

# ASN REPORT

on the state of nuclear safety  
and radiation protection in France in | **2022** |



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The French Nuclear Safety Authority presents  
its report on the state of nuclear safety  
and radiation protection in France in 2022.

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.

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Improving nuclear safety  
and radiation protection





# THE FRENCH NUCLEAR SAFETY AUTHORITY

# 2022

ROLES  
OPERATIONS  
KEY FIGURES

ASN ORGANISATION CHART

ASN was created by the 13 June 2006 Nuclear Security and Transparency Act. It is an independent administrative Authority responsible for regulating civil nuclear activities in France.

On behalf of the State, ASN ensures the oversight of nuclear safety and radiation protection to protect people and the environment. It informs the public and contributes to enlightened societal choices.

ASN decides and acts with rigour and discernment: its aim is to exercise oversight that is recognised by the citizens and regarded internationally as a benchmark for good practice.



# ROLES

## REGULATING

ASN contributes to drafting regulations, by submitting its opinion to the Government on draft decrees and Ministerial Orders, and by issuing technical regulations. It ensures that the regulations are clear, accessible and proportionate to the safety issues.

## AUTHORISING

ASN examines all individual authorisation applications for nuclear facilities. It grants licenses and authorisations, with the exception of major authorisations for Basic Nuclear Installations (BNIs), such as creation and decommissioning. ASN also issues the licenses provided for in the Public Health Code concerning small-scale nuclear activities and issues licenses or approvals for radioactive substances transport operations.

## MONITORING

ASN is responsible for ensuring compliance with the rules and requirements applicable to the facilities and activities within its field of competence. Since the Energy Transition for Green Growth Act of 17 August 2015, known as the "TECV Act", ASN's roles now include protecting ionising radioactive sources against malicious acts. Inspection is ASN's primary monitoring activity. More than 1,900 inspections were thus performed in 2022 in the fields of nuclear safety and radiation protection.

ASN has graded enforcement and penalty powers (formal notice, administrative fines, daily fines, ability to carry out seizure, take samples or require payment of a guarantee, etc.). The administrative fine is the competence of the ASN Administrative Enforcement Committee, which complies with the principle of the separation of the examination and sentencing functions.

## EXPERT SUPPORT

When drawing up its decisions, ASN calls on outside technical expertise, in particular that of the French Institute for Radiation Protection and Nuclear Safety (IRSN). The ASN Chairman is a member of the IRSN Board. ASN also calls on the opinions and recommendations of seven Advisory Committees of Experts (GPEs), from a variety of scientific and technical backgrounds.

## INFORMING

ASN reports on its activities to Parliament. It informs the public and the stakeholders (environmental protection associations, Local Information Committees, media, etc.) about its activities and the state of nuclear safety and radiation protection in France.

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 of the nuclear facilities.

The *asn.fr* website is ASN's main information channel.

## IN EMERGENCY SITUATIONS

ASN monitors the steps taken by the licensee to make the facility safe. It informs the public and its foreign counterparts of the situation. ASN assists the Government. More particularly, it sends the competent Authorities its recommendations regarding the civil security measures to be taken.

## REGULATION AND MONITORING OF DIVERSIFIED ACTIVITIES AND FACILITIES

Nuclear power plants, radioactive waste management, fabrication and reprocessing of nuclear fuel, packages of radioactive substances, medical facilities, research laboratories, industrial activities, etc. ASN monitors and regulates an extremely varied range of activities and installations.

This regulation covers:

- 56 nuclear reactors producing 70% of the electricity consumed in France, as well as the Flamanville EPR reactor under construction;
- about 80 other facilities participating in civil research activities, radioactive waste management activities or "fuel cycle" activities;
- 35 facilities which have been finally shut down or are being decommissioned;
- several thousand facilities or activities using sources of ionising radiation for medical, industrial or research purposes;
- several hundred thousand shipments of radioactive substances performed annually in France.

# OPERATIONS

## THE COMMISSION

The Commission defines ASN's general policy regarding nuclear safety and radiation protection. It consists of five Commissioners, including the ASN Chairman, appointed for a term of 6 years<sup>(\*)</sup>.

<b>Bernard DOROSZCZUK</b> Chairman	<b>Sylvie CADET-MERCIER</b> <sup>(*)</sup> Commissioner	<b>Géraldine PINA JOMIR</b> Commissioner	<b>Laure TOURJANSKY</b> <sup>(*)(**)</sup> Commissioner	<b>Jean-Luc LACHAUME</b> <sup>(*)</sup> Commissioner
from 13 november 2018 to 12 november 2024	from 21 december 2016 to 9 december 2023	from 15 december 2020 to 9 december 2026	from 21 april 2021 to 9 december 2023	from 21 december 2018 to 9 december 2026
↓ <b>APPOINTED BY the President of the Republic</b>			↓ <b>APPOINTED BY the President of the Senate</b>	↓ <b>APPOINTED BY the President of the National Assembly</b>

\* The Environment Code, modified by Act 2017-55 of 20 January 2017, introducing the general status of the independent administrative Authorities and the independent public Authorities, provides for the renewal of half of the ASN Commission, other than its Chairman, every three years. Decree 2019-190 of 14 March 2019 (codifying the provisions applicable to BNIs, the transport of radioactive substances and transparency in the nuclear field) sets out the relevant interim provisions and modifies the duration of the mandates of three Commissioners.

\*\* By Decree of the President of the Republic dated 21 April 2021, Laure Tourjansky was appointed Commissioner for the remainder of the mandate of Lydie Évrard, called to other duties.

## IMPARTIALITY

The Commissioners perform their duties in complete impartiality and receive no instructions from either the Government or any other person or institution.

## INDEPENDENCE

The Commissioners perform their duties on a full-time basis. Their mandate is for a six-year term. It is not renewable. The duties of a Commissioner can only be terminated in the case of impediment or resignation duly confirmed by a majority of the Commissioners.

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.

## COMPETENCIES

The Commission takes decisions and issues opinions, which are published in ASN's *Official Bulletin*. The Commission defines ASN's oversight policy. The Chairman appoints the ASN inspectors. The Commission decides whether to open an inquiry following an incident or accident.

Every year, it presents the *ASN Report on the State of Nuclear Safety and Radiation Protection in France* to Parliament. Its Chairman reports on ASN activities to the competent committees of the National Assembly and of the Senate and to the Parliamentary Office for the Evaluation of Scientific and Technological Choices. The Commission defines ASN's external relations policy at national and international level.

## THE DEPARTMENTS

ASN comprises departments placed under the authority of its Chairman. The departments are headed by a Director General, appointed by the ASN Chairman. They carry out ASN's day-to-day duties and prepare draft opinions and decisions for the ASN Commission. They comprise:

- **head office departments organised according to topics**, which oversee their field of activity at a national level, for both technical and transverse matters (international action, preparedness for emergency situations, information of the public, legal affairs, human resources and other support functions). They more specifically prepare draft doctrines and texts of a general scope, examine the more complex technical files and the "generic" files, in other words those which concern several similar facilities;
- **11 regional divisions**, with competence for one or more administrative regions, so as to cover the entire country and the overseas territories. The regional divisions conduct most of the oversight in the field on the nuclear facilities, radioactive substances transport operations and small-scale nuclear activities. They represent ASN in the regions and contribute to public information within their geographical area. In emergency situations, the divisions assist the Prefect of the *département*<sup>(\*\*\*)</sup> who is responsible for the protection of the population, and oversee the operations to safeguard the facility affected by the accident.

\*\*\* Administrative region headed by a Prefect.

# KEY FIGURES 2022

## PERSONNEL



**516**  
staff members

**85%**  
management

**48%**  
women

**329**  
inspectors

## ASN ACTIONS



**1,868**  
inspections of which 4%  
were carried out remotely

**239**  
technical opinions  
sent to ASN by IRSN

**19**  
plenary sessions of the  
Advisory Committees  
of Experts

**2,161**  
individual licensing  
and registration  
resolutions issued

**28,508**  
inspection follow-up  
letters available  
on *asn.fr* as at  
31 December 2022

## BUDGET



**€68.30 M**  
budget for ASN  
(programme 181)

**€85.5 M** IRSN budget devoted  
to expert assessment  
work on behalf of ASN

## INFORMATIONS



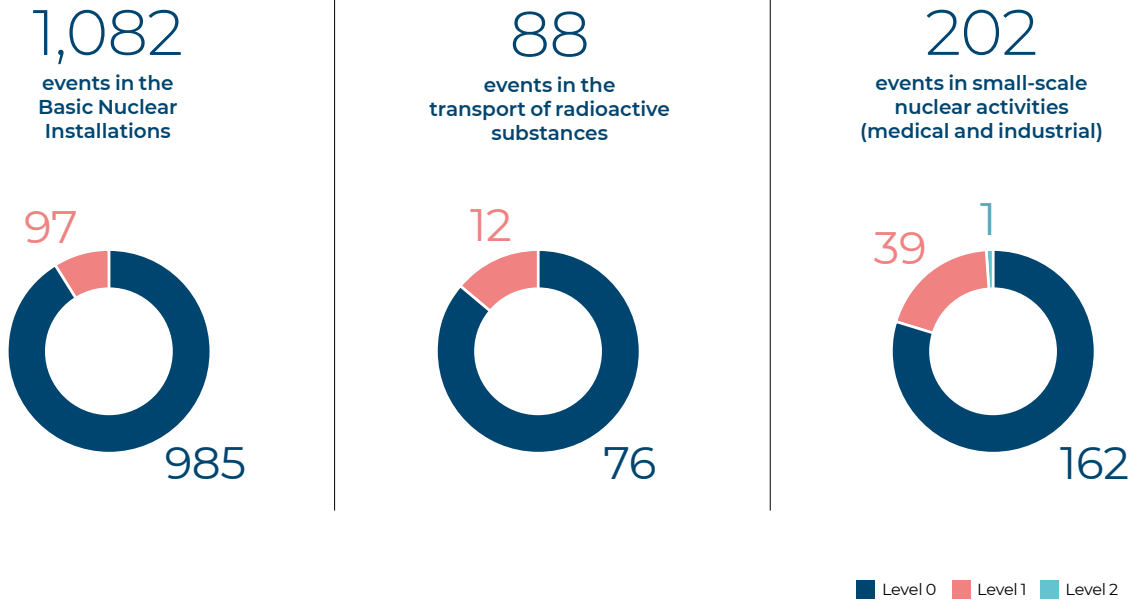
**600**  
replies to queries  
from the public and  
the stakeholders

**81**  
information  
notices

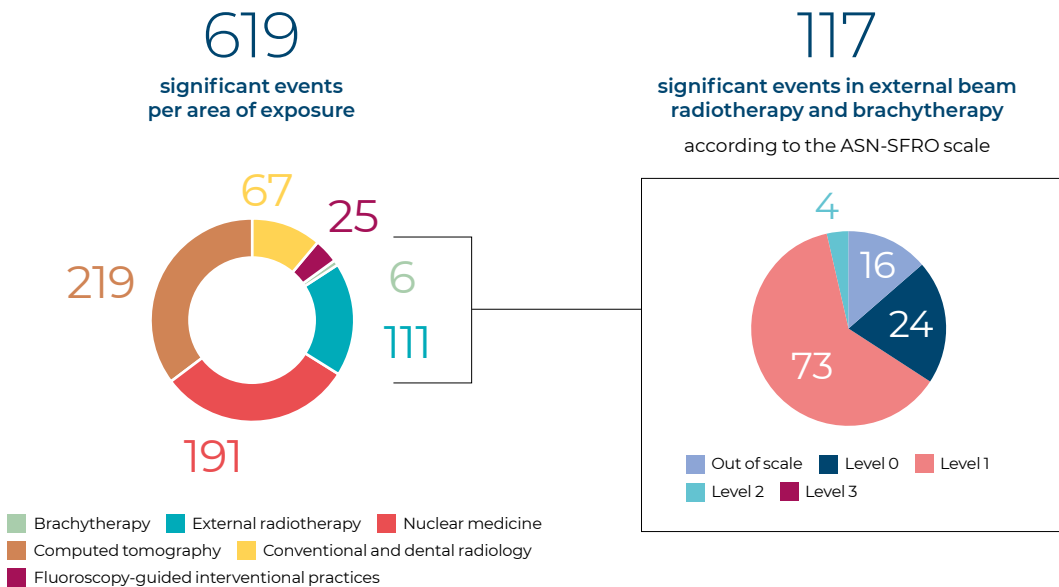
**11**  
press  
conferences

# KEY FIGURES 2022

## NUMBER OF SIGNIFICANT EVENTS RATED ON THE INES SCALE<sup>(\*)</sup>



## NUMBER OF SIGNIFICANT EVENTS IN THE MEDICAL FIELD<sup>(\*)</sup>



\* The INES scale (International Nuclear and Radiological Event Scale) was developed by IAEA to explain to the public the importance of an event in terms of safety or radiation protection. This scale applies to events occurring in BNIs and events with potential or actual consequences for the radiation protection of the public and workers. It does not apply to events with an impact on the radiation protection of patients, and the criteria normally used to rate events (notably the dose received) are not applicable in this case.

As it was pertinent to be able to inform the public of radiotherapy events, ASN – in close collaboration with the French Society for Radiotherapy and Oncology – developed a scale specific to radiotherapy events (ASN-SFRO scale).

These two scales cover a relatively wide range of radiation protection events, with the exception of imaging events.

# ORGANISATION CHART<sup>(\*)</sup>

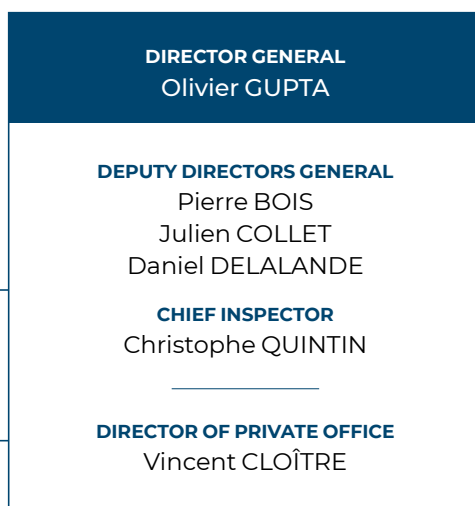
## COMMISSION



**HEAD OF PRIVATE OFFICE**  
Sylvie RODDE



## GENERAL DIRECTORATE



**MANAGEMENT AND EXPERTISE OFFICE**  
Adeline CLOS

**REGULATION AND OVERSIGHT SUPPORT MISSION**  
Julien HUSSE

**GENERAL SECRETARIAT**  
Jean-Patrick GOUDALLE

## DEPARTMENTS

**NUCLEAR POWER PLANTS**  
Rémy CATTEAU

**NUCLEAR PRESSURE EQUIPMENT**  
Corinne SILVESTRI

**WASTE, RESEARCH, FACILITIES AND FUEL CYCLE**  
Cédric MESSIER

**TRANSPORT AND SOURCES**  
Fabien FÉRON

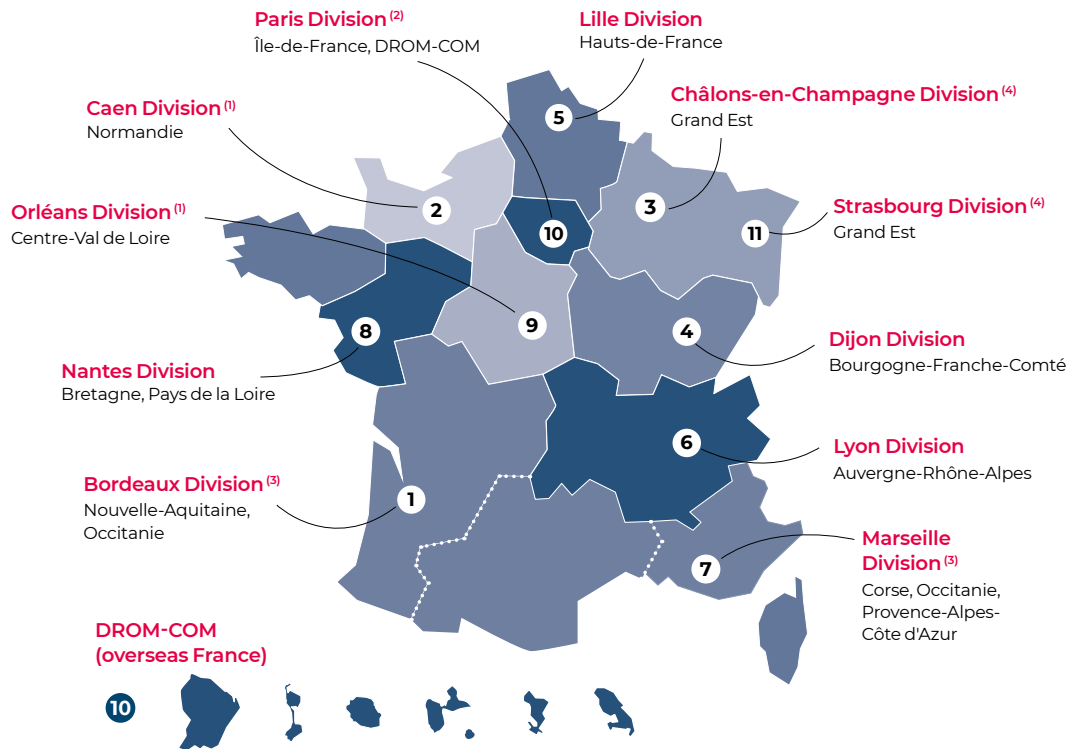
**IONISING RADIATION AND HEALTH**  
Carole ROUSSE

**ENVIRONMENT AND EMERGENCY SITUATIONS**  
Olivier RIVIÈRE

**INTERNATIONAL RELATIONS**  
Luc CHANIAL

**LEGAL AFFAIRS**  
Olivia LAHAYE

**INFORMATION, COMMUNICATION AND DIGITAL USAGES**  
Clémence PICART



(1) For BNI oversight only, the Caen and Orléans divisions hold responsibility for the Bretagne and Île-de-France regions respectively.

(2) The Paris division is responsible for Martinique, Guadeloupe, Guyane, Mayotte, La Réunion, Saint-Pierre-et-Miquelon.

(3) The Bordeaux and Marseille divisions jointly regulate nuclear safety, radiation protection and the transport of radioactive substances in the Occitanie region.

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

## REGIONAL DIVISIONS

**1**  
**BORDEAUX**  
REGIONAL REPRESENTATIVE  
Alice-Anne MÉDARD  
REGIONAL HEAD  
Simon GARNIER

**4**  
**DIJON**  
REGIONAL REPRESENTATIVE  
Jean-Pierre LESTOILLE  
REGIONAL HEAD  
Marc CHAMPION

**7**  
**MARSEILLE**  
REGIONAL REPRESENTATIVE  
Sébastien FOREST  
REGIONAL HEAD  
Bastien LAURAS

**10**  
**PARIS**  
REGIONAL REPRESENTATIVE  
Emmanuelle GAY  
REGIONAL HEAD  
Agathe BALTZER

**2**  
**CAEN**  
REGIONAL REPRESENTATIVE  
Olivier MORZELLE  
REGIONAL HEAD  
Gaëtan LAFFORGUE

**5**  
**LILLE**  
REGIONAL REPRESENTATIVE  
Julien LABIT  
REGIONAL HEAD  
Rémy ZMYSLONY

**8**  
**NANTES**  
REGIONAL REPRESENTATIVE  
Anne BEAUVAL  
REGIONAL HEAD  
Émilie JAMBU

**3**  
**CHÂLONS-EN-CHAMPAGNE**  
REGIONAL REPRESENTATIVE  
Hervé VANLAER  
REGIONAL HEAD  
Mathieu RIQUART

**6**  
**LYON**  
REGIONAL REPRESENTATIVE  
Jean-Philippe DENEUVY  
REGIONAL HEAD  
Nour KHATER

**9**  
**ORLÉANS**  
REGIONAL REPRESENTATIVE  
Hervé BRÛLÉ  
REGIONAL HEAD  
Arthur NEVEU

**11**  
**STRASBOURG**  
REGIONAL REPRESENTATIVE  
Hervé VANLAER  
REGIONAL HEAD  
Camille PERIER

\* As at 1 March 2023.

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Competence  
Independence  
Rigour  
Transparency

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## ADVICE TO THE READER

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

Only regulatory news for the year 2021 is present in this report.  
All the regulations can be consulted on [asn.fr](https://asn.fr), under the heading “L’ASN réglemente”.

# 2022, AN EXCEPTIONAL YEAR AND CONTEXT

Montrouge, 7 March 2023

In 2022, the level of safety in the nuclear installations remained at a satisfactory level, as did radiation protection in the industrial, medical and radioactive substances transport sectors. However, the year 2022 was marked by issues in the nuclear installations hitherto never encountered, as well as by a period of intense heatwave. These events once again highlighted the need to maintain safety margins and to anticipate the challenges ahead, including dealing with exceptional situations linked to climate change.

The year 2022 was also the year of debate on the French energy mix and the new prospects for nuclear energy, whether the continued operation of the existing installations or the construction of new ones. These come against the backdrop of the war in Ukraine and international tensions, which accentuate the issues of energy sovereignty and re-industrialisation.

Given this context, the French Nuclear Safety Authority (ASN) considers that the discussions being held in preparation for the next Multi-year Energy Programme (MEP) should tackle the nuclear sector as a system (nuclear power generation, operation and future of the “fuel cycle”, management of the associated wastes). This nuclear system has to be taken in an holistic way, in order to be able to anticipate the safety, radiation protection and environmental protection issues as a whole, including those linked to climate change, with a medium and long term vision, thereby ensuring that these issues are at the heart of public decisions-making process.

From left to right:

**Géraldine PINA JOMIR**, Commissioner  
**Jean-Luc LACHAUME**, Commissioner  
**Sylvie CADET-MERCIER**, Commissioner  
**Bernard DOROSZCZUK**, Chairman  
**Laure TOURJANSKY**, Commissioner



**An unexpected stress corrosion phenomenon on the nuclear fleet which recalls the need for safety margins**

In 2022, the number and duration of reactor outages were unprecedented. This situation was partly foreseeable given the operations involved in the “major overhaul” of the nuclear fleet decided on by EDF and the consequences of the postponement of certain maintenance operations as a result of the health crisis. It was made worse by the detection, during periodic inspections, of a phenomenon of stress corrosion on the welds of the safety injection system, something never before encountered on the international Pressurised Water Reactors fleet.

Faced with this unexpected phenomenon EDF, which has prime responsibility for safety, decided to shut down, or extend the outage of about fifteen reactors

from all plant series, in order to perform additional inspections and initiate a major investigation plan. This identified the main factors in the onset of stress corrosion and determined which reactors were most sensitive to this phenomenon, that is the four N4 type reactors and the twelve P4 type reactors. On this basis, EDF proposed a prioritised inspection strategy to be gradually deployed on all operating reactors in the fleet. ASN considered this strategy to be appropriate and underlined that it could be revised in the light of any new knowledge.

EDF decided to opt for the systematic replacement of the lines considered to be more sensitive to the phenomenon on the sixteen reactors likely to be the most severely affected, by the end of 2023. This choice is positive with regard to safety, but it does however come at a time of workload pressure in the industrial segments concerned.





### **A summer marked by an exceptional heatwave and drought which had no impact on nuclear safety**

The summer of 2022 was marked by an exceptional heatwave and drought which, for the first time since 2003, obliged ASN to issue resolutions waiving thermal discharge requirements and keeping five reactors in operation. This situation had no consequences for nuclear safety. Environmental monitoring was specifically strengthened so that any deterioration of the environment could be rapidly detected. The initial results of this monitoring, produced at the end of 2022, revealed no impact on the environment downstream of the facilities.

According to the Intergovernmental Panel on Climate Change (IPCC), the frequency of this summer's extreme episodes could double or even triple by the year 2050. The management of their consequences will require consolidation of scientific knowledge on the environmental consequences of water intake and discharge, along with forward planning concerning the long-term global issues.

### **A backdrop of war in Ukraine that is undermining safety responsibilities**

With regard to the situation of the nuclear facilities in Ukraine, ASN together with its European counterparts conducted a joint assessment of the radiological consequences of a possible accident scenario. The work to reinforce nuclear facilities in the wake of the accident on the Fukushima Daiichi Nuclear Power Plant – NPP (Japan) led to an increase in the robustness of the Zaporizhzhia NPP (Ukraine), notably regarding the loss of off-site power risk. However, nuclear facilities are not designed to withstand acts of war.

ASN considers that it is fundamental that the licensee of a facility can in all circumstances exercise its prime responsibility for safety, notably by maintaining control of the decision-making chain, and that the operators can act without being subjected to physical and psychological pressure, whether for day-to-day management of safety or in the event of a possible accident situation. ASN also recalls that Ukraine's State Nuclear Regulatory Inspectorate of Ukraine (SNRIU), which is legally responsible for the oversight of nuclear safety, should be able to carry out its duties without hindrance.

### **EPR commissioning which remains conditional on the final milestones to be reached**

In 2022, EDF devoted major efforts on the Flamanville site to carry out the final activities required prior to commissioning, to requalify the facility following the modifications and repairs made. ASN however underlines that significant work is still to be done ahead of commissioning, to carry out the final hot testing campaign on the site and also to complete the conformity justifications of the nuclear pressure equipment.

At the request of ASN, EDF conducted in-depth analyses to identify the causes of the anomalies affecting the fuel and the core, which had been observed in the first EPR reactors abroad, along with their consequences for safety. EDF in particular learned the lessons regarding the design of the fuel assemblies which will be incorporated as from the first loading into the reactor, to prevent the risk of loss of fuel integrity. EDF is also examining the design of a system to prevent the hydraulic phenomena observed in the first reactors.

ASN recalls that analyses are still needed to substantiate the design of certain safety-related equipment, notably the reliability of the pressuriser valves and the performance of the filters for the water reinjected from the bottom of the reactor building in an accident situation.

### **Innovative small reactor projects which raise unprecedented safety issues**

In a context where the aim is decarbonised energy production, there is considerable interest worldwide in Small Modular Reactors (SMR), more particularly in those countries with no NPPs. This interest should not however overshadow the nuclear safety and security issues raised by these reactors. They should be accorded just as much importance as the decarbonised electricity generation concerns. The deployment of these small reactors for various uses could in particular lead to them being sited in industrial or built-up areas, raising specific questions such as the licensee's capacity to control the risk of malicious acts or the proliferation of nuclear materials.

Moreover, the deployment of these small reactors will not only require an industrial chain for their construction, but also the development and implementation of specific management for spent fuel and waste which do not yet exist.

Finally, the level of safety to be set in the context of the strong call for international harmonisation is a subject of debate. For ASN, the level to be adopted should not simply aim to equal that of the existing generation 3 reactors (Evolutionary Power Reactors – EPR – in France) but should exploit the potential for improvement offered by this type of reactor.

In 2022, ASN continued its discussions with several French companies developing SMR projects involving different technologies. At the initiative of ASN, the French, Finnish and Czech regulators and their respective technical support organisations, initiated a preliminary examination of the main safety options of the Nuward project sponsored by EDF. The conclusions of their joint evaluation will be shared with the European safety authorities under the Community SMR development initiative launched by the European Union in 2021. For ASN, this type of concrete initiative on sufficiently mature reactor designs constitutes a crucial step towards greater convergence of safety requirements for SMR.

### **Vulnerabilities in the “fuel cycle” facilities which remain a concern for ASN**

The vulnerabilities found in 2021 in the “fuel cycle” facilities remain a concern for ASN despite the progress observed. The operators must continue their actions to enhance the operational robustness of their units, each being often unique in the “fuel cycle” process.

In the light of this situation, ASN recalls the importance of rapidly obtaining new spent fuel storage capacity meeting the most recent safety standards, in order to address the problem of saturation of the existing capacities. Over the long term, the densification of the existing pools could not be considered an alternative to the centralised storage pool project presented by EDF.

Generally speaking, spent fuel management raises questions of short-, medium- and long-term forward planning, each of which has major safety implications. ASN reaffirms that, in the short term, the question of whether or not to continue with the existing reprocessing strategy must be settled so that there are sufficient margins for safety with respect to the choice to be made. Whatever the decision taken, the consequences will have to be anticipated at least a decade in advance.

This decision should be preceded by a strategic review on the future of the “fuel cycle” as a whole. In this respect, ASN suggests that a pluralistic review be undertaken of the possible futures of the “fuel cycle” and the corresponding waste, similar to that performed by the *Réseau de transport d’électricité* (RTE) grid utility on future energy scenarios in their “Energy Pathways 2050 study”.

### **Decommissioning and waste retrieval and conditioning operations which must be more transparent**

Decommissioning is a complex operation which generally takes several decades. ASN remains vigilant with regard to the progress made for the successive milestones to be reached in the coming years and aims to enhance the visibility of these milestones. As part of its oversight of complex projects, it has set up an “observatory of waste retrieval and conditioning (RCD) and decommissioning” which it now includes in this report. This observatory presents the priority projects: for RCD, these are operations concerning waste with the highest source term or with specific safety implications; for decommissioning, this concerns the facilities for which important milestones are to be reached in the coming five to ten years. These priority projects will now be subject to a monitoring approach by project phase or milestone.

### **An important step in the Cigéo project which opens up a period of examination during which the consultative process must continue**

The *Cigéo* project for the geological disposal of high and intermediate level long-lived waste has reached an important milestone with the submission of the creation authorisation application for the facility by the French National Radioactive Waste Management Agency (Andra), in January 2023.

In 2022, ASN continued the detailed technical work prior to the submission of this file which is of considerable scope. It also played an active role in the work done under the aegis of the High Committee for Transparency and Information on Nuclear Safety (HCTISN) to define the arrangements for continued consultation on the project over the coming years: it will include workshops with the stakeholders most concerned by the project, in order to guarantee that all technical issues that raise concerns are taken into account.





### **A medical and industrial radiation protection culture that must be nurtured**

In 2022, the level of radiation protection remained at a satisfactory level in the medical field. This field, in which the radiation protection issues are particularly high, is under significant pressure, in particular with regard to human resources, a problem that has been exacerbated over the past two years. This has led to the implementation of new work organisations, notably multi-site or calling on outside contractors. ASN remains particularly vigilant in ensuring that these new organisations do not lead to any impairment of worker radiation protection. These unprecedented situations, such as a complete change in the medical team, must be anticipated, notably regarding change management and professional qualification procedures.

Knowledge of and commitment to radiation protection requirements are well established in teams specialising in techniques using ionising radiation. However, the observations made over the past four years show that this radiation protection culture could still be improved in the field of fluoroscopy-guided interventional practices, for which staff training in patient and worker radiation protection is struggling to progress. In addition, the lessons learned from previous events are sometimes forgotten. External radiotherapy calibration errors were once again observed in 2022, despite the fact that similar events had been the subject of ASN *Feedback* sheets shared within the profession. The same observation can be made in other fields, such as industrial gamma radiography, where there have been further cases of poor practices in the management of source blockages. These events remind us that the radiation protection culture can never be taken for granted, but must be maintained in order to avoid the loss of the competence and experience needed to deal with unexpected or undesirable events.

As part of the 2018-2022 action plan for control of the doses delivered to patients, ASN is promoting all measures liable to contribute to the implementation of the justification and optimisation principles, both for routine activities and for the introduction of technological innovations or new practices. In accordance with these principles, ASN stresses the importance and added value of external clinical peer audits, in particular in areas where the risks are high. Similarly, given the significant percentage of radiotherapy treatments in oncology and the improved survival rates, ASN recalls the need to set up follow-up registers for patients who received radiotherapy treatment, to allow improved assessment of the long-term radiation induced effects, in particular for the new practices (hypofractionation, flash-radiotherapy).

### **Codirpa's innovative and partnership-based approaches which are continuing**

The Steering Committee for the Management of the Post-Accident Phase (Codirpa) published its report to the Prime Minister containing recommendations on foodstuffs in an area contaminated by a nuclear accident around an NPP, recommendations which are backed up by field work carried out with a panel of local residents. It also continued its work on the management of post-accident situations around facilities other than NPPs, as well as its work on waste management.

As part of the work done under the mandate given to Codirpa by the Prime Minister regarding the safety and radiation protection culture among the population, its members were involved on 13 October 2022 in the United Nations International Day for Disaster Risk Reduction. The aim of this was to prepare the populations for the appropriate reflexes to deal with in the event of nuclear emergency. ASN, together with the National Association of Local Committees and Commissions (Anccli) and the Institute for Radiation Protection and Nuclear Safety (IRSN), coordinated the actions of the various stakeholders within Codirpa.



### **A new Strategic Plan<sup>(1)</sup> for ASN which takes account of a changing context**

The year 2022 was marked by ASN's adoption of a new five-year Strategic Plan.

After a decade that could be characterised as “post-Fukushima”, new long-term prospects are emerging for the nuclear sector. They are primarily driven by the need to accelerate the decarbonisation of the economy and by sovereignty issues. This new context is accompanied by innovations and initiatives to develop new types of reactors, which are forcing the regulators to take a fresh look at how they work together.

Safety questions will lie at the heart of the debate and will need ASN to be able to explain matters and ensure that the safety and radiation protection issues are anticipated by all stakeholders, both for new constructions and for the continued operation of the reactors, management of the “fuel cycle”, or waste management, in the nuclear system taken as a whole.

The new prospects will make it even more necessary for ASN to cultivate consultation and pluralism and, in addition to its oversight and regulation duties, to contribute to the development of a safety and radiation protection culture within the population.

In the coming period, ASN will have to work on an unprecedented number of new facility applications in recent years, while remaining mobilised on the facilities in operation or being decommissioned, as well as on medical, industrial and transport of radioactive substances activities.

In this general context, ASN has defined four points that will underpin its strategy for the next five years:

- 1/ **state and share its short-, medium- and long-term vision of the challenges relating to nuclear safety, radiation protection and environmental protection**, for the nuclear system as a whole;
- 2/ **enhance knowledge of the risks and, together with the other stakeholders concerned, promote a safety and radiation protection culture** to meet the expectations and demands of society;
- 3/ **adapt our regulation and oversight to a new context**, reaffirming our refocusing on high-stakes activities and installations and reinforcing our project management actions;
- 4/ and finally, **make a success of the internal transformations in order to be more attractive and efficient.**

Faced with these challenges, ASN will need additional and appropriate resources, along with a greater capability for independent management of these resources, in a manner comparable to its counterparts abroad. ■

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1. The 2023-2027 multi-year strategic plan is available on french-nuclear-safety.fr.

# REGULATION AND OVERSIGHT EQUAL TO THE CHALLENGES AHEAD

Montrouge, 7 March 2023

2022 was a pivotal year for the nuclear sector in France, with the President of the Republic's announcement of a programme to build new reactors and the desire to see the existing Nuclear Power Plants (NPPs) to continue to operate. It was more generally a pivotal year on an European scale, with an unprecedented energy crisis which completed the process of ushering in a new era for the nuclear industry.

In a joint declaration, the heads of Europe's nuclear safety regulators recalled the importance of nuclear safety in this new context. They urge all the stakeholders to fully exercise their responsibilities in this field, whether Governments, industrial firms or the regulatory authorities themselves.

It is up to these latter to take balanced decisions. To this end, the in-depth technical dialogue between the French Nuclear Safety Authority (ASN), with the support of the Institute for Radiation Protection and Nuclear Safety (IRSN) when necessary, and industry, is the best guarantee for obtaining a high level of safety while taking account of industrial realities.

In the current period, more than ever, it is essential for the regulation and oversight of nuclear safety and radiation protection to be independent and equal to the challenges.



Olivier Gupta



### **The importance of nuclear safety in the current energy crisis context: a call for collective vigilance**

The energy crisis that we are currently experiencing in France, along with many other countries, notably in Europe, merits particular attention from the nuclear safety viewpoint. This question was discussed within the WENRA association, which brings together the heads of Europe's nuclear safety regulators.

With the growing concerns regarding the balance between electricity supply and demand, and the need to combat climate change, many countries are once again turning to nuclear energy, whether by extending the service life of existing NPPs or by building new reactors.

Given the urgent need for electricity production capacity, this situation could place pressure on a number of stakeholders, in particular industry or the nuclear safety regulators, to the detriment of project quality. In a joint declaration, these regulators, including ASN, issued a number of recommendations aimed at mitigating this risk:

- first of all, energy policy decisions must be taken sufficiently well in advance, taking account of the time needed to carry out industrial projects, and must be stable over time. These two aspects are important, because a lack of visibility and stability is prejudicial to safety;
- then, the Governments and all the stakeholders must recognise that the licensees have prime responsibility for nuclear safety: they must not be stripped of this responsibility. It is therefore up to them to construct safety cases for the operation of their facilities or their new projects and to do so

within the time allowing examination by the safety regulators in good conditions;

- finally, the independence of the safety regulators is essential in this current period. They must work efficiently and issue their resolutions within an appropriate time.

As we can see, each of these stakeholders has a role to play in obtaining the high level of safety that the citizens are entitled to expect as a new nuclear programme dawns.

### **Striking the right balance in the resolution through in-depth technical dialogue**

As is often the case in a context of nuclear development – this was already the case at the end of the 1970s when the existing reactors were being built – questions were heard in 2022 regarding the potentially excessive level of stringency shown by the safety authorities in general, and ASN in particular. At the same time, some expressed the fear that ASN was “under pressure”.

In this context, it is important to recall how ASN issues its resolutions: this is done by a Commission – in other words not by a single person – and following





an examination process which allows broad scope for technical dialogue with industry and the nuclear activity licensees.

During this technical dialogue, the possibilities for improving safety are explored in the light of what is reasonably achievable. The state of the art regarding the subject in question, including international experience feedback, is examined. Dialogue covers not only questions of nuclear safety, radiation protection and environmental protection, but also technical and industrial feasibility and the implementation lead-times.

Over and above dialogue with industry, the licensees or the nuclear activity managers, the ASN resolutions process includes wide-ranging consultations. On the more important subjects, ASN may call on the opinion of its Advisory Committees of Experts (GPEs). They comprise experienced experts from French and foreign safety organisations, but also from industry, universities, as well as non-institutional experts, and allow a rich debate offering a degree of perspective with respect to the conclusions of the expert assessments – whether from ASN or the IRSN – and the arguments put forward by industry. Barring a few rare exceptions, the opinions issued by the GPEs are the result of a consensus by all members.

The use of this in-depth technical dialogue is of benefit both for safety and for the development of innovative technologies, such as the Small Modular Reactors (SMR) or Advanced Modular Reactors (AMR). As this dialogue takes place well upstream of the regulatory procedures, it enables ASN to inform the project sponsor of the choices made in terms of safety, as of the first discussions concerning a new installation project. Dialogue is iterative, in other words, the industrial firm presents initial options at the preliminary design studies stage. Very early upstream in the process, it is possible to state whether such or such an option envisaged is likely to lead to a dead-end, thus helping the industrial concern to avoid wasting time. This dialogue also helps the industrial firms by giving them visibility regarding the applicable baseline safety requirements. Above all, it helps ensure that safety issues are correctly taken into account at each step in the projects.

