those relative to source acquisition and transfer; they do not apply to the distribution, importing and exporting of radioactive sources, which remain subject to ASN licensing under the Public Health Code.

Only the facilities possessing unsealed radioactive substances in quantities exceeding 1 tonne (t) or managing radioactive waste in quantities exceeding 10 cubic metres (m³) for either of the activities are subject to the system governing ICPEs (excluding the medical sector and particle accelerators). Any sealed radioactive sources also possessed or used by these establishments are regulated by ASN under the Public Health Code.

Nuclear materials are subject to specific regulations provided for in Article L. 1333-1 *et seq.* of the Defence Code. Application of these regulations is overseen by the Minister of Defence for nuclear materials intended for defence needs, and by the Minister in charge of energy for nuclear materials intended for any other use.

2.2 Unjustified or prohibited activities

2.2.1 Application of the ban on the intentional addition of radionuclides in consumer goods and construction products

The Public Health Code states “*that any addition of radionuclides [...] to consumer goods and construction products is prohibited*” (Article R. 1333-2). Thus, the trading of accessories containing sources of tritium such as watches, key-rings, hunting equipment (sighting devices), navigation equipment (bearing compasses) or river fishing equipment (strike detectors) is specifically prohibited. Article R. 1333-4 of this same Code provides that waivers to these prohibitions can, if they are justified by the advantages they bring, be granted by Order of the Minister responsible for health and, depending on the case, by the Minister responsible for consumer goods or the Minister responsible for construction, after obtaining the opinion of ASN and of the High Council for Public Health (HCSP). ASN considers that granting waivers to the regulations must remain very limited.

This waiver to the regulations was implemented for the first time in 2011 for a waiver request concerning the use of a neutron analysis device in several cement works of the Lafarge-Holcim group, a waiver that has since been renewed. In 2022, a waiver on neutron analysis was also granted for one of the cement works of the Ciments Calcia group. This neutron analysis device is based on a different technology to that used in the Lafarge-Holcim group cement works, namely an accelerator rather than a sealed radioactive source. In 2023, ASN was asked to give its opinion on the waiver requests concerning another cement works of the Ciments Calcia group and three cement works of the Eqiom group. These requests are related to the use of a particle accelerator, are currently under review and were the subject of additional information requests in 2024.

It was also applied in 2014 for light bulbs containing very small quantities of radioactive substances (krypton-85 or thorium-232), serving mainly for applications requiring very high intensity lighting such as public places, work places, or for certain vehicles (Order of 12 December 2014 of the Ministers responsible for

health and construction, ASN opinion 2014-AV-0211 of 18 September 2014). The waiver was renewed in 2019 (Order of 25 May 2020 of the Ministers responsible for ecological and solidarity-based transition, for solidarity, health, and the economy and finance (ASN opinion 2019-AV-0340 of 26 September 2019).

A waiver was moreover granted in 2019 to the Tunnel Euralpin Lyon-Turin for the use of neutron analysis devices (Order of the Ministers responsible for health and the energy transition of 19 August 2019, ASN opinion 2019-AV-0326 of 21 May 2019).

Conversely, a waiver request to allow the addition of radionuclides (tritium) in some watches was denied (Order of 12 December 2014, ASN opinion 2014-AV-0210 of 18 September 2014).

The list of consumer goods and construction products concerned by an ongoing waiver request or for which a waiver has been granted is published on the website of the French High Committee for Transparency and Information on Nuclear Safety (HCTISN).

2.2.2 Application of the principle of justification for existing activities

The justification of existing activities must be re-assessed periodically in the light of current knowledge and technological changes in accordance with the principle described in point 2.4.1. If the activities are no longer justified by the benefits they bring, or with respect to other non-ionising technologies that bring comparable benefits, they must be withdrawn from the market. A transient period for definitive withdrawal from the market may be necessary, depending on the technical and economic context, particularly when a technological substitution is necessary.

Smoke detectors containing radioactive sources

Devices containing radioactive sources were used for several decades to detect smoke in buildings as part of the fire-fighting policy. Several types of radionuclides have been used (americium-241, plutonium-238 and radium-226). The activity of the most recent sources used does not exceed 37 kBq, and the structure of the detector, in normal use, prevents any release of radioactive substances into the environment.

New non-ionising technologies have gradually been developed for this type of detection. Optical devices now provide comparable detection quality, and can therefore satisfy the regulatory and normative fire detection requirements. ASN therefore considers that smoke detection devices using radioactive sources are no longer justified and that ionic smoke detectors must be replaced.

The regulatory framework governing their withdrawal was put in place by the Order of 18 November 2011 and the two ASN resolutions 2011-DC-0252 and 2011-DC-0253 of 21 December 2011.

This regulatory framework aimed at:

- planning the removal of some 7 million Ionisation Chamber Smoke Detectors (ICSDs) from approximately 300,000 sites over ten years;
- supervising the maintenance or removal operations, which necessitate certain precautions with regard to worker radiation protection;
- preventing any uncontrolled removals and organising the collection operations in order to avoid detectors being directed to an inappropriate disposal route, or even simply being abandoned;
- monitoring the pool of detectors.

In this context, as at 31 December 2024, ASN had issued 415 acknowledgements of notification and 7 national licenses (issued to industrial groups with a total of 74 agencies) for ICSD removal activities. Among these companies, four are authorised to perform ICSD decommissioning operations, thereby guaranteeing a disposal route for the existing detectors

In order to keep track of the pool of ICSDs, the French Institute for Radiation Protection and Nuclear Safety (IRSN) set up in 2015, in collaboration with ASN, a computerised system enabling the professionals working in this sector (maintenance technicians, installers and removal companies) to file annual activity reports on line. The transmitted information is nevertheless not exhaustive enough to establish a reliable assessment.

Although the removal operations have progressed over the last few years, not all the ICSDs have been removed by the deadline set in the Order of 18 November 2011, that is to say 5 December 2021. It is estimated that nearly one million ICSDs are still installed. It is considered that nearly 600,000 detectors have been removed since 2021. Faced with this situation, ASN has been discussing with the professionals on continuing regulating the possession of such detectors and their removal and dismantling operations in order to complete the transition of all the fire detection devices to the optical technology, while at the same time allowing for safe disposal of the removed ICSDs and the radioactive sources they contain. ASN has also continued discussions with other actors concerned by the removal of these devices, notably the Ministry of Energy Transition (MTE), in order to study the various possible regulatory options. These reflections have not resulted in new regulatory provisions, but this does not call into question the removal and dismantling operations governed by the notifications, registrations or licenses issued by ASN, which enables the removal of the ionic detectors to continue, which remains the desired aim.

The deadline of 5 December 2021 indicated in the abovementioned Order led to an increase in removal operations at the end of 2021. Since then, the removal operations are continuing and the number of ICSDs remaining is gradually decreasing.

ASN continues to maintain close relations with Qualdion, an association created in 2011 which labels the companies that comply with the regulations relative to radiation protection and fire safety. The list of Qualdion-labelled companies is available on the Internet. ASN participates with the association in communication campaigns targeting the holders of ionic detectors and the professionals (Expoprotection trade fair, Mayors' trade fair, etc.).

Surge suppressors

Surge suppressors (sometimes called lightning arresters), not to be confused with lightning conductors, are small objects with a very low level of radioactivity used to protect telephone lines against voltage surges in the event of lightning strike. These are sealed devices, often made of glass or ceramic, enclosing a small volume of air containing radionuclides to pre-ionise the air and facilitate electrical sparkover. The use of surge suppressors has been gradually abandoned since the end of the 1970s, but the number remaining to be removed, collected and disposed of is still very high (several million units). When installed, these devices represent no risk of exposure for individuals. However, there can be a risk of exposure and/or contamination, albeit very low, if these objects are handled without precautions or if they are damaged. ASN issued a reminder to the company Orange (formerly *France Télécom*), which has begun an experimental process to identify, remove, sort and dispose of surge suppressors in the Auvergne-Rhône-Alpes region and has proposed a national removal and disposal plan. This plan was presented to ASN, and led in September 2015 to the issuing of a license governing the removal of all surge suppressors containing radionuclides present on the Orange network in France and their interim storage on identified sites. This license was renewed in 2021. The search for a disposal route is in progress in collaboration with Andra, the French National Agency for Radioactive Waste Management. This progressively implemented removal and disposal plan was completed in 2024. Lastly, *Réseau de Transport d'Électricité* (RTE), the French power transmission utility, has also filed an application for a license in order to start a national plan for removal of the surge arresters installed on its network. A national licence regulating these surge arrester removal operations and their interim storage on specified sites was issued to RTE late 2022. As with Orange, RTE is working with Andra to find a disposal route.

Additional characterisations are going to begin, with the aim more specifically of determining whether or not occluded gases are present in the surge arresters (gases which could be present from the manufacturing stage in certain models) in order to subsequently determine the appropriate methods of dealing with these devices.

Lightning conductors

Radioactive lightning conductors were manufactured and installed in France between 1932 and 1986. The ban on the sale of radioactive lightning conductors was declared in 1987. This Order did not make the removal of installed radioactive lightning conductors compulsory. Consequently, there is no obligation at present to remove the radioactive lightning conductors installed in France, except in certain ICPEs (Order of 15 January 2008 which set the removal deadline at 1 January 2012) and in certain installations under Ministry of Defence responsibility (Order of 1 October 2007 which set a removal deadline at 1 January 2014).

ASN nevertheless considers it necessary for all existing radioactive lightning conductors to be removed and transferred to Andra, given the risks they can represent, depending in particular on their physical condition. For several years now ASN has been working to raise professional awareness of the radiation risks for workers and the public. ASN has stepped up its action in this respect by reminding the professionals of their obligations, particularly that of being licensed or registered by ASN for the removal and storing of lightning conductors pursuant to Articles L. 1333-1 and 2, L. 1333-8, and R. 1333-104 of the Public Health Code ASN conducts field oversight operations targeting the companies involved in recovering these objects, combined with unannounced inspections on the removal sites.

The number of lightning conductors installed in France was estimated at about 40,000 in the 1990's. Slightly more than 12,000 have already been removed and recovered by Andra. The current rate of removal is about 200 radioactive lightning conductors per year.

2.3 The regulatory changes

2.3.1 Tightening the regulation of electrical devices emitting ionising radiation

ASN considers that the regulatory oversight of suppliers of electrical devices emitting ionising radiation is still insufficient, when the placing of devices on the market is so vitally important for the optimisation of the future radiation exposure of users. The work carried out by ASN in this area, which at present is directed towards the use of these generators, particularly

in enclosures, has led to the publication of ASN resolution 2017-DC-0591 of 13 June 2017 setting the minimum technical design rules applicable to facilities that use X-rays.

This resolution came into effect on 1 October 2017. It replaced ASN resolution 2013-DC-0349 of 4 June 2013 without creating additional requirements for already compliant facilities. It concerns facilities in the industrial and scientific (research) sectors, such as industrial X-ray radiography in bunkers and veterinary radiology. It takes account of experience feedback and sets the radiation protection goals by adopting a graded approach to the risks.

ASN considers that these provisions, which are directed exclusively at the use these devices, must be supplemented by provisions concerning their actual design.

This is because, for electrical devices used for non-medical purposes, there is no equivalent of the "CE" marking that is mandatory for medical devices, certifying conformity with several European standards that cover various aspects, including radiation protection. Furthermore, experience feedback shows that a large number of devices do not have a certificate of conformity to the standards applicable in France. These standards have been mandatory for many years now, but some of their requirements have become partly obsolete or inapplicable due to the lack of recent revisions.

On the basis of the work done in collaboration with the Electrical Certification and Testing Entity (LCIE), the Alternative Energies and Atomic Energy Commission (CEA) and IRSN, draft texts have been produced with the aim of defining minimum radiation protection requirements for the design of these devices and an informal technical consultation of the stakeholders (suppliers, French and foreign manufacturers and the principal users) was conducted in 2015. The various contributions are currently being analysed with the assistance of IRSN and the reference players (CEA and LCIE). The conclusions of this work will be taken into account to adapt the regulatory framework and subject the supply of electrical devices emitting ionising radiation to licensing, in the same way as for radioactive sources. Since 2021, ASN has thus been conducting work to characterise the advantages, drawbacks and the feasibility of various regulatory provisions for regulating, on the basis of appropriate technical baselines (work conducted with IRSN in particular), the design of industrial radiography devices. The discussions with the General Directorate for Labour (DGT) on the various options are continuing and highlight the need to strengthen their link with the existing European framework.

Categorisation of radioactive sources

Radioactive sources have been classified by the IAEA since 2011 on the basis of predetermined exposure scenarios, in five categories from 1 to 5, according to their ability to create early harmful effects on human health if they are not managed safely and securely. Category-1 sources are considered extremely dangerous while those in category 5 are considered very unlikely to be dangerous. Sources in categories 1 to 3 are considered dangerous for humans to varying degrees.

This categorisation is based solely on the capacity of the sources to produce

deterministic effects in certain exposure scenarios and must not under any circumstances be considered as proof that there is no danger in exposure to a category 4 or 5 source, as such exposure could cause stochastic effects in the longer term. The principles of justification and optimisation (see point 2.4.1) must therefore be respected in all cases. This IAEA work has been taken up in an Appendix to the Public Health Code amended by Decree 2018-434 establishing various provisions in the nuclear field. Nevertheless, the IAEA categories 4 and 5 have been grouped together in category D of this Code.

2.3.2 The protection of ionising radiation sources against malicious acts

Although the safety and radiation protection measures provided for by the regulations guarantee a certain degree of protection of ionising radiation sources against the risk of malicious acts, they cannot be considered sufficient. Reinforcing the oversight of protection against malicious acts targeting sealed radioactive sources has therefore been encouraged by the International Atomic Energy Agency (IAEA), which published a Code of Conduct on the Safety and Security of Radioactive Sources, approved in 2003, supplemented in 2012 by two implementation guides relative to the security of radioactive sources and the security of radioactive material transport. As of 2004, France confirmed to the IAEA that it was working on applying the guidelines set out in this Code.

The organisation adopted for the oversight of protection against malicious acts

Measures implemented to ensure radiation protection, safety, and protection against malicious acts have many interfaces. Generally speaking, ASN's counterparts in other countries are responsible for oversight in these three areas (see Table 2 in chapter 2).

In France, the protection against malicious acts concerning nuclear materials, particularly those used in certain facilities termed "of vital importance" because they contribute to productions or services that are essential for the functioning of the country, is coordinated by a service under the authority of the Defence and Security High Official (HFDS) of the Ministry responsible for energy.

The changes in regulations adopted since early 2016 have led to an organisation for oversight of the protection of ionising radiation sources against malicious acts which takes into account the existing organisation by entrusting this oversight:

- to the service of the HFDS of the Ministry responsible for energy in facilities whose security is already under its control;
- to the Ministry of the Armed Forces in the locations placed under its authority;
- to ASN for the other nuclear activities.

The process necessary to set up this oversight, initiated by the Government in 2008 with the assistance of ASN, resulted in Ordinance 2016-128 of 10 February 2016 and then Decree 2018-434 of 4 June 2018 introducing various provisions concerning nuclear activities. These texts, which amend the Public Health Code, divide up the oversight duties in the various installations as indicated above, by including protection against malicious acts in the risks that must be taken into account by the persons/entities Responsible for Nuclear Activities (RNAs) and by the regulatory bodies when reviewing the licensing applications.

The sources and installations concerned

Oversight of source protection against malicious acts concerns all sources of ionising radiation, that is to say all the devices that could cause exposure to radiation. The majority of the regulatory measures are however taken to increase the security of the sources presenting the greatest radiological risks: this concerns radioactive sources of categories A, B and C as defined in the Public Health Code, which stems directly from that of the IAEA. The protection requirements are proportionate to the intrinsic dangerousness of the sources. The graded approach therefore implies stricter obligations for the sources (or batches of sources) in category A than in category C. Sealed sources that are not in categories A, B or C and whose activity exceeds the exemption threshold, and the other ionising radiation sources such as X-ray generators, are classified in category D.

In France, 270 facilities in the civil sector hold just under 6,200 radioactive sources of category A, B or C presenting real security

risks. These sources are used essentially for industrial purposes (irradiation, radiography, measurements, etc.) or medical purposes (such as telebrachytherapy and brachytherapy). Due to their frequent movements when on worksites, industrial radiography sources present particular security risks.

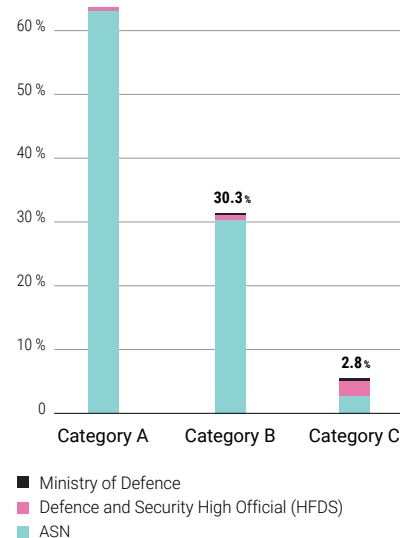
If sources of different categories are stored together, the lower category sources may be subject to the stricter security measures applicable to the higher category sources.

Regulations

The Decree modifying the regulatory part of the Public Health Code taken in application of Ordinance 2016-128 of 10 February 2016 (Decree 2018-434 introducing various provisions with regard to nuclear activities) was published on 4 June 2018. It contains several provisions concerning the protection of sources against malicious acts, and more specifically:

- the classification of ionising radiation sources and aggregation (batching) of radioactive sources into category A, B, C or D according to the intrinsic level of risks presented by these sources or batches of sources. The category A sources are the most dangerous and the category D sources the least dangerous (Article R. 1333-14 of the Public Health Code);

GRAPH 5 Breakdown of high-activity sealed sources according to their category and their oversight authority for protection against malicious acts



The sources in category A of the Public Health Code correspond to the IAEA category 1 sources.

The Public Health Code category B sources correspond to:

- the IAEA category 2 sources,
- the IAEA category 3 sources contained in a mobile or portable device.

The Public Health Code category C sources correspond to the IAEA category 3 sources not contained in a mobile or portable device.

International transfers of radioactive sources: the prior consent procedure



It is of crucial importance to ensure the control of sealed radioactive sources and to protect them against malicious acts during their import or export. The IAEA has published a document entitled "Guidance on the Import and Export of Radioactive Sources", with the aim of providing its members with a consistent international framework. This framework is not mandatory, but is intended to be taken into account by the IAEA member states in their regulations. It aims to ensure regulatory control that is as harmonised as possible throughout the transfer of the sources between the originating and destination countries.

The guidelines are complementary to those of the IAEA's Code of Conduct on the Safety and Security of Radioactive Sources. To date, 135 countries, including France, have undertaken to take up these principles in their regulations.

The Guidance on the Import and Export of Radioactive Sources was first published in 2005, two years after the approval of the Code of Conduct. The current version, revised in 2012, focuses primarily on category 1 and 2 radioactive sources (the most dangerous), used predominantly in medical and industrial applications.

Maintaining control of these sources during their import or export is vital given their high radioactivity, which makes them a threat in

the event of accidental radiation exposure or illegal or unauthorised use.

The guidance notably recommends that the consent of the importing country be obtained before export of category 1 sources is permitted and that the exporting company send notification to the importing country one week before the planned shipping date (for category 1 or 2 sources).

The aim is to know the dates on which category 1 or 2 sources or batches of sources arrive in or leave the national territory, so that a rapid response can be made in the event of an actual or attempted malicious act or an emergency situation (accident, climatic event, etc.).

ASN resolution 2015-DC-0521 of 8 September 2015 (see box page 260) has laid down these principles in French law. Forms have been drafted and "points of contact" have been appointed to streamline international information exchanges, as recommended in the IAEA guidance.

The consent requests involving France come essentially from three countries: the United States, Canada and the United Kingdom. There are just under ten import consents per year, and about half as many export consents.

ASN took part in the meeting organised by the IAEA in Vienna in 2024 on the occasion of the twentieth anniversary of the adoption

of the International Guidance on the Import and Export of Radioactive Sources, which was attended by 219 participants from 120 countries.

The objective was to discuss the regulatory methods adopted in each country (on the basis of the IAEA recommendations), to promote the best practices and to address the difficulties encountered with requests for radioactive source transfers between countries.

The need to continue to improve transparency and communication between the IAEA member countries in order to facilitate the consent processes during these movements was underlined.

ASN gave a presentation emphasising the importance of the accuracy of the information exchanged between countries and provided by the requesting parties.

The discussions confirmed both the need to train the personnel involved and the difficulties frequently encountered during these operations. For example, what action should be taken if the exporting country does not acknowledge the IAEA guidance principles or if the importing country is slow in providing the required information? Questions of this type were at the centre of the discussions, demonstrating the shared desire to find solutions that streamline the exchanges and ensure safe international transfers of sources.

- the obligation to notify promptly the various administrative authorities, particularly the regionally competent law enforcement agencies, of any actual or attempted malicious act or loss concerning a source of ionising radiation or a batch of radioactive sources of category A, B or C (R. 1333-22);
- the sending of sensitive information, that is to say elements that could facilitate malicious acts by separate, specially identified mail (R. 1333-130);
- the issuing of a nominative and written authorisation to the persons having access to ionising radiation sources or batches of radioactive sources in category A, B or C, transporting them, or having access to information concerning their protection against malicious acts (R. 1333-148).

Subsequently, the Ministerial Order setting the organisational and technical requirements to protect sources of ionising radiation (or batches of radioactive sources) against malicious acts was signed on 29 November 2019 and published in the *Official Journal of the French Republic* on 11 December 2019. Its provisions were brought progressively into effect over a period extending to the end of 2022. Today they are all applicable.

The Order of 29 November 2019 amended also applies to the transport of category A, B and C sources, whether individually or in batches.

The main requirements of this Order aim, by adopting a graded approach based on categories A, B, C (and D for two items), to have the licensee put in place physical barriers and equipment, along with a policy and an internal organisation to protect sources against malicious acts. These technical and organisational provisions are intended to:

- prevent or delay the theft of radioactive sources through access control measures, reinforcement of physical barriers and their openings (doors, windows, etc.), alarms and crossing-detection;
- protect sensitive information (access limited to duly authorised personnel, promotion of good information technology security practices);
- detect an actual or attempted malicious act (theft in particular) as early as possible;
- take action or alert the local law enforcement agencies after preparing their on-site actions;
- raise awareness, inform, and regularly train the personnel in the issue;
- periodically check the effectiveness of the equipment and organise exercises.

For obvious reasons of restricting access to sensitive information, some of the provisions of this Order, detailed in its appendices, were not published in the *Official Journal*. ASN therefore, within its area of competence, sent the relevant appendices by personalised letter to each of the RNAs concerned.

ASN also accompanied the publishing of the Order by actions in the regions at professional events between 2020 and 2022 and by holding ad hoc meetings with professionals concerned.

To help with the understanding of this Order, which introduced a new regulatory field that is little known to the RNAs, two important documents have also been produced:

- A guide produced jointly by ASN/SHFDS (Service of the Defence and Security High Official) so that professionals and inspectors alike have a common understanding of the requirements of the Order.
- A guide on assessing the break-in resistance of opening elements: doors, shutters, windows, etc. Nowadays, professional reference systems and standards addressing protection against malicious acts enable this aspect to be covered satisfactorily from the technical viewpoint. However, the majority of the facilities concerned were built at a time when little consideration was given to the question of malicious acts. Based on the work of IRSN, which has an office specialised in the physical protection of facilities, a guide assigning a number of points to the leaves, locks and hinges of an opening element enables it to be given an overall rating and decide whether it complies with the requirements of the appendices of the Order.

The forms used to apply for authorisation to exercise a nuclear activity have moreover been adapted, and two dedicated forms have been created for the category A, B or C sources or batches of sources.

Lastly, to supplement the information for professionals, a brochure intended for RNAs who only possess category D sources (for which the number of regulatory obligations is limited) is also available on asn.fr.

2.4 Licensing, registration and notification of ionising radiation sources used for industrial, research or veterinary purposes

2.4.1 Integration of the principles of radiation protection in the regulation of non-medical activities

With regard to radiation protection, ASN verifies application of the three major principles governing radiation protection which are written into the Public Health Code (Article L. 1333-2), namely: justification, optimisation of exposure and dose limitation.

Assessment of the expected benefit of a nuclear activity and the corresponding health drawbacks may lead to prohibition of an activity for which the benefit does not seem to outweigh the risk. Either generic prohibition is declared, or the license required for radiation protection purposes is not issued or is not extended. For the existing activities, the elements supporting implementation of the justification

principle are recorded in writing by the RNA, and are updated every five years and whenever there is a significant change in available knowledge or techniques.

Optimisation is a notion that must be considered in the technical and economic context, and it requires a high level of involvement of the professionals. ASN considers in particular that the suppliers of devices are at the core of the optimisation approach (see point 4). They are effectively responsible for putting the devices on the market and must therefore design them such that the exposure of the future users is minimised. ASN also checks application of the principle of optimisation when examining the license applications, when conducting its inspections, and when analysing reported significant events.

2.4.2 The licensing, registration and notification systems

Applications relating to the possession and utilisation of ionising radiation are examined by the ASN regional divisions, while those concerning the manufacture and supply of sources or devices containing sources are examined at the ASN head office by the Department of Transport and Sources (DTS). The entry into effect on 1 July 2018 of Decree 2018-434 of 4 June 2018, introducing various provisions in the nuclear field, has introduced a third administrative system lying between the notification system and the licensing system: it is a simplified authorisation system called the “registration system”.

ASN has prepared a classification system to allocate the various categories of

nuclear activities to one of these three systems, whose implementation began on 1 January 2019 with the entry into effect of the ASN resolution extending the notification system to additional nuclear activities which until then were subject to licensing, and continued on 1 July 2021 with the entry into effect of the resolution concerning the registration system.

The licensing system

Small-scale nuclear activities in the industrial sector stand out by their considerable diversity and the large number of licensees involved. The licensing system is designed to regulate the nuclear activities involving the greatest radiation protection implications, for which ASN checks, when examining the license application, that the applicant has identified the risks and that the measures intended to limit their effects have been studied and planned for. To support this process, licensing application forms adapted to each activity are available on asn.fr.

These forms are designed for the licensing applications to be formulated by the representative of a legal person, although it is possible for a physical person to apply for a license. These forms list the documents that must be enclosed with the application. All the documents listed in the appendix to ASN decision 2010-DC-0192 of 22 July 2010 must be held by the applicant and kept at the disposal of the inspectors in the event of inspection. On completion of the examination, and provided that the measures described by the applicant are satisfactory, a limited-term (usually 5 years) license is issued for the exercise of the nuclear activity.

International focus group on alternative technologies

Radioactive sources present radiation exposure and safety risks for their users, the general public and the environment, which must be taken into consideration in the reflection phase preceding the deployment of a nuclear activity. Consequently, in France, when technologies presenting lower risks than a nuclear activity are available under technically and economically acceptable conditions, they must be implemented instead of the nuclear activity initially envisaged: this is the principle of justification.

On this basis, as of 2014 and subsequently at the Nuclear Security Summit in Washington in April 2016, France was the initiator of an international initiative now supported by 31 countries and by Interpol. The aim is to support research into and the development of technologies that do not use high-activity sealed radioactive sources and to promote the use of these technologies.

In this context, since April 2015, ASN and the National Nuclear Security Administration (NNSA) of the United States of America have created an informal focus group, comprising several countries, to explore the replacement of high-activity radioactive sources by alternative technologies. The aim of this group, which meets once a year, is to foster greater awareness of the benefits of such alternatives and to share experience feedback from each country in this respect.

In December 2018, during the International Conference on Nuclear Security organised by the IAEA, the subject of alternative technologies was addressed by several presentations and two panel sessions, and the relevance of this focus group was underlined.

The group's meeting of 2024, like that of 2023, was a virtual on-line meeting held over three days and attended by 150 participants (experts representing governments, international organisations, private

enterprises and research institutes). The discussions focused on innovative applications of alternative technologies other than in the medical sector, thereby breaking away from the themes of the previous years. The significant progress made in the development of compact e-beam techniques, which consist in exposing products to be sanitised to a beam of accelerated electrons which can destroy certain microorganisms, was noted in particular. This technology, which does not use radioactive sources, has numerous applications ranging, for example, from sterilisation to the depollution of water and effluents and the reduction of the microbial load in foodstuffs.

These regular meetings provide the opportunity to highlight both successful initiatives in the implementation of alternative technologies and difficulties in the development or implementation of these technologies which must be the subject of complementary work.

To further the implementing of a graded approach in the oversight of the nuclear activities coming under the Public Health Code, ASN continued working on the update of the abovementioned resolution. A first step will be completed at the beginning of 2025, with the on-line availability of the new application form for authorisation to possess and use sealed radioactive sources. This update will complete the work started in 2018 which has already led to revising of the notification system and creation of the registration system (see next page).

The notification system

As part of the overhaul of the classification of nuclear activities into the three administrative systems introduced by the abovementioned Decree of 4 June 2018, ASN decided to implement a more graded approach, proportionate to the risks.

Its initial work focused on the notification system. Notification is a simple procedure which does not require the submission of any supporting documents. It is particularly suited to the nuclear activities that present the lowest risks for people and the environment.

Since April 2018, RNAs in the industrial, research or veterinary sectors, that comes under the notification system, can carry out the notification procedure via the ASN “on-line services” portal.

Through ASN resolution 2018-DC-0649 of 18 October 2018 amended, approved on 21 November 2018, ASN has extended the list of activities subject to notification. The notification system extension has to date concerned about 8,000 files which were previously subject to the licensing system.

The new registration system (simplified authorisation)

The new registration system came into effect on 1 July 2021, after approval on 4 March 2021 of ASN resolution 2021-DC-0703 of 4 February 2021. This resolution governs nuclear activities in industry, research and veterinary applications, as nuclear activities for medical purposes that come under this system are governed by another resolution (see chapter 7). This system applies to certain sources of ionising radiation, whether in the form of sealed or unsealed radioactive sources, and X-ray generators, where the risks and drawbacks of possessing or using them can be prevented by complying with the specific general requirements set by the resolution. The resolution therefore defines, apart from the nuclear activities concerned, the content of the simplified authorisation application and the conditions for exercising (specific general requirements) the nuclear activity with which the licensees must comply.

Its entry into effect marks the second stage – following that of extension of the notification system – of effective implementation of the reform of small-scale nuclear activity regulation, aiming to better materialise a graded approach to the risks. The resolution effectively implies significant alleviations in the administrative procedures compared with those for nuclear activities subject to licensing, such as: a simplified application (both in the information and the substantiation documents to provide), ten year registration validity by default (and even unlimited validity by default for certain nuclear activities), the possibility of applying for registration via the on-line registration service which is available on *asn.fr*, review and assessment by ASN within six months, with silence after six months being considered as acceptance of registration of the applicant nuclear activity.

Entry into effect of the registration system should ultimately concern between 1,200 and 2,000 licensees in industry, research and veterinary applications, hitherto subject to the licensing system. However, the number will not be able to be accurately quantified until a five-year period has expired (1 July 2026). This is because, in accordance with the principle of grandfathering, the licenses issued before 1 January 2021 will act as registration until the license reaches term, on condition that in the interim there is no change in the nuclear activity.

2.4.3 Statistics for the year 2024

Suppliers

In view of the fundamental role played by the suppliers of radioactive sources or devices containing them in the radiation protection of future users (see point 2.4.1), ASN exercises tightened oversight in this field. During 2024, 126 radioactive source supply license applications or license renewal applications were examined by ASN, and 35 inspections were carried out (all ionising radiation sources combined).

Users

The case of radioactive sources

In 2024, ASN reviewed and issued 6 new licences, 202 license renewals or updates, 46 license cancellations, and 166 registration decisions. ASN also issued 426 notification acknowledgements for sealed radioactive sources in 2024. Graph 6 shows the regulatory acts issued by ASN for radioactive sources in 2024 and, where applicable, their development over the last five years. The entry into effect of ASN resolution 2018-DC-0649 of 18 October 2018 amended (see point 2.4.2) is the main reason for the very large drop in the number of licenses issued in favour of the issuance of notification acknowledgements,

Administrative tracking of radioactive sources



Articles R. 1333-154, 156 and 157 of the Public Health Code provide for the prior registration by IRSN of transfers of radioactive sources and Article R. 1333-158 for administrative tracking of these sources.

ASN resolution 2015-DC-0521 of 8 September 2015 relative to the tracking and methods of registering radionuclides in the form of radioactive sources and products or devices containing them details the methods of registering transfers and the rules for tracking radionuclides in the form of radioactive sources.

This resolution, applicable as of 1 January 2016, takes into account the existing mode of functioning and supplements it as follows by:

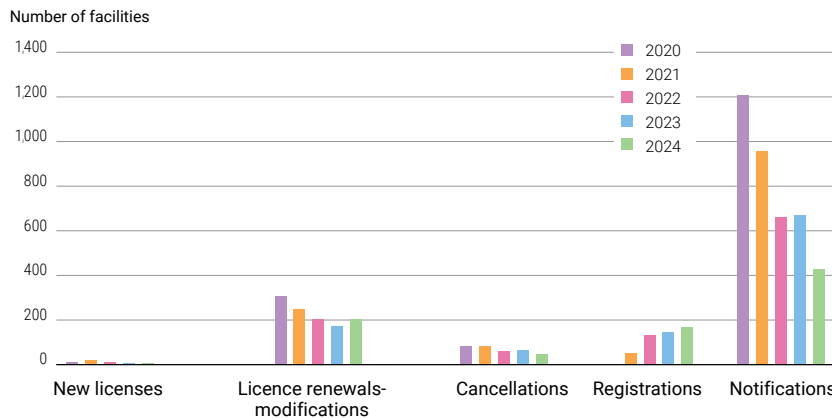
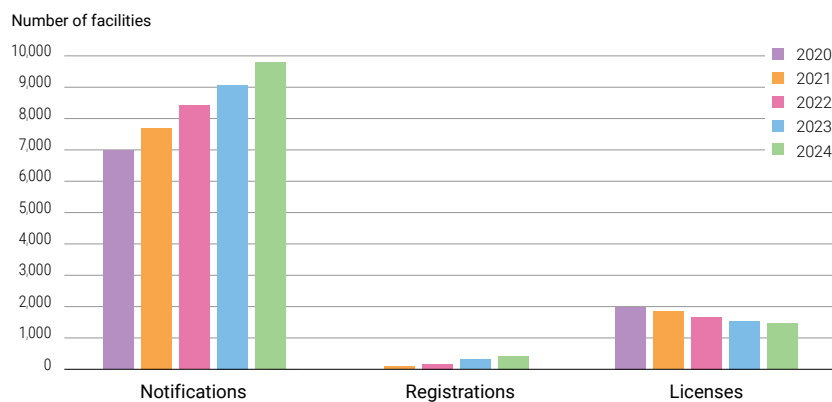
- grading source administrative tracking according to how dangerous the sources are;
- confirming the non-registration of sources whose activity is below the exemption thresholds;
- imposing deadlines between the registering of source transfer and the actual transfer;
- making it an obligation for each source to be accompanied by a “source certificate” indicating all its characteristics and which must be transmitted to IRSN within two months after receiving the source.

As of 1 January 2025, the missions ASN and IRSN are taken over by ASNR.

and illustrates the concrete application of the graded approach to risk control.

This drop will become greater in the coming years as the new registration system (see point 2.4.3) applicable since 1 July 2021 gradually increases in scale.

Once the license, registration or notification acknowledgement is obtained, the holder can procure sources. To do this, it receives supply request forms from IRSN, enabling IRSN to verify – as part of its duty to keep the national inventory of ionising radiation sources up to date – that the orders are in conformity with the license, registration or notification acknowledgement issued to the user and the license of its supplier. If the order is correct, the transfer is then recorded by IRSN, which notifies the interested parties that delivery can take place. In the event of difficulty, the transfer is not validated and IRSN refers the case to ASN (see box page above). As of 1 January 2025, further to the merging of ASN and IRSN, the entire process will be managed by the Authority for Nuclear Safety and Radiation Protection (ASNR), without this calling into question the verification and validation steps.

GRAPH 6 "User" licences, registrations and notifications for radioactive sources issued each year**GRAPH 7** "User" licences, registrations and notifications for electrical generators of ionising radiation in effect over the last five years

The case of electrical generators of ionising radiation

ASN has been responsible for the oversight of these devices since 2002, devices for which numerous administrative compliance actions are still required.

In 2024 it granted 23 new licenses, 115 license renewals or updates and issued 135 registration decisions for the use of electrical devices emitting X-rays. ASN also delivered 716 notification acknowledgements for electrical generators of ionising radiation. As with radioactive sources, the large reduction in the number of licenses issued and, conversely, the significant increase in notification acknowledgements and issuing of the first registration decisions, are the direct consequence of the entry into effect of the abovementioned ASN resolutions 2018-DC-0649 of 18 October 2018 and 2021-DC-0703 of 4 February 2021.

Altogether, 1,456 licences, 430 registrations and 9,785 notification acknowledgements for electrical devices emitting ionising radiation are in effect at the end of 2024. Graph 7 illustrates the development over the last few years.

3 — Assessment of the radiation protection situation in applications involving radiation risks in the industrial, research and veterinary sectors

3.1 Industrial radiography

Industrial radiography is a non-destructive inspection method that consists in obtaining an image of the material density of an object through which electromagnetic radiation is passed in the form of X-rays or gamma rays (gamma radiography). The image is obtained via a detector which can be a photographic silver film, a photostimulable screen with reusable memory or a set of digital detectors.

Industrial radiography can be used in particular to assess defects in material uniformity, such as weld beads, or to check for fatigue. It is widely used in fabrication and maintenance operations in diverse industrial sectors such as boilermaking, petrochemicals, nuclear power plants, public works, aeronautics and armament.

Radiography can be carried out in an indoor facility (in which case physical protection of the operators is ensured by the facility's radiation protection features and safety devices) or in worksite conditions (in which case the work area must be marked out).

3.1.1 The different methods used

Gamma radiography

Gamma radiography devices usually contain high-activity sealed sources, mainly iridium-192, cobalt-60 or selenium-75, whose activity can reach about twenty terabecquerels. A gamma radiography device is usually a mobile device which can be moved from one worksite to another.

It consists primarily of:

- a source projector, which acts as a storage container and ensures radiological protection when the source is not in use;
- a guide tube which guides the movement of the source up to the object to be examined;
- and a remote control cable allowing remote manipulation by the operator.

When the source is ejected out of the projector, the dose rates can reach several grays per hour at one metre from the source, depending on the radionuclide and its activity level.

As a result of the activity of the sources and the movement of the sources outside the storage container when the device is being used, gamma radiography can entail significant risks for the operators in the event of incorrect use, failure to comply

Retrospective on the inspections relating to the protection of ionising radiation sources against malicious acts



Since 2019, when ASN inspects facilities where sealed radioactive sources of category A, B or C are present, whether individually or in batches, it checks compliance with the regulations relative to the protection of sources against malicious acts. National administrative tracking indicators have been put in place.

This administrative tracking has been adapted to take account of the gradual entry into effect of the requirements of the Order of 29 November 2019 amended; the number of indicators has therefore evolved in line with the entry into effect of these various requirements.

Altogether, the number of inspection items – which depends on the activity – is 10 at the most: the technical devices are more numerous for category A or B sources or batches than for category C.

Moreover, certain inspection items address transport vehicles which the RNAs in the medical sector do not possess, as they prefer to subcontract transport operations to their source suppliers. In the industrial sector it can happen that the vehicle is not available on the day of the inspection or that the transport operation has been subcontracted.

- Out of all the inspection items, four concern questionnaires stemming from obligations figuring in the non-published appendices of the Order of 29 November 2019 amended. As this is sensitive information, it cannot be addressed in a publication.
- The changes indicated in the medical sector must be taken with caution as the number of inspections dedicated to malicious acts is relatively small.
- The figures compare the values for the years 2020 to 2023 with those recorded in 2024. The figures for 2019, considered old, are no longer taken into account. Some inspection items were nevertheless put in place after 2020, because they concern provisions which did not enter into application until 2021 or 2022.

In such cases the findings for 2024 are compared with the average for the years 2021 to 2023 for indicators 3 and 4 and 2022 to 2023 for indicators 5 and 6.

1. Classification of radioactive sources or batches of sources

In 2024, nearly 90% of the inspections performed in industrial facilities raised no comment on this point. This good result is very much the same as the findings over the previous four years, which witnessed a continuous improvement in conformity. The conformity of the medical facilities inspected in 2024 is identical to that of

the industrial facilities. It is also identical to the result of the previous years.

This is that indicator that obtains the highest score of conformity and the number of sites that have not yet classified their sources is therefore very small. The fact that some sites do not have a classification leads obligatorily to nonconformities because it is this classification that is the basis for the deployment of the technical provisions of the protection plan against malicious acts which is applicable since 1 July 2022.

2. Nominative authorisations

These are delivered by the RNA to allow access to the sources, their carriage, or access to the information relating to the means or measures that protect them.

In the industrial facilities inspected in 2024, half of the nominative authorisations issued raise no observations. This result is comparable with the values recorded in the previous four years.

A similar level has been found in the medical sector, even though it would in principle seem more difficult to comply on this point given the large staff numbers concerned and the very nature of the facilities whose function is to receive the public.

It also noteworthy that the number of critical situations (no authorization issued) has again been found in five facilities, all in the industrial sector. To conclude, the industrial sector must make further efforts to comply with this provision.

3. Policy of protection against malicious acts

This indicator makes it possible to determine the senior management's involvement in the change necessary for all the personnel to acquire a security culture, including in terms of cybersecurity, which is a long process by nature. Such a statement signed by senior management is not enough in itself, but it must allow the initiation of an acculturation process that makes all the personnel aware of the question of malicious acts.

More than two thirds of the sites in the industrial sector are found to be in compliance in this respect. This is a great improvement compared with the last three years.

Only one facility in two in the medical sector was considered to comply correctly with this provision. A slight improvement is nevertheless noted.

4. Identification and control of sensitive information

In 2024, slightly over half the industrial facilities had a procedure in this respect which was correctly applied and raised no

comments. This is a slight improvement on the findings over the last three years. Nevertheless, in nearly one company in five inspected in 2024 this question is not addressed.

The level of conformity in the medical sector is similar. This is an improvement compared with the previous four years and in particular with respect to the situation observed in 2023.

5. Principle of barriers

This inspection item concerns the identification by the site RNA of the barriers to be protected. If this is not done, the RNA cannot make any effective reinforcements that might be necessary, which can result in additional delays and costs.

Slightly over half the industrial sites inspected in 2024 are considered to have clearly identified "barriers". This figure is very similar to what has been observed over the last two years.

In the medical sector, however, this indicator is poor, with the barriers clearly identified in only about one situation in four in 2024. This result is distinctly poorer than in the previous two years and showing the greatest deterioration of all the tracked indicators.

6. Maintenance of technical protection systems

The systems adopted to protect against malicious acts necessitate the installation of detectors forming part of a chain of components allowing surveillance of the site. This electronic equipment requires maintenance to prevent failures. It is therefore vital to establish a verification programme and comply with it.

Such a programme existed in the industrial sector in 2024 but was implemented in just slightly over 40% of the inspected companies, a level which is about 10% higher than in 2022-2023. In slightly under a third of the companies inspected in 2024, however, there was no maintenance plan.

One third of the medical sites inspected have a maintenance plan that is correctly implemented, a figure that is comparable with the preceding years. The inspections in 2024 nevertheless confirmed that in slightly less than half the sites this question was not addressed at all, exactly the same proportion as in the previous two years.

While maintenance is an everyday function in industry and for the devices used in brachytherapy, these low levels indicate that the protection devices are monitored less rigorously than the "work tool". This indicator (along with the previous one for the medical sector) is the one with the greatest room for improvement.

with radiation protection rules, or operating incidents. Furthermore, it is often carried out on work sites under difficult conditions (working at night, or in places that are exposed to the elements, or in cramped spaces, etc.). On this account, it

is an activity with serious radiation protection implications that figures among ASN's inspection priorities.

Industrial X-ray radiography

Industrial X-ray radiography devices are very varied, ranging from fixed devices

(integrated in a facility of very variable size) to mobile devices which can be used equally well in worksite conditions as in a facility. In application of the principle of optimisation, they must be used instead of gamma radiography devices when the

conditions so permit because they do not make use of a radioactive source.

Apart from non-destructive inspection, these devices can also be used for more specific and therefore rarer purposes, such as radiography for the restoration of musical instruments or paintings, archaeological study of mummies or the analysis of fossils.

3.1.2 Evaluation of the radiation protection situation

Industrial radiography activities are high-risk activities which have been an inspection priority for ASN for several years now.

In 2024, ASN conducted 149 inspections in this area, a figure that is in line with the average of the last few years, after a slight drop in 2023. Among these inspections, 61 were unannounced inspections on night-time worksites, where applicable.

The on-line notification of worksite schedules for industrial radiography companies put in place by ASN in 2014 facilitates the planning of these inspections. ASN notes that virtually all the companies concerned routinely use this system for giving notification of their worksites. The reliability of the information transmitted however, is still very varied. The points to improve include:

- the updating of schedules when they are changed or cancelled;
- the accuracy of the worksite location information (not to be confused with the address of the ordering company);
- the completeness of the worksite notification;

- the identification of the device used on the worksite (gamma radiography or X-ray device).

ASN observes that the large majority of companies maintained the necessary rigour to meet the regulatory requirements concerning the appointing of a RPE (less than 5% of the inspected companies failed to meet the requirements), worker dose monitoring and radiological zoning of their facilities (about 15% of the companies failed to meet the requirements in these latter two areas, slightly more than in 2023). Furthermore, the inspectors noted that the frequency of maintenance of gamma radiography devices on the whole complies with regulations, even if there is a slight increase in the number of non-compliances (6% for projectors, 7% for accessories). Similarly, nearly all the operators inspected by ASN held, when it was necessary, the Certificate of competence in the use of industrial radiology devices (CAMARI) required by Article R. 4451-61 of the Labour Code (only one case of non-compliance observed, concerning use in worksite conditions).

It should be noted that as from 1 January 2025, pursuant to the new Articles R. 4451-62 and R. 4451-63 of the Labour Code, the utilisation of an industrial radiology device containing one or more high-activity sealed sources in a work zone will require at least two of the owner company's employees to hold the CAMARI certificate (*see point 5*).

The inspectors also noted that the efforts made by the companies to train newly-arrived classified workers had been maintained. Consequently, this information was

duly dispensed to the new staff in 93% of the inspected facilities concerned in 2024.

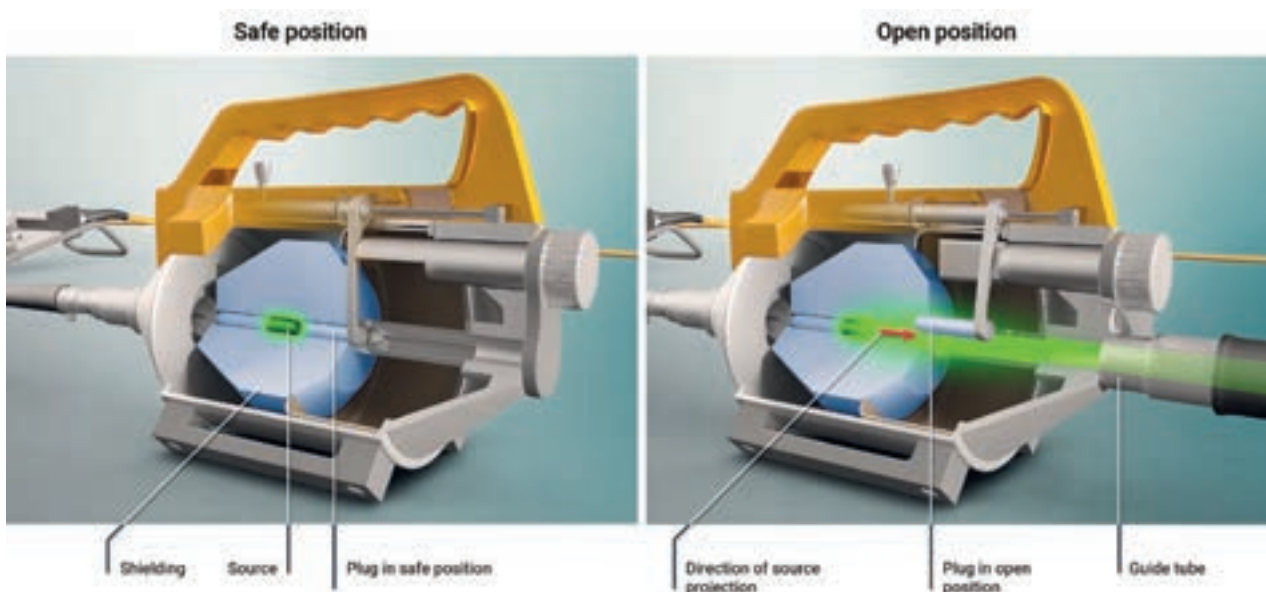
Furthermore, although only one inspection revealed noncompliance with the licence issued by ASN concerning the radionuclides or maximum activity held, companies must nevertheless be more thorough in checking that their inventory of sealed radioactive sources is consistent with the national inventory held by IRSN (inconsistencies were found in 12% of the inspected companies).

Lastly, the companies must continue to devote considerable efforts not only to defining an exhaustive programme of verifications as required by the Labour Code and implementing it correctly, but also to correcting the nonconformities found during these verifications and ensuring the traceability of the corrections made (nonconformities were noted in nearly half the inspections).

Despite a slight improvement in 2023 and in 2024, ASN still considers that the deviations observed in cordoning off the work zones on worksites (found in virtually one inspection in five) give cause for concern. ASN underlines that the lack of preparation and cooperation between the ordering customers and the radiography contractors before starting worksites is one of the causes of these deviations. Thus, nearly half the inspections found deviations concerning the prevention plan (for example: no plan, operators unaware of the plan, plan not available on the worksite, or shortcomings in the content).

ASN points out that the work area must be cordoned off before the work begins and, in all events, before the radiography

Schematic diagram of the functioning of a gamma ray projector



Selenium-75 gamma radiography



The use of selenium-75 in gamma radiography has been authorised in France since 2006. Implemented in the same devices as those functioning with iridium-192, selenium-75 offers significant radiation protection advantages. This is because the equivalent dose rates are about 55 millisieverts per hour and per terabecquerel (mSv/h/TBq) one metre from the selenium-75 source, as opposed to 130 mSv/h/TBq for iridium-192. Yet it can be used in place of iridium-192 in numerous

industrial fields, especially the petrochemical or boilermaking industry, and it enables the cordoned-off safety area to be significantly reduced and facilitates intervention in the event of an incident. In France, about 11% of the devices are equipped with selenium-75 sources. The use of selenium-75 has stagnated over the last few years and has even been decreasing since 2023 (20% in 2022 and 15% in 2023). More specifically, the current geopolitical context (sanctions against Russia because of the war in Ukraine)

is resulting in a restructuring of the global supply chain for gamma radiography sources, accompanied in particular by delays in delivery. Nevertheless, new procurement routes have been set up by the source suppliers in the last few years, and new ones are being explored in order to reduce procurement times and restore the 2022 level. ASN therefore still encourages the use of selenium-75 whenever possible.

Gamma radiography: serious accidents abroad



The number and consequences of gamma radiography accidents in France have remained limited since March 1979, when a worker had to have a leg amputated after having picked up a 518 GBq source of iridium-192 and put it in his pocket. This incident had led to a tightening of the regulations in effect at the time. This must not be taken for granted. ASN keeps a watchful eye on accidents occurring abroad which have sometimes had serious effects. Over the last few years (in 2024, no accidents have been reported to date), examples brought to ASN's attention confirming the risks to which operators can be exposed as a result of inappropriate actions, include:

- In 2023 in South Korea, a radiographer was exposed (116 millisieverts – mSv – for the whole body, 1,957 mSv to the hand) when manipulating a gamma ray projector whose iridium-192 source was no longer connected to the remote control cable. Owing to a lack of adequate radiation protection equipment, the radiographer did not notice the situation until the work was finished and the developed images were found to be overexposed.
- In 2023 in Germany, a radiologist was exposed to a dose of 71.5 mSv after entering a facility when the electrical device emitting ionising radiation used in that facility was still in operation. The causes of the event are still being investigated. Another radiologist was exposed (230 mSv for the whole body, 546 mSv to the lens of the eye) when he placed his head in an X-ray beam for two minutes in order to align the part being X-rayed, despite the radiation protection measures in place (flagging tape, flashing signal light and audio warning from the active dosimeter).
- In 2023 in the United States, a trainee radiographer was exposed several times to a source of iridium-192 on a worksite when carrying out various operations

(replacement of the film, movement of the guide tube) while the source was still positioned in the irradiation endpiece due to the detachment of the source holder. In the course of this incident, several radiation protection barriers were not observed, notably by the lack of supervision of the trainee radiographer (particularly during the source holder connection phase), failure to wear a dosimeter or use a radiation meter and verify that the source had returned properly into the projector (check of the indicator light, measurements, etc.). The trainee radiographer only noticed the problem when the guide tube became disconnected from the source projector. The dosimetric reconstruction (as no dosimeter was worn) gave an effective received dose estimate of 75 mSv and 258 mSv at the extremities.

- In 2022 in the United States, a team of three operators of a non-destructive testing company was performing gamma radiography work. One of the operators was close to the cobalt-60 source when it was ejected by his colleague who did not have direct visual contact with him. Given the very noisy environment of the worksite, the operator did not hear the alarm of his monitoring devices and was exposed to a dose of 55 mSv for about one minute.
- In 2022 in Belgium, a radiographer was exposed (14 mSv whole body, extremity dose not specified) to a selenium-75 source for a short period (60 to 90 seconds) when he tried to disconnect the device collimator while the source was still present in it. The alarm of his active dosimeter did not function because its battery was discharged; furthermore, the operator was not wearing his radiation meter. It was the triggering of his assistant's active dosimeter alarm when he approached the source that signalled the incident.
- In 2022 in Hungary, an operator was exposed to about 134 mSv when handling the collimator and the guide tube, as the

selenium-75 source was not retracted into the safe position in the projector.

- In 2021 in the USA, an employee of a non-destructive testing company was exposed to a dose of 70 mSv (whole body) while carrying out gamma radiography exposures within a dedicated facility. The procedures in force at the time of this accident authorised the operator to be present inside the facility even when the source was in the irradiation position. An employee of another non-destructive testing company was exposed to a dose of 93 mSv (whole body) when manipulating a defective gamma radiography projector whose source was not in the safe position. These two events were rated level 2 on the International Nuclear and Radiological Event Scale (INES).
- In 2021 in Serbia, an iridium-192 source became detached from the remote control cable during an outdoor non-destructive test. The two operators did not check that the source had returned to the safe position at the end of the inspection and did not notice its absence until they got back to their company base. The source was found the next day after the intervention of a specialised laboratory. The two operators were exposed to doses of 451 mSv and 960 mSv.
- In 2021 in Spain, an employee of a non-destructive testing company was exposed after entering a gamma radiography bunker when the iridium-192 source was not in the safe position (source jammed). The passive dosimeter of the first employee indicated a dose of about 70 mSv, and that of the second about 3 Sieverts (Sv). The event was rated level 2 on the INES scale.

The data for earlier incidents can be consulted in the previous issues of this annual report, which are available on asn.fr, under the headings "ASN informs", "Publications", "ASN Reports".

equipment is installed, that the cordoning off must be continuous and that it is essential to have warning lights in sufficient quantity. To ascertain that cordoning off ensures compliance with the effective dose integrated over one hour set by the regulations, it is vital for the operators to have the necessary tools to verify that the equivalent dose rate outside the work zone is that which is expected (deviations observed in one in four inspections in 2024), more specifically by taking one or more measurements with a functional dose rate meter whose calibration has been verified (deviations observed in one in ten inspections in 2024), and recording the results. Cordoning off the work zone effectively constitute the main safety barrier in worksite configurations, particularly to prevent unintended exposures. Consequently, ASN remains

extremely vigilant regarding this point, which is systematically checked during worksite inspections. Moreover, penal enforcement actions have already been proposed for serious breaches.

The recurrence of the deviations observed in the last few years in cordoning off the work zone induced ASN to address a circular letter to the profession as a whole in 2021, asking for tightened vigilance in this respect. ASN also points out that in the case of gamma radiography, it is vital to approach a measuring device to the projector in order to check that the radioactive source is effectively in the safe position. It is still found too frequently (in nearly one in three inspections in 2024) that this check is either not carried out or does not go right up to the tip of the

projector (where the guide tube is connected to the projector), which could lead to significant exposures of the operators in the event of an equipment failure.

ASN also notes disparities in the quality of the technical files it has to examine for inspection preparation or follow-up, and those received for license applications. The companies must in particular be more attentive to the reports establishing the conformity of their facilities with the appropriate technical baseline requirements. ASN still detects errors too frequently, particularly when production of these reports has been subcontracted, and these errors sometimes lead to nonconformities, even if few deviations are found during the inspections of components of the safety, signalling and alarm system.

ASN considers that the risks of incidents and the workers' occupational exposure are generally well controlled by the companies when radiography is performed in a bunker complying with the applicable regulations.

France has a good network of permanent industrial radiography facilities, despite some regional disparities. The figures in 2024 stand at:

- 97 licensed gamma radiography facilities (39 gamma radiography facilities and 58 combined facilities, that is to say which can accommodate either gamma ray projectors or electrical devices emitting X-rays or particle accelerators);
- 511 licensed X-ray radiography facilities (447 facilities using electrical devices,

Loss of control of the source in gamma radiography

Loss of control of the source ("source jamming") is one of the main causes of incidents in this area of gamma radiography. It can lead to significant exposure of the workers situated nearby, or even of the public when working in urban areas. This loss of control is primarily encountered in two situations:

- The radioactive source remains jammed in its guide tube. The cause of the blockage is often the presence of foreign bodies in the tube, or deterioration of the tube itself.

- The front of the projector is not fully blanked due to either the presence of foreign bodies in the channel preventing full retraction of the source, or breaking of the plug.

In France, gamma radiography projectors comply with technical specifications that are stricter than the international ISO standards. However, equipment failures can never be ruled out, especially in the event of poor upkeep of the equipment. In the last few years, incorrect manipulations have also been observed further to "source jamming" incidents.

Loss of control of a gamma ray project in Colmar (Haut-Rhin département) with off-site consequences

On 10 April 2024, during an industrial radiography operation conducted at the end of the day by a contractor in the ordering customer's facility in Colmar (Haut-Rhin département), control of the iridium-192 gamma radiography source was lost during the first exposure. The ensuing high equivalent ambient dose rate led to the intervention of the Prefecture to coordinate the action of the emergency services (fire brigade, police force, civil protection, ASN, etc.) and the setting up of a no-go area extending beyond the boundary of the ordering customer's site, leading to the evacuation of neighbouring companies and homes (an extremely rare decision given that events involving loss of control of gamma radiography sources usually have no impact on the public).

The following day, the intervention of the gamma ray projector manufacturer, the fire brigade and the civil protection services succeeded in decreasing the ambient

equivalent dose rate, enabling the no-go area to be considerably reduced (to within the bounds of the ordering customer's site) and the evacuation order to be lifted. During a subsequent intervention, the manufacturer managed to regain control of the gamma radiography source and safely take it away.

The reactive inspection by ASN revealed insufficient preparation and coordination between the radiography contractor and the ordering customer when determining the conditions of the industrial radiography work, which was decisive in the chain of events that led to the setting up of a no-go area extending onto public land.

First of all, the optimisation approach was not stringent enough given the dense site environment (first exposure done without using an ionising radiation collimator which could have been replaced by several exposures with a collimator, especially given that the delimiting of the work area for this exposure extended substantially beyond the

limits of the ordering customer's site). In actual fact, firstly the work area effectively put in place was not the area planned for the exposure without a collimator but a smaller area intended for the subsequent exposures (planned to be carried out using a collimator); and secondly there was no verification of the equivalent dose rate at boundary of the area.

Lastly, as is found regularly during ASN's worksite inspections, the prevention plan was incomplete, more specifically given the particular nature of the operation with inadequate equipment at the operators' disposal, be it for the performing the radiography work or for managing an emergency situation (in particular, no lead mats available).

For further information on the event, refer to the information notice and its complement published by ASN on its website.

58 combined facilities and 6 facilities using particle accelerators).

This network thus enables 83% of the professionals to propose industrial radiography services within facilities (55% for gamma radiography).

Despite the availability of such facilities, ASN still observes too often that parts that undergo radiography on worksites could have been easily moved to a facility. Apart from optimising doses for the workers, it would also eliminate the risk of having to temporarily shut down the worksite (which could last several days) due to the setting up of an exclusion area, in the event of an

incident preventing the radioactive source of a gamma ray projector from returning to the safe position.

ASN considers that the ordering customers have a key role to play to improve radiation protection in industrial radiography, by favouring industrial radiography services in a facility, or even turning to alternative technologies. Indeed, with regard to application of the principles of justification and optimisation, the long-term reflections undertaken by the non-destructive testing professionals have resulted in guidelines which aim to promote the use of alternative methods to industrial radiography. The work is

continuing within the professional bodies, in particular with the updating of the construction and maintenance codes for industrial equipment, in order to promote the use of non-ionising inspection methods.

Enhancing the awareness of all the players is therefore a priority. The regional initiatives to establish charters of good practices in industrial radiography implemented for several years now at the instigation of ASN and the labour inspectorate, particularly in areas corresponding to the (former) regions of Provence-Alpes-Côte d'Azur, Normandie, Auvergne-Rhône-Alpes, Nord-Pas-de-Calais, Bretagne and Pays de la Loire, allow regular exchanges between

Detection of lead in paint: a low-risk nuclear activity but requiring greater vigilance on account of malicious acts

Portable X-ray fluorescence devices used for analysing the components of a sample can be based on two different technologies: sealed-source devices and electrical devices.

Electrical devices are used primarily in the recovery and recycling of metallic materials, whereas the devices for detecting lead in paint which are used in the mandatory technical diagnostics for real-estate sales, rely on the technology of sealed source devices, the only technology recognised to date by the health authorities as guaranteeing a reliable response regarding the presence of lead.

Two radionuclides are used: cobalt-57 and cadmium-109. The sources come under category D for which the IAEA considers that it is *"unlikely to be dangerous to the person"* and *"it is very unlikely that the source would cause permanent injury. However, if this quantity of unshielded radioactive material is not safely managed or securely protected, it may cause temporary injuries to a person who handled it or who was otherwise in contact with it for several hours or close to it for several weeks."*

About 4,500 companies in France are involved in the detection of lead in paint. Some sites possess several devices, which therefore leads to the routine circulation of several thousand devices. Consequently, even if the radiation protection risks remain low (the nuclear activities in question come under the notification system, *see point 2.4.2*), the large number of devices in transit every day means that certain precautions must be taken. The consequences of a malicious act using this type of source could raise challenges, as much for the contractor as for the authorities, particularly as regards the media impact and the concerns it would raise for the public. Furthermore, the detailed examination of the Significant Radiation Protection Events (ESRs) reported to ASN reveals the theft or unaccountability of about fifteen devices for detecting lead in paint each year. About two-thirds of these situations arise when the device has been left in an unattended vehicle on the public highway, sometimes for a whole weekend.

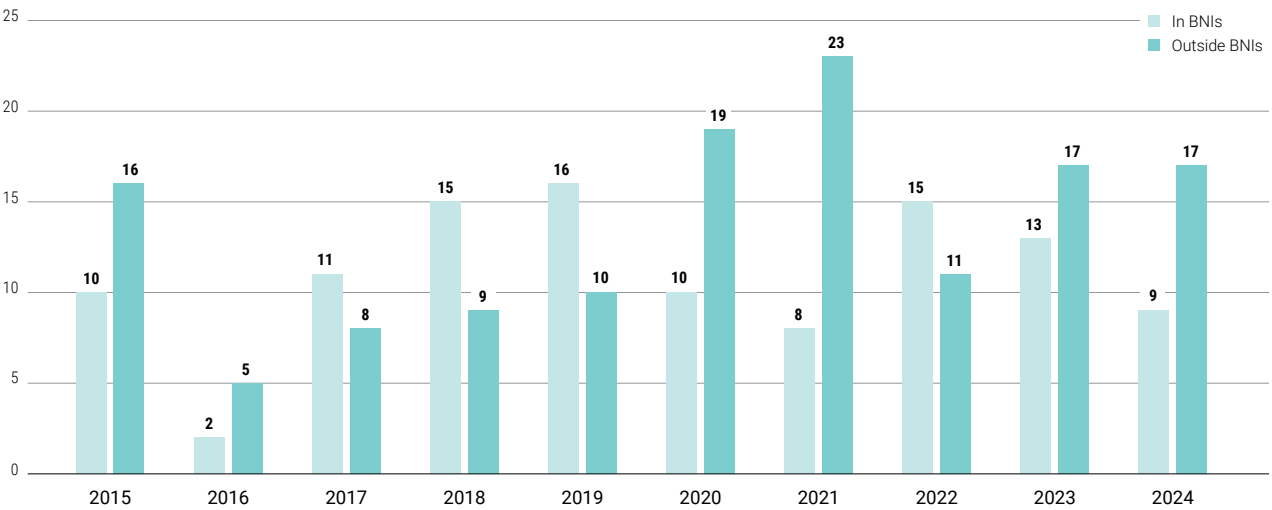
Lead detector devices in paint reported as stolen or lost to ASN

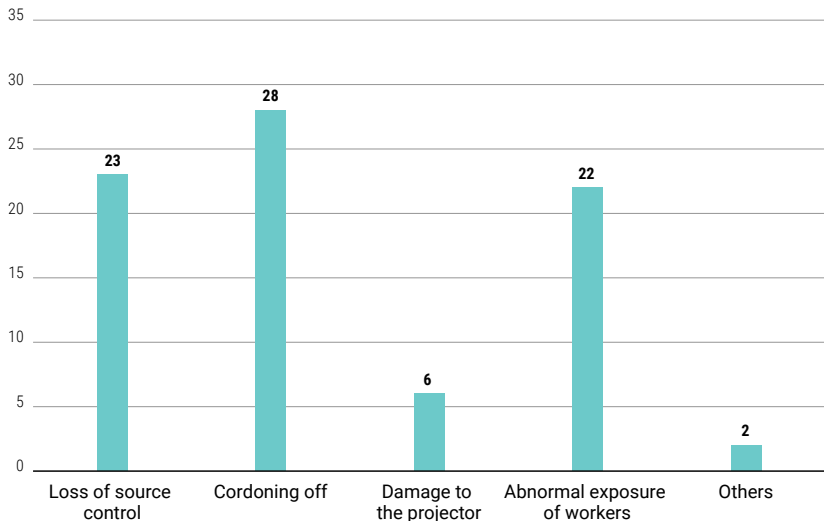
2021	2022	2023	2024
19	18	14	11

Consequently, in response to these early warning signs, ASN decided to send a letter reiterating the regulations and good practices to the two professional unions of real-estate diagnosticians, asking them to pass on the basic safety rules to their members.

Lastly, the analysis of the abovementioned events also identified one user with several agencies which had experienced recurrent thefts over the last few years. That user was sent an explicit request to revise its internal procedures: the tracking of device transfers (in and out of agency storage), the conditions of transport in vehicles (enhanced protection of the devices, return to the agency outside opening hours), and personnel training and awareness of the risks were thus improved in particular.

GRAPH 8 Trend in the number of industrial radiography events reported to ASN



GRAPH 9 Main factors leading to the reporting of significant industrial radiography events to ASN over the 2021-2023 period

the various stakeholders. The ASN regional divisions and other regional administrations concerned also regularly organise regional awareness-raising and discussion symposia for which the actors of this professional branch show a real interest.

Lastly, in 2024 as in the last few years, no cases of overexposure of industrial radiography operators were reported to ASN, even if several significant events linked to loss of source control (source “jamming”) did occur during the use of gamma ray projectors. Like last year, the operators have undertaken no inappropriate or prohibited actions or manipulations, thereby avoiding causing unnecessary exposure or complicating the subsequent work that would be necessary to restore a normal situation.

ASN points out the obligation for all gamma ray projector users to obey the instructions applicable in the event of a situation of “source jamming” outside the projector, which consists during the emergency phase in immediately stopping any handling of the projector or its accessories, rapidly cordoning off the area to avoid any further exposure to ionising radiation and contacting the device supplier for assistance. Penal enforcement actions have already been proposed for serious breaches, and will continue to be so.

The companies must moreover make every effort to ensure that their operators have the applicable safety instructions and the necessary means to respond should “source jamming” or any other anomaly occur (deviation found in one in four inspections in 2024).

Furthermore, when performing operations in worksite conditions, the outside contractors and their ordering customers must, during the preparation phase, check that any such incident would not

produce serious consequences outside the worksite, as was the case with the event that occurred in Colmar (see box page 265).

ASN remains particularly attentive to the management of “source jamming” events. The need to plan for an emergency organisation for managing such events was moreover recalled in the circular letter that ASN sent to the radiography professionals in 2021.

3.2 Industrial irradiators

3.2.1 The devices used

Industrial irradiation is used for sterilising medical equipment, pharmaceutical or cosmetic products and for the conservation of foodstuffs. It is also used to voluntarily modify the properties of materials, such as for the hardening of polymers.

These consumer product irradiation techniques can be authorised because, after being treated, these products display no residual artificial radioactivity (the products are sterilised by passing through radiation without themselves being “activated” by the treatment).

Industrial irradiators often use cobalt-60 sources, whose activity can be very high and exceed 250,000 terabecquerels (TBq). Some of these facilities are classified as BNIs (see chapter 13). In many sectors, X-ray generators are gradually replacing high-activity sealed sources for the irradiation of products (see point 1.3.1).

3.2.2 Evaluation of the radiation protection situation

BNIs excluded, ASN carried out 10 inspections from 2022 to 2024 (of which 5 were in 2024) in this sector, out of the 21 facilities currently licensed.

These inspections show that the radiation protection organisation is satisfactory, particularly as regards the appointing of an RPE (no deviations observed), the radiological zoning put in place on the inspected licensees’ premises (no deviation observed), the informing of new employees (just one deviation observed), compliance with the licenses issued by ASN with regard to the radionuclides or maximum activities held (just one deviation observed), the consistency of the licensee’s inventory of sealed radioactive sources in its possession with the national inventory held by IRSN (just one deviation observed) and the performance of verifications (two deviations observed).

The risk is well controlled, in particular thanks to the generally satisfactory verification, upkeep and maintenance of the facilities in accordance with the provisions described in the licensing applications. Nevertheless, ASN found in about one in three inspections that it would be worthwhile adding safety devices or improving their verification.

Furthermore, in about one inspection in three, ASN observed that the operator entered the irradiation facility without a radiation monitoring device, even though checking the ambient radiological activity level is a means of ensuring that the sealed radioactive source has indeed returned to the safe position in its biological shielding, thereby preventing any risk of accidental exposure.

The availability and proper functioning of the safety devices and the prevention measures taken by the operators will remain points on which ASN will focus particular attention in the future inspections in this sector.

3.3 Particle accelerators

3.3.1 The devices used

A particle accelerator is defined as being a device or installation in which particles are subjected to acceleration, emitting ionising radiation with an energy greater than 1 Megaelectronvolt (MeV).

When they meet the characteristics specified in Article R. 593-3 of the Environment Code concerning the BNI nomenclature, these facilities are listed as BNIs.

Some applications necessitate the use of beams of photons or electrons produced by particle accelerators. The installed base of particle accelerators in France, whether linear (linacs) or circular (synchrotrons), comprises in 75 licensed facilities⁽¹⁾ (excluding cyclotrons – see point 4.2 – and BNIs), possessing nearly

1. To which can be added seven licenses to use an accelerator, either exclusively under worksite conditions, or for the shared use of a device of which possession is regulated by the other party’s license.

150 particle accelerators⁽²⁾ which can be used in highly diverse areas such as:

- research, which sometimes requires the coupling of several machines (accelerator, implanter, etc.);
- radiography (fixed or mobile accelerator);
- radioscopy of lorries and containers during customs checks (fixed-site or mobile accelerators);
- modification of material properties;
- sterilisation;
- conservation of foodstuffs;
- others.

In the field of research, two synchrotron radiation production facilities can be mentioned in France: the ESRF (European Synchrotron Radiation Facility) in Grenoble, and the Soleil (Optimised Source of Intermediate-Energy Light of the Lure Laboratory) synchrotron in Gif-sur-Yvette.

Today one sees more and more particle accelerators used for research purposes and functioning on the principle of laser-plasma interactions: these devices can generate beams of highly energetic particles (up to a few hundreds of MeV in some facilities) and over very short times, down to the femto second (10^{-15} second).

Particle accelerators have been used for several years now in France to fight fraud and large-scale international trafficking. This technology, which the operators consider effective, must however be used under certain specific conditions in order to comply with the radiation protection rules applicable to workers and the public, in particular:

- a ban on activation of construction products, consumer goods and foodstuffs as specified by Article R. 1333-2 of the Public Health Code, by ensuring that the maximum energy of the particles emitted by the accelerators used excludes any risk of activation of the materials being verified;
- a general ban on the use of ionising radiation on the human body for purposes other than medical;
- the setting up of procedures to ensure that the checks conducted on the goods or transport vehicles do not lead to accidental exposure of workers or other individuals.

The use of ionising technologies to seek out illegal immigrants in transport vehicles is prohibited in France. During customs inspections of trucks using tomographic techniques, for example, the drivers must be kept away from the vehicle and other checks must be performed prior to irradiation to detect the presence of any illegal immigrants, in order to avoid unjustified exposure of people during the inspection.

3.3.2 Evaluation of the radiation protection situation

The use of particle accelerators presents significant radiation exposure risks for the workers; ASN is particularly attentive to these facilities and therefore inspects them regularly.