## **A nuclear safety and radiation protection regulation and oversight organisation equal to the challenges**

In the current context, independent regulation and oversight based on technical dialogue is of particular importance.

ASN already has a solid in-house skills base enabling it to carry out this technical dialogue. Competence – one of ASN's four values – is acquired through high-level recruitment, a systematic initial training programme such as very few institutions possess, and career paths enabling the personnel to commit to the long-haul and develop their experience of regulation and oversight.

These skills, some of which are expert assessment skills, enable ASN to issue a significant percentage of its resolutions without having recourse to its external support organisations. It is important to preserve and even reinforce this capacity because the very credibility of ASN's resolutions is based on science and technology: the existence of a continuum between expert assessment and resolution is therefore already in reality an essential component of the existing regulation and oversight system.

At the beginning of February 2023, the Government announced its intention to change the regulation organisation to reinforce its independence and the competence of ASN. At the time I am writing these lines, this proposal is still being debated by Parliament.

Whatever the regulatory organisation finally chosen, the personnel at ASN and the personnel at IRSN will continue to work together, in pursuit of the same goal of protecting people and the environment. I know that I will be able to count on their commitment to continuing the mission our fellow citizens expect of them. ■

# NOTABLE EVENTS 2022

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**Stress corrosion phenomenon affecting  
the French nuclear power reactors**

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# Stress corrosion phenomenon affecting the French nuclear power reactors

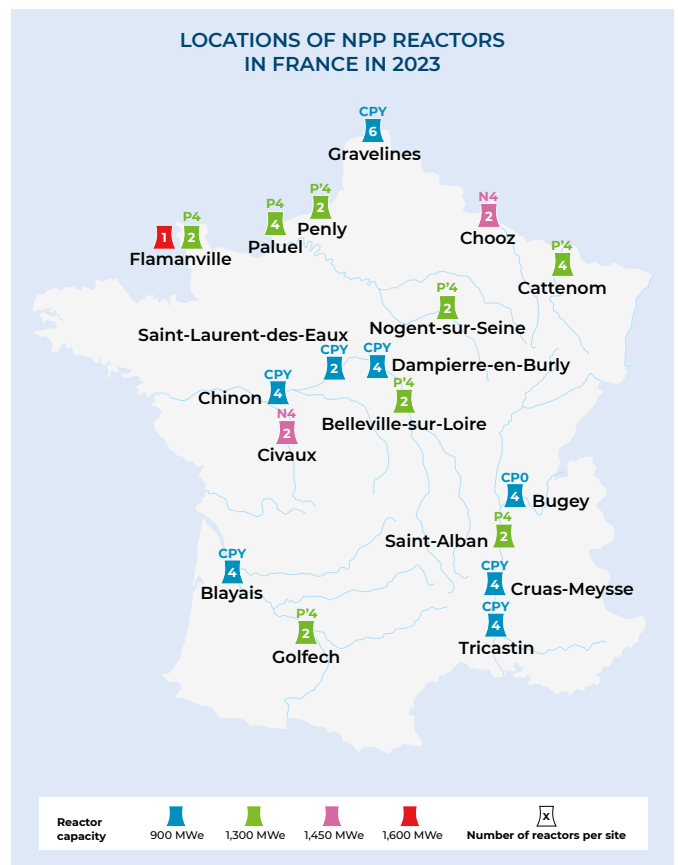
The presence of stress corrosion cracking was the major event encountered by the French Nuclear Power Plant (NPP) fleet in 2022. This unexpected event led EDF to mobilise significant resources to identify the causes and carry out repairs. ASN considers that EDF was reactive and responsible in response to this event with significant safety implications and affecting a large percentage of its reactors. This situation illustrates the electricity supply problems that could arise in the event of a generic problem concerning several reactors on the same time. As early as 2013, ASN had underlined the need for sufficient margins in the electrical system in order to deal with an event of this type.

At the end of 2021, EDF informed ASN that it had discovered cracks resulting from a stress corrosion phenomenon on the lines of the Safety Injection System (SIS) of the main primary system of Civaux NPP reactor 1 (N4 type reactor), and then on that of Penly reactor 1 (P'4 type reactor). Although stress corrosion is a known phenomenon and one that had already occurred on other components of the French NPP fleet, this type of crack had not been expected on these lines. This is because they are made of stainless steel, which is considered to be resistant to this type of damage.

By leading to cracking of the material on the inner wall of the lines, this phenomenon weakens them mechanically. It is thus liable to lead to rupture of the SIS or Residual Heat Removal System (RHRS) in the event of major mechanical stresses. As a result of this situation, EDF shut down its four N4 type reactors, which were considered to be the most susceptible, and brought forward the outage of several reactors in order to carry out inspections.

These cracks are particularly hard to detect. In 2022, EDF developed a new inspection process, notably using ultrasounds, capable of measuring the depth of the cracks.

During the first half of 2022, EDF initiated an in-depth programme of inspections and expert assessments<sup>(1)</sup> on the various types of reactors<sup>(2)</sup>. This programme enabled it to identify the geometry of the lines and the thermomechanical stresses to which they are subjected as being the main factors liable to influence the appearance of stress corrosion and thus identify the reactors most susceptible to the phenomenon. EDF defined an inspection strategy, which was validated by ASN on 26 July 2022.





Preparation of the line before installation on the auxiliary system

The second half of 2022 was devoted to repairing several reactors and completing the investigations on those most susceptible.

This problem justified close monitoring by ASN, in close collaboration with the Institute for Radiation Protection and Nuclear Safety (IRSN), which enabled rapid and informed decisions to be made.

ASN considers that the choices made by the licensee are appropriate, whether regarding the reactor outages or the in-depth investigations.

ASN considers that EDF acted as a responsible licensee given the safety issues related to the cracks revealed on equipment for which the integrity must be guaranteed.

ASN carried out more than 40 dedicated inspections. These inspections notably took place as part of the lines verification or replacement operations in the EDF engineering departments, in the NPPs and at the subcontractors.

The High Committee for Transparency and Information on Nuclear Safety (HCTISN), the Local Information Committees (CLIs) and, more broadly, the public – through information meetings and notices – were informed of the important stages of this dossier. ASN held regular discussions with its foreign counterparts, some of whom intend to request inspections on this same subject.

The reactors of the French NPP fleet will be inspected using the new inspection system developed by EDF, by the end of 2025. In 2023, EDF will carry out preventive replacement of the areas of interest on the susceptible lines of the P'4<sup>(3)</sup> type reactors.



Welding training

The Flamanville EPR reactor is also undergoing analysis and checks with regard to this issue.

With the technical support of the IRSN, ASN will remain focused on this dossier in 2023 and will closely monitor the results of the checks carried out by EDF. It will examine any EDF strategy changes that could result from this.

**For the latest information on the subject:**  
[asn.fr/l-asn-controle/corrosion-sous-contrainte](https://asn.fr/l-asn-controle/corrosion-sous-contrainte)

1. More than 110 metallurgical expert assessments have been performed in the laboratory, after cutting of the welds on several reactors. Further assessments are to be carried out in order to consolidate the data acquired.

2. The reactors are classified according to their model – or “plant series” – and according to the electrical power they deliver: 900 Megawatts electric (MWe), 1,300 MWe and 1,450 MWe.

There are **32 reactors of the 900 MWe type**: 4 reactors of the CP0 plant series (4 at Bugey) and 28 reactors of the CPY series (4 at Tricastin, 6 at Gravelines, 4 at Dampierre-en-Burly, 4 at Le Blayais, 4 at Chinon, 4 at Cruas-Meysses and 2 at Saint-Laurent-des-Eaux).

The **20 reactors of 1,300 MWe** can be subdivided into two plant series: the P4 series with 8 reactors (4 at Paluel, 2 at Saint-Alban and 2 at Flamanville) and the P'4 series with 12 reactors (2 at Belleville-sur-Loire, 4 at Cattenom, 2 at Golfech, 2 at Nogent-sur-Seine and 2 at Penly).

There are **4 reactors of the 1,450 MWe type**, in the N4 plant series (2 at Chooz and 2 at Civaux).

3. With the exception of those of Cattenom NPP reactor 4, on which the expert assessments carried out in 2022 revealed no stress corrosion cracks. EDF will define the strategy concerning this reactor following the inspections scheduled for 2023.



# Impact of the summer of 2022 heatwave and drought on the nuclear power plants



Saint-Alban NPP (Isère)

In France, the year 2022 was marked by several episodes of intense heatwave, a historic drought and unprecedented pressure on the energy resources.

In this context, the flow discharge of many watercourses in France fell, while their temperature rose.

ASN made sure that this situation had no consequences for the safety of the Nuclear Power Plants (NPPs) and the environmental monitoring results, produced at the end of 2022, revealed no impact downstream of the installations. The frequency of this type of extreme episode could increase in the coming years. The management of their consequences will require consolidation of scientific knowledge on the environmental impact of water intake and discharge, along with forward planning concerning the long-term global issues.

A period of heatwave and drought has three main consequences for the operation of nuclear reactors.

### **Operation of equipment participating in reactor safety during a heatwave**

The heatwaves led to high air temperatures, causing an increase in the temperature in the NPP premises. Within these premises, the correct working of the equipment contributing to the safety of the nuclear reactors is guaranteed up to a certain ambient temperature. Ventilation and air-conditioning equipment is needed to prevent this temperature from being exceeded. During the heatwaves of 2003 and 2006, EDF reinforced the ventilation and air-conditioning capacity of the premises containing the safety systems. The temperatures that nuclear reactors are required to deal with are defined in the safety case at the end of 2022; they are regularly reassessed, notably during the periodic safety reviews. These reassessments take account of climate change.

During the heatwave episodes of the summer of 2022, the maximum temperatures recorded in the NPP premises remained below the temperatures considered in the safety case.

ASN noted that these high temperatures had no consequences for reactor safety.

### **The power produced by the reactors in a situation with high watercourse temperatures**

To contribute to cooling its reactors, a NPP takes water from a watercourse or from the sea. This water is then returned to the watercourse or the sea at a higher temperature, either directly ("once through" reactor), or after cooling in cooling towers ("closed loop" reactor), enabling the dissipation of some of the heat into the atmosphere.

This water discharged by the NPP leads to an increase in the temperature of the watercourse between the upstream and downstream of the discharge point. Depending on the reactor, this increase ranges from a few tenths of a degree (closed-loop) to several degrees (once-through). In order to manage the consequences for the environment, the thermal conditions of these discharges are regulated by ASN resolutions specific to each NPP. The prescriptions set apply limit values concerning the temperature of the cooling water discharged into the natural environment and the heating downstream of the NPP, along with the environmental monitoring procedures. Thus, when the temperature of the watercourse upstream of the NPP is too high, EDF must reduce the power output by the reactors, or even shut them down, in order to meet the limit values associated with the downstream temperature.

Between July and September 2022, the heatwave and drought episodes led to a rise in the temperature of certain watercourses used to cool the NPPs, in particular the Rhône and Garonne rivers and the estuary of the Gironde. However, the security of the electricity grid and the preservation of natural gas and hydroelectric dam water in order to meet the needs of next autumn and winter, led EDF to ask for a temporary modification of the thermal discharge specifications for these NPPs.

After examining the environmental protection questions, ASN adopted four resolutions in turn, setting temporary requirements for the thermal discharges of the NPPs at Golfech, Bugey, Saint-Alban, Blayais and Tricastin, for the period from 15 July to 11 September. ASN also instructed EDF to conduct reinforced monitoring of the aquatic environment, by means of sampling and measurements.

These NPPs only resorted to the temporary provisions for a total of 24 days (9 days for Tricastin, 8 days for Bugey, 6 days for Golfech and 1 day for Saint-Alban). The Blayais NPP was able to maintain its electricity production without having to resort to these temporary provisions.

The initial results of the reinforced environmental monitoring stipulated by ASN show no impact between the upstream and downstream of the NPPs concerned, whether in terms of physical-chemical parameters, or microbiology values (bacteria). No fish mortality or alteration of the health of the environment was identified between the upstream and downstream of the NPPs concerned.

ASN also carried out inspections with respect to the implementation of these resolutions. It found no deviations from the provisions it had prescribed.

### **Management of radioactive effluents during periods of drought**

The discharge flow of the watercourse can also prevent EDF from discharging the liquid effluents from the nuclear reactors. In order to limit the impact of these discharges on the receiving medium, ASN determined a minimum watercourse discharge flow value, for each riverside NPP, below which no radioactive effluent discharge is permitted. Below these values, EDF must store this effluent until the return of favourable watercourse discharge flow conditions. The NPPs have emergency tanks with additional effluent discharge capacity in order to deal with exceptional situations. Their use requires prior approval from ASN.

During the course of 2022, ASN granted EDF permission to use one or two emergency tanks for the NPPs at Belleville-sur-Loire, Cattenom, Chinon, Dampierre-en-Burly, Nogent-sur-Seine and Saint-Laurent-des-Eaux, during periods in which the watercourse discharge flow levels were lowest, thus preventing it from discharging radioactive effluents.

ASN will analyse the consequences of climate change on the safety of the NPPs and on protection of the environment, as part of the approach it has initiated with regard to continued operation of these installations up to and beyond 60 years.

# ASN mobilises against the backdrop of the war in Ukraine

**T**he war in Ukraine is weakening the safety of the nuclear installations, some of which are within actual combat zones. Although these installations generally offer significant levels of robustness to external natural or industrial hazards, they are however not designed to withstand the full range of weapons and ammunition to be found in an armed conflict.

Although no radioactivity release accident has as yet been observed, 2022 saw a series of events which lastingly and worryingly affect the safety of the country's four nuclear sites, more specifically that of the Zaporizhzhia Nuclear Power Plant (NPP). As early as the month of February, ASN and its counterparts came together to ensure that, in the case of an event on a Ukrainian nuclear installation, they would be able to provide the public authorities with coordinated assistance.

## The war in Ukraine is weakening the safety of the nuclear facilities

As of the beginning of the war, in February 2022, the Ukrainian nuclear installations found themselves at the centre of the conflict and were lastingly affected.

Damage from shelling was observed very early on, at the Kharkiv site, on a radioactive waste disposal site near Kyiv and at the Zaporizhzhia NPP.

Loss of electrical power<sup>(1)</sup> affected the Chernobyl NPP in March and then since August has repeatedly affected the Zaporizhzhia NPP, which is home to six of the country's fifteen nuclear power reactors.

Nuclear safety is not purely a technical issue, depending solely on the condition of the installations: it is also built around people and organisations. At the beginning of the conflict, the shift rotation for the Ukrainian personnel present on the Chernobyl site only took place after more than two weeks of Russian occupation; this absence of shift rotation is in itself a factor that weakens safety.

Current preoccupations surrounding the Zaporizhzhia NPP also concern organisational and human issues, following the capture of the site by the Russians and the replacement of several Ukrainian managers with personnel they appointed themselves.



Zaporizhzhia NPP – september 2022

This situation raises questions concerning the clarity of the chain of responsibility and decision-making, which is essential in situations where several options are possible and where a decision must be taken quickly and executed reliably.

Furthermore, in the current context of fighting close to the plant, the teams are subjected to permanent stress and – according to the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU) –





The IAEA Director General, Rafael Mariano Grossi, inspects the damage from shelling during his visit to Zaporizhzhia in september 2022

to physical and psychological pressure from the Russian occupiers. These conditions are thus far from being the best for a calm response to any incident and for correct performance of the day-to-day activities.

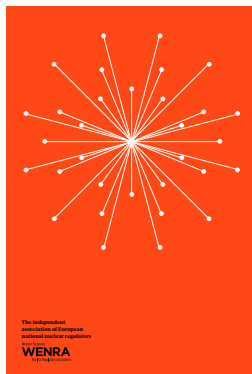
The SNRIU is also finding it increasingly difficult to conduct oversight of the Zaporizhzhia NPP, because it no longer has access to the site since its occupation by the Russians and it receives little direct information from the site.

Finally, the uncertainty regarding the ability of the licensee and the SNRIU to manage any accident on the NPP is compounded by the question of the ability of the authorities to take any population protection measures that would be needed.

### ASN mobilisation and actions

As of the beginning of the conflict, the nuclear safety authorities took preventive action, notably at a European level, so that in the case of an event at a Ukrainian nuclear installation, they could provide the public authorities with coordinated assistance. Various initiatives were carried out to recall the international principles of nuclear law, produce situation briefings, share analyses of the possible safety developments and provide the SNRIU and the Ukrainian Government with material or human assistance.

ASN assisted the European Nuclear Safety Regulators Group (ENSREG) with its analyses of the situation and its position statements.



It also coordinated the national response drawn up under the Response Assistance Network (RANET) to meet the needs for individual protection and radiation protection resources expressed by Ukraine.

As Chair of the Western European Nuclear Regulators' Association (WENRA) the ASN Director General took the initiative of creating an expert group specifically mandated to carry out activities related to the war in Ukraine.

This expert group regularly performed technical analysis of situations with safety implications and published its resulting position statements.

These position statements, based on the potential consequences of any worsening of the situation, express the joint view of the regulators regarding the safety of the installations concerned, the time available for a response and the possible impacts of a deterioration of the situation.

In addition, in order to harmonise the recommendations in the event of an accident, this expert group identified the capacity available in Europe for modelling the progress of an accident and the dispersal of releases, and compared the results to a test case, which enabled the various models to be readjusted to ensure consistency.

This action will continue until such time as the nuclear safety situation in Ukraine has returned to normal.

1. The power lines take away the current generated by the NPPs but also enable the fuel to be cooled when the plant is shut down or enable facilities other than NPPs to function correctly.

# ASN ASSESSMENTS

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

ASN considers that the quality of operations in the Nuclear Power Plants (NPPs) was maintained at a satisfactory level in 2022. However, improvements to the quality of operations in the underperforming NPPs are often proving to be a lengthy process.

The year 2022 was marked by the prolonged outage of numerous reactors following the discovery of stress corrosion-related cracks in the systems connected to the main lines of the primary system. ASN considers that the steps taken by EDF following this discovery were appropriate in terms of nuclear safety and that cutting sections of pipes to carry out expert assessments was essential for the definition of a pertinent inspection and treatment strategy.

#### REACTOR IMPROVEMENTS AND CONTINUED OPERATION

The modifications made to the facilities and operational methods by EDF within the framework of the reactor periodic safety reviews are significantly improving the safety of the facilities and enabling their level of safety to be brought closer in line with that of the third generation reactors. EDF is deploying considerable engineering resources for these reviews. For a number of years now, ASN has seen that the volume of studies and modifications required is leading to saturation of the engineering capacity. EDF therefore regularly has to postpone the transmission of certain studies to ASN. This situation also requires that EDF deploy a number of modifications within a very

tight time-frame. EDF must ensure that this situation does not lead to these deployments being made in degraded conditions.

ASN considers that all the provisions specified by EDF and those that it itself stipulates, open up the prospect of continued operation of the 900 Megawatts electric (MWe) reactors for the ten years following their fourth periodic safety review. Implementation of this review on each reactor includes specific checks and takes account of the particularities of each installation.

The public inquiries concerning the provisions planned by EDF for the periodic safety reviews of Tricastin NPP reactors 1 and 2 took place in 2022.

## THE CONFORMITY OF THE FACILITIES

As in previous years, ASN considers that the conformity of the facilities with the rules applicable to them needs to be improved. EDF must continue the targeted inspection actions it has been gradually deploying over the last few years. More particularly, the specific inspections implemented during the fourth ten-yearly outages are enabling a large number of deviations to be detected.

The organisation adopted by EDF to process deviations has been improved in recent years and is now satisfactory. EDF notably reinforced the dedicated teams, both in its head office departments and in the NPPs, notably with respect to reactor outages.

Overall, EDF is processing deviations within a time-frame that is acceptable. However, ASN considers that analysis of the potentially generic nature of a deviation affecting several plants after detection on one particular site should be carried out more rapidly.

Following the discovery of stress corrosion cracking at the end of 2021, EDF implemented a wide-ranging programme of inspections and repairs. This will continue in the coming years (see "Notable events" in the introduction to this report).

## MAINTENANCE

As a general rule, the organisation implemented in the NPPs for large-scale maintenance operations was again relatively satisfactory in 2022, notably in the light of the disruptions caused by discovery of the stress corrosion cracks.

However, as in previous years, ASN again in 2022 found points to be improved regarding reactor maintenance, such as the quality of the operational documentation placed at the disposal of the personnel for performance of the activities, or the management of spare parts. With regard to the numerous maintenance activities resulting from the continued operation of the reactors and the "major overhaul" programme, ASN considers that it is important for EDF to maintain the efforts started in order to remedy these difficulties and improve the quality of its maintenance activities.

A number of improvements were observed in 2022 in the field of subcontracted activities quality control, notably through the use of a new tool used to monitor the contractors. However, difficulties continue with regard to the quality of the monitoring carried out by EDF.

## OPERATION

Although unauthorised operating range excursion situations fell in 2022, significant events linked to poor monitoring of the control room increased. ASN also notes an increase in systems configuration deviations and continues to observe shortcomings in communication or positioning with the operating teams.

The training of the operating teams in charge of operating the reactors is satisfactory, even if particular attention must be paid to the attractiveness of the training professions and the time given to the trainers and staff being trained.

No major fire occurred in an EDF NPP in 2022. However, to control the fire risk, EDF must further improve management of equipment temporary storage sites and warehouses, which represent significant calorific potential, along with management of sectorisation in order to contain any outbreak of fire.

The ASN inspections focusing on the emergency organisation and resources confirmed that the organisation, preparedness and management principles for emergency situations covered by an On-site Emergency Plan (PUI) have been correctly assimilated. However, EDF must continue its efforts concerning training of the personnel in reorganising the emergency response following an external hazard of extreme intensity.

The analyses conducted by the sites further to significant events are generally relevant and the identification of organisational causes continues to progress.

Finally, ASN observes a shortage of personnel in the teams in charge of conducting independent evaluations of reactor safety in certain NPPs. EDF plans to remedy this situation.

## ENVIRONMENTAL PROTECTION

ASN considers that the management of discharges into the environment of the various NPPs is on the whole well controlled. During the heatwave episodes of the summer of 2022, EDF implemented appropriate reinforced monitoring of the environment downstream of the NPPs concerned.

In 2022, the ASN inspections with situational exercises demonstrated that the organisation of the response in the event of a non-radiological accident with potential consequences off the sites should be improved and that material measures designed to prevent or mitigate the effects of these accidents must be reinforced.

ASN considers that corrective measures must be taken regarding waste management, notably in terms of signage, inventory-keeping and traceability.

## WORKER RADIATION PROTECTION AND OCCUPATIONAL SAFETY

In 2022, ASN observed continued improvement in how worker radiation protection issues are addressed on several NPPs, after a clear deterioration seen in 2019 and 2020. EDF must continue with the steps taken to improve the way in which radiation protection is handled. There are continuing anomalies notably with the management of industrial radiography work.

With regard to occupational health and safety, the number of accidents with time lost is down on 2021. However, progress is still needed to improve the management of situations presenting risks for the workers, notably with regard to the quality of risk assessment, electrical lock-outs and the handling of concomitant activities within the same location.

## INDIVIDUAL NPP ASSESSMENTS

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

With regard to safety, the NPPs at Saint-Alban and Tricastin stand out positively in 2022, whereas, the NPP at Dampierre-en-Burly and, to a lesser extent, at Bugey, Cruas-Meysses, Golfech and Gravelines under-performed by comparison with the other NPPs operated by EDF. The reactors of the Chooz B and Civaux NPPs not having operated in 2022 owing to repair work on the lines

with stress corrosion cracks, ASN was unable to compare their safety performance with that of the other NPPs.

With regard to radiation protection, the NPPs of Civaux and Paluel stood out positively. However, ASN considers that the NPPs of Dampierre-en-Burly and Gravelines had under-performed.

With regard to environmental protection, the Saint-Laurent-des-Eaux NPP stood out positively, whereas, the NPPs at Cattenom and Golfech under-performed.

## The Flamanville EPR reactor under construction

**In 2022, EDF continued with work to complete the installation, to make modifications to certain equipment and to draw up the various documents needed for the future operation of the reactor. EDF also continued to analyse and process anomalies, notably those affecting the welds on the main secondary systems, along with three main primary system nozzles.**

The equipment conservation strategy implemented by EDF is satisfactory, provided that EDF can set up a programme to inspect the equipment at the end of the conservation phase.

EDF also continued to conduct the reactor start-up test programme and initiated preparations for the requalification phase for all equipment, scheduled in 2023 in preparation for commissioning.

Certain important technical subjects still need to be dealt with in full before the reactor can be commissioned.

This is in particular the case with the design of the primary system safety valves, Instrumentation and Control (I&C) upgrades, the performance of the containment internal water tank filtration system, the general operating rules that will be applicable as of commissioning and incorporation of the lessons learned from the commissioning of the first EPR reactors abroad, in particular the various anomalies found on the cores of the EPR reactors in Taishan (China), including the fuel clad perforations observed in 2021.

## Nuclear power plants being decommissioned and waste management facilities

### FACILITIES UNDERGOING FINAL SHUTDOWN

The EDF reactors finally shut down (Brennilis, Chooz A, Fessenheim, Superphénix, Gas-Cooled Reactors – 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.

Generally speaking, 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. 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.

ASN also considers that the decommissioning or decommissioning preparation operations on the facilities other than the GCRs is progressing at a satisfactory pace. Significant milestones were reached in 2022 for these facilities, in particular regarding the preparation of Fessenheim for decommissioning. With regard to the GCRs, EDF continued with decommissioning work outside the pressure vessel on the Saint-Laurent A, Bugey 1 and Chinon A3 reactors in satisfactory conditions of safety. However, the progress of these projects is significantly slower and the decommissioning completion deadlines envisaged by EDF remain a subject of concern for ASN.

Finally, the conclusions reached this year regarding the Chooz A review demonstrate the same methodological weaknesses as the previous reviews performed on the facilities undergoing decommissioning. ASN will be vigilant in ensuring that EDF takes account of these conclusions when performing its future reviews, notably with regard to the condition of floors or the conformity check.

### 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. Improvements are however required in waste management in the activated waste packaging and interim storage installation (Iceda). Finally, concerning the centralised storage pool that EDF intends to build at La Hague, ASN considers that EDF must take all necessary steps to submit the creation authorisation application (DAC) file for this new facility no later than the end of 2023, with a view to commissioning in 2034. ASN recalls the importance of having new spent fuel storage capacity compliant with the most recent safety standards in order to deal with the problem of saturation of the existing capacity.

## ORANO

**The facilities operated by Orano, on the La Hague, Tricastin and Marcoule sites, all have major safety implications, but of different types, both chemical and radiological.**

Despite the progress made in 2022 in terms of materials and waste management on the La Hague and Tricastin sites, and a wide-ranging action plan aiming to overcome both Melox production difficulties and the risks of saturation of radioactive materials storage capacity, ASN considers that there is very little room for manoeuvre in the operation of the “fuel cycle” and that this remains a point requiring particular attention.

Once again ASN stresses the need for significant improvement in forward planning and in the quality of the files submitted, to allow calm preparation and on-time implementation of the provisions needed to prevent the risk of situations that block the cycle and the production of nuclear electricity.

ASN also considers that Orano must undertake work to review the issues related to the ageing of all the facilities at La Hague, in terms of both safety and the robustness of the “cycle”, in order to produce a general review of the site and consolidate the prospects for operation of its various units in the medium and long term, up to and indeed beyond the 2040 time-frame.

From this viewpoint, ASN sees as positive the good progress of the work to replace six evaporators in the La Hague plants in 2022. It will remain vigilant with regard to the correct performance of the operations to connect the first three evaporators in 2023, followed by their actual commissioning.

Finally, in a geopolitical context marked in 2022 by the war in Ukraine, Orano has launched a project to significantly increase the production capacity of the Georges Besse II plant to separate uranium isotopes using the centrifuge process (BNI 168). In 2023, ASN will issue an opinion on the safety options selected by Orano.

### LONG TERM COSTS AND PROVISIONS FOR DECOMMISSIONING AND FOR WASTE MANAGEMENT

In its opinion submitted to the General Directorate for Energy and Climate (DGEC) on Orano’s three-year report regarding the creation of financial provisions for decommissioning and waste management for the period 2022-2024, ASN considers that Orano’s decommissioning and spent fuels and radioactive waste management strategy is consistent with the safety and radiation protection requirements. However, improvements are needed if ASN is to be able to verify that the hypotheses adopted to justify the amount of the long-term costs are prudent. Orano shall in particular fine-tune the costs relating to the future post-operational clean-out of polluted soils on its sites and the long-term management of the waste resulting from this clean-out.

### THE SAFETY OF FACILITIES IN OPERATION

ASN considers that La Hague’s management of the safety of its facilities is satisfactory. However, this site must make progress in complying with the deadlines in the regulatory requirements and with its undertakings. The La Hague site must also boost its vigilance with regard to the performance of periodic inspections and management of deviations. Finally, the measures designed to counter the effects of equipment ageing in the facilities, some of which is nearing an operating life of 40 years, or its replacement by new equipment, is still a major issue for its continued safe operation.

Following the inspections it conducted in 2022, ASN considers that the level of safety of the Orano facilities on the Tricastin site is satisfactory. In 2022, the Tricastin site improved its organisation for analysing the conformity of the facilities with the regulations and made progress in its follow-up of the commitments made to ASN.

With regard to the Melox plant, ASN considers that the level of safety is satisfactory in the field of fire risk management and satisfactory overall in the fields of operations and waste management. ASN also observes an improvement in the extent to which the regulatory baseline requirements in the field of pressure equipment are assimilated.

Generally speaking, ASN considers that the organisation put into place by Orano for evaluation of the conformity of its facilities and for reassessment of their safety during the periodic safety reviews, is satisfactory. It finds that the licensee’s action plan for the periodic safety review of the uranium storage areas at Tricastin is very well followed. However, the La Hague site must reinforce its vigilance with respect to compliance with the deadlines in the regulatory requirements and the undertakings made, notably those made following the periodic safety reviews of the facilities.

### 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 requirements and present major safety risks. This legacy Waste Retrieval and Conditioning (RCD) is a key step in the progress of decommissioning in the definitively shut down plants.

With regard to the organisation and management of these complex projects, ASN regrets that, despite the progress made, such as the adoption of immediate dismantling objectives, the creation of the major projects department, the evaluation of the maturity of the projects, or the development of progress management tools, Orano has once again revised a number of waste retrieval and processing scenarios. In order to reinforce the transparency and legibility of these projects and of their main challenges for the coming years, ASN has set up an observatory for these projects (see chapter 13).



### MATERIALS AND WASTE STORAGE CAPACITY

ASN considers that the creation of additional uranium storage capacity on the Tricastin site and the commissioning of a new vitrified waste storage pit on the La Hague site in 2022 contribute to improved management of materials and waste.

However, inadequate forward planning of the consequences of the malfunctions encountered by the Melox plant concerning the plutonium materials storage capacity at La Hague led Orano to belatedly transmit the extension application files for this capacity, and they are also incomplete. This situation is prejudicial to the degree of calm needed to examine them. ASN therefore considers that Orano must reinforce its forward planning regarding management of the materials and spent fuel storage facilities, along with its project management, in order to produce safety files with a satisfactory level of maturity, and submit them sufficiently in advance of the target date for their implementation.

### PERSONNEL RADIATION PROTECTION

With regard to radiation protection, the year 2022 was marked by the creation of radiation protection expertise centres. Numerous significant radiation protection events reported for the Orano group sites are linked to anomalies in the annual inventory of sealed sources and to the validity date for the periodic inspections on the atmospheric monitors being exceeded, as well as non-compliance with limited access area access conditions.

Although ASN considers that the level of radiation protection on the Tricastin site is satisfactory, the year 2022 was marked by an upturn in the number of significant radiation protection events

at La Hague. ASN considers that the licensee must continue with and intensify its action plan to prevent this type of event from happening again.

Finally, ASN remains particularly vigilant with regard to the Melox facility, owing to the increase in the 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. This situation leads to an increase in the average exposure of a large number of personnel and in the collective dose for this facility.

### ENVIRONMENTAL PROTECTION

ASN welcomes the steps taken by the La Hague site to ensure the regulatory conformity of the facilities, with occasional additional measures to control fluorinated greenhouse gases.

In 2022, ASN continued to monitor the actions taken by the Tricastin site to reduce coolant fluid releases into the atmosphere and considers that the licensee has maintained its efforts to mitigate this type of release.

The Orano group's sites reported 33 significant environmental events in 2022 (as against 11 in 2021). ASN considers that Orano needs to reinforce its vigilance with regard to authorised discharge limits being exceeded and non-compliance with measurement monitoring frequencies.

### INDIVIDUAL FACILITY ASSESSMENTS

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

## CEA

**The vast majority of the nuclear facilities operated by the Alternative Energies and Atomic Energy Commission (CEA) are concerned by the decommissioning and radioactive materials and waste management strategy implemented by this licensee. ASN considers that the safety of these facilities remains under control, but finds that the results of the decommissioning and RCD projects differ widely and remain vulnerable to major contingencies. In this respect, it considers that CEA must reinforce its management of these projects. This reinforcement should also concern the construction of emergency management buildings, which is significantly behind schedule.**

**Regarding the Jules Horowitz Reactor (JHR) under construction, ASN observes that progress was made in 2022 in understanding certain phenomena with an impact on safety.**

**Finally, ASN considers that the emergency situations management organisation and the monitoring of outside contractors require further improvement.**

### MANAGEMENT OF NUCLEAR SAFETY AND RADIATION PROTECTION

In 2022, CEA presented the steps taken to promote the incorporation of nuclear safety and radiation protection issues into the operational practices of the facilities for which it is the nuclear licensee. More specifically, CEA clarified the latest organisational changes, succession planning in order to guarantee the availability of rare skills that are vital to the safety issues, as well as training arrangements, in particular training related to the safety culture. During a dedicated inspection, ASN was able to observe that fundamental actions are being

taken in this direction at the national level and it will remain vigilant with regard to their implementation in the field in the coming years.

ASN also considers that the implementation of the "major safety commitments", managed at the highest level of CEA, is improving the monitoring of the most important nuclear safety and radiation protection issues. More particularly in 2023, it will be necessary to ensure that the potential reduction in resources available to CEA, as a result of inflation, has no consequences on CEA's ability to meet its other commitments.

### 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 monitoring of the deadlines with the greatest safety implications. For the period 2019-2022, ASN thus observes that the strategy defined by CEA and approved by ASN in 2019 is producing results. In recent years, CEA has notably removed a certain number of spent fuels from its definitively shut down reactors, which helps reduce the potential risks from the facilities it operates. ASN nonetheless finds that, despite CEA's clear intention to carry out facilities decommissioning and RCD operations, this licensee is experiencing major difficulties in meeting the deadlines initially set. For many situations, these delays are caused by technical or contractual difficulties. The implementation of this strategy also remains at the mercy of the financial resources available to this licensee.

### MANAGEMENT OF COMPLEX DECOMMISSIONING PROJECTS

In 2021 and 2022, CEA voluntarily embarked on the exploratory approach promoted by ASN for the oversight of complex projects. ASN's inspection of the decommissioning project for BNI 37-B, the former effluent treatment plant on the Cadarache site, took place in good conditions. This approach was a catalyst for CEA's development of improvements to its project management practices, which is satisfactory and should be pursued. In the particular case of BNI 37-B ASN identified three priority areas for improvements:

- contracts management, at a time when contractual difficulties were also observed on priority safety operations conducted in BNIs 72 and 166;
- evaluation of the maturity of the complex projects, in particular those with particular implications for engineering, buying, construction and the preparation for commissioning of equipment;
- the methods for evaluating human resources requirements, to substantiate the sustainability of the schedules.

### LONG TERM COSTS AND PROVISIONS FOR DECOMMISSIONING AND FOR WASTE MANAGEMENT

In its opinion submitted to the DGEC on CEA's three-year report on the creation of financial provisions to cover decommissioning and waste management for the period 2022-2024, ASN considers that this report reflects the significant changes resulting from the implementation of CEA's decommissioning and materials and waste management strategy. It is of high quality, but should be supplemented by an improved evaluation of the costs of post-operational clean-out and the management of the resulting pollutions, as well as the uncertainties surrounding the estimates of waste volumes. This is notably the case for BNIs 37-B, 165 and 166. Clarifications are also expected regarding the costs linked to the management of the legacy waste repositories and those concerning the performance of R&D studies into the solutions for reprocessing some or all of the bituminous radioactive waste.

### THE SAFETY OF FACILITIES IN OPERATION AND UNDERGOING DECOMMISSIONING

ASN considers that the safety of the facilities in operation is generally satisfactory. During the course of the inspections carried out in 2022, it nonetheless identified certain topics which require improvements. This mainly concerns management of the fire risk, but also waste management, safety commissions and on-site permits, periodic checks and tests, Human and Organisational Factors (HOF), as well as the prevention of pollution and management of detrimental effects. ASN's opinion on each of these topics is detailed in the following sections.

### RADIOACTIVE WASTE MANAGEMENT

ASN finds that the management of radioactive waste in the CEA facilities is satisfactory and an improvement on 2021, even though the situation differs from one facility to another.

The traceability of waste monitoring could be improved, notably with regard to legacy waste which cannot be immediately removed from the facilities. The operations to characterise this waste also needs to continue, so that it can be removed through the appropriate routes.

ASN considers that particular attention must be paid by CEA to the management of the storage areas for the waste produced by the facilities, notably with regard to aspects concerning monitoring of the inventories and compliance with the waste storage conditions, the justification of the storage durations, and the existence of storage areas not provided for in the baseline safety requirements of certain facilities. Finally, CEA must remain vigilant with regard to correct forward planning for and performance of very low-level (VLL) waste storage area extension projects, made necessary for the facilities producing large quantities of waste (notably the facilities undergoing decommissioning).

### THE CONFORMITY AND REASSESSMENT OF THE SAFETY OF THE 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. Generally speaking, ASN also underline's the licensee's satisfactory follow-up and performance of the actions identified during the reviews. The inspections carried out by ASN on the topic of the periodic safety reviews nonetheless identified some points for improvement which must be addressed by CEA, notably concerning the exhaustiveness of the conformity checks. 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 review can be started once the deployment of the action plan from the previous review has been completed.

### MANAGEMENT OF DEVIATIONS

ASN generally finds that the deviations management process has made progress at CEA. It must however continue its efforts, notably with regard to analysis of the causes or trends regarding the repetition of similar deviations, for example those linked to non-compliance with the periodic checks and tests.

## CHANGE MANAGEMENT

As in 2021, ASN considers that the quality of the safety analyses sent to ASN when CEA submits an authorisation application for a noteworthy modification is satisfactory and that the modifications made in the field do indeed correspond to the information provided by CEA in its authorisation applications.

## MAINTENANCE AND THE SCHEDULING OF PERIODIC CHECKS AND TESTS

As in 2021, maintenance work and the scheduling of the periodic checks and tests, their performance and their follow-up within the CEA facilities are on the whole satisfactory. However, in 2022, during an inspection on the Cadarache site, ASN found shortcomings in the traceability of the technical checks carried out to confirm that the maintenance work performed on the Protection Important Component (PIC) of interests is carried out in accordance with the requirements defined for the PIC concerned.

In addition, as maintenance and periodic checks and tests are generally subcontracted, CEA must at all times remain attentive to the technical expertise of the personnel involved and the traceability of the checks conducted. In this context, the findings made during ASN inspections on the subject of ageing show that CEA monitors, checks and satisfactorily maintains its facilities, even if there are still differences between the facilities.

## MANAGEMENT OF IRREGULARITIES AND FRAUD

CEA's organisation for the prevention of the risk of fraud is satisfactory. Since 2018, the licensee has notably implemented a specific policy, a whistle-blower alert procedure and new training in operational safety culture (currently being deployed) part of which is devoted to this topic.

## OUTSIDE CONTRACTORS

Although the surveillance of outside contractors had been reinforced in recent years, the inspections carried out by ASN on this topic in 2022 are still highlighting the fact that CEA needs to continue with the measures started in this respect. Furthermore, there are still disparities in the quality of this surveillance between the various facilities operated by CEA, and harmonisation is thus required.

## RISK CONTROL AND EMERGENCY MANAGEMENT

As in 2021, ASN considers that CEA must continue its efforts concerning the protection of its facilities against the fire risk. Management of the technical devices (fire doors and dampers, detection systems, etc.), must be improved and fire loads limited, particularly on worksites. CEA must also remain vigilant with regard to adapting the available fire risk control resources to the present uses of the premises, in particular for those facilities undergoing decommissioning.

In 2023, ASN will ensure the participation of the local safety organisation for CEA's Saclay and Fontenay-aux-Roses sites in the emergency exercises and active situational exercises.

ASN also observes significant delays in the commissioning of the emergency management buildings designed to take account of the lessons learned from the Fukushima Daiichi NPP accident in Japan. More specifically, CEA has asked for a postponement to 2027 of the deadlines for commissioning of the new emergency management building for the Cadarache centre. CEA has also announced a postponement for the Saclay site, with commissioning of the new premises scheduled for 2024. With regard to the Marcoule centre, significant delays have also been observed in the transmission of the justification data regarding the operability, accessibility and civil engineering behaviour of the emergency situations management building. ASN considers that CEA must reinforce its management of these construction projects in order to meet the specified deadlines.

## PERSONNEL RADIATION PROTECTION

The CEA teams have completed considerable work on creating the radiation protection expertise centres, authorised by ASN at the end of 2022, and this constitutes a positive point. ASN remains vigilant with regard to the performance of worker individual ionising radiation exposure evaluations, and the monitoring of outside contractors (handling of deviations, traceability and application of the ALARA – As Low As Reasonably Approach – approach).

Most of the significant radiation protection events reported by CEA are linked to failure to wear a passive dosimeter, notably by the outside contractors, and inappropriate levels of radiological cleanliness. In 2023, ASN will in particular ensure that CEA ensures compliance with the requirement to wear the dosimeter, notably by licensee monitoring of outside contractors in its facilities.

## ENVIRONMENTAL PROTECTION

For the year 2022, control of the detrimental effects and impact of the CEA facilities on the environment is on the whole satisfactory. The number of deviations (significant environmental events) in 2022 is of the same order of magnitude as in previous years, with no notable events (only events level 0 on the INES scale, or out of the INES scale).

ASN however considers that CEA must step up its efforts to take measures on several subjects associated with environmental protection and in particular ensure the conformity of the network of piezometers, the positioning of sampling devices in the gaseous discharge outlets and the management of contaminated land.

## INDIVIDUAL FACILITY ASSESSMENTS

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



## ANDRA

The Bataille Act of 1991 set a framework for the management and disposal of high-level (HLW) and intermediate-level long-lived (ILL-LL) waste in France. ASN underlines the importance of the work done for more than 30 years on drafting the Creation Authorisation Decree file for the *Cigéo* deep geological disposal facility, which was submitted on 16 January 2023. The finalisation of this file is a key step in the development of this project and for the creation of a management solution for HLW and ILL-LL waste.

With regard to the other radioactive waste disposal BNIs, for which the French National Radioactive Waste Management Agency (Andra) is the only licensee in France, ASN considers that their operation remains satisfactory.

### SUBMISSION OF THE *CIGÉO* CREATION AUTHORISATION APPLICATION FILE

In 2022, dialogue continued between ASN, Andra and the Institute for Radiation Protection and Nuclear Safety (IRSN) on the technical subjects identified following examination of the *Cigéo* Safety Options Dossier (DOS). On the basis of this dialogue and the work done since the examination of the DOS by ASN in 2017, ASN considers that submission of the *Cigéo* DAC file to the Minister responsible for nuclear safety on 16 January 2023 is a key milestone for the management of HLW and ILL-LL waste. In preparation for this examination, ASN together with IRSN in 2022 defined the methods to be used for the technical examination of this dossier, which will take at least three years.

### PROGRESS OF THE STUDIES FOR THE LLW-LL WASTE DISPOSAL FACILITY PROJECT

The discussions between ASN and Andra concerning the low-level, long-lived waste (LLW-LL) disposal facility project continued in 2022. ASN considers that this positive dynamic must be maintained in order to meet the deadlines defined in the fifth National Radioactive Materials and Waste Management Plan (PNGMDR), and which notably aims for the submission of a file in mid-2023 presenting the technical safety options selected, with a level of maturity corresponding to a preliminary design document, for disposal on the site of the Vendeuve-Soulaines municipal federation.

### OPERATION OF ANDRA'S EXISTING FACILITIES

ASN considers that operating conditions in Andra's facilities are satisfactory in the areas of nuclear safety, radiation protection and environmental protection. It also notes the quality of the safety analyses produced by Andra and the fact that the performance of the periodic safety reviews on the disposal facilities is satisfactory. ASN nonetheless points out that the evaluation of the long-term impacts of the radiological and chemical substances in the disposal facilities on the flora and fauna must be consolidated.

Finally, ASN considers that the provisions adopted by Andra concerning the review of the conditioning agreement applications and the radioactive waste packages disposal approval and acceptance applications are satisfactory.

## ASN Assessments – BY ACTIVITY SECTOR –

### THE MEDICAL SECTOR

On the basis of the inspections carried out in 2022 and an analysis of the period 2018-2022 enabling the entire fleet of facilities to be covered, ASN considers that the state of radiation protection in the medical sector is being maintained at a good level, relatively comparable from one year to the next, although with a number of persistent shortcomings.

In nuclear medicine and for Fluoroscopy-guided Interventional Practices (FGIPs), deviations persist as the years go by, in terms of radiation protection training of the professionals and the coordination of prevention measures during concomitant activities, notably during interventions by private practitioners. In radiotherapy, the evaluation of the effectiveness of the corrective measures taken is still the weak point of the Operating Experience Feedback (OEF) approaches and the preliminary risk assessments remain insufficiently updated ahead of an organisational or technical change, or following OEF from events that have occurred in the profession. In the field of FGIPs, and more particularly in the operating theatre, work to bring the premises into conformity with the technical design rules and steps to optimise the doses received both by the workers and the patients are progressing too slowly and the awareness of non-specialists in ionising radiation, such as surgeons, needs to be increased to ensure a clearer perception of the issues and enhance the assimilation of radiation protection measures.

Although the fundamentals of quality assurance are today well-established in the radiotherapy departments, they are still being gradually deployed in the other sectors, in particular concerning the requirements for internal reporting of events and formalisation of the procedures for qualifying professionals for the particular positions.

The events reported to ASN underline the fact that the training of professionals, management of maintenance work and the implementation of technical barriers controlling the use of medical devices, which constitute the fundamental basis of safety, are areas for improvement in order to make practices safer. ASN also observes that the lessons learned from past event reports are forgotten.

In 2023, ASN will continue its inspections in the radiotherapy, nuclear medicine, FGIPs and computer tomography sectors, following on from the checks carried out in 2022, with particular attention being paid to the weak points identified in 2022, as well as to implementation of the quality assurance obligations.

From the regulatory viewpoint, ASN will in 2023 continue revising resolution 2008-DC-0095 of 29 January 2008 setting out the technical rules for the elimination of effluents and waste contaminated by radionuclides. ASN will also continue to contribute to the regulatory work conducted by the Ministry responsible for health concerning the organisation of medical physics and the deployment of clinical audits, which could be a pertinent means of ensuring progress with regard to the justification of procedures.

Finally, ASN will maintain its commitment to subjects linked to the spread of new techniques and practices, jointly with the various institutional players in the health sector and the learned societies, while calling on its expert groups, in particular the Committee for the analysis of new techniques and practices using ionising radiation (Canpri), in order to promote and facilitate safe working frameworks and improve the evaluation of long-term radiation induced effects for therapeutic procedures. As part of the 2nd National imaging dose management plan (2018-2022), ASN will aim to encourage all actions to promote implementation of the justification principle, access to the least irradiating imaging techniques and the automated collection and analysis of doses for the purposes of optimisation and monitoring of exposure from medical imaging among the French population.

**In radiotherapy**, the inspections carried out by ASN in nearly one quarter of the radiotherapy units in 2022, in conjunction with those carried out over the period 2018-2021, enabling the entire fleet to be covered, confirm that the safety fundamentals are in place: organisation of medical physics, equipment verifications, training in the radiation protection of patients, deployment of quality assurance procedures, recording and analysis of events. However, the analysis of the period 2018-2022 confirms that evaluation of the effectiveness of the corrective actions is still the weak point of the OEF approaches and is struggling to become more widely adopted. Although the preliminary risk assessments are inadequately updated ahead of an organisational or technical change or following OEF from events, ASN sees as positive the voluntary development of peer review practices in medical physics, when new equipment is installed. ASN underlines that the buy-outs of centres are situations entailing considerable disruptions that lead to risks if the impact on the working activity of the professionals is not analysed and if these changes are not prepared for with all the teams. ASN also observes that the formalisation of the position qualification procedures, which have been mandatory since August 2021, is being deployed although with differences between the professional categories. Finally, the occurrence of events such as patient identification errors, delineation of organs at risk and/or target organs, and once again calibration, still reveals organisational weaknesses and the need to regularly assess practices. ASN also observes that the lessons learned from past Significant Radiation protection Events (ESR) are forgotten, along with a regular fall in the number of ESR reported to ASN since 2015. Although this can be partly ascribed to safer treatments, a drop in the internal events reporting culture is perceptible with less numerous significant event reports and less detailed analyses. The occurrence of cyber-attacks also underlines the new changes faced by radiotherapy professionals at a time of increasing digitisation of data. Finally, the new techniques and practices, which are constantly evolving, are not always sufficiently evaluated to allow an assessment of the long-term radiation induced effects (adaptive radiotherapy, hypofractionation, flash-radiotherapy, etc.).

**In brachytherapy**, the inspections carried out in 2022 in nearly one quarter of the brachytherapy units, in conjunction with those carried out over the period 2018-2021, enabling the entire fleet to be covered, reveals no breach of the radiation protection rules. The radiation protection of the professionals and the management of high-level sealed sources are thus considered to be satisfactory. The training effort for professionals in possession of a high-level source must be maintained and reinforced for certain centres. ASN notes that the new requirements relative to safeguarding access to high-level sources, which fully came into force in 2022, are continuing to be gradually deployed, in particular regarding measures to prevent unauthorised access to these sources. However, some centres are faced with conformity difficulties when this demands significant work. The events reported in 2022 underline the importance of having an active events recording system so that malfunctions can be identified as rapidly as possible, equipment quality controls can be formalised, performed and recorded, while ensuring that these latter comply with professional standards and the manufacturer's recommendations.

**In nuclear medicine**, the inspections in 2022, in conjunction with those performed over the period 2018-2021, enabling the entire fleet to be covered, reveal that radiation protection is correctly taken into account in the vast majority of the departments, with improvements observed for those departments inspected in the past two years, in particular for radiation protection of patients. Nonetheless, improvements are required in three fields: effluent management, in order to control discharges into the sewage networks, formalising the coordination of prevention measures with outside contractors (for maintenance, cleaning of premises, intervention by private practitioners, etc.) and radiation protection training of professionals. Similarly, the organisation of medical physics was felt to be inadequate in 20% of the units inspected in 2022, notably with respect to the radiation protection issues associated with the therapeutic treatments; its improvement is an area for progress at a time new therapies based on innovative radiopharmaceuticals are being deployed. The engagement by the nuclear medicine units in the deployment of quality management systems is continuing and ASN notes progress in the formalisation of the procedures for qualifying professionals for the positions. Even if the undesirable events reporting culture is indeed present in most of the units inspected in 2022, it must continue to be developed further. The reported events again reveal that the drug administration process must be regularly evaluated in order to control it, particularly for therapeutic procedures, due to the potentially serious consequences of a drug administration error.

**In the FGIPs field**, the 2022 inspections, in conjunction with those performed over the period 2018-2021, 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 is still better in the intervention rooms than in the operating theatres, along with persistent shortcomings. Thus, 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 radiation protection expert-officers, the marking out of regulated areas, the performance of technical checks and quality controls of medical devices are considered to be satisfactory, deviations from the regulations are still frequently observed, both for radiation protection of the professionals and for that of the patients, with unsatisfactory situations concerning the radiation protection training of workers and patients and the coordination of prevention measures during concomitant activities, in particular with private practitioners. Although the use of medical physicists and formalisation of the medical physics organisation plans appear to be gaining ground, 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 can still be observed. The reporting culture, however, has been spreading in the past four years, with the deployment of events recording systems. The reporting 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 professionals in the centres is still necessary to give them a clearer perception of the risks, especially for operating theatre staff.

**In computed tomography**, ASN's oversight mainly concerns actual implementation of the requirements of its resolution 2019-DC-660 of 15 January 2019 notably concerning the formalisation of the justification principle, in order to avoid unnecessary doses for the patients, along with qualification of the professionals for the position. During its inspections in 2022, ASN again observed differing deployments of the quality assurance system concerning the traceability of examinations justification in the centres, with practices that are satisfactory in some units and far less so in others. Progress is also required in the formalisation of qualification of the professionals for the position.

## 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 is to a large extent comparable to that of 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 rigorously 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. Although 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 terms of the signalling of the operations area during site work. More generally, ASN considers that the ordering parties should give priority to industrial radiography services in bunkers and not on the worksite. Furthermore, unlike in recent years, in the few situations in which the radioactive source could not be returned to the safe position in the gamma ray projector, inappropriate actions and handling were undertaken by the operators in the majority of cases, although without generating exposure of the operators or their hands beyond the regulation limits. ASN considers that the reoccurrence of such cases, albeit few in number, is a subject requiring particular attention because inappropriate actions can lead to significant over-exposure, as is shown by international operating experience feedback every year.

In the other priority sectors for ASN oversight in the industrial sector (**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 the areas in which practices still need to be improved are advance preparations for the expiry of the sources administrative recovery period (which by default is 10 years), information for the purchasers regarding future source recovery procedures, and the checks prior to delivery of a source to a customer.

The actions carried out by the licensees in recent years are continuing to improve radiation protection within the **research laboratories**. 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. It would appear to be necessary for the licensees to reinforce the organisational provisions designed to ensure compliance with the prescriptions of their licenses, notably that regarding the maximum activity they possess, or to perform all the technical checks required by the regulations, and that they anticipate the costs related to the handling of "legacy" sources or waste.

With regard to the **veterinary uses of ionising radiation**, ASN can see the result 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.

With regard to the **protection of sources of radiation against malicious acts**, more particularly when high-level radioactive sources or batches of equivalent sources are used, 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. Thus, the categorisation of sources, an essential step in identifying the applicable requirements and in implementing an approach proportionate to the risks, has been done by the vast majority of the facilities concerned. Similarly, the issue of nominative permits for access to sources is progressing, even if it still needs to be implemented in nearly half the facilities. ASN therefore considers that significant progress is still needed, in particular because, since mid-2022, the requirements regarding the presence of physical systems to prevent unauthorised access to sources have become applicable, offering intrusion resistance compliant with that stipulated by the Order. In 2023, 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 2022, 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 with the 770,000 transport operations carried out each year.**

The number of significant TSR events on the public highway (88 events reported to ASN in 2022) is slightly up on 2021, with an increase in the number of events rated level 1 on the INES scale. The number of events concerning transports of radiopharmaceutical products also rose appreciably. 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 and research facilities, ASN finds that the licensees carry out numerous checks and are therefore better able to detect any deviations. It 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. In addition, if this demonstration is performed by a third-party company, it is up to the consignor to check that it is appropriate and to monitor the third-party company *via* the usual methods of a quality assurance system, which is not always the case.

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 quality management system, and 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 quality management systems have not yet been formally set out and deployed, more specifically with regard to the responsibilities of each member of staff involved. ASN considers that the radiation protection of carriers of radiopharmaceutical products, who are significantly more exposed than the average worker, needs to be improved.

Finally, for transport operations involving packages that do not require ASN approval, progress continues to be observed with respect to the 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 it is impossible to exceed the applicable dose rate limits with the maximum authorised content.

# REGULATORY NEWS

The year 2022 was marked by the publication of important texts, notably concerning whistle-blowers, the environmental assessment, nuclear civil liability, the creation of a new nuclear interministerial programme delegation, radioactive waste, radon and radiation protection. This year also saw continued work to revise the Order of 7 February 2012 laying down the general rules relating to Basic Nuclear Installations (known as the “BNI Order”).

## National news

### ACTS AND ORDINANCES

- **Constitutional Act 2022-400 of 21 March 2022 aiming to reinforce the role of the Defender of Rights regarding whistle-blowing and Act 2022-401 of 21 March 2022 aimed at improving whistle-blower protection**

Before the so-called “Sapin 2 Act” 2016-1691 of 9 December 2016, seven sectoral Acts comprised measures to protect whistle-blowers, notably the “Blandin Act” 2013-316 of 16 April 2013 “relative to the independence of expert assessment in the field of health and the environment and the protection of whistle-blowers<sup>(1)</sup>”.

Incorporating the recommendation of a study from the *Conseil d'État*<sup>(2)</sup> on the adoption of a common core, Act 2016-1691 of 9 December 2016 “relative to transparency, the fight against corruption and the modernisation of economic life<sup>(3)</sup>” comprises a common definition of a whistle-blower and implements a common and graded alert procedure.

Constitutional Act 2022-400 of 21 March 2022 and Act 2022-401 of the same date<sup>(4)</sup> reinforce the whistle-blower protection system<sup>(5)</sup>

and transpose EU Directive 2019/1937 of 23 October 2019 which defines a common framework for this protection<sup>(6)</sup>. 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 whistle-blowing are the main contributions of these Acts.

- **Ordinance 2022-582 of 20 April 2022 adapting French law to regulation (EU) 2017/745 of the European Parliament and Council of 5 April 2017 regarding medical devices**

The European regulations concerning medical devices were modified in 2017 by European regulation (EU) 2017/745, adopted by the European Parliament and the Council of the European Union (EU).

The purpose of this new regulatory framework is to take account of a certain number of changes, based on experience, in order to guarantee patient safety, and technological developments in the medical devices sector.

1. Initial Act 2013-316 of 16 April 2013 in force. Before its modification by the “Sapin 2 Act” of 2016, the “Blandin Act” comprised a sectorial definition of whistle-blower, in the field of public health and the environment. Other provisions of the “Blandin Act”, still in force: the obligation to keep a registry of external alerts for expert assessment or research organisations in the field of health or the environment, which include the Institute for Nuclear Safety and Radiation Protection - IRSN (see Decree 2014-1628 of 26 December 2014); the creation of an administrative commission: the national Commission for ethics and alerts concerning public health and the environment (cnDAspe).

2. Study of the Conseil d'État: *The whistle-blower right: report, process, protect* of 25 February 2016.

3. Act 2016-1691 of 9 December 2016 (initial version).

4. Act 2022-401 of 21 March 2022 aimed at improving whistle-blower protection and Constitutional Act 2022-400 of 21 March 2022 aiming to reinforce the role of the Defender of Rights regarding whistle-blowing. Also see opinions 404000 and 404001 of 4 November 2021 from the Conseil d'État regarding the Bills.

5. The inadequacies in the protection afforded to whistle-blowers by the “Sapin 2 Act” were notably identified in the Parliamentary information report of July 2021 on the evaluation of the impact of Act 2016-1691 of 9 December 2016 (AN report n° 4325).

6. Directive (EU) 2019/1937 of the European Parliament and Council of 23 October 2019 on the protection of persons reporting violations of EU law.



The scope of application of this regulation includes the medical purpose in the definition of the medical devices and expands the new provisions to certain products with no medical purpose, for which the same safety requirements should apply owing to their operation and their risk profile.

This new regulation notably organises improved regulation of the procedures for designating and monitoring notified organisations, which certify the conformity of medical devices, and sets a more restrictive framework for evaluations and clinical investigations for these products.

It provides for an increase in the general requirements regarding safety and performance, as well as enhancement of the technical documentation, the implementation of traceability and identification of the medical devices.

It also contains provisions on updating of the conformity evaluation procedures, improved information of the patient with regard to implantable devices and the medical devices entailing the highest risks, by providing the patient with an implant card or the publication of a summary of the safety and performance characteristics of these products.

Finally, it organises the structuring and formalisation of European coordination by setting up a coordination group of competent authorities.

The Ordinance adapts national law to these new rules, notably that applicable to the operators, from clinical evaluation up to monitoring of the medical devices market.

## DECREES AND ORDERS

### ● Decree 2022-114 of 1 February 2022 relative to the technical conditions for operation of the nuclear medicine activity

This Decree sets the technical operating conditions for diagnostic and therapeutic nuclear medicine activities.

It creates a sub-section 17 concerning “nuclear medicine” after sub-section 16 of section 1 of Chapter IV of Title II of Book I of the sixth part of the Public Health Code.

This new sub-section contains a certain number of obligations for the licensee of a category “B” nuclear medicine facility. These latter refer to the demarcation of an area with rooms dedicated to the administration of RadioPharmaceutical Drugs (RPD), patient recovery after the administration of RPD, the examinations performed after the administration of RPD, rooms for the preparation and reconstitution of RPD, RPD checks, cellular labelling of blood elements by one or more radionuclides, the storage of contaminated solid waste and radioactive effluents.

Other provisions of this Decree concern the possession of certain equipment, appropriate initial and continuous training in radiopharmacy and radiation protection of personnel, patients, the public and the environment, but also the connection of an image and dose analysis archival and retrieval system.

It also stipulates that the patient shall be informed of the dosimetric data concerning him or her.

Finally, the license is subject to the quality assurance obligation.

### ● Decree 2022-422 of 25 March 2022 relative to the environmental assessment of projects

This Decree introduces a “safety net clause” in the environmental assessment procedure for those projects below the thresholds of the classification system of projects subject to the environmental

assessment appended to Article R. 122-2 of the Environment Code: in the event of risks with notable impacts on the environment, these projects shall be examined on a case by case basis.

The “safety net clause” does not concern projects for the creation, substantial modification or decommissioning of basic nuclear installations, which admittedly appear in the classification system of projects subject to the environmental assessment, but without thresholds.

In practice, ASN – which is the competent authority responsible for the case by case examination of projects for notable modifications to Basic Nuclear Installations (BNIs), shall check that the project complies with the following principles:

- the question of the risk of notable negative impacts must be posed on receipt of any application for authorisation of a notable modification to a BNI, as set out in the second section of II of Article R. 122-2 of the Environment Code;
- in the more particular cases of creation or extension of Installations Classified for Protection of the Environment (ICPEs) within the perimeter of a BNI, the question of the risk of notable negative impacts should be posed, regardless of whether or not the project is below the thresholds appearing in the line concerning ICPEs in the classification system appended to Article R. 122-2 of the Environment Code.

### ● Decree 2022-689 of 26 April 2022 relative to the layout conditions of the cancer treatment activity and Decree 2022-693 of 26 April 2022 relative to the technical operating conditions of the cancer treatment activity

These Decrees set out the conditions for the layout of cancer treatment activities (according to the procedures used in the activity concerned: oncological surgery, external radiotherapy, brachytherapy and systemic drug treatments for cancer), the conditions for licensing the activity and its renewal and the technical operating conditions for the cancer treatment activity (such as the organisation off a multi-disciplinary consultation meeting on significant changes in therapeutic orientations, provisions specific to minors and young adults, the definition of a multi-year training plan, or the conditions specific to oncological surgery, external radiotherapy, brachytherapy and systemic drug treatments for cancer).

### ● Decree 2022-907 of 20 June 2022 relative to the local and inter-municipal safeguard plans, modifying the Domestic Security Code

The purpose of this Decree is to define the procedures set out in the new Articles L. 731-3 and L. 731-4 of the Domestic Security Code regarding the Local Safeguard Plan (PCS) and the Inter-Municipal Safeguard Plan (PICS). The aim is to specify the methods for producing and implementing these plans, in order to manage emergencies at all regional levels.

The PCS is an overall organisational document for management of emergency situations affecting the population, according to their nature, their scale and how they develop. This plan prepares and ensures the operational response for protection and safeguard of the population.

The PICS is an organisational document for the operational response at the inter-municipal level to deal with emergency situations, on behalf of the municipalities affected. It organises inter-municipal coordination and solidarity.



● **Decree 2022-1186 of 25 August 2022 implementing Article L. 597-4 of the Environment Code relative to civil liability in the field of nuclear energy and codifying the provisions applicable to the sites comprising only facilities which represent a lesser risk**

In Chapter VII of Title IX of Book V of the Environment Code (regulatory part) entitled “Provisions applicable to civil liability in the field of nuclear energy”, this Decree sets out the characteristics of the facilities with a lesser risk in terms of nuclear civil liability.

It also stipulates the conditions for benefiting from a reduced civil liability ceiling when the site only comprises facilities with a lesser risk as defined in this Decree and appears on a list produced by Ministerial Order.

As an interim provision, the sites listed as presenting a lesser risk and entitling their licensees to a reduced liability amount, pursuant to Decree 2016-333 of 21 March 2016 implementing Article L.597-28 of the Environment Code and relative to civil liability in the field of nuclear energy, as at the date of publication of this Decree, shall remain so without the licensee having to submit a new application.

Finally, it is applicable to New-Caledonia, French Polynesia, Wallis and Futuna and the French Southern and Antarctic Lands.

● **Decree 2022-1165 of 20 August 2022 creating and organising the General Inspectorate for the Environment and Sustainable Development**

This Decree was adopted in accordance with the provisions of Article 17 of Decree 2022-335 of 9 March 2022 relative to the general inspectorate or oversight services and to employment within these services.

It creates the General Inspectorate for the Environment and Sustainable Development (IGEDD) in place of the General Council for the Environment and Sustainable Development (CGEDD).

It defines the organisation and the roles of the IGEDD and specifies the working conditions and methods aimed at guaranteeing the independence and impartiality of the work of its members.

● **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 Act 2022-401 of 21 March 2022 aiming to improve whistle-blower protection**

Constitutional Act 2022-400 of 21 March 2022 aiming to reinforce the role of the Defender of Rights with regard to whistle-blowing and Act 2022-401 of 21 March 2022 aiming to improve whistle-blower protection and amending Act 2016-1691 of 9 December 2016 relative to transparency, the fight against corruption and the modernisation of economic life, known as the “Sapin 2 Act” were adopted in order to transpose Directive (EU) 2019/1937 of the European Parliament and Council of 23 October 2019 on the protection of persons reporting violations of EU law.

Whistle-blowers have a number of possibilities: submit their report internally; send the report to an external authority listed by Decree in the *Conseil d’État*, to the Defender of Rights, to the judicial authority, to a competent European authority.

Decree 2022-1284 of 3 October 2022 sets out the regulatory provisions which, with the above Acts, ensures complete transposition of the above-mentioned Directive into internal law.

It thus contains provisions relative to the internal procedure for collecting and processing whistle-blower alerts and the external

procedure for collecting and processing alerts by the competent authorities designated in a list appended to the Decree.

The text is applicable in French Polynesia, the Wallis and Futuna islands and in New-Caledonia, and also applies in the overseas communities subject to the principle of identical legislation: Guadeloupe, French Guiana, Martinique, Reunion Island, Mayotte, Saint-Martin, Saint-Barthélemy and Saint-Pierre-et-Miquelon.

● **Decree 2022-1411 of 7 November 2022 instituting a new nuclear interministerial programme delegation**

This Decree creates a new nuclear interministerial programme delegation reporting to the Prime Minister.

This delegation supervises the performance of the industrial programmes to build new nuclear power reactors in France.

It carries out its role together with the central administrations and the national departments of the Ministries responsible for energy, the environment, nuclear safety, industry, the economy and the budget and with the Prefects of the regions in which new reactors are to be sited.

● **Decree 2022-1547 of 9 December provided for in Article L. 542-1-2 of the Environment Code and establishing the prescriptions of the National Radioactive Materials and Waste Management Plan**

This Decree sets the requirements of the National Radioactive Materials and Waste Management Plan (PNGMDR).

In addition to the general provisions of this Plan, it contains the provisions applicable to those in possession of radioactive materials and waste regarding the management of radioactive materials and waste storage facilities, the management of radioactive materials, and the long-term management of radioactive waste.

These latter provisions notably concern the ordering of works by the PNGMDR or by the Order mentioned in Article D. 542-74 of the Environment Code, the keeping of an updated statement of the availability of storage capacity for substances, per category of materials and waste, and the identification of future needs, the means for keeping a memory of the legacy radioactive waste disposal sites, the transmission and updating of the cost of managing the substances, notification of the Minister responsible for energy if it is impossible to meet the deadlines set, communication to the Minister responsible for energy of information regarding the costs of the main major projects deployed within the framework of the PNGMDR.

● **Order of 1 February 2022 setting the number of nuclear medicine appliances for an authorised site, pursuant to II of Article R. 6123-136 of the Public Health Code**

The first section of II of Article R. 6123-136 of the Public Health Code contains provisions concerning the licensing of a nuclear medicine activity and the maximum number of nuclear medicine appliances for a licensed site. It refers the determination of this number to an Order of the Minister responsible for health.

This Order therefore sets the maximum number of these appliances at three (Article 1).

The third section of II of Article R. 6123-136 of the Public Health Code states that the Minister sets a higher number for these appliances if the volume of procedures, the specialisation of the activity or the regional situation so warrants.

This number is set by the Order at three times the number set by Article 1 (Article 2).

In practice, the Director General of the competent Regional Health Agency can authorise the licensee to have a number of appliances higher than the maximum authorised number.

- **Order of 24 October 2022 relative to the procedures and frequency of checks on the rules put into place by the party responsible for a nuclear activity**

This Order defines the procedures and frequency of the checks on the rules put into place by the party responsible for a nuclear activity when the activity is subject to the authorisation, registration or notification systems, mentioned in Article L. 1333-8 of the Public Health Code, and generates effluents or waste contaminated by radionuclides or liable to be so contaminated.

### Basic Nuclear Installations

- **Order of 7 February 2012 setting the general rules concerning Basic Nuclear Installations (“BNI Order”)**

The work to revise this Order continued in 2022.

## ASN RESOLUTIONS

### Nuclear Pressure Equipment

- **ASN resolution 2021-DC-0713 of 23 September 2021 relative to Nuclear Pressure Equipment (NPE), regulating the performance of certain tests and analyses (approved by the Order of 6 January 2022 approving ASN resolution 2021-DC-0713 of 23 September 2021 relative to NPE, regulating the performance of certain tests and analyses)**

This resolution sets out a list of tests and chemical analyses that must be performed by accredited laboratories. The list contains the complex tests and analyses for which the results are the most important in demonstrating the conformity of an equipment item, such as the tensile tests, impact strength tests, or the characterisation of certain chemical species used in the composition of alloy parts or which could be harmful to the equipment. For each test and chemical analysis, it specifies the date as of which this test is to be performed by an accredited laboratory. The resolution contains no mandatory application of any standard. The list of tests given in the resolution does however refer to international standards. Accreditation of the laboratories in accordance with these standards will enable the requirements of the resolution to be met. A laboratory will be able to apply for accreditation in accordance with any equivalent standard.

- **ASN resolution 2021-DC-0714 of 23 September 2021 relative to integration within a BNI of certain NPE undergoing conformity evaluation (approved by the Order of 6 January 2022 approving ASN resolution 2021-DC-0714 of 23 September 2021 relative to the integration within a BNI of certain NPE undergoing conformity evaluation)**

This resolution specifies the type of equipment which could be integrated when the equipment is still undergoing conformity evaluation. It also specifies how the conformity evaluation is performed on the integrated equipment as well as permanent integration assemblies.

### Radon

- **ASN resolution 2022-DC-0743 of 13 October 2022 relative to the approval conditions for the organisations in charge of the services mentioned in 1, 2 and 3 of I of Article R. 1333-36 of the Public Health Code (approved by the Order of 23 December 2022 relative to the approval of ASN resolution 2022-DC-0743 of 13 October 2022 relative to the approval conditions for organisations responsible for the services mentioned in 1, 2 and 3 of I of Article R. 1333-36 of the Public Health Code)**

Pursuant to II of Article R. 1333-36 of the Public Health Code, this resolution sets the procedures for issuing, checking and revoking approval, the detailed list of information to be enclosed with the approval application and the approval criteria for the organisations.

The prior approval process is retained and takes up the existing provisions of resolution 2009-DC-0134 of 7 April 2009 on the submission of files, their examination by ASN, the issue or refusal of an approval further to the opinion of an approval commission.

The quality management requirements remain identical: the organisations are required to conduct measurements using standardised methods but are under no obligation to have an organisation subject to quality assurance.

What is new in this resolution is that it defines two levels of approval, as against three at present, and updates the regulatory provisions by introducing the drafting and the new regulatory references of the Public Health Code derived from Decree 2018-437 of 4 June 2018 relative to the protection of workers against the hazards of ionising radiation.

Finally an interim provision enables the validity of the existing level 1 option B and level 2 approvals to be maintained until they expire.

- **ASN resolution 2022-DC-0744 of 13 October 2022 relative to the objectives, duration and content of the training programmes for persons carrying out radon activity concentration measurements (approved by the Order of 23 December 2022 relative to the approval of ASN resolution 2022-DC-0744 of 13 October 2022 relative to the objectives, duration and content of the training programmes for persons carrying out radon activity concentration measurements)**

Pursuant to II of Article R. 1333-36 of the Public Health Code, the resolution updates the provisions of ASN resolution 2009-DC-0136 of 7 April 2009 relative to the objectives, duration and content of the training programmes for persons carrying out radon activity concentration measurements.

The content of the training programme takes up that of the existing level 1 option A and level 2, while limiting the scope to the application of the provisions of the Public Health Code. The drafting was revised with regard to the teaching objectives and level of competence to be acquired, expressed in terms of knowledge and know-how. The minimum duration of level 2 training is raised to 14 hours instead of one day (a number of hours was set rather than a number of days). The “concrete cases” are replaced by “a situational exercise inside a building”.

An interim provision enables the validity of the existing level 1 option A and level 2 proficiency certificates to be maintained.

- **ASN resolution 2022-DC-0745 of 13 October 2022 relative to the transmission of the results of radon activity concentration measurements carried out in Public Access Buildings (PAB) mentioned in Article D.1333-32 of the Public Health Code (approved by the Order of 21 December 2022 relative to the approval of ASN resolution 2022-DC-0745 of 13 October 2022 relative to the transmission of the results of radon activity concentration measurements carried out in the PABs mentioned in Article D. 1333-32 of the Public Health Code)**

Article R. 1333-36 of the Public Health Code stipulates that IRSN and the approved organisations must send ASN the results of the radon activity concentration measurements carried out by these establishments and that an ASN resolution defines the nature of the data and how they are transmitted. They are currently set by ASN resolution 2015-DC-0507 of 9 April 2015 concerning the technical rules for the transmission of the radon measurement results produced by approved organisations and the conditions for access to these results.

This resolution sets the information that the radon organisations are required to enter on the *demarches-simplifiees.fr* on-line platform, which replaces the Environmental Health Information System for Public Access Buildings (SISE-PAB) created by the General Directorate for Health (DGS).

## Waste

- **ASN resolution 2022-DC-0749 of 29 November 2022 amending ASN resolution 2015-DC-0508 of 21 April 2015 relative to the study of waste management and the inventory of waste produced in the BNIs and ASN resolution 2017-DC-0616 of 30 November 2017 relative to notable modifications to BNIs (pending approval by Order of the Minister responsible for nuclear safety)**

All waste produced in a BNI, whether or not radioactive, must undergo rigorous management appropriate to its characteristics. In this respect, the regulations stipulated that the BNI commissioning authorisation application must comprise a “waste management study”, presenting and justifying the waste management procedures in this installation and the corresponding management means, in order to reduce the quantity and harmfulness of the waste produced.

Decree 2019-190 of 14 March 2019 codifying the provisions applicable to BNIs, the transport of radioactive substances and transparency in the nuclear field modified the regulations. The impact assessment, transmitted with the BNI creation authorisation application and updated at each major stage in its life, must now demonstrate waste management optimisation, notably in the light of the effects of the installation on the environment and health.

On this occasion, the waste management study was cancelled as a stand-alone document and its content was to a large extent incorporated into the impact assessment. The parts of the study not incorporated into the impact assessment and concerning the operational waste management procedures, will be taken up in the BNI General Operating Rules (RGEs).

In order to take account of these regulatory changes, this resolution modifies:

- ASN resolution 2015-DC-0508 of 21 April 2015 relative to the study of waste management and the inventory of waste produced in the BNIs;
- ASN resolution 2017-DC-0616 of 30 November 2017 relative to notable modifications to BNIs.

The modifications made are of several types:

- firstly, they divide the content of the waste management study between the impact assessment – which is to present the waste produced in the BNI and demonstrate that the objectives set by the Environment Code, such as the hierarchy of waste management methods or compliance with the guidelines of the national and regional waste management plans have actually been taken into account – and the RGEs, which contain the provisions relating to the routine operation of the BNI and may change more frequently;
- secondly, they reinforce certain waste management requirements, to ensure better control of the duration of waste storage in the installations, guarantee a periodic reassessment of the organisation of waste management and allow improved coordination between the various radioactive or conventional waste management plans.

Finally, the resolution makes provision for improved management of waste from a conventional waste area but with radioactive contamination, which is an abnormal situation needing to be dealt with as such.

## Resolutions issued pursuant to the Public Health Code

- **ASN resolution 2022-DC-0747 of 6 December 2022 setting rules that the party responsible for the nuclear activity is required to have checked pursuant to Article R. 1333-172 of the Public Health Code and ASN resolution 2022-DC-0748 of 6 December 2022 setting the conditions and procedures for the approval of organisations responsible for the checks mentioned in Article R. 1333-172 of the Public Health Code (these two resolutions are awaiting approval by Order of the Minister responsible for radiation protection)**

Resolution 2022-DC-0747 supplements the Order of 24 October 2022 relative to the procedures and frequency of the checks on the rules put into place by the party responsible for the nuclear activity, pursuant to III of Article R. 1333-172 of the Public Health Code, in its version derived from Decree 2018-437 of 4 June 2018 relative to the protection of workers against the hazards of ionising radiation. With regard to the provisions relative to the Public Health Code, this resolution – as at its date of entry into force – repeals ASN resolution 2010-DC-0175 of 4 February 2010 which previously regulated the technical inspections both for the Public Health Code and for the Labour Code.