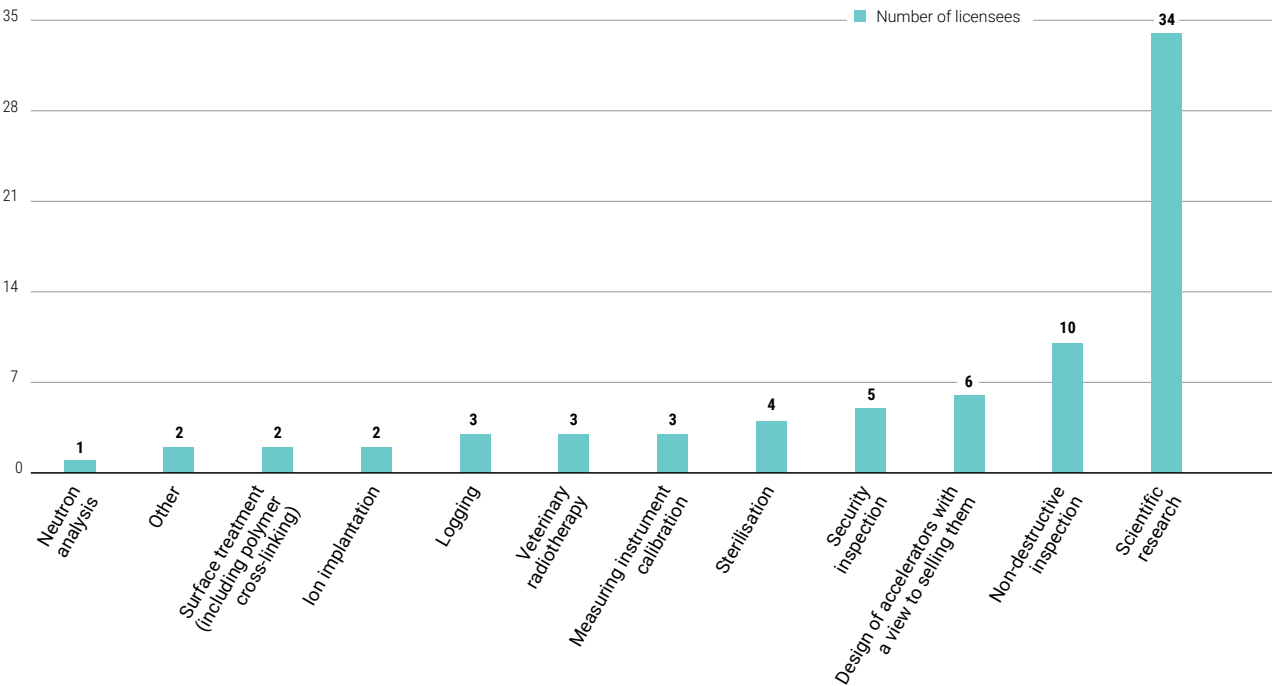
Between 2022 and 2024, 45 facilities equipped with these devices were inspected by ASN, 16 of them in 2024.

ASN considers the radiation protection situation in the facilities using these devices to be satisfactory on the whole. In effect, the key requirements for conducting this activity with a satisfactory level of radiation protection (organisation of radiation protection, informing and training, technical verifications, radiological zoning and design of the premises in which these devices are used) are appropriately implemented by the large majority of the licensees concerned.

Nevertheless, the inspections have also highlighted areas for improvement on which ASN will remain vigilant:

- compliance with the regulations concerning the frequency of technical verifications of radiation devices and associated equipment and the formalised processing of any nonconformities detected during these checks;

GRAPH 10 Breakdown of particle accelerators by end-purpose in 2024



2. The number of devices has increased compared with the previous years, due notably to a more precise division of large installations into several sub-systems, each representing an accelerators (as is the case for the synchrotrons, for example).

- the presence of an unlocking device which can be actuated from inside the rooms in which particle accelerators are used;
- the correct operation of the audio signal associated with the in-situ check process to ensure nobody is in the room before the emission of ionising radiation can be enabled;
- the presence of locks with captive keys on the control console⁽³⁾ and on all the accesses to the rooms in which particle accelerators are used. Although the main access is always equipped with this type of lock, this is not always the case for the secondary access points which are used more occasionally;
- the control of the technical means (password, dedicated key, etc.) allowing the safety systems to be overridden in the context of highly specific maintenance and servicing procedures. These means must be monitored constantly to ensure they are not used otherwise than for these specific procedures;
- the availability of radiation monitoring devices in sufficient quantities for the operators who access these rooms and the keeping of these devices in good working order.

Lastly, with regard to experience feedback, two Significant Radiation Protection Events (ESRs) were reported to ASN in 2024 by facilities using particle accelerators for scientific research purposes: ambient environment measurements taken by the licensees revealed exposure levels that were higher than usual and incompatible with the radiological zones in place on their premises, including in areas that were not subject to radiological zoning.

In the first case, the event was caused by a change in the experimental conditions of use without informing the RPE. The second case was caused by a maintenance operation on the accelerator that led to a malfunction: the anomaly was detected at an early stage in the maintenance process. These two events, which were well managed from the radiation protection viewpoint, did not lead to overexposure of persons.

Furthermore, recurrent events linked to the use of particle accelerators during customs cargo checks were reported to ASN, as happens each year. When conducting these checks, the customs services take precautions (such as broadcasting information messages in several languages) to avoid the unjustified irradiation of people who could be hiding in these vehicles (see point 3.3.1). However, despite these

precautions, the customs services regularly notify ASN of events relating to the exposure of people hidden in checked vehicles. Although this exposure is unjustified, it nevertheless remains extremely low with effective doses of just a few microsieverts per person.

3.4 Research activities involving unsealed radioactive sources

3.4.1 The devices used

In the research sector, as at 31 December 2024, ASN counted 318 licenses and 174 registrations issued under the Public Health Code, of which nearly 90% are issued to public or mixed (public/private) entities. The number of licenses is constantly decreasing, essentially due to the replacement of ionising radiation sources by alternative technologies that do not use ionising properties, but also to the changes in the system introduced in the last few years. Since 2019, certain nuclear activities have switched from the licensing system to the notification system (see point 2.4.2) and, since July 2021, other activities are now subject to the registration system (see point 2.4.3). This new system addresses in particular the possession/use of unsealed source which until then were governed solely by the licensing system.

The complete transitions of research laboratories from the licensing system to the registration system will continue over the coming years, particularly for the laboratories that reduce the quantities of radionuclides handled. These facilities and laboratories use mainly unsealed sources for medical and biomedical research, molecular biology, the agrifood business, the sciences of matter and materials, etc. They can also be suppliers of unsealed sources. They also use sealed sources for performing gas-phase chromatography, liquid scintillation counting or in irradiators. Electrical devices emitting ionising radiation are also used for X-ray fluorescence or X-ray diffraction spectrum analysis. Particle accelerators are used in research into matter or for the production of radionuclides.

3.4.2 Evaluation of the radiation protection situation

In 2024, ASN carried out 43 inspections in this sector⁽⁴⁾ (compared with 52 inspections per year on average over the 2022-2024 period). Broadly speaking, the actions undertaken over the last few

Synchrotrons

Belonging to the same family of circular particle accelerators as the cyclotrons (see point 4.2), the synchrotron, which is much larger, can attain energy levels of several gigaelectronvolts by using successive accelerators. Owing to the low mass of the particles (generally electrons) the acceleration created by the curvature of their trajectory in a storage ring, produces an electromagnetic wave when the speeds achieved become relativistic: this is synchrotron radiation. This radiation is collected at various locations called beam lines and is used to conduct scientific experiments.

Research activities

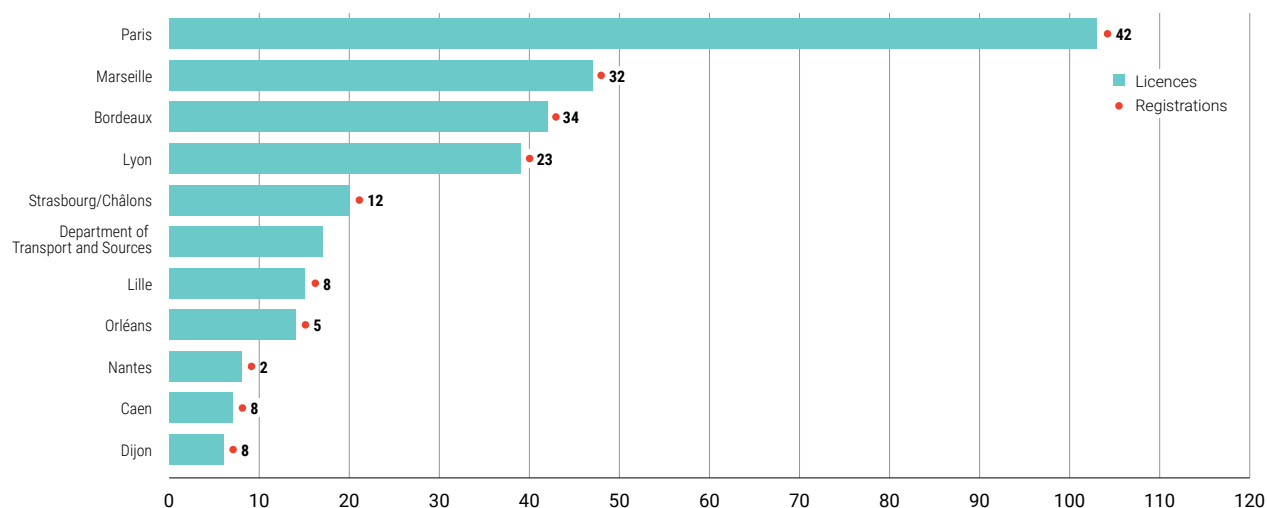
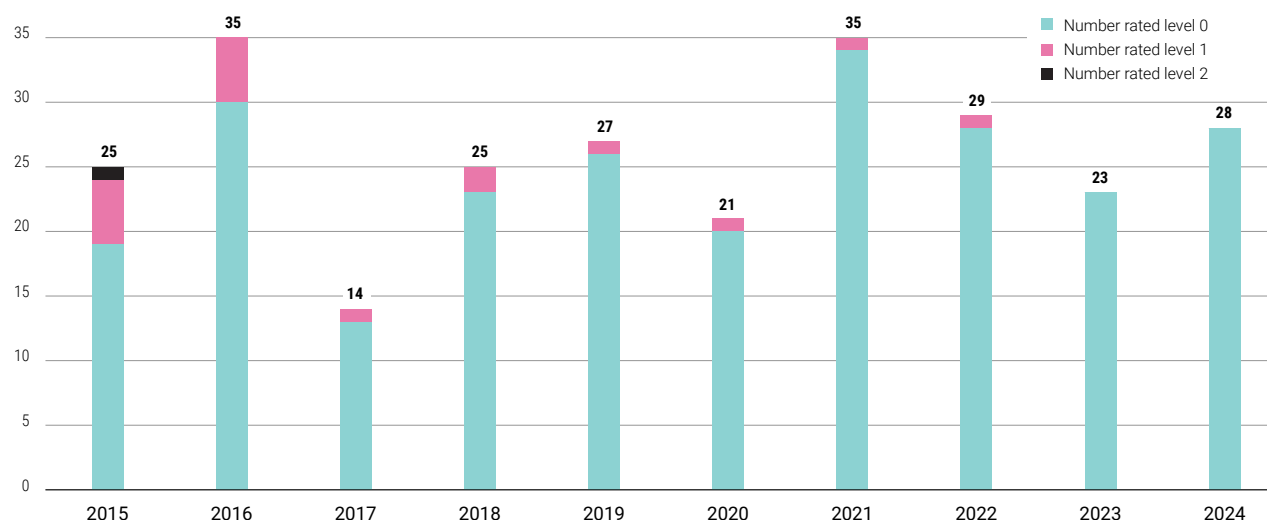
The use of ionising radiation in research activities extends to various fields such as medical research, molecular biology, the agri-food industry, materials characterisation, etc. It primarily involves the use of unsealed sources (iodine-125, phosphorous-32, phosphorous-33, sulphur-35, tritium-3, carbon-14, etc.). Sealed sources (barium-133, nickel-63, caesium-137, cobalt-60, etc.) are also used in gas chromatographs or scintillation counters or, with high-level sources, in irradiators. X-ray generators rays are used for X-ray fluorescence or X-ray diffraction spectrum analyses. The use of scanners for small animals (cancer research) in research laboratories and faculties of medicine should also be noted. Particle accelerators are used in research into matter or for the manufacture of radionuclides.

years have brought improvements in the implementation of radiation protection within research laboratories. However, this trend is slowing down, with recurrent nonconformities persisting from one year to the next, as is the case with waste management for example.

Even if the standard of radiation protection in the research laboratories remains broadly satisfactory, it remains dependent on the involvement of the individuals designated as RPEs and the means at their disposal. The radiation risks in many research laboratories are fairly low or tending to decrease, resulting in their nuclear activity changing from the

3. One and the same key can be used to gain access to the room and render operational the accelerator's control console. Furthermore, these keys cannot be removed from the access door locks if the doors are open.

4. Among these inspections, 17 exclusively concerned the use of sealed radioactive sources or electrical devices emitting ionising radiation.

GRAPH 11 Breakdown over the French territory, according to the competent ASN entity, of licensed or registered facilities using sources of ionising radiation in the research sector in 2024**GRAPH 12** Trends in the number of events reported to ASN in the research sector from 2015 to 2024

licensing system to the registration system. This trend is being confirmed from one year to the next. Furthermore, the cessation of nuclear activities in the research sector continues as techniques using ionising radiation are abandoned in favour of alternatives that do not.

ASN has nevertheless identified areas for improvement on which particular attention will be focused in the next inspections, particularly regarding the management and storage of sources and waste/effluents, where shortcomings in the performance and recording of checks prior to their disposal persist.

The research laboratories still have difficulties in assimilating the new regulations concerning radiation protection verifications, which can prove complicated to apply in the “Unités Mixtes de Recherche” – UMRs (Joint Research Units).

ASN therefore considers that the conditions of storage and disposition of disused sealed radioactive sources and of radioactive waste and effluents are still the main difficulties encountered by the research units. This situation is particularly pronounced in universities, where the limited financial resources of public laboratories can be an obstacle hindering more specifically the disposal of waste and disposition of expired/disused sources.

ASN thus remains attentive to the situation in certain universities, with tightened monitoring or even enforcement measures, particularly regarding the management of the substantial “legacy” in certain laboratories which have not removed their waste or expired/disused sources.

The technical, economic and regulatory difficulties concerning the disposal of legacy sealed sources also persist.

With regard to occupational radiation protection, the inspections in 2024 confirmed persistent shortcomings in the organisation and performance of the radiation protection verifications of equipment, workplaces and radiation protection instrumentation due to the difficulties the research units have in assimilating the regulations in force. This still concerns the full application of the periodic verifications programme (verifications incomplete or not carried out). This indicator still indicates that performance is dropping, confirming the trend observed since 2022. In effect, only 43% of the inspected facilities are correctly implementing these verifications.

The same goes for the verifications provided for under the Public Health Code by the Order of 24 October 2022 and the Order of 18 January 2023 approving ASN

resolution 2022-DC-0747, for which the situation can be improved. These regulations are still poorly understood, which means that the inspectors also have an informative role.

In 2024, 72% of the inspected sites have systems for recording and analysing adverse events and ESRs, compared with 61% in 2023. This restores the level of conformity observed in 2022 (76%) and curbs the drop observed since 2021. In 2024, ASN registered 28 ESRs concerning research activities (see Graph 12), all rated level 0 on the INES scale.

The majority of the reported ESRs concern the discovery of sources (68%). These chance discoveries of “forgotten” sources are often made during tidying-up operations. In the majority of cases these are remnants from past nuclear activities,

sometimes out of regulatory control, sometimes having undergone formal cessation but with shortcomings or omissions regarding the scope of the verifications before stopping the activity. In some cases the cessation request is made after a change of personnel with a view to settling liabilities, but without the full knowledge of the history of the activity in question. Lastly, the failure to take measures to effectively eliminate sources on cessation of the activity or irregular or incomplete source inventories are also contributing factors.

The other ESRs are one-off events and concern the reception or possession of radioactive sources with higher-than-authorised activity, the incorrect use of a device emitting X-rays during a maintenance operation, the mixing of radioactive effluents with rainwater having infiltrated

into the tank retention pit, and three cases of surface contamination of equipment or in unexpected locations.

With regard to worker exposure, no cases of personnel contamination were reported to ASN in 2024.

ASN reactivated its collaboration with the General Inspectorate for Education, Sport and Research (IGESR) in 2023. The IGESR is the competent body for labour inspection in the public research sector. The agreement signed in 2014, has been updated and is currently being signed. It provides for mutual exchanges of information intended to improve the efficiency and complementarity of the inspections. Annual meetings are also organised between ASN and IGESR.

4 — Manufacturers and distributors of radioactive sources and their oversight by ASN

4.1 The issues and challenges

The aim of ASN oversight of the suppliers of radioactive sources or devices containing them is to ensure the radiation protection of the future users. It is based on the technical examination of the devices and sources with respect to operating safety and radiation protection conditions during future utilisation and maintenance. It also allows the tracking of source transfers and the recovery and disposal of disused or end-of-life sources. Source suppliers also play a teaching role with respect to users.

At present, only the suppliers of sealed radioactive sources (or devices containing them) and of unsealed radioactive sources are regulated in France (see point 2.3.1). ASN lists some 100 suppliers with safety-significant business, including 38 low and medium-energy cyclotrons on 33 sites which are currently licensed under the Public Health Code. Among these 38 cyclotrons, 34 are in operation and produce radionuclides.

Cyclotrons are used to produce positron-emitting radionuclides in unsealed sources (primarily fluorine-18). These radionuclides are used either for medical applications, especially *in vivo* diagnosis, or in clinical trial protocols (human subject research), or for research activities.

Cyclotrons apart, the company Orano Med is currently setting up a production site for lead-212-based radiopharmaceutical drugs in the north of France. This site will produce and supply, for the European

market, these radiopharmaceutical drugs which are intended for alphatherapy (see chapter 7), initially for clinical trials. The manufacturing process is to be carried out in shielded enclosures. Acceptance of the facilities and the first tests related to radioactive source production process are scheduled during the first half of 2025.

4.2 Cyclotrons

Operation

As at 31 December 2024, one cyclotron was on standby, three shut down and 34 in service. Among the 34 cyclotrons in routine operation, 27 are used to produce radiopharmaceuticals intended for *in vivo* diagnosis, sometimes with medical or non-medical research as an additional end-purpose, six produce radionuclides for medical or non-medical research purposes, and one produces radionuclides exclusively for non-medical research.

The cyclotron of the university hospital (CHU) of Martinique started functioning in early 2024 to produce fluorine-18 and carbon-11 for performing *in vivo* diagnostics and participating in clinical trials. It may subsequently also produce oxygen-15, copper-64, gallium-68 and zirconium-89 for the same purposes.

Two new licenses for cyclotrons producing radiopharmaceutical drugs in the Paris region were issued by ASN in 2024: one cyclotron was on standby and has been put back into service, while the other is a new machine installed on a site that already had two cyclotrons.

In addition to this, a new cyclotron facility for producing radiopharmaceutical drugs has been built in the suburbs of Rennes. It is intended to replace the cyclotron installed within the university hospital of Rennes. ASN issued a license to perform the various equipment qualification tests in 2024. Completion of this test phase and acceptance of the facility are expected during the first half of 2025; the production activity should begin after this.

Lastly, a new project to install a cyclotron in the Toulouse “Cancéropôle” (cancer centre) is expected in 2025. Preliminary discussions on this project were held with ASN in 2024 and the future licensee plans submitting its license application in the first quarter of 2025.

Evaluation of radiation protection in facilities using cyclotrons

ASN has been exercising its oversight in this area since early 2010. Each new facility or any major modification of an existing facility undergoes an extensive examination by ASN. The main radiation protection issues concerning these facilities must be considered as of the design stage. Application of the industrial standards, particularly standard NF M 62-105 “Industrial accelerators: installations”, ISO 10648-2 “Containment enclosures” and ISO 17873 “Ventilation systems for nuclear installations”, guarantees safe utilisation of the equipment and brings a significant reduction in risks.

Facilities that have a cyclotron used to produce radionuclides and products containing radionuclides are subject to gaseous

effluent discharge limits specified in their license. The discharge levels depend on the frequency and types of production involved.

Systems for filtering and trapping gaseous effluents are installed in the production enclosures and in the facilities' ventilation systems in order to minimise the activity discharged at the stack outlet. An increasing number of licensees are also installing – as close as possible to the shielded enclosures – systems for collecting and storing the gases to let them decay before being discharged, bringing a substantial reduction in the activities discharged into the environment. These radioactive gas compression systems are then emptied after a decay time that is appropriate for the type of radionuclide.

Consequently, the discharged activity levels and the short half-life of the radionuclides discharged in gaseous effluents mean there is no significant impact on the public or the environment.

The work undertaken by ASN and IRSN over the last few years on the gaseous discharges into the environment from cyclotrons has clarified the regulatory requirements in this respect. New assessments of the impacts of discharges from the facilities situated near residential areas have been carried out using, for some facilities, modelling tools that are better suited to near-field studies. Alongside this, IRSN acquired a computing tool in 2020 that provides a more accurate estimate of the radiological impacts by modelling the discharges in the immediate vicinity of the site concerned and performing, if necessary, counter-assessments of the studies provided by the licensees.

In 2022, at the request of ASN, IRSN provided the cyclotron licensees with a document specifying the methodological steps for producing the radiological impact study of the atmospheric discharges from their facilities. This document details the different steps of an impact assessment, particularly the characterisation of the source term (discharges), a precise description of the local environment and of the transfers to the environment, emphasising the importance of the choice of dispersion calculation method and the final dose assessment.

It is available on the ASN and IRSN websites.

ASN and IRSN worked jointly, with the participation of the cyclotron licensees, to clarify in particular the way atmospheric discharge limits are worded in the licences. At present, only the maximum dischargeable activity is usually indicated. The conclusions of this work will be an input for

developing the future draft regulation relative to cyclotrons (*see next page*).

ASN performs about ten inspections at facilities of this type each year. Eight inspections were carried out in 2024. Of the eight sites inspected, three have transfer lines between the cyclotron and an industrial player (research laboratories).

Apart from the distribution of unsealed radioactive sources, the aspects relating to radiation protection, safety of use and the correct operation of cyclotrons and production platforms receive particular attention during the inspections. The scope of the inspections performed includes – apart from topics relating to radiation protection – management of in-house abnormal events, the monitoring and maintenance of the production equipment, the inspection of the surveillance and control systems, the gaseous discharge results and management of the waste and liquid effluents.

The supply of radiopharmaceuticals and radiochemicals is duly taken into account by the licensees.

The organisation of radiation protection on the eight sites inspected is satisfactory. All the sites have appointed at least one RPE, and in just one case the RPE's training certificate was not up to date, but the situation was being rectified. All the inspected sites have at least one person who holds the CAMARI certificate.

The exposed workers are trained and are all subject to appropriate dose monitoring.

All the companies have an equipment and radiation protection instrumentation verification programme that is established, except for one case where certain instrumentation calibration verifications had not been carried out. Likewise, the inspections and verifications of the presence and correct functioning of the cyclotron safety and alarm devices, of the shielded enclosures and of the recipients containing radionuclides are carried out on all the sites.

Concerning the management of radioactive sources, the maximum activity of the radionuclides held complies with the licence conditions and appropriate measures are taken to prevent unauthorised access to the sources.

The checks prior to final disposal of the contaminated waste and effluents are carried out and documented in all the inspected facilities. However, waste management remains a point requiring particular attention regarding the regular removal of the waste (to avoid cluttering the premises, especially on the oldest ones with cramped waste storage areas) that is to be recovered by Andra. Atmospheric discharges are generally well monitored.

It was this monitoring that led to the rapid detection of discharges beyond authorised limits mentioned in the paragraph on ESRs.

Lastly, national action plans are put into place by the licensees of the two major French radiopharmaceutical production groups and are reviewed annually by ASN to ensure continuous improvement of radiation protection and safety in these facilities.

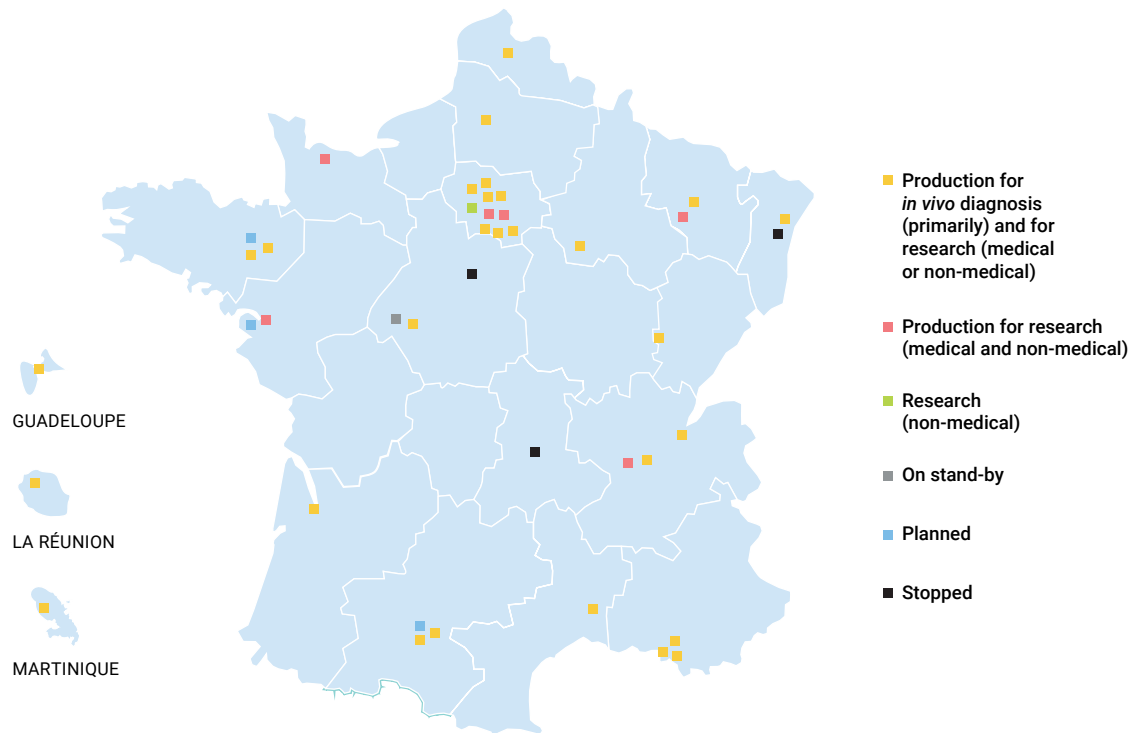
Four ESRs were reported by the cyclotron licensees in 2024. None of these events led to significant exposure of workers or the public.

Two of the reported events involved a slight exceedance of the authorised limit for radioactive atmospheric discharges, detected further to a metrological problem with the measuring probes. Measures have been taken to limit the discharges, such as early replacement of the charcoal filters and the installation of storage tanks to allow radioactive decay of gases before discharge, as well as measures to enhance measurement reliability, particularly the installation of screens around the measurement probes to reduce spurious radiation.

The first of the other two ESRs concerns the delivery of radiopharmaceuticals that did not comply with the activity authorised by the client's license. The second event concerns the triggering of a worker's active dosimeter alarm after opening a shielded enclosure when a synthesis was in progress, due to a failure of the enclosure locking system.

There are disparities in the technical and organisational means implemented by the licensees, depending on the age of the facilities and the type of activities performed (research or industrial production). Experience feedback in this area has led ASN, assisted by IRSN, to draw up a draft resolution on the technical design and operating rules applicable to facilities producing radionuclides using a cyclotron and on the control and monitoring of their gaseous effluent discharges. The draft resolution has already undergone several informal consultations with the stakeholders and discussions with the DGT; its preparation is continuing in order to create a single regulatory baseline for the whole sector concerned. The main conclusions of this regulatory work are already being used when examining license applications for these facilities in order to include appropriate requirements in the individual licences. The conclusions resulting from the considerations on the wording of the atmospheric discharge limit values will also be included.

Location of cyclotrons in France



4.3 The other suppliers of sources

Evaluation of the radiation protection situation

Suppliers of radioactive sources, cyclotrons excluded, propose technical solutions for the industrial, medical and research sectors. Suppliers may be manufacturers of “bare” sources or of devices containing sealed radioactive sources, manufacturers of unsealed sources, or distributors who import sources from other countries. Whatever the case, ASN reviews the license applications for the sources these suppliers wish to distribute in France.

In 2024, cyclotrons excluded, 27 inspections were carried out at the manufacturers/suppliers of radioactive sources or sources emitting ionising radiation. These inspections were carried out at manufacturers/distributors of sealed and unsealed radioactive sources, companies removing lightning conductors or removing and dismantling ICSDs, and companies manufacturing, installing, or maintaining electrical generators of ionising radiation or particle accelerators (although they are not yet subject to a distribution authorisation, these devices are subject to utilisation regulations, including in particular the commissioning or maintenance operations carried out by the companies that sell them). Several of the inspections

concerned priority themes other than those mentioned above, such as four inspections focusing on the protection of radioactive sources against malicious acts. Lastly, two inspections concerned a foreign company supplying ionising radiation sources in France.

These inspections covered about a third of the suppliers with safety-significant business, considering specific inspection criteria, more particularly linked to the suppliers’ responsibilities in the tracking and recovery of disused sealed radioactive sources from the users in order to dispose of them appropriately, taking into account the radiation risks they present for people and the environment.

ASN considers the radiation protection situation associated with the radionuclide supply activity to be satisfactory on the whole. The large majority of licensees meet the main requirements and assume their responsibilities adequately (transfer of documents on delivery, setting up the source recovery streams, transmission of information to IRSN). More specifically, compliance with the obligation of unconditional recovery of distributed sealed radioactive sources that have expired (ten years counting from the date of the first registration figuring on the supply form) or have become disused, is stable with respect to 2023.

The inspections carried out in 2024 moreover found significant improvements in the tracking of particle accelerators and electrical devices emitting ionising radiation by the suppliers compared with 2023, thanks to the deployment of appropriate tracking tools.

Likewise, there is a significant improvement compared with 2023 in the identification by the suppliers of the sealed radioactive sources they supplied and which have expired (sources of more than ten years) but not yet been recovered.

These inspections nevertheless also revealed certain points requiring particular attention, such as the exhaustiveness of the verifications performed by the suppliers prior to the delivery of all sources, which has regressed compared with 2023. These verifications, for which the supplier must take appropriate organisational measures (by computer blocking or verifications during actual preparation of the order), include verification of the existence of an administrative document (license or registration or notification acknowledgement) authorising the customer to hold the source concerned, verification of the fact that the delivery of the source in itself will not, considering the other sources already delivered by the supplier, result in exceeding of the customer’s license limits, and lastly that the delivery address is consistent with the authorised

holding sites. Moreover, the inspected suppliers did not all specify the source recovery conditions as is required on delivery of the sources, a situation which is worse than in 2023.

There is a very slight increase in the number of ESRs reported compared with 2023, but for the second year running no significant event rated level 1 or higher on the

INES scale was recorded. The ESRs notified in 2024 mainly concerned poor management of dosimeters (dosimeter left in luggage during X-ray security checks in an airport zone) resulting in incorrect dose recordings, and the discovery of radioactive substances (tritium luminous paint, loss of integrity of a cobalt-57 source and the discovery of a contaminated source holder) in

places not listed in the site's license. Four other incidents led to abnormal exposures of workers, but without causing any of the regulatory dose limit values to be exceeded. These incidents resulted mainly from failure to comply with the maintenance protocols. None of the supplier ESRs reported in 2024 had significant consequences on the environment or the workers.

Cyclotrons

A cyclotron is a device 1.5 to 4 metres in diameter, belonging to the circular particle accelerator family. The accelerated particles are mainly protons, with energy levels of up to 70 MeV.

A cyclotron consists of two circular electromagnets producing a magnetic field and between which there is an electrical field, allowing the rotation and acceleration of the particles at each revolution. The accelerated particles strike a target containing a liquid, gaseous or solid product which, once irradiated, will produce the desired radionuclide.

Low and medium energy cyclotrons are primarily used in research and in the pharmaceutical industry to produce positron

emitting isotopes, such as fluorine-18 or carbon-11. The radionuclides are then combined with molecules of varying complexity to form radiopharmaceuticals used in medical imaging. The best known of them is ^{18}F -FDG (fluorodeoxyglucose marked by fluorine-18), which is an industrially manufactured injectable drug, commonly used for early diagnosis of certain cancers.

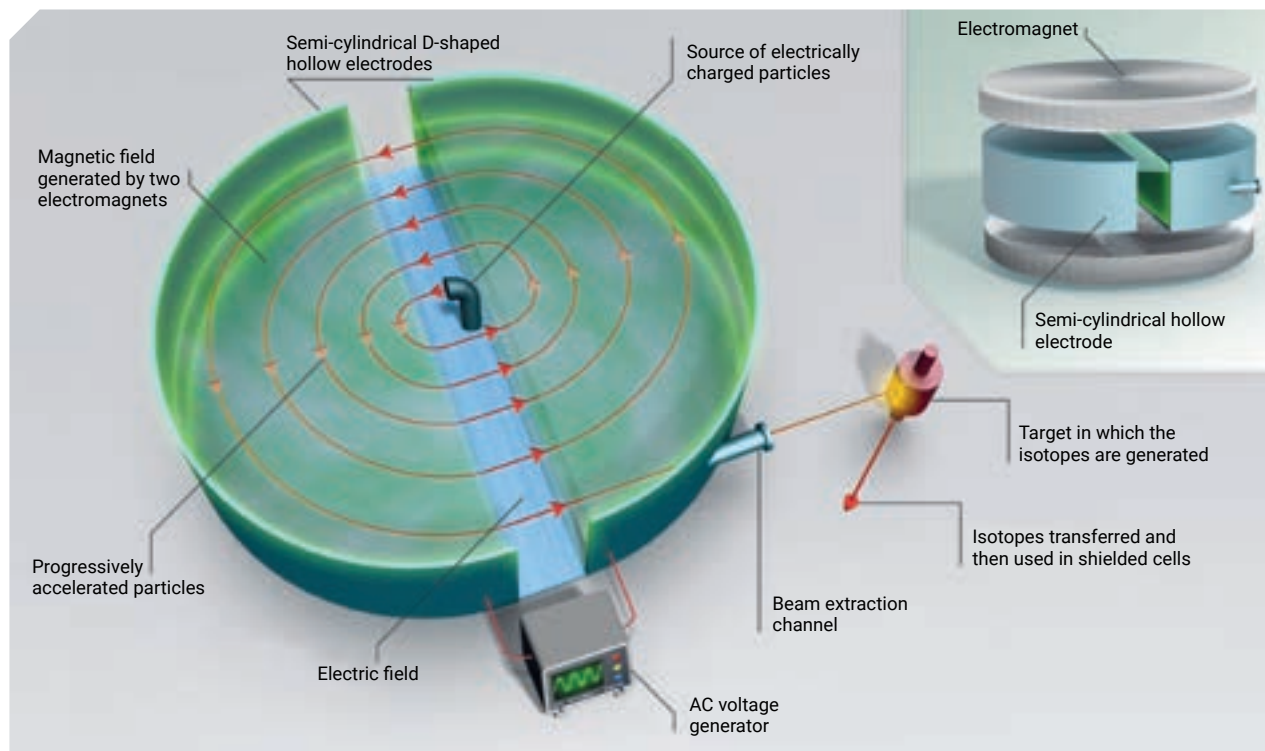
Other radiopharmaceuticals manufactured from fluorine-18 have also been developed in recent years, such as ^{18}F -Choline, ^{18}F -Na, ^{18}F -DOPA, as well as radiopharmaceuticals for exploring the brain. To a lesser extent, the other positron emitters that can be manufactured with a cyclotron of an

equivalent energy range to that necessary for the production of fluorine-18 and carbon-11 are oxygen-15 and nitrogen-13. Their utilisation is however still limited due to their very short radioactive half-life. Some facilities are also starting to produce copper-64 or zirconium-89, which are still used today in research and clinical tests.

The approximate levels of activities involved for the fluorine-18 usually found in pharmaceutical facilities vary from 30 to 500 GBq per production batch.

The positron emitting radionuclides produced for research purposes involve activities that are usually limited to a few tens of gigabecquerels.

Simplified diagram of the operation of a cyclotron



5 — Conclusion and outlook

Implementation of the new regulatory framework applicable to nuclear activities

In 2021, reinforcing of the graded approach to oversight, based on a classification of the different categories of nuclear activities involving sources of ionising radiation continued, with the entry into effect of resolutions relative to the registration system and the development of the associated on-line registration service allowing the application files to be submitted on line. ASN supplemented the information available on the on-line services portal in 2024 to better assist the users of this new system.

In 2022, to finalise the overhaul of the systems of the Public Health Code as a whole, ASN began the process to revise the three existing resolutions concerning the content of applications to carry out nuclear activities subject to the licensing system; this update will include, if necessary, the part relating to the supply of devices emitting X-rays. This work continued in 2024 with the placing on line in early 2025 of the new application form for a licence to possess and use sealed radioactive sources. The work in 2025 will concern the possession and use of unsealed radioactive sources.

ASN is continuing, in collaboration with the DGT, its preliminary work on the updating of the regulatory framework concerning the technical design rules and the certification procedures for industrial radiography devices (Article R. 4312-1-3 of the Labour Code), ensuring that it ties in properly with the existing European framework.

In 2024, ASN also participated in the updating of the part of the Labour Code relative to the protection of workers against the risks arising from ionising radiation (Decree 2024-1238 of 30 December 2024).

More specifically, as from 1 January 2026, the utilisation in work zones of industrial radiology devices whose manipulation presents a high risk of exposure to ionising radiation and which contain one or more high-activity sealed sources, will necessitate at least two CAMARI-certificated employees of the company possessing the device.

In this context, the provisions of the current ASN resolution 2007-DC-0074 of 29 November 2007 amended, (which establishes the list of devices or device categories whose operation requires the CAMARI certificate) and those of the Order of 21 December 2007 amended (which defines the conditions of CAMARI training and certification), will be updated by a new order in 2025. This new Order, in whose drafting ASN has been involved since 2024, will also set the conditions of utilisation of mobile industrial radiology devices in a work zone.

Oversight of the protection of radioactive sources against malicious acts

ASN has been designated as the authority to oversee the provisions to protect radioactive sources against malicious acts in the majority of facilities. This essentially concerns activities associated with gamma radiography and brachytherapy. Publication of the Decree of 4 June 2018 brought into effect the first provisions in this respect in mid-2018: RNAs must more specifically give individual authorisations for access to the most hazardous sources, including for their transport, and for access to sensitive information.

These initial provisions have been reinforced with the entry into effect on 1 January 2021 of part of the amended Order of 29 November 2019 which requires company functioning and organization to be adapted to these specific risks.

Although these are new regulatory provisions, it is above all an additional risk to be managed and integrated in the corporate culture particularly through measures to raise awareness and inform the personnel, which must be renewed periodically.

On this account, the quality management system must include measures to combat malicious acts, and senior management of the companies concerned must henceforth define and formalise a policy of protection against malicious acts implemented by the RNA. This person must be assigned the necessary resources and have the requisite skills (assisted if necessary by a person trained in this area) and sufficient authority.

The measures adopted must also take account of the “cyber” aspect in order to fight against the compromising of sensitive information, a matter provided for explicitly by the Order of 29 November 2019 amended. All the company staff and external partners must be made aware of this subject. In order to have appropriate rules, the company’s sensitive information must be clearly identified.

On 1 July 2022, the Order entered fully into effect and the technical provisions for the physical protection of sources should have been put in place, both within facilities and at worksites (utilisation, possession) and for road transport operations.

Since 2019, the ASN inspections address the protection of sources against malicious acts with more and more emphasis. Inspections devoted entirely to this question began in limited numbers in 2021 and reached “cruising speed” as of 2023 with more than 60 annual inspections. This level of inspection will be maintained in 2025.

When reviewing the nuclear activity license applications, ASN also ensures that the necessary technical and organizational provisions have been put in place.

The content of the application takes this question into account.

ASN has moreover continued the actions initiated to train its personnel in this new duty and has made in-house aids available (inspection guide, license application review matrices, question-and-answer sheets, networks of regional correspondents).

To conclude, some effects of the Order of 29 November 2019 amended have been clearly visible for slightly more than a year: reduction in the number of sealed radioactive sources possessed by some licensees, grouping of industrial radiography agencies and equipping of vehicles, improvement in the systems protecting the sources (physical protection, detection, access control, surveillance, etc.). The task is not finished however. The licensees must, for example, prepare for the impact of the reduction in the number of agencies or storage sites, which can lead to greater constraints.

The year 2025 should see the continuation of two works in progress:

- the modification of the Order of 29 November 2019 amended. Based on what has been learned from past inspections, it is more a question of clarifying or even relaxing certain provisions than adding requirements. Discussions will be held with the Ministry responsible for energy transition, signatory of the Order, to move forward on these points;
- the reflection concerning the protection of unsealed sources. IRSN had been mandated by the Ministry responsible for energy transition to conduct field investigations to assess the overall level of protection of unsealed sources. These sources, which are used mainly in the medical or research sectors, very often have a radiological half-life of a few days at the most.

However, some activities use products which no longer really have such reassuring characteristics. Based on the result of the investigations, the Ministry should adopt a position on the principle of regulating such sources or not in 2025. ASNR, which is directly concerned, particularly due to its monitoring of the medical sectors, shall participate in each stage of the reflection;

- the effective entry into force of the licensing system for the transportation of category A, B or C sources by road. This change will undoubtedly raise new questions of policy and of implementation concerning the Order relative to the protection of sources against malicious acts, particularly as regards transport operation with neighbouring countries.

09

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The transport of radioactive substances is a specific sector of dangerous goods transport characterised by the risks associated with radioactivity. The radioactive substance transports being regulated cover a wide range of activities in the industrial, medical and research sectors. This is based on strict international regulations.

1 — Radioactive substances traffic

The regulations divide the dangerous goods liable to be transported into nine “classes” according to the nature of the corresponding risk (for example: explosive, toxic, flammable materials, etc.). Class 7 covers radioactive substances.

The transport of radioactive substances stands out owing to its considerable diversity. Packages of radioactive substances can weigh from a few hundred grams up to more than a hundred tons and the radiological activity of their content can range from a few thousand becquerels to billions of billions of becquerels for the packages of spent nuclear fuel. The safety implications are also extremely varied. The vast majority of packages have limited individual safety implications, but for a small percentage of them, the potential safety consequences are very high.

About 770,000 consignments of radioactive substances are transported each year in France. This represents about 980,000 packages of radioactive substances, or just a few percent of the total number of dangerous goods packages transported each year in France. The vast majority of shipments are made by road, but some also take place by rail, by sea and by air (see Table 1). These shipments concern three activity sectors: the non-nuclear industry, medical sector and nuclear industry (see Graph 1).

Most of the packages transported are intended for the non-nuclear industry, or for research: this mainly involves devices containing radioactive sources which are not used in a single location and which therefore need to be transported with considerable frequency. For example, these could be devices for detecting lead in paint, used for real estate sale diagnostics, or gamma radiography devices used to detect defects in materials. Travel to and from the various worksites explains the very large number of shipments for the non-nuclear industry. The safety issues vary considerably: the radioactive source contained in lead detectors has very low radiological activity, while that contained in gamma radiography devices has a far higher activity.

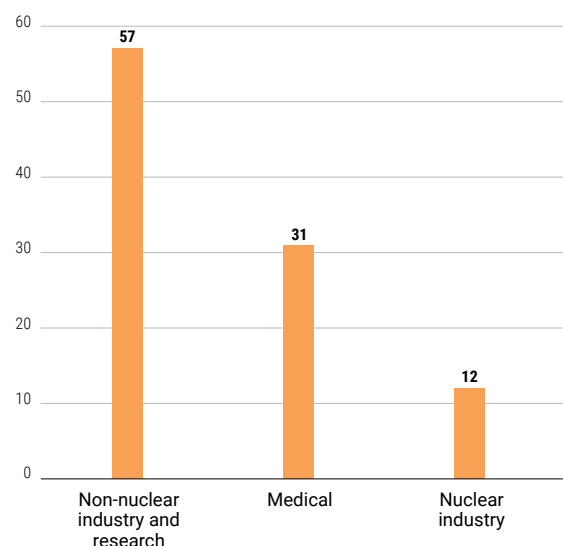
About one third of the packages transported are used in the medical sector: this involves providing health care centres with radioactive sources, for example sealed sources used in radiotherapy, or radiopharmaceutical products, and removing the corresponding radioactive waste. The activity of radiopharmaceutical products decays rapidly (for example, the radioactive half-life of fluorine-18 is close to two hours). Consequently, these products have to be regularly transported to the nuclear medicine units, creating a large number of shipments, which have to be carried out correctly to ensure the continuity of the health care given. Most of these products have low activity levels, although a small proportion of them, such as the sources used in radiotherapy or the irradiated sources used to produce technetium (used in medical imaging) have significant safety implications.

Finally, 12% of the packages transported in France are for the nuclear industry. This represents about 19,000 shipments annually, involving 114,000 packages. These shipments are required to ensure the working of the “fuel cycle”, owing to

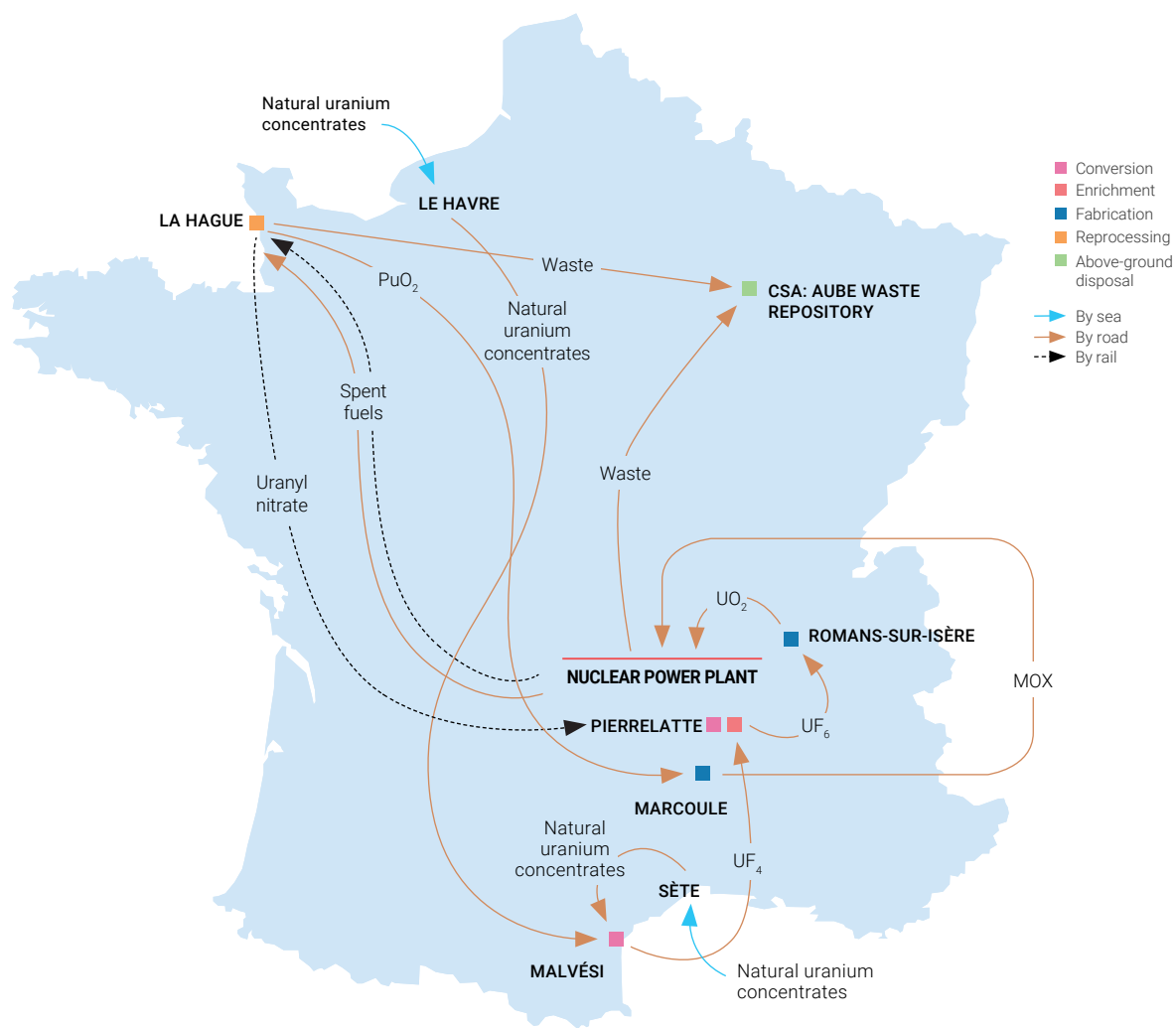
the distribution of the various facilities and Nuclear Power Plants (NPPs) around the country (see map next page). Depending on the step in the “cycle”, the physicochemical form and radiological activity of the substances varies widely. The transport operations with very high safety implications are notably the shipments of uranium hexafluoride (UF₆) whether or not enriched (dangerous more specifically owing to the toxic and corrosive properties of the hydrogen fluoride formed by UF₆ in contact with water), the spent fuel shipments to the La Hague reprocessing plant and the transport of certain nuclear wastes. The annual transports linked to the nuclear industry can be broken down approximately as follows:

- 200 shipments transporting spent fuel from the NPPs operated by EDF to the Orano reprocessing plant at La Hague;
- about 100 shipments of plutonium in oxide form between the La Hague reprocessing plant and the Melox fuel production plant in the Gard *département*;
- 250 shipments of UF₆ used for fuel fabrication;

GRAPH 1 Proportion of packages transported per field of activity in %



Transport operations relating to the “fuel cycle” in France



- 400 shipments of fresh uranium-based fuel and some fifty shipments of fresh uranium and plutonium-based “MOX” (Mixed OXides) fuel;
- 2,000 shipments from or to foreign countries or transiting *via* France, representing about 58,000 packages shipped (industrial, A and B type packages).

The statistical data presented in this chapter come from a study conducted by ASN in 2012. They are based on information collected from all the consignors of radioactive substances (Basic Nuclear Installations – BNIs, laboratories, hospitals, source suppliers and users, etc.), as well as on reports from the transport

safety advisers. A summary is available on asn.fr (heading “L’ASN informe/Dossiers pédagogiques/Transport des substances radioactives en France”). The information available to ASN shows that these statistical data are still currently valid.

TABLE 1 Breakdown per mode of transport of radioactive materials

Approximate number of packages and shipments		Road	Road and air	Road and rail	Road and sea	Road, sea and rail	Road, sea and air
Packages approved by ASN	Number of packages	18,000	1,300	460	1,900	0	0
	Number of shipments	12,500	1,250	380	390	0	0
Packages not requiring approval by ASN	Number of packages	870,000	47,000	2,900	6,800	34,500	5,300
	Number of shipments	740,000	21,000	530	910	80	5,300

2 — Regulations governing the transport of radioactive substances

Given that shipments can cross borders, the regulations governing the transport of radioactive substances are based on international requirements established by the International Atomic Energy Agency (IAEA). They are contained in the document entitled “Specific Safety Requirements – 6” (SSR-6), which constitutes the basis for European and French regulations on the subject.

2.1 Risks associated with the transport of radioactive substances

The major risks involved in the transport of radioactive substances are:

- the risk of external irradiation of persons in the event of damage to the radiological shielding provided by the package (material which reduces the radiation in contact with the packages of radioactive substances);
- the risk of inhalation or ingestion of radioactive particles in the event of release of radioactive substances outside the packaging;
- contamination of the environment in the event of release of radioactive substances;
- the initiation of an uncontrolled nuclear chain reaction (criticality risk) that can cause serious irradiation of persons. This risk only concerns fissile substances.

In addition, radioactive substances may also present a chemical risk. This, for example, is the case with shipments of natural uranium with low radioactivity, for which the major risk for humans is related to the chemical nature of the compound, more particularly if it is ingested. Similarly, UF₆, used in the manufacture of fuels for nuclear power plants can, in the event of release and contact with water, form hydrofluoric acid, a powerful corrosive and toxic agent.

By their very nature, transport operations take place across the entire country and are subject to numerous contingencies that are hard to control or anticipate, such as

the behaviour of other vehicles using the same routes. A transport accident at a given point in the country cannot therefore be ruled out, possibly in the immediate vicinity of the population. Unlike events occurring within BNIs, the personnel of the companies concerned are generally unable to intervene immediately, or even to give the alert (if the driver is killed in the accident) and the first responding emergency services are not in principle specialists in dealing with a radioactive hazard.

To deal with these risks, specific regulations have been set up to regulate radioactive substance transport operations.

2.2 Principle of “Defence in Depth”

In the same way as the safety of facilities, the safety of transport is based on the concept of “Defence in Depth”, which consists in implementing several technical or organisational levels of protection, in order to ensure the safety of the public, workers and the environment, in routine conditions, in the event of an incident and in the event of a severe accident. In the case of transport, “Defence in Depth” is built around three complementary levels of protection:

- The robustness of the package is designed to ensure that the safety functions are maintained, including in the event of a severe accident if the implications so warrant. To ensure this robustness, the regulations stipulate reference tests which the packages must be able to withstand.
- The reliability of the transport operations, which helps reduce the occurrence of anomalies, incidents and accidents. This reliability relies on compliance with the regulatory requirements, such as training of the various persons involved, the use of a quality assurance system for all operations, compliance with the package utilisation conditions, effective stowage of packages, etc.

- Management of emergency situations, so that the consequences of incidents and accidents are mitigated. For example, this third level entails the preparation and distribution of instructions to be followed by the various parties in the event of an emergency, the implementation of emergency plans and the performance of emergency exercises.

The robustness of the packages is particularly important: the package must, as a last resort, offer sufficient protection to mitigate the consequences of an incident or accident (depending on the level of hazard represented by the content).

2.3 The requirements guaranteeing the robustness of the various types of package

There are five main package types: excepted packages, industrial packages, type A packages, type B packages and type C packages. These package types are determined according to the characteristics of the material transported, such as total radiological activity, specific activity which represents the degree of concentration of the material, and its physico-chemical form.

The regulations define tests, which simulate incidents or accidents, following which the safety functions must still be guaranteed. The severity of the regulatory tests is graded according to the potential danger of the substance transported. Furthermore, additional requirements apply to packages carrying UF₆ or fissile materials, owing to the specific risks these substances entail.

2.3.1 Excepted packages

Excepted packages are used to transport small quantities of radioactive substances, such as very low activity radiopharmaceuticals. Due to the very limited safety implications, these packages do not undergo any reference tests. They must nevertheless comply with some general specifications, notably regarding radiation protection, to ensure that the level of radiation around the excepted packages remains very low.

2.3.2 Type A packages and industrial packages containing non-fissile substances

Type A packages can, for example, be used to transport radionuclides for medical purposes commonly used in nuclear medicine departments, such as technetium generators. The total activity which

TABLE 2 Breakdown of transported packages by type

Type of package	Approximate share of packages transported annually
Packages approved by ASN	2%
Packages not requiring approval by ASN	32%
Type B packages, packages containing fissile materials and packages containing UF ₆	8%
Type A package not containing fissile radioactive substances	58%
Industrial package not containing fissile radioactive substances	
Excepted packages	

can be contained in a type A package is limited by the regulations.

Type A packages must be designed to withstand incidents which could be encountered during transportation or during handling or storage operations (small impacts, package stacking, falling of a sharp object onto the packages, exposure to rain). These situations are simulated by the following tests:

- exposure to a severe storm (rainfall reaching 5 cm/hour for at least 1 hour);
- drop test onto an unyielding surface from a height varying according to the weight of the package (maximum 1.20 metres);
- compression equivalent to 5 times the weight of the package;
- penetration by dropping a standard bar onto the package from a height of 1 metre.

Additional tests are required if the content of the package is in liquid or gaseous form.

Industrial packages allow the transportation of material with a low specific activity, or objects with limited surface contamination. Uranium-bearing materials extracted from foreign uranium mines are, for example, carried in France in industrial drums with a capacity of 200 litres loaded into industrial packages. Three sub-categories of industrial packages exist according to the hazards presented by the content. Depending on their sub-category, the industrial packages are subjected to the same tests as type A packages, some of the tests or only the general provisions applicable to excepted packages.

As a result of the restrictions on the authorised contents, the consequences of the destruction of a type A package or an industrial package would remain limited, provided that appropriate accident management measures are taken. The regulations do not therefore require that this type of package be able to withstand a severe accident.

Due to the limited safety implications, type A and industrial packages are not subject to ASN approval: the design of the packages and the performance of the tests are the responsibility of the manufacturer. These packages and their safety case files are subject to spot checks during the ASN inspections.

2.3.3 Type B packages and packages containing fissile substances

Type B packages are those used to transport the most radioactive substances, such as spent fuels or high-level vitrified nuclear waste. The packages containing fissile substances are industrial, A or B type packages, which are also designed to carry materials containing uranium-235 or plutonium and which can thus lead to the start of an uncontrolled nuclear chain reaction. These packages are essentially used

by the nuclear industry. Gamma radiography devices also fall into the type B package category.

Given the high level of risk presented by these packages, the regulations require that they must be designed so that, including in the case of a severe transport accident, they maintain their ability to confine the radioactive substances and ensure radiological protection (for type B packages) as well as sub-criticality (for packages containing fissile materials). The accident conditions are simulated by the following tests:

- A 9 metres drop test onto an unyielding target. The fact that the target is unyielding means that all the energy from the drop is absorbed by the package, which is highly penalising. If a heavy package actually falls onto real ground, the ground will deform and thus absorb a part of the energy. A 9 metres drop onto an unyielding target can thus correspond to a fall from a far greater height onto real ground. This test can also be used to simulate the case of the vehicle colliding with an obstacle. During the 9 metres free-fall test, the package reaches the target at about 50 km/h. However, this corresponds to a real impact at far greater speed, because in reality, the vehicle and obstacle would both absorb a part of the energy.

- A penetration test: the package is released from a height of 1 metre onto a metal spike. The aim is to simulate the package being damaged by perforating objects (for example debris torn off a vehicle in the event of an accident).

- A fire test at 800 °C for 30 minutes. This test simulates the fact that the vehicle can catch fire after an accident.

- An immersion test under 15 metres of water for 8 hours. This test is used to test the pressure-resistance of the package if it were to fall into water (river by the side of the road or port during offloading from a ship). Certain type B packages must also undergo a more severe immersion test, which consists in immersion under 200 metres of water for one hour.

The first three tests (drop, penetration and fire test) must be performed in sequence on the same package specimen. They must be performed in the most penalising configuration (package orientation, outside temperature, position of content, etc.).

The type B package models and those containing fissile substances must be approved by ASN or, in certain cases, by a competent foreign authority, before they can be allowed to travel. To obtain this approval, the designer of the package model must demonstrate the ability to withstand the above-mentioned tests in the safety case. This demonstration is usually provided by means of tests on a reduced-scale mock-up representing the package and by numerical calculations (to simulate the mechanical and thermal behaviour, or to evaluate the criticality risk).

2.3.4 Packages containing uranium hexafluoride

UF₆ is used in the “fuel cycle”. This is the form in which the uranium is enriched. UF₆ can thus be natural (*i.e.* formed from natural uranium), enriched (*i.e.* with an isotopic composition enriched in uranium-235), or depleted.

Apart from the dangers arising from its radioactivity, or even its fissile nature, UF₆ also presents a significant chemical risk. The regulations thus set out particular prescriptions for packages of UF₆. They must meet the requirements of the 2020 edition of standard ISO 7195, which governs the design, manufacture and utilisation of packages. These packages are also subject to three tests:

- a free-fall test of between 0.3 and 1.2 metres (depending on the weight of the package) onto an unyielding target;
- a thermal test, with an 800 °C fire for 30 minutes;
- a hydrostatic resistance test at 27.6 bar.

Packages containing enriched, and therefore fissile UF₆, are also subject to the prescriptions previously presented (*see point 2.3.3*).

The UF₆ is transported in type 48Y or 30B metal cylinders. In the case of enriched UF₆, this cylinder is transported within a protective shell, which provides the necessary protection for withstanding the tests applicable to packages containing fissile materials. The package models containing UF₆ must also be approved by ASN or a competent foreign authority, before they can be allowed to travel.

2.3.5 Type C packages

Type C packages are designed for the transport of highly radioactive substances by air. In France there are no approved type C packages for civil uses.

2.4 The requirements guaranteeing the reliability of the transport operations

2.4.1 Radiation protection of workers and the public

The radiation protection of workers and the public during shipments of radioactive substances must be a constant concern. The public and non-specialist workers must not be exposed to a dose greater than 1 millisievert per year (mSv/year). However, this limit is not intended to be an authorisation to expose the public to up to 1 millisievert (mSv). Moreover, the justification and optimisation principles applicable to all nuclear activities also apply to the transport of radioactive substances (*see chapter 2*).

Training organisations for drivers of road vehicles carrying radioactive substances

In December 2023 and December 2024, ASN renewed the accreditation of organisations responsible for training the drivers of vehicles carrying class 7 dangerous goods. These accreditations were issued following the favourable opinion of the Interprofessional Committee for the Development of Training in the Transport of Dangerous Goods (CIFMD) and the High Council for the Prevention of Technological Risks (CSPRT). Only the National Institute of Nuclear Science and Technology (INSTN) and Form-Edit are approved to carry out this training for a period of five years.

Radiation protection is the subject of specific requirements in the regulations applicable to the transport of radioactive substances. Thus, for transport by road, the regulations stipulate that the dose rate at the surface of the package must not exceed 2 millisieverts per hour (mSv/h). This limit may be raised to 10 mSv/h in “exclusive use”⁽¹⁾ conditions, because the consignor or consignee can then issue instructions to restrict activities in the vicinity of the package. In any case, the dose rate must not exceed 2 mSv/h in contact with the vehicle and must be less than 0.1 mSv/h at a distance of 2 metres from the vehicle. Assuming that radiation at the surface of a transport vehicle reaches the limit of 0.1 mSv/h at 2 metres, a person would have to spend 10 consecutive hours at a distance of 2 metres from the vehicle for the dose received to reach the annual public exposure limit.

These limits are supplemented by requirements relative to the organisation of radiation protection within companies. The companies working in transport operations are required to implement a radiological protection programme, comprising the steps taken to protect the workers and the public from the risks arising from ionising radiation. This programme is more specifically based on a forecast evaluation of the doses to which the workers and the public are exposed.

According to the results of this evaluation, optimisation measures must be taken to ensure that these doses are As Low as Reasonably Achievable (ALARA⁽²⁾ principle): for example, lead-lined trolleys could be made available to handling

staff to reduce their exposure. This evaluation also makes it possible to decide on whether to implement dosimetry to measure the dose received by the workers, if it is anticipated that it could exceed 1 mSv/year.

Finally, all the transport players must be trained in the risks linked to radiation, so that they are conscious of the nature of the risks, as well as how to protect themselves and how to protect others.

The workers involved in the transport of radioactive substances are also subject to the provisions of the Labour Code concerning protection against ionising radiation.

ASN Guide No. 29 aims to help carriers meet their regulatory obligations relative to the radiation protection of workers and the general public.

2.4.2 Package and vehicle marking

So that the workers can be informed of the level of risk arising from each package and so that they can protect themselves effectively, the regulations require that the packages be labelled. There are three types of labels, corresponding to different dose rate levels in contact and at 1 metre from the package. The workers operating close to the package thus have a visual means of knowing which packages entail the highest dose rates, and can thus limit the time they spend close to them and can put them as far away as possible (for example by loading them towards the rear of the vehicle).

The packages containing fissile materials must also display a special label. This is to ensure that these packages are kept apart to prevent the triggering of a nuclear chain reaction. The special label enables compliance with this prescription to be easily verified.

Finally, the markings on packages must comprise their type, the address of the consignor or consignee and an identification number. This enables delivery errors to be avoided and allows packages to be identified if lost.

The vehicles carrying packages of radioactive substances must also have specific markings. Like all vehicles carrying dangerous goods, they carry an orange-coloured plate at the front and back. They must also carry a placard with the radiation trefoil and the word “Radioactive”. The purpose of these vehicle markings is

to provide the emergency services with the necessary information in the event of an accident.

2.4.3 Responsibilities of the various transport players

The regulations define the responsibilities of the various parties involved during the lifetime of a package, from its design up to the actual shipment. These responsibilities entail special requirements. Therefore:

- The package model designer shall have designed and sized the packaging in accordance with the intended conditions of use and the regulations. It must obtain an ASN certificate (or in certain cases a certificate from a foreign authority) for type B packages or packages containing UF_6 or fissile material.
- The manufacturer must produce packaging in accordance with the description given by the package designer.
- The consignor is responsible for providing the carrier with a package complying with the requirements of the regulations. It must in particular ensure that the substance is authorised for transport, verify that the package is appropriate for its content, use a package that is approved (if necessary) and in good condition, carry out dose rate and contamination measurements and label the package.
- Transport may be organised by the forwarding agent. They are responsible, on behalf of the consignor or the consignee, for obtaining all the necessary authorisations and for sending the various notifications required by the regulations. The forwarding agent also selects the conveyance, the carrier and the itinerary, in compliance with the regulatory requirements.
- The loader is responsible for loading the package onto the vehicle and for stowing it in accordance with the consignor’s specific instructions and the rules of good professional practice.
- The carrier and, more particularly, the driver, is responsible for carriage of the shipment to its destination. Their duties include checking the good condition of the vehicle, the presence of the on-board equipment (extinguishers, driver’s personal protection equipment, etc.), compliance with the dose rate limits around the vehicle and the display of the orange plates and placards.
- The consignee is under the obligation not to postpone acceptance of the goods, without imperative reason and, after unloading, to verify that the requirements concerning them have been satisfied. It must more

1. Exclusive use corresponds to cases in which the vehicle is used by a single consignor. This consignor may then give specific instructions for all the transport operations.

2. The ALARA (As Low As Reasonably Achievable) principle appeared for the first time in Publication 26 from the International Commission on Radiological Protection (ICRP) in 1977. It was the end-result of a review of the radiation protection optimisation principle.

specifically perform dose rate measurements on the package after receipt in order to detect any problems that may have occurred during shipment.

- The package owner must set up a maintenance system in conformity with that described in the safety case and the approval certificate in order to guarantee that the elements important for safety are maintained in good condition.

All the transport players must set up a quality management system (previously called a “management system”), which consists of a range of provisions for guaranteeing compliance with the regulatory requirements and providing proof thereof. This for example consists in performing double independent checks on the most important operations, in adopting a system of checklists to ensure that the operators forget nothing, in keeping a trace of all the operations and all the checks performed, etc. The quality management system is a key element in ensuring the reliability of transport operations.

ASN Guide No. 44 informs professionals involved in radioactive substances transport operations of ASN’s requirements regarding the contents of a quality management system. It highlights the graded approach, with the level of requirements for the management system being proportionate to the safety implications of the activity of these professionals and the size of the company concerned.

The regulations also require that all operators involved in transport receive training appropriate to their functions and responsibilities. This training must in particular cover the steps to be taken in the event of an accident.

Contractors which carry, load, unload or handle (after loading and before unloading) packages of radioactive substances on French soil shall declare these transport activities to the ASN on-line services portal before carrying them out. This on-line service is also available in English.

The transport of certain radioactive substances (notably fissile substances) must first be notified by the consignor to ASN and to the Ministry of the Interior, seven days prior to departure. This notification stipulates the materials carried, the packagings used, the transport conditions and the details of the consignor, the carrier and the consignee. It is a means of ensuring that the public authorities have rapid access to useful information in the event of an accident.

In 2024, 848 notifications were sent to ASN.

2.5 Preparedness for management of emergencies

The management of emergency situations is the final level of “Defence in Depth”. In the event of an accident involving transport, it should be able to mitigate the consequences for persons and the environment.

As a transport accident can happen anywhere in the country, it is probable that the emergency services arriving on the scene would have no specific training in radiological risks and that the population in the vicinity would be unaware of this particular risk. It is therefore particularly important that the national emergency response organisation be robust enough to take account of these points.

In this respect, the regulations set obligations on the various stakeholders in the field of transport. All those involved must therefore immediately alert the emergency services in the event of an accident. This is more particularly true for the carrier, who would in principle be the first party to be informed. It must also transmit the alert to the consignor. Furthermore, the vehicle crew must have written instructions available in the cab, stipulating the first steps to be taken in the event of an accident (for example: trip the circuit-breaker, if the vehicle is so equipped, to prevent any outbreak of fire). Once the alert has been given, the parties involved must cooperate with the public authorities to assist with the response operations, including by providing all pertinent information in their possession. This in particular concerns the carrier and the consignor who have information about the package and its contents that is of great value for determining the appropriate measures to be taken. To meet these regulatory obligations, ASN recommends that the parties involved implement emergency response plans allowing the organisation and tools to be defined in advance, enabling them to react efficiently in the event of an actual emergency.

ASN Guide No. 17 details the essential topics to be developed in a management plan for incidents and accidents involving the transport of radioactive substances for civil use.

The driver may be unable to give the alert, if injured or killed in the accident. In this case, detection of the radioactive nature of the consignment would rely on the emergency services. The plates bearing the trefoil signal on the vehicles, indicating the presence of radioactive substances, also signal the presence of dangerous goods: the emergency services are then instructed

to automatically evacuate an area around the vehicle, usually with a radius of 100 metres, and to notify the radioactive nature of the load to the office of the Prefect, which will then alert ASN.

Management of the accident is coordinated by the Prefect, who oversees the response operations. Until such time as the national experts are in a position to provide him or her with advice, the Prefect relies on the emergency plan adopted to deal with these situations.

ASN is able to offer the Prefect assistance by providing technical advice on the more specific measures to be taken. The Institute for Radiation Protection and Nuclear Safety (IRSN) assists ASN in this role, by assessing the condition of the damaged package and anticipating how the situation could develop. Furthermore, the ASN regional division dispatches a staff member to the Prefect to facilitate liaison with the national Emergency Centre. As of 1 January 2025, the roles of ASN and IRSN concerning the transport of radioactive substances are taken over by the Authority for Nuclear Safety and Radiation Protection (ASNR – see chapter 4 on radiological emergency and post-accident situations).

At the same time, human and material resources would be sent out to the scene of the accident as rapidly as possible (radioactivity measuring instruments, medical means, package recovery means, etc.). The fire service teams specialising in the radioactive risk (the Mobile Radiological Intervention Units – CMIR) would be called on, along with IRSN’s mobile units, or even those of nuclear installation licensees (such as the Alternative Energies and Atomic Energy Commission – CEA, or EDF), which could be requisitioned by the Prefect if needed, even if the shipment in question does not concern these licensees.

As with other types of emergency, communication is an important factor in the event of a transport accident so that the population can be informed of the situation and be given instructions on what to do.

In order to prepare the public authorities for the eventuality of an accident involving a shipment of radioactive substances, exercises are held to test the entire response organisation that would be put into place.

ASNR, which takes over the roles of ASN and IRSN, will continue in 2025 to support adequate preparedness by the public authorities for emergency situations involving a transport operation, in particular by promoting the performance of local emergency exercises and issuing recommendations on the steps to be taken in the event of an accident.



Overview of the trailer with mechanical protection of the EMEM docking device

Reinforcing the safety of on-site transports at La Hague

Operation of the Orano Recyclage facility at La Hague requires the on-site transport of dangerous materials and waste between the various units. The facility thus has Mobile Docking Chambers for Material Removal (EMEM) to carry samples, but also irradiating technological waste, used parts replaced for safety reasons (ventilation filters, valves, pumps, etc.). ASN ordered Orano Recyclage to

improve this transport system, specifically concerning radiological protection and containment in incident and accident situations, including in the event of a collision. In response, Orano Recyclage reinforced the safety of these transports in 2024 by notably adding mechanical protection around the EMEM, and using a new and appropriate transport trailer.

ASN recommendations in the event of a transport accident

The response by the public authorities in the event of a transport accident comprises three phases:

- The emergency services reach the site and initiate “reflex” measures to limit the consequences of the accident and protect the population. The radioactive nature of the substances involved is discovered during this phase.
- The entity coordinating the emergency response confirms that the substances are indeed radioactive, alerts ASN and IRSN and gives more specific instructions to the responders, pending activation of the national Emergency Centres.
- Once the ASN and IRSN Emergency Centres are operational, a more detailed analysis of the situation is performed in order to advise the person in charge of the emergency operations.

During the first two phases, the emergency services must manage the situation without the support of the national experts. In 2017, with the assistance of IRSN and the national Nuclear Risk Management Aid commission, ASN produced a document to help direct the actions of the emergency services. It contains general

information about radioactivity, general recommendations for the emergency services so that their response can take account of the specific nature of radioactive substance transports, plus sheets organised per type of substance, providing more detailed information and advice for the emergency response coordinator during phase 2. This document will be updated in 2025.

2.6 Regulations governing the transport operations within the perimeter of nuclear facilities

Dangerous goods transport operations can take place on the private roads of nuclear sites, in what are referred to as “on-site transport operations”. Such operations are not subject to the regulations governing the transport of dangerous goods, which only apply on public roads. However, these operations present the same risks and detrimental effects as dangerous goods transports on the public highway. The safety of these operations must thus be overseen with the same rigour as for any other risk or detrimental effect present within the perimeter of BNIs.

This is why the on-site transport of dangerous goods is subject to the requirements of the Order of 7 February 2012 setting out the general rules applicable to BNIs. This Order requires that on-site transport operations be incorporated into the baseline safety requirements for BNIs.

The Environment Code, supplemented by ASN resolution 2017-DC-0616 of 30 November 2017, defines the on-site transport operations for which authorisation must be requested from ASN. In addition, ASN published Guide No. 34 providing the licensees with recommendations for implementing the regulatory requirements concerning on-site transport operations.

3 — Roles and responsibilities in regulating the transport of radioactive substances

3.1 Regulation of nuclear safety and radiation protection

In France, ASN has been responsible for regulating the nuclear safety and the radiation protection of transports of radioactive substances for civil uses since 1997, while the Defence Nuclear Safety Authority (ASND) fulfils this role for transports relating to national defence. Within its field of competence, ASN is responsible, in terms of safety and radiation protection, for the regulation and oversight of all steps in the life of a package: design, manufacture, maintenance, shipment, actual carriage, receipt and so on.

3.2 Protection against malicious acts

The prevention of malicious acts consists in preventing sabotage, losses, disappearance, theft and misappropriation of nuclear materials (as defined in Article R*. 1411-11-19 of the Defence Code) that could be used to manufacture weapons. The Defence and Security High Official (HFDS), under the Minister responsible for energy, represents the Regulatory Authority responsible for preventing malicious acts targeting nuclear materials.