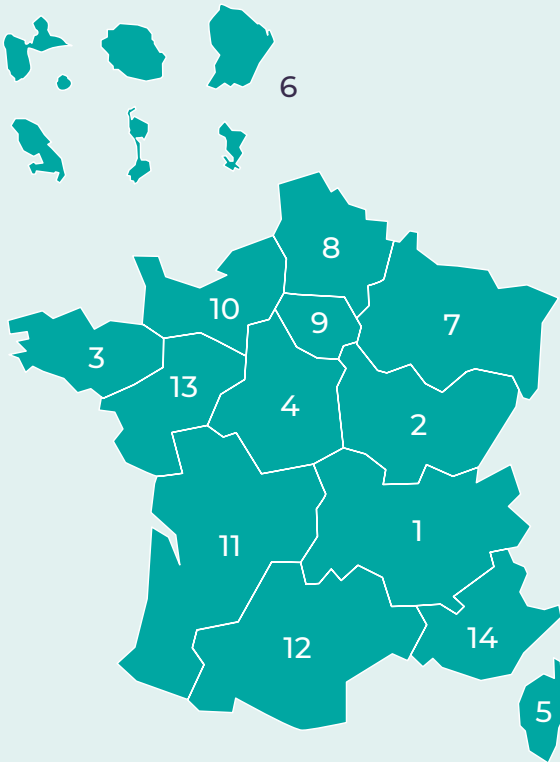
Resolution 2022-DC-0748 is in response to Article R. 1333-174 of the Public Health Code, which required an ASN resolution for organisations approved to conduct checks in the field of radiation protection concerning the detailed list of information to be enclosed with the approval and approval renewal applications mentioned in II of Article R. 1333-172 and the procedures for the issue, renewal, verification and suspension of approvals.



# REGIONAL OVERVIEW

of nuclear safety and  
radiation protection

The French Nuclear Safety Authority (ASN) has 11 regional divisions through which it carries out its regulatory duties throughout metropolitan France and in the overseas *départements* and regions. Several ASN regional divisions can be required to coordinate their work in a given administrative region. As at 31 December 2022, the ASN regional divisions totalled 217 employees, of whom 172 are inspectors.



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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 operations and of small-scale nuclear activities; they examine the majority of the licensing applications submitted to ASN by the persons/entities responsible for nuclear activities within their regions. The regional divisions check, for these activities and within these installations, application of the regulations relative to nuclear safety and radiation protection, to Pressure Equipment (PE) and to 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 make the installation safe and assist the Prefect of the *département*<sup>(1)</sup>, who is responsible for protection of the population. To ensure emergency situation preparedness, they help draw up the emergency plans established by the Prefects and take part 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 Local Information Committees (CLIs) of the BNIs and maintain regular relations with the local media, elected officials, associations, licensees and local administrations.

This section presents ASN's oversight action in the BNIs of 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.

1. Administrative region headed by a Prefect.

**i 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**





# Auvergne-Rhône-Alpes

## REGION

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

In 2022, ASN carried out 330 inspections in the Auvergne-Rhône-Alpes region, comprising 116 in the Bugey, Saint-Alban, Cruas-Meysses and Tricastin Nuclear Power Plants (NPPs), 91 in plants and installations undergoing decommissioning, 107 in small-scale nuclear activities and 16 in the radioactive substance transport sector.

ASN also carried out 19 days of labour inspections in the four NPPs and on the Creys-Malville site.

In 2022, ASN was notified of 36 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale), of which 30 occurred in Basic Nuclear Installations (BNIs) and 6 in small-scale nuclear activities.

Furthermore, one event was rated level 2 on the ASN-SFRO scale (scale specific to radiation protection events affecting patients undergoing radiotherapy procedures).

In the context of their oversight duties, the ASN inspectors issued one violation report. ASN also served formal notice on one nuclear licensee and one head of a nuclear activity to comply with the regulations.

ASN temporarily modified the requirements regulating thermal discharges from the Bugey, Saint-Alban and Tricastin NPPs during the heat waves of summer 2022 (see “Notable events” in the introduction to this report).

## 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 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 packaging 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 FARN, the special Nuclear Rapid Intervention Force 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.

## Bugey nuclear power plant

### Reactors 2, 3, 4 and 5 in operation

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

With regard to nuclear safety, ASN considers that the NPP's performance has deteriorated in 2022, despite an industrial context with lower workloads than in the preceding years. ASN still observes vulnerabilities in the configuring of the systems, the management of the periodic tests, the scheduling and performance of the maintenance activities and requalification tests, and the problems of spare parts. Despite some initial improvements, progress must be made in emergency situation management and the control of fire risks. Progress must also be made in keeping the first barrier, that is to say the fuel containment cladding, in good condition. The management of the modifications associated with the fourth ten-yearly outages now seems to be satisfactory on the whole. Nevertheless, following the detection in 2022 of deterioration of a seal of the system for maintaining dryness, installed between the pool and the vessel mating surface on reactors 2 and 4 during their fourth ten-yearly outages, ASN served EDF formal notice on 3 August 2022 to comply with the applicable provisions of the safety analysis report of reactors 2, 4 and 5 at the



next refuelling outage and by 24 March 2024 at the latest. The restarting phase of reactor 5 after its fourth ten-yearly outage was also marked by unforeseen technical events and numerous significant safety events. Lastly, reactor operation, control room monitoring and management of the operating team are satisfactory on the whole.

With regard to radiation protection, ASN noted positively during its inspections the setting up of radiation protection skills centres. Nevertheless, vulnerabilities persist in the culture of worker radiation protection, radiological cleanliness of the installations and containment on work sites with contamination dispersion risks. ASN expects progress in the prevention of contamination of roadways, which remains a weak spot on the site.

With regard to environmental protection, ASN considers that waste management remains at a generally satisfactory standard. Despite the organisational enhancements observed in 2021 on the handling of deviations affecting retention areas, a number of deviations were again detected in 2022. ASN is awaiting an ambitious plan of action to lastingly restore the sealing of the site's ultimate retention structures.

As far as occupational health and safety are concerned, ASN considers that the site's accident rate results remain satisfactory. The efforts must be maintained to improve the perception and prevention of risks in the planning and conducting of the work interventions and worksite teardown operations, particularly with regard to contractors.

### Reactor 1 undergoing decommissioning

Bugey 1 is a graphite-moderated GCR. This first-generation reactor functioned with natural uranium as the fuel, graphite as the moderator and it was cooled by gas. The Bugey 1 reactor is an "integrated" GCR, whose heat exchangers are situated inside the reactor vessel beneath the reactor core.

In March 2016, in view of the technical difficulties encountered, 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" rather than "under water" as initially envisaged. Through ASN Chairman's resolution CODEP-CLG-2020-021253 of 3 March 2020, further to the change in EDF's decommissioning strategy, ASN requires EDF to complete the decommissioning operations on the building and equipment that are not necessary for decommissioning of the reactor pressure vessel, by 2024 at the latest.

In 2020, the Bugey 1 reactor received ASN authorisation to create a new effluents storage facility, on which work started in 2022, to replace the old facility which will be put out of service, decommissioned and cleaned out.

After analysing the periodic safety review concluding report for the GCR reactors, ASN stated in December 2021 that it had no objection to continuing the decommissioning of this reactor. ASN considers that the Bugey 1 reactor decommissioning and vessel characterisation operations are proceeding with a satisfactory level of safety.

## 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;

### ■ the Operational Hot Unit (BCOT) at Tricastin, operated by EDF;

### ■ The High Flux Reactor (RHF) operated by the Laue-Langevin Institute (ILL) in Grenoble;

### ■ the Activated waste packaging 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 Superphénix reactor undergoing decommissioning at Creys-Malville and its auxiliary installations, operated by EDF;

### ■ the Ionisos irradiator in Dagneux;

### ■ the Effluents and Solid waste Treatment and decay storage Station (STED) of the Alternative Energies and Atomic Energy Commission (CEA) in Grenoble, which is waiting to be delicensed following its decommissioning;

### ■ 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 field:



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- 23 external-beam radiotherapy departments,
- 6 brachytherapy departments,
- 23 nuclear medicine departments,
- 121 facilities using fluoroscopy-guided interventional procedures,
- 157 scanners within 115 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 500 veterinary practices (surgeries or clinics),
- 33 industrial radiography agencies,
- about 600 users of industrial equipment,
- more than 70 public or private research units;

### ■ activities associated with the transport of radioactive substances;



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### ■ ASN-approved laboratories and organisations:

- 3 organisations and 8 agencies approved for radiation protection controls.

## Activated waste packaging and storage installation

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

- low-level long-lived graphite waste (LLW-LL) from the dismantling of the Bugey 1 reactor, which is destined – after interim storage – for near-surface disposal in a facility whose concept is still being studied;
- activated metallic intermediate-level long-lived waste (ILW-LL) from the operation of the in-service power plants, for example parts which have spent time near the reactor core, such as control rod clusters, destined for deep geological disposal after interim storage;
- some low-level or intermediate-level short-lived waste (LL/ILW-SL), called “deferred transfer” waste, intended for above-ground disposal but requiring a period of radioactive decay ranging from several years to several decades before being accepted at the Aube repository (CSA – BNI 149), operated by the French national agency for radioactive waste management (Andra).

On 28 July 2020, ASN authorised the commissioning of Iceda and regulated operation of the facility through requirements relative to the operating range, the maximum storage durations for radioactive waste, the defining of criteria for activating the On-site Emergency Plan (PUI), the content of the end-of-startup file which was submitted on 24 March 2022, compliance with waste package qualification heights, and the conditions of reception of source rods from Chooz A. The first activated waste package was received in late September 2020.

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

Regarding packaging of the waste, ASN authorised EDF to package its waste in the CIPGSP package through resolution CODEP-DRC-2021-013808 of 19 July 2021. ASN nevertheless noted that complementary studies were still in progress and decided, in its authorisation, to limit the thermal power released by each package and within each storage hall and to limit the validity of its packaging agreement to 31 December 2023. The extension of this agreement is conditional upon submittal of the above-mentioned additional studies no later than 31 December 2022 and the agreement of ASN following their examination. These studies were submitted to ASN on 19 December 2022 and are currently being examined by ASN.

The inspections carried out in 2022 on the installation revealed weaknesses in the organisation for managing the waste produced by the process on the site. An action plan was submitted by EDF in December 2022 and will undergo examination and oversight by ASN.

## 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.

MIR presented a satisfactory overall level of safety in 2022, year in which its operating activities resumed following the renovation of various items of equipment.

## 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 performance of the Saint-Alban 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 the general assessment of the fleet.

With regard to nuclear safety performance in 2022, ASN notes that the Saint-Alban NPP maintains its level. The site installations are operated and maintained satisfactorily. ASN considers that the site must continue the actions undertaken to improve the integration of Social, Human and Organisational Factors (SHOF). With regard to maintenance, reactor 2 was shut down

for its refuelling and maintenance outage. ASN considers that EDF ensured the quality of performance of the planned activities and met the corresponding safety requirements.

With regard to worker radiation protection, ASN considers that the operational results were satisfactory. ASN nevertheless still expects a reinforcement of the radiation protection culture and the rigour in marking out work sites, tools and nuclear waste.

As far as protection of the environment is concerned, ASN wants to see faster responses to the technical problems impacting the environmental protection systems.

With regard to occupational safety, ASN considers the site's results to be relatively satisfactory. There were no serious accidents or accidents related to critical risks. This being said, several “near-accidents” associated with the electrical risk require particular attention.

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

With regard to nuclear safety, in 2022 ASN observed an increase in deviations and non-qualities in the maintenance activities during the four reactor outages carried out in 2022 and considers that the quality of the maintenance activities does not meet expectations. Only the reactor 1 outage went satisfactorily on the whole. Furthermore, the occurrence of several significant events concerning situations of noncompliance with the General Operating Rules (RGEs) shows that the operating rigour must also be improved. In addition, ASN's inspection campaign on the theme of the operating team's skills management revealed shortcomings leading ASN to ask EDF to implement corrective actions.

ASN therefore expects the site to increase rigour in its operation and maintenance activities before the first of the site's fourth ten-yearly outages, which concerns reactor 3 and will start in 2024.

As far as radiation protection is concerned, 2022 is in line with the preceding years, with controlled collective exposure of workers but difficulties in obtaining satisfactory levels of radiological cleanliness during the reactor outages and maintaining the containment air locks of the worksite areas in good condition. These situations still lead to worker contamination events – without exceeding the authorised doses, and to contaminations of the roadways.

With regard to environmental protection, ASN notes that the management of waste and the storage areas is now satisfactory. Progress is nevertheless required in the containment of effluents. As in 2021, ASN notes shortcomings in the control of the risk of dispersion and proliferation of legionella in the tertiary circuit where progress must be made.

The site's results in occupational health and safety are satisfactory. The accident rate remains under control, although efforts must nevertheless be made in controlling the risk of falling from height and when using construction machinery and lifting equipment. A serious accident occurred during the use of an aerial work platform.

## TRICASTIN SITE

The Tricastin nuclear site, situated in the Drôme and Vaucluse *départements*, constitutes 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 NPP comprising four 900 MWe reactors, "nuclear fuel cycle" facilities, and lastly the Operational Hot Unit (BCOT) which fulfilled maintenance and storage functions.

### Tricastin nuclear power plant

The Tricastin NPP comprises four 900 MWe PWRs: reactors 1 and 2 were commissioned in 1980 and 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 stands out positively with respect to its general assessment of the EDF plants, and that its radiation protection and environmental protection performance is in line with the ASN's general assessment of the EDF nuclear fleet.

With regard to nuclear safety, ASN considers that the performance of the NPP has improved. The site has made progress in equipment maintenance and operation of the facilities. In 2022, the four reactors of the Tricastin NPP were shut down for scheduled maintenance and partial refuelling. Reactor 3 underwent its fourth ten-yearly outage and the modifications planned to enhance safety were integrated satisfactorily. ASN considers that EDF satisfactorily carried out the planned activities for the four reactor outages and complied with the corresponding safety requirements. Vulnerabilities were nevertheless observed in the control of the fire risk associated in particular with the maintenance of fire-fighting means and two reported significant events are related to this risk. ASN nevertheless noted the occurrence of several significant events during the last quarter of 2022 linked to the planning and preparation of the maintenance activities, and will remain attentive to this in 2023.

ASN considers that the radiation protection performance of the NPP is slightly down compared with 2021. Several significant events were effectively reported and deficiencies in the control of radiological cleanliness were noted. Likewise, several cases of worker contamination detection at the site exit were reported in 2022. ASN nevertheless noted improvements in worker dosimetry during the reactor 1 outage at the end of 2022.

With regard to environmental protection, ASN wants to see improvements in the site's practices. Although waste management remains satisfactory on the whole, the analysis of significant environmental events – including the groundwater pollution by effluents containing tritium in December 2021 and the exceeding of the maximum regulatory concentration of hydrocarbons at the outlet of an oil remover in October 2022 – has shown that the control of effluent storage areas and liquid containment, and the maintenance of the associated monitoring devices, need to be improved.

As far as occupational safety is concerned, ASN considers that the site's results are satisfactory and stable with respect to the preceding year. The accident rate, particularly during the reactor outages, was kept down. ASN nevertheless notes that a serious accident occurred this year during work on a ventilation system motor.

## THE “NUCLEAR FUEL CYCLE” FACILITIES

The Tricastin “fuel cycle” installations mainly cover the upstream activities of the “fuel cycle” and, as of the end of 2018, they are operated by a single licensee, Orano Cycle, which became Orano Chimie-Enrichissement on 1 January 2021 and is called “Orano” hereinafter.

The site comprises:

- the **TU5 facility** (BNI 155) for converting uranyl nitrate  $UO_2(NO_3)_2$  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 (BNI 178, 179 and 180) for storing uranium in the form of oxides or  $UF_6$ ;
- the **maintenance, liquid effluent treatment and waste packaging 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 2022, ASN considers that the level of safety of the Orano facilities on the Tricastin site is satisfactory. In 2022, Orano improved its organisation for analysing the conformity of the facilities with the regulations and further improved its follow-up of the commitments made to ASN.

Trident, the new waste processing facility in BNI 138, continued its gradual start-up. Construction of the new Uranium Reprocessing Storage Facility called “FLEUR” (BNI 180) was completed and its commissioning has been authorised by ASN resolution 2023-DC-0750 of 3 January 2023. Lastly, ASN continued examination of the Creation Authorisation Application (DAC) for the future containers maintenance unit (AMC2). This DAC was the subject of a public inquiry from 10 December 2021 to 12 January 2022. The AMC2 unit will take over from the existing unit (AMC) which should stop operating in 2024. Orano did not start the construction work at the end of the public inquiry because of contractual problems, which will delay commissioning of the AMC2 unit.

In 2022, ASN conducted a campaign of simultaneous unannounced inspections on BNIs 93, 105, 138, 155, 168, 178 and 179, focusing on the management of the facilities in normal operating situations with the aim of checking Orano's organisation in this area. During these inspections the inspectors observed changes of shift, operators at work in the control room and during patrols and lockout/tagout operations. The overall result of these inspections is satisfactory.

To check the progress of treating the backlog of diverse radioactive substances stored on the site, ASN asked Orano to present an annual statement on the progress of its action plan for the treatment of these substances. Some operations planned with Russia have been suspended and alternatives must be found.

Lastly, in 2022, to increase its enrichment capacities, Orano initiated the project to extend the Georges Besse II North enrichment plant, which will undergo public consultations as of 2023.

In 2023, ASN will also ensure that Orano has and engages all the necessary resources in the new construction projects, whether to increase its production capacity or to improve certain support functions such as the AMC2 project or treating the backlog of radioactive substances stored on the site.

## Orano uranium chemistry plants TU5 and W

BNI 155, called “TU5”, can handle up to 2,000 tonnes of uranium per year, which enables all the  $UO_2(NO_3)_2$  from the Orano plant in La Hague to be processed for conversion into  $U_3O_8$  (a stable solid compound that can guarantee storage of the uranium under safer 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 Georges Besse II 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. Although 2022 was marked by a significant drop in the number of significant or notable events, ASN was attentive to the lessons learned from the two contamination events in the drumming enclosure of the TU5 plant. In 2023, ASN will be attentive to the maintaining of due operating rigour and will examine the impacts that the project to increase the capacity of the Georges Besse II North plant has on the W plant.

## 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 in the decommissioning preparation phase.

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

Despite relative stability of operation in 2021, the Philippe Coste plant, whose facilities are classified Seveso high threshold and replace those of BNI 105 (formerly Comurhex), encountered various technical problems in 2022. ASN considers nevertheless that the safety of operation of this plant is satisfactory.

For the shutdown facilities, although the decommissioning operations have effectively started, ASN expects greater mobilisation on the part of the licensee to ensure the repackaging of the packages containing hazardous radioactive substances stored on storage areas 61 and 79 within the allocated time frames.

## 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 stopping production at this plant in May 2012, the licensee carried out, from 2013 to 2016, the Eurodif "Prisme" process of "intensive rinsing followed by venting", which consisted in performing repeated rinsing of the gaseous diffusion circuits with chlorine trifluoride (ClF<sub>3</sub>), a toxic and dangerous substance. These operations, which are now completed, allowed the extraction of virtually all the residual uranium deposited in the diffusion barriers.

The licensee submitted its application for final shutdown and decommissioning of the facility in March 2015. The Decree ordering Orano to proceed with the decommissioning of the Georges Besse I 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. In 2022, ASN inspected various decommissioning preparation operations such as the movement of heavy equipment, grouping of the waste storage areas and cutting tests on obsolete materials with a view to qualifying the tool options planned for cutting up the diffusers. The main residual risk of BNI 93 is now associated with the UF<sub>6</sub> containers in the storage yards, which are still attached to the perimeter of the facility. These yards should in the short term be attached to the Tricastin uranium storage areas (BNI 178).

## Georges Besse II enrichment plant

The Georges Besse II plant, BNI 168, is the site's new enrichment facility following the shutdown of Eurodif. It uses the centrifuge process to separate uranium isotopes.

The standard of safety of the plant's facilities in 2022 was satisfactory. The technologies used in the facility enable high standards of safety, radiation protection and environmental protection to be achieved. ASN considers that the licensee is duly following its commitments to ASN.

Due to the deterioration of the handling gantry rolling tracks at Georges Besse II North, the gantries have been unavailable since October 2020. The buffer yard of the North plant has been completely emptied in order to secure this zone. In 2022, ASN continued monitoring the steps taken by the licensee to reduce cooling fluid discharges into the atmosphere and considers that the licensee has kept up its efforts to control this type of discharge.

Lastly, in 2022 Orano began the project to extend the Georges Besse II North enrichment plant with a view to increasing its production capacities by adding centrifuge modules. This project will be opened for public consultation as of 2023.

## Maintenance, effluent treatment and waste packaging 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.

ASN considers that the efforts made by the licensee in 2022 to improve the level of operational safety and the rigour of operation must be continued. In 2022, ASN checked the numerous commitments made to it in 2021 on the subject of fire and waste treatment, and underlines the good progress made in meeting them. This being said, continued vigilance is required regarding the fire-fighting equipment. ASN conducted an inspection dedicated to the surface treatment activities which confirmed that the licensee had duly met the commitments made following an inspection in 2021.

Decree 2019-113 of 19 February 2019 authorised the substantial modification of the BNI to create in particular a site waste processing facility called "Trident", which continued its start-up in 2022.

The technical examination of the update of the discharge resolutions for BNI 138 was carried out in 2021, with a public consultation from 15 November to 6 December 2021. These resolutions entered into effect in July 2022.

ASN will be attentive in 2023 to the continuation of the measures taken by the licensee to reinforce operating rigour. ASN will also examine the integration of the conclusions of the periodic safety review, including prevention of the fire risk and upgrading of certain storage sites which will necessitate the construction of a new building baptised "57L".



## 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) have been created. This facility groups the uranium storage yards and the new emergency management premises of the Tricastin platform. Following on from this delicensing process, facility “P35” (BNI 179) was created. It comprises ten uranium storage buildings. A complementary storage facility called “FLEUR”, for which the DAC underwent a public inquiry from 2 November 2020 to 3 December 2020, was authorised by Decree on 18 March 2022. Commissioning of this new BNI 180 was authorised by ASN resolution 2023-DC-0750 of 3 January 2023.

The overall level of safety of BNIs 178 and 179 was satisfactory in 2022. ASN notes that the licensee’s action plan for the periodic safety review of the storage yards is being followed very closely. In 2022, ASN inspected the end of the construction of the first two additional storage buildings associated with the FLEUR project. ASN approved the baseline safety requirements for the emergency management building and its equipment.

## 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.

In a letter dated 22 June 2017, EDF declared final shutdown of the BCOT in June 2020. The storage activities and maintenance operations are now carried out in its Saint-Dizier maintenance base.

The last operating activity consisted in finishing cutting up the used fuel cluster guide tubes from the PWRs operated by EDF. The decommissioning authorisation application is currently being examined. The public inquiry ran from 15 February to 17 March 2022. ASN considers that the level of safety of the BCOT is on the whole satisfactory. In 2023, ASN will be attentive to compliance with the applicable baseline for conducting the ongoing decommissioning preparation operations until 2024, pending issuing of the decommissioning decree.

## ROMANS-SUR ISÈRE SITE

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 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).

### Framatome nuclear fuel fabrication plants

The fabrication of fuel for electricity generating reactors involves the transformation of  $UF_6$  into uranium oxide powder. The pellets fabricated from this powder in Framatome’s Romans-sur-Isère plant, called “FBFC”, are placed in zirconium metal clads to constitute the fuel rods, then brought together to form the assemblies for use in the NPP reactors. In the case of experimental reactors, the fuels are more varied, with some of them using, for example, highly-enriched uranium in metal form. These fuels are fabricated in the Romans-sur-Isère plant called “Cerca”.

The “Cerca” plant includes building F2, which houses the “uranium zone” in which compacted powder cores placed in aluminium frames and plates are produced. 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 uranium zone of building F2. Construction of the NZU continued in 2022, notably with the manufacture and installation of new equipment and performance of the first operating tests. The update of the safety analysis report and the new RGEs associated

with the NZU were submitted to ASN in the first half of 2021, leading to complementary information requests on its part. With regard to the progress of the NZU project, due to technical problems and the impact of the Covid-19 pandemic, Framatome requested partial commissioning of the NZU (for the material storage premises only), to allow transfers of materials between the MA2, F2 and NZU buildings, for which ASN issued an authorisation in October 2022.

A request for a modification of the Order of 22 June 2000 regulating water intakes, discharges and environmental monitoring of the Romans-sur-Isère nuclear site was also submitted to ASN in July 2020. This request follows on from several changes, including the increase in the production capacity of the FBFC, the stopping of certain activities, the changes made to the liquid effluent treatment facilities, and the changeover from continuous discharging of liquid effluents to discharging via tanks. This case led to two ASN resolutions which came into effect in December 2022: the first setting the environmental discharge limits, the second setting requirements relative to the conditions of effluent discharge, water intakes and consumption and environmental monitoring. In substance, these new resolutions reinforce the regulation of discharges by improving environmental monitoring, the regulation of chemical gaseous discharges and a lowering of the preceding maximum discharge values except for fluorine and hexavalent chrome, for which the absence of significant environmental impacts has been demonstrated.

A substantial modification request submitted for FBFC in December 2020 aims to allow increased production of fuels based on enriched reprocessed uranium. It is currently being examined by ASN.

There was a decrease in the number of significant events relating to control of the criticality risk reported by Framatome and rated level 1 on the INES scale in 2022. However, a fire outbreak on 21 September 2022 in the SE9 unit of the “uranium zone” led to activation of the PUI: this impacted all Cerca’s production; extensive cleaning and verification work had to be carried out in the facilities before restarting the equipment. The management of the event enabled all the lines of defence to be maintained and there was no impact on the population or the environment. This event was rated level 0 on the INES scale.

The results of the inspections carried out on the Romans-sur-Isère site in 2022 are satisfactory on the whole. In 2023, ASN will be attentive to the continuation of the qualification tests for final commissioning of the NZU, and the deployment of the new environmental monitoring plan required by the resolutions concerning water intakes and consumption, effluent discharges and the environmental monitoring of BNI 63-U.

## THE INDUSTRIAL AND RESEARCH FACILITIES

### The Laue-Langevin Institute high flux reactor

The Laue-Langevin Institute (ILL), an international research organisation, accommodates a 58 Megawatts thermal (MWth) heavy-water 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 which accommodates the European Molecular Biology Laboratory (EMBL), an international research laboratory. Employing some 500 persons, this BNI occupies a surface area of 12 hectares situated between the rivers Isère and Drac, just upstream of their confluence, near the CEA Grenoble centre.

On the basis of its oversight activities in 2022, ASN considers that the safety management of the RHF is satisfactory. The year 2022 was devoted to extensive works to renew and reinforce the safety of the installation.

In 2022, the ILL continued progressing with the action plan established for its third periodic safety review and enriched by the commitments made further to the expert assessment associated with this review. ASN resolution 2022-DC-0738 validating the conclusions of this review and governing the continued operation of the RHF was signed on 28 July 2022.

The main works of the major outage, which should have lasted fourteen months, focused on the replacement of technological equipment constituting the reactor vessel, reinforcement of the outside air intake of the reactor building and the installation of anchor points on the containment dome in preparation for the future renovation operations on the main polar crane.

An unforeseeable event occurred on this latter work site when drilling holes in the containment dome. The ILL conducted investigations on the concrete of the containment before installing the anchor points. ASN is examining the supporting documents provided by the ILL.

At the start of the year, more than half of the radioactive inventory of the former detritiation facility was transferred to the reactor building pending its final processing, for which the ILL filed an application for authorisation to modify the functioning of the facility.

In July 2022 the ILL also submitted a “public information notice” file aiming to establish new technical requirements for discharges and environmental monitoring.

ASN will be particularly attentive in 2023 to the restarting conditions following a 16-month outage and the containment dome event. ASN will be attentive to the preparation of the next high-stake issues for ILL, and notably the pre-cleanout operations on the former detritiation facility and the renovation of the polar crane. Lastly, the revision of the requirements regulating discharges will be continued in 2023.

### 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 level of safety of the facility was found to be satisfactory in 2022.

ASN considers that the licensee must continue the foundation work aiming to better define the Components Important to Protection (PIC) of the interests of the facility and more rigorous application of their requirements defined in the periodic inspection and test procedures.

An authorisation for recovery of the sludge from pool D1 (operated until November 1996) was issued by ASN in 2021. This operation was carried out in July 2022 and led to an inspection addressing contractor monitoring, which gave satisfactory conclusions.



## 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. The joint actions concern transport, waste and radiation protection.

Two joint visits by the Swiss and French authorities took place in 2022 on the subject of management of the on-site waste processing centre and the monitoring of outside contractors. These visits 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 in concrete. 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.

EDF has submitted the periodic safety review concluding reports for BNI 141 and BNI 91. ASN made public its conclusions concerning the Superphénix periodic safety review on 28 July 2021 and has approved continuation of the decommissioning operations.

In the light of the APEC periodic safety review conclusions, ASN has regulated its continued operation through a resolution of 17 March 2022 setting requirements concerning the control of the seismic-related risks, beyond design-basis accident situations, removal of the fuel and waste stored in the pool, the handling operations and the management of soda blocks.

ASN considers that the safety of Superphénix decommissioning operations and of APEC operation is on the whole satisfactory. 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 dedicated facilities constructed in the reactor building, by direct or remote manipulation.

In 2022, the large rotating plug was cut into three pieces placed on specific accommodation platforms located on the slab and the vessel was covered by a containment structure to keep it sealed pending its decommissioning.

In 2019, EDF discovered legacy hydrocarbon pollution of the soils in a perimeter near a former buffer pond. ASN is currently examining a soil management plan.

ASN considers that the organisation and the measures implemented by the licensee on 2022 ensure good upkeep of the facilities and good tracking of the various commitments made to ASN.

### Siloette, Siloé, LAMA reactors and effluents and solid waste treatment station – CEA Centre

The CEA Grenoble centre (*Isère département*) was inaugurated in January 1959. Activities associated with the development of nuclear reactors were carried out there before being gradually transferred to other CEA centres in the 1980's. The Grenoble centre now carries out research and development in the areas of renewable energies, health and microtechnology. In 2002, the CEA Grenoble centre began a site delicensing process.

The site accommodated six nuclear installations which have gradually stopped their activities and are now in the decommissioning phase with a view to delicensing. Delicensing of the Siloette reactor was declared in 2007, that of the Mélusine reactor in 2011, of the Siloé reactor in January 2015 and of the LAMA reactor in August 2017.

The last BNIs on the site (BNI 36 and 79) are the Effluents and Solid Waste Treatment Station and the decay storage facility (STED). All the buildings have been dismantled, in accordance with their decommissioning decree.

With regard to radiological and chemical remediation of the STED soils, all the operations technically achievable at a reasonably acceptable cost have been carried out. In view of the presence of residual chemical and radiological contamination, the licensee submitted a new delicensing file in June 2021 which is currently being examined by ASN, which refused its first file in 2019. This delicensing is subject to the implementation of active institutional controls. An order instituting the institutional controls was issued by the Prefect of Isère *département* in December 2022.



# Bourgogne-Franche-Comté

## REGION

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

ASN conducted 58 inspections in small-scale nuclear activities in the Bourgogne-Franche-Comté region in 2022, comprising 20 inspections in the medical sector, 22 in the industrial, research and veterinary sectors, 8 concerning radon exposure, 1 to monitor approved organisations and laboratories, and 7 specific to the transport of radioactive substances.

One significant event in 2022 was rated level 2 on the INES scale following the accidental irradiation of an industrial radiography worker.

ASN also devoted particular attention to the Framatome manufacturing plants situated in the Bourgogne-Franche-Comté region. The actions conducted by ASN in this context are described in chapter 10. In Bourgogne-Franche-Comté in 2022 ASN carried out 3 inspections of Nuclear Pressure Equipment (NPE) manufacturers in their plants and 3 inspections of organisations accredited for the inspection of NPE.

### THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

#### ■ small-scale nuclear activities in the medical field:



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- 8 external-beam radiotherapy departments,
- 4 brachytherapy departments,
- 14 nuclear medicine departments, of which 3 practise internal targeted radiotherapy,
- 35 centres performing fluoroscopy-guided interventional procedures,
- 56 computed tomography scanners for diagnostic purposes,
- 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,
- about 400 industrial and research centres, including 30 companies with an industrial radiography activity,
- 1 industrial irradiator per radioactive source,
- 1 computed tomography scanner dedicated to research,
- 2 accelerators, one for the production of drugs for medical imaging and one for industrial irradiation;

#### ■ activities associated with the transport of radioactive substances;



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#### ■ ASN-approved laboratories and organisations:

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



# Bretagne REGION

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 NPP, currently undergoing decommissioning.

ASN carried out 29 inspections in 2022, comprising 3 at the Brennilis NPP undergoing decommissioning, 2 for the monitoring of accredited organisations and 24 in small-scale

nuclear activities (13 in the medical sector, 11 in the industrial, veterinary and research sectors).

One significant event was rated level 1 on the INES scale in 2022.

## The 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 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 public inquiry from 15 November 2021 to 3 January 2022. ASN notes the involvement of EDF in the public inquiry on the Brennilis decommissioning file and, more generally, its efforts regarding transparency and communication.

In 2022, ASN continued its examination of the complete Decommissioning Decree for the Brennilis NPP and started revising the resolutions regulating intakes and discharges.

During the year, EDF more specifically continued its preparatory work for complete decommissioning:

- inside the reactor containment, continuation of the asbestos removal operations in the accessible places and start of the civil engineering developments to enlarge the existing access points or to demolish bunkers;
- outside the reactor containment, completion of the site road and rail repair operations (removal of rails and railway sleepers, road repairs).

EDF has also signed contracts to initiate execution studies for certain complete decommissioning operations (such as that of the peripheral circuits) and to draw up specifications for upgrading the support functions that are absolutely necessary for complete decommissioning (handling cranes, ventilation in the reactor containment, etc.).

More generally, ASN notes that the schedule milestones for the first part of 2022 were met.

The July and August fires in the Monts d'Arrée had no impact on the work site. Nevertheless, the decommissioning operations in the reactor containment were interrupted on 19 July because the smoke was directed towards the NPP, and resumed on 20 July. The fire of 6 August did not stop any operations.

## THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

### ■ the Basic Nuclear Installation:

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

### ■ small-scale nuclear activities in the medical field:

- 10 external-beam radiotherapy departments,
- 5 brachytherapy departments,
- 9 nuclear medicine departments,
- 38 centres performing 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,
- 23 industrial radiography companies, including 4 performing gamma radiography,
- 25 research units,
- about 400 users of industrial equipment;



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### ■ activities associated with the transport of radioactive substances;



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### ■ ASN-approved laboratories and organisations:

- 10 organisations approved for measuring radon,
- 3 head-offices of laboratories approved for taking environmental radioactivity measurements.

ASN considers that the organisation for preparing the complete decommissioning of the NPP and for ensuring radiation protection is satisfactory. EDF must nevertheless be attentive to the rigour in writing the observations or comments in the periodic inspection procedures and finalise the updating of the document baseline for radiation protection and skills management. As of 2023, ASN will be particularly attentive to EDF's final treatment of the water infiltrations in the facilities.



# Centre-Val de Loire REGION

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.

In 2022, ASN conducted 152 inspections in the Centre-Val de Loire region, of which 118 were in the nuclear installations of the EDF sites of Belleville-sur-Loire, Chinon, Dampierre-en-Burly and Saint-Laurent-des-Eaux, 26 in small-scale nuclear activities, 6 in the transport of radioactive substance and 2 concerning approved organisations or laboratories.

ASN also carried out 51 days of labour inspections in the four NPPs. In the context of their oversight duties, the ASN inspectors issued two violation reports.

In 2022, 21 significant events rated level 1 on the INES scale were reported to ASN.

## 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 comprises two 1,300 MWe reactors commissioned in 1987 and 1988, which constitute 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, in the area of management of the installations, ASN considers that the operating rigour in the control room, although slightly down compared with 2021, remains satisfactory. One significant event rated level 1 on the INES scale was however reported following non-compliance with the RGEs during fuel handling operations, and improvements are expected in the configuration management of circuits and components (alignments, lockouts/tagouts, administrative lockouts). An inspection will be carried out on this theme in 2023. Management of the fire risk is considered stable; corrective actions were taken in 2022 to address the anomalies detected by EDF in fire sectorisation management, and these are being continued.

With regard to maintenance of the facilities, the performance of the Belleville-sur-Loire NPP has improved. The year 2022 saw two reactor outages (one periodic inspection and one refuelling outage), for which the overall management is considered satisfactory.

## 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 field:



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- 8 external-beam radiotherapy departments,
- 3 brachytherapy departments,
- 11 nuclear medicine departments,
- 32 departments performing fluoroscopy-guided interventional procedures;
- 38 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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- 10 industrial radiography companies,
- about 330 industrial, veterinary and research radiography devices;

### ■ activities associated with the transport of radioactive substances;



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### ■ ASN-approved laboratories and organisations:

- 2 organisations approved for radiation protection controls,
- 4 laboratories approved for taking environmental radioactivity measurements.

In the area of radiation protection, ASN considers the performance of the Belleville-sur-Loire NPP to be stable. It underlines the radiological cleanliness of the premises and good overall control of the various issues.

In the area of environmental protection, ASN considers that effluent management and the monitoring of discharges in normal operating conditions are satisfactory. It notes that action is being taken to correct the deviations in waste management identified in early 2022. The year 2022 was marked by a large increase in cases of exceeding legionella colonisation thresholds (more than ten). The compensatory measures implemented by EDF were not enough to rapidly restore a normal and controlled situation, pending the commissioning of a monochloramine treatment station, planned for the end of 2024. The examination and consultations concerning the modification of the environmental resolutions regulating the site discharges continued in 2022.

As far as labour inspection was concerned, ASN focused its attention on monitoring the accidents and “near-accidents” in the Centre-Val de Loire region. With no serious accidents having occurred at the Belleville-sur-Loire NPP in 2022, cross-functional subjects were examined (right to strike, radiation protection skills centre). As in 2021, some of these inspections were conducted jointly by the labour inspectorate and safety inspection.

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## 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 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 the nuclear safety and radiation protection performance of the Dampierre-en-Burly NPP to be far below the national average. The environmental performance on the whole is in line with ASN’s general assessment of the EDF plants.

With regard to nuclear safety, normal operational management performance deteriorated markedly in 2022, with the number of significant events reported during the year being among the highest for the EDF NPPs (about ten of the events were

rated level 1 on the INES scale). The identified causes are organisational deficiencies relating to shortcomings in documents, insufficient communication between operational management teams, and inadequate command of the RGEs (particularly when material difficulties arise). Management of the periodic tests was also found to be far below average in 2022. In view of these factors, the unit director gave ASN a presentation of the plan of “operational management” rigour put in place as of May 2022, for which ASN will conduct various inspections in 2023 to verify its application and judge its effectiveness. The site’s management of the fire risk is also sub-standard and must remain a priority target for action in 2023.

As far as maintenance of the facilities is concerned, the site’s performance is considered below the national average, in an industrial context where the second reactor on the site is undergoing its fourth ten-yearly outage. The year 2022 was marked by several situations of out-of-service equipment necessitating reactor shutdowns and reflecting a problem of reliability of these equipment items. ASN also expects the improvements in the quality of the site’s operational documents used to conduct maintenance activities and in the methods of requalification following work interventions.

As far as radiation protection is concerned, the performance of the Dampierre-en-Burly NPP improved slightly in 2022 but remains insufficient. The radiological cleanliness of the facilities and the management of radiological work regimes must notably be improved to bring them in line with the general assessment of the EDF plants. ASN nevertheless underlines the effectiveness of the site’s action plan implemented further to numerous significant “transport” events that occurred in 2021 due to problems of surface contamination of trailers and wagons.

With regard to environmental protection, the performance of the Dampierre-en-Burly NPP improved in 2022, particularly in its management of the microbiological risk. Although no exceeding of the gaseous and liquid effluents discharge limits was observed in 2022, the management of hazardous substance containment must nevertheless be improved. Moreover, the environmental resolutions regulating the site’s discharges were modified in 2022 to allow the implementation of a new treatment against the proliferation of pathogenic organisms on reactors 2 and 4.

Lastly, with regard to labour inspection, following the actions taken in 2021 and 2022, management of the electrical risks shall remain a priority in 2023. Inspections were moreover carried out on diverse themes such as management of the radiation protection skills centres and the activities and work conducted during a reactor outage.



## 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 900 MWe reactors; the first two constituting BNI 107 were commissioned in 1982-1983, while the second two constituting BNI 132 were commissioned in 1986-1987. To the north, the three old graphite-moderated GCRs designated Chinon A1, A2 and A3, are currently being decommissioned. The site also accommodates the AMI, currently being decommissioned, whose former activities of expert assessment of activated or contaminated materials have been entirely transferred to a new laboratory called “the Lidec”, and to MIR.

### Chinon nuclear power plant

#### Reactors B1, B2, B3 and B4 in operation

ASN considers that the performance of the Chinon NPP is in line with the general assessment of EDF in the areas of safety, radiation protection and the environment. Progress has been noted in 2022, particularly in the area of safety. The results in the area of radiation protection, however, must be consolidated.

With regard to safety, ASN observes that the performance in normal operational management is improving. Operational management in “incident” and “accident” situations is satisfactory, even if improvements are expected in the traceability of staff training and in the emergency situation documentation. Furthermore, particular attention is to be paid to the inspections of the main primary system and the implementation of the post-Fukushima measures.

As far as maintenance of the installations is concerned, the site's performance is stable and satisfactory. Improvements to enhance the reliability of the maintenance operation supporting documents are nevertheless expected. 2022 was marked by an outage associated with the problem of stress corrosion of reactor 3, on which the various inspections have revealed no major anomalies.

ASN considers that the radiation protection performance of the Chinon NPP remains relatively satisfactory. The radiological cleanliness of the inspected work sites did not raise any particular remarks. Progress is however expected in the cordoning off of radiography work areas, and in the effective application of the prevention measures chosen with regard to radiation protection and for the use of the radiographic work regimes.

The environmental performance of the Chinon NPP is improving. The maximum discharge values set for gaseous and liquid effluents are observed. However, the monitoring of contractors on short-term work sites must be improved in order to comply with the environmental protection requirements. In addition, the management of liquid containment can be further improved.

With regard to labour inspection, 2022 was marked by an accident which led to two inquiries, one of which necessitated numerous investigations conducted in collaboration with the gendarmerie of Chinon. In addition to this, on the Chinon site – as with all the Centre-Val de Loire region NPPs – ASN maintained its joint inspections between the labour inspectorate and safety inspection in order to benefit from the existing synergies. This was the case in particular with an inspection of the radiation protection skills centre, which evidenced a few minor deviations without calling into question the organisation adopted by the NPP.

#### 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 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” GCR reactors. They were shut down in 1973, 1985 and 1990 respectively.

Reactors A1 and A2 were partially decommissioned and transformed into storage facilities for 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 is decommissioning “in air” and the Chinon A2 reactor pressure vessel would be decommissioned first (see chapter 13). In this context, ASN has analysed the periodic safety review concluding reports submitted by EDF for the six GCR reactors, supplemented further to the requests 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). It will verify during the examination of the decommissioning files for these reactors, submitted by EDF at the end of 2022, that the decommissioning operations are carried out under suitable conditions of safety and radiation protection, within controlled time frames.



For the Chinon A2 reactor, EDF has 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. EDF also continued the decommissioning of the Chinon A3 heat exchangers. After completing the decommissioning work in the heat exchangers “South” building and transferring all the cylinders to the Industrial centre for grouping, storage and disposal (Cires), the decommissioning work on the “North” heat exchangers building has started, with the transfer of the first cylinders in June 2022.

ASN considers that the level of safety of the Chinon nuclear installations undergoing decommissioning (Chinon A1, A2 and A3) is satisfactory. The inspections conducted in 2022 revealed in particular the use of high-performance computing aids for the management of the work sites and the documents. In this respect, one must nevertheless note the reporting of two significant events associated with a lack of equipment and document modification tracking which occurred in 2017 and 1993. The procedures currently implemented contain provisions to avoid the recurrence of such deviations. Improvements are expected in the tracking of the periodic inspections of the NPP equipment items which are under the responsibility of the Chinon dismantling organisation.

## NUCLEAR “FUEL CYCLE” FACILITIES

### Inter-regional fresh fuel warehouse

Commissioned in 1978, the Chinon 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 has been operating nominally since the reception and storage of fresh fuel assemblies resumed in 2020, in a configuration in which the facility was equipped with a new handling crane in 2019 and under an updated baseline authorised by ASN. During its inspection in 2022, ASN observed a generally satisfactory level of safety, and more specifically good upkeep of the premises and the availability of the fuel assembly reception and shipping files.

## RESEARCH FACILITIES UNDERGOING DECOMMISSIONING

### Irradiated materials facility

The AMI, which was declared and commissioned in 1964, is situated on the Chinon nuclear site and operated by EDF. This facility (BNI 94) has stopped operating and is being decommissioned. It was primarily intended for performing examinations and expert assessments on activated or contaminated materials from the PWR reactors.

The expert assessment activities were completely transferred in 2015 to a new facility on the site, the Integrated Laboratory (Lidec) of the Construction and Operation Expert Appraisal and Inspection Centre (Ceidre).

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 and necessitating inerting operations<sup>1</sup> to meet the disposal criteria of the French radioactive waste management agency (Andra) has been packaged and re-characterised in 2021. The characterisation results were not as expected, making it necessary to apply to Andra for a waiver to allow acceptance of the waste. The waste removal work was therefore stopped pending the outcome of this procedure. The work is expected to resume by the end of 2023. Lastly, in early February 2021, EDF filed a decommissioning authorisation application for the highly active liquid effluent circuits, which is currently being examined. Given that EDF reported technical and contractual difficulties as of April 2022, these operations – which were initially planned as of 2023 – will have to be rescheduled.

On the basis of the checks made during these inspections, ASN considers that the safety management applied at the AMI is satisfactory, particularly with regard to the application of the new RGEs approved further to the decommissioning transition. The outside contractor monitoring methods implemented are satisfactory on the whole, and vigilance is expected in the continuation of the operations initiated to deal with the legacy chemical products.

1. Inerting is a procedure that consists in replacing a reactive atmosphere (oxidising, inflammable, explosive) by an inert gas such as nitrogen, CO<sub>2</sub> or argon.

## 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 comprises two operating reactors, 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 protection performance of the Saint Laurent-des-Eaux NPP stands out positively with respect to its general assessment of EDF plant performance, and that safety and radiation protection performance is in line with the general assessment on these themes.

ASN considers that the site's nuclear safety performance improved in 2022. The changes in the safety management plan have restored a satisfactory level of performance. The in-depth inspection conducted by ASN in June 2022 confirmed this improvement. These factors must nevertheless be considered alongside the fact that only one refuelling outage was carried out in 2022 instead of the usual two. There remains room for progress in supervision rigour (monitoring in the control room, operating range excursion), configuring of the systems and application of reliability-enhancement practices. This recovery will have to be confirmed in 2023 with the performance of two refuelling outages, including the fourth ten-yearly outage of reactor 2.

Maintenance at the Saint-Laurent-des-Eaux NPP improved in 2022 compared with 2021, and reached a level considered to be relatively satisfactory. Few significant events are caused by maintenance deficiencies. Here again these elements must be considered alongside the fact that there was only one refuelling outage in 2022. It is to be noted that a significant event was again reported in 2022 further to errors during inspections of the anti-chatter devices which limit the movements of the primary cooling system in the event of high stresses, such an earthquake situation, which shows that the subject is still not fully mastered.

Generally speaking, the management of radiation protection at the Saint-Laurent-des-Eaux NPP meets ASN expectations. The site's performance is considered stable with respect to 2021. The setting up of the radiation protection skills centre in 2022 is found to be satisfactory on the whole.

The site's organisation to meet the regulatory environmental requirements is considered highly effective, particularly in view of the quantities of effluents discharged. The use of retention areas to store equipment must be monitored and the control of the sheets framing the discharge conditions must be consolidated.

As far as labour inspection was concerned, ASN focused its attention on monitoring the accidents and "near-accidents" in the Centre-Val de Loire region. In this context, and with no serious accidents necessitating specific investigations on the Saint-Laurent-des-Eaux site, only cross-functional subjects underwent checks (post Fukushima, radiation protection skills centre, reactive inspection). As in 2021, these checks were conducted jointly by the labour inspectorate and safety inspection. In 2023, following on from the actions carried out in 2021 and 2022, the electrical risks shall remain a priority for the ASN labour inspectorate.

#### Reactors A1 and A2 undergoing decommissioning

The former Saint-Laurent-des-Eaux NPP constitutes a BNI comprising two "integrated" GCR reactors, reactors 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 GCR reactors, ASN indicated in December 2021 that it has no objection to the continued operation of BNI 46 (Saint-Laurent reactors A1 and A2). It 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 are carried out under suitable conditions of safety and radiation protection, within controlled time frames.

In 2022, EDF continued its decommissioning work sites, and more specifically the decommissioning work outside the reactor vessel (Saint-Laurent A2) and the decontamination of the pool (Saint-Laurent A1). ASN considers that the level of safety of the Saint-Laurent-des-Eaux A reactors is satisfactory. ASN's inspections found that the overall upkeep of the premises and worksites was good. In addition, the organisation put in place to meet the commitments made further to the inspections and significant events is satisfactory. The same goes for the monitoring of outside contractors and the setting up of the radiation protection skills centres. Even though the in-service monitoring of the pressure equipment is performed correctly, improvements are expected, notably to ensure that the particularities of certain equipment items are properly taken into account.

## Saint-Laurent-des-Eaux silos

The facility, authorised by the Decree of 14 June 1971, consists of two silos for storing irradiated graphite sleeves originating from the operation of Saint-Laurent-des-Eaux A GCRs. Static containment of this waste is ensured by the concrete bunker structures of the silos, which are sealed by a steel lining. 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 current assumptions, silo emptying should begin in the early 2030's.



# Corse (Corsica)

## COLLECTIVITY

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

In 2022, ASN carried out 2 inspections in Corsica, one in the medical field and

one of the management of the radon exposure risk.

### THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

#### ■ **small-scale nuclear activities in the medical field:**



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- 2 external-beam radiotherapy departments,
- 2 nuclear medicine departments,
- 8 centres performing fluoroscopy-guided interventional procedures,
- 8 computed tomography scanners,
- about 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 laboratories and organisations:**

- 3 organisations approved for measuring radon.



# Overseas

## DÉPARTEMENTS AND REGIONS

The regulation of radiation protection and the transport of radioactive substances in the 5 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.

In 2022, 24 inspections were carried out in the small-scale nuclear activities sector in the French Overseas *départements*, regions

and collectivities. Four on-site inspection campaigns were carried out by ASN.

### THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

#### ■ small-scale nuclear activities in the medical field:



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- 4 external-beam radiotherapy departments,
- 1 brachytherapy department,
- 3 nuclear medicine departments,
- 23 centres performing fluoroscopy-guided interventional procedures,
- about 30 centres holding at least 1 computed tomography scanner,
- about 100 medical radiology practices,
- about 1,000 dental radiology devices;

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



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- more than 70 users of veterinary radiology devices,
- 3 industrial radiography companies using gamma radiography devices,
- 1 cyclotron;

#### ■ activities associated with the transport of radioactive substances.



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# Grand Est REGION

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.

In 2022, ASN conducted 164 inspections in the Grand Est region, of which 75 were in the NPPs in service, 19 in radioactive waste disposal facilities and on the sites of the Fessenheim and Chooz A NPPs currently being decommissioned, 67 in small-scale nuclear activities, 2 in the transport of radioactive substances and 1 concerning approved organisations or approved laboratories.

ASN also carried out 17 days of labour inspections in the NPPs.

During 2022, 7 significant events reported by nuclear installation licensees in the Grand Est region were rated level 1 on the INES scale.

In small-scale nuclear activities, 3 significant events were rated level 1 on the INES scale (1 in the industrial sector and 2 in the medical sector) and 1 significant event concerning a patient was rated level 1 on the ASN-SFRO scale.

## 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 PWRs each with a power rating of 1,300 MWe, commissioned between 1986 and 1991. Reactors 1, 2, 3 and 4 constitute BNIs 124, 125, 126 and 137 respectively.

ASN considers that the performance of the Cattenom NPP with regard to nuclear safety and radiation protection is in line with its general assessment of the EDF plants. The environmental protection performance of the Cattenom NPP is considered to be below the average for the fleet. 2022 was a special year for the site due to the long outages of three of the four reactors as a result of the stress corrosion phenomenon affecting the safety injection systems.

With regard to the operation and operational management of the reactors, ASN considers that the performance levels confirm the improvement noted since 2020. The inspections have revealed proficiency of the operational management teams and progress with respect to the findings of the in-depth inspection of 2021. A number of issues nevertheless remain, particularly shortcomings in monitoring by the operational management teams observed in several significant events.

With regard to maintenance, the year 2022 was marked by prolonged reactor outages – two refuelling and maintenance outages and one specific unscheduled outage – due to the investigations into the problem of stress corrosion cracking on the safety injection systems observed on some of the EDF NPPs. Due to the long duration of the outages without operating the reactors, the quality of the maintenance activities could not be assessed in detail. ASN nevertheless notes positively the monitoring of the new operations linked to the stress corrosion cracking issue (ultrasonic inspections, welds).

## 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 Soullaines-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 field:



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

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



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- 277 industrial and veterinary activities coming under the licensing system,
- 24 companies exercising an industrial radiography activity,
- 47 research laboratories situated primarily in the universities of the region;

### ■ activities associated with the transport of radioactive substances.



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As in the preceding years, ASN notes that the significant events management process is well mastered on the whole and effectively mobilises the site players up to senior management level.

With regard to fire risk prevention, ASN observes that the site has improved in several areas, such as the management of fire loads and sectorisation. Moreover, weekly patrol rounds have been put in place and are proving effective. Nevertheless, occasional findings reveal that these improvements must be consolidated and further efforts must be made in this area.

The site's emergency response organisation was deployed during a national exercise, as well as in two real situations (discharges causing iridescent sheens on the Moselle River and detection of a discharge of ammonia in the atmosphere). The organisation and resource deployment associated with these events ran smoothly. Nevertheless, the licensee's lack of knowledge of the monochloramine production facility created difficulties in the management of the event involving the ammonia discharge detection.

With regard to environmental protection, the site remains marked by weaknesses, as some events reveal room for improvement in the control of specific facilities and activities relating to discharges and monitoring of the environment. Controlling the risk of proliferation of microorganisms in the cooling towers still necessitates reinforced biocide treatments which have consequences on the aqueous discharges.

Lastly, the site saw an improvement in several radiation protection themes in 2022: management of sources, access to red (prohibited) controlled areas, control of industrial radiography work, number of significant events. The radiation protection skills centres have been put in place and correctly equipped, even if work on facilitation and uptake of the initiative still has to be developed. Deficiencies nevertheless persist, particularly in the control of accesses to and marking out of the limited stay (orange) areas and the dispersion of contamination. Lastly, with regard to occupational safety, the conformity of the electrical installations needs to be improved.

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## 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 (BNI 139 and 144), commissioned in 2001.

### Reactors B1 and B2 in operation

With regard to nuclear safety, given that the reactors did not function in 2022 due to the repair work on the pipes with stress corrosion cracks, ASN considers that the performance of the Chooz B NPP cannot be compared with that of the other NPPs.

ASN considers moreover that the radiation protection and environmental performance of the Chooz B NPP is in line with ASN's general assessment of the EDF plants.

As far as nuclear safety is concerned, even if the reduced level of activity resulting from the reactor outages does not enable a trend to be established with respect to the 2021 assessment, ASN considers that standard of safety has remained satisfactory. It nevertheless notes that the operational documentation and the organisation of the department responsible for operational management of the reactors can be further improved to limit sources of error. Particular attention must also be focused on the equipment lockout/tagout process, which has been the cause of several significant events.

With regard to maintenance, ASN underlines the satisfactory management of the exceptional volume of activity created by the build-up of inspections performed on account of the maintenance outages on the two reactors and the activities induced by the stress corrosion problem.

In the field of radiation protection, the annual result concerning compliance with the collective dosimetry targets is satisfactory. Shortcomings in the control of radiological cleanliness on certain work sites, however, caused numerous contaminations, particularly of garments, at the beginning of the scheduled maintenance operations on reactor 2. ASN noted that the licensee took corrective action immediately, and urges it to remain particularly vigilant on this subject. The licensee must also encourage rigour in workers' individual behaviours and be attentive to the management of industrial radiography work, which showed some weaknesses.

ASN considers that the site's environmental protection organisation is on the whole satisfactory, as it was in the preceding year.

The labour inspections revealed no major findings. The subjects addressed are taken seriously by the employer, with the intention to make them progress.

### Reactor A undergoing decommissioning

In 2022, the works to treat the waste resulting from the decommissioning of equipment inside the pressure vessel were started. The emptying of the reactor building pool in order to decommission the reactor vessel could not be undertaken due to the delay in installing an evaporator intended to treat the pool water prior to discharge. Commissioning of this evaporator is planned for early 2023.

The decommissioning work on all the equipment still present in the bunkers of the "auxiliary" vault continued. This work is carried out mainly by remote operation using a robotic arm.

The decommissioning work on the effluent treatment station equipment items that are not necessary for treating the water from the rock or floor drains also continued.

With regard to radiation protection, the prevention of worker contamination with alpha particles is the main challenge during the facility dismantling phases. ASN considers that the licensee has made progress in this area, with the setting up of a medical monitoring system tailored to ensure faster detection of cases of contamination, which remained at a low level.

The labour inspections on the themes of “worksite coordination” and “lockout/tagout and verification of electrical systems” revealed no major findings. Progress was observed in worksite coordination. The results of these inspections are satisfactory and the interchanges with the site are constructive.

More generally, ASN considers that the licensee is progressing in the various areas inspected and notes a strengthening of the teams which promotes a dynamic of progress.

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## Fessenheim nuclear power plant

The Fessenheim NPP comprises two PWRs, each with a unit power of 900 MWe. It is situated 1.5 km from the German border and about 30 km from Switzerland. The two reactors, which were commissioned in 1977 and definitively shut down in 2020, are currently undergoing preparation for decommissioning.

ASN considers that the site has maintained a robust level of conscientiousness and vigour in the monitoring of operation of the facilities, despite a significantly different level of operating and maintenance activities. Nevertheless, a better adaptation of the site's past practices to the changing context would give a better quality in both operation and performance of the activities.

The year 2022 was essentially taken up by the continuation of the decommissioning preparation activities, such as the preparation, installation and execution of the decontamination work on reactor 1, the installation of new resin storage capacities, the removal of large quantities of waste and continuation of boron

treatment and removal. The decontamination of the primary system turned out to be much more complicated than EDF had expected, resulting in delays in execution.

Major milestones have been reached, such as the finalisation of fuel removal. Several major work sites will be continuing in 2023, notably with the decontamination of the primary system of the second reactor and the creation, in the turbine hall, of the facility for managing the waste resulting from the decommissioning.

With regard to radiation protection, 2022 saw a drop in the number of reported events compared with the preceding years and confirmation of the improvement in the prevention of contamination of the site roads. Nevertheless, some shortcomings persist in the radiation protection culture of certain workers (excess dose alarms, radiation protection marking out) and the management of sources and the associated removal actions were not considered satisfactory.

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## Nogent-sur-Seine nuclear power plant

Operated by EDF and situated in the municipality of Nogent-sur-Seine in the Aube *département*, 70 km northwest 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 in the areas of safety, radiation protection and the environment are in line with ASN's general assessment of the EDF NPPs.

In the field of nuclear safety, ASN considers the results to be satisfactory on the whole, except as concerns system configuring and equipment lockout/tagouts, which were the cause of a large portion of the significant events involving operational management of the reactors. Progress is expected in this area. The licensee must also continue its efforts to maintain adequate staffing of the independent safety organisation.

The maintenance operations during the reactor 1 outage went satisfactorily on the whole.

As far as occupational radiation protection is concerned, ASN observes better management of worksite radiological cleanliness and a reduction in the number of internal exposures of workers. However, deficiencies in the radiation protection culture and rigour of the workers were again noted on several occasions, particularly concerning the conditions of access to controlled areas. The licensee must remain particularly vigilant on this subject, as it must with the management of industrial radiography work, which has shown some weaknesses.

With regard to protection of the environment, ASN considers that the licensee's organisation is satisfactory. Nevertheless, the condition of some installations, particularly regarding the injection of sulphuric acid into the secondary system, requires priority action on the part of the licensee.

The labour inspections revealed nonconformities in the work equipment, particularly with respect to prevention of the risk of falling or of electrocution.

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## 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, benefiting from the experience gained with the latter. This facility, located in Soulaines-Dhuys, has a disposal capacity of one million cubic metres (m<sup>3</sup>) of low and intermediate level, short lived waste (LL/ILW-SL). It constitutes BNI 149. The operations authorised in the facility include the packaging of waste, either by injecting mortar into metal containers of 5 or 10 m<sup>3</sup> volume, or by compacting 200-litre drums.

At the end of 2022, the volume of waste in the facility had reached about 350,000 m<sup>3</sup>, or 37% of the authorised capacity.

According to the estimates made by Andra in 2016 in the concluding report on the CSA periodic safety review, the CSA 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 2022 showed an appropriate organisation for radiation protection and emergency management, and compliance with the deadlines for the commitments made during the second periodic safety review of the facility.

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## Deep geological disposal centre project

ASN considers that the scientific experiments and work conducted by Andra in the underground laboratory at Bure continued in 2022 with a good standard of quality, comparable with that of the preceding years.

Furthermore, on the basis of the work carried out since ASN examined the *Cigéo* project safety options dossier in 2017, Andra filed the Creation Authorisation Application (DAC) for this deep geological disposal centre (see chapter 14 of this report) with the Minister responsible for nuclear safety on 16 January 2023.



# Hauts-de-France

## REGION

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

In 2022, ASN's carried out 124 inspections in the Hauts-de-France region, of which 33 were in the Gravelines NPP, 82 in small-scale nuclear activities and 9 in the transport of radioactive substances.

ASN also carried out 14 days of labour inspection in the Gravelines NPP.

In the course of 2022, 12 significant events rated level 1 on the INES scale were reported by the Gravelines NPP, including 3 concerning radiation protection.

In small-scale nuclear activities, 3 events were rated level 1 on the INES scale. In radiotherapy, 2 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 PWRs (900 MWe) representing a total power of 5,400 MWe. Reactors 1 and 2 constitute 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 radiation protection is below ASN's general assessment of EDF plant performance. The environmental protection performance of the NPP is in line with ASN's general assessment of the EDF plants.

Nuclear safety performance did not improve in 2022, particularly with regard to the rigour of work interventions. The plan of rigour put in place by the licensee has started to bear fruit, particularly in the operational management of the facilities, but some inappropriate practices or behaviours subsist in other activities. The site must therefore continue its efforts to federate all the protagonists. At the end of the first half of 2022, ASN carried out an interim assessment of the measures put in place by the licensee through a tightened inspection on the theme of safety management, supervised by the ASN Chief Inspector, which did not call into question the relevance of the plan of rigour.

The year 2022 was marked by a larger number of significant events reported to ASN than in the preceding years and higher than the average for the EDF reactors, even if the number of events rated level 1 remained stable. The application of new safety baseline requirements linked to the fourth ten-yearly outages and the large volume of modifications deployed (nearly 500) explains some of them. This upward trend does not necessarily indicate a deterioration in the operating conditions as it may also reflect better performance in the detection of deviations or greater receptiveness on the part of the site's internal independent safety organisation.

As far as maintenance is concerned, 2022 was again marked by significant prolongations in the maintenance and refuelling outage durations, despite an alleviation of the maintenance programme applied in late 2022 to limit the downtime of the

### THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

#### ■ the Basic Nuclear Installation:

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

#### ■ small-scale nuclear activities in the medical field:

- 19 external-beam radiotherapy departments,
- 3 brachytherapy departments,
- 30 nuclear medicine departments,
- 92 centres performing fluoroscopy-guided interventional procedures,
- 129 computed tomography scanners,
- some 4,600 medical and dental radiology devices;



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

- about 600 industrial and research establishments, including 29 companies exercising an industrial radiography activity, 6 particle accelerators, including 1 for inspecting freight trains and 2 cyclotrons, 38 laboratories situated mainly in the universities of the region and 11 companies using gamma ray densitometers,
- 340 veterinary surgeries or clinics practising diagnostic radiology;



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#### ■ activities associated with the transport of radioactive substances;



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#### ■ ASN-approved laboratories and organisations:

- 3 agencies approved for radiation protection controls.

last reactor. Three reactors were in outage at the same time, from early July to mid-September, putting an unusual amount of pressure on the services in mid-summer. This increase in activity came on top of an already very full industrial programme with, in particular, the fourth ten-yearly outage of reactor 3, the end of the replacement of the reactor 6 steam generators and of the work on the peripheral protection against external flooding, implemented further to the lessons learned from the Fukushima Daiichi NPP accident in Japan.

Concerning environmental protection, ASN considers that the Gravelines NPP has improved its maintenance response to the challenges presented by the equipment using the insulating greenhouse gas (SF<sub>6</sub>) and that it must continue its efforts on the facilities for treating the radioactive effluents produced by reactor operation. A tightened inspection will be carried out in 2023.

In terms of radiation protection, on the basis of a tightened inspection conducted in 2022 and year-round monitoring, ASN considers that the situation remains sub-standard and that the site is still unable to restore it to a satisfactory level, despite the preventive measures put in place in 2021. The efforts must be increased in order to rapidly and sustainably restore satisfactory performance in occupational radiation protection in 2023.

The labour inspection actions conducted in 2022 were split between the inspections on the maintenance work sites, particularly during reactor outages, and specific inspections focusing on subjects such as lifting, electrical risks and work times. Regular meetings were organised with senior management, members of the health, safety and working conditions committee, and personnel representatives. The number of workplace accidents remains high in 2022 despite the measures taken by the licensee. Non-compliance with certain vital rules, induced by individual behaviours or work organisations, and shortcomings in the control of equipment lockout/tagouts were observed on several occasions. The labour inspectorate will be particularly attentive to these aspects in its next inspections.



On 5 July 2022, the ASN Chairman visited the Gravelines NPP to meet employees and contractors and get their feedback on the effects of the site's "plan of rigour" put in place to improve safety performance. He had met the members of the Gravelines Local Information Committee (CLI) the day before.



# Île-de-France REGION

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

ASN carried out 313 inspections in the Île-de-France region in 2022, of which 107 were in the field of nuclear safety, 149 in small-scale nuclear activities, 27 in the transport of radioactive substances and 30 concerned approved organisations or laboratories.

Ten significant events were rated 1 on the INES scale in the small-scale nuclear activities, 3 in the BNIs and 6 in the transport of radioactive substances.

## CEA SACLAY SITE

Since 2017, the 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 has an authorised power of 70 Megawatts thermal (MWth). It 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.

## 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 Artificial Radionuclide Production Plant (UPRA) 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,
- 41 *in-vivo* nuclear medicine departments and 13 *in-vitro* nuclear medicine departments (medical biology),
- 149 centres performing fluoroscopy-guided interventional procedures,
- more than 200 centres possessing at least 1 computed tomography scanner,
- about 850 medical radiology practices,
- about 8,000 dental radiology devices;

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



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- some 650 users of veterinary radiology devices,
- 8 industrial radiography companies using gamma radiography devices,
- some 100 licenses concerning research activities involving unsealed radioactive sources;

### ■ activities associated with the transport of radioactive substances;



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### ■ ASN-approved laboratories and organisations:

- 4 organisations approved for radiation protection controls.



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 its examination, ASN is waiting for information on the new decommissioning scenario, particularly regarding the management of irradiating waste.

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 fuel stored in the facility was removed in the second half of 2021.

The inspections revealed a robust organisation for conducting the safety review and supervising the associated action plan. Improvements are nevertheless expected in the examination of compliance with regulations and the technical baseline requirements of the facility. The subject of static and dynamic containment is properly understood. The state of conservation of a ventilation duct however, requires particular vigilance.

With regard to the prevention of pollution and detrimental effects, the updating of the hazardous substances inventory must be improved and further information on the facility's water consumption is awaited. The tracking of commitments made to ASN and of deviations is satisfactory.

Two significant events reported in 2022 are linked to problems of equipment aging, an important issue for the facility given the forecast time frames of the decommissioning operations.

The licensee's control of the decommissioning preparation operations, the management of waste and the monitoring of aging of the facilities shall be among the themes to which ASN will be attentive in 2023.

## 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 the decommissioning preparation 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 risks the facility represents. The continuation of the decommissioning preparation operations and the facility decommissioning scenario are currently being discussed following the CEA's re-prioritising of the decommissioning operations and its consequences on the updating of the decommissioning strategy of BNI 101.

Based on the facility inspections and monitoring carried out in 2022, ASN considers that the level of safety of the Orphée reactor is on the whole satisfactory. However, a number of points requiring special attention, such as identification of the safety important activities and their technical monitoring, and the formalising and tracking of the qualification files of safety important components, are necessary. The significant events show that vigilance is required in the monitoring of the periodic inspections and tests and of the effectiveness of the high efficiency particulate air filters. Improvements are expected regarding compliance with the storage rules for certain potentially activated materials or VLL packages.

Following reactor shutdown, the decommissioning preparation phase is subject to particular scrutiny by ASN, notably the adaptation of the organisation and the personnel skills to manage new activities while maintaining the level of safety of the facility and keeping the activity schedules on track.

## 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. ASN is therefore still waiting for the CEA to submit a robust action plan.

As of the end of 2022, BNI 72 will no longer accept 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.

Two significant events rated level 1 on the INES scale were reported in 2022. They concerned the presence of legacy fuel samples not authorised by the baseline requirements, and the absence or incorrect positioning of emergency brakes on a travelling crane and two lifting units. These reports come from the discovery of nonconformities dating back several years, and the facility has started corrective actions to find compatible outlets for the non-compliant samples and upgrading of the handling equipment according to the conclusions of the conformity check of the equipment in order to restore an acceptable situation. ASN will be particularly attentive to the monitoring and implementation of these actions.

The inspections conducted on the LECI in 2022 concluded that the facility’s safety management is satisfactory but improvements are expected in the management of VLL waste and monitoring of the technical controls of activities important for the protection of protected interests (Protection Important Activities – PIA). Moreover, ASN observes an increase in the times taken to reply to follow-up letters and to send in significant event reports.

## 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 *Pagure*, 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 (snow and wind in particular) hazards, and the monitoring of ageing of the Poséidon storage pool.

ASN considers that the facility is operated satisfactorily and with the aim of continuously improving its safety. ASN has effectively observed 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). The periodic inspections and tests are correctly tracked despite an accelerator failure in 2022 which delayed the periodic inspection but had no consequences on the safety of the

facility. With regard to radioactive source management, the licensee has given ASN its undertaking to look into ways of improving the control of sources aged more than ten years for which a service life extension has been requested. Lastly, the work conducted by the licensee to determine the cause of the increase in tritium activity observed in the Poséidon pool water in 2021 enabled it to identify the cause of the phenomenon and to take appropriate corrective action.

## 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 (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”<sup>(1)</sup> 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 13).

The commitments made further to the preceding safety review in 2009 aimed to guarantee an acceptable level of safety of the facility for the next ten years. They concerned in particular the removal of the majority of the dispersible inventory from the facility and stopping the reception of new waste from the Saclay centre in order to concentrate the facility’s resources on the retrieval and packaging of the legacy waste. These commitments have not been met.

In 2017, in view of the delays in the removal from storage operations, the CEA requested that the deadlines prescribed in ASN resolution 2010-DC-0194 of 22 July 2010 for removal of the irradiated fuel from storage and removal of the waste stored in the “40 wells” area be pushed back by several years. In 2020, the CEA asked for a further postponement to 31 December 2030 of the deadline for removal of the waste stored in the 40 wells area, which was approved by ASN Chairman’s resolution CODEP-CLG-2022-005822 of 2 February 2022.

In order to be able to continue using the BNI for managing the radioactive waste from the Saclay BNIs, the CEA in 2017 asked for a change in the date of final shutdown of the facility, postponing it until the first of the following two terms was reached: either the effective date of the decommissioning decree or the date of 31 December 2022. The CEA also asked for arrangements for the acceptance of certain types of waste until 2025.

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.

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. Decree 2022-1107 of 2 August 2022 requiring the CEA to proceed with the decommissioning of BNI 72 was published in the *Official Journal*. It will enter into application on the date ASN approves the General Operating Rules (RGEs) or, at the latest, one year after the publishing of this Decree.

ASN considers that the safety of the facility is satisfactory, while at the same time noting numerous delays in the operations to remove the fuel or waste from storage. ASN nevertheless notes favourably the removal of several fuel cans present in the pool of a building, which contributes to the gradual reduction of its dispersible inventory.

In 2022, ASN examined the progress of the operations concerning removal of fuel from the pool and a fuel rod transport package. Delays are observed due to technical contingencies and problems with the supply of fuel rod transport packages. However, the BNI is implementing corrective actions to overcome the difficulties the organisation has encountered and the actions implemented by the CEA to remove the irradiated fuels from block 108 and from the pool. Despite the observed delays, ASN underlines the CEA's ability to adapt to the various contingencies encountered. Nevertheless, the action plans to ensure compliance with the stated schedules must be more rigorous. ASN underlines that projects that contribute to reducing the dispersible inventory within facilities constitute priorities for safety.

Alongside this, ASN's inspections find the facility to be in good overall condition. ASN nevertheless expects improvements in the rescheduling of corrective actions initiated as a result of surveillance measures.

## Liquid effluents management zone

The liquid effluents management zone 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 Andra's above-ground waste disposal centres.

The evaporation facility used to treat the radioactive effluents has been out of service since 2019 due to technical anomalies on an equipment item. Its return to service requires the preparation of a specific safety assessment file which ASN is waiting to receive. 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).

The process of encapsulation in cement, used to treat the concentrates in the facility, was nevertheless stopped temporarily by the CEA in June 2021. The CEA made this decision further to the production of two active packages that did not comply with the 12H packaging approval obtained from Andra in 2018. ASN authorised entry into service of the process in 2020. Despite the work remaining to be done, the CEA plans resuming encapsulation in cement in the coming months.

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, which raises questions about the possibility of resuming management of liquid effluents in the BNI in the coming years, receives particular attention from ASN in its discussions with the CEA on its effluent management strategy. ASN expects the CEA to make a significant investment to render the facility operational so that, in priority, the legacy effluents stored there can be retrieved and packaged within appropriate time frames.

Several other issues of major importance for the BNI are currently being discussed or examined. These include in particular the emptying of the tanks containing organic effluents in pit 99, an operation authorised for one of the tanks in 2022 and which remains a major clean-out challenge; determining the clean-out strategy for the MA 500 tanks; and finalising the emptying of tank MA 507.

The inspections carried out in 2022 revealed a satisfactory organisational set-up and tools to keep track of the commitments made to ASN. When unannounced inspections were carried out, the inspectors found the facility and the premises to be in good overall condition and the teams to be duly responsive. The theme of static and dynamic containment is suitably monitored by the licensee. Lastly, the operations to characterise the "legacy" organic effluents stored in the facility have started and must now continue.

On the other hand, improvements are expected in waste management, particularly with regard to the presence of legacy waste that is unidentified or to be repackaged, in the management of interim storage durations, and compliance with the storage area operating requirements. More rigorous tracking of chemical products is also necessary. Lastly, ASN observes that the actions prescribed after the periodic safety review of 2007 have not all been completed to date.

## FACILITIES UNDERGOING DECOMMISSIONING

The decommissioning operations performed on the Saclay site concern two finally shut down BNIs (BNIs 18 and 49) and three BNIs in operation (BNIs 35, 40 and 72), parts of which have ceased activity and in which operations in preparation for decommissioning are being carried out. They also concern 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 (LLW-LL). 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 chapter 13).

### Ulysse reactor

Ulysse was the first French university reactor. The facility, which constituted BNI 18, was definitively shut down in February 2007. The BNI Decommissioning Decree was published on 21 August 2014 and provided for a decommissioning duration of five years.

On 8 August 2019, the CEA announced the end of the decommissioning operations provided for in the decommissioning decree, with the completion of final post-operational clean-out.

The CEA sent a delicensing application file to ASN in February 2021. After examining the file, ASN delicensed the Ulysse reactor in June 2022 and BNI 18 has thus been deleted from the list of BNIs (see chapter 13).

### High-activity laboratory

The High-activity laboratory (LHA) comprises several laboratories which were intended for research or production work on 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 unused 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 over the 2019-2021 period. 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.

The year 2022 was marked primarily by the operations prior to the resuming of decommissioning. Several contracts were moreover signed in order to restart, as of 2023, the clean-out and decommissioning operations which have been stopped since late 2018.

ASN considers that the level of safety of BNI 49 undergoing decommissioning is on the whole satisfactory. The inspections revealed meeting of the commitments made by the facility licensee to ASN, and the good condition of the premises and of the ventilation equipment. The performance of unannounced inspections also evidenced good responsiveness on the part of the licensee. On the other hand, the inspections revealed weaknesses in waste management, with the need to repack a large volume of noncompliant waste packages. The management of the VLL waste from the packaging and storage facility for the retrieval of sources surplus to requirements must also be improved in order to rapidly reduce the volume of waste stored in the premises. The surveillance of contractors on worksites must be stepped up to ascertain compliance with the provisions of the facility's baseline requirements.

One significant event rated level 1 on the INES scale was reported by the facility during 2022, caused by a safety culture deficiency on the part of workers responsible for replacing the fire detection system. This event followed on from late reporting of faults on the fire detection control system of part of the facility.

ASN remains vigilant with regard to the management of the VLL 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 turns out to be of major importance for the planned schedule of decommissioning operations.