In the field of transport security, the IRSN Transport Operations Section (EOT) is responsible for managing and processing

applications for approval of nuclear material shipments, for supervising these shipments and for notifying the authorities of any alerts concerning them. This security mission is defined by the Order of 28 February 2023 relative to the security of transport of nuclear materials, implementing Articles R. 1333-4 and R. 1333-17 to R. 1333-19 of the Defence Code. Thus, prior to any transport operation, the Defence Code obliges the carriers to obtain a transport authorisation. The EOT reviews the corresponding application files. This review consists in checking the conformity of the intended provisions with the requirements defined by the Defence Code and the above-mentioned Order of 28 August 2023.

ASN has initiated the process to update its resolution 2015-DC-0503 of 12 March 2015 relative to the notification system for companies transporting radioactive substances on French territory. This update aims to introduce an authorisation system for the transport of the most radioactive sources, in the light of their security implications. The interface between the provisions taken from the new regulations on the protection of ionising radiation sources and batches of category A, B, C and D radioactive sources against malicious acts (Order of 29 November 2019, amended) and the transport regulations will be dealt with.

3.3 Regulation of the transport of dangerous goods

Regulation of the transport of dangerous goods is the responsibility of the Dangerous Materials Transport Commission (MTMD) of the Ministry responsible for the environment. This structure is tasked with measures relative to the safe transport of dangerous goods other than class 7 (radioactive) by road, rail and inland waterways. It has a consultative body (standing sub-committee in charge of dangerous goods transport, within the CSPRT that is consulted for its opinion on any draft regulations relative to the transport of dangerous goods by rail, road or inland waterway. Inspections are carried out by land transport inspectors attached to the Regional Directorates for the Environment, Planning and Housing.

For the regulation of dangerous goods to be as consistent as possible, ASN collaborates regularly with the administrations concerned.

The breakdown of the various inspection duties is summarized in Table 3.

TABLE 3 Administrations responsible for regulating the mode of transport and the packages(*)

Mode of transport	Regulation of mode of transport	Package regulation
By sea	Directorate General for Infrastructures, Transports and the Sea (DGITM) at the Ministry for the Environment. In particular, the DGITM is responsible for regulating compliance with the prescriptions applicable to ships and contained in the International Code for the Safe Carriage of irradiated nuclear fuel, plutonium and high-level radioactive wastes on board ships ("Irradiated Nuclear Fuel" Code).	The DGITM has competence for regulation of dangerous goods packages in general and is in close collaboration with ASN for radioactive substances packages.
By road, rail and inland waterways	General Directorate for Energy and Climate (DGEC) of the Ministry for the Environment.	The General Directorate for the Prevention of Risks (DGPR) is responsible for regulation of packages of dangerous goods in general and, in close collaboration with ASN, of packages of radioactive substances.
By air	General Directorate for Civil Aviation (DGAC) at the Ministry for the Environment.	The DGAC has competence for regulation of dangerous goods packages in general and is in close collaboration with ASN for radioactive substances packages.

* In 2025, ASN takes over the roles and ASN and IRSN regarding transport.

4 — ASN action in the transport of radioactive substances

4.1 Issuance of approval certificates and shipment approvals

The type B and C packages, as well as the packages containing fissile materials and those containing more than 0.1 kilograms of UF_6 must have an ASN approval certificate in order to be used for transportation. The designers of the package models who request approval from ASN must support their application with a safety case demonstrating the compliance of their package with all the regulatory requirements. Before deciding whether or not to issue an approval certificate, ASN reviews these safety cases, drawing as necessary on the expertise of IRSN, in order to ensure that the safety cases are pertinent and conclusive. If necessary, the approval certificate is issued with requests to improve specific items in the safety case.

In some cases the IRSN appraisal may be supplemented by a meeting of the Advisory Committee of Experts for the Transport of radioactive substances (GPT). The opinions of the Advisory Committees are published on *asn.fr*. The approval certificate specifies the conditions for the manufacture, utilisation and maintenance of the transport package. It is issued for a package model, independently of the actual shipment itself, for which no prior ASN opinion is generally required. This shipment may however be subject to security constraints (physical protection of the materials against malicious acts under the supervision of the HFDS of the Ministry for the Environment).

These approval certificates are usually issued for a period of five years. If a package is unable to meet all the regulatory requirements, the regulations nonetheless allow for its transport by means of a shipment under special arrangement. The consignor must then define compensatory measures to ensure a level of safety equivalent to that which would have been obtained had the regulatory requirements been met. For example, if

it cannot be completely demonstrated that a package is able to withstand the 9 metres drop, a compensatory measure may be to reduce the speed of the vehicle, have it escorted and choose a route avoiding such a drop height. The probability of a serious accident, and therefore of a violent shock on the package, is thus considerably reduced. A shipment under special arrangement is only possible with the approval of the competent authority, which then issues approval for shipment under special arrangement, stipulating the compensatory measures to be applied.

In the case of certificates issued abroad, the international regulations provide for their recognition by ASN. In certain cases, this recognition is automatic and the foreign certificate is directly valid in France. In other cases, the foreign certificate is only valid if endorsed by ASN, which then issues a new certificate.

In 2024, 15 approval applications were submitted to ASN by the manufacturers.

ASN issued 25 approval or shipment authorisation certificates, for which the breakdown according to type is presented in Graph 2. The nature of the transports and packages concerned by these certificates is presented in Graph 3.

4.2 Monitoring all the stages in the life of a package

ASN performs inspections at all the stages in the life of a package: from manufacture and maintenance of a packaging, to package preparation, shipment and reception.

In 2024, ASN carried out 102 inspections in the field of radioactive substances transport (all sectors considered). The follow-up letters to these inspections are available on *asn.fr*.

Since 2023 and twice a year, ASN publishes the applicable list of package model approval certificates that it has issued, on its website.

4.2.1 Regulation of package manufacturing

The manufacture of transport packaging is subject to the regulations applicable to the transport of radioactive substances. The manufacturer is responsible for producing packagings in accordance with the specifications of the safety case, demonstrating regulatory compliance of the corresponding package model. To do this, it must implement a quality management system covering all the operations from procurement of parts and raw materials up to final inspections. Furthermore, the manufacturer must be able to prove to ASN that it complies with the regulatory provisions and, in particular, that the as-built packagings are compliant with the specifications of the safety case.

The inspections carried out by ASN in this field aim to ensure that the manufacturer satisfactorily fulfils its responsibilities.

In 2024, ASN carried out nine inspections on the manufacturing of various packagings for which ASN had issued an approval certificate, at various steps in the manufacturing process: welding, final assembly, manufacturing completion checks, assembly of internals (to immobilise the contents), etc.

During these inspections, ASN reviews the quality management procedures implemented for the manufacture of a packaging on the basis of the design data and verifies their effective implementation. ASN ensures that the inspections performed and any manufacturing deviations are traceable. It also visits the manufacturing shops to check the package components storage conditions, the calibration of the inspection instruments and compliance with the technical procedures at the various manufacturing steps (welding, assembly, etc.).

ASN checks the monitoring of package manufacturing by the lead contractor and may intervene directly on the sites of any subcontractors, who may sometimes be located abroad.

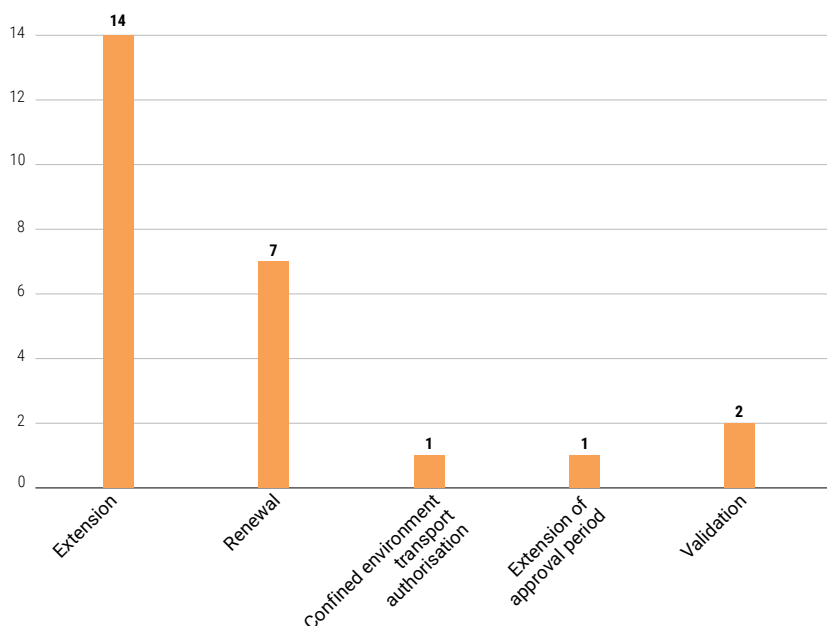
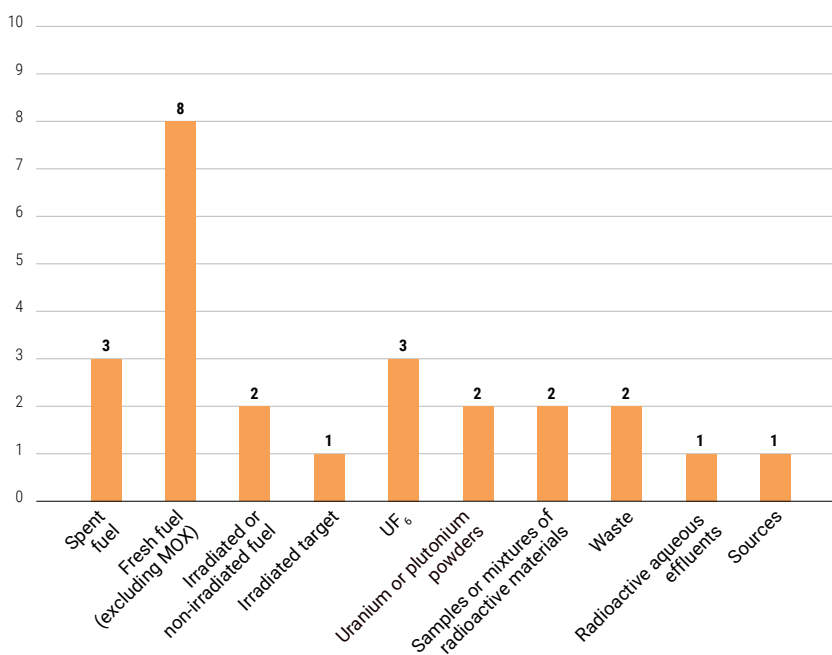
ASN may also inspect the manufacture of the specimens used for the drop tests and fire tests required by the regulations. The objectives are the same as for the series production model because the specimens must be representative and comply with the maximum requirements indicated in the mock-up manufacturing file, which will determine the minimum characteristics of the actual packaging to be manufactured.

In 2025, ASN intends to continue inspections of transport packaging manufacturing. This is because the irregularities detected in 2016 at the Framatome Le Creusot plant, which also affected certain transport packagings, as well as the

First French approval certificate for SCO-III shipment

EDF intends to send the lower parts of the disused Steam Generators (SGs) from the Fessenheim NPP to Sweden, for reuse of the metal parts. To this end, it submitted an authorisation application to ASN in July 2022 for multimodal transport of surface contaminated objects, known as "SCO III". The 2018 edition of the IAEA's international transport regulations, SSR-6, created this additional category of surface contaminated objects in order to meet

the need for the transport of very large sized contaminated objects, resulting for example from installations decommissioning or replacement of heavy components, such as SGs. Owing to their dimensions, it is thus impossible to load these objects into a dedicated transport packaging. Following the review, ASN issued the first approval certificate for SCO-III shipment in July 2023. These SG lower parts are scheduled for transport in mid-2025.

GRAPH 2 Breakdown of number of approvals according to type, issued in 2024**GRAPH 3** Breakdown of number of approvals according to content carried, issued in 2024

discovery in 2022 of falsifications concerning conventional products at the manufacturer of steel castings and forgings, Japan Steel Works Ltd. (JSW) – which also produces parts for transport packagings – confirmed the importance of inspecting the packaging manufacturing and maintenance operations.

4.2.2 Packaging maintenance inspections

The consignor or user of a packaging loaded with radioactive substances must be able to prove to ASN that this packaging is periodically inspected and, if necessary, repaired and maintained in good condition such that it continues to satisfy all the relevant requirements and specifications of its safety case and its approval certificate, even after repeated use. For approved packagings, the inspections carried out by

ASN for example concern the following maintenance activities:

- the periodic inspections of the components of the containment system (screws, welds, seals, etc.);
- the periodic inspections of the securing and handling components;
- the definition of the frequency of replacement of the packaging components which must take account of any reduction in performance due to wear, corrosion, ageing, etc.

4.2.3 Inspections of packages not requiring approval

For the packages that do not require ASN approval, the consignor must, at the request of ASN, be able to provide the documents proving that the package model complies with the applicable regulations. More specifically, for each package, a file demonstrating that the model meets the regulation requirements and that it can in particular withstand the specified tests, along with a certification delivered by the manufacturer attesting full compliance with the model specifications, must be kept at the disposal of ASN.

The various inspections carried out in recent years confirm progress in compliance with this requirement and in implementation of the ASN recommendations detailed in its guide concerning packages which are not subject to approval (Guide No. 7, volume 3).

This Guide proposes a structure and a minimum content for the safety cases demonstrating that packages which are not subject to approval do comply with all the applicable requirements, along with the minimum content of a declaration of conformity of a package design with the regulations.

ASN thus noted improvements in the content of the certificate of conformity and the safety case drawn up by the relevant players, more specifically for the industrial package models. The representativeness of the tests performed and the associated safety case remain the focal points during the ASN inspections, in particular for type A packages.

Furthermore, ASN is still finding shortcomings in the demonstration by some of the players (designers, manufacturers, distributors, owners, consignors, companies performing the regulatory drop tests, package maintenance, etc.) of package conformity with the regulations. The areas for improvement concern the following points in particular:

- the description of the authorised contents per type of packaging;
- the demonstration that there is no loss or dispersion of the radioactive content under normal conditions of transport;

• compliance with the regulatory requirements regarding radiation protection, more specifically the demonstration, as of the design stage, that it would be impossible to exceed the dose rate limits with the maximum authorised content.

4.2.4 Monitoring the shipment and transportation of packages

The scope of ASN inspections includes all regulatory requirements binding on each of the transport players, that is compliance with the requirements of the approval certificate or declaration of conformity, training of the personnel involved, implementation of a radiological protection programme, satisfactory stowage of packages, dose rate and contamination measurements, documentary conformity, implementation of a quality assurance programme, etc.

More particularly with respect to transports concerning small-scale nuclear activities, the ASN inspections confirm significant disparities from one carrier to another. The differences most frequently identified concern the quality assurance programme, actual compliance with the

procedures put into place and radiation protection of the workers.

Knowledge of the regulations applicable to the transport of radioactive substances seems to be sub-standard in the medical sector in particular, where the procedures adopted by some hospitals or nuclear medicine units for package shipment and reception need to be tightened. Their quality management system has not yet been formally set out and deployed, more specifically with regard to the responsibilities of each member of staff involved in receiving and dispatching packages.

More generally, in transport operations for small-scale nuclear activities, the radiological protection programmes and the safety protocols have not yet been systematically defined. ASN also found that checks on vehicles and packages prior to shipment need to be improved. The inspections concerning the transport of gamma ray projectors regularly reveal inappropriate stowage or tie-down.

In the BNI sector, ASN considers that the consignors must improve how they demonstrate that the content actually loaded into the packaging complies with the specifications of the approval certificates and the

corresponding safety cases, including if this demonstration is provided by a third-party. In this latter case, the consignor's responsibilities then require that it verify that this demonstration is appropriate, and that it monitor the third-party company in accordance with the usual methods of a quality assurance system.

As BNI licensees are increasingly using contractors to prepare and ship packages of radioactive substances, ASN is paying particularly close attention to the organisation put into place to monitor these contractors.

Finally, with regard to on-site transports within NPPs, ASN considers that the licensees must remain vigilant to the application of package tie-down rules.

4.2.5 Analysis of transport events

The safety of the transport of radioactive substances relies in particular on the existence of a reliable system for detecting and processing anomalies, deviations or, more generally, any abnormal events that could occur. Therefore, once detected, these events must be analysed in order to:

- prevent identical or similar events from happening again, by taking appropriate corrective and preventive measures;
- prevent a more serious situation from developing by analysing the potential consequences of events which could be precursors of more serious events;
- identify the best practices to be promoted in order to improve transport safety.

The regulations also requires on-line notification to ASN of the most significant events so that it can ensure that the detection system, the analysis approach and the integration of Operating Experience Feedback (OEF) are effective. This also provides ASN with an overview of events so that the sharing of operating experience feedback can be encouraged between the various stakeholders – including internationally – and so that ASN can consider potential changes to the provisions governing the transport of radioactive substances.

As requested in Article 7 of the Order of 29 May 2009, amended, concerning the transport of dangerous goods by land, any significant event concerning the transport of radioactive substances, whether the consequences are actual or potential, must be notified to ASN within four working days, as stipulated in its Guide No. 31 on the notification of events. This Guide can be consulted on asn.fr. After notification, a detailed report of the event must be sent to ASN within two months.



Inspection at the port of Fos-sur-Mer

Inspection on the safety of maritime transport of radioactive materials

An inspection took place on 22 October 2024 at the port of Fos-sur-Mer on the topic of the maritime transport of radioactive materials. It covered the contents and the implementation of the Radiological Protection Programmes (PPR) at Eurofos, as well as the training received by the on-shore personnel on the subject of radiation protection and the safe transport of radioactive materials. The inspectors found that only 10% of the dock workers were trained in the specific requirements

of radioactive materials transport. Following the audit conducted by the International Maritime Organisation (IMO) in 2023, they did however determine that Eurofos intended to extend dangerous goods transport training to a larger number of personnel. ASN asked the port to train the dock workers, ship's captains and the safety coordinator in the radiation protection and safety of radioactive materials transport operations and to make provision for regular refresher courses.



Inspection on the Orano
Recyclage site at La Hague

Inspection of the shipment of the CASTOR HAW28M package to the Valognes rail terminal (Manche département)

On 18 November 2024, ASN inspectors went to the Orano Recyclage site at La Hague. Under a Franco-German intergovernmental agreement, four CASTOR HAW28M packages were transported between the Orano Recyclage plant on the La Hague (50) site and the Phillipsburg site (Germany). Until 9 February 2028, these packagings, loaded with standard vitrified waste containers (CSD-V), will be covered by French certificate F/667/B(U)F-96 (e) validating the initial approval issued by the competent German Authority. During this inspection, the ASN inspectors were accompanied by four radiological measurement experts from IRSN, along with two German experts from the Bundesanstalt für Materialforschung und -prüfung (BAM), with the German federal institute notably contributing expertise in the safety cases of class 7 package models (radioactive materials).

The inspectors checked the preparation and handling of the packages before road shipment to the Valognes rail terminal. Before the trucks left and in addition to the measurements taken by Orano Recyclage, the IRSN experts took independent measurements of equivalent dose rate on contact and at 2 metres from the package and road rigs, as well as independent measurements of non-fixed surface contamination, in order to check compliance with the regulation radiation protection criteria. Based on the results of their examination of the requirements of the approval validation certificate, and of the reports confirming the tightness of the closure of the containments, and those confirming the various radiological measurements, the inspectors considered that shipment of the CASTOR HAW28M packages complied with the requirements of the regulations.

Events notified in 2024

In 2024, in the field of radioactive substances transport, ASN was notified of 100 events rated level 0 on the International Nuclear and Radiological Event Scale (INES) and 3 events rated level 1. A rise in the number of level 0 events is observed by comparison with 2023, whereas the number of level 1 events remains stable. This rise reflects the growing awareness among the licensees of the need to notify a significant event. Graph 4 shows the variations in the number of significant events notified since 2007.

ASN was also notified of 50 Events of Interest for the safety of Transports (EITs), a figure which is 18% down on 2023. Because they have no actual or potential consequences, these events are not rated on the INES scale. There is thus no obligation to notify ASN, but the latter does encourage periodic information so that it has an overview of the EITs and can detect any recurrence or trends which could be indicative of a problem.

Finally, for on-site transport operations, only one event – rated level 0 on the INES scale – was notified in 2024, as against 4 in 2023 (including one rated INES 1).

Sectors concerned by these events

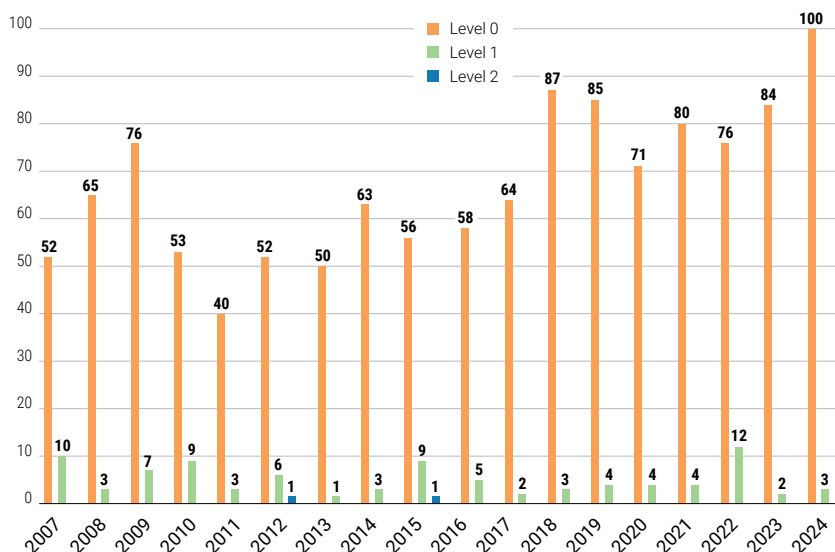
As in the previous years, most of the significant events notified concern the road transport of radiopharmaceutical products (23%). This figure has been constantly dropping for several years, owing to improved monitoring of carriers by the carriage commission agents. However, the number of significant events notified regarding the transport of gamma radiography devices was up 7% on 2023, with the recipients of these devices being particularly vigilant regarding compliance with the transport regulations.

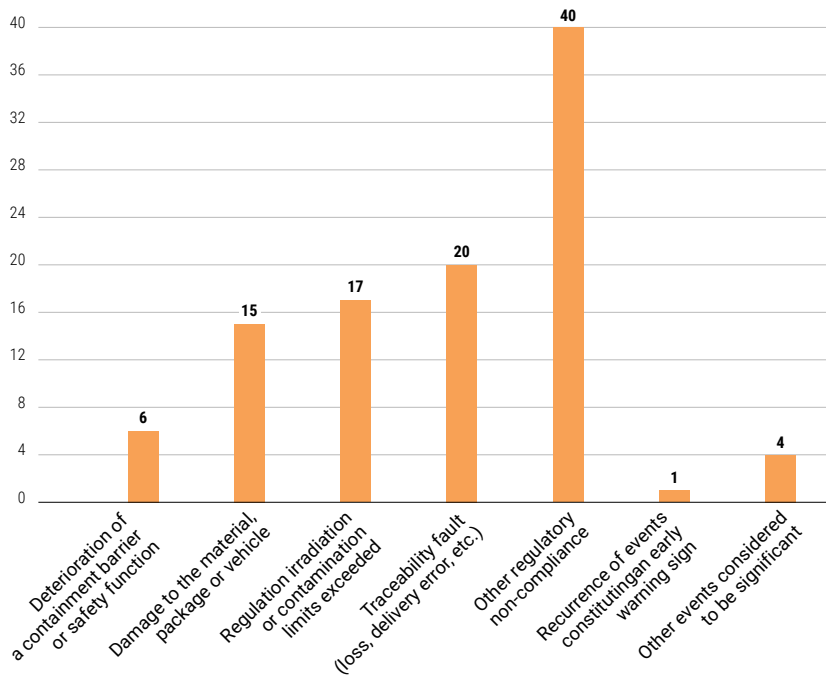
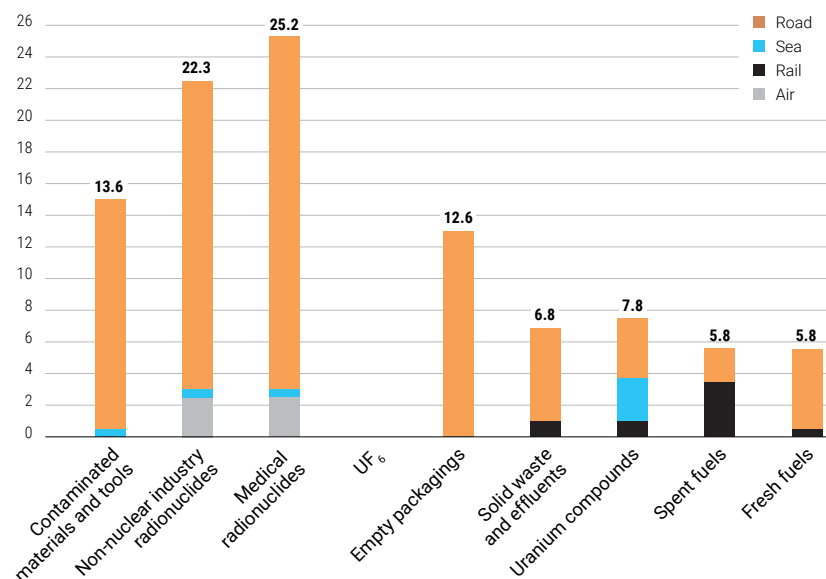
As for the events rated level 1 on the INES scale:

- non-compliance with the transport conditions for a gamma ray projector coming from Chad was rated INES level 1 owing to the lack of identification of the radioactive nature of the load, and additionally the fact that this was not the first occurrence;
- loss of a package containing a flask of fluorine-18 was rated INES level 1, on the grounds of a lack of radiation protection culture;
- the last event rated level 1 on the INES scale concerns the repetition of radiopharmaceutical package delivery errors by a carrier.

None of these three level 1 events on the INES scale had any consequences for the workers, population, or environment.

GRAPH 4 Trend in the number of significant events affecting the transport of radioactive substances notified



GRAPH 5 Breakdown of significant events notified in 2024 by notification criterion**GRAPH 6** Breakdown of notified transport events (as %) by content and mode of transport in 2024

Graph 5 shows the breakdown of significant events reported per notification criterion and Graph 6 presents their breakdown according to content and mode of transport.

Causes of events

The recurring causes of the significant events notified in 2024 include the following:

- Radiopharmaceutical products delivery errors, with no real consequences, as the drugs delivered are appreciably the same. Most of them could therefore be used with no impact on patient treatment or on the environment.

- Nonconformities affecting a package: they mainly concern deviations in the stipulations of the package model safety cases (notably, package stowage), or deviations in the conformity certificates. Labelling defects (error or omission) or signage faults could also be mentioned here. These events had no actual consequences for safety or radiation protection.

- The presence of surface contamination spots slightly exceeding the regulation limits, detected in particular on conveyances which have been used to transport spent fuel packages (under-wagon water collection pans), or contaminated tooling, or on the outer surface of packagings. These

events had very little impact on radiation protection of the public, who cannot have access to the contaminated areas.

- Finally, cases where the regulation dose rate limit of the packages was slightly exceeded. These events had no actual consequences for the radiation protection of workers, the public or the environment.

The EITs reported to ASN are primarily deviations relating to incorrect labelling of packages (consignee or consignor not mentioned), errors in the transport documentation, or deviations consisting in the detection of foreign objects in empty packagings.

As for the on-site transport significant event notified, this concerns a lack of stowage instructions for transport of waste drums and crates in a new vehicle recently acquired.

4.3 Participation in drawing up the regulations applicable to the transport of radioactive substances

4.3.1 Participation in the work of the International Atomic Energy Agency

ASN represents France on the IAEA's Transport Safety Standards Committee (TRANSSC), which brings together experts from all countries and reviews the IAEA safety standards constituting the basis of regulations concerning the transport of radioactive substances. With a view to constant improvement of safety levels, ASN notably played an active part in drafting the 2018 edition of this document, SSR-6. The IAEA guide for application of the regulation of radioactive materials transport (SSG-26) was published in 2022. In 2022, ASN also supported the launch of a new revision cycle for SSR-6, submitting more than a hundred modification proposals to the IAEA in 2023 and 2024.

4.3.2 Participation in drafting of national regulations

ASN takes part in the drafting of French regulations relative to the transport of radioactive substances. These regulations mainly consist of the Order of 29 May 2009 and the Orders of 23 November 1987 concerning the safety of ships and of 18 July 2000 concerning the transport and handling of dangerous materials in sea ports. ASN therefore sits on the CSPRT, which is called on to issue an opinion on any draft regulation for the transport of dangerous goods by rail, road and inland waterway. ASN is also consulted by the Ministry responsible for transport when a modification of the three Orders mentioned above can have an impact on the transport of radioactive substances.

Reinforcing the safety of loading of radioactive packages

During inspections, ASN found that radioactive packages could be loaded into inappropriate compartments below the bed of the vehicles. This is why, at ASN's request, the TMD Order of 29 May 2009 was modified by the Order of 3 July 2024, to specify that packages loaded with dangerous goods must be correctly chocked and stowed, either on the bed of the vehicle, or in racks secured or positioned in the compartment intended for loading and that no dangerous goods could be located in a compartment or box intended for the transport of items (tools, pallet, etc.) other than goods.

4.4 Contributing to public information

Ordinance 2012-6 of 5 January 2012, modifying Books I and V of the Environment Code, extends the obligations for public information to the persons Responsible for Nuclear Activities (RNAs). Article L. 125-10 of the Environment Code sets the thresholds beyond which the person responsible for transport must communicate the information requested by a citizen. The

thresholds are defined as being those “above which, in application of the international conventions and regulations governing the transport of dangerous goods, of the Code of Transport and of their implementing texts, the transport of radioactive substances is subject to the issuance – by ASN or by a foreign Authority competent in the field of radioactive substance transport – of an approval of the transport package design or a shipment approval, including under special arrangement”. Any citizen may therefore ask the persons in charge of transport for information on the risks presented by the transport operations referred to in the Environment Code.

On asn.fr, ASN has also published an information file presenting the transport of radioactive substances.

4.5 Participation in international relations in the transport sector

International regulations are drafted and implemented as a result of fruitful exchanges between countries. ASN incorporates these exchanges into a process of continuous improvement in the level of safety of radioactive substance transports, and encourages exchanges with its foreign counterparts.

4.5.1 Work of the European Association of Competent Authorities on Transport

The European Association of Competent Authorities on the Transport of Radioactive Material (EACA) was created in 2008. Its purpose is to promote the harmonisation of practices in the regulation of the safety of transport of radioactive substances, and to encourage exchanges and experience feedback between the various Authorities. France, which initiated the creation of this association, plays an active part in its work, including by presenting its views on the regulatory changes that may be needed, in particular on the occasion of the association's annual meeting.

4.5.2 Bilateral relations with ASN's foreign counterparts

ASN devotes considerable efforts to maintaining close ties with the competent Authorities of the countries concerned by the numerous shipments to and from France. Prominent among these are Belgium, the United Kingdom and Switzerland.

Belgium

For the production of nuclear electrical power in Belgium, French-designed packagings are sometimes used for “fuel cycle”



Participants at the 49th IAEA TRANSSC Committee meeting in Vienna (Austria) – 18 to 22 November 2024



EACA meeting in Ljubljana (Slovenia) – 6 to 10 May 2024

shipments. In order to harmonise practices and achieve progress in the safety of these shipments, ASN and the competent Belgian Authority (Belgian Federal Nuclear Regulating Agency – AFCN) regularly exchange know-how and experience. The exchanges more particularly concern the review of safety cases of French package models for which ASN approval is validated in Belgium, and inspection practices in each country.

United Kingdom

ASN and the British regulator (Office for Nuclear Regulation – ONR) share many subjects of interest, notably with regard to validation of English approvals by ASN and vice-versa. Bilateral contacts are therefore held regularly to ensure good communication between these two Authorities.

Switzerland

In 2012, ASN began bilateral exchanges on transports with the Swiss Federal Nuclear Safety Inspectorate (IFSN - called *Eidgenössisches Nuklearsicherheitsinspektorat* – ENSI – in German). Since then, ASN and IFSN have met annually in order to discuss the packaging model safety cases and the checks on the requirements associated with the correct utilisation of these transport packages.

10

The EDF Nuclear Power Plants



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The electricity generating reactors are at the heart of the nuclear industry in France. Many other installations described in other chapters of this report produce the fuel intended for the Nuclear Power Plants (NPPs) or reprocess it, store the waste from NPPs or are used to study physical phenomena related to the operation or safety of these reactors.

The French reactors are technically very similar and thus form a standardised fleet operated by EDF. Although this uniformity means that the licensee and French Nuclear Safety Authority (ASN) have extensive experience of their operation, it also means that there is a higher risk if a generic design, manufacturing or maintenance flaw is detected on one of these installations, as it could then affect all the reactors. ASN thus requires a high degree of reactivity and rigour on the part of EDF when analysing the generic nature of these flaws and their consequences for the protection of people and the environment, as well as when processing them.

ASN exercises particularly strict oversight of nuclear safety, environmental protection measures and radiation protection in the NPPs and adapts it continuously on the basis of Operating Experience Feedback (OEF).

ASN is developing an integrated approach to facilities monitoring. It intervenes at all stages in the life of the NPP reactors, from design up to decommissioning and delicensing. Through its expanded scope of intervention it examines the fields of nuclear safety, environmental protection, radiation protection, occupational safety and the application of labour laws, at all stages. For each of these fields, it monitors all aspects, whether technical, organisational, or human. This approach requires that it take account of the interactions between these fields and that it define its monitoring actions accordingly. The resulting integrated overview enables ASN to fine-tune its assessment of the state of nuclear safety, radiation protection, environmental protection and worker protection within the NPPs.

1 — General information about Nuclear Power Plants

1.1 General presentation of a Pressurised Water Reactor

By transferring heat from a hot source to a heat sink, an electricity generating thermal power plant produces mechanical energy that it converts into electricity. Conventional thermal power plants use the heat given off by the combustion of fossil fuels (fuel oil, coal, gas). NPPs use that given off by the fission of uranium or plutonium atoms. The heat produced in a Pressurised Water Reactor (PWR) leads to the creation of steam, which does not come into contact with the nuclear fuel. The steam is then expanded in a turbine which drives a generator producing a three-phase electric current with a voltage raised to 400,000 volts (V) by a transformer. After expansion, the steam passes through a condenser where it is cooled on contact with tubes circulating cold water from the sea, a water course (river) or an atmospheric cooling circuit. The condensed water is reused in the steam production cycle.

Each reactor comprises a nuclear island, a conventional island, water intake and discharge structures and possibly a cooling tower.

The nuclear island mainly comprises the reactor vessel, the reactor coolant system, the Steam Generators (SGs) and the systems ensuring reactor operation and safety: the chemical and volumetric control, residual heat removal, safety injection, containment spray, SG feedwater supply, electrical, Instrumentation & Control (I&C) and reactor protection systems. These elements are also associated with systems providing support functions: monitoring and processing of primary effluents, water supply, ventilation and air-conditioning, back-up electricity supply (diesel electricity generating sets).

The nuclear island also comprises systems for the evacuation of steam to the conventional island, as well as the building housing the fresh and spent fuel storage and cooling pool (BK). When mixed with boric acid, the water in this pool helps

absorb the neutrons emitted by the nuclei of the fissile elements in the spent fuel, to avoid sustaining nuclear fission, to cool the spent fuel and to provide the workers with radiological protection.

The conventional island notably comprises the turbine, the generator and the condenser. Some components of these items take part in reactor safety. The secondary system is partly in the nuclear island and partly in the conventional island.

1.2 Safety principles

The design of the nuclear reactors is based on safety principles aimed at ensuring the safety functions:

- control of core reactivity, that is control of the nuclear chain reactions;
 - removal of the thermal power produced by the radioactive substances and nuclear reactions;
 - containment of radioactive substances.
- The aim is to prevent the dispersal of radioactive substances into the environment

and to protect people and the environment from ionising radiation.

The design of nuclear facilities is based on the principle of “Defence in Depth”, which leads to the implementation of successive defence levels (intrinsic characteristics, material provisions and procedures), intended to prevent incidents and accidents, and then, if the preventive measures fail, to mitigate their consequences.

When the reactor is in operation, radioactive substances are contained by the positioning of three containment barriers between these substances and the outside environment:

- the cladding around the fuel pellets retains the radioactive products contained in them;
- the primary system, which constitutes a second envelope capable of retaining the dispersal of radioactive products contained in the fuel if the cladding fails;

• the containment, which is the concrete building housing the primary system. In the event of an accident, it is designed to contain the radioactive products released by a failure of the primary system.

1.3 The core, fuel and its management

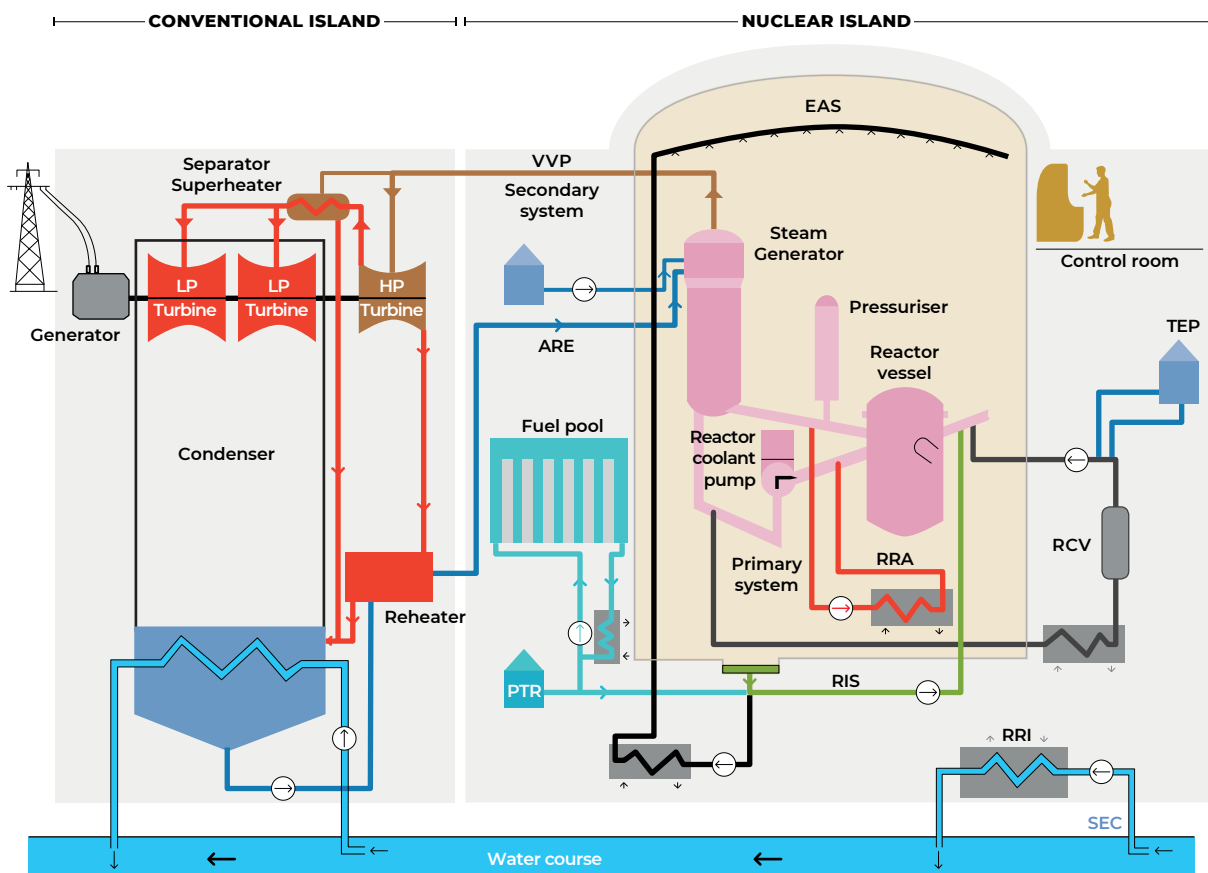
The reactor core consists of fuel assemblies made up of “rods” comprising “pellets” of uranium oxide or depleted uranium oxide and plutonium oxide (for Mixed OXide – “MOX” fuels), contained in closed metal tubes, called “cladding”. When fission occurs, the uranium or plutonium nuclei, said to be “fissile”, emit neutrons which in turn trigger other fissions: this is the chain reaction. The nuclear fissions give off a large amount of energy in the form of heat. The water in the reactor coolant system, which enters the lower part of the core at a temperature of about 285°C, heats

up as it rises along the fuel rods and comes out through the top at a temperature of close to 320°C.

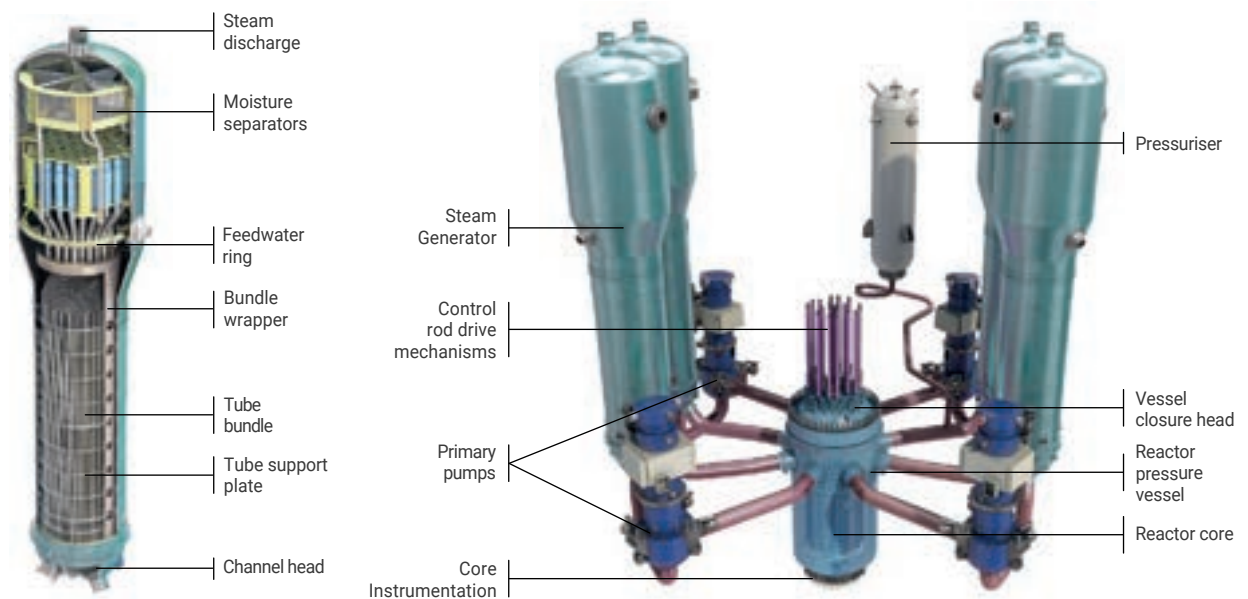
At the beginning of an operating cycle, the core has a considerable energy reserve. This gradually decreases during the cycle, as the fissile nuclei are consumed. The chain reaction and thus the power of the reactor is controlled by:

- the insertion of “control rod clusters”, containing neutron-absorbing elements, into the core to varying extents. This enables the reactor’s reactivity to be controlled and its power adjusted to the required production of electricity. Gravity dropping of the control rods is used for emergency shutdown of the reactor;
- adjustment of the concentration of boron (neutron absorbing element) in the reactor coolant system water, which also helps compensate for the gradual depletion of the fissile elements in the fuel during the cycle;

Pressurised water reactor operating principle



A steam generator and a main primary system for a 1,300 MWe reactor



• the presence of neutron-absorbing elements in the fuel rods which, at the beginning of the cycle, compensate the excess core reactivity after partial renewal of the fuel.

At the end of the cycle, the reactor core is unloaded so that some of the fuel can be replaced.

EDF uses two types of nuclear fuel in its PWRs:

- uranium oxide (UO₂) based fuels enriched with uranium-235 to a maximum of 4.5% by mass. These fuels are fabricated in several French and foreign plants, by Framatome and Westinghouse;
- fuels consisting of a mixture of depleted uranium oxide and plutonium oxide (MOX). MOX fuel is produced by Orano's Melox plant. The maximum authorised plutonium content is currently set at 9.08% (average per fuel assembly) giving an energy performance equivalent to UO₂ fuel enriched to 3.7% uranium-235. This fuel can be used in the twenty-four 900 Megawatts electric (MWe) reactors, for which the Creation Authorisation Decrees (DAC) authorise the use of plutonium fuel. EDF is currently preparing to introduce MOX fuel into a few 1,300 MWe reactors.

1.4 The primary system and the secondary systems

The primary system and the secondary systems transport the energy given off by the core in the form of heat to a turbine generator set which produces electricity.

The reactor coolant (primary) system comprises cooling loops, of which there are three for a 900 MWe reactor and four for the 1,300 MWe and 1,450 MWe type reactors. The role of the reactor coolant system is to extract the heat given off by the core by means of circulating pressurised "primary water" or "reactor coolant". Each loop, connected to the reactor vessel containing the core, comprises a circulating pump, called the "reactor coolant pump" and a SG. The reactor coolant, heated to more than 300°C, is maintained at a pressure of 155 bar by the pressuriser, to prevent boiling. The primary system is entirely situated within the containment.

The primary system coolant transfers its heat to the water of the secondary systems in the SGs. The SGs are heat exchangers which contain from 3,500 to 6,000 U-shaped tubes, depending on the model, through which the primary reactor coolant water circulates. These tubes are immersed in the secondary system water, which thus boils without coming into contact with the reactor coolant.

Each secondary system consists primarily of a closed loop through which water passes, in the form of liquid in one part and in the form of steam in the other. The steam produced in the SGs is partially expanded in a high-pressure turbine and then passes through moisture separator-reheaters before entering the low-pressure turbines for final expansion, from which it passes to the condenser. Once condensed, the water is then sent to the SGs by the extraction pumps, followed by the feedwater pumps after passing through the reheaters.

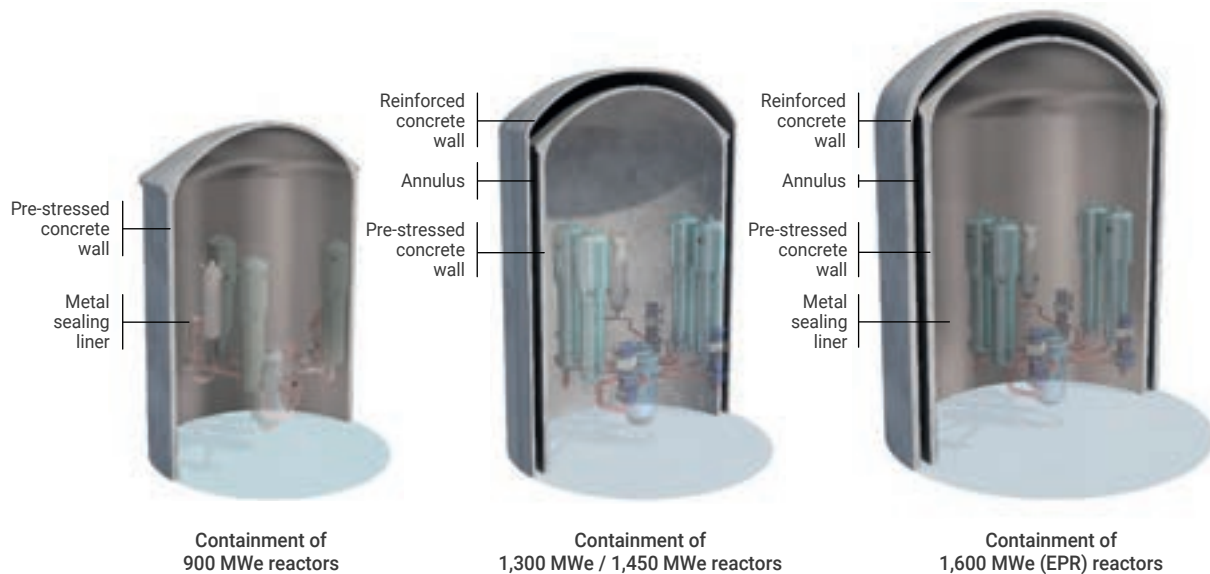
The systems thus contribute to electricity production and reactor safety, because they enable the heat from the core to be evacuated and controlled.

1.5 The secondary system cooling system

The function of the secondary system cooling system is to condense the steam exiting the turbine. To do this, it has a condenser comprising a heat exchanger containing thousands of tubes through which cold water from outside (sea or river) circulates. On contact with these tubes, the steam condenses and can be returned in liquid form to the SGs (see point 1.4). The water in the cooling system heated up in the condenser is then either discharged into the environment (once-through circuit) or cooled in a cooling tower (closed or semi-closed circuit).

The cooling systems are environments favourable to the development of pathogenic micro-organisms. Replacing brass by titanium or stainless steel in the construction of riverside reactor condensers, in order to reduce metal discharges into the natural environment, requires the use of disinfectants, mainly by means of biocidal treatment. The copper contained in brass has bactericidal properties that titanium and stainless steels do not. Air cooling towers can contribute to the atmospheric dispersal of legionella bacteria, whose proliferation can be prevented by stricter maintenance of the works (descaling, implementation of biocidal treatment, etc.) and monitoring.

Reactor containments



1.6 The containment

The nuclear reactor containment performs two functions:

- the containment of radioactive substances liable to be dispersed in the event of an accident; to do this, the containments were designed to withstand the temperatures and pressures that would result from a primary or secondary system rupture and to ensure satisfactory leaktightness in these conditions;
- reactor protection against external hazards.

There are three containment model designs:

- those of the 900 MWe reactors comprise a single pre-stressed concrete wall (concrete comprising steel tendons tensioned to compress the structure in order to increase its tensile strength). This wall provides mechanical pressure resistance and ensures the integrity of the structure in the event of an external hazard. Tightness is provided by a metal liner covering the entire internal face of the concrete wall;
- those of the 1,300 and 1,450 MWe reactors are made of two walls: the inner pre-stressed concrete wall and the outer reinforced concrete wall. Leaktightness is provided by the inner wall and by a Ventilation System (EDE) which, between the two walls, collects and filters residual leaks from the inner wall before discharge. Resistance to external hazards is primarily provided by the outer wall;
- that of the EPR reactor (see point 1.10).

1.7 The main auxiliary and safeguard systems

In normal operating conditions, at power, or in reactor outage states, the auxiliary systems control nuclear reactions, remove heat from the primary system and residual

heat from the fuel and provide containment of radioactive substances. They mainly comprise the reactor's Chemical and Volumetric Control System (RCV) and the reactor's Residual Heat Removal System (RRA).

The role of the safeguard systems is to control and limit the consequences of incidents and accidents. This chiefly concerns the following systems:

- the Safety Injection System (RIS), the role of which is to inject water into the primary system in the event of it leaking;
- the reactor building Containment Spray System (EAS), the role of which is to reduce the temperature and thus the pressure in the containment, in the event of a major primary system leak;
- the SGs Auxiliary Feedwater System (ASG), which supplies water to the SGs if the normal feedwater system is lost, thus enabling heat to be removed from the primary system. This system is also used in normal operation during reactor outage or restart phases. After the Fukushima Daiichi NPP accident (Japan), the decision was taken to install a diversified water source, called the "ultimate water source", which can be used in extreme situations to supply the SGs with water when the water reserves in the ASG system are empty and the various resupply solutions are no longer available.

1.8 The other systems important for safety

The other main systems important for safety and required for reactor operation are:

- the Component Cooling System (RRI) which cools a certain number of nuclear equipment items. This system functions in a closed loop between the auxiliary and safeguard systems on the one hand and the

systems carrying water from the river or sea (heatsink) on the other;

- the Essential Service Water System (SEC) which cools the RRI system with water from the river or sea (heatsink). This is a backup system comprising two redundant lines. In certain situations, each of its lines is capable of removing heat from the reactor to the heatsink;
- the Reactor Cavity and Spent Fuel Pit Cooling and Treatment System (PTR), which in particular removes residual heat from the fuel elements stored in the fuel building pool. The design of the ultimate water source installed in the wake of the Fukushima Daiichi NPP accident, can also - in an extreme situation - inject water into the fuel building pool, if the PTR system and the water make-up systems are lost;
- the ventilation systems, which ensure containment of radioactive materials by creating negative pressure in the rooms and by filtering discharges;
- the fire-fighting water systems;
- the I&C system, which processes the information received from all the sensors in the NPP. It uses transmission networks and sends orders to the actuators from the control room, through the programmable logic controllers or operator actions. Its main role with regard to reactor safety is to monitor reactivity, control the removal of residual heat to the heatsink and take part in the containment of radioactive substances;
- the electrical systems, which comprise sources and electricity distribution. The French nuclear power reactors have two external electrical sources: the step-down transformer and the auxiliary transformer. These two external sources are supplemented by two internal electrical sources: the backup diesel generators. In the event of total loss of these external and internal sources, each reactor has another electricity generating set comprising a turbine

generator and each NPP has an ultimate backup source, the nature of which varies according to the plant in question. Finally, following the Fukushima Daiichi NPP accident, these resources were supplemented by an “Ultimate back-up” Diesel generator set (DUS) for each reactor.

1.9 The “hardened safety core” improving resistance to extreme events

After the accident at the Fukushima Daiichi NPP, ASN instructed EDF to deploy on each reactor a “hardened safety core” of robust material and organisational measures designed, for the extreme situations studied in the 2011 stress tests, to:

- prevent an accident with fuel melt, or limit its progression;
- avoid large-scale radioactive releases;
- enable the licensee to carry out its emergency management duties.

For each reactor, the “hardened safety core” mainly consists of:

- a DUS;
- an ultimate heat sink;
- a new means of injecting borated water into the primary system when it is at high pressure;
- a system for heat removal by the SGs;

- a means for topping up the fuel storage pool from the ultimate heatsink;
- an extra fuel pool cooling system, partly reliant on mobile means;
- an ultimate cooling system for the containment, which relies in part on mobile means;
- measures to stabilise the corium on the basemat, in the event of an accident with core melt and reactor vessel melt-through;
- an ultimate I&C system, electrical distribution and the necessary instrumentation.

In addition, to manage emergency situations, each site shall be equipped with a new local emergency centre capable of withstanding extreme external hazards. These provisions are being deployed as part of the periodic safety reviews.

1.10 The specific features of the Flamanville EPR reactor

The Flamanville EPR is a 1,600 MWe reactor third-generation reactor. It has four cooling loops and uses UO₂ fuel.

Its containment consists of two concrete walls and a metal liner (*see previous page*) covering the entire internal face of the inner wall. A reinforced concrete “shell”

covers the most sensitive buildings: reactor building, fuel storage building, control room and two of the four safeguard auxiliaries buildings.

As for the other reactors, it has safety-important systems needed for reactor operation, the main specific features of which are as follows:

- most of the safeguard systems have four redundant “trains”;
- the electrical power supply sources are independent of each other: main electrical power supply, auxiliary electrical power supply, four main back-up generator sets and two ultimate back-up generator sets;
- the IRWST (In Containment Refueling Water System Tank) is a tank located inside the containment, containing a large quantity of borated water which can be injected into the primary system in the event of an accident;
- to mitigate the consequences of a core melt which could lead to rupture of the vessel and molten materials leaking from it, a very thick concrete recovery device designed to collect the molten fuel and cool it, is located under the reactor vessel;
- the fuel storage pool is cooled by two redundant cooling systems supplemented by a third diversified system.

2 — Monitoring the nuclear safety of the reactors in operation

2.1 Fuel

2.1.1 Fuel in the reactor

The leaktightness of the cladding of the fuel rods, tens of thousands of which are present in each core and which constitute the first containment barrier, receives particularly close attention.

In normal operation, leaktightness is monitored by EDF through permanent measurement of the activity of the radionuclides contained in the primary system. Any significant increase in this activity is a sign of a loss of leaktightness in the fuel assemblies. If the activity of the primary system exceeds a predetermined threshold, the General Operating Rules (RGEs) require shutdown of the reactor before the end of its normal cycle.

At each outage, EDF is required to search for and identify the assemblies containing leaking rods: reloading of fuel assemblies containing leaking rods is not authorised.

EDF conducts examinations of leaking rods in order to determine the origin of the failures and prevent them from reoccurring. The preventive and corrective measures may concern the design of the rods and assemblies, their manufacture or the reactor operating conditions.

The conditions of fuel assembly handling, of core loading and unloading, as well as prevention of the presence of foreign objects in the systems and pools are also covered by operating specifications, in order to prevent the risks of fuel rods leaking.

2.1.2 Assessment of the condition of the fuel in the reactor

In 2024, there were fuel leaktightness defects in six reactors. Despite a rise in this indicator, ASN considers that management of the integrity of the first barrier, that is the fuel rod cladding, was on the whole satisfactory for all the NPPs.

ASN remains attentive to the investigations carried out by EDF on the fuel assemblies concerned, in order to determine the origin of these defects and identify the necessary corrective measures.

With regard to handling the obsolescence of the sipping test container used by EDF on its sites to detect fuel assembly tightness defects, it in 2024 presented a mobile unit project, the performance of which is currently being tested on a mock-up.

2.2 Nuclear pressure equipment

2.2.1 Design and manufacturing of Nuclear Pressure Equipment

Nuclear Pressure Equipment (NPE) is Pressure Equipment (PE) that confines radioactive fluids. Some of this equipment is essential for reactor safety. The primary and secondary systems mentioned in point 1.4 of this chapter in particular consist of NPE.

In the light of the potential risks from the failure of this equipment, both for reactor safety and the safety of the personnel operating them, there are regulations on their design, manufacture and operation, requiring that the manufacturer comply with essential safety requirements designed to preclude their failure. These requirements for example concern the strength of the materials used, the design calculations to be performed, or the in-service inspectability of the equipment. The regulations also state that an NPS manufacturer shall take account of the particular requirements of the reactor’s safety case, which are liable to have an impact on the design of the equipment.

In this respect, the manufacturer must define and apply the provisions enabling it to justify compliance with these requirements in the design and manufacture of the NPE. As licensee of the reactors, EDF is subsequently responsible for their installation, utilisation and in-service monitoring, in compliance with the conditions set out by the manufacturer and taking account of its own OEF.

2.2.2 Assessment of the design and manufacturing of Nuclear Pressure Equipment

ASN assesses the compliance with the essential requirements by the NPEs most important for safety, referred to as “level N1”, corresponding primarily to the reactor pressure vessel, the SGs, the pressuriser, the reactor coolant pumps, the piping, notably that of the Main Primary System (MPS) and Secondary Systems (MSS), as well as the safety valves. ASN can be assisted in this task by organisations that it approves and oversees. The conformity assessment of the other NPE (“level N2 or N3”) is carried out directly by these approved organisations. Four inspection organisations or bodies are currently approved by ASN to assess NPE compliance: *Apave Exploitation France*, *Bureau Veritas Exploitation*, *Vinçotte International* and the inspection body of the EDF users.

This conformity assessment concerns the equipment intended for the new nuclear facilities (more than 200 equipment items for the Flamanville EPR reactor) and the spare equipment intended for nuclear facilities already in service (notably the replacement steam generators). It takes the form of an examination of the technical documentation of each equipment item and inspections in the workshops of the manufacturers, as well as at their suppliers and subcontractors.

In 2024, an increasing share of ASN’s assessment activities concerned the NPE intended for the EPR 2 reactors. In addition, ASN’s actions were reinforced with respect to monitoring of level N2 or N3 NPE suppliers and manufacturers, focusing more particularly on certain sensitive activity sectors such as foundries or piping manufacturers.

The NPE manufacturing operations involve a large number of suppliers, to which the manufacturers sometimes subcontract activities that are decisive for the mechanical strength of the equipment produced. In this context, ASN reinforced its checks, considering that the deficiencies it had identified at certain materials suppliers concern the control of sensitive manufacturing processes (such as welding or casting), or the traceability of manufacturing operations.

The principles of the reactor vessels in-service strength demonstration



Very close attention is paid to preventing the risk of fast fracture of the reactor pressure vessel. On the occasion of each periodic safety review, this requires a verification of the strength of the vessels with a view to the next ten years of operation, taking account of the embrittlement of their steel under the effects of irradiation.

The risk of fast fracture of a reactor pressure vessel depends on the joint presence of three factors: the presence of a flaw (such as a crack in the metal), which is liable to lead to stress concentration, mechanical loading (as a result of routine reactor operations or an incident or accident situation) and insufficient mechanical strength of the material.

The justification process thus relies on analysis of the resistance to fracture of the known flaws in the vessels (which concerns a few EDF reactor vessels, affected by flaws under the liner). In addition, during each ten-yearly outage, the vessels undergo a non-destructive examination of the area subject to irradiation, which is designed to detect flaws of sufficiently large size. To ensure the conservative nature of the demonstrations, the strength of a “reference” flaw, corresponding to the largest flaw that could not be detected during these examinations, must therefore be also checked.

For the reference flaw and for the flaws under liner affecting vessels, the analysis of the risk of fast fracture of the reactor vessels thus consists in:

- assessing the mechanical stresses liable to lead to initiation of propagation of a

crack where these flaws are located, in all reactor operating situations, including an accident;

- assessing the characteristics of the material’s mechanical strength, taking account of steel embrittlement under the effect of irradiation. Embrittlement of the steel is assessed every ten years, based on the results of mechanical tests performed on material samples which were placed in capsules inside the reactor cores. The location of these capsules, close to the fuel assemblies, enables these samples to be subjected to higher irradiation than that which reaches the vessel wall and thus provide an early check on the validity of the assessments made.

The fast fracture analysis process thus leads to a comparison between the loading at the end of the flaw, which is the result of the first step, with the mechanical strength of the material, which is a result of the second. Safety coefficients are also used in the fast fracture analysis, to ensure that they are sufficiently conservative.

Finally, the vessel as a whole undergoes other non-destructive examinations, for example on the closure head, and a pressure test of at least 1.2 times the service pressure. This test is an overall strength test capable of detecting unexpected degradation phenomena. For example, during the test performed in 1991 on the vessel of one of the reactors of the Bugey NPP, a leak was detected from a closure head adapter owing to a stress corrosion phenomenon. This leak led EDF to replace all the closure heads of its 900 and 1,300 MWe reactors between 1994 and 2009.

2.2.3 Operation of Nuclear Pressure Equipment

The reactor MPS and MSS, which contribute to the containment of the radioactive substances, to cooling and to controlling reactivity, operate at high temperature and high pressure.

The monitoring of the operation of these systems is regulated by the Order of 10 November 1999 relative to the monitoring of operation of the MPS and the MSS of PWRs. These systems are thus the subject of monitoring and periodic maintenance by EDF.

These systems are in particular subject to periodic requalification every ten years, which comprises a complete inspection of the systems involving non-destructive examinations of the most sensitive areas, hydrostatic pressure test and verification of the good condition and good operation of the over-pressure protection accessories.

The licensee is also required to keep and update files on the design, manufacture,

overpressure protection, materials, findings made during operation and, as applicable, processing of deviations, as often as necessary and at the time of the periodic requalifications.

Some of the safety issues of the components of the primary or secondary systems are detailed below.

The reactor pressure vessels

The reactor pressure vessel is an essential component of a PWR and contains the reactor core and a part of its instrumentation.

In normal operating conditions, the vessel is entirely filled with water, at a pressure of 155 bar and a temperature of 300°C. It is made of ferritic steel, with a stainless steel inner liner.

Regular inspection of the condition of the vessel is essential for several reasons:

- The consequences of rupture of this equipment are not studied in the reactor safety case. Monitoring thus contributes to the break preclusion approach adopted for this equipment. This approach

is based on particularly stringent design, manufacturing and in-service inspection provisions in order to guarantee its strength throughout the life of the reactor, including in the event of an accident.

- During operation, the vessel's metal slowly becomes brittle, under the effect of the neutrons from the fission reactions in the core. This embrittlement more particularly makes the vessel more susceptible to thermal shocks under pressure, or to sudden pressure rises when cold. This susceptibility is also aggravated by the presence of technological flaws, which is the case for some vessels with manufacturing defects under their stainless steel liner.

- The vessel is a component for which replacement is not envisaged, owing to both technical feasibility and cost.

Cast components of the main primary system

The MPS of some of the reactors of the French fleet comprises several austenitic-ferritic stainless steel cast elbow and nozzle assemblies. The ferritic phase of this steel experiences ageing under the effect of temperature. Certain alloy elements present in the material, molybdenum in particular, aggravate this ageing sensitivity, notably on the 900 MWe reactors and the first 1,300 MWe reactors. The result is a deterioration of certain mechanical properties, such as toughness and resistance to ductile tearing⁽¹⁾.

The elbows also comprise flaws inherent in the static casting manufacturing method. The effects of thermal ageing lessen the fast fracture resistance margins in the presence of defects.

EDF has carried out extensive work to learn more about these materials, their ageing kinetics and to assess the fast fracture margins. These elbows are attentively monitored by ASN, insofar as the continued operation of these components of the main primary system must be justified on the occasion of each periodic safety review, while taking account of this ageing phenomenon. There are particular issues with regard to some cast elbows on the 900 and 1,300 MWe reactors, which are directly connected to the reactor vessel, because they are very hard to replace.

The steam generators

The SGs comprise two parts, one of which is a part of the MPS and the other a part of the MSS. The integrity of the main components of the SGs is monitored, more specifically the tubes making up the tube bundle. This is because any damage to the tube bundle (corrosion, wear, cracking, etc.) can lead to a primary system leak to the

secondary system. In addition, rupture of one of the tubes in the bundle would lead to bypassing of the reactor containment, which is the third containment barrier. The SGs are the subject of a specific in-service monitoring programme, defined and periodically revised by EDF and examined by ASN. Following the inspections, those tubes which are too badly damaged are plugged, to remove them from service.

Over time, the SGs tend to become clogged with corrosion products from the secondary system exchangers. The layer of deposits of corrosion products (fouling) that forms on the tubes reduces the heat exchange capacity. On the tube support plates, the deposits (clogging) prevent the free circulation of the water-steam mixture, which creates a risk of damage to the tubes and the internal structures and which can degrade the overall operation of the SG.

Various solutions can be implemented to limit metal deposits in the secondary system: cleaning with hydraulic jets, preventive chemical cleaning, replacement of certain materials used to manufacture the tube bundles (brass replaced by more corrosion-resistant stainless steel or titanium alloy), modification of chemical products used for conditioning systems and pH increase. Some of these operations must be authorised by ASN beforehand, because they imply discharges of some of the dangerous substances.

Since the 1990s, EDF has been running a programme to replace the SGs with the most severely degraded tube bundles. The SG replacement campaign concerning 26 reactors with a non-heat-treated Inconel 600 tube bundle has now been completed. It is continuing with replacement of SGs on the reactors in which the tube bundle is made of heat-treated Inconel 600 (21 reactors are still concerned).

2.2.4 Assessment of operation of Nuclear Pressure Equipment

Monitoring the operation of reactor main primary and secondary systems

ASN considers that EDF's surveillance of the operation of the MPS and MSS remains a point warranting particular attention. In 2024, EDF more particularly continued its inspections defined after detection of a stress corrosion phenomenon on the auxiliary piping of the primary systems (see box next page). This phenomenon illustrates the possibility that unexpected degradation modes can appear on these systems, including in the absence of French or international OEF.

Through a programme of additional investigations on these systems, on the occasion of each periodic safety review, EDF must schedule appropriate checks to take account of the risk of any unexpected degradation phenomena, in addition to the routine monitoring programmes.

The implementation of the in-service surveillance programmes on the MPS and MSS, along with their adaptation to take account of changing OEF and knowledge of degradation modes, are thus the subject of particular attention by ASN. In this respect, ASN is attentive to ensuring that EDF uses appropriate non-destructive inspection means for which performance has been qualified. EDF must also be able to reactively deploy checks to ensure that there are no particular risks, for example if a new degradation mode is discovered or suspected.

The reactor pressure vessels

During the periodic safety reviews, ASN examines the demonstration of the in-service strength of the reactor pressure vessels every ten years. The generic approach implemented by EDF is to use a worst-case approach to verify that all the vessels of a type of reactor offer sufficient resistance to fast fracture, taking account of the loads to which they are subjected in operation (whether during routine, incident or accident operating situations) and their embrittlement under irradiation. During this examination, account is taken of the mechanical properties of each vessel and the presence of a hypothetical flaw positioned in the worst possible place. For vessels with particular flaws, EDF also checks their mechanical strength.

Following its review, ASN reached a favourable conclusion regarding the ability of the 900 MWe reactor vessels to continue to function until their fifth ten-yearly outage. In 2024, ASN examined the justifications provided by EDF for the 1,300 MWe reactor vessels and the Authority for Nuclear Safety and Radiation Protection (ASNR) will issue a position statement in 2025.

During the ten-yearly outage inspection of each reactor, EDF also carries out checks to ensure that the existing flaws have not developed further, or that prejudicial flaws have not appeared in the steel of the vessels. It also carries out a hydraulic pressure test of the primary system.

ASN issues reports following the checks carried out during each ten-yearly outage inspection of the primary system, and in particular with regard to the pressure vessels. In 2024, the results of the checks carried out were satisfactory.

1. Tearing of a material under the effect of stresses applied to it, following deformation.

Review of auxiliary lines stress corrosion



Following the discovery of stress corrosion cracks at the end of 2021 on auxiliary lines of the primary system of some of its reactors, EDF set up a programme to inspect more than 1,200 welds on the RIS and RRA systems. In 2024, EDF continued with the deployment of significant inspection and analysis resources to identify the causes of this degradation.

In 2024, EDF completed the scheduled preventive replacements for the most sensitive lines. Five other weld repairs were also made elsewhere, following the discovery of new faults.

The inspections carried out since the end of 2021 have so far revealed the presence of 80 cracks more than 2 mm deep on these pipes, which confirms the serious nature of this phenomenon which was not hitherto considered liable to affect these lines.

The inspection strategy focused on the welds which had been repaired during the manufacturing process, which are more susceptible to stress corrosion. Inspection of these welds revealed three large cracks which could have led to a loss of integrity of the pipe in the event of high mechanical loading.

In addition, the inspection campaign carried out since 2021 discovered ten or so fatigue cracks. This phenomenon was known to be liable to affect these lines, but some of these cracks were discovered on welds which were not subject to any particular monitoring. This should lead EDF to increase the robustness of its in-service monitoring strategy concerning the risk of fatigue cracking.

EDF replaced all the lines considered to be the most susceptible to the stress corrosion phenomenon. By the end of the first quarter of 2025, all of the welds on the RIS and RRA lines repaired during manufacturing will have been inspected and, by the end of 2026, EDF will have inspected about 55% of the welds on the RIS and RRA lines liable to be concerned by this phenomenon. ASN considers that this level of inspection will provide a good overview of the stress corrosion susceptibility of these lines and complete the picture regarding the risk of fatigue cracking. EDF is also continuing with spot checks on welds of other stainless steel lines of the reactor primary systems, in order to check that they are not susceptible to stress corrosion.

In 2024, ASN continued its monitoring of EDF's action, by carrying out inspections in the engineering departments, in the NPPs and in the plants of EDF's subcontractors, with respect to line inspection or replacement operations. ASN also continued its discussions with its foreign counterparts, some of whom carried out specific inspections. At this stage, ASN notes that the foreign PWRs do not seem to be concerned by a phenomenon on such a scale.

ASNR will remain mobilised to deal with this issue in 2025, and will closely monitor the results of the inspections carried out by EDF. It will examine any EDF monitoring and inspection strategy changes that could result from this.

For the latest information on the subject:

asn.fr/l-asn-controle/corrosion-sous-contrainte

sensitive to thermal ageing phenomena and their potential for being maintained in service was analysed. The methodology was assessed by IRSN (for the 900 and 1,300 MWe reactors). The low toughness of certain nozzles on Paluel NPP reactors 1 and 2, as a result of ageing, led EDF to propose their replacement, with the time-frame currently being examined by ASN.

The Steam Generators

For ASN, the SGs remain a point meriting particular attention in 2024. The significant fouling and clogging levels detected in certain SGs, liable to alter their operating safety, entails the scheduling of preventive cleaning. Maintenance in order to guarantee satisfactory cleanness has been insufficient in the past and ASN now considers this to be a point warranting particular vigilance. The maintenance strategy regarding clogging and fouling of the secondary part of the SGs deployed by EDF was revised in 2020 to better prevent these situations. ASN is also paying particularly close attention to monitoring the deterioration of the SG feedwater rings on the 1,300 and 1,450 MWe reactors.

SG replacement operations are scheduled at the rate of one reactor per year over the coming years.

Main Primary System auxiliary lines

Numerous stress corrosion or thermal fatigue cracks have been discovered since 2021, in particular on the SIS and RRA lines of the 1,450 MWe and 1,300 MWe type P4 reactors, in the immediate vicinity of certain welds. This led to numerous checks and repairs being carried out. The investigations will continue in 2025 and 2026, notably on other systems (see box above).

2.3 The containments

2.3.1 The containments

The containments, which constitute the third containment barrier, undergo inspection and testing to check their compliance with the safety requirements. More specifically, their mechanical behaviour must guarantee good tightness of the reactor building if the pressure inside it were to exceed atmospheric pressure, which can happen in certain types of accidents. This is why, at the end of construction and then during the ten-yearly outages, these tests include an inner containment pressure rise with leak rate measurement. These tests are required by the creation authorisation decrees of each reactor and by the Order of 7 February 2012, setting the general rules concerning Basic Nuclear Installations (BNIs).

Cast products

ASN is examining the justification for maintaining the cast products of the primary system in service beyond the fourth ten-yearly outage of the 900 MWe reactors.

With regard to the cast elbow assemblies on the MPS, and at the request of ASN, the Institute for Radiation Protection and Nuclear Safety (IRSN) assessed the justifications provided by EDF for the most sensitive elbow assemblies (C elbows, which are directly connected to the reactor vessel, certain E elbows that are hard to replace because they are situated in the reactor pit). ASN convened the Advisory Committee of Experts for Nuclear Pressure Equipment (GPESPN) three times on this subject (2016, 2019 and 2023).

The methodological principles followed by EDF in its mechanical analyses to justify maintaining these components in service were thus validated by ASN. This examination concluded that virtually all the elbow assemblies (A, B, C, D and E) on the 900 MWe reactors can be kept in service at least until the fifth ten-yearly outage.

ASN is at present focusing its review on certain E elbows in the Paluel NPP reactors, for which it is awaiting EDF's submission of a dossier justifying continued operation beyond the forthcoming ten-yearly outages.

To justify maintaining cast elbow assemblies in service beyond the fifth ten-yearly outage, EDF is continuing its justification studies in several areas. It will in particular suggest to ASN that more advanced calculation methods be used to take account of the nature of the defects present in the elbow assemblies. EDF is also developing a new means of non-destructive examination of the inner wall of the E elbow assemblies, as well as a technique for repair of defects on the inner wall, which could be used if EDF is not able to provide justification for maintaining them in service. ASN considers this work to be necessary, as it should allow EDF to define a treatment strategy sufficiently well in advance of the ten-yearly outages.

Certain cast branch connections on the primary legs (RIS system nozzles on the cold leg) are for the same reasons also

Other equipment takes part in the containment function, such as the systems for accessing the interior of the containment (airlocks and equipment hatch), the circuit depressurising the annulus between the double-wall containments, and the control room ventilation system.

2.3.2 Assessment of the containments

Overall management of the containment function

EDF's management of the containment function is on the whole satisfactory. ASN however still observes occasional but recurring unavailabilities affecting certain equipment participating in the containment function. These unavailabilities notably concern the containment penetrations pressurisation system and leak monitoring system, as well as the control room ventilation system.

Since 2014, EDF has been carrying out an action plan with the aim of guaranteeing that the flowrates in the ventilation systems meet the safety requirements both for the containment and for thermal conditioning of the installations, in the light of the changes made to the reactors since they were built. The action plan is being deployed, reactor by reactor, on all the ventilation systems concerned, and includes an inventory of the equipment and ducts. As necessary, EDF carries out repairs and improvements and adjusts the ventilation flow rates. The final phase of this national action plan includes a programme to ensure the lasting nature of the adjustments made. ASN will issue a position statement on this subject in 2025.

Single-wall containments with an internal metal sealing liner

The ten-yearly tests on the 900 MWe reactor containments carried out since 2019 as part of their fourth ten-yearly outages did not bring to light any generic problems liable to compromise their operation.

In 2024, five single-wall containment reactors carried out their containment building pressure tests and the results were satisfactory.

Double-wall containments

The tests on the double-wall containments performed during the first ten-yearly outages of the 1,300 MWe reactors detected a rise in the leak rate from the inner wall of some of them, under the combined effect of concrete deformation and a loss of pre-stressing of certain tendons, that was greater than anticipated at the design stage.

EDF then initiated major work consisting in locally applying a resin sealing coating to the interior and exterior surfaces of the inner wall of the containments of the most severely affected 1,300 MWe reactors, as well as to the 1,450 MWe reactors.

For all the reactors on which it was carried out, this work enabled the leak rate criteria to be met during the containment pressure tests.

In 2024, a double-wall reactor underwent its building pressure test, the result of which was satisfactory. ASN remains particularly attentive to changes in the double-wall containment leak rates and to the steps taken by EDF to control them.

2.4 Organisation for reactor operations

2.4.1 Reactor operations

The Order of 7 February 2012 stipulates that the licensee must have the technical skills needed to manage the activities involved in operation. Furthermore, this Order requires that the licensee define and implement an Integrated Management System (IMS) to ensure that the requirements concerning nuclear safety and protection of the environment are systematically considered in any decision concerning the facility. This IMS must specify

the steps taken with regard to organisation and to resources of all kinds, in particular those adopted to control the activities important for the protection of persons and the environment.

Normal operation

The EDF NPPs are permanently monitored from a control room by a control team which is also in charge of controlling the installations.

The operating limits within which the teams must keep the installation are defined in the RGEs. The licensee ensures that this is done using normal operating documentation, in particular the operating instructions and alarm data sheets. The licensee is regularly required to modify the installation's configuration to allow intervention by the maintenance crews, to test the availability of a system or to change the status of the reactor.

Tests are regularly performed to check the correct working of the systems which could be required in an incident or accident situation and to check the correct behaviour of the reactor's core. Some tests are performed with the reactor operating, while others can only be carried out during reactor outages. The control teams perform some of these tests themselves, while others require intervention by specialised teams.

General Operating Rules

The RGEs present the provisions the licensee intends to implement to operate its installation in compliance with the safety case. They notably specify the rules to be followed in normal operation, the periodic tests to be carried out and the control operations required in an incident or accident situation. They are one of the items making up the commissioning authorisation application for a nuclear reactor.

The operating technical specifications included in the RGEs define the parameters required in normal operation. They also identify the systems essential to maintaining the safety functions and specify what to do in the event of momentary unavailability of a required system or if a limit is exceeded.

With regard to periodic tests, the RGEs detail the checks to be carried out, their frequency, and the criteria for acceptance of the results. There are in particular tests to check that the reactor core complies with the design baseline safety

requirements and the safety case and to calibrate the automatic control and protection systems.

The incident or accident situation control procedures, which are included in the RGEs, detail the steps to be taken by the control teams in these situations in order to restore normal operation or, in the event of an accident, to return the installation to a safe state and limit its consequences.

EDF regularly updates these documents in order to incorporate OEF and take account of the modifications made to the reactors. Temporary amendments can also be made. They require justification and the definition of compensatory measures to control any associated risks. Depending on their significance, RGEs noteworthy modifications that could affect the safety of the installation or protection of the environment, require either submission of an authorisation application to ASN or notification to ASN before they are implemented.

Operation in the event of an incident or accident

The operating strategies and practices to be implemented in an incident or accident situation are developed in various documents (operating rules and instructions) placed at their disposal. They specify what action is to be taken by the control team. To manage these situations, the organisation of the control team changes and each person has a specific role. The control teams are regularly trained in the implementation of these control strategies.

In addition to the control strategies, an On-site Emergency Plan (PUI), implemented by the emergency crews, is activated to help the control teams in incident or accident situations with a risk of consequences for outside the site.

Following an accident, if the safety functions (control of reactivity, cooling and containment) are not guaranteed owing to a series of failures, the situation is liable to develop into a severe accident with severe fuel damage. When faced with such situations, the installation control strategies place emphasis on preserving the integrity of the containment in order to minimise releases into the environment. The implementation of these strategies mobilises the expertise of the local and national emergency teams.

2.4.2 Assessment of reactor operations and operational documentation

ASN reviews the content of the RGEs before they are implemented and checks that they are correctly applied by means of inspections.

More broadly, it ensures that the measures taken by EDF for operation of the reactors are appropriate to the risks created by this operation.

ASN focuses on the conditions which are favourable or prejudicial to the contribution to NPP safety by the operators and worker groups. It defines Human and Organisational Factors (HOFs) as being all the aspects of working situations and the organisation which have an influence on the work done by the operators.

The general organisation

The organisation put into place by EDF to manage risks is on the whole satisfactory. However, ASN has identified areas of improvement for certain NPPs regarding coordination between the professions and the projects, within maintenance departments and operating teams, and with respect to consistency between workload plans, the resources allocated and monitoring of the industrial programmes.

The difficulties observed are often linked to increasingly complex working organisations and environments, the large number of parties involved, the interfaces between entities that are not defined or formalised (shift changes, relations between the shift crews and the crews not on shift, or between the licensee and the contractors), geographical distance, poor anticipation of concomitant activity situations, lack of resources (human and material) and documentation densification (see box page 308).

Normal operation

During its NPP inspections, ASN notably verifies that the licensee complies with the

RGEs and, if applicable, the compensatory measures associated with any temporary modifications. It also checks the consistency between the control documentation and any modifications that have been made to the installations. It also ensures that the procedures used to configure the systems or lock out equipment do actually take account of the requirements arising from the RGEs.

Finally, it is attentive to the good understanding and correct application of these various documents by the control teams and the correct management of sensitive activities, which are regularly the cause of



Inspection campaign on the control of system configurations



Ensuring the correct configuration of the hydraulic and electrical systems of nuclear reactors contributes to the safety of the installations. The configuration of the systems covers line connection activities (configuration of a set of devices enabling a system to function in the way it was designed), lock-out (configuration of a set of devices in defined and locked positions in order to guarantee the required safety conditions for maintenance work) and administrative lock-out (physical immobilisation of a set of devices, which must be kept in this position for the safety of the installation).

After observing a rise in the number of line connection and lock-out errors at the end of 2022, compromising the safety of the installations or leading to a risk of personnel accidents, ASN began a campaign of inspections in 2023 dedicated to checking the steps taken by EDF to control the configuration of the systems in the installations.

In 2024, ASN completed this campaign, which allowed inspection of all the NPPs. The inspectors examined the oversight of all the processes contributing to control of systems configuration. They also carried out checks on the conformity of the configurations of the installations and observed the performance of certain activities. Finally, they conducted

clarification interviews with the personnel in charge of these activities.

This inspection campaign revealed the quality of monitoring of the processes linked to this topic, but also shortcomings in the preparation and performance of these activities.

In 2024, ASN reminded EDF of the need to give greater importance to the administrative lockout activity and to clarify the immobilisation practices for the locked-out devices. It also asked EDF to check the pertinence of the system for immobilising valves under administrative lock-out and involved in fire-fighting. Finally, it alerted EDF to the need for long-term continuity of the position indicators installed on the devices subject to administrative lock-out.

At the end of this campaign, ASN positively notes the efforts made by EDF to improve the performance of the tools designed to take account of the actual configuration of the systems when programming maintenance work. In 2024, EDF also set up periodic skills currency courses for the staff directly involved in systems configuration. The EDF head office departments reinforced their coordination of the administrative lock-out process with the site licensees. These various actions are such as to improve the performance of systems configuration in the coming years.

anomalies. To do this, it holds interviews with the control teams and attends operations needed for the NPPs to function.

Failures to comply with the RGEs constitute significant events which are to be reported to ASN. ASN analyses the origin and consequences of these events and, during its inspections, checks that measures have been taken by the licensee to correct the deviations and prevent them from happening again.

With regard to the operation and control of the reactors, ASN considers that performance remained at a good level in 2024. The action plans on operational rigorously initiated by the NPPs in recent years would appear to be effective. However, the number of situations for which the reactors were operated outside the planned limits rose in 2024, even though industrial activity was similar to that in 2023. ASN also finds that the quality of monitoring in the control room is continuing to degrade. Moreover, there were several significant events in 2024 related to reactivity control, but which were due to poor organisation, operational documentation faults or shift crew errors. Given the rise in this type of events, ASN will incorporate specific inspections on this subject into its 2025-2026 inspection programme.

In 2024, ASN continued its inspection campaign on systems configuration management (*see box previous page*). It positively notes the efforts made by EDF to improve the performance of the tools designed to take account of the actual configuration of the systems when programming maintenance work. In 2024, EDF also brought in periodic skills currency training courses for the field operatives involved.

The Independent Safety Organisation

At EDF, the Independent Safety Organisation (FIS) verifies the actions and decisions taken by the departments in charge of operating the installations, from the viewpoint of safety. On each NPP, the FIS notably comprises safety engineers and auditors, who conduct a daily check on the safety of the reactors. The working of each FIS is checked and evaluated at a national level by the FIS of EDF's Nuclear Production Division. Finally, the EDF internal inspectorate services, in particular the general inspector for nuclear safety, reporting to the Chairman of the EDF group, and assisted by a team of inspectors, represents the highest level of independent verification of nuclear safety within the EDF group.

ASN checks that the periodic tests of safety-important equipment items do effectively check their operation and level of performance. It carries out this verification during the review of RGE modification authorisation applications. During inspections, it also verifies that these periodic tests are carried out in accordance with the test programmes stipulated in the RGEs.

As in previous years, the origin of several Significant Safety Events (ESS) was the periodic tests. The main causes of these significant events are incorrect specification of the test rules in the operating documents, errors in application of the test procedure when performing tests, inconsistencies between documents, or periodic test programming errors.

Further to OEF from these events, EDF is adapting its organisations to ensure better sharing of information between the various actors responsible for defining, programming and carrying out tests. In this respect, EDF launched an action plan in October 2023, with the aim of setting up more structured and appropriate support for the sites on this topic, in order to improve the performance of the periodic tests.

In 2024, ASN started a programme of specific inspections on the organisation of the sites for management of periodic tests. A large number of the NPPs was inspected during these inspections, which will continue in 2025. ASN will issue the results at the end of this campaign.

Skills management

In 2022 and 2023, ASN ran an inspection campaign on the skills management of the teams in charge of operating the installations. This campaign led EDF to deploy national and local action plans aimed at reinforcing the skills of the control teams and revitalising the management of skills as a whole. EDF thus took measures to reinforce the training teams, revive the training committees, support the clarification and adoption of the training processes and increase the amount of training equipment.

In 2024, difficulties linked to skills management, which had already been raised in 2023, continue and concern both EDF internal staff and outside contractors. The persistence of difficulties with skills management, despite the numerous action plans, calls into question the effectiveness of the steps taken by the licensee to support skills learning and currency among the teams. ASN notably observed difficulties with identifying training needs. The adoption of "rubbing off" training (informal process for learning based on contact with peers) - with no definition of the teaching objectives - makes it complicated to establish a true view of the

competence of the teams. Moreover, training via e-learning, including for technical fields, limits practical implementation in the field. Weaknesses were also found in the organisation of the recycling sessions, owing to the unavailability of training resources or trainers, and the use of questionnaires with no practical work. Skills management linked to subcontracted activities also has difficulties in identifying and securing the skills needed.

The Independent Safety Organisation

During its inspections, ASN examines the actions of the Independent Safety Organisation (FIS - *see box above*) and checks that its opinions are correctly taken into account by the operational departments. The inspectors noted the competence, correct working and independence of the FIS. Some sites are however still encountering resource problems, with the number of safety engineers often being below the target levels, for long periods of time. In 2023, EDF took steps to boost its safety engineer numbers, so that they can calmly perform their independent verification of reactor safety. These measures enable the situation to be gradually improved, EDF having set itself a target time-frame of 2027.

Operation in an incident, accident, or severe accident situation

ASN checks the processes to draft and validate the incident or accident operating rules, their pertinence and how they are implemented. ASN thus carried out several inspections in 2024 on the organisational and technical arrangements made by EDF to deal with an incident and accident situation. These inspections always include a situational exercise for the facility's control teams, to check the application of instructions and intervention and communication practices within these teams.

Following these inspections, as in previous years, ASN once again found errors and lack of precision in the operating documents.

Validation by control room simulation of the incident and accident operating instructions is an important step in ensuring the operability of these instructions. These validations generally enable anomalies to be detected. However, ASN found that some sites do not systematically carry out this validation step. ASN considers that EDF should generalise this step.

ASN also found that the time taken to correct anomalies detected following local simulation validations remains too long. This delay is notably linked to the fact that a significant share of these anomalies requires exchanges with issue of a position statement by the engineering head office departments.

Complexity of reactor operating baseline requirements



The complexity of the operating baseline requirements, notably the RGEs, is regularly highlighted. It may cause the operators to lose sight of the meaning of their work and have effects on risk management. It has risen significantly since the reactors first entered service.

To address these findings, EDF began work on short and medium-term simplification, along with a long-term project for a complete overhaul of its RGEs. EDF aims on the one hand to simplify the baseline operating requirements, to make them more legible and easier to use by the operator, and on the other to guarantee the operability of the installations, using an approach proportionate to the safety

issues. Discussions were held on the subject by ASN, IRSN and EDF in 2024.

For its part, ASN convened the profession in 2024 during a brainstorming cycle by the Steering Committee on Social, Organisational and Human Factors (Cofsoh), as well as to look at the complexity of activities related to the operation of nuclear facilities. A summary of this work will be published in 2025.

ASN is also currently financing a thesis on the parameters and dynamics of the complexity of reactor safety governance in France. This thesis should be defended and its conclusions communicated by the end of 2025.

preparedness and management of emergency situations to the extent that they can take the required action in the event of an emergency. ASN also underlines the professionalism and motivation of the on-call personnel mobilised. EDF must however continue its efforts concerning monitoring of through-life support for the resources that could be mobilised in an emergency situation, and the corresponding procedures, the practice and training of the emergency crew members, and in terms of carrying out and monitoring experience feedback from real situations and exercises. Finally, EDF must continue to reinforce preparedness for emergency situations of non-radiological origin.

Campaign of inspections on the management of accidents with core melt



Between 2023 and 2024, ASN carried out a campaign of inspections aimed at checking the operators' preparedness for managing an accident with core melt and checking the operability of the required control actions.

Even if ASN found that the condition of the equipment required during an accident with core melt was generally satisfactory, the inspections also revealed that the baseline requirements documentation produced by the EDF head office departments was not always correctly deployed within the NPPs. In addition, the situational exercises performed during the

inspections showed that the field operatives were poorly prepared for accident situations with core melt. The operational documentation allowing performance of the required actions was also sometimes unsuitable (missing or erroneous information, unavailable tools, etc.). These deviations can notably be explained by the fact that the sites do not systematically test the operational documentation before validating it.

In response to these findings, EDF defined an action plan, the implementation of which will be monitored by ASN.

2.4.3 The Operating Experience Feedback process

It is essential for EDF to take account of OEF from the operation of its installations and those of other licensees if safety is to be continuously improved. This is based on the collection and analysis of events.

Significant events are analysed individually. This analysis aims to identify their root causes and the changes required to prevent them from happening again. Analyses of trends and weak signals are regularly performed by EDF to identify the deterioration of installations safety as far upstream as possible.

EDF pays particular attention to detecting and analysing potentially generic significant events detected on one reactor, but which could affect others.

Between 2023 and 2024, ASN carried out a campaign of specific inspections on the operability of the control actions required in the event of an accident with core melt. The conclusions of this inspection campaign are presented in the specific box (see box above).

Emergency organisation

When the situation in the installation deteriorates or additional means are needed to manage the situation, the incident or accident operating procedures provide for activation of the PUI, which leads to deployment of an emergency organisation.

In 2024, three NPPs activated their emergency organisation for a fire outside the controlled area, in other words in an area not containing any radioactive substances: on 10 February in the Chinon NPP, on 28 May in the Paluel NPP and on 3 June in the Cattenom NPP.

The Belleville-sur-Loire NPP also deployed its emergency organisation for a hydrochloric acid leak on 22 May, although without triggering the PUI, which contains no provision for this type of scenario. The NPP reactively applied the relevant instructions and notified ASN. A project

for updating the specific organisation to manage non-radiological emergency situations, called "PUI TOX", was transmitted to ASN. This organisation should be deployed nationwide to all NPPs by the end of 2025.

These four situations had a limited impact inside the installations and required no population protection measures.

In order to test the emergency organisation of EDF and the public authorities, ASN takes part in national exercises. Four exercises of this type were held in 2024 on the NPPs (Civaux, Bugey, Belleville-sur-Loire and Tricastin).

ASN also carried out several inspections on the EDF emergency organisation and resources. These inspections, some of which are based on unscheduled situational exercises leading to activation of the site's emergency organisation, were also an opportunity to test the operational nature of the system on specific subjects (emergency premises equipment, documentation, training, compliance with processes, etc.). Overall, these exercises and inspections demonstrated that the EDF sites have assimilated the principles of organisation,

2.4.4 Assessment of the Operating Experience Feedback process

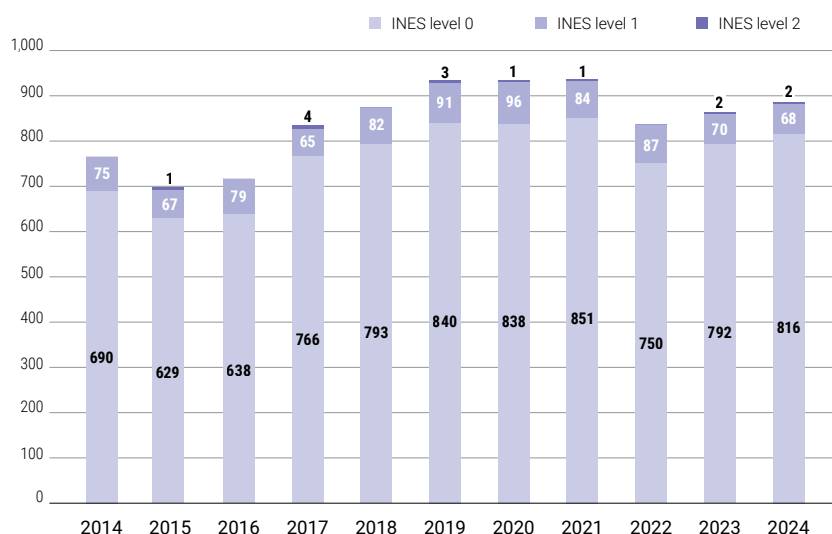
The Operating Experience Feedback process

ASN analyses the significant event notifications and reports transmitted by EDF to ensure that they are pertinent. It also carries out inspections on the NPPs to ensure that the OEF process is correctly implemented.

The quality and availability of the resources assigned to the in-depth analyses of significant events are satisfactory on all the sites, which is a positive point. However, ASN finds that the involvement of HOF specialists is sometimes inadequate, owing to a lack of trained personnel.

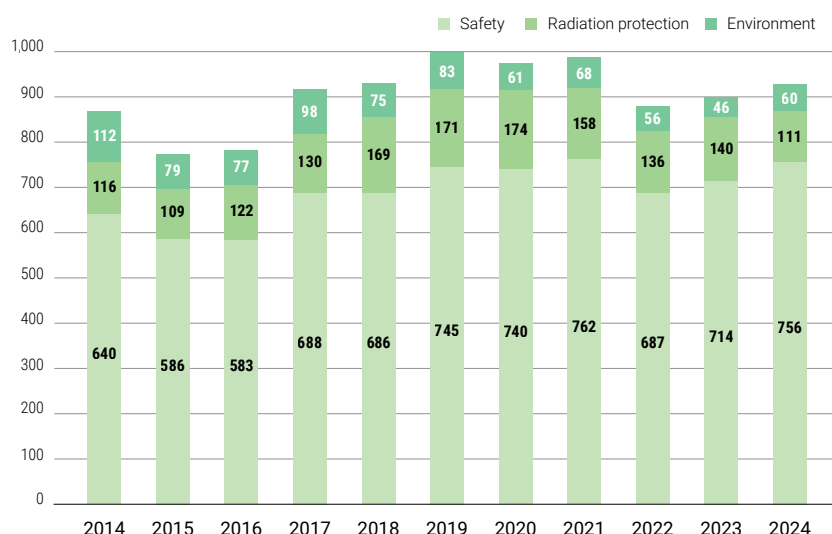
The analyses reveal that the apparent causes and the root causes are generally correctly identified and dealt with through adequate measures, even if the analyses all too often simply focus on human failures without sufficiently investigating the influence of the working situation or the organisational processes involved.

GRAPH 1 Trend in the number of significant events rated on the INES scale in the EDF Nuclear Power Plants between 2014 and 2024



This Graph includes data for the Fessenheim NPP up until 2020.
Source : ASN

GRAPH 2 Trend in the number of significant events by domain in the EDF Nuclear Power Plants between 2014 and 2024



This Graph includes data for the Fessenheim NPP up until 2020.
Source : ASN

Finally, ASN considers that EDF needs to make further progress on evaluating the effectiveness of the corrective measures and the conditions for closure of these measures. Building on lessons learned and sharing OEF remain points to be monitored.

Notification of significant events by EDF

Pursuant to the rules for the notification of significant events (see chapter 3, point 3.3), ASN received 756 ESS reports from EDF in 2024, along with 111 Significant Radiation protection Event (ESR) reports and 60 Significant Environmental Protection

Event (ESE) reports. It should be noted that, since 2021, the significant events at the Fessenheim NPP, which was finally shut down in June 2020, are no longer counted in these results. These results also include operation of the Flamanville EPR reactor which was commissioned in May 2024 (50 ESS, including 15 level 1).

Graph 1 presents the trend in the number of significant events notified by EDF and rated on the International Nuclear and Radiological Event Scale (INES), which is graded from 0 to 7 in increasing order of severity, since 2014.

Graph 2 shows the trend since 2014 in the number of significant events according to the notification field.

Significant events affecting several nuclear reactors are grouped under the term generic significant events. In 2024, 10 events of this type were reported in the field of nuclear safety (26 in 2020, 31 in 2021, 21 in 2022, 16 in 2023).

In 2024, two significant events rated level 2 were notified by EDF. Both of these events concern external contamination of a worker. The first in the Tricastin NPP and the second in the Saint-Laurent-des-Eaux NPP (see box page 316).

2.4.5 Protection against internal and external hazards

The NPPs must be able to withstand a variety of hazards, originating either inside or outside the installations. The main hazards constituting a risk for safety are detailed below.

Fire risks

A fire can lead to failure of the equipment needed to control the fundamental safety functions. Steps must thus be taken to protect the sensitive parts of the facility against fire.

In the same way as the other BNIs, NPPs are covered by ASN resolution 2014-DC-0417 of 28 January 2014, relating to the rules applicable to BNIs for controlling fire risks.

The way the fire risk is taken into account in the NPPs is based on the “Defence in Depth” principle built around three levels, that is the design of the facilities, fire prevention, fire detection and firefighting.

Design rules aim to prevent a fire from spreading and mitigate its consequences; they are based primarily on “fire sectorisation”. This involves dividing the facility into sectors and containment areas designed to keep the fire within a given perimeter bounded by items (doors, walls and fire dampers) offering a specified fire resistance duration. The main purpose is to prevent a fire from spreading to two redundant equipment items performing a fundamental safety function.

Explosion risks

An explosion can damage the items essential for maintaining safety or lead to rupture of the containment and the dispersal of radioactive materials into the facility, or even into the environment. Steps must thus be taken by the licensee to protect the sensitive parts of the installation.

Internal flooding risks

An internal flood, that is originating inside the facility, can lead to failure of the equipment needed to control the fundamental safety functions. Flooding

may in particular be caused by an earthquake. Steps are therefore taken to prevent internal flooding (maintenance of piping carrying water, etc.), or mitigate its consequences (presence of floor drains and water extraction pumps, installation of sills or leaktight doors to prevent the flood from spreading, etc.).

Seismic risks

Although seismic activity in France is moderate, EDF's inclusion of this risk in the safety case for its nuclear power reactors is the subject of constant attention on the part of ASN, given the potential consequences for the safety of the facilities. Seismic protection measures are designed into the facilities. They are periodically re-examined in the light of changing knowledge, on the occasion of the periodic safety reviews.

Basic Safety Rule (RFS) 2001-01 of 31 May 2001 defines the methodology used to determine the seismic risk for surface BNIs.

This RFS is supplemented by ASN Guide No. 2/01 of May 2006 which defines acceptable calculation methods for a study of the seismic behaviour of nuclear buildings and particular structures such as embankments, tunnels and underground pipes, supports or tanks.

The design of the buildings and the equipment important for safety in the NPPs must thus enable them to withstand earthquakes of an intensity greater than the strongest earthquakes that have occurred in the region. EDF's NPPs must thus be able to withstand seismic levels incorporating the local geological features specific to each one.

As part of the periodic safety reviews, the seismic reassessment consists in verifying the adequacy of the seismic design of the facility, taking account of changing knowledge about seismic activity in the region of the site or the methods for assessing the seismic behaviour of structures and equipment. The lessons learned from international experience feedback are also analysed and integrated into this framework. The seismic reassessments regularly lead EDF to reinforce the strength of its installations.

Heatwave and drought risks

During the heat waves in 2003 and 2006, some of the watercourses used to cool NPPs experienced a reduction in their flow rate and significant warming. Significant temperature rises were also observed in certain NPP premises housing heat-sensitive equipment.

EDF took account of this experience feedback and reassessed the operation of its facilities in air and water temperature conditions more extreme than those initially

Reactor outages

The nuclear power reactors must be periodically shut down for replacement of the fuel depleted during the electricity production cycle. One third or one quarter of the fuel is thus renewed at each outage.

These outages mean that certain parts of the installations which are not accessible during the production phase then become temporarily accessible. They are thus put to good use by EDF to carry out checks, tests and maintenance, as well as to perform works on the facility.

These outages can be of several types:

- Refuelling Outage and Maintenance Outage: these outages, which last from a few weeks to a few months, are devoted to replacing a part of the fuel and to carrying out a verification and maintenance programme, which is more extensive during a maintenance outage than during a refuelling outage.
- Ten-yearly outage: this is an outage involving a programme of in-depth verification and maintenance. This type of outage, which lasts several months and takes place every ten years, enables the licensee to carry out large-scale operations

such as the complete inspection and hydraulic testing of the reactor coolant system, hydrotesting of the containment or incorporation of design changes resulting from the periodic safety reviews.

These outages are scheduled and prepared by the licensee several months in advance. ASN checks the steps taken by the licensee to ensure the safety of the facility, environmental protection and radiation protection of the workers during the outage, as well as the safety of the reactor for the next production cycle.

In the light of the provisions of its resolution 2014-DC-0444 of 15 July 2014 concerning PWR outages and restarts, the monitoring performed by ASN involves spot-checks. These mainly concern the activities with the most significant safety implications, as well as the processing of any unforeseen events. It consists of on-site inspections and documentary checks, throughout the duration of the outage and in particular prior to restart of the reactor. It is after this inspection that ASN may or may not approve reactor restart.

included in the design. In parallel with development of these "extreme heat" baseline safety requirements, EDF modified its installations (such as the increase in the capacity of certain heat exchangers) and implemented operating practices optimising the cooling capacity of the equipment and improving the resistance of equipment susceptible to high temperatures.

During the reactors' periodic safety reviews, EDF takes account of climate change and is continuing to improve the capacity of its installations to deal with the effects of a heat wave. The capacity of certain cooling systems for equipment required for the nuclear safety case will in particular be improved. EDF has also initiated a climatic monitoring programme to anticipate climate changes which could compromise the temperature hypotheses adopted in its baseline requirements.

As with the other hazards, ASN asks EDF to learn the lessons from the various heat-wave events, along with their effects on the installations.

Consideration of natural hazards of extreme intensity

Following the accident that struck the Fukushima Daiichi NPP on 11 March 2011, stress tests led ASN to prescribe the installation of a "hardened safety core" of material and organisational provisions to deal with situations arising from external natural hazards of extreme intensity, the severity of which exceeds that considered hitherto in the baseline safety requirements of each installation. The external natural hazards considered for the design

of the "hardened safety core" are the following: earthquake, flooding (including extreme rainfall) and associated phenomena (extreme winds, lightning, hail) as well as tornados.

2.4.6 Assessment of the risk prevention measures relating to hazards

ASN checks that risks linked to hazards in the NPPs are taken into account, notably based on the reassessment of the design of the installations during the periodic safety reviews, analysis of the licensee's baseline safety requirements, examination of significant events and the inspections performed on the sites.

The Fukushima Daiichi NPP accident led EDF to reinforce its organisation for the management of risks relating to hazards. More specifically, networks of coordinators were set up in all the NPPs to oversee the implementation of the actions defined to deal with these hazards. Annual reviews are also held to improve this organisation.

In general, ASN considers that major efforts are still needed on most of the sites to improve how hazard risks are dealt with, in particular with regard to:

- the maintenance of equipment (sluice gates, fire doors, sensors, floor drains, etc.);
- risk assessments during maintenance operations and in the event an equipment malfunction is detected;
- training of the coordinators and awareness-raising among the EDF and contractor personnel.

Fire risks

ASN finds no significant change with regard to control of fire risks within the NPPs. The overall performance level is below that expected. Although progress can be seen on some sites, performance is deteriorating on others. The number of fire outbreaks in 2024 is very slightly up on 2023. Three of these fire outbreaks led to triggering of the PUI on the site concerned, including two for transformer fires, which were the year's most significant fires.

ASN has observed certain improvements in the management of the fire risk in the NPPs, notably in management of detection and in personnel training. However, ASN considers that on all the NPPs, EDF must improve management of the temporary storage of combustible materials during construction work and maintenance operations. ASN also noted the need on certain sites to improve the oversight of sectorisation and how anomalies on this subject are dealt with.

ASN found that EDF is continuing with its measures to improve management of the fire risks in the premises identified as being particularly susceptible to this hazard in the light of the potential consequences for safety.

Finally, EDF is working on deploying a new firefighting organisation on its sites, so that it can more effectively tackle fires and prevent them from spreading. Changes are thus planned with regard to personnel individual protection equipment, training and organisation with the Departmental Fire and Emergency Services (SDIS). EDF's goal is to complete the deployment of these changes in 2024. On several sites, this will lead to improvements to the response capacity jointly with the SDIS.

Explosion risks

ASN checks the prevention and monitoring measures taken by EDF with regard to the risk of explosion. As part of its labour inspectorate duties, ASN also ensures compliance with the "EXplosive ATmospheres" (ATEX) regulations to ensure worker protection.

ASN considers that the level of explosion-related risk management is not yet up to the required standard for all the NPPs. The maintenance and inspection doctrine and, on certain sites, compliance with prevention measures, is not always applied satisfactorily, notably with regard to the risks related to the presence of hydrogen in the installations. ASN however notes the efforts made by EDF to reduce the deviations observed. ASN considers that EDF must continue to pay particular attention to this subject and ensure that it is dealt with using all necessary rigour on all the sites.

Internal flooding risks

In 2019, ASN asked EDF to supplement its approach for controlling the internal flooding risk, notably to ensure correct operation of the floor drains, reinforce maintenance of the lines liable to lead to internal flooding and ensure improved management of their ageing. In response to these requests, EDF implemented improvement measures.

In addition, EDF is continuing its field visits to identify the piping which could cause internal flooding in the electrical buildings, which are particularly vulnerable to this risk, in order to assess the need to reinforce its maintenance. In accordance with ASN's requests, EDF will extend these surveys to the other buildings. ASN sees as positive the fact that EDF has initiated the refurbishment of the circuits of certain cooling systems that are particularly susceptible to corrosion.

Seismic risks

The inspection programmes implemented by EDF lead it to regularly notify ESS owing to the lack of seismic resistance of certain equipment. These events are the result of targeted inspections gradually being deployed by EDF. These non-compliances can have serious consequences in the event of an earthquake and they are thus systematically analysed.

On 11 November 2019, an earthquake occurred in the municipality of Le Teil. It led EDF to shut down the reactors of the Cruas-Meysses NPP so that it could conduct checks, which revealed no anomaly. In November 2019, ASN asked EDF to determine whether this earthquake should lead to a revision of the seismic levels to be adopted for protection of the Tricastin and Cruas-Meysses NPP sites. After investigations in the field, EDF defined a new hazard level to be used in the seismic reassessment studies associated with the fourth periodic safety review of the Cruas-Meysses site.

ASN also asked EDF to continue with its investigations in order to obtain an improved characterisation of the existing faults round the Tricastin and Cruas-Meysses NPPs. EDF undertook a wide-ranging programme of field investigations which continued in 2024 and the conclusions of which are to be taken into account during the fifth periodic safety review of the reactors on the sites concerned.

Risks linked to extreme temperatures

The inspections concerning the risks associated with extreme temperatures show that EDF's organisation must be improved on the majority of sites. On several sites, ASN more particularly found a lack of forward planning in preparing the facility for the summer or winter configuration

or that the operational implementation of the recommendations of the particular control rules could be improved.

In recent summers, at ASN's request, EDF ran operating tests on the emergency diesel generator sets during a period of high temperatures. The purpose of these tests, which continued in 2024, is to confirm the demonstration of the qualification of this equipment for heatwave conditions.

2.5 Conformity and maintenance of the installations

2.5.1 Maintenance of the installations and management of subcontracted activities

Maintenance of the installations

Preventive maintenance is an essential line of defence in ensuring the conformity of a facility with its baseline safety requirements.

In order to improve the reliability of the safety-important equipment but also the industrial performance, EDF is optimising its maintenance activities, drawing on practices used in conventional industry and by the licensees of NPPs in other countries. In 2008, EDF decided to deploy the maintenance methodology called "AP913", developed by the American nuclear licensees and built around two main points: organisational changes to enhance monitoring of the reliability of the equipment and systems and implementation of a new type of preventive maintenance programmes.

The AP913 implementation diagnostic performed by EDF in mid-2016 revealed difficulties with implementing performance monitoring and with the increase in the maintenance tasks generated by the AP913 maintenance programmes.

In 2017, EDF thus defined strategic guidelines for maintenance and reliability. It specified the roles of the various departments and professions related to the performance of maintenance, by reaffirming that the maintenance departments are responsible for the project ownership of the equipment they maintain, in particular in a context of continued operation of the reactors beyond 40 years. EDF also adopted function reviews to obtain an integrated view of the equipment and systems participating in each function, as well as implementing a new phase of its project to control the volume of maintenance.

Management of subcontracted activities

Reactor maintenance operations are to a large extent subcontracted by EDF to outside contractors. EDF justifies the use of subcontracting by the need to call on

Oversight of suppliers of equipment important for nuclear safety

In 2024, ASN carried out 68 inspections of the procurement chain for safety-important equipment intended for NPPs. These inspections checked the manufacturing processes used by the suppliers, their organisational provisions and the monitoring carried out by EDF. Of these inspections, 45 were linked to NPE manufacture and the procurement of components intended for the first EPR 2 reactors and the EDF reactors in operation. These inspections took place in France, Spain, Italy and Japan, in the plants of the NPE manufacturers and their subcontractors (forging and casting). ASN was thus able to check the quality of manufacturing and how the manufacturers, the approved organisations for evaluation of the conformity of equipment and EDF assumed their responsibilities for oversight of procurement. The inspectors found good practices in the performance of the activities entrusted to the outside contractors as well as progress in the dissemination of the safety culture,

notably thanks to the deployment of standard ISO 19443 within the companies. These inspections however also revealed gaps in knowledge and a lack of dissemination along the supply chain of certain regulatory or technical requirements, shortcomings in management of the implementation of processes, as well as the need to improve the quality of EDF's monitoring. In some cases, the inspections also showed that the suppliers' organisational procedures needed to be reinforced, along with their safety culture. In 2024, ASN published a practical guide in French and English, intended for the equipment suppliers and their subcontractors. The purpose of this guide is to make the regulations and their objectives more accessible. It explains the design and manufacturing requirements for safety-important equipment, as well as the industrial practices that ASN considers to be satisfactory. The principles described are illustrated by industrial examples, with a resolutely practical approach.

specific or rare expertise, as well as the highly seasonal nature of reactor outages and thus the need to absorb workload peaks.

EDF's decision to resort to subcontracting must not compromise the technical skills it must retain in-house in order to exercise its responsibility as licensee with regard to the protection of people and the environment and to be able to effectively monitor the quality of the work performed by the subcontractors. Poorly managed subcontracting is liable to lead to poor quality work and have a negative impact on the safety of the facility and the radiation protection of the workers involved.

EDF takes the necessary steps to control the risks associated with the subcontracted activities and regularly updates them. EDF has thus reinforced the preparation of reactor outages, more particularly to guarantee the availability of human and material resources.

2.5.2 Assessment of maintenance and subcontracted activities

Maintenance of the installations

Maintenance of the NPPs is also subject to regular checks by ASN during its inspections. In 2024, ASN considers that the management of the quality of maintenance activities in the NPPs is relatively satisfactory.

In this respect, ASN observes that the various sites deployed EDF's changes to the maintenance policy and that their organisation enables them to successfully carry out the required maintenance work. ASN

nonetheless finds that the significant industrial workload on some sites is an obstacle to the adoption of these changes and sometimes places them in a difficult situation.

ASN views positively that the number of significant events caused by an anomaly during a maintenance operation has decreased since 2022. ASN however finds that when certain maintenance work is performed, monitoring, first level analyses and requalification tests were not sufficient, because they did not systematically detect all the equipment anomalies.

EDF must continue its ongoing work on the competence of the personnel and improve preparation for maintenance activities, how experience feedback is taken into account and the quality of the risk assessments, against a backdrop of a significant industrial workload linked to continued operation of the reactors and the "Major overhaul" programme.

Finally, spares management remains a source of problems in the control of maintenance work, that was already identified in 2022 and 2023. Several maintenance operations had to be cancelled in 2024 owing to a lack of spare parts, either because the spares were unavailable or because of procurement delays, or for reasons of nonconformity of the spare part received. ASN considers that it is important for EDF to continue with its efforts to remedy the difficulties encountered.

The organisation for performance of maintenance

ASN notes that the scheduling of maintenance work has clearly improved on most NPPs, even if there are still problems of

Counterfeit, falsification and suspected fraud in the nuclear field

Further to the detection of new cases of suspected fraud in the nuclear sector, the ASN Commission held a hearing of the EDF Chief Executive Officer on 26 February 2024.

At a time when new projects are being launched and given the findings of recent years, the fight against fraud at all levels of the subcontracting and procurement chain must be a point meriting particular vigilance for the entire nuclear sector. It is thus primarily up to the licensees, who are responsible for nuclear safety, to prevent fraud, detect it and take steps to put an end to it.

ASN thus asked EDF to significantly strengthen its organisation, as well as the steps it planned to take to intensify the fight against fraud in its subcontracting and procurement chain, whether for its reactors in operation or those under construction or planned. ASN stressed the importance of building this action plan on an identification of the root causes leading a person or organisation to commit fraud.

The action plan defined by EDF is currently being implemented operationally. In 2025, ASN will continue to monitor this implementation and check its actual application.

coordination with the other disciplines and the project teams. Moreover, ASN's examination of the maintenance programmes for the equipment of the primary and secondary systems regularly reveals errors and omissions that EDF has to correct before they can be applied.

Management of subcontracted activities

ASN checks the conditions surrounding the preparation (schedule, required resources, etc.) and performance of the subcontracted activities (relations with the licensee, monitoring by the licensee, etc.). It also checks that the workers involved have the means needed (tools, operating documentation, etc.) to perform their tasks, in particular when these means are made available by EDF.

A number of improvements have been observed since 2023 in quality management of subcontracted activities. ASN also observes a very positive move within the NPPs to improve the skills of the contractors. EDF is implementing tangible measures, such as the increase in the provision of spaces for preparation work on a mock-up.

However, there are still difficulties regarding the quality of the monitoring provided (inappropriate monitoring plans,

monitoring overly focused on quality assurance and safety rules, to the detriment of actual technical operations, contractors lacking certain required skills, etc.). EDF also initiated a process to bring certain skills back in-house to ensure better monitoring. The situation varies among the sites.

2.5.3 Regulation of the conformity of facilities with the applicable requirements

Maintaining the conformity of the facilities with their design, construction and operating requirements is a major issue insofar as this conformity is essential for ensuring compliance with the safety case. The processes employed by the licensee, notably during reactor outages, contribute to maintaining the conformity of the facilities.

The identification and processing of deviations

The checks initiated by EDF within the framework of its operating baseline requirements and the additional verifications requested by ASN, on the basis more particularly of operating experience feedback, can lead to the detection of deviations from the defined requirements, which must then be processed. These deviations can have a variety of origins: design problems, construction errors, insufficient expertise in maintenance work, deterioration through ageing, organisational shortcomings, etc.

The steps taken to detect and correct deviations, specified in the Order of 7 February 2012, play an essential role in maintaining the level of safety of the facilities.

"Real-time" checks

Carrying out periodic test and preventive maintenance programmes on the equipment and systems contributes to identifying deviations. Routine visits in the field and technical inspection and verification of activities considered to be important for the protection of people and the environment are also effective means of detecting deviations.

Verifications during reactor outages

EDF takes advantage of nuclear reactor outages to carry out maintenance work and inspections which cannot be performed when the reactor is generating electricity. These operations more particularly correct already known deviations, but can also lead to the detection of new ones. Before each reactor restart, ASN asks EDF to list any deviations not yet remedied, to take appropriate compensatory measures and to demonstrate the acceptability of these deviations with respect to the protection of people and the environment for the coming production cycle.

Ten-yearly verifications: conformity checks

EDF carries out periodic safety reviews of its nuclear reactors every ten years, in accordance with the regulations (*see point 3.2*). EDF then carries out an in-depth review of the actual state of the facilities by comparison with the applicable safety requirements, more particularly on the basis of the in-service monitoring hitherto carried out, and lists any deviations. These verifications are supplemented by a programme of additional investigations, the aim of which is to check parts of the facility for degradation modes which are not covered by the inspections involved in the preventive maintenance programme.

The additional verifications in response to ASN requests

In addition to the steps taken by EDF with regard to its operating baseline requirements, additional checks are carried out at the request of ASN, whether, for example, further to OEF about events which have occurred on other facilities, after inspections, or after examination of the provisions proposed by the licensee within the context of the periodic safety reviews.

ASN requirements concerning repairs

ASN published its Guide No. 21 in 2015 regarding the handling of conformity deviations. This Guide specifies ASN's requirements concerning the correction of non-conformities and presents the approach expected of the licensee in accordance with the proportionality principle. This is based more specifically on an assessment of the potential or actual

consequences of any deviation identified and on the licensee's ability to guarantee the safety of the reactor in the event of an accident, by taking appropriate compensatory measures. The Guide also recalls the principle of the correction of compliance deviations as soon as possible and in any case defines the maximum times allowed.

2.5.4 Assessment of oversight of facilities compliance with the applicable requirements

Condition of equipment and conformity

In the past, ASN has found that the organisational measures taken by EDF to deal with deviations comprised shortcomings and that the time taken to characterise, check and process the deviations did not always comply with the requirements of the Order of 7 February 2012. In 2019, EDF therefore revised its internal baseline requirements for management of deviations, in order to improve how they are processed and provide ASN with reactive information proportionate to the safety implications. Since these new internal baseline requirements have been applied, ASN finds that in most situations, EDF corrects the deviations within the required time. These efforts will need to be continued in the coming years, notably on the occasion of the ten yearly outages.

Significant events concerning several reactors were once again reported in 2024 following the detection of conformity deviations; some of these deviations date back to

Thermal discharges from the NPPs during periods of heatwave or drought

To help cool its reactors, an NPP takes water from a watercourse or from the sea. The water returned to the watercourse is at a higher temperature, which warms up the watercourse downstream of the plant. This represents a few degrees for NPPs without cooling towers and a few tenths of a degree for those with them.

These warm water discharges, known as thermal discharges, are liable to have an impact on the aquatic environment.

They are thus regulated by ASN resolutions specific to each NPP. These set limits for heating of the watercourse between upstream and downstream of the plant and the maximum temperature downstream of it. When these limits are liable to be exceeded, the licensee reduces the power of the reactors and may even shut them down completely. These power reductions notably take place during periods of heatwave or drought.

ASN defined a second, higher, limit level, applicable when the manager of the *Réseau de Transport d'Électricité* (RTE) expresses the need to maintain a minimum power to ensure the security of the grid. This applies with no intervention on the part of ASN, which is informed, as are the other administrations concerned and the Local Information Committee (CLI). It is associated with a reinforced environmental monitoring programme.

In the event of an exceptional situation and public necessity, ASN may also temporarily modify the limits it has defined. This was the case in the summer of 2022.

Faced with the continuing increase in the effects of climate change, ASNR considers that a medium and long-term vision is required to address the thermal discharges in a heat wave period, given their implications for each region and the potential combined effects linked to the presence of several NPPs in the same catchment area.

the construction of the reactors, while others arose when making modifications to or performing maintenance on the facilities.

ASNR will continue to be particularly attentive to the conformity of the facilities in 2025 and will in this respect continue its inspections of the condition of equipment and systems.

2.6 Prevention and management of environmental and health impacts and non-radiological risks

2.6.1 Water intake, discharges, waste management and health impacts

Limiting water intake and environmental discharges

The NPPs intake water and discharge liquid and gaseous effluents into the natural environment. Water intake is primarily to cool the reactor's systems and, to a lesser extent, for industrial uses such as the production of demineralised water or the supply of fire-fighting systems. The effluents, which can be radioactive or chemical, come from chemical conditioning of the systems, which helps preserve them, the production of demineralised water, biocidal treatments and effluent from the wastewater treatment plant.

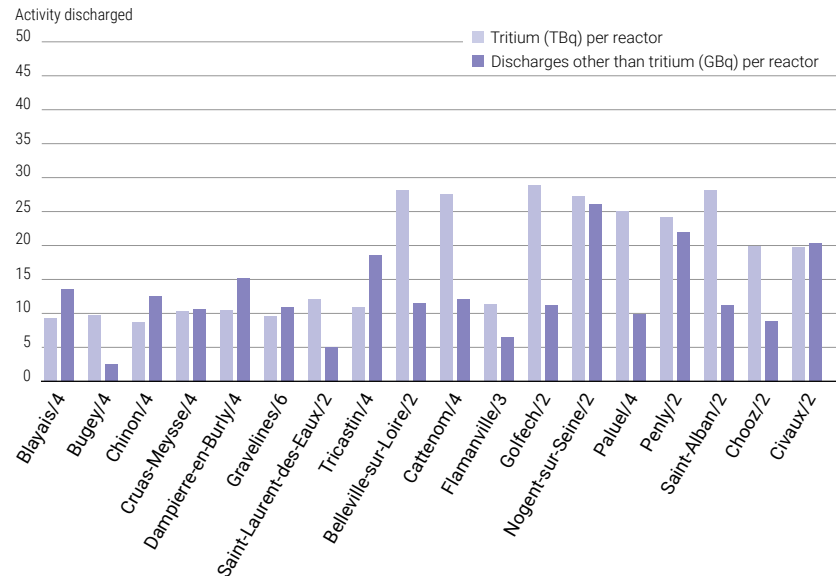
For each site, ASN sets the limit values for water intake and effluents discharge on the basis of the best available techniques in technically and economically acceptable conditions and taking into consideration the characteristics of the installation, its location and the local conditions of the water resource. It verifies that these limits have acceptable environmental and health impacts.

ASN also sets the rules concerning the management of detrimental effects and the impact on health and the environment of the reactors. These rules are notably applicable to the management and monitoring of water intake and effluent discharge, to environmental monitoring and to information of the public and the authorities (see chapter 3, point 4.1).

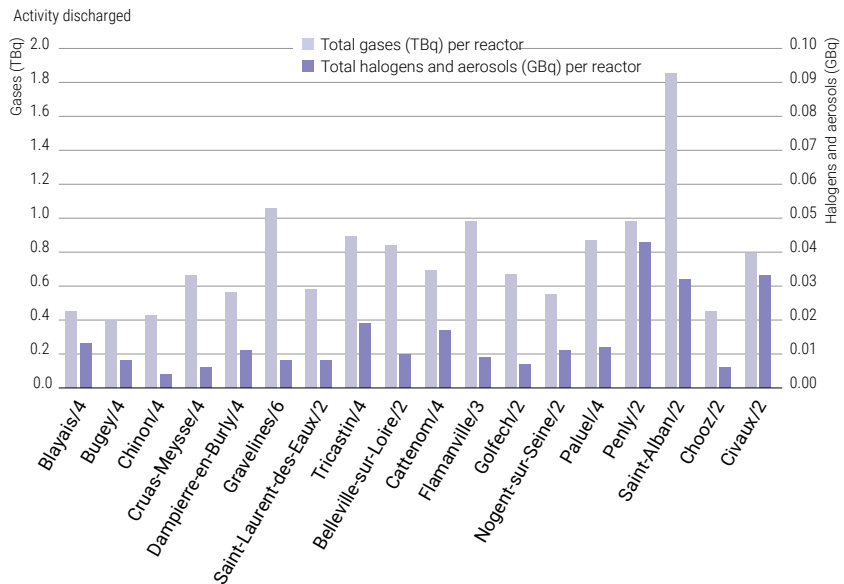
In 2024, ASN updated the resolutions governing the conditions for the intake and consumption of water as well as the conditions and limits for discharge into the environment for the Belleville-sur-Loire NPP. This update mainly concerns the use of a biocidal treatment and anti-scaling treatment of the water cooled by the site's cooling towers.

Finally, every year, the licensee of each NPP sends ASN an annual environmental report which notably contains a summary of the intakes from and discharges into the environment, any impacts they

GRAPH 3 Liquid radioactive discharges for the NPPs in 2024 (per reactor)



GRAPH 4 Gaseous radioactive discharges for the NPPs in 2024 (per reactor)



As there can be a different number of reactors on each site, the results are given per reactor, to enable a comparison to be made from one site to another. This therefore amounts to dividing the site's discharges by the number of reactors. For example, for the Golfech site, which has two reactors, the discharges are divided by two; for the Chinon site, which has four reactors, the discharges are divided by four. For the Gravelines site, which has six reactors, the discharges are divided by six.

may have, and any significant events which have occurred.

The impact of thermal discharges from the NPPs

NPPs discharge hot liquid effluents into watercourses or the sea, either directly, from those NPPs operating with "once-through" cooling, or after cooling of these effluents in cooling towers, enabling some of the heat to be dissipated to the atmosphere. These thermal discharges lead to a temperature rise in the natural environment between the points upstream and downstream of the discharge which, depending on the reactors, can range from a few tenths of a degree to several degrees. These thermal discharges are regulated by ASN resolutions specific to each NPP.

Since 2006, provisions have been incorporated into the ASN resolutions for advance definition of the operations of NPPs in exceptional climatic conditions leading to significant warming of the watercourses upstream of the NPPs. These special provisions are nonetheless only applicable if the security of the electricity grid is at stake (see box previous page).

Waste management

In compliance with the provisions of the Environment Code, EDF carries out waste sorting at source, differentiating in particular between waste from nuclear zones and other waste. For each installation, EDF produces a summary of the management of this waste, in particular presenting a description of the operations which are

the cause of production of the waste, the characteristics of the waste produced or to be produced, an estimation of the waste traffic volumes and a waste zoning plan.

In addition, every year, each site sends ASN a summary report on its production of waste and the corresponding disposal routes, a comparison with the results of previous years, a summary of the site organisation and the differences observed with respect to the management procedures specified in the waste management study, the list of significant events which have occurred and the outlook for the future.

Prevention of the health impacts caused by the growth of legionella and amoeba in certain cooling systems of the NPP secondary systems

The secondary cooling systems of nuclear reactors equipped with a cooling tower are environments favourable to the development of legionella and other amoeba. EDF monitors the legionella and amoeba concentrations and takes preventive measures and, if necessary, remedial measures in accordance with the provisions of ASN resolution 2016-DC-0578 of 6 December 2016 on the prevention of risks resulting from the dispersion of pathogenic micro-organisms (legionella and amoeba) by the cooling installations of the systems.

For most of these reactors, preventive and remedial measures to limit the development of legionella and amoeba are based on the injection of a biocidal product (monochloramine) into the cooling system.

2.6.2 Prevention and control of the non-radiological risks

Prevention of non-radiological risks with airborne effects

The accidents with effects said to be “non-radiological” are those which can arise from the release of hazard potentials not specific to the nuclear activity, insofar as they do not concern radioactive substances. These hazard potentials, which can also be present in other industries covered by the system for Installations Classified for Protection of the Environment (ICPEs), are associated with storage facilities and processes using gaseous or liquid chemical substances.

The consideration of these non-radiological accidents is included in the nuclear safety case in accordance with the provisions of Title III of the Order of 7 February 2012, through a specific study known as the non-radiological risks study. This study is drawn up using the methodology applicable to ICPEs. The purpose of this study is to justify the thermal and toxic effects, projectiles or over-pressure effects generated by release of the hazard potentials present on the site and leading to no effects beyond

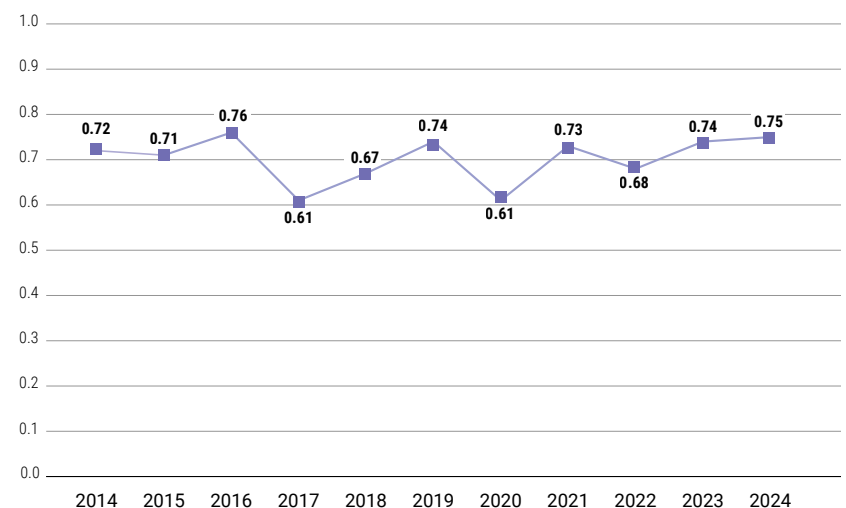
the perimeter of the site. This justification is based, on the one hand, on identification of the hazard potentials (storage facilities or processes) and their potential hazard sources and, on the other, on characterisation of the possible dangerous phenomena and the specific prevention measures for reducing both probability and effects.

Each NPP thus has a study of non-radiological risks which analyses and as necessary identifies the possible dangerous phenomena, as well as the specific material and organisational provisions for preventing these phenomena or limiting their effects.

Prevention of liquid pollution resulting from accidental spillage of dangerous substances

As with numerous industrial activities, the operation of an NPP involves the handling and storage of dangerous liquid chemical substances. The management of these substances and the prevention of pollution, which are the responsibility of the licensee, are regulated by the Order of 7 February 2012 and ASN resolution 2013-DC-0360 of 16 July 2013 and must also comply with the requirements of the European texts. The licensee has obligations regarding the operational management of these substances and the identification of the corresponding potential

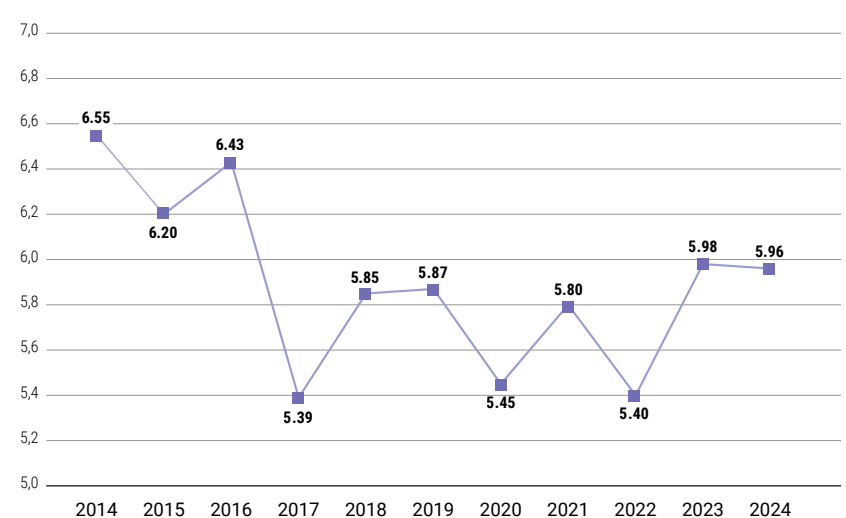
GRAPH 5 Mean collective dose per reactor (Man.Sv/reactor)



This Graph includes data for the Fessenheim NPP up until 2020 but does not include the data for the Flamanville NPP EPR reactor in 2024.

Source: EDF

GRAPH 6 Collective dose for one hour of work in a controlled area (in µSv)



This Graph includes data for the Fessenheim NPP up until 2020 but does not include the data for the Flamanville NPP EPR reactor in 2024.

Source: EDF

External contamination of two workers in the Tricastin and Saint-Laurent-des-Eaux NPPs

In 2024, two significant worker contamination situations, each detected during the radiological checks performed on exiting the reactor building, led to the notification of two ESR rated level 2 on the INES scale¹⁹.

The first event occurred on 6 June 2024 in the Tricastin NPP. It concerns the contamination of the foot of a worker who had been performing heat insulation installation work in the reactor 4 building.

The second event occurred on 25 October 2024 in the Saint-Laurent-des-Eaux NPP. It concerns contamination of the head of a worker who had been supervising the decontamination of the pool in the reactor 2 building.

In both cases, the medical service took charge of the employee and removed the radioactive particle causing the

contamination. Despite the investigations into precisely where they had worked, the areas where contamination took place could not be determined. The doses liable to have been received were thus estimated on the basis of the worst-case exposure duration hypotheses. They were thus evaluated as being higher than the annual regulation limit for the equivalent dose to the skin, set at 500 mSv for a skin surface area of 1 cm².

EDF notified an ESR for both situations. Owing to the regulatory occupational exposure limit being exceeded, these events were rated 2 on the INES scale.

Following notification of these events, ASN carried out an inspection in the Tricastin and Saint-Laurent-des-Eaux NPPs in order to check that EDF had taken all necessary steps for adequate management of these events and analysis of their causes.

* International scale of nuclear and radiological events, graded from 0 to 7 in increasing order of severity.

2.6.3 Assessment of control of environmental and health impacts and non-radiological hazards

ASN monitors the organisational and material measures put into place by EDF to prevent non-radiological risks and the liquid pollution that could result from the dangerous substances present in its installations. It also checks those designed to guarantee control of the detrimental effects arising from the operation of the installations, such as water intake, effluent discharges into the natural environment, and pathogenic hazards.

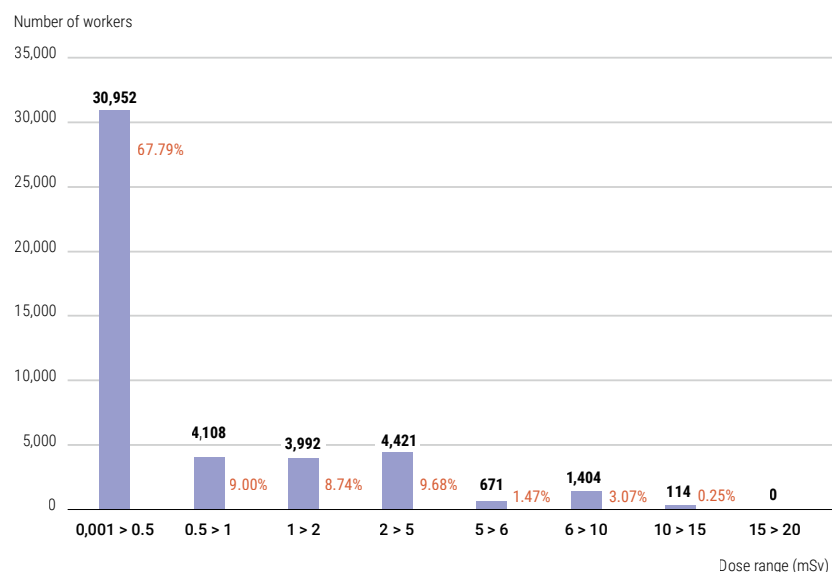
As each year, ASN carried out inspections on these measures in 2024. ASN in particular ran a campaign of tightened inspections in the Golfech, Blayais and Civaux NPPs on the topics of managing liquid containment in the event of spillage of a dangerous or radioactive substance, as well as the regulatory conformity and environmental performance.

Concerning the management of liquid containment, ASN considers that the sites need to progress further in taking steps associated with the preliminary checks on the containment means and structures currently in use, on implementing the operational documentation in the event of an emergency, as well as in raising the awareness and training the persons concerned. For each of the NPPs concerned, the inspectors also underlined the need to run field checks on the hypotheses adopted for the sizing of the long-term provisions made for liquid containment in order to meet the requirements set by ASN resolution 2013-DC-0360 of 16 July 2013.

Finally, ASN found that certain installations involved in the treatment of water or effluents are undergoing refurbishment or diagnostic programmes designed to identify the short-term improvements to be made. In this respect, the inspectors consider that, in its diagnostics and refurbishment programmes, EDF must give greater priority to the water consumption and effluent discharge reduction targets. More generally, ASN underlines the importance of the fact that in the operational and maintenance choices concerning its installations, each site must adopt a forward-looking vision taking account of hydro-climatic changes and the sensitivity of the water resource, in order to identify the possible measures to attenuate the impacts on this resource.

More generally, ASN in 2024 found that even if discharge management remains on the whole well-controlled, the situation in this field is more contrasted than in 2023. The deviations involving non-compliance with the effluent or

GRAPH 7 Number and percentage of workers per dose range in 2024



This Graph does not include data for the Flamanville NPP EPR reactor in 2024.

Source: EDF

hazards. It must also be able to take the necessary steps in the event of any incident or accident situations which would lead to pollution.

The licensee must thus for instance precisely identify the location of each dangerous substance on its site, along with the corresponding quantities. Drums and tanks must be labelled in compliance with the European Classification, Labelling, Packaging (CLP) regulation and there must be retention areas designed to collect any spills.

The NPPs must also adopt an organisation and resources to prevent pollution of the natural environment (groundwater, river, estuary, sea, soil).

At the request of ASN, EDF has for several years been carrying out steps to improve its management of the pollution risk by working to improve the confinement of dangerous liquid substances on its sites.

environment monitoring and surveillance procedures determined by ASN, increased in 2024. For example, the number of events associated with bypassing of the normal effluent discharge routes more than doubled between 2023 and 2024. ASN will be particularly vigilant with respect to the measures taken by EDF to correct these deviations and prevent them in the future.

With regard to waste management, the general improvement trend observed since 2022 continued in 2024. However, the checks carried out by ASN are still revealing cases of non-compliance with the operational baseline requirements, in particular concerning the storage durations and inventory-keeping, as well as non-conforming storage facilities. More broadly, for waste to be conditioned on many sites, ASN observes saturation of the storage spaces in the buildings specifically set aside for that purpose, making their management more complex.

2.7 Radiation protection of workers

2.7.1 Exposure of workers to ionising radiation

Exposure to ionising radiation in a nuclear power reactor comes primarily from the activation of corrosion products in the primary system and fission products in the fuel. All types of radiation are present (neutrons, α , β and γ), with a risk of internal and external exposure. Most of the doses received come from external exposure to β and γ radiation and are primarily linked to maintenance operations during reactor outages.

In 2024, the average collective dosimetry per reactor (see Graph 5 page 315), and the average dose received by the workers for one hour of work in a controlled area (see Graph 6 page 315) are comparable to the values recorded for 2023.

Graph 7 (see previous page) shows the breakdown of the workers according to whole body external dosimetry. In 2024, the share of workers exposed to a dose of less than one millisievert (mSv), remains comparable to the previous years (about 76%). The annual regulation limit for whole body external dosimetry (20 mSv) was exceeded on no occasion in 2024.

Graph 8 (see next page) shows the trend in whole body average individual dosimetry according to the categories of disciplines of the workers in the NPPs. As in previous years, those workers most exposed are the personnel in charge of heat insulation. The average individual dosimetry increased for this professional category in 2024 (+15% by comparison with 2023).

The other professional categories most exposed remain unchanged: welders, personnel in charge of non-destructive inspections, mechanical and ancillary activities. For these latter discipline categories, the average individual dose fell in 2024 by comparison with 2023.

Significant contamination events

In 2024, EDF reported seven significant contamination events involving workers in the NPPs, as opposed to two in 2023. Five of these events (rated level 1 on the INES scale) entailed an exposure of the workers concerned of more than one quarter the annual regulation limit for the skin and two of them (rated level 2 on the INES scale) entailed exposure greater than the annual regulation limit for the skin (see box previous page). Although the workers concerned by these events were treated, with removal of the radioactive particles responsible for their contamination, ASN considers that the rise in the number of events reported, which occurred in a variety of working situations, should lead EDF to take a closer look at how the contamination risk is addressed when preparing worksites.

2.7.2 Assessment of worker radiation protection

ASN monitors compliance with the regulations relative to the protection of workers liable to be exposed to ionising radiation in NPPs. In this respect, ASN is attentive to all the workers on the sites, both EDF personnel and those of contractors.

This monitoring is performed on each NPP during inspections, either on the specific topic of radiation protection, or on activities performed during reactor outages, or as a result of specific events. This monitoring is also carried out during examination of the worker radiation protection files (significant event reports, design, maintenance or modification files, documents implementing the regulations produced by EDF, etc.).

During the course of the inspections carried out in 2024, in particular during the tightened inspections on the topic of radiation protection in the NPPs of Saint-Alban, Nogent-sur Seine, Chooz and Cattenom, the inspectors observed a pro-active approach by EDF to controlling the sources of worker exposure to ionising radiation through the hot spot monitoring and elimination programmes.

In 2024, ASN once again found deviations in several NPPs concerning the prevention of the risks of exposure to ionising radiation for the most vulnerable workers (work-study students with a fixed term contract). In 2025, ASN will continue its oversight actions on this subject. With regard

to industrial radiography operations, ASN observes that the number of significant events reported in this field fell considerably by comparison with 2023. However, given the potential worker exposure consequences of some of these events, EDF must progress further in its coordination of risk prevention.

Finally, ASN once again found points in the field regarding which improvements are required in the control of the risk of contamination dispersal within the installations. ASN sometimes observes work-sites that entail a risk of contamination dispersal, for which the containment provisions are not as required or for which there are insufficient checks on the radiological cleanliness of the routes that could be taken by the contaminated equipment. These findings have been observed by the inspectors for several years now and should lead EDF to take a close look at the steps taken on this subject, so that they now result in effective improvements in the field for all the NPPs. On the occasion of the inspections scheduled for 2025, ASN will be particularly vigilant on this point.

2.8 Labour Law in the Nuclear Power Plants

2.8.1 Labour inspection in the Nuclear Power Plants

ASN is responsible for labour inspectorate duties in the installations of the 57 electricity generating reactors, including the EPR reactor commissioned in 2024, and 11 other installations, most of which are reactors undergoing decommissioning. 800 to 2,000 people work in each NPP, depending on the number of reactors. About 23,000 EDF employees and 11,000 employees from outside contractors are thus assigned to these nuclear sites.

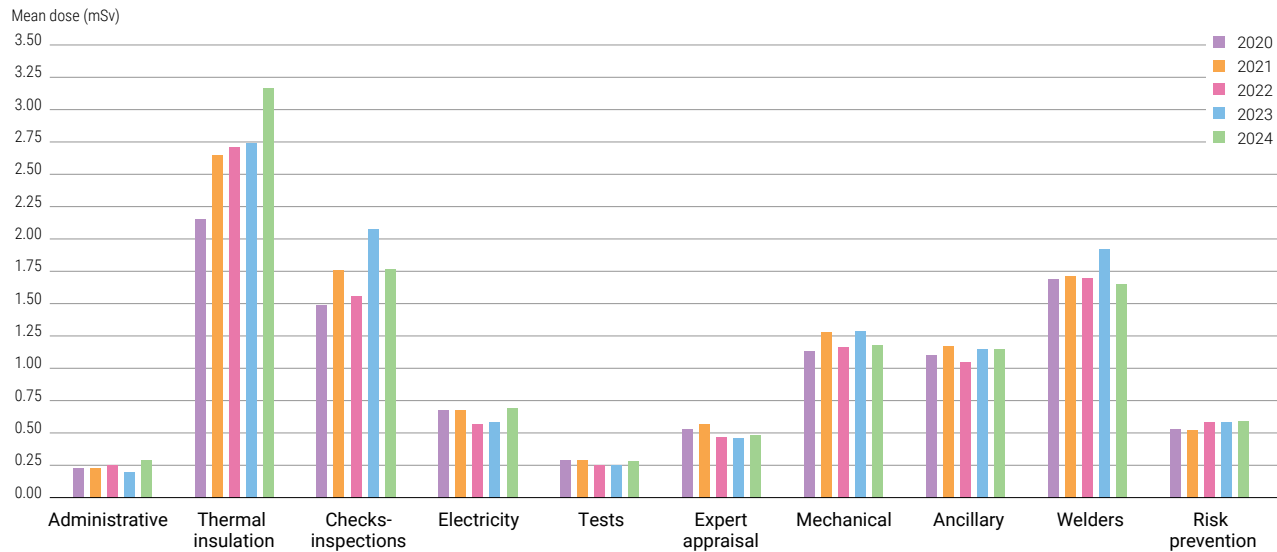
The role of the labour inspectorate is to ensure that the Labour Code as a whole is applied by the employers, whether EDF or its contractors.

The labour inspectorate, which takes part in the integrated vision of oversight sought by ASN, carries out its monitoring work in conjunction with the other activities to monitor and oversee the safety of facilities and radiation protection.

2.8.2 Assessment of health and safety, professional relations and quality of employment in the Nuclear Power Plants

In 2024, the ASN labour inspectors notably performed three inspection campaigns on mobile and lifting equipment, circulation on the sites and the ventilation of premises with specific pollution.

GRAPH 8 Trend in mean individual dosimetry according to the categories of trades of the workers in the NPPs



This Graph includes data for the Fessenheim NPP up until 2020 but does not include the data for the Flamanville NPP EPR reactor in 2024.
Source : EDF

On the whole, the inspections carried out by the labour inspectors show that worksite preparation needs to be improved, notably to limit the risks of exposure to asbestos and lead. Lifting operations and traffic rules on the sites are also points considered by the inspectors to merit particular attention. ASN will be vigilant with regard to the effective deployment of the action plans defined in response by EDF.

The labour inspectors also issued reminders concerning the safety requirements during isolated worker situations and the

prevention of risks during heat wave episodes. Several requests were also made concerning collective protections against falls from height (maintenance of guard rails, gratings and safety ladders).

Finally, the labour inspectors followed up all the events compromising worker safety that had occurred on the sites, systematically initiating inquiries in the event of serious or fatal accidents or serious near accidents. They were also called on to deal with cases relating to psychosocial and working hours risks.

According to EDF's data, ASN finds that overall accident levels in 2024 were 12.7% up on 2023 (+11.5% for accidents with time lost and +13.9% for accidents without time lost). These labour accidents mainly concern tripping, manual handling and handling of objects or tools.

In 2024, the social climate was tense on a few occasions, notably when the organisation notes were revised, or with respect to the organisation of the maintenance disciplines. In 2024, the NPPs began a modification of their internal rules of procedure to incorporate an approach to deal with addiction.

3 — Continued operation of the Nuclear Power Plants

3.1 The age of the Nuclear Power Plants

The NPPs currently in service in France were built over a relatively short period of time: 45 nuclear power reactors representing nearly 50,000 MWe, or three-quarters of the power output by all the French nuclear power reactors, were commissioned between 1980 and 1990, and seven reactors, representing 10,000 MWe, between 1991 and 2000. In December 2024, the average age of the 56 reactors in operation (excluding the EPR reactor), calculated from the dates of first divergence, can be broken down as follows:

- 42 years for the 32 nuclear power reactors of 900 MWe;
- 37 years for the 20 nuclear power reactors of 1,300 MWe;

- 27 years for the four nuclear power reactors of 1,450 MWe.