ASN will conduct an inspection to check the conditions of resumption of the decommissioning work on the TOTEM shielded line, expected during 2023, following the discovery in late 2022 that the initial state of the shielded line was not as expected.

## 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 the continuation in 2022 of the operations to reduce the radiological inventory stored in the BNIs, particularly following several removal operations in BNI 72.

As in 2021, the decommissioning and Waste Retrieval and Packaging (WRP) operations continued to fall behind schedule in 2022. ASN considers that the progress of the decommissioning projects is one of the major safety challenges for the shutdown installations and that the management of the waste from the decommissioning operations is crucial for the smooth running of the decommissioning programmes. The majority of the CEA Saclay site BNIs are concerned, either directly or indirectly, by decommissioning or decommissioning preparation operations. It should nevertheless be noted that the Ulysse reactor (former BNI 18) was delicensed during 2022. ASN therefore expects the CEA to continue its efforts to make its implementation schedules for these operations more robust. Several files are currently being drafted or examined to define the decommissioning schedules of the facilities for the coming decades. ASN will remain particularly attentive to the progress of the decommissioning and WRP projects, with the aim of checking control of the schedules.

In 2021, an abnormally high tritium content was discovered in the Fontainebleau Sands aquifer, at a new piezometer installed on the site. The studies conducted by the CEA during 2022 furthered knowledge of the origin of this pollution and

its development over time, based on models. The installation of new piezometers during 2023 will enable the posited hypotheses to be verified and better identify the extent of the pollution plume.

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 receiving a compliance notice from ASN in September 2019, the CEA submitted in December 2019 its file presenting and justifying the dimensioning of the future emergency management buildings. After discovering faults in the civil engineering reinforcements, the work site was suspended in mid-2021, preventing the CEA from meeting its commitment to have the premises commissioned before the end of 2021. Acceptance of the new emergency premises is now planned for 2024.

With regard to the emergency organisation and resources, an update of the On-Site Emergency Plan submitted by the CEA in late 2021 was discussed during 2022 in order to clarify the chosen provisions. In 2023, ASN will examine emergency management and the holding of exercises with, in particular, active situational exercises involving the site's local safety organisation.

Following a reorganisation of VLL waste management on the CEA Saclay site in early 2021, which led to a few occasional difficulties within the BNIs, ASN conducted a specific inspection focusing on six BNIs on the site in order to review the situation.

The inspections revealed that the BNIs are now capable of managing directly the packaging and removal of this waste. Some of the BNIs are examining the implementation of new measures to meet their future needs. Particular vigilance is nevertheless required in the management of waste storage durations and the quality of the waste inventories in the BNIs. The hazardous substance inventories must also be kept more strictly up to date. Even though the CEA conducted a specific study of the strategy for managing the liquid radioactive effluents produced on the Saclay site at the request of ASN, more specifically to examine the possibility of treating them in BNI 35, the organisational set up for managing the radioactive effluents, which have been treated on the Marcoule site for several years, was found to be appropriate.

With regard to radioactive substance transport, ASN's inspection found the tracking of these operations to be satisfactory, with a transport organisation providing for appropriate management of the safety issues.

Lastly, ASN conducted an inspection on the CEA Saclay site as part of its examination of the file concerning the setting up of radiation protection skills centres within the CEA Paris-Saclay centre. It served to review the substantial work achieved by the CEA teams and examine the methods of integrating the regulatory requirements, and thereby supplement or clarify certain aspects of the file. An inspection on this theme was also carried out on the CEA Fontenay-aux-Roses site. The setting up of radiation protection skills centres constitutes a positive point.



## Artificial Radionuclide Production Plant of CIS bio international

The Artificial Radionuclide Production Plant (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. 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 have been stored in the facility, is well advanced. 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 consequences of accident situations on the site.

The licensee CIS bio international mobilised its resources in 2022 for its ongoing periodic safety review, as well as carrying out operations that significantly improved safety. Thus, more high-activity disused sealed sources have been removed from the facility where they were stored, further reducing the dispersible inventory. The works conducted to improve liquid effluent management further to the deviations observed over the last few years, continued and underwent checks during ASN inspections.

Despite the stability of the internal organisation and better skills management, factors that contributed to the improvement in safety observed in the previous three years, ASN observed in 2022 that CIS bio international was having difficulties in carrying out certain activities within reasonable time frames and under conditions that complied with the safety baseline requirements. This finding applies equally well to ongoing projects, to everyday operation of the facilities, to addressing the responses to inspection follow-up letters and to the in-depth examination of significant events having occurred on the facility.

ASN's inspections in 2022, as in 2021, found that the management of the periodic inspections of Nuclear Pressure Equipment (NPE) must be improved rapidly. This subject has formed the subject of priority corrective action requests from ASN.

The tracking of emergency organisation training courses also needs to be improved. ASN has also observed deviations in occupational radiation protection, such as the signalling of the radiological risk and the management of liquid effluents, particularly fire-extinguishing fluids. CIS bio international's organisation for managing transport movements – which involve large quantities of packages with diverse contents – remains efficient, even if improvements are expected in the associated quality assurance and documentation management.

The number of significant events increased in 2022. Even though the events fall under varied themes, there is a predominance of organisational or human deficiencies. Consequently, compliance with the management and operating rules, alarm management, maintenance operations and the integration of lessons learned remain tenuous. Events reports are submitted beyond deadlines in the majority of cases, but the quality of document drafting and of the events analyses must be underlined. In this respect moreover ASN notes an improvement in the detection of significant events.

In 2022, ASN thus observed that there is still room for progress in several areas, particularly as concerns meeting the deadlines for the licensee's commitments.

To conclude, ASN observes in 2022 that despite CIS bio international's efforts, the action to improve the safety of the facility engaged in the preceding years is no longer progressing. This finding does not, at this stage, call into question the continuation of CIS bio international's activities. However, CIS bio international must focus its efforts in particular on the cross-cutting functioning of the organisation, compliance with the facility's baseline requirements and keeping to schedules. The shortcomings in operating rigour and safety culture observed in 2022 must be addressed by specific actions, taking particular care to meet the completion deadlines.



## THE 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 were stopped 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 chapter 13).

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 2040, perhaps even 2050 in the case of BNI 165. The two draft decommissioning decree modifications are under examination. The new decrees will set the decommissioning characteristics, notably their completion time frame.

### Assessment of the CEA Fontenay-aux-Roses site

The licensee must maintain its efforts to ensure the operational safety of its facilities. Safety is considered acceptable, even if areas for improvement have been identified in a number of technical subjects.

In the light of the inspections carried out in 2022, the noteworthy modifications management process is found to be correctly implemented, even if some areas for improvement have been identified. The management of radioactive substance transport and the setting up of radiation protection skills centres are positive points to be emphasised.

Most of the points requiring particular attention identified in 2022 had already been identified in 2021. They concern in particular control of the lightning risk on the site and control of the fire risk in BNI 165. Vigilance is also required in waste management, particularly in one building of BNI 166. Specific actions by ASN are in progress on these subjects (priority action requests, examination of file or inspection scheduled on the theme in 2023).

Concerning management of the fire risk, particularly in BNI 165, the scheduled or ongoing compliance work must be a priority. The compliance work still to be done on the fire doors, the prolonged unavailability of the fire extinguishing system of the shielded lines, and the reporting of a significant event linked to the malfunction of fire dampers demonstrate that appropriate corrective measures must be implemented rapidly to restore the required level of safety in BNI 165. ASN keeps regular track of the licensee's commitments on these issues.

Further to the significant events reported in 2022, corrective actions are required in the management of the periodic inspections and tests, and especially compliance with the frequencies indicated in the RGEs. The licensee must also be attentive to the conditions of worker access to delimited areas.

In 2023, ASN will examine emergency management and the holding of exercises with, in particular, active

situational exercises involving the site's local safety organisation.

Broadly speaking, ASN concedes that the CEA is encountering real technical difficulties in retrieving the legacy waste currently stored in its facilities, but it again underlines the delays in performing the studies and in the scheduling of these projects. In 2022, as in the preceding year, the CEA presented ASN its forecasts concerning the coordination of the studies and work planned on the site to reduce the dispersible inventory within the facilities. The new organisation deployed since September 2020 for the periodic safety reviews and work on the facility decommissioning files is found to be robust but must continue to prove its effectiveness. ASN expects the CEA to continue to implement proactive measures to control and render reliable the time frames associated with these projects, particularly the deadlines announced for the submission of the decommissioning worksite preparatory studies.



# Normandie REGION

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

In 2022, ASN carried out 208 inspections in Normandie, comprising 67 in the NPPs of Flamanville, Paluel and Penly, 15 on the Flamanville 3 EPR reactor construction site, 65 on “fuel cycle” facilities, research facilities and facilities undergoing decommissioning, 53 in small-scale nuclear activities and 8 in the transport of radioactive substances.

In addition to this, 31 days of labour inspection were carried out on the NPP sites and the Flamanville 3 construction site.

In 2022, 16 significant events rated level 1 on the INES scale were reported to ASN.

## 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 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 that the action plan implemented in the context of tightened surveillance has been effective, particularly with regard to the upgrading of the facilities and integration of the fundamental safety principles by the employees and outside contractors. The difficulties the licensee encountered in the management of the local emergency response centre at the beginning of the year led it to implement an action plan of which ASN will monitor the results in 2023. Improvements are also expected in the completeness and quality of the files submitted to ASN.

With regard to reactor management and operation, ASN considers that the site’s performance is improving. The action plan of the operational management service brought a change in the teams’ practices which notably allowed controlled restarting of reactor 2 following its maintenance and refuelling outage which lasted from February to November 2022. These changes must now be maintained and sustained, particularly for the restarting of reactor 1 in early 2023.

With regard to the maintenance operations, the licensee took advantage of the outage of the two reactors to perform compliance work on various safety important components. On reactor 1 this resulted in the replacement of the four steam generators. As part of the inspections concerning the detection of stress corrosion cracks on the Penly 1 and Civaux 1 reactors in late 2021, the licensee took samples of pipes from reactor 2 in order to perform expert assessments, and also replaced them. As a general rule, ASN considers that the licensee carried out these maintenance operations competently. ASN will nevertheless remain attentive in 2023 to the traceability of the actions carried out for the management of contingencies and

## THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

### ■ Basic Nuclear Installations:

- the NPPs operated by EDF, namely Flamanville (2 reactors of 1,300 MWe), Paluel (4 reactors of 1,300 MWe) and Penly (2 reactors of 1,300 MWe),
- the Flamanville 3 EPR reactor construction worksite,
- the Orano spent nuclear fuel reprocessing plant at La Hague,
- the Manche repository (CSM) operated by Andra,
- the National large heavy ion accelerator (Ganil) in Caen;

### ■ small-scale nuclear activities in the medical field:



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- 8 external-beam radiotherapy departments (27 devices),
- 1 proton therapy department,
- 3 brachytherapy departments,
- 12 nuclear medicine departments,
- 50 centres performing 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.

### Tightened surveillance at Flamanville

In September 2019, ASN decided to place the Flamanville NPP under tightened surveillance further to the difficulties EDF encountered during the two ten-yearly outages which began in 2018. This tightened surveillance was materialised by a larger number of ASN inspections, some thirty per year, and regular interchanges with the licensee on the progress and effectiveness of its practices improvement plan. At the end of 2021, after completing the deployment of its action plan, the licensee asked ASN to lift the tightened surveillance status.

In 2022, ASN conducted two tightened inspections which revealed correct application of nuclear safety principles and rules by the personnel of EDF and the outside contractors, the good overall condition of the facilities, and the improvement in the control of radiation protection on the high-risk worksites. In view of the improvement in the state of the facilities and the safety practices, ASN decided to lift the tightened surveillance of the Flamanville NPP in July 2022. ASN has asked the licensee to continue to maintain a high level of stringency to consolidate the observed improvements.

the licensee's surveillance of worksites. Improvements are also expected in the robustness of the process for managing the periodic inspections of pressure equipment, which has shown vulnerabilities on several occasions.

The site's radiation protection performance improved in 2022. ASN observes progress in the organisation of radiation protection and notes that the process for identifying and reporting significant radiation protection events is effective. Improvements are however still expected in the preparation, by the workers – including those of outside contractors, of activities involving major radiation protection implications, including outside contractors, and in the control of the radiological cleanliness of the facilities.

ASN observes progress in environmental protection, the site having more specifically improved its organisation. ASN underlines the actions undertaken through the action plan to remove the legacy waste hulls and observes the good upkeep of the facilities and competent management of hazardous chemical products. Progress is nevertheless expected in the stormwater network, and particularly in the control of discharges and the monitoring of renovation work. These subjects will receive particular attention in 2023.

With regard to labour inspection, ASN considers that the licensee must make improvements in several areas. Deviations have been observed in particular in the verification of the electrical installations or the protection of certain areas with respect to the risk of falling from height.

## 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 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 performance of the Paluel NPP with regard to nuclear safety and environmental protection is broadly in line with the general assessment of the EDF plants. ASN considers that the radiation protection performance stands out positively with respect to its general assessment of the EDF plants.

The nuclear safety performance of the Paluel NPP was satisfactory, despite some weaknesses. In the area of reactor operational management, an action plan deployed to control activities involving a reactor trip risk gave satisfactory results. Nevertheless, there is room for progress in mastering the control of sensitive transients, particularly during the shutdown and restarting phases. Moreover, several significant safety events reported were caused by a deficiency in the preparation of the activity or shortcomings in the operational documentation. ASN considers that action must be taken to improve the quality of the operational documentation and the activity preparation and performance documents.

With regard to maintenance, ASN considers that the site's performance in 2022 still remains below average. Several inspections during the maintenance outages highlighted deviations in the monitoring of activities and of certain worksites. This was the case for example during the refuelling and maintenance outage of reactor 4, when a video inspection revealed a crack on a control rod drive shaft, a crack which had not been identified during the previous outages. In addition, the analysis of several safety-related significant events revealed a lack of preparation and shortcomings in the risk analyses before carrying out the activities. Improvements are therefore required, firstly through more rigorous preparation of the work interventions, and secondly by good uptake of the activities by the operators before carrying them out.

With regard to radiation protection, ASN notes that the site's performance is stable with respect to 2021. The dosimetry of all the maintenance outages during 2022 was below their initial forecast. The inspections confirmed the good upkeep of the work sites and, more generally, satisfactory management of the contamination risk. Improvements are nevertheless expected regarding compliance with the procedures for managing contaminated persons and in the contamination follow-up actions determined by the preparation committee for activities with high radiological risks. ASN notes that in 2022 a worker received a skin dose exceeding one quarter of the regulatory limit; this incident led to the reporting of a significant radiation protection event rated level 1. ASN will be attentive to the deployment of the action plan decided upon further to the analysis of the root causes of this event.

As regards environmental protection, ASN notes stable performance and considers that the organisational set-up for protection of the environment is satisfactory, and that the equipment necessary for monitoring environmental discharges is correctly maintained. Concerning atmospheric discharges of greenhouse gases, ASN observes a reduction in discharges of SF<sub>6</sub> but a significant increase in discharges of cooling fluids. ASN expects to see improvements in this latter point.

With regard to labour inspection, ASN observes that the workers know and comply with the safety requirements, but that the observed improvements must be continued. The ASN inspections have also found deviations in the verifications of handling cranes and the management of the fire evacuation plans in some parts of the facility. ASN will be attentive to the remedial actions taken to prevent the recurrence of such situations.

## 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 performance of the Penly 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 that operating rigour is improving, despite a few persistent weaknesses. ASN considers that particular attention must be paid to the quality of work preparation, particularly when performing the periodic tests. Some significant events for safety still reveal shortcomings in personnel training, and in the monitoring of the installations during the management of transient operating phases. ASN will be particularly attentive to these points in 2023, particularly during the restarting of the two reactors.

As far as maintenance is concerned, at the end of 2021 during the ten-yearly outage of reactor 1 the licensee detected stress corrosion cracks on systems connected to the main pipes of the primary cooling system. This led to a programme of inspections, expert assessments, and large-scale repairs throughout the year 2022. With regard to the maintenance and refuelling outage of reactor 2, the maintenance operations were well managed on the whole and will continue in 2023, also further to the discovery of cracks. During the work on the two reactors, ASN observed repeated shortcomings in contractor monitoring, both in the documentation part and in the checking of the workers' practices. Greater rigour is expected on this subject. Alongside this, although ASN notes a reduction in the number of significant events linked to the detection of maintenance nonqualities, it considers that the safety impacts of the detected deviations must be analysed in greater depth.

In the area of radiation protection, ASN considers that shortcomings persist in the control of the contamination risk and in the radiation protection culture during reactor outage periods, particularly in the deployment and maintaining of measures to limit occupational exposure on the worksites. Organisational improvements are also expected, particularly for the setting up of the radiation protection skills centre.

As for environmental protection, ASN considers that the Penly NPP has obtained satisfactory results in waste monitoring and management and notes an improvement in the measures taken to control discharges of ozone-depleting gases. Improvements are nevertheless expected in the management of non-radiological risks. Although ASN has observed, in an exercise held during an inspection, that the NPP teams' organisation for managing non-radiological emergency situations is responsive and appropriate, the operational documentation available to the teams must be supplemented in order to integrate certain risks which are not taken into account at present.

With regard to labour inspection, ASN observes that the workers generally know and comply with the safety requirements. However, the inspections have occasionally found deviations in the prevention of vital risks (such as the prevention of the risk of anoxia or electrocution) and risks relating to lifting operations. ASN will therefore be attentive to the steps taken to reinforce the measures to prevent these risks.

### In-depth inspection at Penly

**In November 2022, ASN conducted a week-long in-depth inspection at the Penly NPP addressing themes such as safety management, operational control, maintenance, dealing with deviations and the modification of the facilities. This inspection, which mobilised some ten ASN inspectors, found the site organisation and operation to be efficient on the whole.**

## Flamanville 3 EPR reactor construction worksite

Following issuing of the Creation Authorisation Decree 2007-534 of 10 April 2007 and the building permit, the Flamanville 3 EPR reactor has been under construction since September 2007.

Overall, ASN notes that a substantial amount of work remains to be done in 2023 in preparation for reactor commissioning. In effect, apart from the actions relating to the examination of the commissioning file, which are continuing, EDF will have to check completion of the installation in order to demonstrate its conformity and the adequacy of preparation for reactor operation.

In 2022, EDF continued with work to complete the installation, to make modifications to certain equipment and to draw up the various documents needed for operation. EDF also continued the analysis and correction of deviations, particularly those affecting the welds of the Main Secondary Systems (MSS), three branch pipes of the Main Primary System (MPS), and the shrinkage of adhesive causing clogging of the filters of the safety injection system in the rooms concerned. ASN considers, on the basis of its inspections, that EDF is addressing these deviations appropriately. For the MSS welds in particular, ASN considers that the various parties involved have set up an organisation and a system for monitoring the activities conducive to achieving, with confidence, a high standard of quality in the production of these welds, thereby making it possible to meet the break preclusion baseline requirements. In 2023, ASN will continue its oversight of these activities and of the due preparation and performance of the hydrostatic tests of these systems.

Numerous systems, structures and components have been shut down for the work on the MSS's. After reviewing the preservation doctrine defined by EDF, ASN conducted several inspections in 2021 and 2022 to check its implementation, which turns out to be satisfactory on the whole. EDF must remain attentive to the preservation exit phase and to the implementation of appropriate means for the period between preservation exit and reactor commissioning.

Apart from the main deviations mentioned above and currently being corrected, ASN observed in 2022 that a lot of work remained to be done to finalise the fitting out of the installations (such as addressing the other deviations, performing certain start-up tests, making several equipment modifications and the finishing work). In this respect, ASN has asked EDF to submit periodic progress reports on installation completion and has initiated a verification campaign. ASN has noted that EDF has set up a dedicated organisation and taken appropriate corrective action in response to its demands. ASN nevertheless drew EDF's attention to the fact that a large amount of work remained to be carried out prior to reactor commissioning in order to demonstrate conformity of the installation with the commissioning file. Alongside this, ASN continued the verification of the equipment quality review which was requested in 2018 due to the serious shortcomings observed in EDF's monitoring of its outside contractors. ASN ascertained in 2022 that a programme of complementary verifications was established and implemented, and will examine the results of these actions and the main conclusions EDF draws from them.

Alongside the completion of the facility, EDF is preparing for future operation of the reactor with dedicated teams, whether in terms of defining and implementing organisational set-ups, skills management, or the preparation and familiarisation with the documents and equipment necessary for operation. ASN's oversight has confirmed the defining and implementation of the organisational set-ups on the various themes, but it has also highlighted the substantial amount of work still to be carried out prior to reactor commissioning. ASN will continue its oversight in this respect in 2023 through dedicated inspections, including an in-depth inspection.

ASN also ensures the labour inspection duties on the Flamanville EPR reactor construction site. In 2022, in addition to checking that the contractors working on the site complied with the provisions concerning labour law, ASN checked the conformity of the facilities regarding evacuation and fire risks. ASN considers that the organisation of safety is on the whole appropriate with respect to the regulations and shall allow satisfactory transfer of the facilities to the future licensee.

## Manche waste repository

The Manche waste repository (CSM), commissioned in 1969, was the first radioactive waste disposal centre operated in France. 527,225 m<sup>3</sup> 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.

Examination of the periodic safety review guidance file had resulted in ASN formulating specific demands at the end of 2017, concerning the justification of the technical principles of deployment of the long-term cover, the CSM memory system and the updating of the impact study.

In this context, ASN is currently examining the CSM periodic safety review report submitted by Andra in 2019. The periodic safety review inspection found that the licensee had conducted the review process in a generally satisfactory manner. Nevertheless, some points require particular attention, namely the replacement of the geomembrane in the event of loss of integrity, formalising of the licensee's in-house check and the action plan (updating and level of detail). A meeting of the Advisory Committee for Waste (GPD) pertaining to the CMS periodic safety review was held on 1 February 2022 and underlined that the licensee's commitments enable continued operation to be envisaged for ten years following submission of the file.



In 2022, ASN considers that the organisation defined and implemented for operation of the CSM facilities with regard to radiation protection and environmental monitoring is satisfactory. The licensee has notably taken measures to improve the monitoring of outside contractors. It must nevertheless

continue to embrace the requirements associated with the creation of the radiation protection skills centres and consolidate the operational control of the actions planned for the management of situations that could take the facility outside its operating range.

## 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 of the 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. For the purpose of the technical examination conducted jointly with IRSN, ASN underlines the speed with which Ganil provided the complementary information requested. In the light of the file and the complementary information provided, ASN informed the Nuclear Safety and Radiation Protection Mission (MSNR) in November 2022 that the file submitted by the Ganil was sufficiently robust for the examination to continue, and in particular for the consultations provided for by the regulations to be launched.

As far as the existing facilities are concerned, ASN considers that the licensee’s organisation for nuclear safety in 2022 was satisfactory. This being said, improvements are expected in the time frames and the exhaustiveness in the transcription of the new regulatory requirements into the documents, in order to avoid delays such as were observed with the formalising and implementation of the new radiation protection regulations.

## 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, 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 tonnes per year. The limits and conditions for discharges and water intake by the site are defined by ASN resolutions 2022-DC-724 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 installations at La Hague

### SHUT DOWN INSTALLATIONS UNDERGOING DECOMMISSIONING

#### BNI 80 – Oxide High Activity (HAO) facility:

- 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 to 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 ATI 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 of 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,
- BST1: 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.

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 solid compound ( $\text{U}_3\text{O}_8$ ) called “reprocessed uranium” in the TU5 facility on the Tricastin site.

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 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 et CSD-C packages).

## Marking events of the year 2022

### Fission product evaporators-concentrators

Six evaporators are used in facilities R2 and T2 to concentrate the fission product solutions before they undergo vitrification treatment. After measuring the thickness of the walls of these evaporators during the periodic safety reviews of the facilities as from 2012, a more advanced state of corrosion than predicted at the design stage was discovered. ASN therefore decided to regulate the continued operation of these evaporators in order to tighten their surveillance and to have additional means installed to mitigate the consequences in the event of a leak or rupture. In the course of this special surveillance, thickness measurements taken in September 2021 on evaporator 4120.23 of the T2 facility had shown that the operational criterion for shutting down the evaporator had been reached, which led Orano to decide not to restart the evaporator.

To replace these evaporators, Orano is building new facilities baptised "New Fission Product Concentrations" (NCPF) and comprising six new evaporators. This particularly complex project has necessitated several authorisations. It was the subject of two ASN resolutions in 2021, concerning the active connection of the process of the three evaporators of NCPF T2 on the one hand and the three evaporators of NCPF R2 on the other.

With regard to the NCPF T2 project, the T2 facility has been shut down since September 2022 in order to connect the new evaporators to the existing facilities and to continue the tests prior to commissioning, which is planned for April 2023. ASN has performed two inspections concerning the tests conducted by the licensee in 2022 and will continue its specific oversight operations in 2023.

The NCPF R2 project is offset by about one year with respect to

NCPF T2, meaning that the first tests were started at the end of 2022. The operations to connect the new evaporators to the existing facilities are planned as of autumn 2023, with commissioning scheduled for the first half of 2024.

### Storage of plutonium-bearing materials

Since the end of 2021, the Orano La Hague site been faced with a problem of saturation of the storage capacities for these materials, linked to the operating difficulties encountered by the Melox plant. This problem gave rise to a hearing of Orano by the ASN Commission on 28 September 2021 and was also examined during the joint hearing of Orano and EDF relative to the balance of the "nuclear fuel cycle" on 10 February 2022.

To cope with this storage capacity problem, Orano has submitted several noteworthy modification authorisation applications with the aim of increasing its plutonium-bearing material storage capacities:

- a first application was filed in September 2021 to increase the storage capacities for plutonium-bearing materials in the BSTI facility. This led to an ASN authorisation in April 2022;
- a second application was filed in September 2022 to increase the storage capacities for plutonium-bearing materials in the R4 facility. This file is currently being examined by ASN with the technical assistance of IRSN.

Orano plans filing further applications of the same nature if the storage capacity problems persist.

### Revision of the resolutions regulating the site's discharges

On 16 June 2022, ASN adopted two resolutions regulating the conditions of water intake, consumption, discharge into the environment, and the effluent discharge limits for the La Hague site. As of 1 January 2023, these resolutions update the resolutions of 2015

which were applicable until now. In accordance with the regulations, the resolution modifying the limits applicable to effluent discharges from the installation was approved by Ministerial Order published in the *Official Journal* of 7 December 2022.

The resolutions adopted by ASN take into account some of the licensee's requests concerning more specifically the modification of the maximum monthly activity concentration of rare gases, including krypton-85, measured at the regulatory environmental monitoring stations, and regulation of the limits and conditions of monitoring discharges into the sea of eleven chemical substances detected by the licensee in small quantities in the discharges during a regulatory compliance evaluation procedure. Other requests from the licensee, representing lower risks, have also been accepted if justified in view of the environmental risks and compatible with the applicable regulatory provisions, for example concerning the management of drainage waters from certain facilities, the conditions of effluent analyses and the frequency of submitting the regulatory studies determining the possibilities of reducing radiological and chemical discharges. Lastly, some requests asking for a relaxation of the requirements concerning water intakes, monitoring of the marine environment or the effluent discharge conditions, were rejected.

These resolutions ratify the principle of a significant reduction in the discharges into the sea authorised for certain radiological or chemical substances, in view of experience feedback and the improvement in effluent management practices and techniques. They also impose complementary provisions for environmental monitoring, evaluation of the radiological impact on the populations and effluent monitoring.

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 current 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 incurred in WRP. Consequently, ASN will continue to monitor the management of these projects in 2023.

## LEGACY WASTE RETRIEVAL AND PACKAGING OPERATIONS

Unlike the direct on-line packaging of waste, as is done with the waste produced in the new UP2-800 and UP3-A plants at La Hague, the majority of the waste produced by the first UP2-400 plant was stored in bulk without final 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 storage facilities.

### Retrieval and packaging of the STE2 sludges

The STE2 station of UP2-400 was used to collect the effluents from the UP2-400 plant, treat them and store the precipitation sludge 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 Cycle 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.

### Silo 130

Silo 130 is a reinforced concrete underground storage facility, with 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”. Today, 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 (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 risks of fire and explosion.

The scenario for retrieving and packaging this waste comprises four stages:

- 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 sorting and packaging operations.

The various works conducted on silo 130 in 2022 enabled the licensee to validate industrial commissioning of the waste retrieval process. Quantitatively, 36 drums of waste were retrieved in 2022, bringing the total number of drums retrieved since the facility started operation in 2021 to about sixty. The licensee is nevertheless encountering numerous difficulties in terms of rates of waste retrieval and equipment reliability, which have a significant impact on the waste retrieval time frame. Waste retrieval has thus been stopped since the end of August 2022 following the rupture of the retrieval rake cable. ASN considers that the licensee must take measures to restore an operating capacity as close as possible to what was planned for at the design stage and must take into account the lessons learned for the other WRP projects.

### HAO silo and Organised Storage of Hulls

The Oxide High Activity (HAO) facility (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 Organised Storage of Hulls (SOC) comprising three pools in which the drums containing the hulls and end-pieces are stored.

In 2022, the licensee continued the operations prior to retrieval of the waste from the HAO silo and implementation of the physical modifications defined on completion of the analysis of hard spots identified during the functional tests of the waste retrieval system. The efforts focused in particular on upgrading the cement encapsulation carriage for fines and resins. Resolution CODEP-DRC-2022-02887 of 15 July 2022 authorised the partial commissioning of the unit for retrieval and packaging of the waste from the HAO silo and the SOC pools in “ECE” drums. The time frames are consistent with the “integrated schedule” of the project transmitted in February 2022 to meet the requirements to keep to the schedule in accordance with resolution 2014-DC-0472 of 9 December 2014, amended.

## Assessment of the La Hague site

ASN considers that the performance of the Orano Recyclage La Hague site in 2022 is satisfactory in the areas of nuclear safety, radiation protection and environmental protection.

With regard to nuclear safety however, ASN considers that Orano must be more attentive to compliance with the deadlines for regulatory requirements and commitments.

From the operational aspect, Orano has continued the improvements initiated in the formalising of operator authorisations and deployment of the operational management teams. ASN also views positively the weighted and cautious approach of the operational management teams observed during the inspection of the STE3 facility. Particular attention must however be paid to the formalising of operating instructions for managing downtimes of the various operational control systems, and correct application of the provisional controller modification authorisations and the equipment lockout/tagout procedures. Greater rigour is also expected in the filling out and traceability of certain checks and registers, as this information is necessary to track parameters that are important for the safety of the facilities.

Further to the in-depth inspection conducted in early February 2022 on the themes of periodic inspections and tests and maintenance, ASN considers that Orano must significantly reinforce the requirements associated with the PIA relative to the periodic inspections and the management of deviations.

ASN underlines the generally good organisation of outside contractor monitoring. The monitoring reports are available but in some cases do not give the references providing proof of the monitoring actions, therefore greater rigour is required in filling them out.

As regards management of worksites, ASN observes their good general upkeep, with the exception of the worksite for the extension of the plutonium oxide discards storage areas in the BST1 facility, conducted with very tight deadlines, in which ASN noted significant deviations, such as worksite tracking folders not up to date, absence of proof of monitoring and non-validated

documents. ASN notes that these shortcomings make it impossible to ensure satisfactory traceability of the verifications and ultimately to guarantee compliance with the safety requirements defined by the licensee. Orano must therefore take care to maintain the quality of outside contractor monitoring, irrespective of the various constraints on the worksites.

ASN considers that the work programmes to reinforce fire detection and protection are on the whole proceeding satisfactorily. With regard to the situational exercises, improvements are required in the adoption of the actions to be taken by the local response groups and greater rigour is necessary in the management of hot work permits, fire loads and the fire-fighting means specific to worksites.

With regard to the storage of plutonium-bearing materials, Orano commissioned a first storage area extension within a room of the BST1 facility in May 2022. This project was examined and deployed under very tight timelines. Orano filed another application in May 2022 for a storage extension within the R4 facility which also requires examination and deployment in very short time frames. ASN thus again considers that Orano must reinforce its forward-looking initiatives for managing the capacities of certain storage areas, such as those for plutonium-bearing materials or spent fuels, in order to define and deploy storage arrangements and solutions with more reasonable time frames.

With regard to radiation protection, the year 2022 was marked by the creation of the radiation protection skills centre. The organisation in place broadly meets the regulatory requirements and the licensee has made commitments regarding the last points to address.

The year 2022 was however also marked by an increase in significant radiation protection events concerning noncompliance with the conditions of access to delimited areas. ASN considers that the licensee must continue and intensify its action plan to prevent this type of event from happening again. Alongside this, ASN notes that the management of radioactive sources within the site

can be improved. Numerous expired sources are still in service or have not been removed. It is important that the licensee steps up its ongoing action plan in this respect so as to be able to remove the expired sources as quickly as possible. These various aspects were examined in depth during the ASN's tightened inspection on radiation protection carried out in October 2022.

Concerning environmental protection in 2022, ASN takes positive note of the licensee's actions in response to the findings of a tightened inspection conducted the preceding year. The improvement actions undertaken to ensure the regulatory compliance of the facilities presenting risks and drawbacks for environmental protection must be continued, and stepped up as regards the control of fluorinated greenhouse gases.

Concerning the treatment of effluents, ASN also observes the operational control teams' proficiency in the process and the ability of the licensee to mobilise the appropriate resources for the contingencies. This being said, measures are awaited to improve the availability of certain items of equipment and control of the defined requirements applicable to the environmental discharges. In this context, ASN also points out the need to continue the actions to reduce environmental discharges, an objective that was taken into account in ASN's revision of the resolutions regulating the site's discharges completed in 2022.

With regard to the management of the decommissioning and WRP projects, significant progress was made in 2022, particularly in the MAU, MAPu and HADE facilities. Orano has also continued to implement the fundamental improvements in the organisation of the decommissioning and WRP projects, which began in 2021, aiming to achieve greater robustness.

ASN nevertheless still observes that several decommissioning and WRP projects continue to encounter problems leading to further delays. As far as decommissioning is concerned, Orano must continue the efforts made to address the issues with major implications for the scenario and hence for the associated



time frames. As for the WRP projects, difficulties encountered in 2022 on the projects associated with silo 130, silo 115 and sludge treatment are significantly delaying the lowering of the dispersible inventory of the facilities concerned. Regarding silo 130, which is the most advanced project and is in the industrial operation phase, the licensee is faced

with numerous problems of equipment reliability, which have a significant impact on the waste retrieval times. ASN considers that the licensee must take measures to restore an operating capacity as close as possible to what was planned for at the design stage and must take into account the lessons learned for the other projects.

Lastly, ASN considers that Orano must take care to maintain the facilities undergoing decommissioning in good condition in order to control the infiltrations in certain buildings, guarantee the radiological characterisation of the residual materials in cells, and ensure that the required controls are properly performed.





# Nouvelle-Aquitaine

## REGION

The Bordeaux division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 12 *départements* of the Nouvelle-Aquitaine region.

In 2022, ASN carried out 140 inspections in the Nouvelle-Aquitaine region, comprising 52 in the Blayais and Civaux NPPs, 77 in small-scale nuclear facilities, 6 in the area of radioactive substance transport and 5 concerning ASN-approved organisations and laboratories.

ASN also carried out 13 days of labour inspection at the Blayais NPP and 9.5 days at the Civaux NPP.

During 2022, 6 significant events rated level 1 on the INES scale were reported by the NPP licensees in Nouvelle-Aquitaine. In small-scale nuclear activities, 1 significant radiation protection event rated level 1 on the INES scale and 1 event rated level 2 on the ASN-SFRO scale were reported to ASN.

ASN temporarily modified the requirements regulating thermal discharges from the Blayais NPP during the heat waves of summer 2022 (see “Notable events” in the introduction to this report).

### Blayais nuclear power plant

The Blayais NPP situated in the Gironde *département*, 50 km north of Bordeaux, is operated by EDF. This NPP comprises four 900 MWe PWRs, commissioned in 1981 and 1982. Reactors 1 and 2 constitute BNIs 86 and 110 respectively.

ASN considers that the performance of the Blayais NPP with regard to nuclear safety, radiation protection and environmental protection is in line with ASN's general assessment of the EDF plants. ASN considers that further improvement measures must be taken to raise the standard of nuclear safety performance. It considers that the radiation protection and environmental protection performance is progressing, but that the improvement efforts already undertaken need to be continued.

With regard to nuclear safety, the performance of the Blayais NPP dropped during 2022. ASN considers that the licensee's performance in the operational control of the reactors was below the expected standard, particularly during operational operations conducted at the end of the reactor 3 refuelling and maintenance outage, during which inappropriate actions on the electrical power supplies caused several significant events for safety. Furthermore, some inspections revealed the presence of malfunctions in the control of the fire loads, shortcomings in the integration of a number of “post-Fukushima” requirements, and the need to improve primary system monitoring for prevention of the stress corrosion risk. On the other hand, in the area of maintenance, ASN notes a good command of the activities carried out during the reactor outages and appropriate addressing of the anomalies encountered.

With regard to occupational radiation protection, ASN considers that performance has improved with respect to 2021, with the continued deployment of the action plan in this area. ASN more specifically notes an improvement in dosimetry

monitoring and control of the “red area” process. Nevertheless, ASN still observes dysfunctions in the field regarding the wearing of dosimeters, the marking out of controlled areas and the provision of contamination meters expected in zone transition areas. These deficiencies are indicative of a lack of monitoring, training, and informing of workers: the radiation protection culture must therefore be improved.

With regard to environmental protection, ASN notes the licensee's constant efforts to remedy the degraded situations which have existed for several years, such as remediating the legacy presence of pollutants in the soils and in the site's confined groundwater tables. Alongside this, ASN underlines the proactive measures implemented to control the discharges of SF<sub>6</sub>, a greenhouse gas used for electrical insulation. It nevertheless considers that control of the discharges of other greenhouse gases can be substantially improved and that improvements are expected regarding the consistency of the performance of the discharges from the site's wastewater treatment plant. Lastly, ASN finds persistent weaknesses in that the containment of accidental spillages of non-radioactive liquids on the site cannot be guaranteed under all circumstances.

Concerning labour inspection, ASN considers that the results regarding worker safety are still not of the expected standard. ASN has observed risk situations for personnel working at height, and the occurrence of events affecting safety linked to hand-held power tools. ASN considers that the relevance of the risk analyses must be improved. It also underlines poorly managed situations that have led to the accidental exposure of several employees to asbestos fibres. A strong response is expected of the licensee on this subject. ASN nevertheless notes positively the setting up of worksite protection reviews.

## Civaux nuclear power plant

The Civaux NPP is operated by EDF in the Vienne *département*, 30 km south of Poitiers in the Nouvelle-Aquitaine region. It 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 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.

The Civaux NPP had a highly singular year in 2022 with its two reactors shut down. This situation is linked to the management of the stress corrosion phenomenon detected in 2021 on reactor 1 which affects certain pipes connected to the primary system, and the proceedings of the ten-yearly outages on the two reactors. Consequently, with regard to safety, ASN is unable to compare the performance of the Civaux NPP with that of the other NPPs. It considers that the radiation protection performance of the Civaux NPP stands out positively with respect to its general assessment of the EDF plants, and that its environmental protection performance is in line with this general assessment.