3.2 The periodic safety review

The principle of the periodic safety review

Every ten years, EDF must carry out a periodic safety review of its installations. The periodic safety reviews of nuclear power reactors comprise the following two steps:

- A check on the condition and conformity of the facility: this first step aims to assess the situation of the installation with respect to the rules applicable to it. It is based on a range of inspections and tests in addition to those performed in real-time. These verifications may comprise design

reviews, field inspections of the equipment, or even ten-yearly tests such as the containment pressure tests. Any deviations detected during these investigations are then restored to conformity within a time-frame commensurate with their potential consequences. Ageing management is also incorporated into this part of the review.

- The safety reassessment: this second step aims to improve the level of safety, notably taking account of the experience acquired during operation, changing knowledge, the requirements applicable to the more recent installations and international best practices. Following these reassessment studies, EDF identifies the changes it intends to make to its facilities in order to enhance safety.

The review process for the EDF nuclear power reactors

In order to benefit from the standardisation of its nuclear power reactors, EDF first of all implements a review of the provisions common to all the reactors of a given type (900 MWe, 1,300 MWe or 1,450 MWe reactors). The results of this programme are then applied to each of them on the occasion of its periodic safety review. EDF more particularly carries out a large part of the checks and modifications related to the periodic safety reviews during the ten-yearly inspections of its reactors. In accordance with the provisions of Article L. 593-19 of the Environment Code, following this periodic safety review, the licensee sends ASN a periodic safety review concluding report. In this report, the licensee states its position on the conformity of its facility and details the modifications made to remedy deviations observed or to improve the safety of the facility and, as necessary, specifies the additional improvements that it will be making.

ASN analysis

ASN examines the periodic safety reviews in several stages. It first of all issues a position statement on the objectives of the review and the guidelines of the generic programmes to verify the state of the facility and the safety reassessment proposed by EDF, after obtaining the opinion of the Advisory Committees of Experts (GPEs).

On this basis, EDF carries out safety reassessment studies and defines the modifications to be made. ASN then issues a position statement on the results of these studies and on these modifications, after

again consulting the GPEs. This position statement closes the generic phase of the periodic safety review, common to all the reactors.

This generic review does not take account of any specific individual aspects and ASN gives a ruling on the suitability of each nuclear power reactor for continued operation, notably on the basis of the results of the conformity checks and the assessment made in the periodic safety review concluding report for the reactor submitted by EDF. Following examination of this report, ASN communicates its analysis to the Ministry responsible for nuclear safety. It can issue new requirements governing its continued operation.

A public inquiry is held concerning the concluding report for the periodic safety reviews beyond the 35th year of operation of a nuclear power reactor. Five years after submission of this report, the licensee sends ASN an interim report on the implementation of the requirements stipulated by the review, as a result of which ASN may add to these requirements.

3.3 Ongoing periodic safety reviews in the Nuclear Power Plants

3.3.1 The 900 MWe reactors

The fourth periodic safety review

EDF's 32 reactors of 900 MWe in operation were commissioned between 1978 and 1987. More than half of them have reached the milestone of their fourth periodic safety review.

This fourth periodic safety review comprises particular challenges:

- Some items of equipment are reaching their design-basis lifetime. The studies concerning the conformity of the installations and the management of equipment ageing therefore need to be reviewed to take account of the degradation mechanisms actually observed and the maintenance and replacement strategies implemented by EDF.
- The safety reassessment of these reactors and the resulting improvements must be carried out in the light of the safety objectives of the new-generation reactors, such as the EPR, the design of which meets significantly reinforced safety requirements.

The modifications associated with this periodic safety review incorporate those linked to deployment of the "hardened safety core".

ASN's position statement on the generic phase of the periodic safety review

In 2013, EDF sent ASN its proposed objectives for this periodic safety review, notably the level of safety to be achieved for continued operation of the reactors.

After examining the objectives proposed by EDF, with the support of IRSN, and following consultation of its GPEs, ASN released a position statement on these objectives and issued additional requests in April 2016. EDF supplemented its programme of work and in 2018 presented ASN with the measures it envisages taking in response to these requests.

In 2020, with the support of IRSN, ASN finalised its examination of the generic studies linked to this review. At the beginning of 2021, ASN issued a position statement on the conditions for continued operation of the reactors. ASN considered that the measures planned by EDF combined with those prescribed by itself open up the prospect of continued operation of these reactors for the ten years following their fourth periodic safety review.

In October 2023, EDF asked ASN for postponement of the deadlines for some of the requirements in the resolution adopted in February 2021. Unexpected technical issues during implementation of some of the requirements, changes in the refuelling outages schedule, notably linked to the discovery of stress corrosion on the auxiliary lines, unexpected long-duration shutdowns or the needs of the electricity grid during the winter period, as well as a logjam with other periodic safety reviews, creating pressure on its engineering capacity, led EDF to revise its ability to carry out the activities needed to comply with the

The ageing of Nuclear Power Plant equipment

As in any industrial installation, the equipment in NPPs experiences ageing. This ageing is the result of physical phenomena (corrosion of metals, hardening of polymers, hardening of certain steels under the effect of irradiation or temperature, swelling of certain concretes, etc.) which can degrade their characteristics according to their age or their operating conditions. This degradation obliges the licensee to repair or replace the equipment or to limit the lifetime of non-replaceable equipment, such as the reactor pressure vessel (see point 2.2.4).

The ageing management process implemented by EDF is based on three main points: anticipating the effects of ageing as of the design stage, monitoring the actual condition of the facility and repairing or replacing equipment degraded by the effects of ageing. Before being installed, safety-important equipment more

particularly undergoes a qualification process to ensure its ability to perform its functions in conditions corresponding to the situations in which it will be needed, accident situations in particular.

The management of equipment ageing, and of the risk of obsolescence – which refers to difficulties linked to guaranteeing the procurement of spares over time – are essential to maintaining a satisfactory level of safety. They also contribute to reactor conformity with the applicable rules being maintained over time.

The control of ageing is given particular attention by ASN during the fourth periodic safety reviews. The provisions adopted or planned by EDF are examined and inspected, to ensure that the risks associated with ageing and obsolescence are controlled satisfactorily. EDF intends to use a similar approach again for the fifth periodic safety review of the 900 MWe reactors.

requirements, on time. ASN considered EDF's request to be acceptable in the light of the explanations provided.

Deployment of the periodic safety review on the site

EDF carried out the first of the fourth ten-yearly outages in 2019 (Tricastin NPP reactor 1). At the end of 2024, EDF had carried out or initiated 22 of these ten-yearly outages. These outages are a major step in the fourth periodic safety reviews. During these outages, EDF carries out the required inspections and deploys most of the safety improvements associated with the review. The fourth ten-yearly outages for the 900 MWe reactors will run until 2031.

In 2024, the public inquiries were held for the fourth periodic safety reviews of Gravelines NPP reactors 1 and 3.

The fifth periodic safety review

In 2023, EDF sent ASN the envisaged guidelines for the generic phase study programme for the fifth periodic safety review of the 900 MWe reactors.

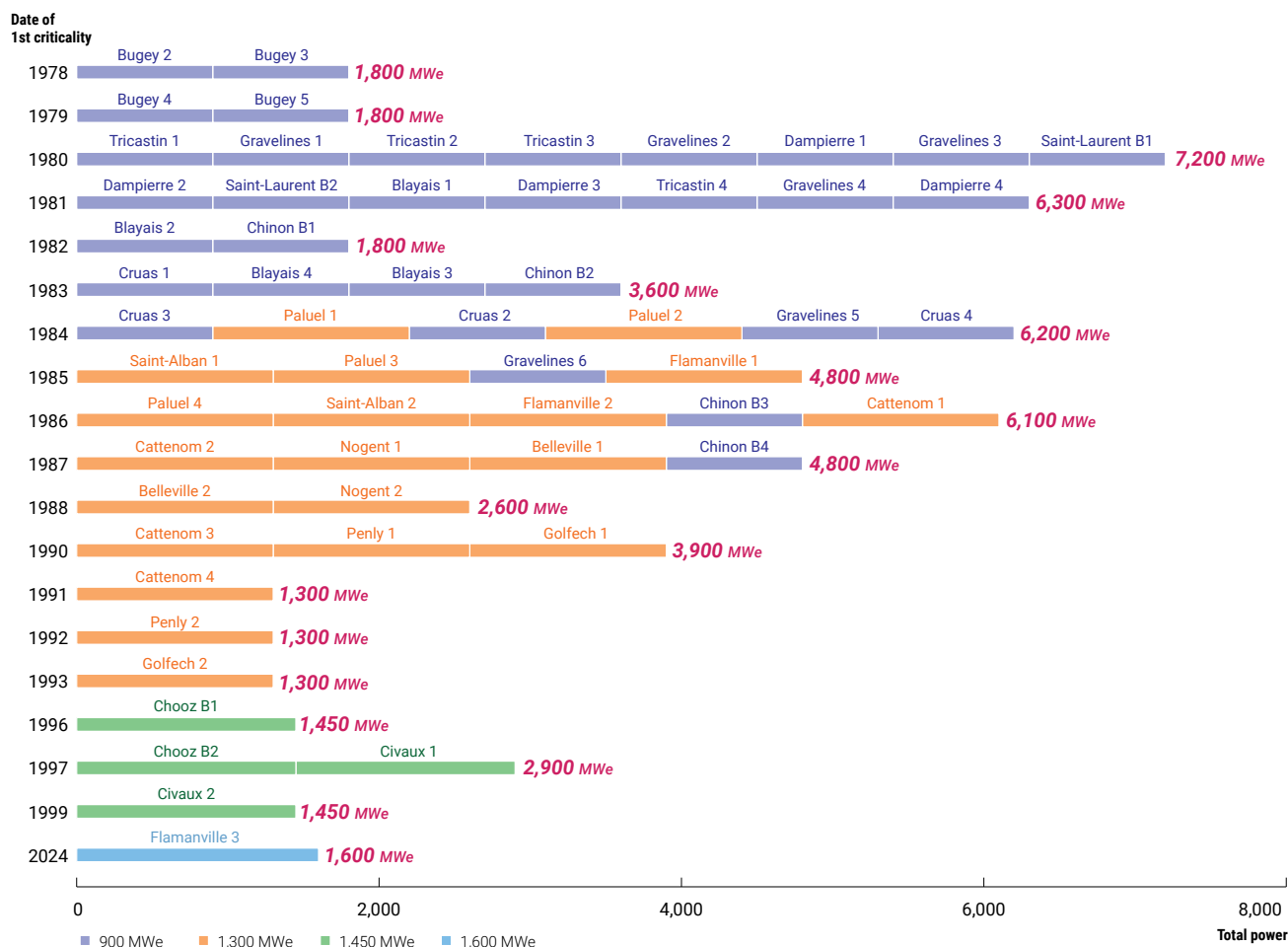
In the light of the major modifications made during the fourth periodic safety review, which will continue up until 2036 for the last reactor, EDF intends to focus the fifth periodic safety review:

- on verifying the conformity of the installations with their applicable requirements, maintaining equipment qualification and managing ageing, for operation up to 60 years;
- on reassessing the management of risks and detrimental effects, anticipating the effects of climate change (external hazards, water resource, etc.).

After consulting the public and further to the opinion of the Advisory Committee of Experts for nuclear Reactors (GPR) ASN issued a position statement in December 2024 on these guidelines (*see corresponding notable event page 20*). This periodic safety review serves to determine the conditions for continued operation of the reactors beyond 50 years.

ASN considers that the general guidelines adopted by EDF for this review are pertinent and consistent with the current level of knowledge. This fifth periodic safety review should allow consolidation of the major safety improvements made to the reactors during their fourth periodic safety review and reinforce the way in which the effects of climate change are addressed. However, ASN asks EDF to supplement or clarify some of these general objectives.

Time-line of first criticality of the French nuclear power reactors



3.3.2 The 1,300 MWe reactors

The third periodic safety review

At the beginning of 2015, ASN issued a position statement on the generic aspects of the continued operation of the 1,300 MWe reactors beyond thirty years of operation. On this occasion, ASN underlined the importance of the modifications made by EDF following their third periodic safety review. Within the framework of this review, EDF is notably deploying material and operational modifications in order to mitigate the consequences of an SG tube break accident, to prevent the occurrence of severe accidents with early loss of containment, and to reduce the risk of uncovering the fuel assemblies present in the spent fuel pool. With regard to hazards, EDF is modifying its installations in order to guarantee operation of the equipment needed for the safety of these reactors in the event of a heatwave, to protect the safety-important equipment against projectiles created by strong winds and to prevent the risks of explosion further to an earthquake.

To help conclude the generic phase of this review, ASN issued additional requests in 2021 applicable to all the 1,300 MWe reactors, with the aim of reinforcing their safety.

The third ten-yearly outages for the 1,300 MWe reactors will run until 2025.

The fourth periodic safety review

In July 2017, EDF sent ASN the guidelines it envisaged for the generic phase of the fourth periodic safety review of the 1,300 MWe reactors. In 2019, ASN issued a position statement on these guidelines, after involving the public and consulting the GPR: ASN considered that the general objectives set by EDF for this review are acceptable in principle. Similarly to those adopted for the fourth periodic safety review of the 900 MWe reactors, these objectives aim to demonstrate that in the event of a design basis accident it would not be necessary to implement population protection measures and that, in the event of a severe accident, only population protection measures that are limited in space and time would be required. With regard to the safety of the spent fuel pool, ASN asked EDF to set an objective of no uncovering of the assemblies and to eventually return the installation to and permanently maintain it in a state without pool water boiling. The modifications associated with this periodic safety review will also incorporate those linked to deployment of the “hardened safety core”.

Involvement of the public in the 4th periodic safety review of the 1,300 MWe reactors



After having organised technical dialogue days in 2023 with IRSN and the National Association for Local Information Committees and Commissions (Anccli), covering the issues of the fourth periodic safety review of the 1,300 MWe reactors, ASN took part in 2024 in the national consultation held under the aegis of the High Committee for Transparency and Information on Nuclear Safety (HCTISN) with regard to the provisions proposed by EDF for the generic phase of this periodic safety review.

This national consultation was held from 18 January to 30 September 2024 on a dedicated website, and through public meetings held close to each 1,300 MWe NPP, with the assistance of the CLIs, and during webinars.

This national consultation looked at various technical themes, such as ageing of the installations, adaptation to climate change or the prevention and mitigation of the consequences of accidents.

ASNR will take account of the conclusions of this prior consultation in preparing its position statement on the generic phase of this periodic safety review, scheduled for 2025. This position statement will itself be the subject of a public consultation on the ASNR website.

In 2024, ASN continued with the examinations performed for the generic phase of this periodic safety review. ASN convened its GPEs on four occasions with respect to hazards, accidents without core melt, severe accidents and the in-service strength of the reactor vessels and changes to the calculation methods used to justify the mechanical strength of the equipment of the MPS and MSS. On the basis of the conclusions of these expert assessments, ASNR will issue a position statement in 2025 on the generic phase of this periodic safety review. EDF will begin the first ten-yearly outage associated with this periodic safety review at the beginning of 2026.

3.3.3 The 1,450 MWe reactors

The second periodic safety review

In 2011, EDF transmitted the envisaged guidelines for the generic study programme for the second periodic safety review of the 1,450 MWe reactors, notably concerning the prevention of core melt and mitigation of the consequences of severe accidents.

ASN issued a position statement in February 2015 regarding the guidelines of this second periodic safety review. It in particular asked EDF to look for measures to mitigate the radiological consequences of design-basis accidents and measures with a strong impact in terms of preventing and mitigating the consequences of severe accidents.

ASN issued a position statement on this generic phase in 2022. It underlined the significant safety improvements made to the reactors on the occasion of this periodic safety review.

The concluding reports for the review of the four 1,450 MWe reactors were submitted between 2020 and 2023.

The third periodic safety review

After consulting the public and obtaining the opinion of the GPR, ASN issued a position statement in July 2023 regarding the guidelines envisaged by EDF for its study programme of the generic phase of the third periodic safety review of the 1,450 MWe reactors. The periodic safety review will allow definition of the conditions for continued operation of these reactors for up to 40 years. ASN considered that the general objectives set by EDF for this review were acceptable in principle. These objectives are consistent with those set for the fourth periodic safety reviews of the 900 MWe and 1,300 MWe reactors. ASN asked EDF to add to or clarify some of these general objectives, in the same way as it had done for the 900 MWe and 1,300 MWe reactors. The safety reassessment of these reactors and the resulting improvements will be carried out in the light of the safety objectives of the new-generation reactors, such as the EPR, the design of which meets significantly reinforced safety requirements. In addition, the modifications associated with this periodic safety review will incorporate those linked to deployment of the “hardened safety core”.

4 — Oversight of the Flamanville EPR reactor

The EPR is a PWR using a design that contains a number of changes by comparison with that of the reactors currently in operation in France. It meets reinforced safety objectives: reduction in the frequency of incidents or accidents, limitation of discharges, reduced volume and activity of waste, reduced individual and collective doses received by the workers (in normal operation and incident situations), reduced overall frequency of core melt, taking account of all types of failures and hazards and reduced radiological consequences of any accidents, in particular in the case of core melt.

In May 2006, EDF submitted a creation authorisation application to the Ministers responsible for nuclear safety and for radiation protection, for an EPR type reactor with a power of 1,600 MWe on the Flamanville site, which was already home to two 1,300 MWe reactors.

The Government authorised its creation through Decree 200-534 of 10 April 2007, after a favourable opinion issued by ASN following the examination process. This Decree was modified in 2017 and in 2020, to extend the time allowed for commissioning of the reactor.

After the issue of this DAC and the building permit, construction of the Flamanville EPR reactor began in September 2007. The first concrete was poured for the nuclear island buildings in December 2007.

The large nuclear components, such as the reactor vessel and the SGs were brought into the reactor building in 2014 and 2015. The main tests of the installation as a whole began in 2017.

Fuel was stored on the site as of 2020, then loaded into the reactor vessel in May 2024, following the commissioning authorisation from ASN. Since then, EDF has begun

start-up tests with the core loaded. EDF in particular carried out first reactor divergence in September 2024.

4.1 The commissioning authorisation

In a resolution of 7 May 2024, ASN authorised commissioning of the Flamanville EPR reactor. This authorisation allowed EDF to load nuclear fuel into the reactor and carry out start-up tests, followed by operation of the reactor.

This authorisation concluded the process conducted by ASN, with the support of IRSN, to examine EDF's authorisation application. ASN also oversaw the construction of the reactor, which involved the performance of nearly 600 inspections. More specifically, at the beginning of 2024 and prior to commissioning, ASN carried out start-up test inspections on completion of the installation, conformity of the nuclear pressure equipment and preparedness of the teams who will be operating the reactor.

The authorisation issued by ASN is accompanied by binding technical requirements which:

- regulate the performance and monitoring of the installation's start-up tests following loading of nuclear fuel into the reactor;
- stipulate how experience feedback from the operation of other EPR type reactors around the world is taken into account;
- define the deadline for replacement of the exchangers between the component RRI and essential SEC so that a sufficient level of performance is guaranteed throughout the lifetime of the installation;
- define the deadline for replacement of the bodies of two main secondary systems safety valves.

ASN has already required that the vessel closure head be replaced and this will take place during the reactor's first refuelling outage.

During its examination, ASN consulted the public regarding the EDF file and the draft commissioning authorisation. ASN also obtained the opinion of the Environmental Authority and the regional authorities concerned by the project. Finally, it held a hearing for the CLI of the Flamanville NPP.

ASN published a report summarising the conclusions of its examination as well as a summary of the public consultations held during the course of this examination. As a result of these consultations, ASN supplemented the technical requirements appended to the commissioning authorisation resolution, so that EDF regularly informs the CLI and the public regarding the performance of the start-up tests.

4.2 Monitoring start-up and the beginning of reactor operations

The commissioning authorisation enabled EDF to start loading the 241 nuclear fuel assemblies into the reactor. These operations ended on 15 May 2024. They underwent a specific inspection on 10 May 2024. ASN considers that they were well prepared and carried out.

The reactor vessel was closed at the end of May 2024: this step enabled EDF to begin the pre-critical cold and then hot tests, which could only be conducted once the reactor core was loaded in the vessel.

The licensee periodically submits information about the progress of operation and testing, which notably enables ASN to carry out its oversight work.



View of the Flamanville EPR reactor.

The commissioning decision set several milestones requiring ASN approval during the reactor start-up operations:

- before commissioning of the MPS and MSS, EDF transmitted a file to ASN notably listing the work and checks carried out on these systems by EDF. ASN examined this file and carried out an inspection;
- before first divergence of the reactor, EDF transmitted a file to ASN presenting the results of the start-up tests and the conformity of the composition of the reactor core. ASN also examined this file and carried out a campaign of five unannounced inspections. In a resolution of 2 September 2024, ASN authorised EDF to carry out the first criticality search and first divergence of the reactor.

In autumn 2024, EDF continued with the start-up tests, notably with core testing at nil power and then at 10% reactor nominal power, as well as a large number of tests on the non-nuclear part of the installation

using steam (turbine in particular). ASN monitored these activities and also carried out several thematic inspections, as it does periodically for the other EDF reactors in operation.

Since commissioning of the reactor, EDF has reported a large number of ESS, about third of which were rated level 1 on the INES scale. ASN is particularly vigilant with regard to the analysis of the root causes of these events and the steps taken by EDF to learn all relevant lessons and safeguard the upcoming start-up activities and the future operation of the reactor. The large number of events reported is notably linked to the learning curve followed by the staff in initial reactor operations and the transition from a construction culture to one of operation. The causes of the vast majority of the events are organisational and human, with few being linked to equipment failures. A large share of the events is also linked to human errors that were immediately detected, leading

to rapid conformity of the installation. ASN considers that the measures taken by EDF following these findings are pertinent and appropriate for the difficulties encountered during this phase.

International experience feedback

ASN takes part in the forum of authorities overseeing the safety of EPR reactors around the world. It thus regularly meets the Finnish, Chinese and British safety regulators in order to benefit from their experience of start-up tests, preparation for operation and the actual working of the EPR reactors.

ASN closely examines the OEF from EPR reactors in operation and regularly verifies that the lessons learned are taken into account by EDF at Flamanville. In particular, a number of phenomena linked to the physical behaviour of the core, observed at start-up of the first EPRs, were taken into account before commissioning.

5 — Regulation and oversight of the EPR 2 reactors project

EDF has started a programme to build EPR 2 type reactors in France. A first pair of reactors is planned for the Penly site in the Seine-Maritime *département*, a second on the Gravelines site in the Nord *département* and a third on the Bugey site in the Ain *département*.

For the Penly site, a public debate was held from 27 October 2022 to 27 February 2023, following which at the end of June 2023, EDF submitted a BNI creation authorisation application to the Minister responsible for nuclear safety. The construction work required for siting of the reactors was authorised by a Decree of 3 June 2024. The construction of the nuclear island may only begin after issue of the creation authorisation.

For the Gravelines site, a public debate was held from 17 September 2024 to 17 January 2025.

EPR 2 reactors safety options

The EPR 2 is a new PWR model, which aims to incorporate operating experience feedback from the design, construction and commissioning of the EPR reactors, as well as experience feedback from the operation of the existing reactors. In the same way as the EPR reactors, it aims to meet the general safety objectives for third-generation reactors. Furthermore, this reactor will integrate all the lessons learned from the Fukushima Daiichi NPP accident, as of the design stage. This more specifically entails reinforcing the design against external natural hazards and consolidating the independence of

the installation and the site in an accident situation (with or without core melt) until such time as the off-site resources can intervene.

ASN examined the Safety Options Dossier (DOS) for this reactor project, with the support of IRSN, taking account of the recommendations of Guide No. 22 on PWR design. In its opinion published on 16 July 2019, ASN considered that the general safety objectives, the baseline safety requirements and the main design options were on the whole satisfactory and, in its opinion and in a supplementary letter sent to EDF in July 2021, identified the subjects to be considered in greater detail for a future BNI DAC.

Technical reviews carried out in 2024

As set out in Article L. 592-29 of the Environment Code, the Minister responsible for nuclear safety instructed ASN to carry out the technical review of the creation authorisation application for the two EPR 2 reactors on the Penly site. This review is currently in progress. It follows on from the review of the EPR 2 reactors safety options. In 2024, ASN notably sent EDF its requests on the baseline requirements for taking account of internal hazards and the rating approach adopted to determine the requirements applicable to items performing a function necessary for the nuclear safety case.

In addition to the technical review of the creation authorisation application file, ASN began a process to monitor the organisation put into place by EDF to manage

its project. The purpose of this process is to check that the requirements relating to the protection of people and the environment to be met by the EPR 2 reactors are taken into account appropriately during the design and then construction phases of these reactors.

With regard to the equipment to be installed as part of the Nuclear Steam Supply System (NSSS) for these reactors, ASN continued with the reviews to check their design and manufacture in 2024. Between 2021 and 2024, ASN issued a position statement on the design options of the main equipment intended for the MPS and MSS of these reactors, such as the reactor vessel and the SGs.

ASN also approved the start of manufacturing of certain equipment, such as the reactor vessel and the SGs.

In parallel with the evaluation of the design documentation, procurement of the components intended for this equipment is inspected, in particular the large forged items. The purpose of these inspections is to ensure that the manufacturing processes adopted offer sufficient guarantees that materials meeting the required quality level will be produced.

ASN also started monitoring of the procurement chain for other safety-important items intended for the EPR 2 reactors, in order to evaluate the management of the manufacturing activities by the suppliers and EDF's monitoring of them.

11

The emergence of small modular reactor projects



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7 /	Standardisation and international cooperation goals p. 331



Several Small Modular Reactor (SMR) projects are currently being developed around the world. These are reactors with a power of less than 300 Megawatts electric (MWe), built mainly in a factory. They use a variety of technologies: that of the Pressurised Water Reactors (PWRs) or advanced technologies (high-temperature, molten salt, fast neutron, etc. reactors).

The characteristics of the SMRs, in particular their low power and compactness, contribute to their safety. The French Nuclear Safety Authority (ASN) considers that the designers should take advantage of these characteristics to propose reactors meeting more ambitious safety objectives than the existing high-power reactors.

ASN is also participating in international SMR working groups. Within this framework, it is holding discussions with its foreign counterparts in order to promote the definition of ambitious international baseline requirements, share its practices and benefit from operating experience feedback from its counterparts.

1 — The Government's call for project proposals

In March 2022, the Government launched a call for project proposals for innovative nuclear reactors, aiming to create a new ecosystem of nuclear start-ups, in addition to the existing heavyweights in the sector.

This call for project proposals is part of the France 2030 Plan to decarbonise the economy, in particular aiming to develop new nuclear reactor concepts which:

- in addition to producing electricity, will also meet the need for the production

of heat with temperatures of several hundred degrees, offering an alternative to the use of gas for a large number of industrial processes;

- can help close the “nuclear fuel cycle”⁽¹⁾ and improve radioactive waste management, by helping to reduce its volume or its activity.

This was the context in which about ten new companies developing SMR projects appeared in France in 2022 and 2023.

This emergence of numerous SMR projects is a global and not a purely national phenomenon: a large number of countries are concerned, especially the major nuclear nations: the United States, Canada, China and Russia. In total, more than sixty or so SMR projects are currently under development around the world.

2 — From power reactors to small modular reactors

The industrial nuclear reactors operated in France have until now only focused on the large-scale production of electricity. The French Nuclear Power Plant (NPP) fleet was gradually created with a regular trend being to increase the power of these reactors, from 900 MWe for the first reactors, to 1,600 MWe for the Flamanville EPR reactor.

By more specifically targeting the market to supply energy directly to industrial customers, the new reactor designers responding to the Government's call for project proposals are moving away from the traditional model, by developing reactors 10 to 400 times less powerful than the Flamanville EPR reactor, hence the term “small” reactors (see Table 1).

This significant power reduction also implies a radical adaptation of the development business model for these small reactors, on the one hand by seeking to reduce construction times and, on the other, by relying on standardisation and mass production.

This new industrial model with mass production involving a large share of prefabrication in the factory is why these small reactors are referred to as “modular”.

TABLE 1 Comparative thermal power of the reactors

	Thermal power ^(*) of the reactor core (MWth)
Flamanville EPR reactor	4,300
Small Modular Reactors which responded to the call for projects	20 to 540

* In the light of the supply of energy which is now not exclusively in the form of electricity, the characteristic power of these SMRs is expressed in terms of the thermal power of their core rather than the electrical power output.

1. France opted for a “nuclear fuel cycle” including the reprocessing of spent fuel. This reprocessing enables reusable materials (uranium and plutonium) to be recovered, while the other compounds (fission products and minor actinides) constitute the ultimate waste. At present, only a part of the reprocessed materials can actually be reused to fabricate new fuels. The notion of a “closed” nuclear fuel cycle corresponds to the goal of reprocessing the fuels several times and reusing all of the recovered materials or even, for some innovative reactor projects, also consuming the waste such as the fission products and minor actinides.

3 — Overview per technology of the small modular reactor projects being monitored by ASN and IRSN

The different types of SMR technologies in France



Light water reactors

- Solid uranium fuel
- Water moderator
- Water coolant



Liquid metal reactors

- Mixed uranium and plutonium oxide solid fuel (MOX-RNR)
- No moderator
- Liquid metal coolant (sodium, lead)



High-temperature reactors

- Solid uranium fuel (TRISO particles)
- Graphite or heavy water moderator
- Helium or sodium gas coolant



Molten salt reactors

- Liquid plutonium fuel in salt form
- No moderator
- Molten salt coolant

Water reactors represent the vast majority of the reactors currently in operation around the world, whereas the other SMR technologies, which are already known and have been developed for many years, have so far generally only led to the construction of a few experimental or prototype reactors, with no industrial scale operation.

In 2015, the Institute for Radiation Protection and Nuclear Safety (IRSN) evaluated the maturity of these other reactor technologies and identified the needs for development of scientific and technical knowledge. IRSN had concluded that only sodium-cooled Fast Neutron Reactors (FNRs – such as the Phénix and Superphénix reactors which were operated

in France) and High-Temperature gas-cooled Reactors (HTR) using graphite as a moderator, offered usable Operating Experience Feedback (OEF) for envisaging a transition to a possible industrial phase in the short term.

This difference in the maturity of the various technologies notably means that some projects are beginning with an experimental reactor development phase before envisaging the development of an industrial prototype.

Table 2 presents the list of the ten SMR projects currently being monitored by ASN and IRSN, ranked according to the degree of technological maturity of the reactor.

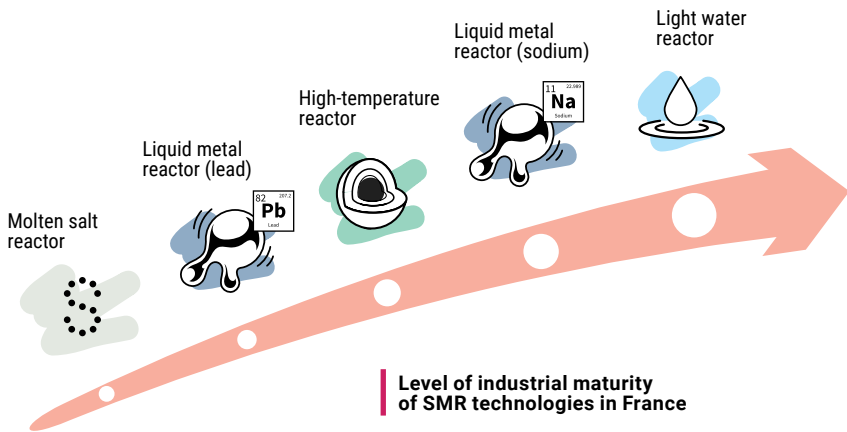


TABLE 2 SMR projects being studied

Technology	Project	Power of one reactor (MWth)	Target step in the short term
Light water reactor	Nuward	540	Industrial prototype
	Calogena	30	
Sodium-cooled reactor	Otrera	300	
	Hexana	400	
High-temperature reactor	Jimmy	20	Experimental reactor
	Blue Capsule	150	
Lead-cooled reactor	Newcleo	90	
Molten salt reactor	Naarea	20	Experimental reactor
	Stellaria	A few hundred kWth	
	Thorizon	250	Industrial prototype

4 — Implementation of a framework of incremental technical exchanges with ASN and IRSN

In order to optimise preparations for any creation authorisation applications for these innovative reactor projects, and in order to mobilise resources proportionate to the level of maturity of each project, a four-phase framework of incremental technical exchanges was set up.

PHASE 1

Screening phase

During a first meeting, the project developer is asked to present the following to ASN:

- the main characteristics of its reactor project (technology, power, form of energy output, front and back ends of the “fuel cycle”, etc.),
- the state of progress of the reactor design and its safety case,
- the development schedule of its project,
- the current technical and financial capacity of the company developing the project, along with its growth plan (calls for funds and staffing).

At the end of this prospective contact, ASN assesses the maturity of the project as a whole, with regard to the following three elements:

- **Minimum maturity of the technical project:** the project developer has an initial complete and stabilised conceptual design of its project.
- **Project developer’s capacity to conduct technical exchanges:** the project developer has a sufficient in-house technical team to be able to carry out technical exchanges with ASN on all the technical topics associated with the safety case of its reactor.

- **Minimum financial security of the project developer:** the company developing the project has sufficient financial guarantees for medium-term development.

If the overall maturity of the project does not appear sufficient to initiate a preparatory review, the project developer is asked to continue with development before contacting ASN again.

PHASE 2

Project preparatory review

Once project maturity is considered to be sufficient with respect to the three above-mentioned criteria, a cycle of thematic technical meetings is scheduled.

This aim of this cycle of meetings is to enable ASN to obtain a clear overview of the project, through presentations and technical dialogue, to understand the design choices, to take stock of the state of knowledge available or to be acquired, and to understand the main safety guidelines the project developer intends to follow in order to establish and justify its safety case.

A summary seminar may be organised to close this cycle of meetings.

This phase is simply an exchange of information in preparation for future examinations. No opinion or decision is expressed on the project at this stage by ASN.

PHASE 3

Preliminary review of the fundamental safety options of the project

Pursuant to Article R.593-14 of the Environment Code, before finalising the detailed design of its reactor, the project developer that intends to apply for a creation authorisation procedure can then ask ASN for its opinion on some or all of the fundamental aspects of its project.

With regard to these innovative reactor projects, ASN recommends that the project developers take advantage of this pre-licensing step. This step enables initial technical assessments to be started and enables the positions of the regulator to be obtained on a jointly agreed list of identified high-stakes subjects highlighted during the preparatory review phase.

PHASE 4

Review of the creation authorisation application

Finally, once the detailed design of the reactor project is ready, submission of a creation authorisation application can be envisaged.

This phase represents a new step in the increasing commitment of resources by ASN. Following the complete technical evaluation of the project, there will also be an evaluation of the characteristics of the planned site and a programme of inspections of the applicant, who acquires the *de facto* status of licensee, notably with the aim of checking its management system and its ability to manage subcontracting.

TABLE 3 Status of technical exchanges between the SMR project developers, ASN and IRSN as at 31 December 2024

Project	Prospective follow-up	Preparatory review	Preliminary examination (safety options)	Review of the creation authorisation application
Nuward			File withdrawn ^(*)	
Calogena			In progress ^(**)	
Otrera	x			
Hexana	x			
Jimmy				In progress ^(***)
Blue Capsule	x			
Newcleo		Completed		
Naarea		Completed		
Stellaria	x			
Thorizon		In progress		

* On 12 September 2024, EDF withdrew its request for an opinion on the safety options of the Nuward SMR.

** On 31 October 2024, the Calogena company submitted a request to ASN for its opinion on a part of the safety options chosen for its CAL30 SMR project.

*** On 3 May 2024, filing of a creation authorisation decree application for construction of a reactor designed to provide industrial heat to a plant of the Cristal Union Group, located on the Bazancourt site (51). ASN has completed the file acceptability analysis. The action subsequent to this analysis is being reviewed by the Nuclear Safety and Radiation Protection Mission.

Creation authorisation application for the first small modular reactor in France



On 3 May 2024, the Jimmy Energy company submitted a creation authorisation application for its first SMR, called “Fermi”, to the Minister responsible for nuclear safety. This is a project for an HTR reactor with a power of 20 Megawatts thermal (MW_{th}) designed to provide decarbonised industrial heat to a plant of the Cristal Union Group located on the Bazancourt site (Marne *département*), at a distance of about 15 km from Reims (see map below).

This reactor technology is notably characterised by the use of a particular ball-shaped fuel, called “TRISO particles”. These particles about 1 mm in diameter consist of a kernel of uranium oxide with successive coats of ceramic and silicon carbide.

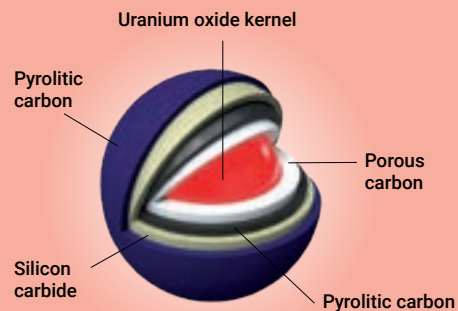
The advantage of using these TRISO particles is that their strength and leaktightness characteristics are claimed to provide intrinsic guarantees that

the radioactive materials they contain will be confined in all accident situations liable to affect the reactor.

With the support of IRSN, ASN in 2024 completed an analysis of the acceptability of the dossier submitted. The conclusions and the follow-up by the Minister responsible for nuclear safety regarding the acceptability of the dossier are expected at the beginning of 2025.



Triso particles (TRI-structural ISOtropic)



5 — New safety challenges and safety objectives to be adapted

Whereas the siting of a new power generating reactor is one of the aspects of the project which can to a certain extent be a choice, this is not the case for numerous SMR projects.

If the particular target is the industrial heat production market, then the siting of an SMR is determined by the location of the customer to whom it will be delivering the energy. Numerous SMR projects are thus aiming for deployment on industrial sites located near to or even within urban areas.

This type of siting near to densely populated or industrial areas is being envisaged by the project developers, because these SMRs are likely to be able to achieve safety levels significantly better than those of today’s large power generating reactors. With these SMRs, the low power to be removed in the event of an accident

should make it possible to combine passive and active safety systems, leading to increased diversification of the safety provisions, longer grace periods⁽²⁾ and better protection of the containment barriers. In addition, some of the new technologies proposed have specific characteristics (such as the intrinsic containment performance of the particular fuels of HTR), which also make it possible to envisage a significant reduction in radioactive releases in the event of an accident, even the most severe.

Even if these SMRs can in principle achieve safety levels higher than those of high-power electricity generating reactors, ASN considers that the safety objectives to be attained must be defined before envisaging siting close to population centres and existing industrial facilities which may themselves present risks.

ASN thus set up a pluralistic working group to consider the reinforced safety objectives to be defined before envisaging such siting choices. The initial results of these discussions, which reflect society’s expectations with regard to the reinforced safety level required for such reactor siting projects close to urban areas, were used by ASN in the harmonisation work undertaken with its European counterparts.

2. Time during which safety can be guaranteed with no intervention being required (for example the time for which – in the event of total loss of electrical power – safety can be guaranteed passively, pending the restoration of a back-up power source).

6 — The need for a vision incorporating the “fuel cycle”

The development of these modular reactor projects would appear to be inextricably linked to the availability of the fuel they need in order to operate. This availability refers not only to the existence of industrial production means for the fuels, but also the production capacity (see Table 4).

Two SMR project developers have also initiated technical discussions with ASN and IRSN on projects to develop fabrication plants for their fuel:

- Jimmy, concerning a project for a TRISO fuel fabrication plant;
- Newcleo, concerning a project for a MOX⁽³⁾ fuel fabrication plant for an FNR.

With regard to the molten salt reactor projects (Naarea, Stellaria and Thorizon), these project developers are working in collaboration with Orano, which could eventually envisage developing production means for this type of fuel.

Apart from the subject of fuel fabrication, ASN also underlines the need to have the transport systems approved for these fresh and used fuels, and to anticipate

the development of technologies for reprocessing and for management of the associated waste.

TABLE 4 Presentation of technologies and corresponding fuels envisaged for the SMRs

Technology	Current availability of the associated specific fuel
Light water reactor	• Existing industrial capacity
Fast Neutron Reactor, sodium or lead cooled	• Industrial production capacity to be developed
High-temperature reactor	• No industrial production capacity for this particular type of fuel (TRISO) ^(*) + • Need for uranium enriched to nearly 20% (HALEU) ^(**)
Molten salt reactor	• No industrial production capacity for this particular type of fuel (mixture of U and PU integrated into chloride salts) • Need to develop natural chlorine ^(***) to chlorine-37 enrichment capacity to avoid the formation of chlorine-36

* The particle fuel is referred to as “TRISO” for Tri-Structural Isotropic. The kernel consisting of uranium oxide, carbon and oxygen is surrounded by three insulating layers acting as the first containment barrier to retain the fission products.

** HALEU (High-Assay Low-Enriched Uranium) type uranium is enriched to a higher level of the uranium-235 isotope (from 5 to 20%) than the conventional Low-Enriched Uranium (LEU) used in the fuel for PWRs.

*** Natural chlorine consists of two stable isotopes: chlorine-35 (75%) and chlorine-37 (25%). The problem with chlorine-35 is that in the reactor core, it is transformed by neutron capture into chlorine-36 which is a very long half-life radioactive isotope and whose solubility and mobility through geological layers make it waste that is hard to manage.

7 — Standardisation and international cooperation goals

Despite the already high level of harmonisation of the safety standards of the International Atomic Energy Agency (IAEA) and the Europe-wide objectives and safety reference levels adopted by the Western European Nuclear Regulators Association (WENRA) each project to build a new reactor model in a country generally leads to the design being adapted to comply with the national regulations and the specific requirements of the local licensee (notably the organisation envisaged for routine operations, but also for management of emergency situations, jointly with the local public authorities).

The economic model of the SMRs is based on mass production to reduce costs through economies of scale. The project developers thus aim to have a single model authorised in several countries.

In order to remove the potential obstacles to the development of these new small reactors capable of contributing to decarbonisation of the global economy, a number of international initiatives are emerging. The IAEA is mobilising its members through the Nuclear Harmonization and Standardisation Initiative (NHSI) aiming to develop and encourage international cooperation modes for joint reviews of a given reactor model by several safety regulators, or to enable a country to familiarise itself with the evaluations already performed by other countries, in order to potentially reduce its own review workload.

ASN is taking part in this work and at the International Convention on Nuclear Safety presented the lessons learned and the concrete results of the Joint Early Review (JER) of the Nuward reactor conducted with the safety regulators from Finland (STUK) and Czech Republic (SUJB). In view of the interest in and success of this cooperation between three safety regulators, Nuward aimed to take this JER further by launching a second phase in which the nuclear safety regulators from the Netherlands (ANVS) and Poland (PAA) joined the three regulators already involved.

With respect to the European safety regulators, WENRA issued a position statement in 2021 on the fact that the safety goals set in 2010 for any new reactor remain applicable to the SMRs, but considered them to be a minimum level of requirement. WENRA felt that the state-of-the-art design and technologies used for these small reactors should enable a significant reduction to be achieved in radioactive releases following an accident, by comparison with the existing high-power reactors.

Based on this observation, WENRA then set up a Working Group (WG) to draft proposed revisions to these safety goals. Within this WG, with the backing of other safety regulators, ASN supported the position presented to OPECST in January 2024, that is that the siting envisaged by the nuclear industry close to densely populated urban areas or industrial zones could

only be envisaged if a higher level of safety is achieved, guaranteeing that any radiological releases would remain negligible in the event of an accident, including the most severe. Because at this stage no consensus has been reached at the European level on whether or not to revise the existing safety objectives, exchanges are continuing in order to explain this need for an increase in safety. Some countries are indeed defending the status quo regarding the published existing safety objectives (corresponding to the safety level of the EPR type reactors) and envisage ruling on a discretionary case-by-case basis with respect to the adequacy of the safety level of each project.

3. MOX fuel is a nuclear fuel consisting of a mixture of depleted uranium oxide and plutonium produced by Orano's Melox plant. It can be used in the 24 reactors of 900 MWe. In France, MOX fuel uses only civil plutonium, extracted from spent fuel.

12

**“Nuclear fuel cycle”
facilities**



1

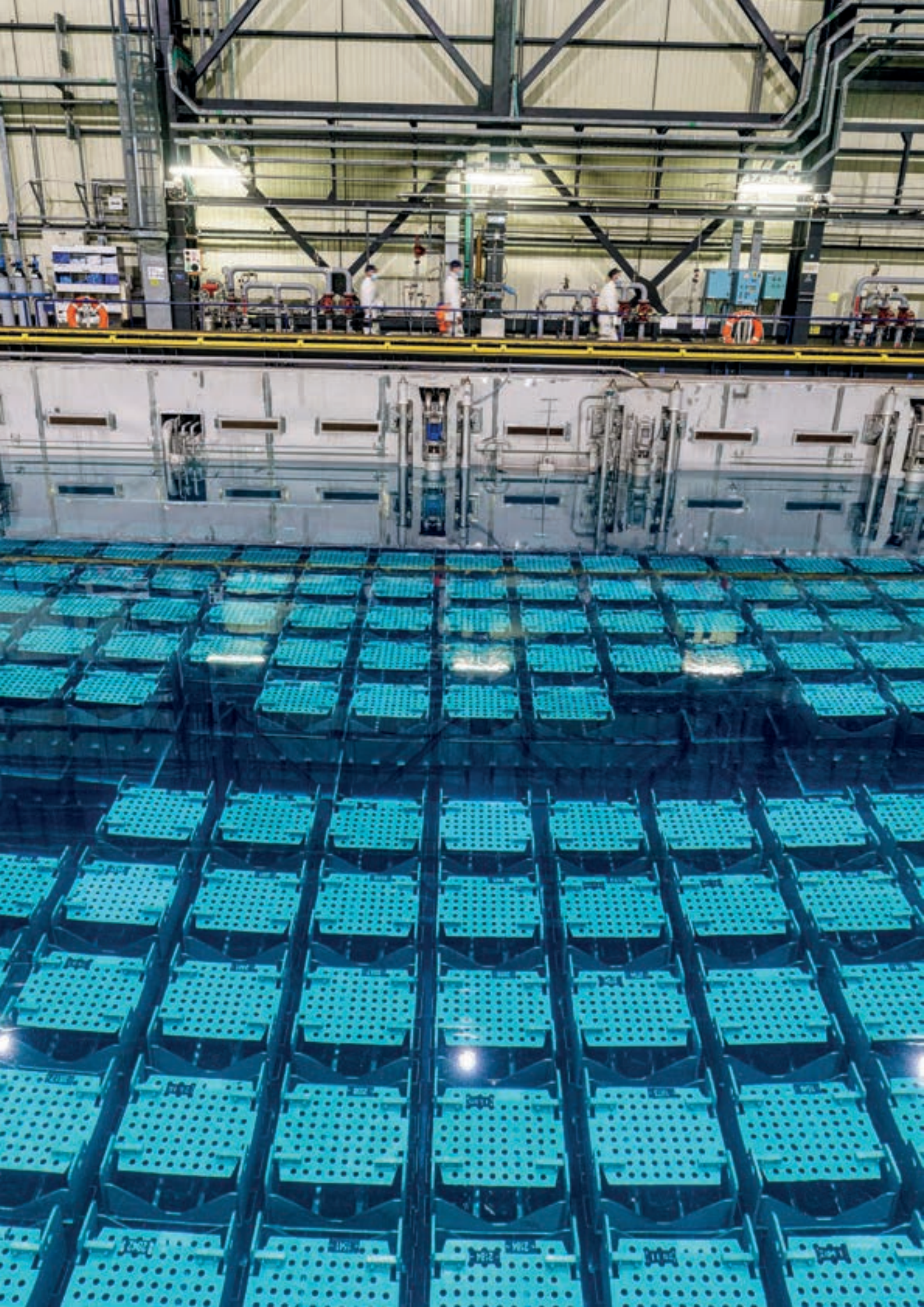
The “fuel cycle” p. 336

- 1.1 The front-end “fuel cycle”
- 1.2 Fuel fabrication
- 1.3 The back-end “fuel cycle” – reprocessing
- 1.4 “Fuel cycle” consistency in terms of nuclear safety and radiation protection
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2

ASN actions in the field of “fuel cycle” facilities: a graded approach p. 341

- 2.1 The graded approach according to the risks of the facilities
- 2.2 Periodic safety reviews of “fuel cycle” facilities



The "nuclear fuel cycle" begins with the extraction of uranium ore and ends with the packaging of the radioactive wastes from spent fuel reprocessing, for subsequent disposal. In France, the last uranium mines closed in the year 2000, so the "fuel cycle" concerns the fabrication of fuel, its reprocessing after use in the nuclear reactors, the reuse of any products resulting from reprocessing that can be recycled, and waste management.

The nuclear facilities involved in the "fuel cycle", each of which is unique, are the links in a chain, the operation of which can be significantly disrupted if one of the links is defective.

The licensees of the "fuel cycle" plants are part of the Orano or EDF (Framatome) groups: Orano Cycle operates the Melox plant in Marcoule, the La Hague plants, all the Tricastin plants, as well as the Malvési facilities. Framatome operates the facilities on the Romans-sur-Isère site. The French Nuclear Safety Authority (ASN) monitors the safety of these industrial facilities, which handle radioactive substances such as uranium or plutonium and constitute specific safety risks, notably radiological risks associated with toxic risks.

ASN also oversees the overall consistency of the industrial choices made regarding the "fuel cycle" and which could have consequences for safety.

In 2024, on the La Hague site, Orano commissioned three new Fission Products Evaporator-Concentrators (NCPF R2) in the UP2-800 plant, thus completing the replacement of the previous equipment which was suffering from more advanced corrosion than imagined at the design stage. The projects aimed at restoring storage margins for spent fuels and plutonium-bearing materials continued, with a view to possible commissioning in 2025 after obtaining authorisations from ASN. The improvements to the situation of the Melox plant, observed in 2023, were confirmed in 2024. They help to stabilise the working of the "fuel cycle", even if there are still limited margins in the case of any unforeseen event and countermeasures are still required to restore said margins, notably by increasing the storage density in the pools at La Hague, as authorised by ASN in December 2024.

In 2024, Orano and EDF presented an update of the projected spent fuel volumes to be stored according to the various production scenarios from the La Hague and Melox plants, in the light of the new nuclear policy guidelines, notably assuming continued operation of EDF's 900 Megawatts electric (MWe) reactors beyond 50 years. These projections push back the prospect of saturation of the spent fuel storage capacity to about 2040. EDF also announced that it was abandoning the centralised storage pool project and opting for new storage capacity operated by Orano, which should also be commissioned in about 2040.

In this context, ASN considers that the overall working of the "fuel cycle" is stabilised. ASN nonetheless remains vigilant given the long-term limits on margins, the lack of redundancy of a certain amount of equipment and the ambitious nature of the hypotheses concerning both production and the absence of unexpected events blocking the La Hague and Melox plants.

1 — The "fuel cycle"

The uranium ore is extracted, then purified and concentrated into Yellow Cake on the mining sites. The solid concentrate is then transformed into uranium hexafluoride (UF_6) following conversion operations. These operations are performed in the Orano plants in Malvési and Tricastin. These plants, which are regulated under the legislation for Installations Classified for Protection of the Environment (ICPEs) use natural uranium in which the uranium-235 content is around 0.7%.

Most of the world's nuclear power reactors use uranium slightly enriched with uranium-235. The Pressurised Water Reactor (PWR) series for example requires uranium enriched with isotope-235. In France, UF_6 enrichment between 3% and 6% is carried out by ultracentrifuges in the Georges Besse II (GB II) plant in Tricastin.

This enriched UF_6 is then transformed into uranium oxide powder in the Framatome plant in Romans-sur-Isère. The fuel pellets manufactured with this oxide are introduced into cladding to make fuel rods, which are then combined to form fuel assemblies.

These assemblies are then placed in the reactor core where they release energy, notably through the fission of uranium-235 nuclei. Irradiation of these assemblies in the core leads to the creation of plutonium. Before it is used in the reactors, new nuclear fuel can be stored in one of the two Inter-Regional fuel Stores (MIR) operated by EDF in Bugey and Chinon. In 2023, Framatome also took over the fabrication of fuel assemblies based on Enriched Reprocessed Uranium (URE) intended for the Cruas-Meysses Nuclear Power Plant (NPP).

After a period of use of about 3 to 4 years, the spent fuel assemblies are removed from the reactor and cooled in a pool, firstly on the site of the plant in which they were used and then in the Orano reprocessing plant at La Hague.

In this plant, the uranium and plutonium from the spent fuels are separated from the fission products and other transuranic elements¹. The uranium and plutonium are packaged and then stored for subsequent re-use.

The plutonium resulting from the reprocessing of uranium oxide fuels is used in the Melox plant operated by Orano in Marcoule, to fabricate MOX (Mixed OXides) fuel which is used in certain 900 MWe NPPs reactors in France. The MOX nuclear fuels are not currently reprocessed after being used in the reactors.

Pending their reprocessing or disposal, the spent MOX fuels are stored in the pools of the La Hague plant.

The main material flows for the "fuel cycle" are presented in Table 1 (*see next page*).

Other facilities are needed for the operation of the Basic Nuclear Installations (BNIs) mentioned below, more particularly the IARU facility (formerly Socatri), which is responsible for the maintenance and decommissioning of nuclear equipment, as well as the treatment of nuclear and industrial effluents from the Orano platform in Tricastin.

1.1 The front-end "fuel cycle"

Before fuels are fabricated for use in the reactors, the uranium ore must undergo a number of chemical transformations, from the preparation of the Yellow Cake through to conversion into UF_6 , the form in which it is enriched. These operations take place primarily on the Orano sites of Malvési, in the Aude *département*, and Tricastin in the Drôme and Vaucluse *départements* (also known as the Pierrelatte site).

On the Tricastin site, Orano operates:

- the TU5 facility (BNI 155) for conversion of uranyl nitrate, produced by reprocessing spent fuel at La Hague into triuranium octoxide (U_3O_8);
- the W plant (ICPE within the perimeter of BNI 155) for converting depleted UF_6 into U_3O_8 ;
- the former Comurhex facility (BNI 105) for converting uranium tetrafluoride (UF_4) into UF_6 , which contains the Philippe Coste plant;
- the GB II (BNI 168) UF_6 ultra-centrifuge enrichment facility;
- the Atlas analysis laboratory (BNI 176);
- areas for the storage of uranium and thorium in various forms (BNI 93, 178, 179 and 180);
- the IARU facility (BNI 138 – formerly Socatri) which manages waste from the Tricastin site and carries out nuclear equipment maintenance and decommissioning;
- a Defence Basic Nuclear Installation (DBNI) which more particularly operates the radioactive substances storage areas, virtually all of which are for civil uses.

The TU5 facility and the Orano W plant – BNI 155

BNI 155, called "TU5", can handle up to 2,000 tonnes (t) of uranium per year, enabling it to reprocess all the uranyl nitrate produced by the Orano plant at La Hague, converting it into U_3O_8 (a stable solid compound able to guarantee safer uranium

storage conditions than in liquid or gaseous form). Once converted, the reprocessed uranium is placed in storage on the Tricastin site.

The Orano uranium conversion plants – BNI 105

BNI 105, which notably transformed reprocessed uranyl nitrate into UF_4 or U_3O_8 , is being decommissioned (*see chapter 14*).

The Philippe Coste plant is located inside its perimeter and is devoted to the fluorination of UF_4 into UF_6 , to allow its subsequent enrichment in the GB II plant.

It has a production capacity of about 14,000 t of UF_6 from the UF_4 coming from the Orano facility in Malvési. It has ICPE status subject to authorisation with institutional controls ("Seveso" class installation) and is monitored by ASN accordingly.

The Georges Besse II ultra-centrifuge enrichment plant – BNI 168

BNI 168, called "GB II", for which creation was authorised in 2007, is a plant enriching uranium by means of gas ultra-centrifugation. This process involves injecting UF_6 into a cylindrical vessel rotating at very high speed. Under the effect of the centrifugal force, the heavier molecules (containing uranium-238) are separated from the lighter ones (containing uranium-235). By combining several centrifuges, creating a cascade, it is then possible to recover a stream of uranium enriched with fissile 235 isotope and a depleted stream. The GB II plant comprises two enrichment units (South and North units) and a support unit, REC II. On 19 June 2023, Orano sent the Minister in charge of nuclear safety a substantial modification authorisation application, with the aim of increasing the nominal production capacity of the GB II plant by 30%.

Enrichment of the uranium resulting from reprocessing, which would require prior authorisation from ASN, is not currently carried out in this plant.

The Atlas facility – BNI 176

The purpose of the Atlas facility is:

- to carry out industrial physico-chemical and radio-chemical analyses;
- to monitor liquid and atmospheric discharges and monitor the environment of the Tricastin facilities.

The Atlas facility, commissioned in 2017, meets the most recent safety requirements.

1. Transuranic elements are chemical elements heavier than uranium (atomic number 92). The main ones are neptunium (93), plutonium (94), americium (95), curium (96). In a reactor, they are derived from uranium during secondary reactions other than fission.

The Tricastin uranium storage facility – BNI 178

Following the delicensing of part of the Pierrelatte DBNI by decision of the Prime Minister, BNI 178 – or the Tricastin uranium storage facility – was created. This facility groups the uranium storage facilities and the platform's new emergency management premises. ASN registered this facility in December 2016. It comprises the Containers Maintenance Shop 2 (AMC2), in which the containers intended for the transport and storage of UF₆ are washed and rinsed, as authorised by Decree 2023-1220 of 19 December 2023.

The P35 facility – BNI 179

Following on from the delicensing process for the Pierrelatte DBNI by decision of the Prime Minister, BNI 179, known as "P35" was created. This facility comprises ten uranium storage buildings. ASN registered this facility in January 2018.

The FLEUR facility – BNI 180

Decree 2022-3091 of 18 March 2022 authorises the Orano Chimie-Enrichissement company to create a storage BNI called "Local Supply of Reprocessed Uranium Storage" (FLEUR acronym in French), intended for the storage of containers of depleted uranium mainly produced by reprocessing of spent fuels. It currently comprises two buildings and could eventually comprise up to four.

The IARU facility (formerly Socatri) – BNI 138

The facility primarily carries out repair, decontamination and dismantling of industrial or nuclear equipment, radioactive and industrial liquid effluent treatment and reprocessing and conditioning of radioactive waste.

1.2 Fuel fabrication

The fabrication of fuel for electricity generating reactors involves the transformation of UF₆ into uranium oxide powder. The pellets fabricated from this powder in the Framatome "FBFC" plant in Romans-sur-Isère are placed in zirconium metal cladding to constitute the fuel rods, which are then grouped together to form the fuel assemblies.

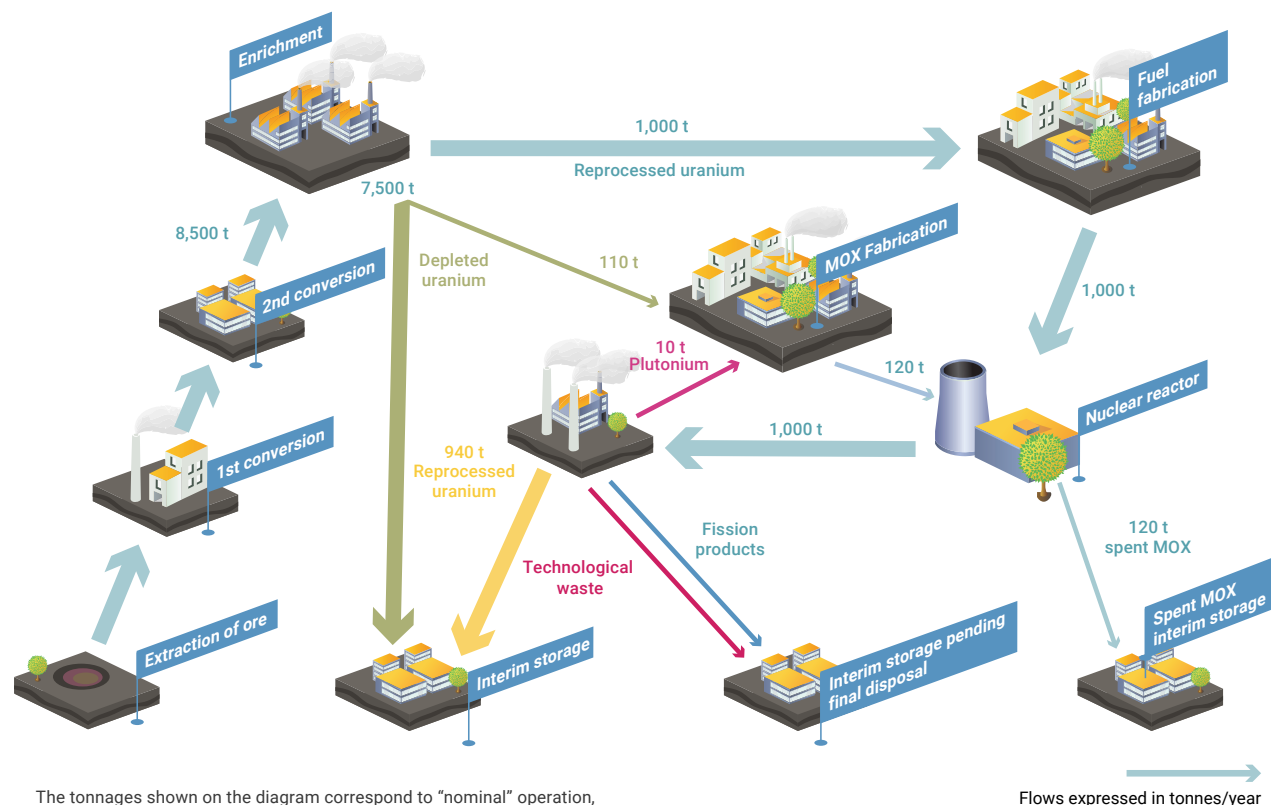
The fuels used in the experimental reactors are more varied and, for example, some of them use highly-enriched uranium in metal form. These fuels are fabricated in the Framatome plant at Romans-sur-Isère usually called "Cerca".

The FBFC and Cerca plants were combined in a single BNI (63-U), by a Decree of 23 December 2021.

TABLE 1 "Fuel cycle" industry movements in 2024

		Product processed		Product obtained		Product shipped	
Installation	Origin	Product processed	Tonnage	Product obtained	Tonnage	Destination	Tonnage
Orano Tricastin Conversion	Orano Malvési	UF ₄	13,155	UF ₆	15,722	Orano storage areas Tricastin	15,722
Orano Tricastin TU5 Unit	Orano La Hague	Uranyl nitrate	1,557	U ₃ O ₈	462	Orano storage areas Tricastin	444
Orano Tricastin W plant	Orano Tricastin GB II	UF ₆ depleted	8,829	U ₃ O ₈	7,023	Orano storage areas Tricastin	7,087
Orano Tricastin GB II	Orano Tricastin Conversion	UF ₆	11,632	UF ₆ depleted	9,948	Orano Tricastin Plant W	9,948
				UF ₆ enriched	1,483	Fuel fabrication plants	1,483
Framatome Romans	Orano Tricastin GB II	UF ₆ enriched	492	Fuel assemblies	642	EDF	579
	Urenco (Netherlands, Germany and United States)		74			Taishan (China)	53
	Tenex (Russia)		62			OL3 (Finland)	4
	ANF Lingen (Germany)	Gadolinium rods	10	UO ₂ and U ₃ O ₈ powder	4	Framatome Richland (United States)	8
						CEA	4
						Enusa (Spain)	3
Orano Melox Marcoule	WSE Vasteras (Sweden)	UO ₂ depleted	72	MOX fuel assemblies	63	EDF	70
	Orano La Hague	PuO ₂	7				
Orano La Hague	Fuels reprocessed in the La Hague plant						
	EDF and other licensees	UOX and MOX	871	Uranium in form of uranyl nitrate	882	Orano Tricastin	563
				PuO ₂	11	Melox Marcoule	8
	Fuels stored in the La Hague plant pools						
	EDF and other licensees	Irradiated fuel elements	10,156	–	–	–	–

"Fuel cycle" diagram



The MOX fuel is fabricated in BNI 151 Melox, operated by Orano and located on the Marcoule nuclear site, by mixing uranium oxide and plutonium oxide powder and sintering it into pellets, which are then placed in cladding and assemblies of the same geometry as those produced by FBFC.

1.3 The back-end fuel cycle – reprocessing

The Orano reprocessing plants in operation at La Hague

The La Hague plants, intended for reprocessing of spent fuel assemblies from nuclear reactors, are operated by Orano.

The various facilities of the plants reprocessing irradiated fuel elements from ordinary water nuclear reactors (UP3-A – BNI 116 and UP2-800 – BNI 117) and of the Effluent Treatment Station (STE3 – BNI 118) were commissioned from 1986 (reception and storage of spent fuel assemblies) to 2002 (R4 plutonium reprocessing facility), with most of the process facilities being commissioned in 1989-1990.

The Decrees of 10 January 2003 set the individual reprocessing capacity of each of the two plants at 1,000 tonnes per year (t/year), in terms of the quantities of uranium and plutonium contained in the fuel assemblies before burn-up (in the reactor), and limit the total capacity of the two plants to 1,700 t/year. The limits

and conditions for water discharges and intake defined in 2015, were updated by two ASN resolutions of 16 June 2022 (resolution 2022-DC-0724 and resolution 2022-DC-0725). The resolutions notably modify the maximum monthly value of the activity concentration of the noble gases, including krypton-85, and regulate the limits and procedures for the discharge at sea of eleven chemical substances, detected by the licensee in small quantities in the discharges during a regulatory conformity evaluation.

Operations carried out in the plants

The reprocessing plants comprise several industrial units, each of which performs a specific operation. Consequently, there are facilities for the reception and storage of spent fuel assemblies, for their shearing and dissolution, for the chemical separation of fission products, uranium and plutonium, for the purification of uranium and plutonium, for treating the effluents and for vitrification and conditioning the waste.

When the spent fuel assemblies arrive at the plants in their transport casks, they are unloaded either "under water" in the spent fuel pool, or dry in a leaktight shielded cell. The fuel assemblies are then stored in pools for several years, for cooling.

The fuel assemblies are then sheared and dissolved in nitric acid to separate the pieces of metal cladding from the spent nuclear fuel. The pieces of cladding,

the retaining grids and the fuel assembly end-pieces, which are insoluble in nitric acid, are transferred to a compacting and conditioning unit.

The nitric acid solution comprising the dissolved radioactive substances is then processed in order to extract the uranium and plutonium and leave the fission products and other transuranic elements.

After purification, the uranium is concentrated and stored in the form of a uranyl nitrate solution. It is intended for conversion in the TU5 facility on the Tricastin site into a solid compound (U_3O_8), called "reprocessed uranium".

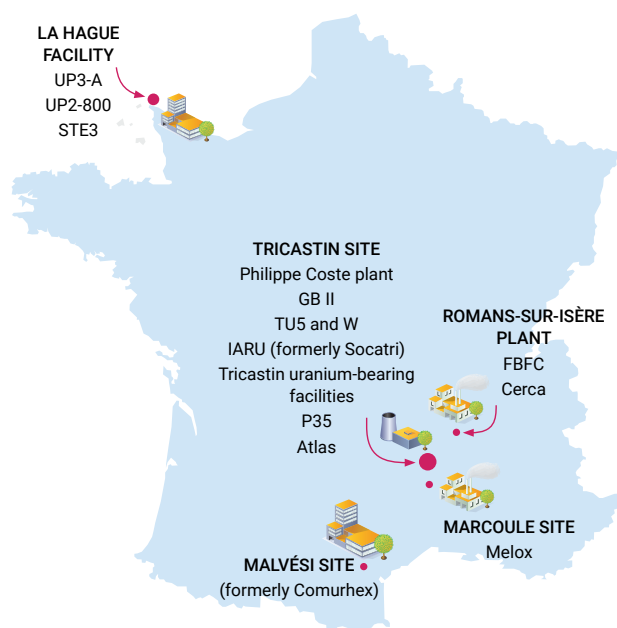
After purification and concentration, the plutonium is transformed back into plutonium oxide, packaged in sealed containers and stored. It is then intended for the fabrication of MOX fuels in the Orano plant in Marcoule (Melox).

The effluents and waste produced by the operation of the plants

The fission products and other transuranic elements resulting from reprocessing are concentrated, vitrified and packaged in standard vitrified waste packages (CSD-V). The pieces of metal cladding are compacted and packaged in standard compacted waste packages (CSD-C).

These reprocessing operations also use chemical and mechanical processes, the operation of which generates gaseous and liquid effluents as well as solid waste.

The “fuel cycle” facilities in service



The gaseous effluents are released mainly when the fuel assemblies are sheared and during the dissolution process. These gaseous effluents are treated by washing in a gas treatment unit. The residual radioactive gases, particularly krypton and tritium, are checked before being discharged into the atmosphere.

The liquid effluents are treated and usually recycled. After verification and in accordance with the discharge limits, certain radionuclides, such as iodine and tritium, are sent to the marine outfall. The other effluents are routed to on-site packaging units (solid glass or bitumen matrix).

The solid waste is conditioned on-site, either by compacting, or by encapsulation in cement, or by vitrification. The solid radioactive waste from the reprocessing of spent fuel assemblies from French reactors is, depending on its composition, either sent to the low-level and intermediate-level, short-lived waste (LLW/ILW-SL) repository at Soulaïnes (see chapter 15) or stored on the Orano site at La Hague, pending a final disposal solution; this is notably the case for the CSD-V and CSD-C, for which final disposal is envisaged in the planned *Cigéo* project (see chapter 15).

In accordance with Article L. 542-2 of the Environment Code, the radioactive waste from the reprocessing of spent fuel assemblies from abroad, is sent back to the producer country. It is however impossible to physically separate the waste according to the fuel from which it originates. In order to guarantee an equitable distribution of the waste resulting from the reprocessing of the fuels of its various customers, the licensee has proposed an accounting system that tracks the entries into and

exits from the La Hague plant. This system, called “Exper”, was approved by the 2 October 2008 Order from the Minister responsible for energy.

1.4 “Fuel cycle” consistency in terms of nuclear safety and radiation protection

The “nuclear fuel cycle” comprises the fabrication of the nuclear fuel used in the nuclear power plant reactors, its storage, its reprocessing after irradiation and management of the resulting waste. Several licensees are involved in the cycle: Orano, Framatome, EDF and the French National Radioactive Waste Management Agency (Andra).

ASN monitors the overall consistency of the industrial choices made with regard to fuel management and which could have consequences for safety. Over and above the safety issues specific to each facility, there are systemic safety issues affecting the “fuel cycle”, notably from the viewpoint of balancing the operation of the various facilities and managing the inventories of radioactive substances and the corresponding storage needs.

On 18 October 2018, ASN issued its opinion 2018-AV-0316 on the “Impact Cycle 2016” dossier, jointly drafted with the industrial stakeholders in the “cycle”. This dossier presents the consequences for each step in the “fuel cycle” of the strategy implemented by EDF for use of different types of fuels in its reactors, different energy mix scenarios envisaged by the Multi-Year Energy Programme (PPE), or the operating contingencies of the plants involved in the “fuel cycle”.

It underlines the need to anticipate any strategic change in the functioning of the “fuel cycle” by at least ten years so that it can be designed and carried out under controlled conditions of safety and radiation protection. It is a question for example – given the incompressible development times for industrial projects – of ensuring that the needs for the creation of new spent fuel storage facilities or for new transport packaging designs are addressed sufficiently early.

In collaboration with Framatome, Orano and Andra, EDF annually updates its “fuel cycle” management outlook according to energy mix scenarios consistent with the guidelines of France’s energy policy. Forward-looking simulation work is regularly presented to ASN by the licensees concerned, notably during joint hearings of Orano and EDF by the ASN Commission. In the light of the new nuclear policy guidelines, and notably the hypothesis of continued operation of EDF’s 900 MWe reactors beyond 50 years, the licensees given a hearing presented ASN in 2024 with the projected spent fuel volumes to be stored according to the various production scenarios from the La Hague and Melox plants.

In this new context, ASN duly noted that saturation of the spent fuel storage capacity, envisaged to occur before 2030 on the basis of the PPE published in April 2020, would now not take place before 2040.

However, ASN finds that even if the spent fuel inventories to be stored would thus appear to be stabilised for about an additional ten years, the available margins in the pools on the La Hague site remain limited over the long-term and are based on ambitious hypotheses for both production and the absence of contingencies blocking the La Hague and Melox plants. ASN therefore urges the licensees to exercise great prudence and underlines the need for the “cycle” facilities and associated storage capacities to have significant margins with respect to the various energy scenarios envisaged and with regard to the contingencies liable to affect the operations.

In the light of the challenges relating to the risk of saturation of spent fuel storage capacity, ASN underlines the fact that the new long-term spent fuel storage capacities planned by Orano at La Hague will have to be commissioned within the scheduled time-frame and with high-level safety objectives. In the meantime, countermeasures to restore margins before saturation is reached, and which could be used in the event of contingencies, should be considered a priority.

ASN considers that the overall working of the "fuel cycle" is stabilised, but nonetheless remains vigilant. This is because:

- The action plan implemented by Orano since 2019 to overcome the production difficulties at Melox is still in progress. The use of a "wet process" depleted uranium powder, qualified in September 2022, is ongoing. Production by the Melox plant in 2024 was slightly higher than in 2023. The production of radioactive materials containing plutonium and not suitable for use as fuel in reactors, referred to as "MOX scrap", was also stabilised at a low level. The use of this "wet process" powder thus helps improve the situation, pending the use of a comparable uranium powder from a new unit called "New Wet Process" (NVH) which Orano aims to qualify in its Malvési plant in 2025, before undertaking a qualification phase at Melox.
- The problems with Melox production led to faster than anticipated saturation of the storage capacity for plutonium-bearing materials, requiring the creation of new storage areas for these materials at La Hague. An initial extension was authorised by ASN in April 2022, a second in April 2023 and a third is currently being examined by the Authority for Nuclear Safety and Radiation Protection (ASNR), with a view to commissioning in 2025.
- Replacement of the Fission Products Evaporator-Concentrators ("NCPF" project) in the UP3-A plant was completed in 2023, while that of the UP2-800 plant was completed in 2024. Commissioning took place satisfactorily.
- Densification of the La Hague pools was authorised by ASN in December 2024, with a view to deployment as of June 2025. This project, which consisted in replacing the baskets currently used in the pools by more compact versions, in compliance with the limits set by the Creation Authorisation Decrees (DACs) of BNIs 116 and 117, constitutes one of the countermeasures identified to deal with the postponed commissioning of new spent fuel storage capacities. At this stage, this project does not entail any modification of the limits regarding the mass of fuel stored, the thermal power and the water temperature in the pools. Commissioning of these baskets will restore storage margins, which could be used as a last resort to counter any saturation, but not as part of routine operations. This last resort would then require specific authorisation by ASNR.

1.5 Outlook: planned facilities

Construction of new storage capacity for waste packages on the La Hague site

To anticipate the saturation of storage capacity for CSD-V (units R7, T7 and E/EV/SE), construction work on new storage facilities, known as the "glass storage extension on the La Hague site" (E/EV/LH) began in 2007. These facilities are being built module by module, with the construction of identical units called "pits". On 8 September 2022, ASN authorised the introduction of radioactive waste packages into pit 50 in the E/EV/LH2 unit. Pit 60 is under construction in order to boost storage capacity.

In addition, an extension of CSD-C storage, authorised by the Decree of 27 November 2020, is currently under construction; radioactive substances should be introduced into this extension for the first time in 2025, after authorisation by ASNR.

In 2023, Orano submitted an application for a substantial modification to the DAC of BNI 116 (UP3-A) to increase the storage capacity for CSD-C waste packages and CSD-V waste packages. This application will be the subject of a public inquiry.

Extension project for the North unit of the George Besse II plant on the Tricastin site

In July 2022, Orano sent ASN a Safety Options Dossier (DOS) concerning a project to extend the North unit of the GB II plant, in order to increase the plant's production capacity by about 30%. ASN issued a position statement on the file on 7 February 2023. A prior consultation was organised on this project by Orano, under the aegis of the National Commission for Public Debate (CNDP) from 1 February to 9 March 2023. The guarantors designated by the CNDP submitted the results of the consultation on 9 May 2023, to which Orano responded on 13 June 2023, indicating that it intended to continue with the project.

On 19 June 2023, Orano submitted an application for modification of the DAC in order to increase the production capacity of the GB II plant by about 30%. The application was the subject of a public inquiry in 2024 and ASNR is currently examining it.

EDF centralised storage pool project at La Hague

During the public debate held in 2019, prior to the 5th edition of the National Radioactive Materials and Waste Management Plan (PNGMDR), EDF reaffirmed that its strategy to increase spent fuel storage capacity is based on the construction of a new centralised storage pool. This new facility should allow storage of spent fuels for which reprocessing or disposal can only be envisaged in the long-term future. The envisaged operating life for this storage facility was therefore about a century.

On 15 October 2024, during the plenary meeting of the High Committee for Transparency and Information on Nuclear Safety (HCTISN), EDF and Orano announced that they were abandoning the spent fuel centralised storage pool project supported by EDF, in favour of another project, still at La Hague, but with Orano as owner. This new spent fuel storage capacity should be commissioned in 2040. ASN recalls the importance of obtaining new spent fuel storage capacities meeting the most recent safety standards, in order to provide a lasting solution to the risk of saturation of the existing capacity.

Project for dry storage of spent fuels on the La Hague site

In November 2021, Orano submitted the first version of a DOS to ASN, which considers it to be insufficient at this stage to enable it to issue a ruling. The updated DOS transmitted by Orano in 2023 is currently being examined by ASNR and a position statement will be issued in 2025.

2 — ASN actions in the field of "fuel cycle" facilities: a graded approach

2.1 The graded approach according to the risks of the facilities

At each step in the "fuel cycle", the potential risks in the facilities are different:

- The conversion and enrichment facilities mainly entail toxic risks (owing to the chemical form of the radioactive substances they use), criticality risks (when they use enriched materials) and the risk of dissemination of radioactive substances (in powder, liquid or crystallised form).
- The fuel fabrication facilities mainly entail toxic risks (when they have conversion units), criticality, fire or explosion risks (processes using heating methods), as well as the risk of dissemination of radioactive substances (in powder form) and of exposure to ionising radiation (when they use reprocessed substances).
- The spent fuel reprocessing facilities mainly entail risks of dissemination of radioactive substances (the substances used are mainly liquids and powders), of criticality (the fissile substances employed change geometrical shape) and exposure to ionising radiation (the fuels contain highly irradiating substances).

Their common point is that they never seek to create chain reactions (prevention of the criticality risk) and that they use substances that are dangerous, owing to their radiological or chemical properties, in industrial quantities. Conventional industrial risks are often preponderant; certain plants, such as Orano at Tricastin and La Hague or Framatome at Romans-sur-Isère, are in this respect subject to the Seveso Directive.

ASN devotes efforts to applying oversight that is proportionate to the potential risks of each facility. These are thus classified by ASN in one of the three categories defined according to the scale of the risks and their impacts on safety, health and the environment. This BNI classification enables the oversight and monitoring of the facilities to be adapted, reinforcing the inspections and the scope of the reviews carried out by ASN for the higher risk facilities.

When the installations are substantially modified or when they are finally shut down, ASN is in charge of examining these modifications, which are the subject of an amending decree from the Government, after prior consultation of ASN. ASN also establishes binding requirements for these main steps. Finally, ASN also reviews the safety files justifying the operation of each BNI.

For each facility, ASN monitors the organisation and means chosen by the licensee to enable it to assume its responsibilities in terms of nuclear safety, radiation protection, emergency management in the event of an accident and protection of the environment and public health and safety. ASN monitors the working of the organisations put into place by the licensees mainly through inspections, more specifically those devoted to safety management.

2.2 Periodic safety reviews of "fuel cycle" facilities

Since the publication of the Decree of 2 November 2007, all the BNI licensees must carry out periodic safety reviews of their facilities at least every ten years. These exercises were carried out gradually on the "fuel cycle" facilities. Defining the review procedures may be somewhat complex, because unlike nuclear power reactors, most of these facilities are in fact unique. There are thus few baseline requirements or other facilities with which a comparison can be easily made.

Examination of these periodic safety reviews confirmed the pertinence of an upstream definition, in the "guidance" phase, of the priority subjects for examination by the licensee during the periodic safety review, along with the associated methodologies, such as the probabilistic analyses which could enhance the safety cases. The periodic safety review of plant UP2-800 (BNI 117) ended with ASN issuing technical requirements for the continued operation of this BNI. For plant UP3-A (BNI 116), Orano transmitted its review concluding report at the

end of 2020, and it will be examined by the Advisory Committee of Experts for Laboratories and Plants (GPU) during the course of several meetings scheduled between 2023 and 2026. In November 2022, following examination of the review concluding report for STE3 (BNI 118) and considering that the provisions put into place or planned by the licensee on this point are appropriate, ASN validated continued operation of this facility. With regard to the fresh fuel fabrication plants, the licensee of the Melox plant submitted its review concluding report in September 2021. This report was reviewed by the GPU in June 2024. The report for the periodic safety review of the FBFC and Cerca plants, combined in a single BNI (63-U) by the Decree of 23 December 2021, submitted by Framatome in June 2023, will have to be significantly added to in 2025 before it is examined.

With regard to the "fuel cycle" back-end facilities, the periodic safety review of the uranium-bearing materials storage facilities at Tricastin (BNI 178, 179 and 180) was completed in 2023, with ASN issuing technical requirements for the continued operation of these BNIs. The periodic safety reviews of the GB II plant (BNI 168) and of the IARU facility (BNI 138) are currently being examined by ASN. The report on the periodic safety review of the TU5 facilities (BNI 155) was submitted by Orano in November 2024 and will be examined by ASNR.

The periodic safety reviews show the importance of an *in situ* verification of the conformity of the Protection-Important Elements (EIPs) that is as exhaustive as possible, or as representative as possible of the EIP that are not accessible. They also illustrate the need for a robust approach to the control of the ageing of fuel cycle facilities. This is notably the case for the facilities in the back-end of the "cycle", for which the control of ageing is a priority issue. This is the subject of dedicated inspections and increased vigilance when examining the ongoing periodic safety reviews.

13

**Nuclear research
and miscellaneous
industrial facilities**



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 - 1.2.1 Laboratories
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- 1.3 **Materials storage facilities**

2 **ASN actions in the field of research facilities: a graded approach** p. 348

- 2.1 **The graded approach according to the risks of the facilities**
- 2.2 **The periodic safety reviews**



Nuclear research or industrial facilities differ from the Basic Nuclear Installations (BNIs) involved directly in the generation of electricity (nuclear power reactors and “fuel cycle” facilities) or waste management. Traditionally, most of these BNIs are operated by the Alternative Energies and Atomic Energy Commission (CEA), but also by other research organisations (for example the Laue-Langevin Institute (ILL), the ITER international organisation and the National Large Heavy Ion Accelerator – Ganil) or by industrial firms (for instance CIS bio international, Steris and Ionisos, which operate facilities producing radiopharmaceuticals, or industrial irradiators).

1 — Research facilities, laboratories and other facilities in France

1.1 Research reactors

The purpose of research reactors is to contribute to scientific and technological research and to improve the operation of the Nuclear Power Plants (NPPs). Some of these facilities also produce radionuclides⁽¹⁾ for medical uses. They are facilities in which a chain reaction is created and sustained, to produce a neutron flux of varying density, used primarily for scientific experimentation purposes. Unlike in NPPs, the energy produced by research reactors is not used but simply removed by cooling. The quantities of radioactive substances used are smaller than in nuclear power reactors.

An overview of the various types of research reactors present in France and the main corresponding risks is presented below.

In their design, these reactors take account of reference accidents, both core melt “under water” (failure of the cooling system) and core melt “in air” (after uncovering of the core or during handling). They also take account of accidents specific to the particular design of certain research reactors.

Neutron flux reactors

Neutron flux reactors are pool-type reactors. They are mainly designed for fundamental research (solid physics, molecular physico-chemistry, biochemistry, etc.), using the neutron diffraction method to study matter. The neutrons are produced in the reactor, at different energy levels and are captured by channels in the reactor before being routed to experimentation areas.

In France, there is now only one neutron beam reactor in service: the High-Flux Reactor (RHF – BNI 67) operated by the

ILL in Grenoble (rated power limited to 58 Megawatts thermal (MWth). The RHF operates in cycles of about 50 to 100 days. The main safety issues are reactivity control, cooling and containment.

In 2024, ASN authorised works to improve the safety of the facility which were defined during the last periodic safety review, in particular the renovation of the polar crane in the reactor building, reinforcement of fire protection and removal of the residual tritium from the facility. The ILL started these works following the long outage of the facility which began in July 2024.

The Orphée reactor (BNI 101), operated by CEA in Saclay (rated power limited to 14 MWth), was finally shut down at the end of 2019.

“Test” reactors

The “test” reactors are pool-type reactors. They are designed to study accident situations. They are able to reproduce certain accidents postulated in the safety case of nuclear power reactors in a controlled manner and on a small scale and gain a clearer understanding of the evolution of physical parameters during accidents.

In France there is one “test” reactor in service subject to the oversight of the French Nuclear Safety Authority (ASN): the Cabri reactor (BNI 24) operated by CEA in Cadarache. The reactor, whose power is limited to 25 MWth, can produce the neutron flux needed for the experiments. The safety issues are similar to those of the other reactors: controlling the reactivity of the driver core, cooling to remove heat and containment of the radioactive substances in the fuel rods making up the core.

Modifications were made to the facility so that it could run new research programmes to study the behaviour of high burn-up

fraction fuel during reactivity insertion accident situations. Reactor divergence in its new configuration was authorised in 2015. On 30 January 2018, ASN authorised the first active experimental test of the facility’s pressurised water loop after major renovation work.

The Cabri “test” reactor, the design of which was modified so that it could also carry out object irradiation experimental programmes, was licensed for this type of use by a Decree of 2 August 2022.

The test programmes (Cabri International Programmes – CIP) and electronic component irradiation tests continued in 2024. Alongside these tests in 2024, ASN authorised the underwater repair of the hodoscope, which should be carried out at the end of the ongoing programme of tests, by the end of 2025. ASN checks the implementation of the actions undertaken further to the conclusions of the last periodic safety review of the facility, particularly regarding the improvement of the measures to prevent fire risks and risks associated with handling operations.

Irradiation reactors

The irradiation reactors are pool-type reactors. They are used to study the physical phenomena linked to the irradiation of materials and fuels, as well as their behaviour. As the neutron fluxes obtained by these facilities are more powerful than those in a Pressurised Water Reactor (PWR) type nuclear power reactor, the experiments enable ageing studies to be performed on the materials and components subjected to a high neutron flux. After irradiation, the samples undergo destructive examination, notably in the research laboratories, in order to fully characterise the effects of irradiation. They are thus an important tool for the qualification of materials subjected to a neutron flux.

1. The use of radionuclides offers medical analysis and treatment possibilities: for diagnosing cancers using scintigraphy and tomography, allowing advanced examinations of functioning organs, or for treating tumours by radiotherapy, which uses the radiation from radionuclides to destroy the cancerous cells (see chapter 7).

Nuclear research and miscellaneous industrial facilities



These research reactors are also significant sources for the production of certain radionuclides for medical uses.

The power of these reactors varies from a few tens to a hundred MWth. These reactors operate in cycles of about 20 to 30 days.

In France, since the final shutdown of the Osiris reactor (BNI 40) on CEA's Saclay site in 2015, there have been no technological irradiation reactors in operation.

The Jules Horowitz reactor (JHR – BNI 172), which is intended to replace Osiris, is under construction in Cadarache. Commissioning of the facility, which comprises a number of milestones, is currently being examined by ASN. On 19 July 2023, the Nuclear Policy Council also ratified the continued investment by the State and the sector to finalise the construction of the JHR, so that France would have this new operational facility by 2032-2034. This reactor will be able to support research on extending the lifetime of the existing NPP fleet, on the EPR 2, but also on Small Modular Reactors (SMRs – see chapter 11). It is also intended to provide a significant capacity for producing radionuclides for medical purposes.

Fusion reactors

Unlike the research reactors previously described and which use nuclear fission reactions, some research facilities aim to produce nuclear fusion reactions.

In France, the International Thermonuclear Experimental Reactor (ITER facility – BNI 174) is an international fusion reactor project currently under construction in Cadarache. The purpose of ITER is to scientifically and technically demonstrate control of nuclear fusion by magnetic confinement of a deuterium-tritium plasma, during long-duration experiments with significant power (500 Megawatts - MW - for 400 seconds).

The main risk control challenges and detrimental effects of this type of installation include controlling the containment of radioactive materials (tritium in particular) and the risks of exposure to ionising radiation owing to significant activation of materials under an intense neutron flux. The management of tritiated or activated wastes is also a major issue for these facilities, even though their radiotoxicity and half-lives are in principle very much lower than those of the operational wastes from fission reactors.

In 2024, Iter Organization (IO) continued the validation of the facility's experimentation programme of the “new reference scenario”. IO has moreover started the repairs of the defective welds found on the first sectors of the tokamak⁽²⁾ vacuum chamber, and the repairs of the thermal shield cooling systems which have been subject to stress-corrosion cracking. ASN underlines an improvement in the transparency of the interactions on the associated safety risks. The hold points associated with the project, notably the one relating to assembly of the tokamak, will be redefined within the context of the review associated with this new experimentation programme.

1.2 Laboratories and miscellaneous industrial facilities

1.2.1 Laboratories

The laboratories carrying out research and development work for the nuclear sector contribute to enhancing knowledge for nuclear power production, fuel fabrication and reprocessing, and waste management. They can also produce radionuclides for medical uses.

Principles and safety issues

The main challenges inherent in these facilities are protecting persons against ionising radiation, preventing the dispersal of radioactive substances, controlling fire risks and controlling the chain reaction (criticality).

The design principles for these laboratories are similar. Special areas, called “shielded cells” allow handling of and experimentation with radioactive substances, using appropriate handling systems. These shielded cells are designed with particularly thick walls and windows, to protect the operators against the ionising radiation. They also allow the containment of radioactive materials by means of a specific ventilation and filters system. The criticality risk is controlled through strict instructions regarding the handling, storage and monitoring of the materials being studied, and the use of specially designed equipment. Finally, the fire risk is managed using technical systems (fire doors, dampers, detectors, fire-fighting equipment, etc.) and an organisation limiting the fire loading. Personnel training and rigorous organisation are essential factors in guaranteeing the control of these main risks.

2. Tokamak, a Russian acronym meaning “toroidal chamber with magnetic coils”, is a machine that uses magnetic fields to create, confine and control a hot plasma of hydrogen isotopes in which the fusion reaction can occur.

Fuels and materials test laboratories

Some of these laboratories, operated by CEA, are used to carry out a variety of experiments on irradiated materials or fuels. The purpose of some research programmes for example is to allow higher burn-up of fuels or improve their safety. Some of these facilities are also operated for fuel preparation and repackaging.

The following fall within this category of laboratories:

- the Active Fuel Examination Laboratory (LECA), in Cadarache and its extension, the Treatment, Clean-Out and Reconditioning Station (STAR), which make up BNI 55;
- the Laboratory for Research and Fabrication of Advanced Nuclear Fuels (Lefca – BNI 123), located in Cadarache;
- the Spent Fuel Testing Laboratory (LECI – BNI 50), located in Saclay.

Research and development (R&D) laboratories

R&D on new technologies is also carried out for the nuclear industry in laboratories, more particularly with regard to the development of new fuels, their recycling, or the management of ultimate waste.

The Alpha facility and laboratory for transuranium elements analysis and reprocessing studies (Atalante – BNI 148), situated in Marcoule and operated by CEA, provides Orano Cycle with technical support for optimising the processes implemented in the La Hague plants. It carries out experimental work to qualify the behaviour of nuclear glass matrices in order to guarantee the long-term confinement properties of high-level waste packages.

ASN checks the implementation of the measures taken further to the last periodic safety review.

In 2024, CEA submitted the Guidance File (DOR) for the new periodic safety review of the facility, which is currently being examined by the French Authority for Nuclear Safety and Radiation Protection (ASNR).

This step before the licensee sends the periodic safety review concluding report serves to determine the methodology, the scope and the methods of the studies conducted as part of the forthcoming safety review.

Artificial Radionuclides Production Facility

The Artificial Radionuclides Production Facility (UPRA), situated in Saclay and operated by CIS bio international, is a nuclear facility designed according to the same principles as a laboratory (special areas for handling and experimenting with radioactive substances, using

appropriate means), for the purposes of research and to develop radionuclides for medical uses. CIS bio international is a subsidiary of the Curium group, a manufacturer of radiopharmaceuticals.

ASN is currently examining the facility's periodic safety review and it was also the subject of an opinion from the Advisory Committee of Experts for Laboratories and Plants (GPU) dated 16 March 2023. The reduction of the inventories of radioactive substances in the facility initiated by the licensee contributes significantly to reducing the risks inherent to the facility.

1.2.2 Particle accelerators

Some particle accelerators are BNIs. These installations use electrical or magnetic fields to accelerate charged particles. The accelerated particle beams produce strong fields of ionising radiation, activating the materials in contact, which then emit ionising radiation even after the beams have stopped. Exposure of the population, the personnel and the environment to ionising radiation is thus the primary risk in this type of facility.

The Ganil

The Large National Heavy Ion Accelerator (Ganil – BNI 113), located in Caen, carries out fundamental and applied research work, more particularly in atomic physics and nuclear physics. This research facility produces, accelerates and distributes ion beams with various energy levels to study the structure of the atom. An examination is currently under way on the construction of a new building to receive bundles, called “Désir”, so that new experimental research programmes can be carried out.

ASN gave a favourable opinion in December 2024 on the Decree modifying the facility's Creation Authorisation Decree in order to integrate the “Désir” building. This Decree will be published in 2025.

CERN

The European Organisation for Nuclear Research (CERN) is an international organisation whose role is to carry out purely scientific and fundamental research programmes concerning high-energy particles. On several interconnected sites, the CERN operates a whole chain of research devices looking at the structure of matter, which currently includes several linear and circular accelerators, along with several detectors and acquisition systems. Owing to its cross-border location, CERN is subject to particular verifications by the French and Swiss Authorities.

1.2.3 Industrial ionisation installations

Industrial ionisation facilities, called “irradiators”, use the gamma rays emitted by sealed sources of cobalt-60 to irradiate targets in the irradiation cells. These irradiation cells are designed with particularly thick walls and windows, to protect the operators against the ionising radiation. The sealed sources are either stored in a pool under a layer of water which protects the workers, or are taken out of the storage pool to irradiate the target item. Personnel exposure to ionising radiation is thus the primary risk in these facilities.

The main applications of irradiators are to sterilise medical equipment, agri-food products and pharmaceutical raw materials. Irradiators can also be used to study the behaviour of materials under ionising radiation, notably to qualify materials for the nuclear industry.

These irradiators are used by:

- the Ionisos Group, which operates three facilities located in Dagneux (BNI 68), Pouzauges (BNI 146) and Sablé-sur-Sarthe (BNI 154);
- a new irradiator project (D7) is currently being examined for the Dagneux site;
- further to an analysis of the implications of the facility and inspections on the topic of the facility's periodic safety review, ASN made no objection to the continued operation of BNI 154 for the next few years;
- the Steris group, which operates the Gammaster (BNI 147) and Gammatec (BNI 170) facilities in Marseille and Marcoule;
- CEA, which operates the Poséidon irradiator (BNI 77) on the Saclay site. In 2024, ASN completed the examination of the facility's periodic safety review and made no objection to its continued operation

1.3 Materials storage facilities

The materials storage facilities operated by CEA are primarily devoted to the conservation of non-irradiated (or slightly irradiated) uranium and plutonium-bearing fissile materials from other CEA facilities. This enables the laboratories (Atalante, Lefca, etc.) to be supplied according to the needs of their experiments. More recently, they have become a temporary storage solution for the fissile materials which were present in facilities that are now shutdown, such as the research reactors (Éole, Minerve, Osiris, Masurca in particular).

Principles and safety issues

The main challenges inherent in these facilities are to prevent the dispersal of radioactive substances and to control the chain reaction (criticality).

The safety of these facilities is based on a series of static physical barriers (walls and doors of rooms and buildings) to prevent the dispersal of radioactive substances. When operations are carried out on these substances, static confinement is also provided by the equipment (gloveboxes, shielded cells) in which these operations

are performed. This static confinement is supplemented by dynamic confinement consisting on the one hand of a cascade of negative pressure environments between the rooms where there is a risk of radioactive substance dissemination and, on the other, filtration of the gaseous releases into the environment. The chain reaction is controlled by strict instructions regarding the handling, storage and monitoring of the materials being stored and the use of specially designed equipment.

Dedicated storage facilities

The Magenta facility (BNI 169), commissioned in 2011 and operated by CEA on its Cadarache site, is dedicated to the storage of non-irradiated fissile material and the non-destructive characterisation of the nuclear materials received. It is more particularly replacing the Central Fissile Material Warehouse (MCMF, BNI 53), which was finally shut down at the end of 2017. The examination of the facility's first periodic safety review continued in 2024.

2 — ASN actions in the field of research facilities: a graded approach

2.1 The graded approach according to the risks of the facilities

The BNI System applies to more than about a hundred facilities in France. This system concerns various facilities with widely differing nuclear safety, radiation protection and environmental protection challenges: nuclear research or power reactors, radioactive waste storage or disposal facilities, fuel fabrication or reprocessing plants, laboratories, industrial ionisation facilities and so on.

The safety principles applied to nuclear research or industrial facilities are similar to those adopted for nuclear power reactors and nuclear “fuel cycle” facilities, while taking account of their specificities with regard to risks and detrimental effects. ASN has implemented an approach that is proportional to the extent of the risks or drawbacks inherent in the facility. In this respect, ASN has divided the facilities under its oversight into three categories from 1 to 3 in descending order of the severity of the risks and drawbacks they present for the interests mentioned in Article L. 593-1 of the Environment Code (ASN resolution 2015-DC-0523 of

29 September 2015). This BNI classification enables the oversight of the facilities to be adapted, thus reinforcing oversight of the facilities with major implications in terms of inspections and the examinations conducted by ASN. For example, the RHF and Cabri research reactors are placed in categories 1 and 2 respectively, while the Ganil particle accelerator is placed in category 3.

2.2 The periodic safety reviews

The Environment Code requires that the licensees carry out a periodic safety review of their facilities every ten years. This periodic safety review is designed to assess the status of the facility with respect to the applicable regulations and to update the assessment of the risks or detrimental effects inherent in the facility, notably taking into account the condition of the facility, acquired operating experience, changes in knowledge and the rules applicable to similar facilities. They are thus an opportunity for upgrades or improvements in fields in which the safety requirements have changed, in particular seismic resistance, protection against fire and confinement.

To date, all the nuclear research and miscellaneous facilities have undergone a periodic safety review. ASN implemented an examination method commensurate with the issues in the facilities: some of them require particular attention due to the risks they present, while for others – with a lower level of risk – the extent of the inspections and examinations is adapted accordingly.

In 2024, ASN completed the examination of the periodic safety reviews of the Poséidon irradiator (BNI 77) operated by CEA and of the irradiator situated in Dagneux (BNI 68) operated by Ionisos.

In 2024, ASN continued examining the periodic safety reviews of the Cabri (BNI 24) and Magenta (BNI 169) facilities operated by CEA, and the irradiator situated in Pouzauges (BNI 146) operated by Ionisos, the heavy ion accelerator (BNI 113) operated by the Ganil GIE and UPRA (BNI 29) operated by CIS bio international.

In 2024, ASN started its examination of the new periodic safety reviews of three CEA facilities: LECI (BNI 50), LECA (BNI 55) and Lefca (BNI 123).

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Decommissioning of Basic Nuclear Installations



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In 2024, 36 nuclear installations of all types (power and research reactors, laboratories, fuel reprocessing plants, waste treatment facilities, etc.) were shut down or are undergoing decommissioning in France, representing more than one quarter of the Basic Nuclear Installations (BNIs) in operation.

With the exception of the Pressurised Water Reactors (PWRs) in the Nuclear Power Plants (NPPs), whose design follows a generic model, the majority of the BNIs being decommissioned present varied technologies, uses and operating histories, rendering complex the decommissioning operations. The duration of BNI decommissioning operations can thus vary significantly from one facility to another. The French Nuclear Safety Authority (ASN) notes that if it takes about twenty years to decommission the PWRs, decommissioning may extend well beyond 2050 for some of the “fuel cycle” facilities or old waste storage facilities, as several of them still contain large quantities of waste to be retrieved and conditioned. For these facilities, new equipment and processes have to be developed and built, leading to long and complex decommissioning operations.

ASN thus notes that the schedules established by the licensees in the years 2000 with a view to issuing the first decommissioning decrees are having to be updated to integrate the lessons learned from the first operations and to introduce more realistic operational margins, thereby pushing back the end-of-decommissioning dates much further. ASN is vigilant regarding the safety risks linked to significant extensions of decommissioning times.

1 — Technical and legal framework for decommissioning

The term decommissioning covers all the technical and administrative activities carried out after the final shutdown of a nuclear installation, following which it can be delicensed, in other words removed from the list of BNIs. These activities comprise the removal of radioactive materials and waste still present in the facility and operations to dismantle the equipment and components used during operation, as well as clean-out of the premises and soils plus civil engineering structures demolition work as necessary.

The aim of the decommissioning and clean-out operations is to achieve a predetermined final state that allows prevention of the risks and impacts that the site may present for the environment and people, taking into account its possible future uses.

The decommissioning of a nuclear installation is prescribed by Decree issued after consulting ASN. This phase in the life cycle of the installations is characterised by a succession of operations which are sometimes highly complex, are lengthy, produce large amounts of waste, and are costly; optimum forward planning is essential – especially given that they must be carried out within the shortest time frame possible, as stipulated in the regulations. The continuous changes that installations undergo in the course of decommissioning alter the nature of the risks and represent challenges for the licensees in terms of project management.

1.1 Decommissioning challenges

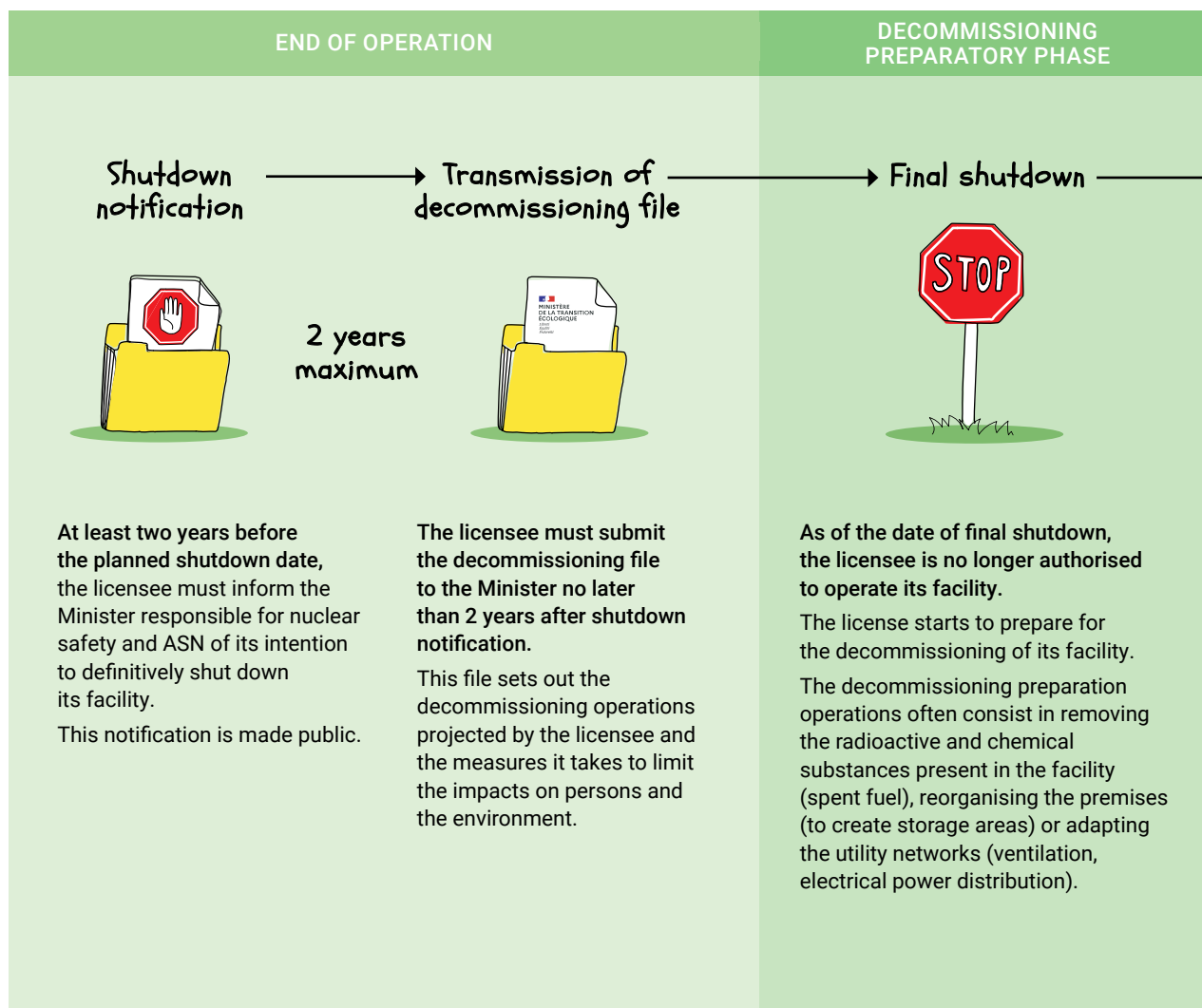
Accomplishing the decommissioning operations – which are often long and costly – within the set time frames is a challenge for the licensees in terms of project management, skills maintenance and coordination of the various operations which involve numerous specialist companies. Despite this, the principle of immediate dismantling in France obliges the licensees to carry out their decommissioning operations within the shortest time frame possible under economically acceptable conditions (see point 1.2).

Decommissioning comprises a series of operations which tend to gradually reduce the quantity of radioactive substances present in the facility, resulting in evolving risk levels. Although the reduction in the quantities of substances present in the facility tends to reduce the risks, the decommissioning work, which sometimes takes place very close to the radioactive substances, nevertheless presents significant radiation exposure risks for the workers. Other risks also increase as the work proceeds, such as the risk of dispersion of radioactive substances into the environment or certain conventional risks, such as risks of falling loads when handling large components, or of fires during hot work in the presence of combustible materials, instability of partially dismantled structures, or chemical risks during decontamination operations.

One of the major challenges in the decommissioning of an installation is linked to the large volumes of waste produced, which are usually very much greater than the volumes produced during its operation. The decommissioning of the former facilities of the Alternative Energies and Atomic Energy Agency (CEA) and Orano's first generation plants (in particular the plants which were involved in France's deterrence policy, such as the gaseous diffusion facilities of the Pierrelatte Defence Basic Nuclear Installation (DBNI – defence sector) in Tricastin, and the UP1 facility at the Marcoule DBNI, will thus lead to the production of a very large quantity of very low-level (VLL) waste). The scale and the difficulty of the work must be assessed as early as possible in the life of the installation, and as of the design stage for new facilities, in order to ensure that they can be decommissioned safely within as short a time frame as possible.

Furthermore, radioactive substances are still present in some old installations, sometimes in large quantities; these substances are not always readily accessible and some of them remain to be characterized. The conditions of retrieving and conditioning these substances in such cases constitute projects in their own right within the decommissioning projects. This is the case in particular with the former effluent treatment facilities of CEA and Orano (see chapter 15).

Phases in the life cycle of a Basic Nuclear Installation



Lastly, correct performance of the decommissioning operations is also dependent on the availability of the decommissioning support facilities (waste storage, processing and conditioning facilities, effluent treatment facilities) and of appropriate management routes for all the types of waste likely to be produced. When the final waste disposal outlets are likely not to be available at the time the decommissioning waste is produced, the licensees must prudently set up the facilities necessary for the safe interim storage of this waste pending opening of the corresponding disposal route. The adequacy of the available interim storage capacities for the waste resulting from BNI operation and decommissioning, and the progress of the studies concerning the various definitive radioactive waste management options, are regularly examined in this respect under the French National Radioactive Material and Waste Management Plan (PNGMDR – see chapter 15).

The question of management of the waste resulting from the decommissioning operations is addressed with particular attention

during the assessment of the decommissioning and waste management strategies established by the CEA, EDF and Orano (see point 4 and “Les cahiers de l’ASN” #04).

1.2 The ASN decommissioning doctrine

Many factors can influence the choice of one decommissioning strategy rather than another: national regulations, social and economic factors, financing of the operations, availability of waste disposal routes, decommissioning techniques and qualified personnel, knowledge of the operating history, exposure of the personnel and the public to ionising radiation resulting from the decommissioning operations, etc.

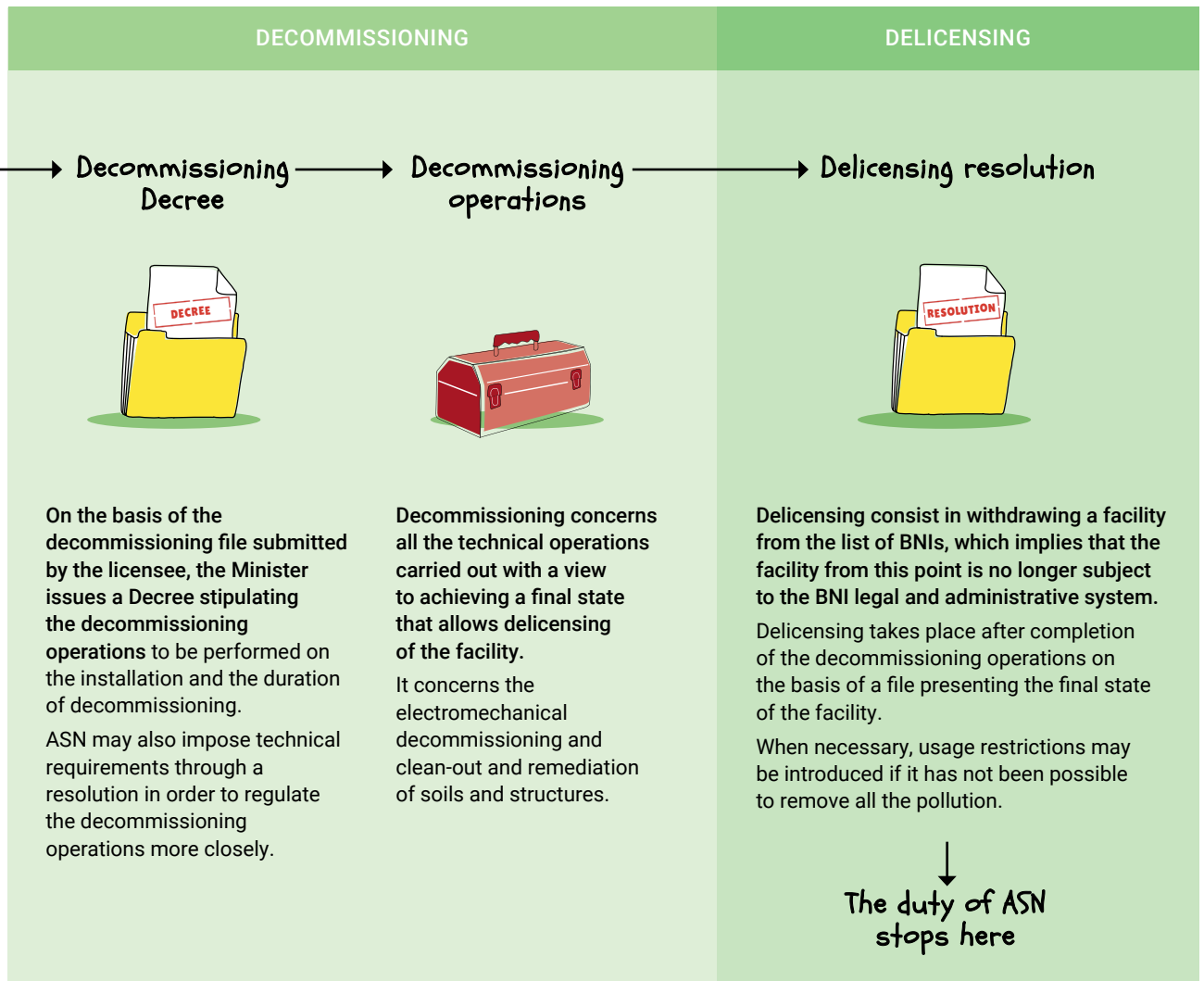
1.2.1 Immediate dismantling

The principle of decommissioning “in the shortest time frame possible under economically acceptable conditions” figures in the regulations applicable to BNIs (Order of 7 February 2012 setting the general rules relative to BNIs). This principle, which ASN has affirmed since 2009

as regards BNI decommissioning and delicensing, has been enshrined in legislation by Act 2015-992 of 17 August 2015 relative to Energy Transition for Green Growth. This approach aims to avoid placing the technical and financial burden of decommissioning on future generations. It also provides the benefit of retaining the knowledge and skills of the personnel present during operation of the installation, which are vital during the first decommissioning operations.

The regulatory framework in effect in France aims to ensure that:

- The licensee prepares the decommissioning of its installation as of the design stage and updates this preparation throughout the life of the installation.
- The licensee anticipates decommissioning and sends ASN the decommissioning application file before it stops operating the installation.
- The licensee has the financial resources to finance decommissioning, covering its anticipated expenses by dedicated assets.



• The decommissioning operations are carried out in as short a time frame as possible after shutting down the installation, a time frame which can nevertheless vary from a few years to a few decades, depending on the type of installation and the decommissioning complexity.

The decommissioning plan, which describes the operations the licensee intends implementing to decommission its facility, aims to ensure optimal preparation and forward planning for decommissioning. Since 2007, this document has been required as from commissioning of the facility, and is then updated regularly during its lifetime. It capitalises on Operating Experience Feedback (OEF) by identifying any impacts on the future decommissioning operations, and must enable the licensee to justify the chosen decommissioning strategy on the basis of technical and economic criteria.

1.2.2 Post-operational clean-out and achieving the final state

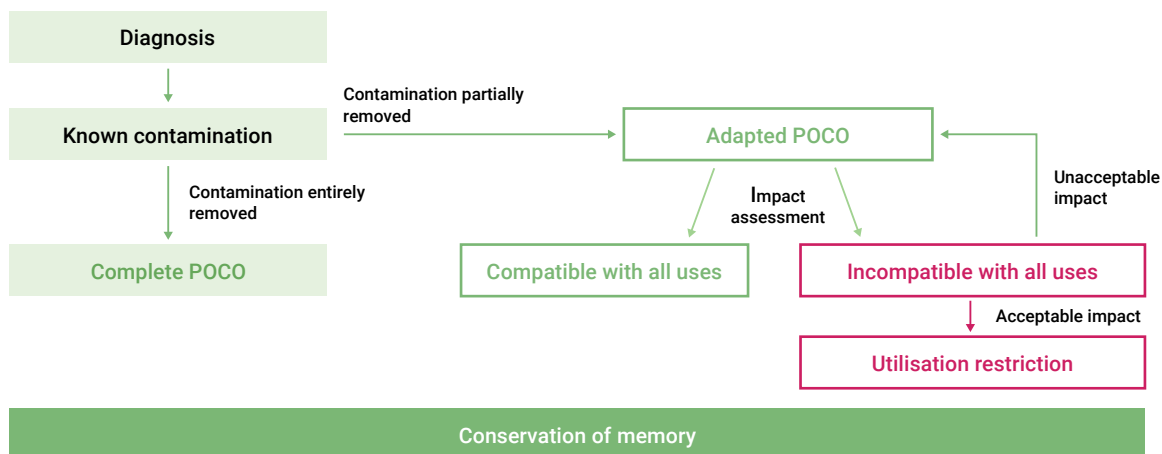
The decommissioning and Post-Operational Clean-Out (POCO) operations of a nuclear facility must lead to the gradual removal of the radioactive or hazardous substances from the structures and soils, with a view to delicensing the facility and its subsequent withdrawal from the list of BNIs. The radioactive substances can result from activation or deposition phenomena caused by the activities of the BNI or the incidents it has experienced. Hazardous chemical substances can also be present in the facility due to the use of certain processes or products (hydrocarbons, hydrofluoric acid, sodium, etc.).

In some cases, the radioactive or hazardous substances migrate into the structures of the BNI buildings, or even into the soils of the site and its surroundings, in which case they must be cleaned out. POCO corresponds to the operations to reduce or eliminate radioactivity or any other hazardous substances remaining in the structures or soils alike.

ASN asks the licensees of nuclear facilities to implement POCO practices that integrate the best available methods and techniques under economically acceptable conditions. The complete POCO scenario must always be envisaged as the reference scenario. This scenario, which leads to unconditional release of the buildings and sites, effectively enables the protection of people and the environment to be guaranteed over time with no reservations.

In the event of identified technical, economic or financial difficulties, the licensee can submit one or more appropriate POCO scenarios compatible with the site's futures usages (confirmed, planned and practicable) to ASN. Whatever the case, the licensee must provide elements proving that the reference scenario cannot be applied under acceptable technical and economic conditions and that the planned POCO operations constitute a technical and economic optimum. ASN then examines the scenarios proposed by the licensee and ensures that the POCO will be taken as far as reasonably possible in order to meet the objectives set

Simplified flowchart of ASN's "contaminated sites and soils" doctrine



out in the Decommissioning Decree. If the POCO carried out does not allow unconditional release of the site, ASN may make administrative delicensing of the facility conditional upon the implementation of active institutional controls, limiting the right of ownership and use of the soil, instituted by the public authority at the request of the licensee (*see flowchart above*).

Whatever the case, the regulations stipulate that the POCO strategy implemented by the licensee must lead to a final state of the BNI and its site that is compatible with administrative delicensing (*see point 1.3*).

In accordance with the general principles of radiation protection, the dosimetric impact of the site on the workers and public after delicensing must be as low as reasonably possible (ALARA principle¹). ASN is not in favour of introducing generalised thresholds and considers it preferable to adopt an optimisation approach, based on technical and economic criteria, according to the future usages of the site (confirmed, planned and practicable). Nevertheless, whatever the case, once the site has been delicensed, the induced radiological exposure must not exceed the statutory value prescribed in the Public Health Code of 1 millisievert (mSv) over one year for all the usage scenarios.

The doctrine implemented by ASN is specified in the guides relative to the structure clean-up operations (Guide No. 14, available at asn.fr), and the management of contaminated soils in nuclear installations (Guide No. 24, available at asn.fr). The provisions of these guides have already been implemented on numerous installations with varied characteristics, such as research reactors, laboratories, fuel manufacturing plants, etc.

1.3 Decommissioning regulatory framework

Once a BNI is definitively shut down, it must be decommissioned. Its purpose therefore has to change with respect to that for which its creation was authorised, as the Creation Authorisation Decree (DAC) specifies the operating conditions of the installation. Furthermore, the decommissioning operations imply a change in the risks presented by the installation. Consequently, these operations cannot be carried out within the framework set by the DAC. The decommissioning of a nuclear installation is prescribed by a new decree issued on the basis of an opinion from ASN. Among other things, this decree sets out the main decommissioning steps, the planned decommissioning end date and the final state to be achieved. As part of its oversight duties, ASN monitors the implementation of the decommissioning operations as directed by the Decommissioning Decree.

In order to avoid fragmentation of the decommissioning projects and to improve their overall consistency, the decommissioning file must explicitly describe all the planned operations, from final shutdown to attainment of the targeted final state and, for each step, describe the nature and scale of the risks presented by the facility as well as the means of managing them. The licensee must demonstrate in its decommissioning file that the decommissioning operations will be carried out in as short a time frame as possible. This file undergoes a public inquiry during which the local residents, local authorities and Local Information Committee (CLI) are called upon to respond. Furthermore, the decommissioning files representing the most significant risks are examined by the Advisory Committee for Decommissioning (GPDEM), set up in 2018.

The facility decommissioning operations are often very long and are not always known in detail when constituting the decommissioning file.

This is why the Decommissioning Decree may stipulate that some steps will, in due course, be subject to prior approval by ASN on the basis of specific safety analysis files drawn up as close as possible in time to the scheduled operations taking into account the best techniques available at the time and in compliance with the objectives set by the Decommissioning Decree (particular as regards the final status and the targeted POCO level).

The "Phases in the life of a BNI" Diagram (*see previous pages*) describes the corresponding regulatory procedure.

The decommissioning phase may be preceded by a preparatory stage, provided for in the initial operating licence. This preparatory phase permits for example the removal of a portion of the radioactive and chemical substances, notably the spent fuel in the case of a nuclear reactor, and preparation of the decommissioning operations (readying of premises, preparation of worksites, training of teams, etc.). It is also during this preparatory phase that the installation characterisation operations can be carried out (radiological mapping, analysis of the operating history), which are vital for establishing the targeted POCO scenarios.

The Environment Code requires that the safety of a facility undergoing decommissioning be reviewed periodically and at least every 10 years as is the case for all other BNIs. ASN's objective with these periodic safety reviews is to ascertain that the installation complies with the provisions of its Decommissioning Decree and the associated safety and radiation

1. ALARA: As Low As Reasonably Achievable.

protection requirements through to its delicensing by applying the principles of “Defence in Depth” specific to nuclear safety, with an approach that is proportionate to the risks.

This is because, if the decommissioning operations result in a weakening, or even the disappearance of the existing physical barriers, the licensee must, depending on the residual safety and radiation exposure risks, maintain appropriate lines of defence necessary for the protection of workers and the environment (setting up of air locks, nuclear ventilation, radiation monitors, etc.).

On completion of decommissioning, a nuclear facility can be delicensed by an ASN resolution approved by the Minister responsible for nuclear safety. It is then removed from the list of BNIs and is no longer subject to the BNI regulatory framework. Some twenty facilities, most of them old research reactors, have been decommissioned and delicensed to date.

As at 31 December 2024, ASN was examining 23 decommissioning files for definitively shut down facilities whose decommissioning has not yet been prescribed or whose decommissioning conditions have substantially changed.

1.4 The financing of decommissioning and radioactive waste management

Articles L. 594-1 to L. 594-10 and D. 594-1 to D. 594-18 of the Environment Code define the system for ring-fencing funds to meet the costs of decommissioning nuclear facilities and managing the spent fuel and the radioactive waste. This system is clarified by the Order of 21 March 2007 relative to ring-fencing the funding of the nuclear costs.

This Order aims to secure the funding for nuclear costs, applying the “polluter-pays” principle. It is therefore up to the nuclear

licensees to take charge of this financing by setting up a dedicated portfolio of assets capable of covering the expected costs.

These costs must be evaluated conservatively, taking the various uncertainties into account. The licensees are thus obliged to submit three-yearly on these costs along with annual update notices to the Government.

Provisioning is carried out under direct control of the State, which analyses the situation of each licensee and can prescribe the necessary measures should it be found to be insufficient or inadequate. The General Directorate of the Treasury and the General Directorate for Energy and the Climate (DGEC) constitute the administrative authority with competence for this control. The DGEC asks ASN to issue a technical opinion on the hypotheses adopted by the licensees.

Whatever the case may be, the nuclear licensees remain responsible for the satisfactory financing of their long-term costs.

2 — Situation of nuclear facilities undergoing decommissioning: specific challenges

At the end of 2024, 36 nuclear facilities in France are definitively shut down or undergoing decommissioning, that is to say about a quarter of the BNIs (*see map page 360*). These facilities are varied (nuclear power reactors, research reactors, “fuel cycle” facilities, support facilities, etc.) and the decommissioning challenges differ from one facility to the next. These risks are nevertheless all linked to the large quantity of waste to be managed during decommissioning and the need to carry out work very close to contaminated or activated zones. The risks for safety and radiation protection are all the higher if the facilities contain legacy waste; this in particular is the case with the Orano former spent fuel reprocessing plants and CEA’s old storage facilities. One of the major decommissioning problems is the loss of memory of the design and operation of the installation. Therefore maintaining skills and the installation characterisation phase to determine its initial state (state of the installation at the start of decommissioning) are of vital importance.

2.1 Nuclear power reactors

2.1.1 Pressurised water nuclear power reactors

PWRs decommissioning benefits from experience feedback from numerous projects across the world and the design of these reactors facilitates their

decommissioning compared with other reactor technologies. The decommissioning of this type of installation presents no major technical challenges and its feasibility is guaranteed. Nevertheless, whatever the service life of the reactors in operation, EDF will be confronted with the simultaneous decommissioning of several PWRs. EDF will therefore have to organise itself to industrialise the decommissioning process in order to meet the requirement to decommission each installation in the shortest time possible.

The first PWR decommissioning work site in France is the Chooz A reactor (BNI 163). This is a small model compared with the nuclear power reactors in operation. It presents some specific technical difficulties due to its construction inside a cavern. This makes some operations more complex, such as the removal of large components like the steam generators. Decommissioning of the Chooz A reactor pressure vessel began in 2014 and is continuing satisfactorily.

The Fessenheim NPP was definitively shut down in 2020. EDF submitted the decommissioning file for this facility in November 2020. In April 2022, ASN asked the GPDEM to examine the file for which it issued a favourable opinion in June 2023, subject to EDF providing further information before starting decommissioning of the reactor vessels and their

internal components. The Environmental Authority issued its opinion on this file in December 2023; the file then underwent a public inquiry in spring 2024, the opinion and conclusions of which were delivered in June 2024. These will be the first two 900 Megawatts electric (MWe) reactors to be decommissioned in France and are representative of the fleet of reactors currently operated by EDF. Decommissioning of the Fessenheim reactors will therefore also provide EDF with considerable experience feedback for its other PWRs (*see “Regional overview” in the introduction of this report*).

2.1.2 Nuclear power reactors other than pressurised water reactors

The nuclear power reactors that are not PWRs are all industrial prototypes. These comprise the first-generation Gas-Cooled Reactors (GCRs), the EL4-D heavy water reactor on the Brennilis site, and the sodium-cooled fast-neutron reactors Phénix and Superphénix. The decommissioning of these reactors is characterised by the lack of prior experience in France or elsewhere in the world, and the fact that when they were designed, the prospect of their future decommissioning was not as fundamental a concern as it may have been for the more recent reactor series. In view of their unique nature, specific and complex operations have to be devised

and carried out to decommission them. Furthermore, some of these reactors have been shut down for several decades, which has led to loss of knowledge of the installation and its operation and loss of the associated skills.

As with the PWRs, decommissioning begins with the removal of the nuclear fuel, which removes 99% of the radioactivity present in the installation. As these reactors have relatively high thermal power (all greater than 250 Megawatts thermal – MWth), their decommissioning requires the use of remotely operated means in certain highly irradiating zones, particularly in the vicinity of the reactor core.

The GCRs have the particularity of being extremely massive and large-sized reactors, necessitating innovative cutting and access techniques under highly irradiating conditions. The decommissioning of these reactors will oblige EDF to manage significant volumes of waste. The final disposal route for some of this waste is currently being determined, such as for the graphite bricks, representing some 15,000 tonnes of waste that will be produced, for which appropriate disposal will have to be defined (see chapter 15, point 1.3.3).

Decommissioning of the prototype heavy water reactor (EL4-D) on the Brennilis site has been slowed down, firstly due to the lack of prior experience in the decommissioning techniques to use, and secondly due to difficulties concerning the Conditioning and Storage Facility for Activated Waste (Iceda – see the “Regional Overview” in the introduction to this report) which must take in some of this decommissioning waste. Given that Iceda is now in service and the reactor building decommissioning scenario has been established, decommissioning of the complete installation started late 2024 and should be completed by the end of 2041. The decommissioning of this facility is regulated by Decree 2023-898 of 26 September 2023.

Decommissioning of the sodium-cooled reactors (Phénix and Superphénix) has met with no major technological obstacles, but specific challenges lie in the control of the fire risk due to the presence of sodium and the safety of its treatment processes. The treatment of the primary and secondary sodium from Phénix requires the creation of specific treatment facilities, and the long-term management of the sodium blocks resulting from the treatment of the sodium from Superphénix still has to be defined.

2.2 Research facilities

2.2.1 Research laboratories

Four research laboratories are currently undergoing decommissioning or preparation for decommissioning. These are the High Activity Laboratory (LHA) at Saclay (BNI 49), the Chemical Purification Laboratory (LPC) at Cadarache (BNI 54), the Irradiated Materials Plant (AMI) at Chinon (BNI 94) and the “Procédé” (Process) laboratory at Fontenay-aux-Roses (BNI 165).

These laboratories, which began operating in the 1960s, were dedicated to research to support the development of the nuclear power industry in France.

These very old facilities are all confronted with the issue of managing the “legacy” waste, stored on site at a time when the waste management routes had not been put in place, such as intermediate-level long-lived waste (ILW-LL) and waste without a disposal route (for example, non-incinerable organic oils and liquids and waste containing potentially water-soluble mercury compounds). Moreover, incidents occurred during their operation, contributing to the emission of radioactive substances inside and outside the containment enclosures and to the varying levels of pollution of the structures and soils, which makes the decommissioning and clean-out operations longer and more complex. One of the most important steps in the decommissioning of this type of facility, and which is sometimes rendered difficult due to incomplete archives, therefore consists in inventorying the waste and the radiological status of the facility as accurately as possible in order to define the decommissioning steps and the waste management routes.

2.2.2 Research reactors

Eight experimental reactors are preparing or undergoing decommissioning at the end of 2024: Rapsodie (sodium-cooled fast neutron reactor), Masurca, Éole and Minerve (critical mock-up), Phébus (test reactor), Osiris and Orphée (“pool” type reactors), and ISIS (teaching reactors). The Decommissioning Decrees of the Phébus and Éole/Minerve facilities have been published since the end of 2023. The Ulysse teaching reactor was delicensed in 2022. These reactors are characterised by a lower power output (from 100 Watts thermal – Wth – to 70 MWth) than the nuclear power reactors. When they were designed back in the 1960s to 1980s, the question of their decommissioning was not considered.

At the time of decommissioning, these installations usually present a low radiological source term, as one of the first

operations after final shutdown consists in removing the spent fuel. One of the main challenges comes from the production and management of large volumes of very low-level waste, which must be stored then disposed of *via* an appropriate route.

There is a considerable amount of decommissioning experience feedback for the research reactors, given the decommissioning of numerous similar installations in France (Siloé, Siloette, Mélusine, Harmonie, Triton⁽²⁾, the Strasbourg University Reactor – RUS) and abroad. Their decommissioning usually spans about ten years, but the large number of installations to be decommissioned simultaneously may lead to significantly longer prospective decommissioning durations for some of CEA’s reactors. After clean-out of the activated or contaminated areas and subsequent removal of all the radioactive waste to appropriate disposal routes, the majority of these reactors were demolished and the waste sent to conventional waste disposal routes.

2.3 The front-end “nuclear fuel cycle” facilities

Two front-end “nuclear fuel cycle” facilities are undergoing decommissioning. They are located on the Tricastin site, one specialising in uranium enrichment by gaseous diffusion (George Besse I plant – BNI 93), the other in uranium conversion (former Comurhex plant – BNI 105).

The only radioactive materials used in these plants were uranium-bearing substances. One of the particularities of these facilities therefore lies in the presence of radioactive contamination associated with the presence of “alpha” particle-emitting uranium isotopes. The radiation protection issues are therefore to a large extent linked to the risk of internal contamination.

Furthermore, these are older facilities whose operating history is poorly known. Determining the initial state, particularly the pollution present in the soils beneath the structures, therefore remains an important issue. Moreover, the industrial processes implemented back then involved the use of large quantities of toxic chemical substances (such as chlorine trifluoride and hydrogen fluoride, in addition to the uranium itself): the containment of these chemical substances therefore also represents a risk on these facilities and can necessitate the deployment of dedicated means (ventilation, containment air locks, respiratory protection masks, etc.). Materials and wastes are currently being retrieved at the Comurhex facility (BNI 105), with the aim of removing them from legacy storage areas for reprocessing and final conditioning.

2. Triton was one of the first highly compact and flexible pool-type research reactors called “MTR” (Material Test Reactor). Triton (6.5 MWth) was installed on the Fontenay-aux-Roses site in 1959.

2.4 The back-end “nuclear fuel cycle” facilities

The back-end facilities of the “nuclear fuel cycle” are the spent fuel storage pools, the spent fuel reprocessing plants and the facilities for storing waste from the treatment process. These facilities operated by Orano are situated on the La Hague site.

The first processing facility at La Hague was commissioned in 1966, initially for reprocessing the fuel from the first-generation GCRs. This facility, BNI 33, called “UP2-400” standing for “Production Unit No. 2 – 400 tonnes”, was definitively shut down on 1 January 2004 along with its support facilities: the Effluent Treatment Station (STE2) and the Spent fuel reprocessing unit (AT1 – BNI 38), the radioactive sources fabrication unit (ELAN IIB – BNI 47) and the “Oxide High Activity” (HAO) unit, created for reprocessing fuels from the “light water” reactors (BNI 80). Some of these facilities experienced accidents which contaminated the premises and their near environment, such as the fire in silo 130 belonging to BNI 38, in 1981.

Unlike the direct on-line packaging of the waste generated by the UP2-800 and UP3-A plants in operation, most of the waste generated by the first reprocessing plant was stored without treatment or packaging. Decommissioning is therefore carried out concomitantly with the legacy Waste Retrieval and Packaging (WRP) operations.

About ten projects of this type are currently in progress in the old facilities (silos STE2, 115 and 130 in BNI 38 and the HAO silo in BNI 80). They will span several decades and are a prerequisite to the complete decommissioning of these facilities, whereas the decommissioning of the process parts of the plant is continuing with more conventional techniques.

2.5 The support facilities (storage and treatment of radioactive effluent and waste)

Many of these facilities, most of which were commissioned in the 1960’s and whose level of safety does not comply with current best practices, have been shut down.

Old storage facilities were not initially designed to allow the removal of the waste, and in some cases they were seen as being the definitive waste disposal site. Examples include the silos at Saint-Laurent-des-Eaux (BNI 74), the pits, trenches and hangars of BNI 56, and the shafts of BNIs 72 and 166. Retrieval of the waste from these facilities is complex and will span several decades. The waste must then be packaged and stored again in safe conditions. New packaging and storage facilities are thus either planned or actually under construction.

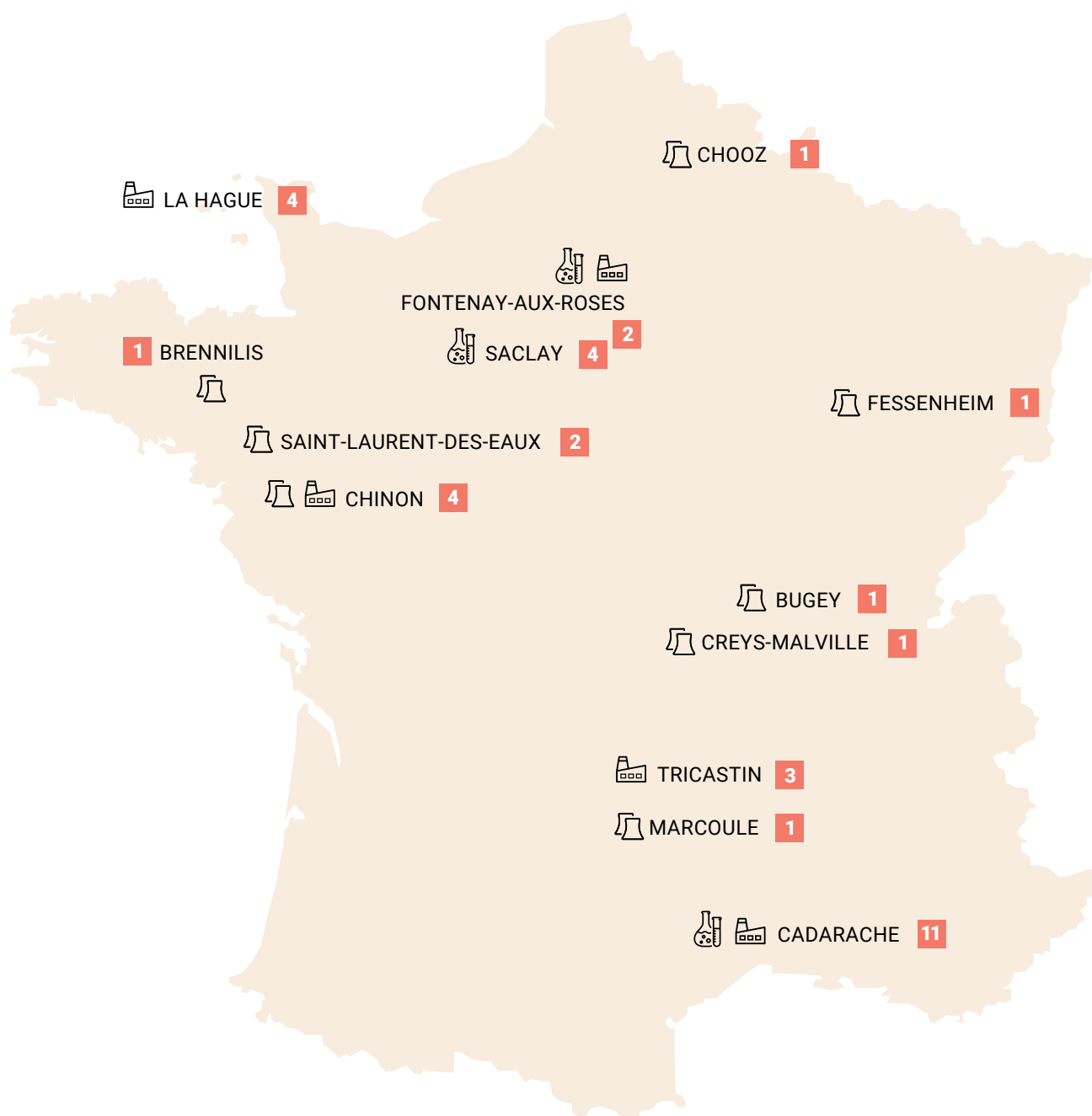
The STEs for their part have been shut down due to their ageing or because the facilities producing the effluents treated in these stations have stopped functioning. Examples include BNI 37-B at Cadarache and STE2 at the La Hague plant (BNI 38). The difficulties associated with decommissioning of the STEs are closely linked to their shutdown conditions, particularly the emptying and rinsing of their tanks.

The decommissioning of these support facilities raises many issues. Firstly, poor knowledge of the operating history and the state of the facility to be decommissioned (taking account of the corrosion of waste drums or pollution of soils resulting from significant events that occurred when in service, for example) necessitates prior characterisation of the stored legacy waste and of the sludges or deposits present in certain tanks and silos. Moreover, taking into account the quantities, the physical

and chemical forms and the radiotoxicity of the waste contained in these facilities, the licensee must develop means and skills that involve complex engineering techniques (radiation protection, chemistry, mechanics, electrochemistry, robotics, artificial intelligence, etc.). In fact, this waste is highly irradiating and heterogeneous, as it comprises structural elements from fuel reprocessing, technological waste, rubble, soils and sludge. Some of the waste has been stored in bulk with no prior sorting. The retrieval operations therefore require remotely operated pick-up means, conveyor systems, sorting systems, sludge pumping and waste packaging systems. The development of these means, carrying out the operations under conditions ensuring a satisfactory level of safety and radiation protection, and perhaps even the creation of new waste retrieval and packaging facilities represent a major challenge for the licensee. Given that these operations can last several decades, the management of ageing of the facilities is also a challenge.

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36 NUCLEAR FACILITIES DEFINITELY SHUT DOWN OR IN THE PROCESS OF DECOMMISSIONING AS AT 31 DECEMBER 2024



KEY



Reactor



Plant



Laboratory and
research reactor

BRENNILIS REACTOR EDF BNI 162 • EL4-D - Commissioned: 1967 - Decommissioning in progress	CHINON UTILISATION OF RADIOACTIVE SUBSTANCES EDF BNI 94 • Irradiated Material Facility – AMI - Commissioned: 1964 - Decommissioning in progress	MARCOULE REACTOR CEA BNI 71 • Phénix - Commissioned: 1973 - Decommissioning in progress
BUGEY REACTOR EDF BNI 45 • Bugey 1 - Commissioned: 1972 - Decommissioning in progress	REACTORS BNI 133 – BNI 153 – BNI 161 • Chinon A1D – A2D – A3D - Commissioned: 1963 – 1965 – 1966 - A1D et A2D: final shutdown - A3D: decommissioning in progress	SACLAY RESEARCH REACTORS CEA BNI 40 • Osiris-Isis - Commissioned: 1966 - Final shutdown BNI 101 • Orphée - Commissioned: 1980 - Final shutdown
CADARACHE RESEARCH REACTORS CEA BNI 25 • Rapsodie - Commissioned: 1967 - Decommissioning in progress BNI 39 • Masurca - Commissioned: 1966 - Final shutdown BNI 42-U • Éole / Minerve - Commissioned: 1965 / 1977 - Decommissioning in progress BNI 92 • Phébus - Commissioned: 1978 - Final shutdown	CHOOZ REACTOR EDF BNI 163 • Chooz A - Commissioned: 1967 - Decommissioning in progress	UTILISATION OF RADIOACTIVE SUBSTANCES BNI 49 • High Activity Laboratory – LHA - Commissioned: 1954 - Decommissioning in progress BNI 72 • Solid radioactive waste management zone – ZGDS - Commissioned: 1971 - Final shutdown
MANUFACTURE, TRANSFORMATION OR STORAGE OF RADIOACTIVE SUBSTANCES BNI 22 • Pégase-Cascad - Commissioned: 1964 - Final shutdown only for the Pégase facility BNI 32 • Plutonium technology facility – ATPu - Commissioned: 1962 - Decommissioning in progress BNI 37-B • Effluent Treatment Station – STE - Commissioned: 2015^(*) - Final shutdown BNI 52 • Enriched uranium processing facility – ATUe - Commissioned: 1963 - Decommissioning in progress BNI 53 • Central fissile material warehouse – MCMF - Commissioned: 1966 - Final shutdown BNI 54 • Chemical Purification Laboratory – LPC - Commissioned: 1966 - Decommissioning in progress BNI 56 • Storage area - Commissioned: 1968 - Final shutdown	CREYS-MALVILLE REACTOR EDF BNI 91 • Superphénix - Commissioned: 1985 - Decommissioning in progress	SAINT-LAURENT-DES-EAUX REACTORS EDF BNI 46 • Saint-Laurent A1 – A2 - Commissioned: 1969 / 1971 - Decommissioning in progress BNI 74 • Saint-Laurent silos - Commissioned: 1971 - Final shutdown
	FESSENHEIM REACTORS EDF BNI 75 • Fessenheim 1 – 2 - Commissioned: 1977 - Final shutdown	TRICASTIN TRANSFORMATION OF RADIOACTIVE SUBSTANCES ORANO CHIMIE ENRICHISSEMENT BNI 93 • Georges Besse plant for separating uranium isotopes by gaseous diffusion - Commissioned: 1979 - Decommissioning in progress BNI 105 • Comurhex uranium hexafluoride preparation plant - Commissioned: 1978 - Decommissioning in progress
	FONTENAY-AUX-ROSES RESEARCH FACILITY CEA BNI 165 • Procédé - Commissioned: 2006^(**) - Decommissioning in progress EFFLUENT REPROCESSING AND WASTE STORAGE FACILITY BNI 166 • Support - Commissioned: 2006^(**) - Decommissioning in progress	UTILISATION OF RADIOACTIVE SUBSTANCES EDF BNI 157 • Tricastin operational hot unit – BCOT - Commissioned: 2000 - Decommissioning in progress
	LA HAGUE TRANSFORMATION OF RADIOACTIVE SUBSTANCES ORANO RECYCLAGE BNI 33 • Spent fuel reprocessing plant – UP2-400 - Commissioned: 1964 - Decommissioning in progress BNI 38 • Effluent and Solid Waste Treatment Station – STE2 - Commissioned: 1964 - Decommissioning in progress BNI 47 • ELAN IIB facility - Commissioned: 1970 - Decommissioning in progress BNI 80 • Oxide High Activity facility – HAO - Commissioned: 1974 - Decommissioning in progress	[*] This date is because of the separation of BNI 37 (commissioned in 1964) into two BNIs: 37-A and 37-B. ^{**} This date results from the joining of former BNIs, commissioned in 1966 and 1968.

Observatory of waste retrieval and packaging and decommissioning projects

Given the large number of their facilities in final shutdown status or undergoing decommissioning, CEA, Orano and EDF must carry out various Waste Retrieval and Packaging (WRP) and decommissioning projects simultaneously.

Some of these projects present particular difficulties due to the extent of their radiological inventory or their unprecedented nature. In effect, progressing with these projects sometimes requires the devising of specific processes based on technologies that are not yet tried and tested or the establishing of management routes for radioactive waste for which there is as yet no disposal solution.

The scale of these projects and the particular difficulties they can present has led the CEA and Orano to prioritise those presenting the greatest importance, applying a strategy approved by ASN, and to define the first steps necessary for them to progress under the oversight of ASN, even when their completion time frame is very

distant. In such cases the licensee commits to intermediate completion deadlines targeting major steps in the progress of the project and governing its successful execution (identification of critical and sub-critical paths) and the meeting of deadlines. These milestones, which are recognised by ASN, are set for a time frame of about five years to guarantee correct performance of the operations within the set deadline.

The following table gives a summarized presentation of the next deadlines for the main decommissioning and WRP projects, along with the difficulties encountered in their implementation.

CEA Cadarache

	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY STEPS	ASN OBSERVATIONS
BNI 22	Decommissioning of Pégase facility	- Safety of storage pool with respect to a seismic hazard - Limitation of dependency of Cascad in terms of active institutional controls	- Retrieval and packaging of araldite-encapsulated fuels^(*) from the Pégase facility (planned to start in 2025^(**)) - Decoupling of Pégase and Cascad facilities (planned from 2030 to 2035)	- The end of decommissioning is scheduled for 2065^(**). - In 2022, ASN authorised the "removal of araldite-encapsulated fuels from storage" (DECAP) process allowing reconditioning of the araldite-encapsulated cans for storage in the Cascad facility. This process began in April 2024. - BNI 22 comprises two facilities: the Pégase facility being decommissioned and the Cascad facility in operation. The decoupling work is planned as of 2030.
BNI 37B	Retrieval and packaging of all the residues in the facility's tanks	Safety of the pits containing waste with respect to seismic and fire hazards	- Construction of a new building and commissioning of an entirely automated retrieval process requiring substantial preliminary operations (scheduled for 2052) - Definition of the definitive packaging process	The facility decommissioning file is currently being examined; its time frame targets are set for the very distant future, beyond 2100 for completion of decommissioning; these will be examined with particular attention.

* Araldite is a polyepoxide formed by bringing an epoxy resin into contact with a polymerising agent. The presence of araldite in the fuel cans creates a risk of producing gas, particularly hydrogen, which can cause overpressure or an explosion.

** Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

CEA Cadarache

	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY STEPS	ASN OBSERVATIONS
BNI 54	Decommissioning of the cryogenic treatment facility for final clean-out and remediation of the structures and soils	Safety of the operations with respect to the risk of dissemination of radioactive materials	- Decommissioning of the cryogenic treatment process chambers - Characterisation of the soils under the facility	- End of decommissioning was scheduled for 2024^(*). ASN is currently reviewing an application to modify the Decree authorising the decommissioning of BNI 54, given the slippage in the decommissioning operations schedule. - Decommissioning of the cryogenic treatment facility takes priority in CEA's "DEM/Waste" strategy. It started in 2021.

BNI 56	Retrieval and packaging of the waste stored in the trenches	Risk of flooding by water table upwelling	- Development of packaging routes for certain particular types of waste - Design of automated means of retrieval	The retrieval scenario for the waste in the trenches was transmitted to ASN at the beginning of 2024.
	Retrieval and packaging of all the intermediate level bulk waste present in the old pits ("vrac MI" (bulk IL) project)	Safety of the pits containing waste with respect to a seismic hazard	Construction of new buildings and commissioning of an entirely automated retrieval process requiring substantial preliminary operations	ASN is currently examining the decommissioning file.
	Retrieval and packaging of all the waste present under the hangars ("ATC" project)	Safety of the hangars containing waste with respect to a seismic hazard	Definition of the definitive packaging process	The "vrac MI" project is at the detailed design study stage. The "ATC" project is at the preliminary design study stage.