In the area of nuclear safety, ASN commends the attitude of EDF which gave priority to the safety of its facilities by voluntarily maintaining the outage of its two reactors in order to successfully replace pipes potentially affected by stress corrosion cracks. During this period where the operational control teams were less occupied with controlling the facilities, ASN notes that EDF took appropriate measures to maintain and develop its employees' skills by reactively adapting the training programme for the purpose of integrating numerous modifications associated with the second ten-yearly outage. With regard to maintenance, ASN considers that the situation of the site is satisfactory on the whole. It nevertheless considers that the associated documentation needs to be improved, as does the monitoring of contractors. The year 2022 was marked in particular by a maintenance non-quality which caused a sudden loss of sealing of the main primary system during the increase in its pressure for its hydrostatic test. The event had no major consequences. ASN observed the licensee's competent management of this event. Lastly, management of equipment lockouts/tagouts prior to interventions is considered sub-standard and must be improved.

Worker radiation protection was an important issue in 2022 due to the large number of activities associated with the two ten-yearly outages. As in 2021, ASN considers that radiological cleanliness is one of the site's strong points. The collective dosimetry associated with the pipe replacement work to prevent the stress corrosion phenomenon was lower than expected, thereby limiting the ionising radiation exposure of the workers. ASN nevertheless still observes inappropriate behaviours of workers in controlled areas with respect to the applicable radiation protection rules. It notes missing radiation meters and noncompliant worksite air locks.

## 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 field:



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- 19 external-beam radiotherapy departments,
- 6 brachytherapy departments,
- 26 nuclear medicine departments,
- 89 centres performing fluoroscopy-guided interventional procedures,
- 116 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 700 industrial and research centres, including 59 companies with an industrial radiography activity,
- 1 cyclotron particle accelerator,
- 49 laboratories situated mainly in the universities of the region,
- some 500 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,
- 15 organisations approved for measuring radon,
- 8 laboratories approved for taking environmental radioactivity measurements.

With regard to environmental protection, ASN considers that in 2022 the Civaux NPP managed waste and radioactive effluents satisfactorily. Significant progress has been observed in the projects for containing fire extinguishing liquids and for the management of backfill soils, but this must be consolidated.

With regard to labour inspection, ASN considers that the organisational set up for detecting and addressing hazardous situations and the adopting of the key points of the lockout/tagout procedures must be rendered more robust. It notes in particular several risk situations for workers in confined environments. ASN has also observed recurrent deficiencies in the control of the asbestos-related risk, which have resulted in several cases of accidental exposure. ASN considers that the licensee must step up its efforts in this area. Nevertheless, ASN takes positive note of the setting up of weekly workshops intended for the managers to promote the safety culture within their teams, and the site's undertaking to accompany contractors during field visits.



# Occitanie

## REGION

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.

In 2022, ASN carried out 125 inspections in the Occitanie region, comprising 55 inspections in BNIs, 56 in small-scale nuclear activities, 11 in the transport of radioactive substances and 3 concerning ASN-approved organisations and laboratories.

ASN also carried out 15 days of labour inspection at the Golfech NPP.

During 2022, four significant events rated level 1 on the INES scale were reported by the licensees of the nuclear installations in Occitanie. In small-scale nuclear activities, 3 significant radiation protection events rated level 1 on the INES scale were reported to ASN (2 in the industrial sector and 1 in the

medical sector). One significant event in the medical field rated level 2 on the ASN-SFRO scale was reported to ASN.

In the context of their oversight duties, the ASN inspectors issued one violation report. One medical centre was moreover summoned in order to raise senior management's awareness of the issues of occupational and patient radiation protection.

ASN temporarily modified the requirements regulating thermal discharges from the Golfech NPP during the heat waves of summer 2022 (see "Notable events" in the introduction to this report).

### Golfech nuclear power plant

The Golfech NPP operated by EDF is located in the Tarn-et-Garonne *département*, 40 km west of Montauban. This NPP comprises two 1,300 MWe PWRs, 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 and environmental protection is below ASN's general assessment of the EDF plants. The radiation protection performance is in line with the general assessment.

With regard to nuclear safety, ASN considers that deployment of the Safety rigour plan since 2019 demonstrates senior management's commitment to improving the site's nuclear safety performance. Nevertheless, the actions and efforts undertaken in this context have not yet produced sufficiently visible results on the performance levels observed during inspections or on the Golfech NPP indicators. The shortcomings in the area of operational control already identified in previous years persist in 2022 despite some progress: deficiencies in skills, in communication between departments, in compliance with procedures and recording of activities. ASN considers that in 2023 the licensee must improve operating rigour by enhancing operator skills and compliance with procedures.

With regard to maintenance, the marking event of 2022 was the ten-yearly outage of reactor 1. The work undertaken by the site to improve the quality of maintenance has resulted in visible progress in this area. ASN notes more particularly improvements in the identification and addressing of deviations, in the consolidation of technical controls and in the

consideration of the positions of the independent safety organisation. ASN nevertheless considers that the site must increase its efforts to improve assimilation of the safety risks prior to work interventions.

ASN considers that the site's occupational radiation protection performance is stable with respect to 2021. ASN notes the strong involvement of the members of the workers' radiation protection skills centre in the training course and the increase in the monitoring of radiation protection contractors. Improvements are nevertheless expected in the control of the procedures for accessing limited stay (orange) areas and in industrial radiography activities.

In the area of environmental protection, ASN considers that the performance of the Golfech NPP deteriorated in 2022. The year was marked by a relatively large number of events. Improvements in the management of the containment of non-radioactive liquid substances are expected in 2023.

Concerning labour inspection, ASN considers that there is a deterioration in worker safety results. Compliance with the requirements of the Labour Code must be improved, particular regarding work at height and handling and lifting operations. The ASN labour inspectorate considers that coordination of the risks associated with the interface between different activities must be improved, as must the quality of activity preparation and risk analyses. It also notes the existence of design faults in certain electrical installations, witnessed by an inspection organisation.

## 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 downstream part of the “fuel cycle” and the irradiation of materials, and to industrial activities concerning in particular the fabrication of MOX 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 of 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 Laboratory for research and fabrication of advanced nuclear fuels (Lefca), were transferred here from the CEA Cadarache centre in 2017.

On completion of the analysis of the facility’s periodic safety review report submitted in December 2016, ASN published resolution 2022-DC-0720 of 19 April 2022 which sets the CEA requirements applicable to Atalante, intended to regulate the continued operation of the BNI. More specifically, the frequency of treatment of Radioactive Organic Liquids (LOR) by the “DELOS” process, for which the final date has been prescribed, shall form the subject of specific ASN oversight in the coming years. The licensee must moreover improve the organisation adopted to ensure the monitoring and traceability of the actions defined at the end of this periodic safety review.

In 2022, ASN authorised the implementation of new software for managing material and monitoring criticality, which broadly improves the integration of measurement uncertainties when evaluating fissile material masses. The commissioning of a liquefied nitrogen reservoir on the new gas platform of Atalante has also been authorised.

Deficient periodic inspections and tests, essentially due to human errors, led to significant discharges of greenhouse gases and failure to perform periodic tightness inspections of glove boxes and of fire-extinguishing gas cylinders. These deviations were reported to ASN as significant events. The licensee informed the outside contractors concerned and shared a feedback analysis on the identified risks with them in order to prevent the recurrence of this type of event.

### 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 ioniser,
- the Écrin waste storage facility on the Malvési site;

#### ■ small-scale nuclear activities in the medical field:



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- 14 external-beam radiotherapy departments,
- 6 brachytherapy departments,
- 21 nuclear medicine departments,
- 100 centres performing fluoroscopy-guided interventional procedures,
- 111 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, 28 companies exercising an industrial radiography activity and 58 laboratories situated mainly in the universities of the region,
- some 630 veterinary surgeries or clinics practising diagnostic radiology;

#### ■ activities associated with the transport of radioactive substances;



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#### ■ ASN-approved laboratories and organisations:

- 7 laboratories approved for taking environmental radioactivity measurements,
- 7 organisations approved for measuring radon,
- 4 organisations approved for radiation protection controls.

ASN considers that the level of safety of Atalante is satisfactory on the whole, particularly regarding the management of the waste zoning plan and the monitoring of outside contractor activities. The measures taken in 2022 have improved the static and dynamic containment of the BNI. A working group has been set up on the subject of piercing of gloves, with an action plan that will be applied within Atalante.

## Assessment of the CEA Marcoule centre

ASN considers that the level of nuclear safety and radiation protection of the CEA Marcoule centre is on the whole satisfactory.

The organisation of outside contractor monitoring must be improved, particularly to clarify the distribution of monitoring actions between the Marcoule centre and the BNIs and improve the sharing of Operating Experience Feedback (OEF) between the CEA centres.

The organisation of on-site transport operations and the application of the on-site transport rules are robust. ASN has observed an improvement but will remain attentive to the measures taken for transport package maintenance.

ASN has authorised the setting up of the CEA Marcoule radiation protection skills centres under Articles R. 593-112 of the Environment Code and R. 4451-113 of the Labour Code, along with the General Operating Rules (RGEs) of the CEA Marcoule. The organisational provisions regarding radiation protection observed in inspections are satisfactory on the whole; ASN will be attentive to the emergency situation organisation of the radiation protection, particularly where duties necessitating service continuity are involved.

In 2020, the CEA submitted its study on the sanitary and environmental evaluation of the liquid and gaseous chemical discharges from the Marcoule platform, for which ASN has requested complementary information. An ASN resolution concerning the requirement for a third-party expert assessment of this study shall be formalised.

## 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 spent fuel and equipment continued in 2022 in accordance with the ASN requirements and the licensee's commitments made during the facility's periodic safety review, which was completed in 2012, and the transition to the decommissioning phase.

Uncertainties as to the future and the processing of the spent fuel from Phénix nevertheless remain (see chapter 11 – "Fuel cycle").

ASN considers that the level of nuclear safety and radiation protection of the Phénix NPP is satisfactory on the whole, particularly with regard to waste management, deviation management, organisation for tracking ongoing worksites and meeting commitments. Improvements are however expected in the management of accident-situation instructions, particularly for their periodic review and their integration in the modification process.

A significant event concerning the falling of a shock-absorbing device in a cell further to a safety culture deficiency was rated level 1 on the INES scale.

Construction of the NOAH facility, which will treat some of the sodium from Phénix and other CEA facilities, progressed in 2022 with the continuation of the pre-commissioning operating tests.

The reference decommissioning scenario for the facility, defined in the Decommissioning Decree of June 2016, is currently being redefined by the licensee, in line with the decommissioning strategy for all the CEA facilities. The licensee moreover submitted the conclusions of its periodic safety review on 26 October 2022.

## Diadem facility – CEA centre

The Diadem facility, currently under construction, shall be dedicated to the storage of containers of radioactive waste from decommissioning emitting beta and gamma radiation, or waste rich in alpha emitters, pending construction of facilities for the disposal of long-lived waste (LLW) or LL/ILW-SL whose characteristics – especially the dose rate – mean they cannot be accepted in their present state by the CSA.

In 2022, the CEA continued the procedures initiated further to ASN's findings in 2021 to improve the exercising of its responsibilities as nuclear licensee, its project management and the handling of deviations.

ASN considers that the organisation in place for the powered-on qualification tests of the facility's electrical equipment is on the whole satisfactory.

ASN emphasises that this facility is destined to play a key role in the CEA's overall decommissioning and waste management strategy, and that it is the only facility planned for the interim storage of the waste packages it is to receive.

The CEA filed a request to modify the Creation Authorisation Decree in 2021 further to change in the package closure technology. It also filed its commissioning authorisation application file for the facility in 2021. The operations necessary for its effective commissioning, which corresponds to reception of its first radioactive waste package, must be a priority for the CEA.



## 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 satisfactory in the field of fire risk management and broadly satisfactory in the fields of operational control and waste management. ASN also observes an improvement in the extent to which the regulatory baseline requirements for pressure equipment are assimilated.

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.

In addition, for several years now the licensee has had difficulties in producing the planned quantities of fuel in accordance with the safety specifications of the nuclear reactors. This situation results in the production of a large quantity of fabrication rejects which are sent to La Hague for interim storage, leading in the short term to the site's plutonium storage areas being filled to maximum capacity. These difficulties could have major consequences for the "fuel cycle" as a whole and for French nuclear power production.

This situation induces significant maintenance needs at Melox, which have consequences in terms of radiation protection,

with a growing reliance on outside contractors and a very high collective dosimetry.

An ASN inspection conducted on these themes revealed that the increase in the maintenance operations had led to a significant increase in waste production, leading in turn to a risk of saturating the local storage capacities.

In 2022 the licensee qualified a new uranium oxide powder which should normally bring a reduction in the quantity of rejects. The industrial production of this new type of powder requires the creation of a new facility on Orano's Malvési site (see chapter 11 – "Fuel cycle").

The other solutions deployed to lastingly improve this situation in the facility consist firstly in thoroughly cleaning the glove boxes to reduce the ambient dose levels, and secondly in deploying a major maintenance programme with the aim of restoring the level of availability of the production tools. Furthermore, the programme to repair the machines, baptised "PPRM" project, continued in 2022. An inspection on these themes was carried out in 2022 and found that the resources and areas of work engaged by Orano Recyclage should resolve the facility's production and maintenance difficulties.

The construction of the emergency centre should be completed shortly, allowing the building to be commissioned in 2023, as prescribed by ASN.

## Centraco plant

The Centraco plant (BNI 160), was created in 1996 and is operated by Cyclife France, a 100% subsidiary of EDF. The purpose of the Centraco plant is to sort, decontaminate, reuse, treat and package – particularly by reducing their volume – waste and effluents with low and very low levels of radioactivity. The waste resulting from the plant's processes is then routed to Andra's CSA repository. The facility comprises:

- a melting unit, melting a maximum of 3,500 tonnes of metallic waste per year;
- an incineration unit, in which the incinerable waste is burned, with a maximum of 3,000 tonnes of solid waste and 2,000 tonnes of liquid waste per year;
- and storage areas.

ASN considers the level of safety of the facility to be broadly satisfactory, particularly as regards the management of transport and of aging. Waste management, for its part, must undergo radical changes in order to meet the storage deadlines defined in the baseline safety requirements. ASN also conducted an inspection concerning the BNI's periodic safety review.

Furthermore, Cyclife France sent ASN modification requests for its facility in 2020 to allow the treatment of particular types of waste in Centraco with specific sorting put in place for this waste. ASN considers that the technical and organisational

provisions presented by the licensee for this prior sorting operation in dedicated units are satisfactory in principle, but double-checking of the conformity of the waste introduced into the incineration or melting furnaces must be maintained. ASN thus modified the requirements of its resolution 2008-DC-0126 of 16 December 2008 through resolution CODEP-CLG-2022-003400 of 19 January 2022.

In March 2022, Cyclife submitted a noteworthy modification application file with the aim of creating a VLL asbestos waste processing facility in order to be able to treat waste from the decommissioning of Chinon A. This file, which is currently being examined by ASN, provides for the creation of a new facility baptised "asbestos facility" allowing the sorting of bags of asbestos waste before repackaging.

The investigations conducted following the discovery of a waste item having exceeded its storage deadline, which formed the subject of a significant event report to ASN in July 2022, revealed numerous other waste items whose storage duration exceeds the time stipulated in the facility's Creation Authorisation Decree. This led the licensee to deploy an action plan to conduct an in-depth review of its technical and organisational arrangements for managing its waste in the facility. The implementation of this action plan and the meeting of the commitments made shall be checked by ASN.



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## Gammatec ioniser

The Gammatec ioniser (BNI 170) is an industrial irradiator operated by the company Stéris 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 cobalt-60 which provide the radiation necessary for the facility's activity.

The level of safety and the control of source security are broadly satisfactory in 2022. Improvements must be made in formalising the documentation.

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## Écrin facility

The Écrin facility, BNI 175, is situated in the municipality of Narbonne in the Aude *département*, within the Malvésí 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 entire plant is subject to the system governing Seveso high-threshold Installations Classified for Protection of the Environment (ICPEs).

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 traces of artificial radioisotopes. This BNI was authorised by Decree of 20 July 2015 for the storage of radioactive waste for a period of 30 years.

The works defined in the Decree of 20 July 2015, which began in 2019, continued in 2022 with the transfer of materials to the vault baptised "PERLE", a French acronym standing for "Project for Reversible Lagoon Storage in the Écrin BNI"), excavated to the south of basin B2.

An unannounced inspection held in July 2022 confirmed that the monitoring of the facility and the state of the worksite remain satisfactory. ASN considers that the level of safety and environmental protection remains satisfactory in view of the risks the facility presents.



# Pays de la Loire

## REGION

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.

In 2022, ASN carried out 62 inspections, comprising 2 inspections in the facilities of the company Ionisos (Pouzauges and Sablé-sur-Sarthe), 3 inspections of approved organisations, 4 in the transport of radioactive substances and 53 in small-scale nuclear activities (31 in the medical sector and 22 in the industrial, research and veterinary sectors).

Three significant events in the industrial sector and one in the transport sector were rated level 1 on the INES scale in 2022.

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

### Ionisos irradiator

The company Ionisos operates two industrial ionisation installations on the sites of Pouzauges (Vendée *département*) and Sablé-sur-Sarthe (Sarthe *département*). These installations constitute BNI 146 and 154 respectively

The gamma radiation emitted is used to sterilise, destroy pathogenic germs or 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 operation of the Pouzauges and Sablé-sur-Sarthe irradiators is generally satisfactory in terms of nuclear safety and radiation protection, with improvements in the management of waste and emergency situations. Improvements must nevertheless be made in equipment monitoring and maintenance. Two modifications to the Pouzauges facility and one modification to the Sablé-sur-Sarthe facility were authorised in 2022, concerning the extension of the use of certain radioactive sources aged more than 10 years.

### 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 field:

- 7 external-beam radiotherapy departments,
- 2 brachytherapy units,
- 12 nuclear medicine departments,
- 39 centres performing fluoroscopy-guided interventional procedures,
- 56 computed tomography scanners,
- 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,
- 36 industrial radiography companies, including 10 performing gamma radiography,
- 18 research units,
- about 400 users of industrial equipment;



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#### ■ activities associated with the transport of radioactive substances;



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#### ■ ASN-approved laboratories and organisations:

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



# Provence-Alpes-Côte d'Azur REGION

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.

In 2022, ASN carried out 131 inspections in the Provence-Alpes-Côte d'Azur region, comprising 63 inspections in BNIs, 63 in small-scale nuclear activities, 2 in the transport of radioactive substances and 3 concerning organisations and laboratories approved by ASN.

During 2022, 3 significant events rated level 1 on the INES scale were reported by the nuclear installation licensees, 1 of which related to on-site transport.

In small-scale nuclear activities, 5 significant events rated level 1 on the INES scale were reported to ASN, 3 in the industrial sector and 2 in the medical sector.

## CADARACHE SITE

### CEA's centre in Cadarache

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 CEA's strategy for decommissioning and management of radioactive materials and waste.

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 research reactor (BNI 42);
- 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 Minerve research reactor (BNI 95);
- 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.

At the Cadarache centre, 10 installations are in final shutdown status, 10 are in operation and one is under construction. The CEA Cadarache centre operates numerous installations which vary in their nature and their safety implications. ASN has moreover started or is continuing the examination of the periodic safety review guidance files or the concluding reports for 14 of the 21 installations: Pégase-Cascad, Cabri, STE, ATPu, Éole, MCMF, LPC, LECA-STAR, Phébus, Lefca, Minerve, Cedra, Magenta and Agate, and has issued its conclusions on the periodic safety review of Chicade and the STD. 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

The Pégase reactor (BNI 22) entered service on the Cadarache site in 1964 and was operated for about ten years. The 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.

As part of the decommissioning preparation operations, the CEA submitted two authorisation application files to ASN in June 2021 concerning the setting up of the project for removal from storage of the araldite-encapsulated fuels of Pégase, for transfer to the Cascad facility, known by its French acronym "DECAP". The DECAP project was authorised in August 2022 by resolution CODEP-DRC-2022-033330 (see chapter 13 – "Decommissioning of Basic Nuclear Installations"). In July 2022, as part of this project, the CEA also sent ASN a request for the acceptance of fuel cans stored within the bounds of

the Cadarache DBNI and which originally came from the Pégase pool. This request led ASN to initiate a process to amend resolution CODEP-CLG-2017-006524 amended relative to the removal from storage operations on the Pégase facility. This amendment will be subject to public consultation in 2023.

ASN considers that the nuclear safety and radiation protection of the Pégase and Cascad facilities for 2022 is on the whole satisfactory. ASN found the worksite organisation to be satisfactory. The actions resulting from the periodic safety review are followed correctly. ASN will nevertheless remain attentive to the consistency between the baseline requirements applicable to the facilities and the progress of the decommissioning preparation operations, as well as to the management of fuel storage capacity saturation in the Cascad facility.

### 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 PWR. Since January 2018, the CEA has been conducting a programme of tests called “CIP” (Cabri International Program), which began in the early 2000's and necessitated substantial modification and safety upgrading work on the facility.

ASN examined the safety of the reactor taking into consideration the action plan and the compensatory measures proposed by the CEA to deal with the two leaks reported in September 2020 and February 2021. It authorised the resumption of the CIP programme tests by resolution CODEP-MRS-2022-022299 of 9 June 2022, after the repair of the fault found on the “core water” system. The licensee has undertaken to provide feedback before 31 October 2023 on the implementation of the compensatory measures which consist in reinforcing monitoring of the condition of the faults still present on the hodoscope.

Decree 2022-1108 of 2 August 2022 amending Creation Authorisation Decree 2006-320 of 20 March 2006 has also been signed by the Minister responsible for nuclear safety, further to ASN's approval. This Decree amendment extends the scope of activities of the facility to include the performance of irradiation tests on electronic components.

ASN considers that the level of nuclear safety and radiation protection of the facility is on the whole satisfactory. The licensee has duly taken into account and dealt with some of the faults detected on the various reactor equipment items. Authorisation requests are currently being examined to address the residual defects of the hodoscope and therefore restore a completely normal situation. In this context, the licensee has taken into account ASN's requests for additional information on reactor operational control in accident situations.

## THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

### ■ Basic Nuclear Installations:

- the CEA Cadarache research centre which counts 21 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 ioniser;

### ■ small-scale nuclear activities in the medical field:



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- 13 external-beam radiotherapy departments,
- 3 brachytherapy departments,
- 16 nuclear medicine departments,
- 104 centres performing fluoroscopy-guided interventional procedures,
- 92 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 21 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,
- 4 organisations approved for measuring radon,
- 5 organisations approved for radiation protection controls.

### Rapsodie research reactor – CEA centre

The Rapsodie reactor (BNI 25) is the first sodium-cooled fast-neutron reactor 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.

At present the core has been unloaded, the fuel evacuated from the installation, a large part of the fluids and radioactive 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 a new perimeter for the facility and regulates, until 2030, the next phase of reactor life, consisting in treating the sodium from the reactor and introducing air into the tank containing it. An authorisation application file will be submitted to ASN for the reactor vessel washing operation. The subsequent decommissioning operations, such as decommissioning of the reactor block or of the civil engineering structures, shall be covered by an update of the decommissioning file.

The decommissioning work during 2022 consisted in characterising, repackaging and removing waste, and starting the preparatory work for renovation of the polar crane of the reactor building.

ASN considers that the level of nuclear safety and radiation protection of this facility in 2022 is broadly satisfactory, particularly with regard to fire protection, emergency management and the monitoring of outside contractors, an area in which the licensee has progressed by taking into account the lessons learned from the significant event reported in 2021 concerning an outside contractor employee.

### **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 the 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.

The continued operation of the STD is conditional on the performance of renovation work – particularly civil engineering works – prescribed by ASN Chairman's resolution CODEP-CLG-2016-015866 of 18 April 2016. ASN authorised these works on 20 January 2022. The CEA was unable to meet the prescribed work completion deadline in 2021, which has been pushed back to 30 June 2028. The preparatory work for this renovation started in late 2022.

The licensee submitted its periodic safety review report in March 2022, and an inspection was carried out on this subject in July 2022. Tracking and execution of the action plan stemming from the periodic safety review is satisfactory on the whole.

ASN considers the level of safety of the STD to be broadly satisfactory, particularly with regard to contractor monitoring and modification management, which has improved. Fire protection, however, must be monitored rigorously, and improvements are expected in the defining of the specified requirements for the Protection Important Components (PIC) necessary for the constitution of the waste packages. In addition, radiation protection management is unsatisfactory. In effect, measures such as displaying temporary modifications in radiation protection zoning, in temporary waste zoning or the application of instructions established inside these zones are either not carried out or they lack stringency.

### **Active Effluents Treatment Station**

– CEA centre

The STE (BNI 37-B) has been shut down since 1 January 2014. The CEA submitted the decommissioning file for this facility in December 2021.

During decommissioning preparation, the licensee characterised the soils and equipment to determine the initial radiological status of the facility. This characterisation work revealed the presence of artificial radionuclides outside the identified contaminated areas and in the stormwater network. These contaminations have again formed the subject of significant event reports to ASN in 2021 and 2022, despite the implementation of an action plan to improve stormwater management, whose effectiveness is monitored by the CEA. In view of the first results and the new significant event reports, this action plan will be continued and will be supplemented in 2023.

ASN conducted an in-depth inspection concerning the facility decommissioning project in 2022. It observed a positive dynamic in the management of the decommissioning. However, the schedule must be put to the test to determine possibilities of reducing the time frames proposed in the decommissioning file.

ASN considers that the standard of nuclear safety of BNI 37-B remains broadly satisfactory in 2022 but the licensee must improve the management of the zones with legacy radiological contamination. ASN has observed improvements in the monitoring of outside contractors.

### **Plutonium Technology Facility and Chemical Purification Laboratory**

– CEA centre

The 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 fuel. The activities of the 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.

The operations associated with monitoring, upkeep and operation, management and monitoring of solid waste and liquid effluents (characterisation, grouping, removal) continued and enabled the dispersible inventory of the two facilities to be reduced.

With regard to the ATPu, in accordance with the last schedule proposed by the CEA in November 2020, all the campaigns for processing the drums containing alpha emitting radionuclides from BNI 56 are now finished.

With regard to the LPC, several glove boxes have been decommissioned. The HV/LV substation has been moved, in connection with the modification of the utilities needed during the BNI decommissioning phases. The cryogenic treatment process removal work also continued.

The inspections conducted in 2022 focused mainly on the static and dynamic containment, on the management of waste in the ATPu and on performance of the periodic safety



review in the LPC. The methods of waste removal were also inspected. ASN considers that the level of nuclear safety of the installation on these subjects is broadly satisfactory.

In October 2022, the licensee reported a significant event rated level 1 on the INES scale that occurred within the LPC, concerning a safety culture deficiency in an employee of the Risks Prevention Service (SPR) of the CEA Cadarache centre, for noncompliance with controlled area access requirements. ASN will check the implementation of the actions proposed by the licensee to prevent the recurrence of this type of event. The methods of controlling accesses to controlled areas at the CEA shall be examined.

### **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 and removal of conventional equipment. At the end of 2021, all the fertile materials had been transferred to the centre's materials storage facility and the ventilation network had been simplified. A provisional building, whose construction was completed in 2022, was built to accommodate the VLL waste from the operations prior to decommissioning.

The licensee has made progress in the management of deviations, which are subject to rigorous tracking. ASN considers that the standard of nuclear safety in 2022, particularly concerning fire protection and decommissioning work, and of radiation protection, is satisfactory on the whole.

### **Éole and Minerve research reactors**

– CEA centre

The experimental reactors Éole and Minerve are very-low-power (less than 1 kW) 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.

The decommissioning files for BNIs 42 and 95, submitted by the CEA in 2018, underwent a public inquiry during October 2022 with a view to preparing the decommissioning decrees.

ASN considers that the standard of safety of BNIs 42 and 95 is broadly satisfactory, but the monitoring of outside contractors must be improved.

The inspection conducted in 2022 showed that the organisational provisions for monitoring the action plan stemming from the periodic safety review are robust, with good coordination between these actions, the ongoing decommissioning preparation operations and the BNI functioning operations. This being said, the feedback from the actions implemented further to the periodic safety review must be better formalised.

### **The Enriched Uranium Processing Facilities – CEA centre**

From 1963 to 1995, the ATUe (BNI 52) converted uranium hexafluoride (UF<sub>6</sub>) from the 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 decree in February 2006.

The licensee had fallen substantially behind the initial schedule in the decommissioning operations. It requested a modification of its decree in 2010 and 2014, to take account of the true radiological status of the facility. The new Decommissioning Decree was published on 16 April 2021. ASN has regulated the performance of certain decommissioning operations by two resolutions of 14 October 2021. In 2022, the licensee was authorised to update its baseline requirements further to the publishing of the BNI Decommissioning Decree. The activities in the facility today are essentially maintenance and periodic and regulatory inspection operations. The decommissioning operations will thus be able to begin.

Most of the actions stemming from the periodic safety review of 2017 have been completed, with the exception of the roof sealing work, which is planned for 2023.

### **Central Fissile Material Warehouse**

– CEA centre

Created in 1968, the 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. The licensee submitted its decommissioning file in November 2018, and ASN is currently examining it.

The public inquiry concerning the MCMF decommissioning application file was held from 26 September 2022 to 28 October 2022.

The decommissioning preparation operations initiated in 2018, notably the chemical and radiological characterisations of the facility, continued in 2022. ASN considers that the licensee's organisational measures for monitoring these preparation operations are on the whole satisfactory.

### **High-Level Activity Laboratory LECA-STAR – CEA centre**

BNI 55 accommodates the LECA laboratory and its extension STAR, which constitute the CEA's expert assessment facilities for the analysis of 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 guidance file for the next periodic safety review (DOR) of LECA was submitted by the CEA in January 2022.

In March 2022, the licensee reported a significant event rated level 1 on the INES scale following the discovery of a fuel storage can that was not in conformity with the criticality risk management rules, in a storage well of cell C5 of the LECA laboratory. An assessment of the cans stored in cell C5 was carried out before resuming the activities, which was authorised by the head of the BNI. Documentary searches for all the dimensional characteristics of the cans in multi-sector wells and inspection operations with opening of wells shall be carried out.

Commissioned in 1999, the STAR facility is an extension of the LECA laboratory, designed for the stabilisation and reconditioning of spent fuel.

The CEA sent ASN the STAR periodic safety review report in February 2018 and its commitment letter in February 2021, on both of which ASN shall issue position statements. The CEA added the STAR impact study to its file in December 2021, pursuant to ASN resolution 2017-DC-0597 of 11 July 2017. In 2022, ASN asked the licensee for additional information on the assessment of the sum of the impacts of the operation of LECA-STAR with the Cadarache platform and the other facilities existing or approved under Article R. 122-5 of the Environment Code.

ASN considers that in 2022 the level of nuclear safety of the LECA-STAR facility is broadly satisfactory, particularly with regard to waste management within the facility and monitoring of outside contractors.

The monitoring of atmospheric discharges from BNI 55 must be improved. ASN expects the Cadarache site to comply with the site's discharges resolution in order to ensure redundancy of the continuous samplings taken at the gas outlets.

## 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.

The CEA continued its WRP operations in the BNI in accordance with the schedule presented at the start of the year. The fitting out and the active tests with radioactive materials have enabled the video inspections of pit 1 to begin, and the clean-up work on the extraction cell of trench T2 has been carried out.

ASN considers that in 2022 the management of static and dynamic containment and the conditions of the systems are satisfactory on the whole. ASN has more specifically observed improvements in the tracking and traceability of the modification work. ASN will nevertheless be attentive to compliance with the new deadlines set for retrieval of the stainless steel "intermediate-level waste" packages from pit 6, and to the management of the BNI's stormwaters.

## Phébus research reactor – CEA centre

The Phébus reactor (BNI 92) is an experimental pool-type reactor with a power rating of 38 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.

The licensee submitted its decommissioning file to the Minister on 14 February 2018 and its periodic safety review report to ASN in October 2017. This file is being examined concomitantly with the decommissioning application. The public inquiry concerning the decommissioning application for the facility was held in October 2022 after the Environmental Authority had issued its opinion in July 2021.

Since December 2021, all the fuel has been removed in accordance with the priority objectives of the decommissioning preparation operations.

ASN considers that the standard of nuclear safety of the facility in 2022 is satisfactory, particularly concerning the monitoring of outside contractors.

## Laboratory for research and experimental fabrication of advanced nuclear fuels

– CEA centre

Commissioned in 1983, 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.

The CEA submitted the final shutdown declaration for the facility in April 2019. In December 2021, the CEA informed ASN of its decision to keep the Lefca facility in operation and conduct new activities in it. An action plan with a consolidated schedule was sent to ASN in January 2022. The forthcoming periodic safety review must integrate this change of strategy. On this account, the CEA submitted the facility's guidance file in March 2022, with this continued operation in mind.

ASN considers that the standard of nuclear safety of the facility in 2022 is satisfactory on the whole, particularly concerning the monitoring of outside contractors. The licensee must nevertheless improve its fire protection measures. ASN has also noted areas for progress in the installation and signalling of fire-fighting equipment. The deviations observed in 2021 in the conformity and integrity of the facility's piezometers for monitoring the groundwater tables were either corrected in 2022 or are currently undergoing remedial action.

### **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.

ASN considers that the level of safety and radiation protection is satisfactory on the whole, particularly with regard to waste management and meeting commitments. Improvements in the management of radioactive waste are currently being implemented, particularly as regards the collection, storage and removal of the radioactive samples produced by the facility.

Further to the examination of the periodic safety review concluding report, ASN has set technical requirements aiming to regulate the continued operation of the facility in resolution CODEP-MRS-2022-004859 of 29 August 2022.

Resolution CODEP-DRC-2022-001529 of 19 September 2022 authorises the licensee to package the disused sealed sources in "870L Bulk Source" packages. This resolution will enable the CEA to carry out a characterisation programme on packages of controlled composition and thereby improve and qualify certain characterisation techniques, and enhance the understanding of the corrosion and radiolysis phenomena within radioactive waste packages.

### **Cedra storage facility** – CEA centre

Since 2006, the Cedra facility (BNI 164) is used to store ILW-LL pending the creation of appropriate disposal routes. The CEA forecasts that this facility will be filled to capacity by 2027. The studies concerning a project to double the storage capacity began in 2020.

ASN considers that the licensee's verifications regarding the monitoring of outside contractors and the meeting of its commitments are satisfactory on the whole. Improvements are expected in management of the fire risk and maintaining the appropriate technical skills and qualifications necessary for operation of the facility.

Due to the CEA's desire to stagger the filing of the conclusions of the periodic safety reviews of its facilities over time, it submitted the concluding report for the periodic safety review of Cedra in November 2022, ahead of schedule.

### **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.

The licensee submitted its safety review conclusion report in February 2021. In 2022, the licensee supplemented this file at the request of ASN and a dedicated inspection was carried out. Shortcomings were found in the conformity check and areas for improvement in action plan monitoring were identified.

An authorisation application file for the densification of storage of certain types of package in the facility was submitted to ASN in January 2022. This file is currently being examined by ASN.

The CEA confirmed the need to commission the Magenta glove boxes, planned for at the design stage but not yet authorised, by 2028/2030.

ASN considers that the level of nuclear safety and radiation protection of the facility in 2022 is on the whole satisfactory, primarily concerning protection of the environment.

### **Effluent advanced management and processing facility** – CEA centre

The Agate facility (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.

ASN considers that the licensee has competently managed the repair work on the superheated non-radioactive water pipe, on which a leak was detected in December 2020. This repair enabled the facility's evaporator to be returned to service in the first quarter of 2022.

ASN sent the CEA its opinion on the periodic safety review guidance file on 25 April 2022. The consequences of the planned changes to the facility must thus be taken into consideration in the concluding report of the facility's first periodic safety review, to be submitted by 29 April 2024 at the latest.

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 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 activities on the construction site and on the suppliers' sites continued in 2022. The work has more specifically concerned lining of the pools and channels of the nuclear auxiliaries building, installation of the door or gate equipment and the hot cells. Numerous in-plant manufacturing operations are in progress.

The CEA continued the studies and analyses concerning the problems detected in 2020 during the qualification tests of certain internal equipment items of the reactor pile block. The expert assessment of the RER pool, displaying signs of corrosion on a weld, was completed and appropriate corrective actions have been defined.

## Assessment of the CEA Cadarache centre

ASN considers that the level of nuclear safety of the CEA Cadarache centre in 2022 is on the whole satisfactory.

ASN considers that the BNIs are operated satisfactorily on the whole, especially modifications management and the meeting of commitments. Improvements are nevertheless expected in the performance and traceability of the technical verifications of maintenance operations and monitoring of the condition of Protection-Important Components, and in the indication of their specified requirements. The monitoring of outside contractors has improved compared with the previous situation, and this progress must be consolidated.

The majority of the outside contractors are subject to monitoring which is framed and formalised by a specific plan. These monitoring plans are broadly followed and applied by the licensee, which is good. A periodic assessment of monitoring appropriateness and effectiveness is now carried out on some but not all of the facilities.

With regard to the containment of radioactive substances, the situation is satisfactory on the whole, but improvements are still to be made in defining the monitoring of certain barriers.

ASN observes that deviation management remains contrasted. In effect, improvements are required in certain services concerning in the analysis of the causes or trends relating to recurrent deviations of similar types.

ASN considers that the organisation in place for the re-assessment and the conformity check of the periodic safety reviews of the facilities is satisfactory. The tracking of action plan implementation is satisfactory on the whole.

With regard to emergency situation management, the licensee has asked for a further extension to the commissioning deadline for the emergency centre that can withstand extreme hazards, further to the difficulties in completing this project. ASN underlines the importance of this centre in the licensee's emergency organisation, and emphasises the need to keep the compensatory measure proposed by the CEA operational pending the availability of an emergency centre capable of withstanding extreme hazards.

The licensee must verify and periodically assess the relevance of the instructions for accident, incident and degraded operating modes. This is because inconsistencies between these instructions and the reality of the facility were discovered in the

instructions tested by sampling in inspections in the course of the year.

With regard to radiation protection, ASN authorised setting up of the CEA Cadarache radiation protection skills centres under Articles R. 593-112 of the Environment Code and R. 4451-113 of the Labour Code.

In the area of waste management, the management of deviations and the traceability of waste monitoring are satisfactory on the whole, but can be improved in certain cases, notably for the legacy waste for which there is no immediate disposal route. The licensee must define action plans to treat and remove the legacy waste which cannot be removed immediately.

ASN observes that the level of environmental protection is relatively satisfactory. A polluted sites and soils management procedure must be applied to the historically contaminated areas of the Cadarache site. This procedure must define and prioritise the management actions as appropriate for the current and future uses of the areas concerned. Improvements are also required in the upkeep and appropriateness of the hazardous substance retention structures and the maintaining of measurement redundancy on the discharges for which monitoring is required.