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

CEA Fontenay-aux-Roses

	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY STEPS	ASN OBSERVATIONS
BNI 165	Packaging of the ILW-LL waste in PETRUS drums and characterisation of the waste from the decommissioning of the PETRUS unit	Access to the contaminated silos under the PETRUS unit	- Construction of the new waste transfer and packaging enclosure (ETCB) - Development work in order to accept and remove the waste drums from decommissioning of the equipment of building 18 (EDB)	- The end of decommissioning was initially scheduled for 2017^(*) and 2018^(*) for BNIs 165 and 166 respectively. ASN is currently examining an application to modify the decrees authorising decommissioning of BNIs 165 et 166, for which some deadlines have already been exceeded. - In view of the numerous technical and organisational difficulties, particularly the lack of knowledge of the initial state of the shielded cells containing legacy waste, the end-of-retrieval deadline will probably be pushed back by several decades.
BNI 166	Retrieval of waste stored in the pits of building 58 of BNI 166	Retrieval of waste to allow decommissioning of the facilities situated in a highly urbanised area	Construction of the new measuring and packaging equipment (EMC)	

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

CEA Marcoule

	OPERATION AND DESCRIPTION ▼	CHALLENGE ▼	NEXT KEY STEPS ▼	ASN OBSERVATIONS ▼
BNI 71	Sodium treatment	Risk of fire, pyrophoricity ^(*) , explosion	- Commissioning of the Noah secondary sodium treatment facility (scheduled for 2029^(**)) - Fuel removal in progress	- Treating the sodium is a prerequisite for decommissioning the facility and will significantly reduce the risks it represents. - Completion of fuel removal will be pushed back a few years. - The ongoing updating of the Phénix decommissioning strategy aiming to prioritise a sodium treatment, led CEA to submit in late 2024 an application to modify the facility's Decommissioning Decree.

* Property of certain substances whose self-ignition temperature is lower than room temperature and which can therefore ignite spontaneously at room temperature.

** Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

CEA Saclay

	OPERATION AND DESCRIPTION ▼	CHALLENGE ▼	NEXT KEY STEPS ▼	ASN OBSERVATIONS ▼
BNI 35	Emptying of tanks MA3 to MA8 of room 98	Safety of the operations with respect to the risk of dissemination of radioactive materials	Investigations into the physical state of the tanks and their retention (end scheduled in 2026)	The investigations must also allow characterisation of the effluents in the tanks; the reliability of the packaging process must be ensured. All these operations shall be regulated by an ASN requirement.
	Clean-out of pit 99		Emptying tank-bottom contents present in the pit	In October 2022, ASN authorised the drainage operations on tank 40/4 considered to be a priority.
	Treatment of the sludges of tanks MA501 to MA507		Characterisation of effluents and clean-out strategy to be consolidated	ASN considers tank MA507 a priority.

BNI 72	Retrieval and packaging of drums containing a mixture of waste and fragments of fuel	Safety of the storage areas with respect to containment and a seismic hazard	• Construction of retrieval equipment • Adaptation of the retrieval equipment, whatever the envisaged state of the waste • Commissioning of retrieval equipment (scheduled for 2029)	• The end of decommissioning is scheduled for 2059^(*). • Commissioning of the retrieval equipment was initially scheduled for 2023. This deadline was pushed back to 2029 due to numerous technical and organisational difficulties. This commissioning deadline must be consolidated owing to the need to repeat the studies already carried out.
	Retrieval and packaging of all the solid waste, fuels, irradiated fuels and radioactive sources		Removal from storage and emptying of the pool (end scheduled for 2024 ^(*))	• The removal operations are in progress. Given the numerous technical and organisational difficulties, the initial deadlines have been pushed back by several years. • The removal from storage of blocks 108 and 116 was completed in 2022. • The removal from storage of the spent fuel in the pool was completed in 2024.
			40 pits zone – Removal of stored irradiating waste (end scheduled in 2030 ^(*))	
			Removal from storage of blocks 108 and 116 (end scheduled in 2023 ^(*))	
			Removal of stored sources from building 116 (end scheduled in 2025 ^(*)).	

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

EDF

	OPERATION AND DESCRIPTION ▼	CHALLENGE ▼	NEXT KEY STEPS ▼	ASN OBSERVATIONS ▼
BNI Chinon A2	Decommissioning of reactor pressure vessel	"Pilot" project for the decommissioning of the other GCRs	- Opening of pressure vessel and installation of the decommissioning platform - Decommissioning of the graphite stack	- Removal of the fuel from the facility has significantly reduced the risks. The facility has moreover already been partly decommissioned. - ASN will issue a position statement on the deadlines presented by EDF for decommissioning its GCRs, as part of the review of the decommissioning files submitted at end of 2022.
BNI 74	Retrieval and packaging of the graphite sleeves	Construction of a new storage facility that meets current safety standards	Construction of the new storage building and of the retrieval and packaging equipment.	ASN will issue a position statement on the safety of the new storage facility project as part of the review of the decommissioning file submitted in 2022.

Orano La Hague

	OPERATION AND DESCRIPTION ▼	CHALLENGE ▼	NEXT KEY STEPS ▼	ASN OBSERVATIONS ▼
BNI 33	Decommissioning of the "High Activity Dissolution Extraction" unit (HADE)	Short-term safety with respect to the seismic hazard	Active commissioning of the DFG building (French acronym for "fine granulometry waste") for retrieval of decladding waste (scheduled for 2028)	- Construction of the DFG building ran smoothly in 2024. - The end of decommissioning is scheduled for 2046^(*). - The decommissioning priority for this facility is given to the expeditious retrieval of the legacy waste, which represents a major risk for safety given the large radiological inventory and the fragility of current storage conditions. - The rinsing and treatment operations on the effluents in the solvent tanks in the HAPF unit could be postponed to about 2035 in the event of technical difficulties.
	Decommissioning of the "High Activity Fission Product" unit (HAPF)		Rinsing and effluent treatment operations on the HAPF unit solvent tanks (scheduled for before the end of 2031)	
	Decommissioning of the "Medium Activity Plutonium" unit (MAPu)	Short term safety of neighbouring units with respect to the seismic hazard	Dismantling of upper storeys to limit risks to the units in operation (scheduled before end of 2028)	

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

Orano La Hague

	OPERATION AND DESCRIPTION ▼	CHALLENGE ▼	NEXT KEY STEPS ▼	ASN OBSERVATIONS ▼
BNI 38	Retrieval and packaging of the waste from silo 130	- Short-term safety of the silo with respect to containment or a seismic hazard - Packaging within time frames compatible with commissioning of the deep geological repository Cigéo	- End of retrieval of solid GCR waste (ILW-LL) - End of retrieval of active effluents and sludge - End of packaging of the ILW-LL waste	- The end of decommissioning is scheduled for 2043^(*). - The retrieval of all the waste from silo 130 is currently scheduled for the end of 2025^(*). - However, the end-of-retrieval deadlines have been pushed back by a few years. Retrieval began in February 2020, but technical malfunctions made technical adjustments necessary and obliged the operating teams to start working 3 x 8-hour shifts in order to guarantee the retrieval deadline of end 2030. - The sludge and effluents retrieval scenario has been determined. Studies into the possibility of retrieving the effluents along with the solid GCR ILW-LL waste are continuing. - Packaging in definitive packages that meet the acceptance criteria for a deep geological repository is pushed back by several decades^(**).
	Retrieval and packaging of the sludge stored in silos of Effluent Treatment Station No. 2 – STE2 (“Sludge Retrieval and Packaging” project – RCB)	Safety of the silos with respect to containment and a seismic hazard	- Construction and commissioning of a new storage facility - Development of equipment for retrieving sludge and transferring it to the new storage facility - Definition of the definitive sludge packaging process	- The end of packaging of the sludge from the silos is scheduled for the end of 2030^(*) (in accordance with Article L. 542-1-3 of the Environment Code). - The new sludge retrieval and management strategy was revised in 2022 and validated in April 2023. Orano has undertaken to build new silos to guarantee the sludge storage conditions. The beginning of sludge retrieval has been postponed to 2037. - The deadlines for the start and end of retrieval are therefore pushed back significantly. - Packaging in definitive packages acceptable in a deep geological repository is pushed back by several decades^(**).
BNI 80	Retrieval and packaging of waste from the HAO silo and Organised Storage of Hulls (SOC) pools	- Safety of the silo with respect to containment, a seismic hazard or resistance to an aircraft crash - Packaging within time frames compatible with commissioning of the Cigéo deep geological repository	- Commissioning of the ILW-LL solid waste and active effluents retrieval unit - End of packaging of waste (scheduled before end 2022^(*))	- In view of the difficulties associated with operation and maintenance of the planned process, the retrieval scenario was updated in 2021. - ASN has authorised the active commissioning of the equipment. - The first tests are planned in the next few years. - Start of retrieval is now pushed back to 2029. This deadline extension was presented to the CLI by Orano and gave rise to a deviation notification. - The end-of-packaging deadline is pushed back significantly.
	Partial dismantling of the filtration building at the end of decommissioning	Reduction of the interactions with the pools of the spent fuel elements unloading and storage facility (NPH), in the event of an earthquake	- Dismantling of the upper storeys of the filtration building - Clean-out of the “900 cells”	- Completion of dismantling of the upper storeys of the filtration building is scheduled before the end of 2031. - Completion of decommissioning of BNI 80 is scheduled in 2033^(*). - ASN is currently reviewing an application to modify the Decree authorising the decommissioning of BNI 80 in order to integrate both the change in scenario and slippages in the decommissioning and WRP operations. - Clean-out of the “900 cells” is planned around 2050; these time frames must nevertheless be supported by additional files to be submitted in the coming years.

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

** Given the complexity of the operations, it will be necessary to modify Article L. 542-1-3 of the Environment Code.

3 — ASN actions related to facilities being decommissioned: a graded approach

3.1 The graded approach according to the risks of the facilities

ASN ensures the oversight of facilities undergoing decommissioning, as it does for facilities in operation. More specifically, the BNI System also applies to definitively shut down facilities. ASN implements an approach that is proportional to the extent of the risks or drawbacks inherent in the facility.

The risks with facilities undergoing decommissioning differ from those for facilities in operation. For example, the risks of significant off-site discharges decrease as decommissioning progresses because the quantity of radioactive substances decreases. Consequently, the requirements relating to the control of risks and impacts are proportionate to the risks inherent in the facilities. ASN thus considers that it is generally inappropriate to start significant reinforcement work on a facility undergoing decommissioning, on condition that the decommissioning operations reduce the sources of danger in the short term.

3.2 The periodic safety reviews of facilities undergoing decommissioning

Given the diversity of the facilities and the situations in question, each periodic safety review necessitates an appropriate examination method. Some facilities undergoing decommissioning warrant particular attention owing to the risks they present and may be reviewed by the GPDEM. For others presenting a lower level of risk, the extent of the inspections and examinations is adapted accordingly. These inspections are used to check the means implemented by the licensee to carry out its review, as well as compliance with the action plan resulting from its conclusions. They led to several requests for corrective action and additional information.

3.3 Financing decommissioning: ASN's opinion on the three-yearly reports

The regulatory framework for ring-fencing the funds necessary for management of the long-term decommissioning and waste management expenses is presented in point 1.4.

In 2022, ASN examined the three-yearly reports submitted by the licensees, regarding the accounts closed at the end of 2021.

It published opinion CODEP-CLG-061286 of 14 December 2022 and sent its observations to the Ministry responsible for energy. The next three-yearly reports will be submitted in 2025.

More generally, ASN notes that the evaluation perimeter of the expenses considered in the majority of these reports must be supplemented because it does not take into account certain operations that could represent major financial issues, particularly the decommissioning preparation operations.

Moreover, ASN considers that the initial states of the sites at the beginning of their decommissioning must be described more precisely, taking account of any pollution present in the soils and structures and evaluating the associated clean-out costs. In effect, the assumptions concerning the initial state of the sites are not sufficiently robust on the whole, whereas it is of fundamental importance to have sound knowledge of the state of the sites in order to evaluate the decommissioning expenses conservatively.

Lastly, ASN underlines that the assumptions adopted for evaluating the complete costs must be reassessed in order to exercise reasonable prudence in the scheduling of the decommissioning projects and programmes, taking account of the risks related to the unavailability of storage, treatment and disposal facilities.

4 — Assessment of the licensees' decommissioning strategies

In a context in which numerous facilities have been shut down for several decades, with concomitant loss of knowledge of the facilities, ageing structures and in some cases large quantities of waste still present, maintaining good progress with the decommissioning operations is of major importance for the safety of these facilities. Yet ASN has noted that the majority of these operations are falling significantly behind schedule. ASN therefore regularly asks CEA, EDF and Orano to present their decommissioning and radioactive waste management strategies, thereby providing an overall view of the decommissioning projects and the management routes necessary for removal of the radioactive waste resulting from the decommissioning operations.

As far as decommissioning is concerned, the licensees must justify the levels of priority assigned to the planned operations, principally through safety analyses. This prioritisation provides a means of checking that even if some projects are substantially behind schedule, the most significant

resources will be devoted to operations with higher risk implications.

With regard to radioactive waste management, ASN checks the consistency of the planned actions with the regulatory framework and the guidelines of the PNGMDR. The assessment of the radioactive waste management strategies is presented in chapter 15.

4.1 Assessment of EDF's decommissioning strategy

The first decommissioning strategy file for the EDF reactors definitively shut down (Chinon A1, A2, A3, Saint-Laurent A1 and A2, Bugey 1, EL4-D, Chooz A and Superphénix) was transmitted in 2001 at the request of ASN. Immediate dismantling was adopted as the reference strategy. This strategy has been updated regularly, in order to adjust the decommissioning schedule or incorporate the complementary studies requested by ASN and elements concerning the future

decommissioning of the reactor fleet in service.

For the six first-generation GCRs (Chinon A1, A2 and A3, Saint-Laurent A1 and A2, and Bugey 1), EDF informed ASN of a complete change of strategy in March 2016, calling into question the technical principle (decommissioning "under water") chosen for the decommissioning of these reactors and the phasing of the operations, resulting in the decommissioning of all the GCRs being pushed back by several decades. ASN will rule on the decommissioning time frames put forward by EDF in the decommissioning files submitted at the end of 2022 (currently being reviewed by ASN), which may also be revised if it turns out in the coming decades that this scenario can be optimised in the light of the OEF acquired. This GCR decommissioning strategy is regulated by two ASN resolutions (resolution 2020-DC-0686 and ASN Chairman's resolution CODEP-CLG-2020-021253 of 3 March 2020).

These resolutions set the next steps required for the change of decommissioning strategy, notably the defining of a robust strategy for managing graphite waste that is independent of disposal outlet availability, the decommissioning operations to continue over the next few years and the information to be transmitted to ASN to check effective implementation of the strategy.

ASN considers that it is appropriate for EDF to develop a graphite industrial demonstrator (commissioned in 2022 in Chinon) before decommissioning the reactor pressure vessels, but decommissioning of the various reactors must nevertheless begin within reasonable time frames in view of the obligation for dismantling to be carried out as rapidly as possible.

Regarding the other shut down EDF facilities (notably Chooz A, AMI Chinon, EL4-D and Superphénix), their decommissioning is under way and on the whole is meeting the objective of achieving as short a time frame as possible.

4.2 Assessment of Orano's decommissioning strategy

The decommissioning of old installations is a major challenge for Orano, which has to conduct several large-scale decommissioning projects over variable time scales (UP2-400 facility at La Hague, Eurodif Production plant, Comurhex plant, individual facilities of the DBNI at Pierrelatte, etc.). Implementation of decommissioning is closely linked to the legacy radioactive waste management strategy, given the quantity and the non-standard and hard to characterise nature of the waste produced during the prior operations phase and during the ongoing decommissioning operations.

Furthermore, Orano must carry out special WRP operations in old waste storage facilities. The deadlines for completion have been stipulated by ASN, particularly for the La Hague site. Completion of these WRP operations determines the progress of decommissioning on the UP2-400 plant, as WRP is one of the first steps of its decommissioning. The WRP work is of particular importance given the large inventory of radioactive substances present and the age of the facilities in which they are stored, which do not generally meet current safety standards.

In addition, WRP projects are considerably complex owing to the interactions with the plants in operation on the site. Further to the difficulties observed in the examination of files relating to the WRP and decommissioning operations on the Orano La Hague site and failure to perform the operations within the prescribed deadlines, ASN and Orano agreed to set up regular monitoring in order to anticipate and address any blocking situations and determine practical measures to be put into place to accomplish the WRP and decommissioning operations in the shortest time frame possible.

In June 2016, at the request of ASN and ASND – the Defence Nuclear Safety Authority – Orano submitted its decommissioning and waste management strategy. The file also includes the application of this strategy to the La Hague and Tricastin sites. In its position statement letter of 14 February 2022, ASN underlined the progress made by the licensee in taking on-board the decommissioning objectives prioritised according to the issues of the BNIs and the decommissioning phases and the Orano governance's oversight of complex WRP and decommissioning projects. ASN conducted two inspections focusing on this strategy in 2024. However, ASN considers that Orano should continue to improve its knowledge of the current state of the facilities and notably the soils, with a view to future POCO, make progress in enhancing the industrial reliability of the waste retrieval processes.

ASN considers that the methodology put in place by Orano for calculating schedule margins can guarantee better control of the time frames of the various WRP and decommissioning projects. Orano notably updated the forecast end-of-decommissioning dates for the UP2-400 plant BNIs in 2024.

4.3 Assessment of CEA's decommissioning strategy

Given the number and complexity of the operations to be carried out for all the nuclear facilities concerned, CEA is giving priority to reducing the “dispersible inventory” which is currently very high in certain facilities, particularly in some of the individual facilities of the Marcoule DBNI and in BNIs 56 and 72.

In their Position Statement Letter of 27 May 2019, ASN and the ASND considered that, given the resources allocated by the State and the large number of facilities undergoing decommissioning for which legacy waste retrieval and storage capacity will need to be built, it was acceptable for CEA to envisage staggering the decommissioning operations and that priority be given to the facilities with the greatest safety risks. ASN however observes very significant drifts in the WRP schedules presented by CEA, particularly the pushing back of waste management deadlines, including for operations considered to be priorities. Some of these operations are effectively being reconsidered in depth after encountering deadlocks in the initially planned operations, or the late discovery of a facility state that is inconsistent with the expected state. ASN and CEA have set up regular monitoring of these operations, notably by means of progress indicators.

ASN observes moreover that CEA's decommissioning and materials and waste management strategies share certain vulnerabilities in particular relative to the availability of support facilities, which are often unique but are needed in order to run numerous projects. CEA's strategies rely on sharing of the resources by its centres and are based on the use of facilities, some of which are simply planned, while others are undergoing commissioning, or being refurbished. Most of them are unique, with no obvious operational alternative in the event of failure. All of these aspects underline the vulnerability of CEA's strategy.

Appendix

List of Basic Nuclear Installations undergoing decommissioning or delicensed as at 31 December 2024

INSTALLATION LOCATION	BNI No.	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
Néréide (Fontenay-aux-Roses)	(Former BNI 10)	Reactor (500 kWth)	1960	1981	1987: Removed from BNI list	Decommissioned
Triton (Fontenay-aux-Roses)	(Former BNI 10)	Reactor (6.5 MWth)	1959	1982	1987: Removed from BNI list and classified as ICPE	Decommissioned
ZOÉ (Fontenay-aux-Roses)	(Former BNI 11)	Reactor (250 kWth)	1948	1975	1978: Removed from BNI list and classified as ICPE	Confined (museum)
Minerve (Fontenay-aux-Roses)	(Former BNI 12)	Reactor (0.1 kWth)	1959	1976	1977: Removed from BNI list	Dismantled at Fontenay-aux-Roses and reassembled at Cadarache
EL2 (Saclay)	(Former BNI 13)	Reactor (2.8 MWth)	1952	1965	Removed from BNI list	Partially decommissioned, remaining parts confined
EL3 (Saclay)	(Former BNI 14)	Reactor (18 MWth)	1957	1979	1988: Removed from BNI list and classified as ICPE	Partially decommissioned, remaining parts confined
Ulysse (Saclay)	(Former BNI 18)	Reactor (100 kWth)	1967	2007	2022: Removed from BNI list	Decommissioned
Mélusine (Grenoble)	(Former BNI 19)	Reactor (8 MWth)	1958	1988	2011: Removed from BNI list	Decommissioned
Siloé (Grenoble)	(Former BNI 20)	Reactor (35 MWth)	1963	2005	2015: Removed from BNI list	Decommissioned-PIC ^(*)
Silhouette (Grenoble)	(Former BNI 21)	Reactor (100 kWth)	1964	2002	2007: Removed from BNI list	Decommissioned-PIC ^(*)
Peggy (Cadarache)	(Former BNI 23)	Reactor (1 kWth)	1961	1975	1976: Removed from BNI list	Decommissioned
César (Cadarache)	(Former BNI 26)	Reactor (10 kWth)	1964	1974	1978: Removed from BNI list	Decommissioned
Marius (Cadarache)	(Former BNI 27)	Reactor (0.4 kWth)	1960 in Marcoule, 1964 in Cadarache	1983	1987: Removed from BNI list	Decommissioned
Former Le Bouchet plant (Vert-le-Petit)	(Former BNI 30)	Ore processing	1953	1970	Removed from BNI list	Decommissioned
Former ore processing plant (Gueugnon)	(Former BNI 31)	Ore processing	1965	1980	Removed from BNI list	Decommissioned
STED (Fontenay-aux-Roses)	(Former BNI 34)	Processing solid and liquid waste	Before 1964	2006	2006: Removed from BNI list	Integrated in BNI 166
STED and High-level waste storage unit (Grenoble)	(Former BNIs 36 et 79)	Waste treatment and storage plant	1964/1972	2008	2023: Removed from BNI list	Decommissioned
STED (Cadarache)	(Former BNI 37)	Transformation of radioactive substances	1964	2015	2015: Removed from BNI list	Integrated in BNIs 37-A and 37-B
Harmonie (Cadarache)	(Former BNI 41)	Reactor (1 kWth)	1965	1996	2009: Removed from BNI list	Building demolished, active institutional controls
ALI (Saclay)	(Former BNI 43)	Accelerator	1958	1996	2006: Removed from BNI list	Decommissioned-PIC ^(*)
Strasbourg University reactor	(Former BNI 44)	Reactor (100 kWth)	1967	1997	2012: Removed from BNI list	Decommissioned-PIC ^(*)
Saturne (Saclay)	(Former BNI 48)	Accelerator	1966	1997	2005: Removed from BNI list	Decommissioned-PIC ^(*)
Attila^(*) (Fontenay-aux-Roses)	(Former BNI 57)	Reprocessing pilot	1968	1975	2006: Removed from BNI list	Integrated in BNI 165
LCPu (Fontenay-aux-Roses)	(Former BNI 57)	Plutonium chemistry laboratory	1966	1995	2006: Removed from BNI list	Integrated in BNI 165
BDG 19 (Fontenay-aux-Roses)	(Former BNI 58)	Plutonium metallurgy	1968	1984	1984: Removed from BNI list	Decommissioned
RM2 (Fontenay-aux-Roses)	(Former BNI 59)	Radio-metallurgy	1968	1982	2006: Removed from BNI list	Integrated in BNI 165
LCAC (Grenoble)	(Former BNI 60)	Fuels analysis	1975	1984	1997: Removed from BNI list	Decommissioned
LAMA (Grenoble)	(Former BNI 61)	Laboratory	1968	2002	2017: Removed from BNI list	Decommissioned
SICN (Veurey-Voroize)	(Former BNIs 65 and 90)	Fuel fabrication plant	1963	2000	2019: Removed from BNI list	Building demolished, active institutional controls

Decommissioning of Basic Nuclear Installations

INSTALLATION LOCATION	BNI No.	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
STEDs (Fontenay-aux-Roses)	(Former BNI 73)	Radioactive waste decay storage	1971	2006	2006: Removed from BNI list	Integrated in BNI 166
ARAC (Saclay)	(Former BNI 81)	Fabrication of fuel assemblies	1981	1995	1999: Removed from BNI list	Decommissioned
LURE (Bures-sur-Yvette)	(Former BNI 106)	Particle accelerators	From 1956 to 1987	2008	2015: Removed from BNI list	Decommissioned-AIC ^(***)
IRCA (Cadarache)	(Former BNI 121)	Irradiator	1983	1996	2006: Removed from BNI list	Decommissioned-PIC ^(*)
FBFC (Pierrelatte)	(Former BNI 131)	Fuel fabrication	1990	1998	2003: Removed from BNI list	Decommissioned-PIC ^(*)
Uranium warehouse (Miramas)	(Former BNI 134)	Uranium-bearing materials warehouse	1964	2004	2007: Removed from BNI list	Decommissioned-PIC ^(*)
SNCS (Osmanville)	(Former BNI 152)	Ioniser	1983	1995	2002: Removed from BNI list	Decommissioned-PIC ^(*)
Pégase (Cadarache)	22	Reactor and storage of radioactive substances	1964	2017	–	Preparation for decommissioning
Rapsodie (Cadarache)	25	Reactor (40 MWth)	1967	1983	2021: Partial Decommissioning Decree	Decommissioning in progress
ATPu (Cadarache)	32	Fuel fabrication plant	1962	2003	2009: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Spent fuel reprocessing plant – UP2-400 (La Hague)	33	Transformation of radioactive substances	1964	2004	2022: Partial Decommissioning Decree	Decommissioning in progress
STE (Cadarache)	37-B	Effluent treatment facility (non-permanent part of former BNI 37)	2015	2016	–	Preparation for decommissioning
STE2 (La Hague)	38	Effluent treatment station	1964	2004	2022: Partial Decommissioning Decree	Decommissioning in progress
Masurca (Cadarache)	39	Reactor (5 kWth)	1966	2018	–	Preparation for decommissioning
Osiris-Isis (Saclay)	40	Reactor (70 MWth)	1966	2015	–	Preparation for decommissioning
Éole / Minerve (Cadarache)	42-U	Reactor (1 kWth) and Reactor (100 Wth)	1965 and 1977	2017	2023: Decree for decommissioning and merging of the two BNIs (Éole and Minerve)	Decommissioning in progress
Bugey 1 (Saint-Vulbas)	45	Reactor (1,920 MWth)	1972	1994	2008: Final Shutdown and Decommissioning Decree	Decommissioning in progress
St-Laurent-des-Eaux A1 (St-Laurent-Nouan)	46	Reactor (1,662 MWth)	1969	1990	2010: Decommissioning Decree	Decommissioning in progress
St-Laurent-des-Eaux A2 (St-Laurent-Nouan)	46	Reactor (1,801 MWth)	1971	1992	2010: Decommissioning Decree	Decommissioning in progress
ELAN IIB (La Hague)	47	Manufacture of caesium-137 sources	1970	1973	2013: Decommissioning Decree	Decommissioning in progress
LHA (Saclay)	49	Laboratory	1960	1996	2008: Final Shutdown and Decommissioning Decree	Decommissioning in progress
ATUe (Cadarache)	52	Uranium processing	1963	1997	2021: Decree amending the Decommissioning Decree of 2006	Decommissioning in progress
MCMF (Cadarache)	53	Storage of radioactive substances	1968	2017	2024: Decommissioning Decree	Decommissioning in progress
LPC (Cadarache)	54	Laboratory	1966	2003	2009: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Storage yard	56	Storage of radioactive substances	1968	2023	–	Préparation au démantèlement
Phénix (Marcoule)	71	Reactor (536 MWth)	1973	2009	2016: Decommissioning Decree	Decommissioning in progress
ZGDS (Saclay)	72	Transformation of radioactive substances	1971	2022	2022: Decommissioning Decree	Decommissioning in progress

INSTALLATION LOCATION	BNI No.	TYPE OF INSTALLATION	COMMISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
Saint-Laurent silos (St-Laurent-Nouan)	74	Radioactive waste storage	1971	2022	–	Preparation for decommissioning
Fessenheim NPP (Fessenheim)	75	Reactors (each of 2,660 MWth)	1977	2020	–	Preparation for decommissioning
HAO facility (La Hague)	80	Transformation of radioactive substances	1974	2004	2009: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Superphénix (Creys-Malville)	91	Reactor (3,000 MWth)	1985	1997	2009: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Phébus (Cadarache)	92	Reactor (40 MWth)	1978	2017	2024: Decommissioning Decree	Decommissioning in progress
Eurodif (Pierrelatte)	93	Transformation of radioactive substances	1979	2012	2020: Partial Decommissioning Decree	Partial decommissioning in progress
AMI (Chinon)	94	Utilisation of radioactive substances	1964	2015	2020: Decommissioning Decree	Decommissioning in progress
Orphée (Saclay)	101	Reactor (14 MWth)	1980	2019	–	Decommissioning in progress
Comurhex (Tricastin)	105	Uranium chemical transformation plant	1979	2009	2019: Decommissioning Decree	Decommissioning in progress
Chinon A1 D – former Chinon A1 (Avoine)	133 (former BNI 5)	Reactor (300 MWth)	1963	1973	1982: Decree for confinement of Chinon A1 and creation of the Chinon A1 D storage BNI	Partially decommissioned, modified to storage BNI for waste left in place. Preparation for complete decommissioning
Chinon A2 D – former Chinon A2 (Avoine)	153 (former BNI 6)	Reactor (865 MWth)	1965	1985	1991: Decree for partial decommissioning of Chinon A2 and creation of storage BNI Chinon A2 D	Partially decommissioned, modified to storage BNI for waste left in place. Preparation for complete decommissioning
Chinon A3 D – former Chinon A3 (Avoine)	161 (former BNI 7)	Reactor (1,360 MWth)	1966	1990	2010: Decommissioning Decree	Decommissioning in progress
EL4-D – former EL4 (Brennilis)	162 (former BNI 28)	Reactor (250 MWth)	1966	1985	1996: Decree ordering decommissioning and creation of the EL4-D storage BNI 2006: Final Shutdown and Decommissioning Decree 2007: State Council decision cancelling the Decree of 2006 2011: Partial Decommissioning Decree 2023: Complete Decommissioning Decree	Decommissioning in progress
Ardennes NPP – former Chooz A (Chooz)	163 (former BNIs 1, 2, 3)	Reactor (1,040 MWth)	1967	1991	2007: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Procédé (Fontenay-aux-Roses)	165	Grouping of former research installations (BNIs 57 and 59) concerning reprocessing processes	2006	2006	2006: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Tricastin Operational Hot Unit (Tricastin)	157	Laboratory	2000	2020	2023: Decommissioning Decree	Decommissioning in progress
Support (Fontenay-aux-Roses)	166	Grouping of former installations (BNIs 34 and 73) for packaging and treating waste and effluents	2006	2006	2006: Final Shutdown and Decommissioning Decree	Decommissioning in progress

* Passive Institutional Controls.

** Attila: reprocessing pilot located in a unit of BNI 57.

*** Active Institutional Controls.

15

Radioactive waste and contaminated sites and soils



1

Radioactive waste p. 375**1.1 Management of radioactive waste (with the exception of mining tailings and waste rock)**

- 1.1.1 Management of radioactive waste in Basic Nuclear Installations
- 1.1.2 Management of waste from small-scale nuclear activities governed by the Public Health Code
- 1.1.3 Management of waste containing natural radioactivity

1.2 Legal framework for radioactive waste management

- 1.2.1 Legal framework for the management of radioactive waste produced in Basic Nuclear Installations
- 1.2.2 Legal framework for the management of radioactive waste produced by activities governed by the Public Health Code
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1.3 Long-term management of waste – existing or projected disposal facilities

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2

Nuclear safety in waste management support facilities, role of ASN and waste management strategies of the major nuclear licensees p. 385**2.1 Radioactive waste management methods and their oversight by ASN**

- 2.1.1 The graded approach
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3

Management of mining residues and mining waste rock from former uranium mines p. 389

4

Management of sites and soils contaminated by radioactive substances p. 390



This chapter presents the role and actions of ASN, the French Nuclear Safety Authority, in the management of radioactive waste and the management of sites and soils contaminated by radioactive substances. It describes in particular the actions taken to define and set the broad guidelines for radioactive waste management. According to the Environment Code, radioactive wastes are radioactive substances for which no subsequent use is planned or envisaged or which have been reclassified as such by the Minister responsible for energy. The waste comes from activities involving artificial or natural radioactive substances (nuclear installations, the medical or research sectors, contaminated sites and soils, etc.).

ASN has competence for the management of contaminated sites and soils linked to the Basic Nuclear Installations (BNIs). For the other radiological contamination situations, ASN may, at the request of the competent authorities, issue an opinion regarding their management procedures. ASN notably ensures that the waste resulting from contaminated site clean-up operations is directed to appropriate management routes.

In March 2024, ASN called upon the Advisory Committee for Waste (GPD) to conduct an expert assessment, assisted by members of the Advisory Committees for Laboratories and Plants (GPU) and for Radiation Protection of Workers, the Public, Patients and the Environment (GPRP), of the application file for authorisation to create "Cigéo", the reversible deep geological disposal facility for high-level long-lived waste (HLW-LL) and intermediate-level long-lived waste (ILW-LL). This file, submitted on 16 January 2023 by Andra, the French National Agency for Radioactive Waste Management, is reviewed and assessed along three thematic lines: the basic data adopted for the Cigéo safety assessment, the safety of the surface and underground installations during the operational phase, and the long-term safety after closure. The GPD met for this purpose in April and December 2024 and will meet again a third and last time in mid-2025 to examine this file.

1 — Radioactive waste

Pursuant to the provisions of the Environment Code, the producers of spent fuel and radioactive waste are responsible for these substances, without prejudice to the liability of those who hold these substances in their role as persons or entities responsible for nuclear activities. Radioactive waste must be managed in accordance with specific procedures. Waste producers must pursue the objective of minimising the volume and harmfulness of their waste, both before production by appropriate design and operation of the facilities, and after production by appropriate sorting, treatment and packaging.

The types of radioactive waste differ widely in their radioactivity (specific activity, nature of the radiation, half-life) and their form (scrap metal, rubble, oils, etc.).

Two main parameters can be used to assess the radiological risk that radioactive waste represents: firstly the activity,

which contributes to the toxicity of the waste, and secondly the half-life of the radionuclides present in the waste which determines the required waste containment time. A distinction is therefore made between very low, low, intermediate and high-level waste on the one hand and, on the other hand, very short-lived waste (whose activity level is halved in less than 100 days) resulting mainly from medical activities, short-lived waste (chiefly containing radionuclides whose activity level is halved in less than 31 years) and long-lived waste (which contains a large quantity of radionuclides whose activity level is halved in more than 31 years).

Each type of waste requires the implementation of an appropriate and safe management solution in order to control the risks it represents, particularly the radiological risk but also risks linked to its chemical composition.

1.1 Management of radioactive waste (with the exception of mining tailings and waste rock)

Defined in Article L. 542-1-1 of the Environment Code, the management of radioactive waste comprises all the activities associated with the handling, preliminary treatment, treatment, packaging, storage and disposal of radioactive waste, excluding off-site transportation.

ASN oversees the activities associated with the management of radioactive waste from BNIs or small-scale nuclear activities, other than those linked to national defence which are overseen by the Defence Nuclear Safety Authority (ASND) and those relative to Installations Classified for Protection of the Environment (ICPEs), which are placed under the oversight of the Prefects.

TABLE 1 Classification of radioactive waste⁽¹⁾

		Very short lived waste, containing radionuclides with a half-life < 100 days	Short lived waste, in which the radioactivity comes mainly from radionuclides with a half-life ≤ 31 years	Long lived waste, containing mainly radionuclides with a half-life > 31 years
0 Bq/g ^(*)	Very low-level (VLL)	Management by radioactive decay on production site then disposal via disposal routes dedicated to conventional waste	Recycling or dedicated above-ground disposal (disposal facility of the industrial centre for collection, storage and disposal – Cires – in the Aube département)	
HUNDREDS Bq/g ^(*)	Low-level (LL)		Surface disposal (Aube waste disposal repository)	Near-surface disposal (being studied pursuant to the Act of 28 June 2006)
MILLIONS Bq/g ^(*)	Intermediate-level (IL)			
BILLIONS Bq/g ^(*)	High-level (HL)	Not applicable ^(**)	Deep geological disposal (planned pursuant to the Act of 28 June 2006)	

* Becquerel per gram (Bq/g).

** There is no such thing as high level, very short-lived waste.

1.1.1 Management of radioactive waste in Basic Nuclear Installations

Two economic sectors are the major contributors to the production of radioactive waste in BNIs.

The nuclear power sector for its part comprises the 18 Nuclear Power Plants (NPPs) operated by EDF, and the plants dedicated to the fabrication and reprocessing of nuclear fuel operated by Orano and Framatome. Operation of the NPPs generates spent fuel, part of which is reprocessed to separate the recyclable substances from the fission products or minor actinides which are waste. Radioactive waste is also produced during the operational and maintenance activities in the NPPs and the fuel reprocessing plants, like the structural waste, the hulls and end-pieces constituting the nuclear fuel cladding, the technological waste, and the waste from the treatment of effluents such as bituminised sludge. Furthermore, decommissioning of the facilities produces a large volume of radioactive waste.

The research sector for its part includes civil nuclear research, in particular the laboratory and reactor in research activities of the Alternative Energies and Atomic Energy Commission (CEA), but also other research organisations. Radioactive waste is produced during the operation, maintenance and decommissioning of these facilities.

This radioactive waste is managed in accordance with specific provisions which take into account its radiological nature and are proportionate to the potential danger it represents.

1.1.2 Management of waste from small-scale nuclear activities governed by the Public Health Code

The issues and challenges

The use of unsealed sources⁽²⁾ in nuclear medicine, biomedical or industrial research creates solid and liquid waste: small laboratory items used to prepare sources, medical equipment used to administer injections for diagnostic or therapeutic purposes, etc. Radioactive liquid effluents also come from source preparation as well as from patients who eliminate the administered radioactivity by natural routes.

The diversity of waste from small-scale nuclear activities, the large number of establishments producing it and the radiation protection issues involved, have led the public authorities to plan for specific provisions for managing the waste produced by these activities.

Management of disused sealed sources considered as waste

Sealed radioactive sources⁽³⁾ are used for medical, industrial, research and veterinary applications (see chapters 7 and 8). Once they have been used, and if their suppliers do not envisage their reuse in any way, they are considered to be radioactive waste and must be managed as such.

The management of sealed sources considered as waste, and their disposal in

particular, must take into consideration both their concentrated activity and their potential attractiveness in the event of human intrusion after loss of the memory of a disposal facility at the end of its monitoring and surveillance phase after closure. These two factors therefore limit the types of sources that can be accepted in disposal facilities, especially surface facilities.

1.1.3 Management of waste containing natural radioactivity

Some professional activities using raw materials which naturally contain radionuclides, but which are not used for their radioactive properties, may lead to an increase in specific activity in the products, residues or waste they produce. The term “Naturally Occurring Radioactive Material” (NORM) is used when its activity exceeds the exemption thresholds figuring in Table 1 of Appendix 13-8 of the Public Health Code (for example the treatment of rare earths, the production of phosphate fertilizers and phosphoric acid, the combustion of coal in thermal power plants, etc.). NORM waste, for which there is no planned or envisaged use, is therefore considered to be radioactive waste within the meaning of Article L. 542-1-1 of the Environment Code. Waste containing radioactive substances of natural origin but which do not exceed the abovementioned exemption thresholds is directed to conventional waste management routes.

NORM waste can be stored in two types of facility depending on its specific activity:

- in a waste disposal facility authorised by Prefectural Order, if the acceptance

1. Appendix 1 of the Order of 9 October 2008 amended relative to the nature of the information that the entities responsible for nuclear activities and the companies mentioned in Article L. 1333-10 of the Public Health Code are obliged to establish, keep up to date and periodically communicate to Andra.

2. Source for which the presentation and the normal conditions of use are unable to prevent all dispersion of the radioactive substance.

3. Source for which the structure or packaging prevents all dispersion of radioactive substances into the ambient environment, in normal use.

conditions stipulated in the Circular of 25 July 2006⁴) relative to waste disposal facilities, coming under sections 2760 of the ICPE classification are satisfied;

- in Cires⁵) (Industrial centre for grouping, storage and disposal) intended for the disposal of very low-level radioactive waste (VLLW).

Some of this waste is however stored while waiting for a disposal route, in particular the commissioning of a disposal centre for low-level long-lived waste (LLW-LL).

Four hazardous waste disposal facilities are authorised by Prefectural Order to receive waste containing NORMs.

Furthermore, following the entry into effect on 1 July 2018 of Decree 2018-434 of 4 June 2018 introducing various provisions with regard to nuclear activities, the provisions of the Labour Code relative to the protection of workers against ionising radiation also apply to professional activities involving materials that naturally contain radioactive substances, which include the NORMs.

1.2 Legal framework for radioactive waste management

The management of radioactive waste comes under the general waste management framework defined in Chapter I or Title IV of Book V of the Environment Code and by its implementation decrees. Particular provisions relative to radioactive waste were introduced first by Act 91-1381 of 30 December 1991 on research into the management of radioactive waste, then by Planning Act 2006-739 of 28 June 2006 on the sustainable management of radioactive materials and waste called the “Waste Act”, which gives a legislative framework for the management of all radioactive materials and waste. A large proportion of the provisions of these Acts are codified in Chapter II of Title IV of Book V of the Environment Code.

The Act of 28 June 2006 more specifically sets a calendar for research into HLW and ILW-LL waste and a clear legal framework for ring-fencing the funds needed for decommissioning and for the management of radioactive waste. It also provides for the development of a National Radioactive Materials and Waste Management Plan (PNGMDR), which aims to conduct periodic situation assessments and define the perspectives of the radioactive waste and materials management policy. It also reinforces the duties of Andra, notably by entrusting it with a public service duty for managing the waste arising from small-scale nuclear activities. Finally, it

prohibits the disposal in France of foreign waste by providing for the adoption of rules specifying the conditions for the return of waste resulting from the reprocessing in France of spent fuel and waste from abroad. These rules provide for the returned reprocessed waste to be allocated according to the activity and mass of spent fuel introduced into France.

However, subject to certain conditions and the opinion of ASN, regulatory provisions introduced in 2017 and 2021 allow waiving of the conditions of allocation of the waste returned to the originating foreign countries by carrying out waste exchanges applying a system of equivalence. Recourse to a system of equivalence (by weight and radiological activity of the waste) was thus authorised by the Minister responsible for energy for the waste intended to be returned to Germany (Metall+ operation) in 2021 and for waste intended to be returned to Japan (CREATES Alternative operation) in 2024.

This framework was amended in 2016 with the publication of Ordinance 2016-128 of 10 February 2016 introducing various provisions with regard to nuclear activities which made it possible to:

- transpose Council Directive 2011/70/Euratom of 19 July 2011 establishing a European community framework for the responsible and safe management of spent fuel and radioactive waste, while reasserting the prohibition on the disposal in France of radioactive waste from foreign countries and of radioactive waste resulting from the reprocessing of spent fuel and the treatment of radioactive waste from abroad, and detailing the conditions of application of this prohibition;
- define a procedure for the administrative authority to requalify materials as radioactive waste;
- reinforce the existing administrative and penal enforcement actions and provide for new enforcement actions in the event of failure to comply with the provisions applicable to the management of radioactive waste and spent fuel.

The conditions for creating a reversible deep geological repository for HLW and ILW-LL radioactive waste are detailed in Act 2016-1015 of 25 July 2016.

1.2.1 Legal framework for the management of radioactive waste produced in Basic Nuclear Installations

In France, the management of radioactive waste in BNIs is governed in particular by the Order of 7 February 2012 setting the general rules relative to BNIs, of which Title VI concerns waste management.

BNI licensees establish a waste zoning plan which identifies the zones in which the waste produced is or could be contaminated or activated. As a protective measure, the waste produced in these zones is managed as if it was radioactive and must be directed to dedicated routes. This absence of release thresholds for waste coming from a zone in which the waste is or could be contaminated or activated, constitutes a particularity of the French regulations. The “release thresholds” applied in some foreign countries determine the contamination levels below which the materials can be exempted from any form of control and used without any restrictions. Waste from other areas, once confirmed as being free of radioactivity, is sent to authorised routes for the management of hazardous, non-hazardous or inert waste, depending on its properties.

The French regulations also oblige nuclear licensees to present, in the General Operating Rules (RGEs) and the environmental impact assessment of their facility, the wastes produced by the facility, whether radioactive or not, indicating the volumes, types, harmfulness and the envisaged disposal routes. The measures adopted by the licensees must consist in reducing, through recycling and treatment processes, the volume and the radiological, chemical or biological toxicity of the waste produced so that only the ultimate waste has to go to final disposal.

ASN resolution 2015-DC-0508 of 21 April 2015 details the provisions of the Order of 7 February 2012, particularly concerning:

- the procedures for drawing up and managing the waste zoning plan;
- the content of the annual waste management assessment each BNI must transmit to ASN.

ASN Guide No. 23 presents the conditions of application of this resolution with regard to the drawing up and modification of the waste zoning plan.

Further to a modification of the regulatory requirements of the Environment Code in 2019, the waste management study is no longer required as a specific document. The provisions it contained must now be carried over to the environmental impact assessment and the BNI RGEs. ASN resolution 2022-DC-0749 of 29 November 2022, approved on 16 February 2023, amended ASN resolution 2015-DC-0508 of 21 April 2015 to take into account this regulatory change.

4. Circular of 25 July 2006 relative to classified installations – Acceptance of technologically enhanced or concentrated natural radioactivity in the waste disposal centres.

5. French acronym standing for «Industrial centre for grouping, storage and disposal», name given in October 2012. It was originally commissioned in 2003 under the name CSTFA, standing for “Very low level waste disposal facility”. Installation subject to licensing under the System of section 2797 of the ICPEs.

The role of ASN in waste management



The public authorities, and ASN in particular, are attentive to the fact that there must be a management route for all waste and that each waste management step is carried out under safe conditions.

ASN thus considers that the development of management routes appropriate to each waste category is fundamental and that any delay in the search for long-term waste disposal solutions will increase the volume and size of the storage areas in the facilities and the inherent risks.

ASN takes care, particularly within the framework of the PNGMDR but also by inspecting the installations and regularly assessing the licensees' waste management strategy, to ensure that the system made up by all these routes is complete, safe and coherent. This approach must take into consideration all the issues of safety, radiation protection, minimising waste volume and toxicity, while ensuring satisfactory traceability of the operations performed.

Finally, ASN considers that this management approach must be conducted in a manner that is transparent for the public and involves all the stakeholders, in a framework that fosters the expression of different opinions.

The PNGMDR is drawn up by the Ministry which at the time was called the Ministry of Energy Transition (MTE). The Ministry has opted, in the light of the public debate of 2019, to rely on a pluralistic "Guidance Commission", in which ASN participates. This Commission is chaired by an independent qualified person. Monitoring of the technical and operational implementation of the PNGMDR is still ensured by a pluralistic working group co-chaired by ASN and the General Directorate for Energy and the Climate (DGEC), as described in chapter 2.

On its website, ASN also publishes the PNGMDR, its summary, the minutes of the abovementioned working group's meetings, the studies required by the Plan and the opinions it has issued on these studies.

and storage of waste from "small producers" that are not in the nuclear power sector. ASN considers that Andra's actions in this area are appropriate to fulfil its mission assigned under the abovementioned Article L. 542-12 and that they must be continued.

In its opinion 2021-AV-0379 of 11 May 2021, ASN recommends that Andra deploys, as soon as possible, the necessary storage capacities to allow the management of the highly tritiated waste and sources containing tritium coming from small producers. Articles 45 to 47 of the Order of 9 December 2022 provide for continuation of the work undertaken by Andra to identify and define management routes for this waste by 31 December 2025.

1.2.3 The National Inventory of radioactive materials and waste

Article L. 542-12 of the Environment Code assigns Andra the task of establishing, updating every five years and publishing the National Inventory of radioactive materials and waste. This Inventory constitutes an input database for preparing the PNGMDR. The last update was published in December 2023. The Inventory presents information concerning the quantities, the nature and the location of radioactive material and waste by category and economic sector as at the end of 2021. A prospective exercise was also conducted considering four contrasting scenarios for France's energy policy, as envisaged in the 2019-2028 Multi-Year Energy Plan (PPE).

1.2.4 The National Radioactive Materials and Waste Management Plan

Article L. 542-1-2 of the Environment Code defines the PNGMDR's objectives:

- draw up the inventory of the existing radioactive material and waste management methods and the chosen technical solutions;
- identify the foreseeable needs for storage or disposal facilities and specify their required capacities and the storage durations;
- set the general targets, the main deadlines and the schedules enabling these deadlines to be met while taking into account the priorities it defines;
- determine the objectives to be met for radioactive waste for which there is as yet no final management solution;
- organise research and studies into the management of radioactive materials and wastes, by setting deadlines for the implementation of new management modes, the creation of facilities or the modification of existing facilities.

1.2.2 Legal framework for the management of radioactive waste produced by activities governed by the Public Health Code

Article R. 1333-16⁽⁶⁾ of the Public Health Code states that the management of effluents and waste contaminated by radioactive substances originating from all nuclear activities involving a risk of exposure to ionising radiation must be examined and approved by the public authorities. This is the case in particular for activities using radioactive substances intended for medicine, human biology or biomedical research.

ASN resolution 2008-DC-0095 of 29 January 2008 lays out the technical rules applicable for the disposal of effluents and waste contaminated or potentially contaminated by radionuclides owing to a nuclear activity. ASN published a guide (Guide No. 18) to the application of this resolution in January 2012.

Management of disused sealed sources

Under the PNGMDR 2016-2018, Andra submitted a report in mid-2018 presenting a review of the situation regarding the acceptance of disused sealed sources considered as waste in the existing and planned disposal facilities.

Furthermore, Decree 2015-231 of 27 February 2015 enables holders of disused sealed sources to call upon not only the initial source supplier but also any licensed supplier or – as a last resort – Andra, to manage these sources. The holders are moreover no longer obliged to

provide proof that they have contacted all the suppliers before turning to Andra. These provisions aimed to bring a reduction in the costs of collecting disused sources and provide a recovery route in all situations. ASN issued a position statement on 11 May 2021 on the management of disused sealed sources that could not be recycled. It considers that disused sealed sources which cannot be accepted in above-ground disposal facilities must be included in the inventories of projected disposal facilities, and that a complete inventory of the existing management routes must be established, indicating the responsibilities of the various actors.

Moreover, ASN recommends that the notion of "last resort" mentioned in Decree 2015-231 must be clarified. The "DECPAR.4" action of the PNGMDR 2022-2026 states that the producers produce an inventory of sealed sources with ownership issues and that a programme of work must be drawn up with Andra to develop management solutions. The volume of sealed sources pending acceptance in a final management solution was introduced as a new monitoring indicator in the PNGMDR 2022-2026.

Management by Andra of waste from small-scale nuclear activities

Article L. 542-12 of the Environment Code entrusts Andra with a public service mission for the management of waste produced by small-scale nuclear activities. Since 2012, Andra operates Cires, a facility situated in the municipalities of Morvilliers and La Chaise in the Aube *département*, designed for the collection

6. Former Article R. 1333-12.

In view of the conclusions of the public debate of 2019, ASN and the DGECC have decided to change the governance of the PNGMDR. The 5th edition was prepared by the MTE, based in particular on the work of a “Guidelines Commission”. Introduced by the resolution of 21 February 2020, this Commission is chaired by an independent qualified personality and brings together, in addition to the legacy members of the pluralistic working group mentioned in chapter 2, elected officials and representatives of the regional authorities. This Commission gave opinions on various major subjects relating to the management of radioactive waste (management of VLL/LLW-LL waste, management of radioactive materials, etc.). ASN participates actively in the Guidelines Commission – albeit without voting rights – to provide its guidance on the safety and radiation protection issues.

Implementation of the plan is followed up at periodic meetings of the PNGMDR working group jointly chaired by ASN and the DGECC. The PNGMDR working group met three times in 2024.

In 2020 and 2021, ASN moreover assessed the studies submitted within the framework of the PNGMDR 2016-2018. For the preparation of the 5th PNGMDR, ASN has thus issued seven opinions on the radioactive material and waste management routes in which it sets out a number of recommendations. In addition, on 9 November 2021, ASN issued a favourable opinion for the 5th PNGMDR, on condition that it is supplemented with a study of worst-case operating scenarios for the “fuel cycle”, an assessment of the impact on the nuclear facilities of continuing the reprocessing of spent fuel beyond 2040 or not, the inclusion of measures relative to the safety of HL/ILW-LL waste management and the management of waste necessitating specific work, such as tritiated waste, and better assessing the recyclability of certain radioactive materials.

Lastly, on 23 June 2022 ASN issued a favourable opinion on the draft Decree and Order establishing the requirements of the 5th PNGMDR, subject to the integration of the modifications proposed in this opinion.

These texts and the 5th PNGMDR covering the 2022-2026 period were published on 9 December 2022.

On 3 December 2024, the Minister responsible for energy called upon the National Commission for Public Debate (CNDP) to organize a public debate concerning the drafting of the 6th PNGMDR for the 2027-2031 period. Further to the deliberations of its members during the plenary session of Wednesday 11 December 2024, in view of the national issues concerning the environment, land-use planning and social and economic issues, the CNDP has decided to organise such a public debate in 2025.

The French Authority for Nuclear Safety and Radiation Protection (ASNR) plans made a position statement in early 2025 prior to the preparation of the 6th PNGMDR.

1.3 Long-term management of waste – existing or projected disposal facilities

1.3.1 Very low-level waste

Very low-level waste (VLLW) comes essentially from the operation, maintenance and decommissioning of nuclear facilities. It consists mainly of inert waste (rubble, earth, sand) and metal waste. Its specific activity is usually less than 100 Bq/g and can even be below the detection threshold of certain measuring devices.

The Cires includes a VLL waste disposal facility. This facility, which has ICPE status, has been operational since August 2003.

At end of 2023, Cires held about 459,000 m³ of VLL waste, which represents 48% of its authorised regulatory capacity. According to the national inventory produced by Andra, the quantity of VLL waste resulting from decommissioning of the existing nuclear facilities will be about 2,200,000 m³. According to current forecasts, the centre could be filled to maximum capacity by 2045. In April 2023, Andra submitted a request to increase the authorised capacity of this disposal facility to 950,000 m³ (Acaci project), on the same surface area (as opposed to the 650,000 m³ authorised at present). Andra obtained the Prefectural Order necessary for deployment of this project in July 2024.

In its opinion 2020-AV-0356 of 30 June 2020 on the management of VLL waste, ASN calls for the continuation and extension of the work undertaken in the 2016-2018 edition of the PNGMDR with the aim of improving current management methods and developing complementary management solutions which remain to be devised and implemented.

ASN reaffirms that, as a general rule, VLL waste management must continue to be based on the place of origin of the waste and guarantee its traceability, thanks to specific routes, from production through to disposal, with the exception of metallic VLL waste that is to be recycled, as stated in the resolution of 21 February 2020.

The recycling of certain types of waste which will be produced in large volumes is encouraged, consistently with the waste management hierarchy defined in the Environment Code. ASN recommends in particular the continuation of the metallic materials recycling facility project, with the setting up of a specific framework for the oversight of this facility. In 2021, the Government worked on setting up this

regulatory framework. In its opinion 2021-AV-0380 of 11 May 2021, ASN expressed its views on the draft regulations. In February 2022, the Government published the regulatory framework for issuing waivers to authorise the recycling of weakly radioactive metal substances after melting and decontamination. Such a waiver will be granted by ministerial order after consulting the public and obtaining ASN’s opinion. In this context, EDF plans building and operating a facility for recycling VLL metals baptised “Technocentre” on the site of the Fessenheim NPP currently being decommissioned. This facility will have ICPE status. A public debate on this EDF project was held between October 2024 and February 2025, with submission of the construction application planned in 2025.

ASN considers it necessary for all the stakeholders, particularly the representatives of the regions concerned or likely to be concerned, to be more closely involved in the defining of the VLL waste management solutions.

It recommends that the studies for putting in place additional disposal facilities, whether centralised or decentralised, be continued and that the government should clarify Andra’s responsibility in this respect.

Consistently with the abovementioned ASN opinion, the 5th PNGMDR contains the following objectives concerning the management of VLL waste:

- continue the studies aiming to deploy new centralised and decentralised storage capacities for VLL waste;
- continue looking into the recycling of VLL waste, particularly defining the conditions of implementation of metallic waste recycling;
- define VLL waste management scenarios, cast light upon their environmental, regional, health and safety issues, and use this to establish an overall management strategy;
- refine the perspectives for the production of VLL waste from the decommissioning of the nuclear installations, by explicitly identifying the waste associated with the clean-out of structures and contaminated soils.

1.3.2 Low and intermediate-level, short-lived waste

Low-level and intermediate-level short-lived waste (LL/ILW-SL) - in which the radioactivity comes primarily from radionuclides with a half-life of less than 31 years – results essentially from the operation of nuclear facilities and more specifically from maintenance activities (clothing, tools, filters, etc.). It can also come from the post-operational clean-out and decommissioning of these facilities. The majority of LL/ILW-SL waste is placed in surface disposal facilities operated by Andra. Once these facilities are closed,

they will be monitored for a period set at 300 years by Basic Safety Rule RFS-I.2. The facility safety analysis reports – which are updated periodically, including during the monitoring phase – must show that at the end of this phase, the activity contained in the waste will have reached a residual level such that human and environmental exposure levels are acceptable, even in the event of a significant loss of the containment properties of the facility. There are two facilities of this type in France, the Manche repository (CSM – BNI 66), which operated from 1969 until 1994 and is currently in the closure preparation phase, and the Aube repository (CSA – BNI 149) which is in operation (*see “Regional overview” in the introduction to this report*).

The quantity of LL/ILW-SL waste emplaced in the CSA repository totalled 372,000 m³ at the end of 2023, which represents 37% of the facility’s maximum authorised capacity. Added to this quantity is the waste emplaced in the CSM, which totals 527,225 m³. The total quantity of LL/ILW-SL waste emplaced in the Andra facilities is therefore about 899,000 m³, to be compared with the quantity of 989,000 m³ produced at the end of 2022. According to the data of the national inventory drawn up by Andra, this waste will represent a maximum volume of 2,000,000 m³ on completion of decommissioning of the existing facilities. According to the estimates made by Andra in 2016 at the time of the second periodic safety review of the CSA, this facility could reach its maximum filling capacity by 2060 instead of 2042 as initially forecast, this new estimate being based on better knowledge of the future waste and the waste delivery schedules.

1.3.3 Low-level long-lived waste

Low-level long-lived waste (LLW-LL) waste initially comprised two main types: graphite waste resulting from operation of the Gas-Cooled Reactors (GCRs) and radium-bearing waste from the radium industry and its offshoots. Other types of waste have been added to this category such as certain bituminised wastes, substances containing radium, uranium and thorium with low specific activity, as well as certain disused sealed radioactive sources.

Furthermore, a fraction of the waste from the Écrin facility (BNI 175) operated by Orano in Malvesi (Aude *département*) produced as from 1 January 2019 is now included in this waste category. The solid waste produced until 31 December 2018, on account of the large volumes it represents, is placed in a specific category of the national inventory called RTCU (French acronym standing for “Uranium Fuel Reprocessing Residues”).

Putting in place a definitive management solution for this type of waste is one of the objectives defined by the Act of 28 June 2006. Finding such a management solution necessitates firstly having greater knowledge of LLW-LL waste and

secondly conducting safety studies on the associated disposal solution. The successive PNGMDRs have set out this objective. ASN also published a notice in 2008 giving general safety guidelines concerning the search for a site capable of accommodating LLW-LL. This notice defines the general guidelines to follow as from the phases of looking for a site and designing an LLW-LL waste disposal facility in order to ensure its safety after closure.

The PNGMDR 2010-2012 opened up the possibility of separate disposal of graphite waste and radium-containing waste, and asked Andra to work on the two design options:

- reworked cover disposal in an out-cropping geological layer by excavation followed by backfilling;
- intact cover disposal dug in an underground layer of clay at a greater depth.

Implementation of the requirements of the PNGMDR 2013-2015 enabled the holders of LLW-LL waste to move forward with characterising their waste and studying the treatment possibilities, particularly as concerns the graphite wastes and certain bituminous waste packages. More specifically, the radiological inventory for chlorine-36 and iodine-129 has undergone a downward reassessment. Alongside this, Andra submitted a report in July 2015 containing:

- proposals of choices of management scenarios for graphite waste and bituminous waste;
- preliminary design studies covering the disposal options referred to as “intact cover disposal” and “reworked cover disposal”;
- the inventory of the waste to be emplaced in it and the implementation schedule.

In 2016, ASN issued an opinion 2016-AV-264 on this report and began a revision of the general safety guidelines notice of 2008, which will ultimately be replaced by an ASN guide. To this end, a working group bringing together ASN, the French Institute for Radiation Protection and Nuclear Safety (IRSN), Andra, the LLW-LL waste producers and representatives of civil society was set up. The recommendations of the IRSN report published in December 2020 and summarising the work were examined by Advisory Committees of Experts (GPEs) in March 2021. On this basis, ASN began technical discussions with Andra and IRSN in 2021, focusing in particular on the assessment of the long-term dosimetric impact of the disposal project.

In 2011, Orano submitted (as part of the PNGMDR 2013-2015 preparatory work) a study concerning the long-term management of the waste already produced by the Malvesi site (baptised “RTCU”), currently stored in the Écrin facility (BNI 175). Various disposal concepts are considered.

- above-ground disposal;
- near-surface (40 m), reworked cover disposal, in the former open-cast mine pit;
- near-surface (40 m) reworked cover disposal, in a new pit.

Given the nature of the waste and the configuration of the site, ASN indicated in its opinion 2012-AV-0166 of 4 October 2012 that it is not in favour of continuing the development of a surface disposal facility, as it considers that it does not meet the long-term safety requirements. Orano has now abandoned this option.

In 2021, pursuant to Article 7 of the Decree of 20 July 2015 authorising the creation of BNI 175 Écrin, Orano sent ASN a report presenting the progress of the studies and investigations carried out. Two disposal options considered for the radioactive waste on the Malvesi site and its immediate environment are being studied. ASN sent its observations concerning this report to Orano in 2024, to be taken into account in the preparation of the next progress report which will be submitted in 2025.

ASN opinion 2020-AV-0357 of 6 August 2020 details the areas of work it recommends for the management of LLW-LL waste. On the basis of this opinion, the 2022-2026 edition of the PNGMDR comprises actions aiming to:

- enhance the reliability of the inventories (by including the legacy RTCU waste stored in Écrin) and the characteristics of the LLW-LL waste;
- clarify the saturation time-lines for the LLW-LL storage capacities;
- define LLW-LL waste management scenarios and evaluate their advantages and drawbacks;
- by involving the representatives of the localities actually or liable to be concerned, continue studies on an RTCU disposal facility.

Pursuant to the Order of 9 December 2022 issued in application of Decree 2022-1547 of 9 December 2022, Andra transmitted a technical and Safety Options Dossier (DOS) in 2024 presenting an assessment of the feasibility of near-surface disposal of low-level long-lived waste on the site of the Municipal Federation of Vendeuve-Soulaines (CCVS), and a project for an industrial scheme for the management of LLW-LL waste presenting the different existing and future management options. These elements will serve in particular as a work basis for a working group set up in early 2025 under the LLW-LL.2 action (“FAVL.2” in French) of the PNGMDR 2022-2026, which will examine the various management options for LLW-LL waste.

1.3.4 High-level and intermediate-level, long-lived waste

Following on from the Act of 30 December 1991, the Act of 28 June 2006 provides for the research into the management of HLW and ILW-LL radioactive waste to be continued along three complementary lines: separation and transmutation of the long-lived radionuclides, interim storage and reversible deep geological disposal.

Separation/transmutation

The report of the Special Public Debates Commission (CPDP) of 25 November 2019 concerning the public debate prior to the 5th edition of the PNGMDR concludes in particular that *"there are two options, each one defended by a certain number of the actors: deep geological disposal and interim sub-surface storage for a sufficient length of time to allow progress to be made in transmutation research in order to reduce the radioactivity of the waste."*

Separation/transmutation processes aim to isolate and then transform the long-lived radionuclides in radioactive waste into shorter-lived radionuclides or even stable elements. The transmutation of the minor actinides contained in the waste would have an impact on the size of the disposal facility, by reducing both the heating power, the harmfulness of the packages placed in it and the repository inventory. Despite this however, the impact of the disposal facility on the biosphere, which originates essentially from the mobility of the radionuclides contained in the fission and activation products, would not be significantly reduced.

In its opinion 2020-AV-0369 of 1 December 2020, ASN points out that the prospects of industrial-scale transmutation of the already packaged waste of the Cigéo reference inventory are not credible. It considers that, although transmutation studies should be continued, they should concern radioactive substances currently qualified as materials or the waste produced by a future fleet of reactors and that they should be carried out with a view to developing complete solutions, including the disposal of the waste resulting from transmutation and offering a high level of safety.

Storage

The second line of research and studies in the Act of 28 June 2006 concerns the storage of waste.

The long-term storage of high-level long-lived waste (HLW-LL), which was one of the lines of research provided for in the Act of 30 December 1991, has not been retained as a definitive management solution for this type of radioactive waste. Storage facilities are nevertheless indispensable pending commissioning of the deep geological disposal facility, to allow the cooling of certain types of waste and then to accompany the industrial operation of the disposal facility, which will develop in stages. Furthermore, if operations to remove emplaced packages were to be decided on in the context of the reversibility of the repository, storage facilities would be needed. Reception of the first radioactive waste packages for deep geological disposal is now scheduled for around 2040.

The Act of 28 June 2006 tasked Andra with coordinating the research and studies on the storage of HL and ILW-LL waste, which are therefore part of the approach of complementarity with the reversible repository. This Act stipulated more specifically

that the research and studies on storage should, by 2015 at the latest, allow new storage facilities to be created or existing facilities to be modified to meet the needs identified by the PNGMDR, particularly in terms of capacity and duration.

Progress in storage

In 2013, Andra submitted a report on the research and studies carried out. This report more particularly presented the established inventory of future storage needs, the exploration of the complementarity between storage and disposal, studies and research on engineering and on the phenomenological behaviour of the warehouses and a review of innovative technical options.

From 2013 to 2015, Andra furthered the study into storage concepts linked to repository reversibility. This concerns facilities which, if necessary, would accept packages removed from the repository. For such facilities, Andra looked for versatility which would allow simultaneous or successive storage of packages of various types in their primary form or placed in disposal overpacks. In the study it submitted in 2013, Andra stated that it had stopped its research into near-surface storage facilities. It justified abandoning this research in particular because of the greater complexity of this type of facility (consideration of the presence of underground water and the need for ventilation if exothermal waste was emplaced, surveillance of the civil engineering structures) and the lower operating flexibility. The multi-criteria analysis submitted in 2018 did not call into question these conclusions.

In the light of industrial experience, research and its studies, Andra issued recommendations in 2014 for the design of future storage facilities that are complementary to disposal. They concern more specifically the service life of the facilities (up to about a hundred years), their monitoring and surveillance and their modularity. Orano has integrated some of the recommendations in the design of the extension of the glass storage facilities at La Hague (E/EV-LH) intended for HLW waste and situated in the UP3-A plant (BNI 116). This extension comprises three pits: 30, 40 and 50, commissioned in 2015, 2017 and 2022 respectively.

Within the framework of the PNGMDR 2013-2015, and after presenting the inventory of HLW and ILW-LL waste packages intended for Cigéo at the end of 2013, and the status of the existing storage locations, the producers more specifically analysed the fundamental elements enabling waste package storage needs to be identified.

The work carried out under the PNGMDR 2016-2018

The studies required by the PNGMDR 2016-2018 focus on the analysis of the storage needs for HL and ILW-LL waste packages and take up the broad lines of the ASN opinion of 25 February 2016.

Article D. 542-79 of the Environment Code, introduced by the Decree of 23 February 2017 relative to the provisions of the PNGMDR 2016-2018, stipulates that the holders of spent fuel and HL and ILW-LL radioactive waste must keep up to date the availability status of the storage capacities for these substances by waste category and identify the future storage capacity needs for the next twenty years at least.

The CEA, EDF and Orano have defined the future storage needs for all families of HL and ILW-LL waste, until 2040. The CEA, EDF and Orano have also studied, within this context, how sensitive the storage needs are to shifts in the Cigéo schedule.

In its opinion 2020-AV-0369 of 1 December 2020, ASN estimates in this respect that the dates of saturation of the existing storage capacities and the future storage needs until 2040 have on the whole been well identified by the producers.

Nevertheless, the storage capacity estimates must be consolidated by all the waste producers, incorporating margins to cope with any contingencies affecting the waste management routes concerned and thereby be able to anticipate the needs for additional storage capacities and the corresponding licensing procedures.

Based on a comparative study of the different types of storage submitted by Andra, ASN in its opinion 2020-AV-0369 of 1 December 2020, confirmed that near-surface storage facilities have no decisive advantage in terms of nuclear safety and radiation protection over above-ground storage facilities.

The PNGMDR 2016-2018 set out several guidelines for the design of HL and ILW-LL waste storage facilities: significant design margins; simple and modular architecture favouring passive systems; definition of provisions for controlling the ambient storage conditions in normal, incident and accident situations; definition of provisions for monitoring and management of deviations as of the design stage, provisions for preserving the memory, etc.). ASN will be attentive to the integration of these recommendations in the new facilities that will be necessary pending commissioning of Cigéo.

The work carried out under the PNGMDR 2022-2026

The PNGMDR 2022-2026 comprises measures to revive discussions on credible or complementary alternatives to deep geological disposal. This approach shows an intention to explore the HL and ILW-LL waste management options more broadly, in anticipation of possible delays in the commissioning of Cigéo. A Committee for assessment and dialogue on alternatives to deep geological disposal, in which ASN is a participant, was set up in 2023 in order to provide recommendations for the next edition of the PNGMDR. This Committee met seven times in 2024 and is expected to submit its conclusions in the course of 2025.

Reversible deep geological disposal

Deep geological disposal is stipulated in Article L. 542-1-2 of the Environment Code, which states that “after storage, ultimate radioactive waste which, for nuclear safety or radiation protection reasons, cannot be disposed of on the surface or at shallow depth, shall be disposed of in a deep geological repository”.

The codified Act of 28 June 2006 assigns Andra the task of devising a project for a deep geological disposal facility which shall be a BNI and therefore, governed by this specific legal system.

The principle of this type of disposal

Deep geological disposal of radioactive waste consists in emplacing the radioactive waste in an underground facility specially designed for this purpose, complying with the principle of reversibility. The characteristics of the geological layer are intended to confine the radioactive substances contained in this waste. Such a disposal facility – unlike storage facilities – must be designed such that long-term safety is ensured passively, that is to say without depending on human actions (such as monitoring or maintenance activities) which require oversight, the durability of which cannot be guaranteed beyond a limited period of time. Lastly, the depth of the disposal structures must be such that they cannot be significantly affected by the expected external natural phenomena (erosion, climate change, earthquakes, etc.) or by human activities.

In 2008, ASN published a safety guide on the final disposal of radioactive waste in a deep geological formation (ASN Guide No. 1) which was an update of the RFS III 2 f of 1991.

The conditions for the creation of a reversible deep geological repository for HL and ILW-LL radioactive waste were specified by the codified Act of 25 July 2016, which defines the principle of reversibility, introduces the requirement for an industrial pilot phase before complete commissioning of Cigéo and brings schedule adaptations concerning the deployment of Cigéo.

This Act defines reversibility as “the ability, for successive generations, to either continue the construction and then the operation of successive sections of a disposal facility, or to reassess previous choices and change the management solutions. Reversibility is materialised by the progressive nature of the construction, the adaptability of the design and the operational flexibility of placing radioactive waste in a deep geological repository which can

integrate technological progress and adapt to possible changes in waste inventory following a change in energy policy. It includes the possibility of retrieving waste packages from the repository under conditions and over a time frame that are consistent with the strategy for operation and closure of the repository”.

In its opinion 2016-AV-0267 of 31 May 2016 relative to the reversibility of the deep geological disposal of radioactive waste, ASN had considered that the principle of reversibility implied a requirement for adaptability of the facility and retrievability of the packages during a period governed by law.

The Decree of 9 December 2022 relative to the provisions of the PNGMDR 2022-2026 details certain principles applicable to Cigéo, and more particularly those set out in Articles D. 542-91 and D. 542-92 of the Environment Code. These specify that the inventory to be adopted by Andra for the studies and research conducted for the design of the Cigéo disposal facility shall include a reference inventory and a reserve inventory. The reference inventory takes account of all HLW and ILW-LL waste already produced and to be produced by the existing nuclear facilities (nuclear power plants, research centres, etc.), as well as that to be produced by the authorised nuclear facilities (Flamanville EPR, ITER, Jules Horowitz experimental reactor), assuming an average reactor operating life of 50 years.

The reserve inventory takes into account the uncertainties associated more specifically with energy policy changes. For waste from the future reactors which are planned for construction in France (in particular the first six EPR 2), Andra shall identify the waste liable to be included in the reserve inventory and ensure that the Cigéo adaptability studies are able to accommodate this waste, but without calling into question the fundamental hypotheses of the project as set out in the Creation Authorisation Decree (DAC) application currently being reviewed (see page 384).

Underground laboratory of Meuse/Haute-Marne

Studies on deep geological disposal necessitate research and experiments in an underground laboratory. Andra has been operating such an underground laboratory within the Bure municipality since 1999.

In the context of the studies on the deep geological disposal, ASN issues recommendations concerning the research and experiments conducted in the laboratory,

and by random sampling during follow-up inspections ascertains that they are carried out using processes that guarantee the quality of the results.

Technical reviews

• Pursuant to the Act of 30 December 1991, and then pursuant to the Act of 28 June 2006 and the PNGMDR, Andra has carried out studies and submitted reports on deep geological disposal. These reports have been examined by ASN – referring in particular to the Safety Guide of 2008 – and it has issued an opinion on them.

• ASN has thus more specifically examined the reports submitted by Andra in 2005 and 2009. It issued opinions on these reports on 1 February 2006 and 26 July 2011. Andra subsequently submitted various files to ASN presenting the progress of the studies and work carried out. ASN thus issued a position statement:

- in 2013, on the documents produced between 2009 and 2013 – the year of the public debate, and on the intermediate design milestone at the outline stage presented by Andra in 2012;
- in 2014, on the safety components of the closure structures and the expected content of the DOS for the facility;
- in 2015, on the control of operating risks and the cost of the project;
- in 2016, on the components development plan;
- in 2018, on the Cigéo DOS;
- in 2022, on the seismic hazard to be considered in the design of the facility.

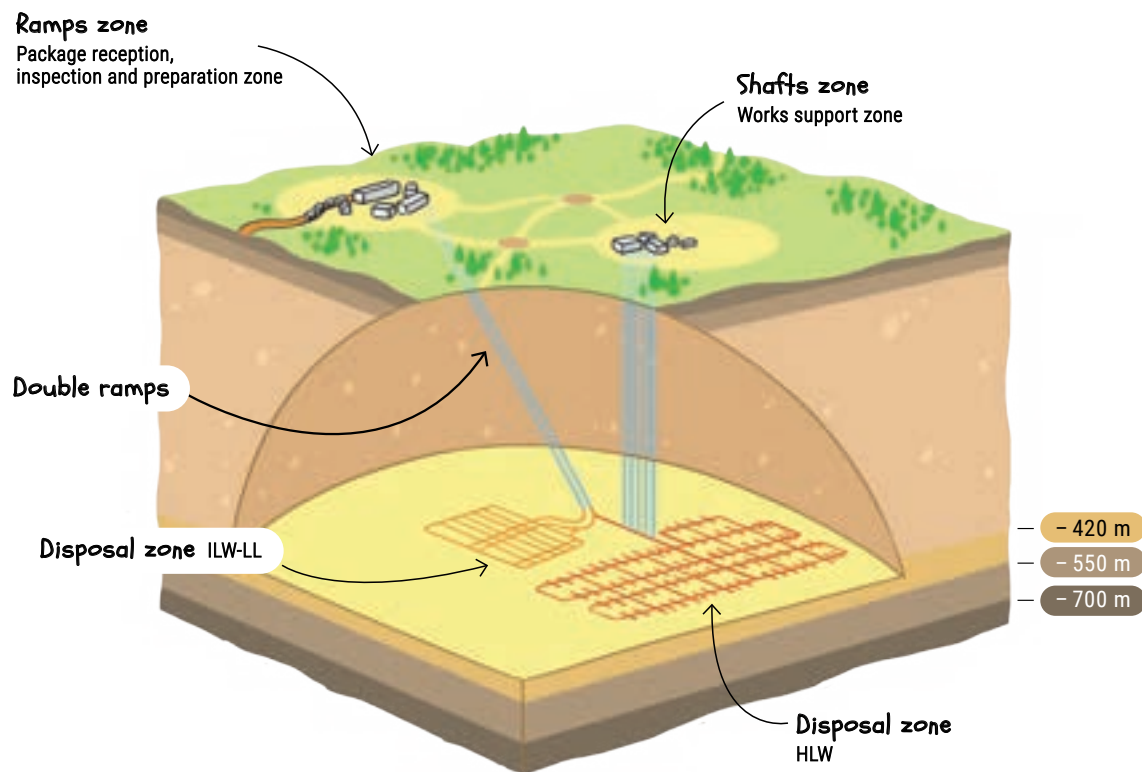
The Cigéo Safety Options Dossier

The filing of a DOS marks the start of a regulatory process⁷. ASN received the DOS for Cigéo in April 2016. At the end of the technical review phase, the ASN draft opinion underwent public consultation and ASN issued its opinion on 11 January 2018. ASN also sent a follow-up letter giving recommendations on the safety options to prevent or limit the risks and asked Andra for additional studies and justifications (corrosion phenomena, low-pH concretes, representativeness of the hydrogeological model, surveillance strategy, etc.). The demands made in this letter took account of the suggestions and comments received through the public consultation.

The examination of the Cigéo DOS highlighted several issues relating to specific aspects (architecture, definition of hazards, post-accident management, etc.). Among these issues, ASN pointed out that the management of bituminised waste required special attention.

7. Article R. 593-14 of the Environment Code stipulates that “any person planning to operate a BNI can, before initiating the creation authorisation procedure, ask ASN for an opinion on all or part of the options it has retained to ensure protection of the interests mentioned in Article L. 593-1. ASN, in an opinion issued and published in the conditions and forms determined by itself, specifies to what extent the safety options presented by the applicant are such as to prevent or limit the risks for the interests mentioned in Article L. 593-1 in view of the technical and economic conditions prevailing at the time. ASN may define the additional studies and justifications that will be required for a prospective creation authorisation application. It can set a validity period for its opinion. This opinion is communicated to the applicant and to the Minister responsible for nuclear safety.”

Schematic diagram of the Cigéo repository showing the surface and underground facilities



Particular case of bituminised waste

The management of bituminised waste is also monitored under the PNGMDR, 2016-2018, which requested several studies relative to the characterisation of these waste packages, their transport conditions and treatment possibilities.

In 2019, ASN made additional information requests⁽⁸⁾ to the waste producers and to Andra further to the examination of the study submitted under Article 46 of the Order of 23 February 2017. The requests focus more specifically on the effect of self-irradiation on the thermal behaviour of the bituminised waste packages, on the thermal reactivity of the bituminised coatings, on the long-term swelling considering the long-term behaviour of the Cigéo repository and on the design changes to control the risks associated with the disposal of packages of bituminised waste.

The Minister responsible for energy and ASN moreover wanted an independent multidisciplinary assessment drawing on international practices to be conducted on this issue. The conclusions of this assessment were presented in September 2019 to the working group tasked with monitoring the PNGMDR.

ASN issued the abovementioned opinion 2020-AV-0369 on 1 December 2020 on the conclusions of the third-party review of bituminised waste management and the

studies on the design changes of the Cigéo ILW-LL disposal vaults which highlight new technical elements since the publication of the opinion of 11 January 2018. ASN therefore considers that the producers must implement an ambitious programme to characterise bituminous waste packages, which is essential in order to demonstrate that some or all of the bituminous waste packages could be disposed of in the projected Cigéo facility with a high level of safety without prior treatment.

ASN considers moreover that the bituminised waste packages whose safety once emplaced in the disposal facility could not be demonstrated must undergo further investigations.

The CEA informed ASN of the launch in 2021 of a new study programme baptised "Babylon" (grouping Andra and the three major licensees, which explains its other name of "quadrupartite" programme), aiming to inform reflections on the methods of managing bituminised waste by contributing elements from research and development work. ASN welcomed this approach, on which it made remarks in 2022, and keeps regular track of the progress of this programme which is expected to last five years. The PNGMDR 2022-2026 provides for the progress and results of this programme to be presented annually to the PNGMDR governance commissions.

From the Safety Options Dossier to the creation authorisation application

The Cigéo project was declared of public utility by Decree 2022-993 of 7 July 2022, published in the *Official Journal of the French Republic* on 8 July. During this process, ASN answered questions from the inquiry commissioners concerning certain technical aspects of the Cigéo project.

Furthermore, in accordance with the resolution of 21 February 2020 of the Minister responsible for energy and the ASN Chairman further to the public debate concerning the 5th PNGMDR which, through its "HAMAVL.6" action, will specify the conditions of reversibility of the facility, particularly regarding package retrievability, the decision-making milestones of the Cigéo project and the required method of governance in order to be able to review the choices made. The objectives and success criteria for the industrial pilot phase, the methods of informing the public between two successive updates of the operations master plan provided for in Article L. 542-10-1 of the Environment Code and the methods for involving the public in the decisive development steps of the Cigéo project shall also be defined.

8. The follow-up letters are available on the ASN website under the heading "ASN informs", "Educational files", "Management of radioactive waste", "French National Radioactive Material and Waste Management Plan", "PNGMDR 2016-2018".

Meetings of the ASN Advisory Committees of Experts to review the Cigéo creation authorisation application



The GPD, assisted by members of the GPU and the GPRP, held a first meeting in April 2024 to examine the first series of subjects relating to the databases and the assumptions used to establish the Cigéo safety case. As a conclusion to this first review meeting, the GPE considered that Andra had acquired a sound and sufficient knowledge base concerning the Meuse/Haute-Marne site, the components of the disposal system and the waste package inventories to assess the safety of Cigéo at the creation authorisation application file stage. The GPD set out recommendations concerning the development of the cementitious components of the HL disposal vaults and the performance of the closure structures, the need to consolidate the chemical inventory of the waste and the waste volumes with a view to packaging them. It also underlined that the definition of the pilot industrial phase, as much in terms of objectives as in limitations, must be formalised by Andra during the review in order to be able to assess its adequacy. The GPD considered that the inventories used by Andra are sufficient to continue its development and to examine its flexibility and adaptability. It noted nevertheless that there remained uncertainties concerning the volume of primary packages whose packaging has not yet been determined. Lastly, the GPD also requested additional information on the subjects of steel corrosion and the pilot industrial phase for the purpose of its second meeting.

ASN made this request to Andra in writing in May 2024.

During its second meeting on 10 and 11 December 2024, the GPD examined the safety issues linked to the building and operating phases of the future deep geological disposal facility. As a conclusion to this meeting, the GPE considered that the safety case for the operation of the above-ground and underground facilities was satisfactory on the whole for the current stage of project development. It nevertheless considered that substantial additional information was necessary for the safety case for disposal of the bituminous waste, closure of the ILW-LL vaults and operation of the HLW vaults. Likewise, the measures for monitoring the first structures have to be detailed before building them. The GPE indicated that it wanted to review these subjects before the excavation work starts.

The third and last meeting of the GPD concerning the review of the Cigéo creation authorisation application will be held in June 2025. The recommendations and positions formulated by the GPD during the three Cigéo creation authorisation application review meetings will help ASN form the opinion it will issue concerning this application in accordance with the provisions of Article L 542-10-1. This opinion will be issued on completion of the technical review and before the consultation phase which includes the public inquiry.

expectations and concerns, as related to nuclear safety and radiation protection, so that they could be taken into account when framing the technical review. Following this exercise, the IRSN referral project was modified, for example, to incorporate aspects related to addressing climate change issues. To guarantee the continuity of participation by society throughout the technical review process, consultation measures will also be taken when drafting the GPE referrals on the three previously mentioned topics, and the public will be regularly informed, notably after each meeting of these GPEs.

The cost of the project

In accordance with the procedure stipulated in Article L. 542-12 of the Environment Code and after consideration of ASN's opinion of February 2015 and the comments of the radioactive waste producers, the Minister responsible for energy issued an Order setting the reference cost of the Cigéo disposal project *"at €25 billion under the economic conditions prevailing on 31 December 2011, the year in which the cost evaluation work began"*. This cost will be reassessed by Andra in 2025. The Minister responsible for energy shall then set the new cost of Cigéo through a new Ministerial Order issued after receiving ASN's opinion on the new Cigéo project costing file.

The review process for the Creation Authorisation Application filed in early 2023

Further to the filing of the Cigéo creation authorisation application on 16 January 2023, ASN initiated the DAC review process for this deep geological disposal facility, which is regulated by Section 4 of Chapter III of Title IX of Book V of the Environment Code and by Article L. 542-10-1 of the Environment Code, specific to this type of facility. Following an initial analysis of the contents of the file, ASN ruled that it was administratively acceptable in June 2023 and formally started the technical review process, for which it requested IRSN's support. This process is expected to last 30 months and will comprise three meetings of the "Waste" GPE. As necessary, experts from the "laboratories and plants" GPE and the "radiation protection" GPE will join these meetings. The review by the GPEs will initially cover the knowledge and the hypotheses used to design the facility and then review operational safety before finally assessing long-term safety.

The first meeting of the GPEs was held on 24 and 25 April 2024 and the second on 10 and 11 December 2024. The third and last meeting will be held in June 2025 (see box above). The estimated duration of the entire authorisation process is about five years. Apart from the technical examination phase, it includes a consultation phase (local authorities, Environmental Authority, etc.), as well as a public inquiry.

Consultation actions

In order to address society's strong desire to take part in the Cigéo project, and consistent with the measures stipulated in this respect by the 5th PNGMDR, ASN has implemented an unprecedented system of consultation around the technical review process. Thus, various different stakeholders (about twenty organisations, including the Local Information Committees (CLIs), the National Association of Local Information Committees and Commissions (Anccli) and environmental protection associations) were consulted as part of the drafting of the referral to IRSN about the Cigéo creation authorisation application, with the aim of identifying their

2 — Nuclear safety in waste management support facilities, role of ASN and waste management strategies of the major nuclear licensees

2.1 Radioactive waste management methods and their oversight by ASN

2.1.1 The graded approach

With regard to radioactive waste management, ASN's oversight aims on the one hand to verify correct application of the waste management regulations on the production sites (for example with respect to zoning, packaging or the controls performed by the licensee), and on the other hand to verify the safety of the facilities dedicated to radioactive waste management (waste treatment, packaging, storage and disposal facilities). This oversight is exercised in a manner proportionate to the nuclear safety issues associated with each waste management step and each facility. Thus, the waste management BNIs are classified in one of three categories, numbered from 1 to 3 in descending order of significance of the risks and adverse effects they present. This categorisation is taken into account in the preparation of the inspection schedule and helps to determine the level of expertise required for the examination of certain files submitted to ASN by the licensees.

The various facilities and ASN's assessment of their level of safety are presented in the introduction to this report.

2.1.2 Radioactive waste management support facilities

Treatment

Treatment is a fundamental step in the radioactive waste management process. This operation serves to separate the waste into different categories to facilitate its subsequent management and to significantly reduce the volume of waste.

The La Hague plants, which process and recycle the spent fuel assemblies, are involved in this process because they apply a dissolution and chemical treatment process to separate the cladding and the fission products. The hulls and end-pieces are then compacted to reduce their disposal footprint.

Centraco (BNI 160), the low-level waste treatment and packaging centre operated by Cyclife France, significantly reduces the volume of the low and very low-level waste that is sent to it. This plant has a unit dedicated to the incineration of combustible waste (solid and liquid) and a melting unit in which essentially ferrous metal waste is melted down.

The radioactive effluents can also be concentrated by evaporation, like the operations carried out in Agate, the advanced

effluent management and processing facility (BNI 171), with this same aim of volume reduction.

Packaging

Radioactive waste packaging consists in placing the waste in a package which provides a first containment barrier preventing radioactive substances from being dispersed in the environment. The techniques used depend on the physical-chemical characteristics of the waste and their typology, which explains the large variety of packages used (overpacks, drums, containers, etc.). The packaging process can include the addition of a matrix (encapsulating or blocking) using processes such as vitrification or cementation. These packages are subject to approval by Andra if they are intended for existing disposal facilities, and to packaging agreements by ASN if they are intended to be directed towards disposal facilities still under study.

In some cases the packaging operations are carried out directly on the site of waste production, but they can also take place in dedicated facilities, like the La Hague plants, which package spent fuel hulls and end-pieces in "standard compacted waste containers" (CSD-C packages), and the fission products in stainless steel "standard vitrified waste containers" (CSD-V packages), and the effluent treatment stations such as the Stella station in BNI 35. The conditioned waste packages are sometimes made up in the facilities where they are to be stored, such as for the ILW-LL type C1PG^{SP} packages in the Iceda facility, or directly in a disposal repository, such as the Cires and CSA which carry out these operations for some of the arriving packages.

Storage

Storage, as defined by Article L. 542-1-1 of the Environment Code, is a temporary management solution for radioactive waste. The waste is kept in storage for a limited period (which can extend to 50 years) pending its transfer to disposal, or in order to achieve a sufficient level of radioactive decay to enable it to be sent to conventional waste management routes in the particular case of very short-lived waste, which comes chiefly from the medical sector.

Some facilities (*see map next page*) are specifically dedicated to the storage of radioactive waste, such as Cedra commissioned in 2006, Écrin, commissioned in 2018, and Iceda, commissioned in 2020. This will also be the case of Diadem, once this facility is commissioned in about 2027. As for the CSD-C and CSD-V packages, they are stored directly in various facilities on the La Hague site pending commissioning of the deep geological repository for HL and ILW-LL waste (Cigéo).

Research and Development

Support facilities are used for research and development work to optimise radioactive waste management.

Among these, the Chicade facility (BNI 156) operated by CEA on the Cadarache site conducts research and development work on LLW and ILW objects and waste. This work primarily concerns aqueous waste treatment processes, decontamination processes, solid waste packaging methods and the expert assessment and inspection of waste packages.

2.1.3 Oversight of the packaging of waste packages

Regulations

The Order of 7 February 2012 defines the requirements associated with waste packaging. Producers of radioactive waste are instructed to package their waste taking into account the requirements associated with their subsequent management, and more particularly their acceptance at the disposal facilities.

ASN resolution 2017-DC-0587 of 23 March 2017 specifies the requirements regarding waste packaging for disposal and the conditions of acceptance of waste packages in the disposal BNIs.

Production of waste packages intended for existing disposal facilities

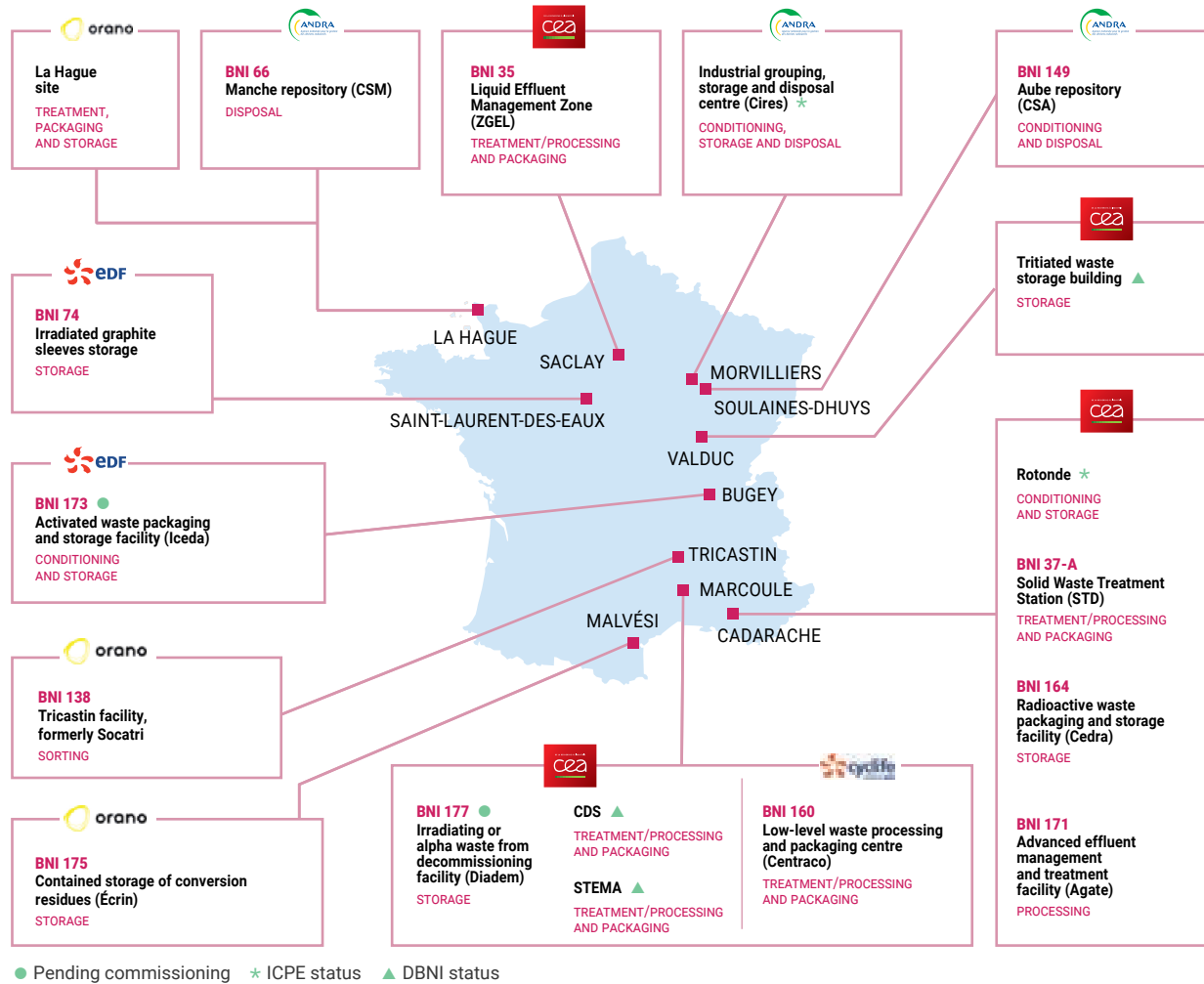
The waste package producers prepare an approval application file based on the acceptance specifications of the disposal facility that is to receive the packages. Andra issues an approval formalising its agreement on the package manufacturing process and the quality of the packages. Andra verifies the conformity of the packages with the delivered approvals by means of audits and monitoring actions on the package producers' premises and on the packages received at its facilities.

Waste packages intended for projected disposal facilities

With regard to disposal facilities currently being studied, the waste acceptance specifications have of course not yet been defined. Andra cannot therefore issue approvals to govern the production of packages for LLW-LL, HLW-LL or ILW-LL waste.

Under these conditions, the production of packages of these types of waste is subject to ASN approval on the basis of a file established by the waste producer called "packaging baseline requirements". This file must demonstrate that on the basis of existing knowledge and the currently identified requirements of the disposal facilities still under study, the packages display no unacceptable behaviour, and

The main support facilities for radioactive waste management



concerning, for example, the geometry and the maximum masses of the packages, waste that is prohibited or subject to restriction or the dose rate or radiological activity limits.

This provision notably also avoids delaying legacy Waste Retrieval and Packaging (WRP) operations in facilities being decommissioned (see chapter 14).

Within the framework of the PNGMDR 2016-2018, the waste producers were asked to study the acceptability of the waste packages intended for Cigéo. In its opinion 2020-AV-0369 of 1 December 2020, and in a letter of 23 July 2021, ASN made several observations relative to the methodology for producing these preliminary acceptance specifications for Cigéo, the chosen parameters and the envisaged modes of disposal. It considered in particular that the methodology for producing these preliminary acceptance specifications for Cigéo was satisfactory. It nevertheless noted that several parameters, qualitative in particular, should be consolidated in order to facilitate their verification. Furthermore, as the producers' analysis of package acceptability could only be considered as partial, notably in view of

the chosen mode of disposal, it will have to be carried out again on the basis of the next version of the preliminary acceptance specifications for Cigéo integrated in the Cigéo creation authorisation application submitted in January 2023.

Checks and inspections

Alongside Andra's surveillance of approved packages, ASN checks the steps taken by the licensee to correctly implement the requirements of the approvals issued by Andra and to master the packaging processes. For waste packages intended for disposal facilities still under study, ASN is particularly attentive to ensuring that the packages comply with the conditions of the packaging approvals issues.

By means of inspections, ASN also ensures that Andra takes the necessary steps to verify the quality of the packages accepted in its disposal facilities. This is because ASN considers that Andra's role in the approvals issuing process and in monitoring the measures taken by the waste package producers is vital in guaranteeing package quality and compliance with the safety case of the waste repositories.

2.1.4 Developing the regulatory framework and issuing prescriptions to the licensees

ASN can issue resolutions of a regulatory nature. Thus, the provisions of the Order of 7 February 2012 which concern the management of radioactive waste have been set out in the ASN resolutions mentioned earlier relative to waste management in BNIs and the packaging of waste. To give an example, the resolution of 23 March 2017 addresses the packaging of radioactive waste and the conditions of acceptance of the radioactive waste packages in the disposal BNIs. Its aim is to specify the safety requirements at the various stages of a management route. Moreover, to ensure a consistent approach to the management of waste in BNIs and Defence Basic Nuclear Installations (DBNIs), ASN and ASND signed an agreement in January 2021 coordinating their actions in this area.

More broadly, ASN issues requirements relative to the management of waste coming from the BNIs.

ASN indicates certain waste management requirements in two guides: Guide No. 18 relative to the management of

radioactive effluents and waste produced by a nuclear activity licensed under the Public Health Code, and Guide No. 23 relative to the BNI waste zoning plan (see points 1.2.1 and 1.2.2).

Lastly, ASN is consulted for its opinion on draft regulatory texts relative to radioactive waste management.

With regard to the subject of the disposal of radioactive waste, ASN in 2023 continued its work to draft a resolution regulating the disposal facilities, as well as a guide on near surface disposal. These texts aim to consolidate the requirements associated with the radioactive waste disposal facilities. From 20 October to 20 November 2023, ASN held a consultation on the Guidance and Supporting Document (DOJ) associated with this work, which will continue in 2025.

2.1.5 Evaluation of the nuclear financial costs

The regulatory framework designed to secure the financing of nuclear facility decommissioning costs or, for radioactive waste disposal facilities, the final shutdown, maintenance and surveillance costs, in addition to the cost of managing spent fuel and radioactive waste, is described in chapter 14 (see point 1.4).

2.2 Periodic safety reviews of radioactive waste management facilities

BNI licensees, including for radioactive waste management facilities, carry out periodic safety reviews of their facilities in order to assess the situation of the facilities with respect to the rules applicable to them and to update the assessment of the risks or adverse effects, notably taking account of the state of the facility, the experience acquired during operation, and the development of knowledge and rules applicable to similar facilities. The diversity and frequently unique nature of each radioactive waste management facility lead ASN to adopt an examination procedure that is specific to each periodic safety review.

In this context, ASN is currently examining several periodic safety reviews of radioactive waste management facilities. They concern:

- three BNIs operated by the CEA: the treatment and packaging facility (BNI 35) on the Saclay site and the Cedra (BNI 164) and Agate (BNI 171) facilities on the Cadarache site;
- one BNI operated by EDF: BNI 74 comprising the Saint-Laurent-des-Eaux storage silos;
- one BNI operated by Cyclife France on the Marcoule site: the Centraco facility for waste treatment by melting or incineration (BNI 160);
- one BNI operated by Orano on the Tricastin site: clean-up and uranium recovery facility (IARU – BNI 138).

2.2.1 Periodic safety reviews of radioactive waste management support facilities

The periodic safety reviews of the oldest facilities such as BNIs 35, 37-A, 74 and 118 present particular challenges. The Saint-Laurent-des-Eaux silos (BNI 74) present safety risks, particularly in view of their inventories. These safety reviews must address the control of the waste storage conditions, including legacy waste, the WRP of this waste with a view to removal via the dedicated route and scheduled post-operational clean-out of the buildings. In relation with these challenges, the safety reviews must ensure that the impacts of discharges into the environment (soils, groundwater, or seawater for certain BNIs) are controlled.

For the most recent facilities, as is the case with Cedra and Chicade, the periodic safety reviews highlight more generic problems. The resistance of the buildings to internal and external hazards (earthquake, fire, lightning, flooding, aircraft crash) is one of the important aspects. ASN released its conclusions on the periodic safety review of the waste conditioning facility 37-A on 4 January 2023 and those for the BNI 118 safety review on 8 December 2022.

2.2.2 Periodic safety reviews of radioactive waste disposal facilities

The safety reviews of the CSM (BNI 66) and the CSA (BNI 149) have the particularity of addressing control of the risks and adverse effects over the long term, in addition to reassessing their operational control. Their purpose is therefore more specifically to update, if necessary, the scenarios, models and long-term assumptions in order to confirm satisfactory control of the risks and adverse effects over time. The periodic safety reviews of these two facilities thus highlight the need for increased knowledge of the long-term impacts associated with the toxic chemicals contained in some waste and of the impacts of the radionuclides on the environment (flora and fauna) ASN issued its conclusions on the second periodic safety review of the CSA on 25 July 2022 and of the CSM on 29 April 2024.

The successive safety reviews must also serve to detail the technical measures planned by the licensee to control the adverse effects of the facility over the long term, notably for the systems for covering these facilities which contributes to the final containment of the disposal concrete blocks. The durability of the CSM cover and the preservation of the site memory for future generations are the two predominant themes of the periodic safety review of a radioactive waste disposal facility.

Lastly, these safety reviews provide the opportunity of detailing, as time goes by, the measures the licensee plans

implementing to ensure the long-term surveillance of the behaviour of the disposal facility.

2.3 CEA's waste management strategy and its assessment by ASN

Types of waste produced by CEA

CEA operates diverse types of facilities covering all the activities relating to the nuclear cycle: laboratories and plants associated with fuel cycle research, as well as experimental reactors.

CEA also carries out numerous decommissioning operations.

Consequently, the types of waste produced by CEA are varied and include more specifically:

- waste resulting from operation of the research facilities (protective garments, filters, metal parts and components, liquid waste, etc.);
- waste resulting from legacy waste retrieval and packaging operations (cement-, sodium-, magnesium- and mercury-bearing waste);
- waste resulting from final shutdown and decommissioning of the facilities (graphite waste, rubble, contaminated soils, etc.).

The contamination spectrum of this waste is also wide with, in particular, the presence of alpha emitters in activities relating to fuel cycle research and beta-gamma emitters in operational waste from the experimental reactors.

CEA has specific facilities for managing this waste (processing, packaging and storage). Some of them are shared between all the CEA centres, such as the Liquid Effluent Treatment Station (STEL) in Marcoule or the STD in Cadarache.

The issues and challenges

The main issues for CEA with regard to radioactive waste management are:

- renovation of the facilities (BNI 37-A for example);
- extension of the existing storage capacities (Cedra);
- commissioning future storage capacities (Diadem);
- conducting legacy WRP projects.

These various undertakings must permit the processing, packaging and storage of the effluents, spent fuel and waste under satisfactory conditions of safety and radiation protection and within time frames compatible with the commitments made for shutting down old facilities which no longer meet current safety requirements.

ASN's examination of CEA's waste management strategy

In response to a request from ASN and ASND dating from 2012, CEA submitted an overall review of its decommissioning and waste management strategy in December 2016. After examining this report, the two Authorities gave a joint opinion on this strategy in May 2019.

ASN and ASND consider that CEA's facility decommissioning strategy and its updating of the waste and material management strategy are the result of an in-depth review and analysis.

CEA's decommissioning and materials and waste management strategies present considerable uncertainties, particularly concerning the availability of support facilities. These strategies rely on the sharing of resources between its research centres and are based on the use of facilities of which some are at the project stage while others are undergoing commissioning, being refurbished, waiting for a periodic safety review or are authorised to continue operation for a limited period of time. Most of them are unique, with no obvious operational alternative in the event of failure.

All these factors constitute vulnerabilities in CEA's strategy, particularly the support facilities and means necessary for the post-operational clean-out & decommissioning and WRP projects, for which the availability requirement appears to be particularly critical given that they fulfil functions that no other CEA facility is able to perform.

ASN and ASND have therefore addressed several demands to the CEA with the aim of limiting these vulnerabilities, consolidating its strategy and detailing the operations schedule.

They demanded that CEA make regular progress reports on the decommissioning and waste management projects, and ensure regular communication with the public, applying procedures appropriate to the nature of the facilities, civil or defence. ASN, ASND and CEA have agreed to set up regular monitoring of these operations, through progress indicators in particular and the periodic updating of CEA's major safety commitments.

Monitoring implementation of CEA's waste management strategy

ASN has observed the difficulty CEA has in fully controlling the challenges associated with these projects, which must be carried out simultaneously and concern as much the management of the decommissioning operations as the operation of the waste management support facilities. It will continue to be particularly attentive to the management and monitoring of these projects. ASN nevertheless underlines the good forward-planning of the work necessary to avoid saturating some of the waste storage capacities, such as phase 3 of the Cedra facility, and the goodness of fit of the blueprint for transport operations with CEA's storage capacities.

2.4 Orano's waste management strategy and its assessment by ASN

The spent fuel reprocessing and recycling plant at the La Hague site presents major radioactive waste management issues. The

waste on the La Hague site comprises on the one hand waste resulting from reprocessing of the spent fuel, which generally comes from nuclear power plants but also from research reactors, and on the other, waste resulting from operation of the various facilities on the site. Most of this waste remains the property of the licensees - whether French or foreign - who have their spent fuel reprocessed. French waste is directed to the management routes described earlier, whereas foreign waste is sent back to its country of origin. On the Tricastin site, Orano also produces waste associated with the front-end activities of the "cycle" (production of nuclear fuel), essentially contaminated by alpha emitters.

In 2016, Orano submitted a file to ASN and ASND, which was supplemented in 2017, presenting its decommissioning and waste management strategy for the group's French facilities, and its practical implementation on the La Hague and Tricastin sites. Moreover, Orano submitted general and particular commitments for the La Hague and Tricastin sites in 2018. ASN issued a position statement on the strategy on 14 February 2022.

Orano has sent information to ASN since 2022 in response to ASN's various requests in its letter of 14 February 2022. These elements are currently being reviewed by ASN.

The issues and challenges

The main issues relating to the management of waste from the licensee Orano are:

- The safety of the legacy waste storage facilities. On the La Hague site, the facilities dedicated to legacy waste retrieval, packaging and storage have to be designed, built and then commissioned. These projects meet with technical difficulties which can make it necessary to adjust deadlines set by ASN (*see chapter 14*). In addition, the on-site radioactive waste storage capacities must be planned for with conservative margins in order to prevent them reaching saturation. The legacy waste stored on the Tricastin site necessitates a large amount of work to characterise it and find management solutions. The storage conditions in some of the Tricastin site facilities do not meet current safety requirements and must be improved.

- The definition of solutions for waste packaging, in particular the legacy waste. The methods of packaging radioactive waste intended for a projected disposal BNI must receive the prior approval of ASN pursuant to Article 6.7 of the Order of 7 February 2012 (*see point 2.2.2*). Keeping control of the packaging deadlines is a particularly important aspect, which requires the development of characterisation and R&D programmes to demonstrate the feasibility and compatibility of the chosen packaging processes with the subsequent management steps and to identify sufficiently early the risks that could significantly affect the associated project. If necessary, when the feasibility of the

defined packaging cannot be determined within times compatible with the prescribed deadlines, the licensee must plan for an alternative solution, including in particular interim storage areas allowing the retrieval and characterisation of the legacy waste as rapidly as possible, while guaranteeing the absence of any counteraction that could jeopardise the safety of their storage, the final packaging and the subsequent management phases of the resulting packages.

Within the framework of the WRP operations, Orano is examining packaging solutions that necessitate the development of new processes, particularly for the following ILW-LL waste:

- the radioactive sludge from the La Hague STE2 facility;
- the alpha-emitting technological waste which comes primarily from the La Hague and Melox (Gard département) plants and is not suitable for above-ground disposal.

For other types of ILW-LL waste resulting from the WRP operations, Orano is examining the possibility of adapting existing processes (compaction, cementation, vitrification). Some of the associated packaging baseline requirements are currently being examined by ASN.

2.5 EDF's waste management strategy and its assessment by ASN

The radioactive waste produced by EDF comes from several distinct activities. It mainly comprises waste from the operation of the NPPs, which consists of activated waste from the reactor cores, and waste from their operation and maintenance. Some legacy waste and waste resulting from ongoing decommissioning operations can be added to this. EDF is also the owner, for the share attributed to it, of HLW and ILW-LL waste resulting from spent fuel reprocessing in the Orano La Hague plant.

Activated waste

This waste notably comprises control rod assemblies and poison rod assemblies used for reactor operation. This is ILW-LL waste that is produced in small quantities. At present this waste is stored in the NPP fuel storage pools pending transfer to the Iceda facility.

Operational and maintenance waste

Some of the waste is processed by melting or incineration in the Centraco facility, in order to reduce the volume of ultimate waste. The other types of operational and maintenance waste are packaged on the production site then shipped to the CSA or Cires repositories for disposal (*see points 1.3.1 and 1.3.2*). This waste contains beta and gamma emitters, and few or no alpha emitters. At the end of 2013, EDF submitted a file presenting its waste management strategy. After examining this file, ASN in 2017 asked EDF to continue its measures to reduce the uncertainties

concerning the activity of the waste sent to the CSA, to improve its organisational arrangements to guarantee the allocation of sufficient resources to radioactive waste management, and to present the most appropriate process for the treatment of used steam generators.

Finally, the spent control rod cluster guide tubes from the EDF fleet shall be disposed of directly in the CSA, following EDF's decision to abandon the Cyclife France reprocessing project in the Centraco facility, in order to reduce the volume of waste.

The issues and challenges

The main issues relating to the EDF waste management strategy concern:

- The management of legacy waste. This mainly concerns structural waste (graphite sleeves) from the GCR fuels. This waste could be disposed of in a repository for LLW-LL waste (see point 1.3.4). It is stored primarily in semi-buried silos at Saint-Laurent-des-Eaux. Graphite waste is also present in the form of stacks in the GCRs currently being decommissioned. In the context of the PNGMDR 2016-2018, EDF conducted a study of the reliability of the

activity predictions for this waste and submitted its conclusions in December 2019. Further to requests from ASN, further information was provided in 2023. This information is subject to review by ASN.

- The changes linked to the “fuel cycle”. EDF's fuel use policy (see chapter 10) has consequences for the “fuel cycle” installations (see chapter 12) and for the quantity and nature of the waste produced. ASN issued an opinion on the coherence of the “nuclear fuel cycle” in October 2018 (see chapter 12).

3 — Management of mining residues and mining waste rock from former uranium mines

Uranium mines were worked in France between 1948 and 2001, producing 76,000 tons of uranium. Some 250 sites in France were involved in exploration, extraction and processing activities. The sites were spread over 27 *départements* in the eight regions: Auvergne-Rhône-Alpes, Bourgogne-Franche-Comté, Bretagne, Grand Est, Nouvelle-Aquitaine, Occitanie, Pays de la Loire and Provence-Alpes-Côte d'Azur. Ore processing was carried out in eight plants. The former uranium mines are now almost all under the responsibility of Orano. The working of uranium mines produced two categories of products:

- mining waste rock, that is to say the rocks excavated to gain access to the ore. The quantity of mining waste rock extracted is estimated at about 170 million tonnes;
- static or dynamic processing tailings, which are the products remaining after extraction of the uranium from the ore. In France, these tailings represent 50 million tonnes spread over 17 disposal sites. These sites are ICPEs and their environmental impact is monitored.

Redevelopment of the uranium processing tailings disposal sites consisted notably in placing a solid cover over the tailings to provide a geochemical and radiological protective barrier to limit the risks of intrusion, erosion, dispersion of the stored products and the risks of external and internal exposure of the neighbouring populations.

The regulatory context

The uranium mines, their annexes and their conditions of closure are covered by the Mining Code. The disposal facilities for radioactive mining tailings are governed by section 1735 of the ICPE classification system. The mines and the mine tailings disposal sites are not subject to ASN oversight.

In the specific case of the former uranium mines, an action plan was defined by Circular 2009-132 of 22 July 2009 of

the Minister responsible for the environment and the Chairman of ASN, along the following work lines:

- monitor the former mining sites;
- improve the understanding of the environmental and health impact of the former uranium mines and their monitoring;
- manage the mining waste rock (better identify the uses and reduce impacts if necessary);
- reinforce information and consultation.

PNGMDR: The long-term behaviour of the sites

The studies submitted for the PNGMDR since 2003 have enhanced knowledge of:

- the dosimetric impact of the mine tailing disposal areas on man and the environment, in particular through the comparison of data obtained from monitoring and the results of modelling;
- the evaluation of the long-term dosimetric impact of the waste rock stockpiles and waste rock in the public domain in relation to the results obtained in the context of the Circular of 22 July 2009;
- the strategy chosen for the changes in the treatment of water collected from former mining sites;
- the relation between the discharged flows and the accumulation of marked sediments in the rivers and lakes;
- the methodology for assessing the long-term integrity of the embankments surrounding tailings disposal sites;
- transport of uranium from the waste rock piles to the environment;
- the mechanisms governing the mobility of uranium and radium within uranium-bearing mining tailings.

Further to ASN opinion 2021-AV-0255 of 9 February 2016, and in the context of the PNGMDR 2016-2018, Orano submitted 11 studies between January 2017 and February 2020 to supplement the studies submitted prior to this. Based on this, ASN issued an opinion on 4 February 2021 to review the situation on these subjects.

Consequently, ASN opinion 2021-AV-0255 of 9 February 2016 specifies the studies still to be carried out to meet the challenges associated with the former mining sites and reiterated above. These studies may lead to the performance of work such as removal of the mining tailings from public land, reinforcement of the structures encircling the disposal sites, and improving preservation of the memory. This opinion also recommends continuing the work of the two technical working groups concerning:

- Maintaining the functions of the structures encircling the uranium ore treatment residue disposal areas. The final report on maintaining the functions of the structures encircling the uranium ore treatment residue disposal areas published on 30 January 2023, was updated on 12 November 2024. This update does not call into question the recommendations, methods and conclusions indicated in the final report published in 2023. From now on, this report shall be taken into consideration by Orano in order to update its assessments of the stability of its structures encircling the mining residue disposal sites. The study concerning the Bernardan site submitted in October 2023 is currently undergoing an expert assessment to verify Orano's integration of the report's methodologies and recommendations. With regard to the assessment of the Montmassacrot site, in November 2024 ASN asked Orano for additional information on the study submitted in October 2021 in order to demonstrate the short- and long-term stability of the structure.
- Management of the water from the former uranium mining sites. With the aim of reducing the overall impact (radiological and chemical) of releases on people and ecosystems, the special technical working group finalised in June 2024 the drafting of the methodology guide for drafting the multi-stakeholder, multi-criterion analysis methodology. This is a decision-making aid guide regarding the questions of maintaining, shutting down or modifying

the treatment of mine water collected on a given site, in some cases housing a uranium ore treatment residues repository. This final version is awaiting publication.

ASN has proposed creating a third working group which will focus on the updating of the methodology for assessing the long-term impact of the mining processing residue disposal sites. This working group will endeavour more specifically to detail the long-term deterioration scenarios for the covers of mining processing

residue disposal facilities, in relation with the radioactive waste disposal site development scenarios and the work carried out by the pluralistic expert assessment group for the uranium mining sites of the Limousin region (GEP Limousin). This working group has not yet started, priority having been given to completing the work of the two working groups mentioned previous page.

The PNGMDR 2022-2026 plans to continue these actions concerning the long-term

environmental and health impact of the management of the former uranium mines. These actions will notably take into consideration the continued updating of the studies on structure stability applying the methodology proposed by the final report on maintaining the functions of the structures encircling the uranium ore treatment residue disposal areas and application of the methodology for management of the waters from former mining sites specified above.

4 — Management of sites and soils contaminated by radioactive substances

A site contaminated by radioactive substances is defined as a site which, due to the presence of old deposits of radioactive substances or waste, or to the utilisation or infiltration of radioactive substances or radiological activation of materials, presents radioactive contamination that could cause adverse effects or a lasting risk for people or the environment.

Contamination by radioactive substances can result from industrial, craft, medical or research activities involving radioactive substances. It can concern the places where these activities are carried out, but also their immediate or more remote vicinity. The activities concerned are generally either nuclear activities as defined by the Public Health Code or activities concerned by natural radioactivity.

However, most of the sites contaminated by radioactive substances and today requiring management have been the seat of past industrial activities, dating back to a time when knowledge of the radioactivity-related risks was not what it is today. The main industrial sectors that generated the radioactive contamination identified today were radium extraction for medical and para-pharmaceutical needs, from the early 1900s until the end of the 1930s, the manufacture and application of luminescent radioactive paint for night vision, and the industries working ores such as monazite or zircons. Sites contaminated by radioactive substances are managed on a case-by-case basis, which necessitates having a precise diagnosis of the site.

Several inventories of contaminated sites are available to the public and are complementary: Andra's national inventory, which is updated every five years and comprises the sites identified as contaminated by radioactive substances (the 2024 edition is available on [andra.fr](https://www.andra.fr), as is the publication of the National Inventory Essentials 2024) and the contaminated sites and soils databases of the Ministry responsible for the environment.

ASN considers moreover that the stakeholders and audiences concerned must be involved as early as possible in the process to rehabilitate a site contaminated by radioactive substances.

In application of the “polluter-pays” principle written into the Environment Code, those responsible for the contamination finance the operations to rehabilitate the contaminated site and to remove the waste resulting from these operations. If the responsible entities default, Andra, on account of its public service remit and by public requisition, ensures the rehabilitation of radioactive contaminated sites.

In cases where contaminated sites and soils have no known responsible entity, the State finances their clean-up through a public subsidy provided for in Article L. 542-12-1 of the Environment Code. The French National Funding Commission for Radioactive Matters (CNAR) gives opinions on the utilisation of this subsidy, as much with respect to fund allocation priorities as to polluted site treatment strategies and the principles of assisted collection of waste.

Under Article D. 542-15 of the Environment Code, the composition of the CNAR is as follows:

- “members by right”: representatives of the Ministries responsible for the environment and energy, of Andra, the French Environment and Energy Management Agency (Ademe), IRSN, CEA, ASN and the Association of Mayors of France;
- members mandated for four years by the Ministries responsible for energy, nuclear safety and radiation protection (the CNAR chair, two representatives of environmental associations and one representative of a public land management corporation).

The Commission met once in 2024, to address the files concerning the retrieval of radioactive objects in the possession of private individuals, the management of polluted sites and the management of soils from the clean-out of legacy sites.

When contamination is caused by an installation that is subject to special policing (BNI, ICPE or nuclear activity governed by the Public Health Code), the sites are managed under the same oversight system. Otherwise, the Prefect oversees the measures taken regarding management of the contaminated site.

ASN actions concerning the various uranium mining sites and soils contaminated by radioactive substances

The uranium mines, their annexes and their conditions of closure are covered by the Mining Code. The disposal facilities for radioactive mining tailings are governed by section 1735 of the ICPE classification system. Oversight of the conditions of management of the mine tailings or mining waste rock outside the production or disposal sites is the responsibility of the Prefect, on proposals from the Regional Directorate for the Environment, Planning and Housing (Dreal). Consequently, the mines, the disposal areas, the mine tailings, the conditions of management of mine tailings or mining waste rock on public land and the management of sites and soils with no solvent responsible entity which are

polluted by radioactive substances are not subject to ASN oversight. ASN assists the State departments at their request in the areas of radiation protection of workers and the public, and the management routes for mining waste, tailings and waste rock. In addition, under the PNGMDR, ASN issues opinions on the studies submitted in order, for example, to further knowledge of the development of the long-term radiological impact of the former mining sites on the public and the environment. ASN can, at the request of the competent authority, issue opinions concerning the management of these sites, in view of the radiation exposure risks and radioactive waste management challenges.

With regard to the management of sites contaminated by radioactivity subject to the ICPE System and the Public Health Code, whether the party responsible is solvent or insolvent, in accordance with its validated doctrine regarding sites contaminated by radioactive substances (*see chapter 14, point 1.2.2*), ASN recalls that the clean-out practices must be implemented taking account of the best available methods and techniques, in economically acceptable conditions. The complete POCO scenario must always be envisaged as the reference scenario. This scenario, which leads to unconditional release of the buildings and sites, effectively enables the protection of people and the environment to be guaranteed over time by the removal of all contamination.

In the event of identified technical, economic or financial difficulties, the party responsible for the contamination (if solvent) or the owner of the site may propose one or more appropriate POCO scenarios compatible with the site's futures usages (confirmed, planned and possible) to the Prefect. Whatever the case, elements proving that the reference scenario cannot be applied under acceptable technical and economic conditions and that the POCO operations

envisaged constitute a technical and economic optimum shall be provided. In the event of incompatibility with the usages as a whole, usage restrictions or prohibitions and technical measures to limit exposure of the occupants, or prescribe surveillance measures may be adopted, through active institutional controls or a soil hazard information sector.

Whatever the case, the Prefect may rely on the opinion of the classified installations inspectorate, ASN and the Regional Health Agency (ARS) to validate the site rehabilitation project, and issues a prefectoral order to govern implementation of the rehabilitation measures. ASN may thus be called upon by the services of the Prefect and the classified installation inspectors to give its opinion on the clean-out objectives of a site.

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APPENDIX

Overview of Basic Nuclear Installations

as at 31 December 2024

To ensure the oversight of all the civil nuclear activities and installations in France, ASN – the French Nuclear Safety Authority – has a regional organisation comprising eleven regional divisions based in Bordeaux, Caen, Châlons-en-Champagne, Dijon, Lille, Lyon, Marseille, Nantes, Orléans, Paris and Strasbourg. The Caen and Orléans divisions are responsible for the oversight of the Basic Nuclear Installations (BNIs) in the Bretagne (Brittany) and Île-de-France regions respectively. The Paris division is responsible for oversight of the overseas regions and the *département*⁽¹⁾ of Mayotte, while the Marseille division oversees radiation protection and radioactive substance transport in the Corse (Corsica) territorial collectivity.

A BNI is an installation which, by its nature or because of the quantity or activity of the radioactive substances it contains, is subject to a specific regulation and oversight system defined by the Environment Code (Title IX of Book V). These installations must be authorised by decree further to a public inquiry and the opinion of ASN. Their design, construction, operation and decommissioning are regulated.

The following are BNIs:

1. nuclear reactors;
2. large installations for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels, or for the treatment, storage or disposal of radioactive waste;
3. large installations containing radioactive or fissile substances;
4. large particle accelerators;
5. deep geological repositories for radioactive waste.

With the exception of nuclear reactors and any future deep geological repositories for radioactive waste, which are all BNIs, Section 1 titled “Classification of Basic Nuclear Installations” of Chapter III of Title IX of Book V of the regulatory section of the Environment Code sets the BNI System thresholds for entry into the BNI System for each category.

For technical or legal reasons, the BNI concept can cover different physical realities: thus, in a Nuclear Power Plant (NPP), each reactor may be considered to be a specific BNI, or a given BNI may be made up of two reactors. Similarly, a “fuel cycle” plant or a centre of the French Alternative Energies and Atomic Energy Commission (CEA) may be made up of several BNIs. These different configurations do not change the conditions of oversight in any way.

The following come under the BNI System:

- installations under construction, if they have formed the subject of a Creation Authorisation Decree (DAC); installations in operation;
- installations that are shut down or undergoing decommissioning, until they are delicensed by an ASN resolution.

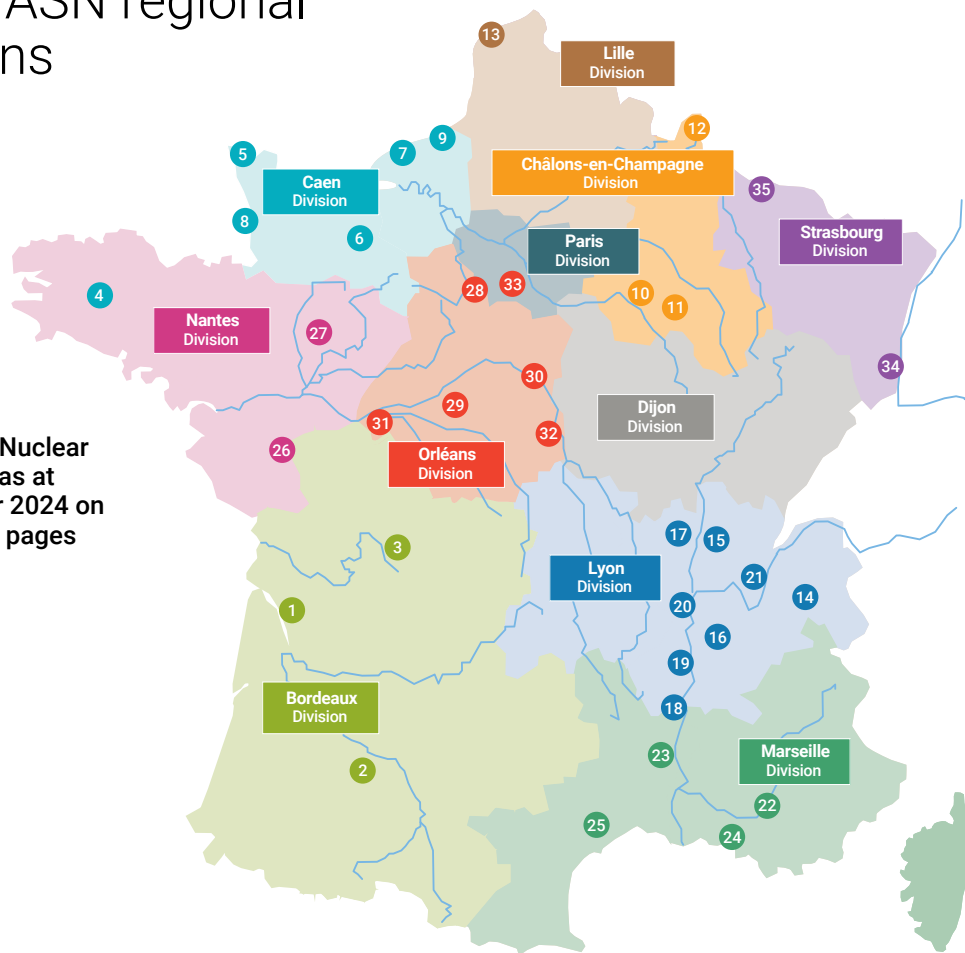
As at 31 December 2024, the number of BNIs (in the sense of legal entities) stood at 120.

The missing BNI numbers correspond to installations delicensed (*see chapter 14*) or licensed as new BNIs (for example, further to the merging of BNIs 42 and 95 into a single BNI 42-U, the numbers “42” and “95” have been removed from the list and number “42-U” has been added). These former BNIs, which no longer exist, are therefore removed from the following list, along with their numbers.

1. Administrative region headed by a Prefect.

Facilities overseen by the ASN regional divisions

List of Basic Nuclear Installations as at 31 December 2024 on the following pages



BORDEAUX

- ① Blayais
- ② Golfech
- ③ Civaux

CAEN

- ④ Brennilis
- ⑤ La Hague
- ⑥ Caen
- ⑦ Paluel
- ⑧ Flamanville
- ⑨ Penly

CHÂLONS-EN-CHAMPAGNE

- ⑩ Nogent-sur-Seine
- ⑪ Soulaïnes-Dhuys
- ⑫ Chooz

LILLE

- ⑬ Gravelines

LYON

- ⑭ Grenoble
- ⑮ Bugey
- ⑯ Romans-sur-Isère
- ⑰ Dagneux
- ⑱ Tricastin
- ⑲ Cruas-Meyssse
- ⑳ Saint-Alban
- ㉑ Creys-Malville

MARSEILLE

- ㉒ Cadarache
- ㉓ Marcoule
- ㉔ Marseille
- ㉕ Malvési

NANTES

- ㉖ Pouzauges
- ㉗ Sablé-sur-Sarthe

ORLÉANS

- ㉘ Saclay
- ㉙ Saint-Laurent-des-Eaux
- ㉚ Dampierre-en-Burly
- ㉛ Chinon
- ㉜ Belleville-sur-Loire
- ㉝ Fontenay-aux-Roses

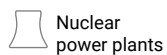
PARIS

The Île-de-France BNIs are overseen by the Orléans division.

STRASBOURG

- ㉞ Fessenheim
- ㉟ Cattenom

Types of facilities



Nuclear power plants



Plants



Research facilities



Waste disposal repositories



Others

Site name	Location of the basic nuclear installations	Licensee	Type of installation	No.
BORDEAUX DIVISION				
① Blayais	LE BLAYAIS NUCLEAR POWER PLANT (reactors 1 and 2) 33820 Saint-Ciers-sur-Gironde (Gironde)	EDF	Reactors	86
① Blayais	LE BLAYAIS NUCLEAR POWER PLANT (reactors 3 and 4) 33820 Saint-Ciers-sur-Gironde (Gironde)	EDF	Reactors	110
② Golfech	GOLFECH NUCLEAR POWER PLANT (reactor 1) 82400 Golfech (Tarn-et-Garonne)	EDF	Reactor	135
② Golfech	GOLFECH NUCLEAR POWER PLANT (reactor 2) 82400 Golfech (Tarn-et-Garonne)	EDF	Reactor	142
③ Civaux	CIVAUX NUCLEAR POWER PLANT (reactor 1) BP 1 – 86320 Civaux (Vienne)	EDF	Reactor	158
③ Civaux	CIVAUX NUCLEAR POWER PLANT (reactor 2) BP 1 – 86320 Civaux (Vienne)	EDF	Reactor	159

CAEN DIVISION				
④ Brennilis	MONT'S D'ARRÉE (EL4-D) 29530 Loqueffret (Finistère)	EDF	Reactor	162
⑤ La Hague	SPENT FUEL REPROCESSING PLANT (UP2-400) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	33
⑤ La Hague	EFFLUENTS AND SOLID WASTE TREATMENT PLANT (STE2) AND OXIDE NUCLEAR FUEL REPROCESSING FACILITY (AT1) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	38
⑤ La Hague	ATELIER ELAN IIB 50100 Cherbourg (Manche)	Orano Recyclage	Transformation of radioactive substances	47
⑤ La Hague	MANCHE REPOSITORY (CSM) 50440 Digulleville (Manche)	Andra	Storage of radioactive substances	66
⑤ La Hague	OXIDE HIGH ACTIVITY FACILITY (HAO) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	80
⑤ La Hague	PLANT FOR REPROCESSING SPENT FUEL ELEMENTS FROM LIGHT WATER Reactors (UP3-A) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	116
⑤ La Hague	PLANT FOR REPROCESSING SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP2-800) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	117
⑤ La Hague	LIQUID EFFLUENTS AND SOLID WASTE TREATMENT STATION (STE3) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	118
⑥ Caen	LARGE NATIONAL HEAVY ION ACCELERATOR (GANIL) 14021 Caen Cedex (Calvados)	G.I.E. GANIL	Particle accelerator	113
⑦ Paluel	PALUEL NUCLEAR POWER PLANT (reactor 1) 76450 Paluel (Seine-Maritime)	EDF	Reactor	103
⑦ Paluel	PALUEL NUCLEAR POWER PLANT (reactor 2) 76450 Paluel (Seine-Maritime)	EDF	Reactor	104
⑦ Paluel	PALUEL NUCLEAR POWER PLANT (reactor 3) 76450 Paluel (Seine-Maritime)	EDF	Reactor	114
⑦ Paluel	PALUEL NUCLEAR POWER PLANT (reactor 4) 76450 Paluel (Seine-Maritime)	EDF	Reactor	115
⑧ Flamanville	FLAMANVILLE NUCLEAR POWER PLANT (reactor 1) 50340 Flamanville (Manche)	EDF	Reactor	108
⑧ Flamanville	FLAMANVILLE NUCLEAR POWER PLANT (reactor 2) 50340 Flamanville (Manche)	EDF	Reactor	109
⑧ Flamanville	FLAMANVILLE NUCLEAR POWER PLANT (reactor 3 – EPR) 50340 Flamanville (Manche)	EDF	Reactor	167
⑨ Penly	PENLY NUCLEAR POWER PLANT (reactor 1) 76370 Neuville-lès-Dieppe (Seine-Maritime)	EDF	Reactor	136
⑨ Penly	PENLY NUCLEAR POWER PLANT (reactor 2) 76370 Neuville-lès-Dieppe (Seine-Maritime)	EDF	Reactor	140

CHÂLONS-EN-CHAMPAGNE DIVISION				
⑩ Nogent-sur-Seine	NOGENT-SUR-SEINE NUCLEAR POWER PLANT (reactor 1) 10400 Nogent-sur-Seine (Aube)	EDF	Reactor	129
⑩ Nogent-sur-Seine	NOGENT-SUR-SEINE NUCLEAR POWER PLANT (reactor 2) 10400 Nogent-sur-Seine (Aube)	EDF	Reactor	130
⑪ Soullaines-Dhuys	AUBE REPOSITORY (CSA) 10200 Bar-sur-Aube (Aube)	Andra	Above-ground disposal of radioactive substances	149
⑫ Chooz	CHOOZ B NUCLEAR POWER PLANT (reactor 1) 08600 Givet (Ardennes)	EDF	Reactor	139
⑫ Chooz	CHOOZ B NUCLEAR POWER PLANT (reactor 2) 08600 Givet (Ardennes)	EDF	Reactor	144
⑫ Chooz	ARDENNES NUCLEAR POWER PLANT (CNA-D – CHOOZ A) 08600 Givet (Ardennes)	EDF	Reactor	163

Site name	Location of the basic nuclear installations	Licensee	Type of installation	No.
LILLE DIVISION				
13 Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 1 and 2) 59820 Gravelines (Nord)	EDF	Reactors	96
13 Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 3 and 4) 59820 Gravelines (Nord)	EDF	Reactors	97
13 Gravelines	GRAVELINES NUCLEAR POWER PLANT (reactors 5 and 6) 59820 Gravelines (Nord)	EDF	Reactors	122
LYON DIVISION				
14 Grenoble	HIGH-FLUX REACTOR (RHF) 38041 Grenoble Cedex (Isère)	Institut Max Von Laue Paul Langevin (ILL)	Reactor	67
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactor 1) BP 60120 – 01150 Saint-Vulbas (Ain)	EDF	Reactor	45
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactors 2 and 3) BP 60120 – 01150 Saint-Vulbas (Ain)	EDF	Reactors	78
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactors 4 and 5) BP 60120 – 01150 Saint-Vulbas (Ain)	EDF	Reactors	89
15 Bugey	BUGEY INTER-REGIONAL STORE (MIR) BP 60120 – 01150 Saint-Vulbas (Ain)	EDF	Fresh fuel storage	102
15 Bugey	ACTIVATED WASTE PACKAGING AND STORAGE FACILITY (ICEDA) 01150 Saint-Vulbas (Ain)	EDF	Conditioning, packaging and storage of radioactive substances	173
16 Romans-sur-Isère	NUCLEAR FUEL FABRICATION PLANT 26104 Romans-sur-Isère Cedex (Drôme)	Framatome	Fabrication of nuclear fuels	63-U
17 Dagneux	DAGNEUX IONISATION FACILITY Z.I. Les Chartinières – 01120 Dagneux (Ain)	Ionisos	Utilisation of radioactive substances	68
18 Tricastin	TRICASTIN NUCLEAR POWER PLANT (reactors 1 and 2) 26130 Saint-Paul-Trois-Châteaux (Drôme)	EDF	Reactors	87
18 Tricastin	TRICASTIN NUCLEAR POWER PLANT (reactors 1 and 2) 26130 Saint-Paul-Trois-Châteaux (Drôme)	EDF	Reactors	88
18 Tricastin	GEORGES BESSE PLANT FOR SEPARATING URANIUM ISOTOPES BY GASEOUS DIFFUSION (EURODIF) 26702 Pierrelatte Cedex (Drôme and Vaucluse)	Orano Chimie-Enrichissement	Transformation of radioactive substances	93
18 Tricastin	COMHUREX URANIUM HEXAFLUORIDE PREPARATION PLANT 26130 Saint-Paul-Trois-Châteaux (Drôme)	Orano Chimie-Enrichissement	Transformation of radioactive substances	105
18 Tricastin	CLEAN-UP AND URANIUM RECOVERY FACILITY (IARU) 26130 Saint-Paul-Trois-Châteaux (Drôme and Vaucluse)	Orano Chimie-Enrichissement	Plant	138
18 Tricastin	FACILITY TU5 AND W BP 16 – 26700 Pierrelatte (Drôme)	Orano Chimie-Enrichissement	Transformation of radioactive substances	155
18 Tricastin	TRICASTIN OPERATIONAL HOT UNIT (BCOT) BP 127 – 84500 Bollène (Vaucluse)	EDF	Nuclear maintenance	157
18 Tricastin	GEORGES BESSE II PLANT FOR SEPARATING URANIUM ISOTOPES BY CENTRIFUGATION (GB II) 84500 Bollène, 26702 Pierrelatte Cedex and 26130 Saint-Paul-Trois-Châteaux (Drôme and Vaucluse)	Orano Chimie-Enrichissement	Transformation of radioactive substances	168
18 Tricastin	AREVA TRICASTIN ANALYSIS LABORATORIES (ATLAS) 26700 Pierrelatte (Drôme)	Orano Chimie-Enrichissement	Laboratory for the utilisation of radioactive substances	176
18 Tricastin	TRICASTIN URANIUM-BEARING MATERIAL STORAGE YARDS 26700 Pierrelatte (Drôme)	Orano Chimie-Enrichissement	Storage of radioactive materials	178
18 Tricastin	P35 26700 Pierrelatte (Drôme)	Orano Chimie-Enrichissement	Storage of radioactive materials	179
18 Tricastin	LOCAL STORAGE SUPPLY FOR REPROCESSED URANIUM (FLEUR) 26700 Pierrelatte (Drôme)	Orano Chimie-Enrichissement	Reception, storage, shipping of uranium containers	180
19 Cruas-Meyssse	CRUAS NUCLEAR POWER PLANT (reactors 1 and 2) 07350 Cruas (Ardèche)	EDF	Reactors	111
19 Cruas-Meyssse	CRUAS NUCLEAR POWER PLANT (reactors 3 and 4) 07350 Cruas (Ardèche)	EDF	Reactors	112
20 Saint-Alban	SAINT-ALBAN NUCLEAR POWER PLANT (reactor 1) 38550 Le Péage-de-Roussillon (Isère)	EDF	Reactor	119
20 Saint-Alban	SAINT-ALBAN NUCLEAR POWER PLANT (reactor 2) 38550 Le Péage-de-Roussillon (Isère)	EDF	Reactor	120
21 Creys-Malville	SUPERPHÉNIX REACTOR 38510 Morestel (Isère)	EDF	Reactor	91
21 Creys-Malville	FUEL STORAGE FACILITY (APEC) 38510 Creys-Mépieu (Isère)	EDF	Storage of radioactive substances	141

Site name	Location of the basic nuclear installations	Licensee	Type of installation	No.
MARSEILLE DIVISION				
22 Cadarache	PROVISIONAL STORAGE FACILITY AND FACILITY FOR DRY STORAGE OF SPENT NUCLEAR FUEL (PÉGASE-CASCAD) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Storage of radioactive substances	22
22 Cadarache	CABRI 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	24
22 Cadarache	RAPSODIE 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	25
22 Cadarache	PLUTONIUM TECHNOLOGY FACILITY (ATPu) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Manufacture or transformation of radioactive substances	32
22 Cadarache	SOLID WASTE TREATMENT STATION (STD) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Transformation of radioactive substances	37-A
22 Cadarache	EFFLUENT TREATMENT STATION (STE) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Transformation of radioactive substances	37-B
22 Cadarache	MASURCA 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	39
22 Cadarache	ÉOLE / MINERVE 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	42-U
22 Cadarache	ENRICHED URANIUM PROCESSING FACILITY (ATUe) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Manufacture of radioactive substances	52
22 Cadarache	CENTRAL FISSILE MATERIAL WAREHOUSE (MCMF) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Holding of radioactive substances	53
22 Cadarache	CHEMICAL PURIFICATION LABORATORY (LPC) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Transformation of radioactive substances	54
22 Cadarache	ACTIVE FUEL EXAMINATION LABORATORY (LECA) AND SPENT FUEL TREATMENT, CLEAN-OUT AND RECONDITIONING STATION (STAR) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Utilisation of radioactive substances	55
22 Cadarache	SOLID RADIOACTIVE WASTE STORAGE AREA 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Storage of radioactive substances	56
22 Cadarache	PHÉBUS 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	92
22 Cadarache	LABORATORY FOR RESEARCH AND EXPERIMENTAL FABRICATION OF ADVANCED NUCLEAR FUELS (LEFCA) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Manufacture of radioactive substances	123
22 Cadarache	CHICADE BP 1 – 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Research and development laboratory	156
22 Cadarache	CEDRA 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Conditioning, packaging and storage of radioactive substances	164
22 Cadarache	MAGENTA 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reception and shipping of nuclear materials	169
22 Cadarache	ADVANCED EFFLUENT MANAGEMENT AND TREATMENT FACILITY (AGATE) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Conditioning, packaging and storage of radioactive substances	171
22 Cadarache	THE JULES HOROWITZ REACTOR (JHR) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	172
22 Cadarache	ITER 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	ITER International Organisation	Experiments on nuclear fusion reactions in tritium and deuterium plasma	174
23 Marcoule	PHÉNIX 30205 Bagnols-sur-Cèze Cedex (Gard)	CEA	Reactor	71
23 Marcoule	ATALANTE 30200 Chusclan (Gard)	CEA	Actinides research, development and production studies laboratory	148
23 Marcoule	NUCLEAR FUEL FABRICATION PLANT (MELOX) BP 2 – 30200 Chusclan (Gard)	Orano Recyclage	Manufacture of radioactive substances	151
23 Marcoule	CENTRACO 30200 Codolet (Gard)	Cyclife France	Treatment of radioactive waste and effluents	160
23 Marcoule	GAMMATEC 30200 Chusclan (Gard)	Synergy Health Marseille	Ionisation treatment of materials, products and equipment for industrial purposes and research and development purposes	170
23 Marcoule	DIADEM 30200 Chusclan (Gard)	CEA	Storage of solid radioactive waste	177
24 Marseille	IONISATION FACILITY (GAMMASTER) M.I.N. 712 – 13323 Marseille Cedex 14 (Bouches-du-Rhône)	Synergy Health Marseille	Ionisation facility	147
25 Malvési	CONTAINED STORAGE OF CONVERSION RESIDUES (ÉCRIN) 11100 Narbonne (Aude)	Orano Chimie-Enrichissement	Storage of radioactive substances	175

Site name	Location of the basic nuclear installations	Licensee	Type of installation	No.
NANTES DIVISION				
26 Pouzauges	POUZAUGES IONISATION FACILITY Z.I. de Monlifiant 85700 Pouzauges (Vendée)	Ionisos	Ionisation facility	146
27 Sablé-sur-Sarthe	SABLÉ-SUR-SARTHE IONISATION FACILITY Z.I. de l'Aubrée 72300 Sablé-sur-Sarthe (Sarthe)	Ionisos	Ionisation facility	154
ORLÉANS DIVISION				
28 Saclay	ARTIFICIAL RADIONUCLIDES PRODUCTION FACILITY (UPRA) 91191 Gif-sur-Yvette Cedex (Essonne)	CIS bio international	Manufacture or transformation of radioactive substances	29
28 Saclay	LIQUID EFFLUENTS MANAGEMENT ZONE (STELLA) 91191 Gif-sur-Yvette Cedex (Essonne)	CEA	Transformation of radioactive substances	35
28 Saclay	OSIRIS-ISIS 91191 Gif-sur-Yvette Cedex (Essonne)	CEA	Reactors	40
28 Saclay	HIGH-ACTIVITY LABORATORY (LHA) 91191 Gif-sur-Yvette Cedex (Essonne)	CEA	Utilisation of radioactive substances	49
28 Saclay	SPENT FUEL TESTING LABORATORY (LECI) 91191 Gif-sur-Yvette Cedex (Essonne)	CEA	Utilisation of radioactive substances	50
28 Saclay	SOLID RADIOACTIVE WASTE MANAGEMENT ZONE (ZGDS) 91191 Gif-sur-Yvette Cedex (Essonne)	CEA	Storage and packaging of radioactive substances	72
28 Saclay	IRRADIATION FACILITIES (POSÉIDON) 91191 Gif-sur-Yvette Cedex (Essonne)	CEA	Utilisation of radioactive substances	77
28 Saclay	ORPHÉE 91191 Gif-sur-Yvette Cedex (Essonne)	CEA	Reactor	101
29 Saint-Laurent-des-Eaux	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors A1 and A2) 41220 Saint-Laurent-Nouan (Loir-et-Cher)	EDF	Reactors	46
29 Saint-Laurent-des-Eaux	GRAPHITE SLEEVE STORAGE SILOS 41220 Saint-Laurent-Nouan (Loir-et-Cher)	EDF	Storage of radioactive substances	74
29 Saint-Laurent-des-Eaux	SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT (reactors B1 and B2) 41220 Saint-Laurent-Nouan (Loir-et-Cher)	EDF	Reactors	100
30 Dampierre-en-Burly	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 1 and 2) 45570 Ouzouer-sur-Loire (Loiret)	EDF	Reactors	84
30 Dampierre-en-Burly	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 3 and 4) 45570 Ouzouer-sur-Loire (Loiret)	EDF	Reactors	85
31 Chinon	IRRADIATED MATERIALS FACILITY (AMI) 37420 Avoine (Indre-et-Loire)	EDF	Utilisation of radioactive substances	94
31 Chinon	CHINON INTER-REGIONAL STORE (MIR) 37420 Avoine (Indre-et-Loire)	EDF	Fresh fuel storage	99
31 Chinon	CHINON NUCLEAR POWER PLANT (reactors B1 and B2) 37420 Avoine (Indre-et-Loire)	EDF	Reactors	107
31 Chinon	CHINON NUCLEAR POWER PLANT (reactors B3 and B4) 37420 Avoine (Indre-et-Loire)	EDF	Reactors	132
31 Chinon	CHINON A1 D 37420 Avoine (Indre-et-Loire)	EDF	Reactor	133
31 Chinon	CHINON A2 D 37420 Avoine (Indre-et-Loire)	EDF	Reactor	153
31 Chinon	CHINON A3 D 37420 Avoine (Indre-et-Loire)	EDF	Reactor	161
32 Belleville-sur-Loire	BELLEVILLE-SUR-LOIRE NUCLEAR POWER PLANT (reactor 1) 18240 Léré (Cher)	EDF	Reactor	127
32 Belleville-sur-Loire	BELLEVILLE-SUR-LOIRE NUCLEAR POWER PLANT (reactor 2) 18240 Léré (Cher)	EDF	Reactor	128
33 Fontenay-aux-Roses	PROCÉDÉ 92265 Fontenay-aux-Roses Cedex (Hauts-de-Seine)	CEA	Research facility	165
33 Fontenay-aux-Roses	SUPPORT 92265 Fontenay-aux-Roses Cedex (Hauts-de-Seine)	CEA	Effluent treatment and waste storage facility	166
STRASBOURG DIVISION				
34 Fessenheim	FESSENHEIM NUCLEAR POWER PLANT (reactors 1 and 2) 68740 Fessenheim (Haut-Rhin)	EDF	Reactors	75
35 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 1) 57570 Cattenom (Moselle)	EDF	Reactor	124
35 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 2) 57570 Cattenom (Moselle)	EDF	Reactor	125
35 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 3) 57570 Cattenom (Moselle)	EDF	Reactor	126
35 Cattenom	CATTENOM NUCLEAR POWER PLANT (reactor 4) 57570 Cattenom (Moselle)	EDF	Reactor	137

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