During its inspections in 2022, ASN noted the rigour applied by the project teams in the investigations into the signs of corrosion and the overall organisation of the worksite. The handling of the manufacturing irregularities in a plant in Portugal and of the modified material certificates was also deemed appropriate and satisfactory.

ASN considers that the organisation in place for construction of the JHR remains satisfactory and that the project is managed rigorously with a commitment to transparency.

## ITER

The ITER installation (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.

The works on the site and the manufacture of equipment are continuing with the targeted utilisation of the first hydrogen plasma pushed back with respect to the previously announced deadline of 2025. The revised schedule, integrating the assessment of the impact of the Covid-19 pandemic, has not yet been received. A further delay was announced by ITER Organization (IO) at the end of 2022 following the discovery of fabrication defects in sectors of the vacuum vessel and stress corrosion defects on the thermal shields.

These defects will necessitate repairs on the first sector, which was lowered into the tokamak pit in May 2022, and on the two other sectors delivered to the site and currently undergoing preparation (installation of the thermal shields and the toroidal coils) in the assembly hall. The civil engineering works this year concerned several areas of the worksite, and more particularly the "Tritium building" of the "Tokamak complex". Fabrication of the cryostat elements is also completed.

In February 2022, IO sent ASN an authorisation application for water intakes and discharges of non-radioactive effluents for the facility construction phase. Complementary information will have to be provided before examination of this file can begin.

The inspections conducted on the site in 2022 showed mixed results, having revealed a lack of safety culture in the handling of certain manufacturing deviations (as is the case for example with the dimensional defects in the vacuum vessel sectors), and shortcomings in the facility's safety case (e.g. for the qualification of the electronic systems necessary for safety), and the strategy for addressing these manufacturing deviations has not yet been established.

Integrating the project developments and addressing the technical difficulties encountered will necessitate in-depth discussions between IO, ASN and IRSN. ASN emphasises the importance of the licensee providing information transparently, promptly and fully on these various subjects.

### Hold point concerning assembly of the tokamak

By Decree 2012-1248 of 9 November 2012, the International Organisation IO was authorised to create the Basic Nuclear Installation 174 called "ITER" on the municipality of Saint-Paul-lez-Durance (Bouches-du-Rhône *département*). ASN resolution 2013-DC-0379 of 12 November 2013 sets the technical requirements that govern more specifically the design and construction of this installation. Certain key stages in the construction are subject to "hold points" requiring the submission of justifications so that ASN can authorise the commencement of these stages.

On 1 February 2021, IO sent ASN a file requesting commencement of assembly of the tokamak equipment inside the cryostat<sup>(\*)</sup> as defined by the technical requirement (BNI 174-07) of the above-mentioned resolution. This stage corresponds to the third hold point since construction of the BNI began, and the regulatory time for examining these elements is set at one year, that is to say a deadline of 1 February 2022.

ASN considers that the elements provided by IO do not enable it to adopt a position on the lifting of the hold point in question. ASN has asked IO to submit a new specific file presenting the finalised design and all the demonstrations on the themes associated with the hold point for starting tokamak assembly.

The awaited justificatory and demonstration elements concern more specifically the addressing of the dimensional nonconformities found on the first vacuum vessel sectors delivered to the site, the behaviour of the civil engineering structures, or controlling the limitation of exposure of workers and the public to ionising radiation.

\* The cryostat is the vacuum enclosure that will surround the vacuum chamber and the supraconductor magnets.

## Gammaster ioniser

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 sealed sources of cobalt-60 which provide the radiation necessary for its activity.

The organisational set-up for monitoring the facility's discharges must be improved. This is because although the environmental discharges are very limited, the implementation times for certain actions must be monitored to avoid time-lags.

The measures taken by the licensee to ensure the security of sources are broadly satisfactory. Improvements must nevertheless be made in formalising the documentation.

ASN considers that the level of safety and of radiation protection and the control of source security are broadly satisfactory in 2022.



Secteur  
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ZONE CONTRÔLÉE



ACCÈS RÉGLEMENTÉ

ACCÈS RÉGLEMENTÉ

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# Nuclear activities: ionising radiation and health and environmental risks

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Ionising radiation may be of natural origin or be produced 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, bronchopulmonary cancers (owing to radon inhalation) and jawbone sarcomas. Outside the professional area, the monitoring for more than sixty years of a cohort<sup>(1)</sup> 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, and enabled the 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 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 Nuclear Power Plant (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 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).

1. Cohort: group of individuals considered together and participating in a statistical study of the circumstances of occurrence of diseases.

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*<sup>(2)</sup> 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; studies on nuclear industry workers published in recent years aim to evaluate the effects of lower doses, which cannot be excluded. They show that the relationship between the risk of death by cancer and chronic exposure at low doses is similar to that already known for doses delivered at high dose rates<sup>(3)</sup>.

These results support the justification for radiological protection of exposed populations, whatever the origin of exposure (natural radiation, medical exposure, nuclear industry, etc.).

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 on very large populations are currently underway to enrich these models.

2. Administrative region headed by a Prefect.

3. Source: Inworks study – IRSN.

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.

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 (Sv) 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<sup>(4)</sup> 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/m<sup>3</sup>) over a period of twenty to thirty years. In 2009, the World Health Organisation (WHO) recommended a reference level of 100 Bq/m<sup>3</sup>, and whatever the case to remain below 300 Bq/m<sup>3</sup>. 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 46,363). A national plan for managing radon-related risks has been implemented since 2004 on the initiative of the French Nuclear Safety Authority (ASN) and is updated periodically. The fourth plan (2020-2024) was published in early 2021 (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.

### 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), while at the same time raising ethical and societal questions.

### 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 an exposure to ionising radiation taking into account the principle of precaution. This relationship posits a risk from the first exposure. There are nevertheless many uncertainties. According to this relationship, there would be a risk from the first exposure, proportionate to the radiation dose received. 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. These same uncertainties lead some to 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.

#### 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<sup>5)</sup> 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.

### ASSESSMENT OF EXPOSURE DUE TO RADON: 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. Its publication 137 (2017) focuses on 14 radionuclides, including 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 proposes 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).

Pending updating of the regulations<sup>6)</sup>, the French Institute of Radiation Protection and Nuclear Safety (IRSN)

has assessed the consequences of adopting the new dose coefficients provided by the ICRP<sup>(\*)</sup>. These calculations lead to an average annual effective dose in France of 3.5 mSv with a variation of 0.75 millisieverts per year (mSv/year) to 47 mSv/year depending on the municipalities, with 95% of the population receiving less than 7.8 mSv/year. The average overall exposure of the population would thus increase from 4.5 mSv/year to 6.5 mSv/year, with exposure to radon representing 54% of the overall exposures compared with 33% at present.

\* Order of 1 September 2003 defining the methods for calculating effective doses and equivalent doses resulting from human exposure to ionising radiation.

\*\* Exposure of the French population to ionising radiation – Results for 2014-2019, IRSN, 2021.

5. The radioactive dose rate determines the absorbed dose (energy absorbed by the material per unit 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.

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 ova) can be transmitted to the progeny. An ICRP working group, TG121, is currently working on the subject of heritable effects and their modes of transmission to future generations.

#### 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, 124 and 148).

### 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).



Workers ("radium girls") painting the pointers of luminous dials with radium in the US Radium plant (United States Radium Corporation) in Orange, New Jersey – 1922

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 calls for a cautious approach with respect 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 66% of the total annual exposure<sup>(6)</sup>.

#### 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), 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 ( $\mu\text{Sv}$ ) for short-haul domestic flight within France to nearly 80  $\mu\text{Sv}$  for a flight from Paris to Ottawa (Canada). The average annual effective dose received by the population in France is 14  $\mu\text{Sv}$ .

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), 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.

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](http://asn.fr) and [irsn.fr](http://irsn.fr)).

Based on 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/m<sup>3</sup>. Using the dose factor of ICRP 65 currently in effect, the effective average dose per inhabitant is estimated at 1.45 mSv/year. The effective dose varies from 0.31 mSv/year to 19 mSv/year depending on the municipality. IRSN has moreover published an assessment of the consequences of the adoption of new coefficients published by the ICRP in its publication 137 (see box page 102).

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.

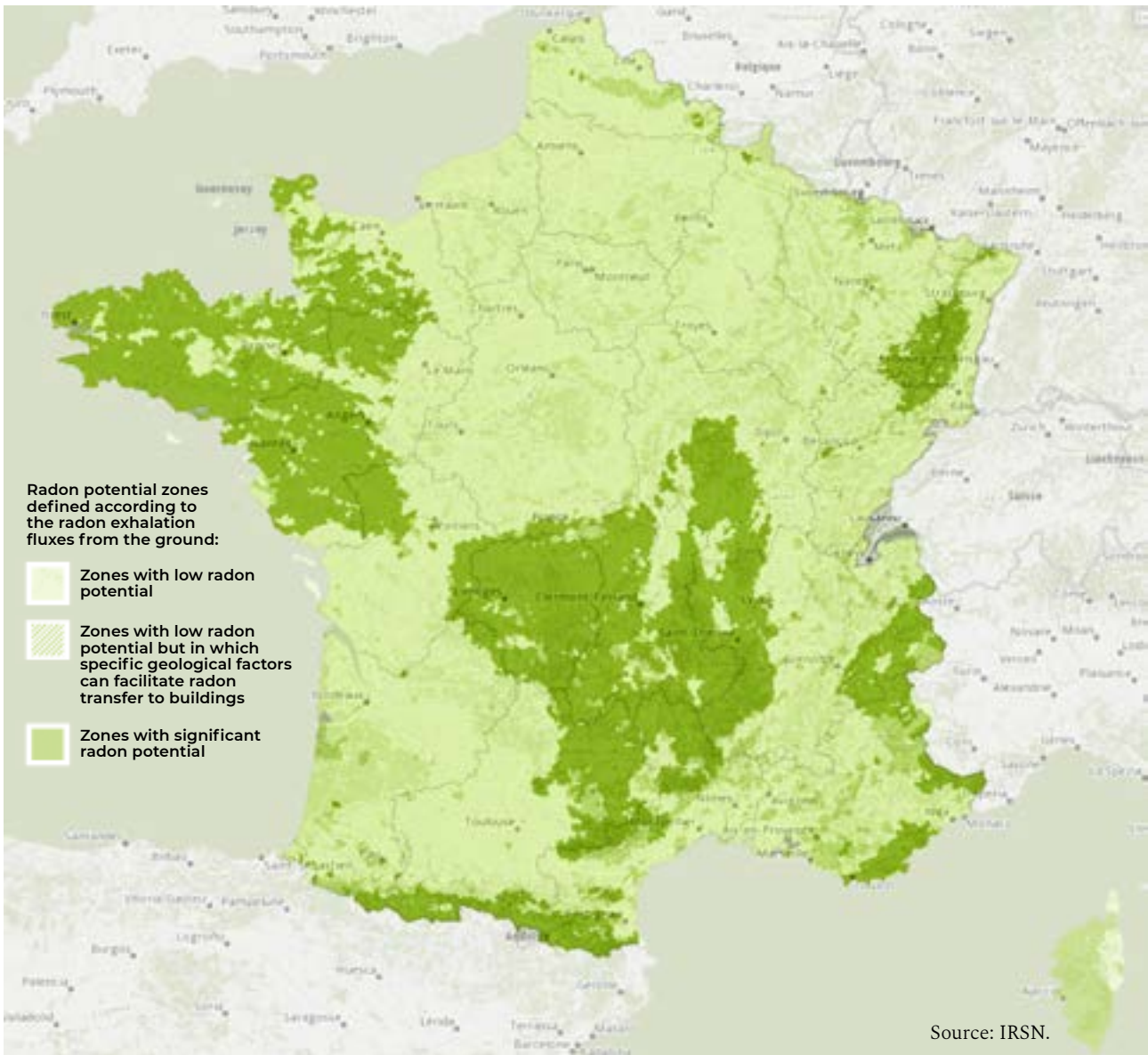
### 2.2 Ionising radiation arising from human activities

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.

6. Exposure of the French population to ionising radiation – Results for 2014-2019, IRSN, 2021.

**RADON POTENTIAL ZONES IN METROPOLITAN FRANCE DEFINED BY THE ORDER OF 27 JUNE 2018**



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**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 Basic Nuclear Installations as at 31 December 2022 figures in the 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.

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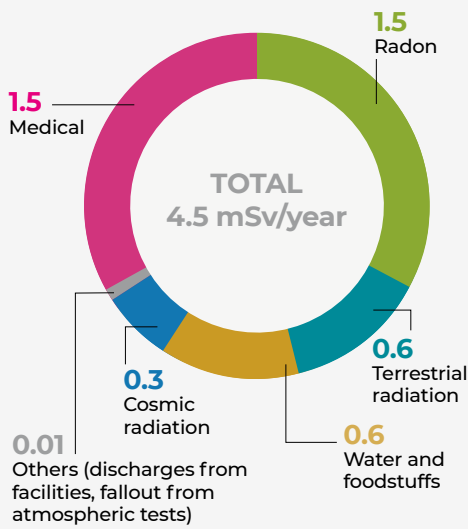
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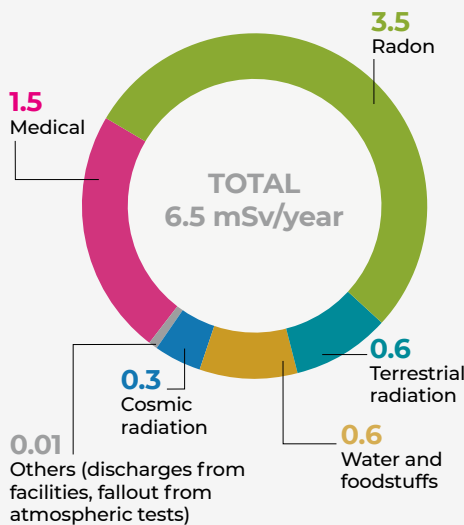
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**DIAGRAM 1A** Average exposure taking into account the radon dose coefficient provided for by the current regulations



**DIAGRAM 1B** Average exposure taking into account the radon dose coefficient recommended by ICRP publication 137



Source: IRSN, 2021.

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 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 and 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 channels for the various categories of waste likely to be produced, from the front-end phase (production of waste and its placing in packages) 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 same 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 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 of 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 4.5 mSv per person per year, but this exposure is subject to wide individual variability, 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). The average annual individual effective dose can thus vary from 1.6 mSv to 28 mSv<sup>7</sup>. The adoption of the new radon dose coefficient recommended by the ICRP (see box page 102 and point 2.1.3), will lead to an increase in the dose resulting from exposure to radon, and thus in the calculated dose relative to total average exposure which would thereby increase from 4.5 mSv to 6.5 mSv. 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, considering firstly the radon dose coefficient stipulated by the current regulations, and secondly the dose coefficient recommended by ICRP 137.

### 3.1 Doses received by workers

#### 3.1.1 Monitoring the exposure of persons working in nuclear facilities

The system for monitoring 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.

Based primarily on the mandatory wearing of passive dosimeters for workers liable to be exposed, this system enables compliance with the regulatory limits applicable to workers to be verified. 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 (month or quarter) for each worker, including those from outside contractors. They are grouped together in the Ionising radiation exposure monitoring information system (Siseri) managed by IRSN and are published annually.

The results of worker exposure to ionising radiation presented below are taken from the IRSN 2021 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 four preceding years, the IRSN 2021 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 2021 are not directly comparable with those of 2020, 2019, 2018 and 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 2021, the breakdown of the populations monitored, the collective dose<sup>8</sup> and the number of exceedances of the annual limit of 20 mSv. They show a large disparity in the breakdown of doses depending on the sector.

For example, the medical and veterinary activities sector, which accounts for a significant share of the population monitored (60%), accounts for only 12% of the collective dose; conversely, the civil nuclear industry, which represents just 22% of the headcount, accounts for 55% of the collective dose and the sector concerned by exposure to natural radioactivity, which represents only 5.5% of the total headcount, accounts for 27% of the collective dose. The non-nuclear industry and the research sectors represent 4.2% and 2.7% of the headcount respectively and account for 3.3% and 0.37% of the collective dose respectively.

7. Exposure of the French population to ionising radiation – Results for 2014–2019, IRSN, 2021.

8. For information, the collective dose is the sum of the individual doses received by a given group of persons.

SOURCES AND ROUTES OF EXPOSURE TO IONISING RADIATION

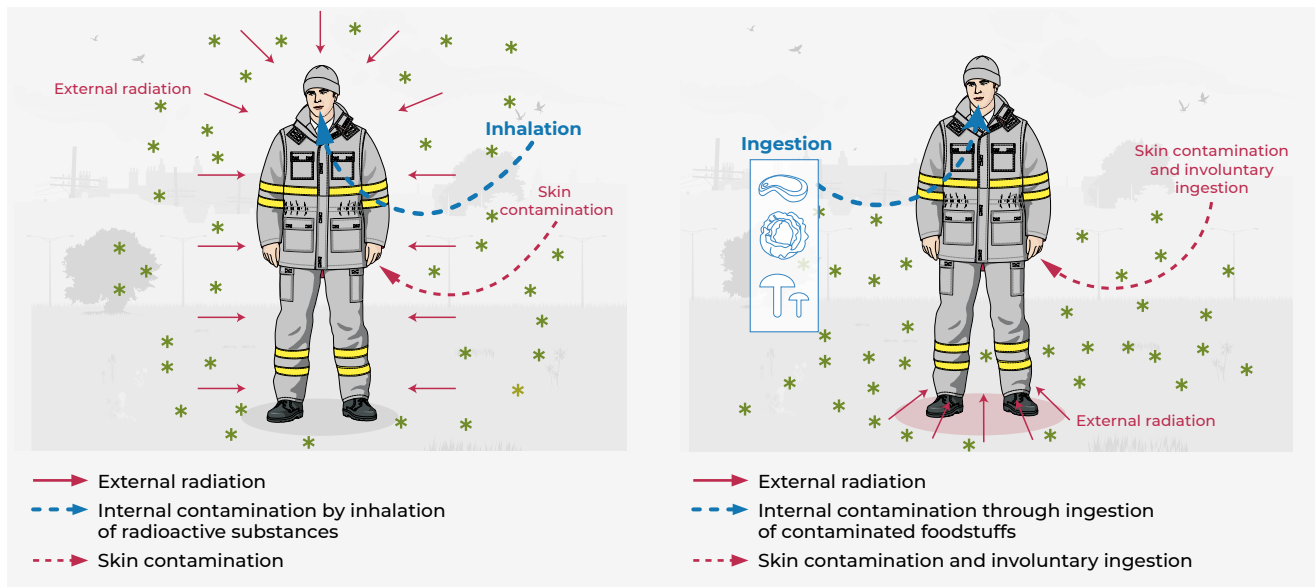


Table 3 shows that the total number of workers monitored by passive dosimetry increased by 5% between 2015 and 2021, all areas combined. At the same time, the collective dose fell by 20% over the same period to reach 82.71 man-Sv<sup>(9)</sup> in 2021. The average individual dose thus decreased from 0.98 mSv in 2015 to 0.85 mSv in 2021.

The increase in the collective dose and the average individual dose for all areas combined between 2020 and 2021 (+14% and +9% respectively) can be explained mainly by the increase in the volume of maintenance work in the nuclear sector due to the improvement in sanitary conditions linked to the Covid-19 pandemic.

For these same reasons, the average annual individual dose, which was 0.85 mSv in 2021, is 9% higher than that observed in 2020.

In 2021, one case of exceeding the regulatory whole body effective dose limit of 20 mSv was recorded in the medical field (diagnostic radiology sector). The exceedance (external exposure of 25.8 mSv over 12 sliding months) was detected during 2021 and corresponded to the accumulation of several doses between June 2020 and May 2021. It should nevertheless be noted that this case was retained by default, as the occupational physician gave no feedback on the conclusions of the investigation.

A case of exceeding the regulatory equivalent dose limit to the skin of 500 mSv was recorded in the civil nuclear sector (in the energy production power reactors sector) with an equivalent dose of 818 mSv. This equivalent dose, associated with the deposition of a radioactive fragment on the body of a worker, was estimated very conservatively given that it was impossible to determine with precision when this fragment was deposited on the worker.

With regard to the dosimetry of the extremities (fingers and wrists), 28,335 workers were monitored in 2021 (i.e. 7% of the total number of persons monitored). For the first time since 2013, no exceedance of the regulatory limit for the equivalent dose to the extremities of 500 mSv was recorded in 2021.

With regard to dosimetric monitoring of the lens of the eye, it has been increasing since 2015. It concerned 5,970 workers in 2021.

A worker in the nuclear medicine sector received a dose exceeding 50 mSv in 2021 (138.1 mSv) which, for the transitional period from July 2018 to June 2023 provided for by the regulations, constitutes an exceedance of the occupational exposure limit<sup>(10)</sup>. Furthermore, four workers (in diagnostic radiology and interventional radiology) received an equivalent dose to the lens of the eye of between 20 mSv and 50 mSv, without the five-year accumulated dose exceeding 100 mSv. The maximum recorded dose is 27.9 mSv. This value should be compared with the future regulatory dose limit for the lens of the eye of 20 mSv/year as from 2023.

To conclude, as in the preceding years, the assessment of monitoring of workers exposed to ionising radiation in France in 2021 published by IRSN in June 2022, shows the overall effectiveness of the prevention system introduced in facilities where sources of ionising radiation are used, because for nearly 94% of the population monitored, the annual dose remained below 1 mSv (effective annual dose limit for the public due to nuclear activities). The last ten years have witnessed a regular reduction in the number of most heavily exposed workers. Cases of exceeding the regulatory limit values remain exceptional (one exceedance of the annual limit of 20 mSv, one exceedance of the equivalent dose to the skin of 500 mSv and one exceedance of the equivalent dose to the lens of the eye of 50 mSv).

Monitoring of exposure of the lens of the eye with, for this tissue, compliance with the new limit, constitutes the main objective of radiation protection in the immediate years and more specifically in the area of FGIPs.

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

9. Man-Sv: unit of quantity of collective dose.

10. In the transitional period from July 2018 – June 2023, the occupational exposure limit for the equivalent dose to the lens of the eye is 50 mSv over 12 months (with a ceiling at 100 mSv over 5 years). As from July 2023, this exposure limit value will be 20 mSv over 12 months.

due to industrial process deposits (scale forming in piping for example).

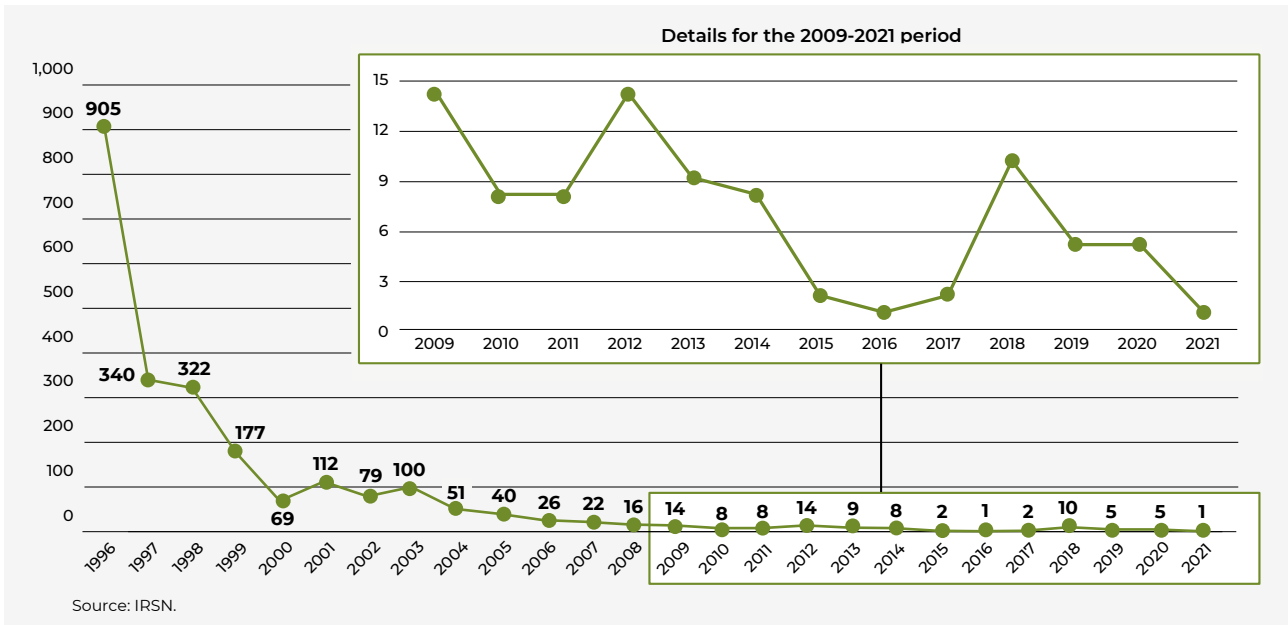
In 2021, the individual monitoring of worker exposure in industrial activities leading to exposure to substances of natural origin or to radon of geological origin (exposure to natural radionuclides of the uranium and thorium decay chains) involved about 440 workers monitored for external exposure (including 1 worker exposed to more than 1 mSv) and 339 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.

DIAGRAM 2 Changes in the number of monitored workers whose annual dose exceeds 20 mSv, from 1996 to 2021



**RESULTS OF DOSIMETRY MONITORING OF WORKER EXTERNAL EXPOSURE TO IONISING RADIATION (EXPOSURE TO NATURAL RADIOACTIVITY INCLUDED) IN 2021**

(Source: Worker radiation protection: occupational exposure to ionising radiation in France, IRSN 2021 report, June 2022)

- Total population monitored: 392,180 workers
- Monitored population for whom the annual effective dose remained below the detection threshold: 294,816 workers, i.e. more than 75%
- Monitored population for whom the annual effective dose remained between the detection threshold and 1 mSv: 72,944 workers, i.e. about 18%
- Monitored population for whom the annual effective dose remained between 1 mSv and 20 mSv: 24,419 workers, i.e. more than 6% of the total population monitored
- Monitored population for whom the annual effective dose exceeded 20 mSv: 1 worker<sup>(1)</sup>
- Monitored population for whom the equivalent dose to the extremities exceeded 500 mSv: no workers
- Monitored population for whom the equivalent dose to the skin exceeded 500 mSv: 1 worker
- Monitored population for whom the equivalent dose to the lens of the eye exceeded 50 mSv: 1 worker
- Collective dose (sum of the individual effective annual doses): 82.71 man-Sv
- Average annual individual effective dose in the population which recorded a dose higher than the detection threshold: 0.85 mSv
- Number of special monitoring examinations or verifications performed: 9,450 (of which 12% are higher than the detection threshold)
- Population having recorded a committed effective dose exceeding 1 mSv: 3 workers

**Results of monitoring of internal exposure to natural radionuclides from the uranium and thorium decay chains in 2021**

- Internal exposure:
  - collective dose for 339 workers: 85.03 man-mSv
  - average annual individual effective dose in the population which recorded a dose higher than the detection threshold: 0.39 mSv

**Results of internal exposure monitoring in 2021 (natural radioactivity excluded)**

- Number of routine examinations carried out: 232,140 (of which 0.4% were considered positive)
- Population for which a dose estimation was made: 531 workers

<sup>(1)</sup> This case was retained by default, as the occupational physician gave no feedback on the conclusions of the investigation.

As at 31 December 2021, SievertPN had transmitted to Siseri all the flight crew doses for 13 airlines having subscribed to the system, giving a total of 20,390 flight crew members monitored by this system. In 2021, nearly 49% of the individual annual doses were below 1 mSv and 51% of the individual annual doses were between 1 mSv and 5 mSv. The maximum individual annual dose was 3.98 mSv.

The collective does in 2021 is stable with respect to 2020, whereas it had dropped by 58% between 2019 and 2020 and had been increasing regularly in the preceding years. This stabilisation can be explained by the Covid-19 pandemic which led to a significant drop in air traffic, not compensated in 2021.

### 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).

**TABLE 1** Monitoring of external exposure of workers in the civil nuclear field (year 2021)

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man.Sv <sup>(1)</sup> )	INDIVIDUAL DOSE > 20 mSv
Reactors and energy production (EDF)	23,875	6.76	0
"Fuel cycle"; decommissioning	12,582	3.8	0
Transport	610	0.077	0
Logistics and maintenance (contractors)	32,702	31.26	0
Effluents, waste	800	0.12	0
Others	7,120	1.57	0
<b>Total civil nuclear</b>	<b>77,689</b>	<b>43.59</b>	<b>0</b>

\* 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 2021 report, June 2022)

**TABLE 2** Monitoring of external exposure of workers in small-scale nuclear activities (year 2021)

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man.Sv <sup>(1)</sup> )	INDIVIDUAL DOSE > 20 mSv
Medicine	164,522	7.67	1 <sup>(1)</sup>
Dental	46,200	1.61	0
Veterinary	23,562	0.54	0
Industry	16,670	2.77	0
Research and education	10,854	0.31	0
Natural (**)	21,424	22.63	0
<b>Total small-scale nuclear activities</b>	<b>283,232</b>	<b>35.53</b>	<b>1</b>

(1) This case was retained by default, as the occupational physician gave no feedback on the conclusions of the investigation.

\* 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 2021 report, June 2022)

**TABLE 3** Development of number of persons monitored and average collective and individual doses in the exposed population from 2015 to 2021<sup>(1)</sup> 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 <sup>(1)</sup>	372,881	352,641	104.41	65.61	0.98	0.76
2016 <sup>(1)</sup>	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

\* 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 2021 report, June 2022)



TABLE 4 Radiological impact of BNIs since 2016 calculated by the licensees on the basis of the actual discharges from the installations and for the most exposed reference groups (data provided by the nuclear licensees)

LICENSEE/SITE	REFERENCE GROUP MOST EXPOSED IN 2021	DISTANCE TO SITE IN km	ESTIMATION OF RECEIVED DOSES, IN mSv <sup>(a)</sup> (the values calculated by the licensee are rounded up to the next higher unit)					
			2016	2017	2018	2019	2020	2021
Andra / CSA	Multi-activity group Ville-aux-Bois	1.7	2.10 <sup>-6</sup>	2.10 <sup>-6</sup>	3.10 <sup>-7</sup>	3.10 <sup>-7</sup>	4.10 <sup>-7</sup>	3.10 <sup>-7</sup>
Andra's Manche repository	Hameau de La Fosse	2.5	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	1.10 <sup>-4</sup>
CEA / Cadarache <sup>(b)</sup>	Saint-Paul-lez-Durance	5	<2.10 <sup>-3</sup>	<2.10 <sup>-3</sup>	<3.10 <sup>-3</sup>	<2.10 <sup>-3</sup>	6.10 <sup>-4</sup>	<5.10 <sup>-4</sup>
CEA / Fontenay-aux-Roses <sup>(b)</sup>	Achères	30	<2.10 <sup>-4</sup>	<2.10 <sup>-4</sup>	<2.10 <sup>-4</sup>	<2.10 <sup>-4</sup>	<2.10 <sup>-4</sup>	<2.10 <sup>-4</sup>
CEA / Grenoble <sup>(c)</sup>	–	–	(c)	(c)	(c)	(c)	(c)	(c)
CEA / Marcoule <sup>(b)</sup> (Atalante, Centraco, Phénix, Melox, CIS bio)	Codolet	2	<2.10 <sup>-3</sup>	<2.10 <sup>-3</sup>	<2.10 <sup>-3</sup>	<2.10 <sup>-3</sup>	<2.10 <sup>-3</sup>	<2.10 <sup>-4</sup>
CEA / Saclay <sup>(b)</sup>	Le Christ-de-Saclay	1	<2.10 <sup>-3</sup>	<2.10 <sup>-3</sup>	<2.10 <sup>-3</sup>	<4.10 <sup>-3</sup>	<2.10 <sup>-3</sup>	<2.10 <sup>-3</sup>
EDF / Belleville-sur-Loire	Beaulieu-sur-Loire	1.8	4.10 <sup>-4</sup>	3.10 <sup>-4</sup>	4.10 <sup>-4</sup>	4.10 <sup>-4</sup>	3.10 <sup>-4</sup>	4.10 <sup>-4</sup>
EDF / Blayais	Braud et Saint-Louis	2.5	5.10 <sup>-4</sup>	4.10 <sup>-4</sup>	5.10 <sup>-4</sup>	4.10 <sup>-4</sup>	5.10 <sup>-4</sup>	2.10 <sup>-4</sup>
EDF / Bugey	Vernas	1.8	9.10 <sup>-5</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	9.10 <sup>-5</sup>	2.10 <sup>-4</sup>
EDF / Cattenom	Kœnigsmacker	4.8	9.10 <sup>-3</sup>	8.10 <sup>-3</sup>	9.10 <sup>-3</sup>	1.10 <sup>-2</sup>	7.10 <sup>-3</sup>	7.10 <sup>-3</sup>
EDF / Chinon	La Chapelle-sur-Loire	1.6	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>
EDF / Chooz	Chooz	1.5	6.10 <sup>-4</sup>	4.10 <sup>-4</sup>	5.10 <sup>-4</sup>	5.10 <sup>-4</sup>	3.10 <sup>-4</sup>	4.10 <sup>-4</sup>
EDF / Civaux	Valdivienne	1.9	2.10 <sup>-3</sup>	8.10 <sup>-4</sup>	8.10 <sup>-4</sup>	2.10 <sup>-3</sup>	1.10 <sup>-3</sup>	1.10 <sup>-3</sup>
EDF / Creys-Malville	Creys-Mépieu	0.95	3.10 <sup>-4</sup>	1.10 <sup>-4</sup>	2.10 <sup>-5</sup>	2.10 <sup>-5</sup>	8.10 <sup>-6</sup>	2.10 <sup>-5</sup>
EDF / Cruas-Meyssse	Savasse	2.4	2.10 <sup>-4</sup>	4.10 <sup>-4</sup>	3.10 <sup>-3</sup>	3.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>
EDF / Dampierre-en-Burly	Lion-en-Sulias	1.6	5.10 <sup>-4</sup>	5.10 <sup>-4</sup>	5.10 <sup>-4</sup>	5.10 <sup>-4</sup>	3.10 <sup>-4</sup>	5.10 <sup>-4</sup>
EDF / Fessenheim	Fessenheim	1.3	3.10 <sup>-5</sup>	2.10 <sup>-5</sup>	5.10 <sup>-5</sup>	4.10 <sup>-5</sup>	3.10 <sup>-5</sup>	7.10 <sup>-6</sup>
EDF / Flamanville	Flamanville	0.8	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	7.10 <sup>-5</sup>	2.10 <sup>-5</sup>	6.10 <sup>-5</sup>
EDF / Golfech	Valence	3.4	3.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	1.10 <sup>-4</sup>	1.10 <sup>-4</sup>
EDF / Gravelines	Grand-Fort-Philippe	2.5	4.10 <sup>-4</sup>	5.10 <sup>-4</sup>	8.10 <sup>-4</sup>	1.10 <sup>-3</sup>	8.10 <sup>-4</sup>	7.10 <sup>-4</sup>
EDF / Nogent-sur-Seine	Saint-Nicolas-la-Chapelle	2.3	7.10 <sup>-4</sup>	5.10 <sup>-4</sup>	5.10 <sup>-4</sup>	4.10 <sup>-4</sup>	4.10 <sup>-4</sup>	5.10 <sup>-4</sup>
EDF / Paluel	Paluel	1.1	3.10 <sup>-4</sup>	3.10 <sup>-4</sup>	4.10 <sup>-4</sup>	3.10 <sup>-4</sup>	3.10 <sup>-4</sup>	2.10 <sup>-4</sup>
EDF / Penly	Berneval-le-Grand	3.1	4.10 <sup>-4</sup>	5.10 <sup>-4</sup>	5.10 <sup>-4</sup>	4.10 <sup>-4</sup>	3.10 <sup>-4</sup>	3.10 <sup>-4</sup>
EDF / Saint-Alban	Saint-Maurice-l'Exil	1.7	3.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	3.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>
EDF / Saint-Laurent-des-Eaux	Lestiou	1.7	1.10 <sup>-4</sup>	1.10 <sup>-4</sup>	1.10 <sup>-4</sup>	1.10 <sup>-4</sup>	1.10 <sup>-4</sup>	9.10 <sup>-5</sup>
EDF / Tricastin	Bollène	1.3	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	1.10 <sup>-4</sup>	1.10 <sup>-4</sup>
Framatome Romans	Ferme Riffard	0.2	3.10 <sup>-4</sup>	2.10 <sup>-5</sup>	2.10 <sup>-5</sup>	3.10 <sup>-5</sup>	1.10 <sup>-5</sup>	1.10 <sup>-5</sup>
Ganil / Caen	IUT	0.6	<2.10 <sup>-3</sup>	8.10 <sup>-3</sup>	8.10 <sup>-3</sup>	7.10 <sup>-3</sup>	7.10 <sup>-3</sup>	7.10 <sup>-3</sup>
ILL / Grenoble	Fontaine (gaseous discharges) and Saint-Égrève (liquid discharges)	1 et 1.4	2.10 <sup>-4</sup>	5.10 <sup>-5</sup>	2.10 <sup>-5</sup>	3.10 <sup>-5</sup>	5.10 <sup>-5</sup>	2.10 <sup>-4</sup>
Orano Cycle / La Hague	Digulleville	2.8	2.10 <sup>-2</sup>	2.10 <sup>-2</sup>	2.10 <sup>-2</sup>	2.10 <sup>-2</sup>	1.10 <sup>-2</sup>	1.10 <sup>-2</sup>
Orano / Tricastin (Areva NC, Comurhex, Eurodif, Socatri, SET)	Les Girardes	1.2	2.10 <sup>-4</sup>	2.10 <sup>-4</sup>	9.10 <sup>-5</sup>	8.10 <sup>-5</sup>	4.10 <sup>-5</sup>	6.10 <sup>-5</sup>

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 reference group of each site for the two age classes (adult or baby) is mentioned. As from 2013, the dose of the reference group is provided for three age classes (adult, child, infant) for all the BNIs. The dose value indicated is the harshest 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 Alternative Energies and Atomic Energy Commission (CEA). As these estimates comprise at least one term of less than 0.01 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.

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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 per 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 life-styles of the chosen reference groups, 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 reference population groups.

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 ( $1.3$  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 in France from the Fukushima Daiichi NPP accident, 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.

### 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  $0.1 \text{ mSv}/\text{year}$  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).

Since 2019, measurement of the radon content of tap water and bottled water has been compulsory. To assist the introduction of this new provision, an instruction was drawn up in consultation with ASN and issued in 2018 to the ARS by the General

Directorate for Health – DGS (ASN opinion 2018-AV-0302 of 6 March 2018 on radon management procedures in the sanitary 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 (PAB), 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  $300 \text{ Bq}/\text{m}^3$  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.
- 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. A radon measurement can be carried out in this context if necessary. If there is a risk of reaching or exceeding the reference level of  $300 \text{ Bq}/\text{m}^3$ , the employer must take action to reduce the radon activity concentration. If the action turns out to be ineffective, the employer must identify potential “radon zones” from the moment the dose received by the workers exceeds  $6 \text{ mSv}/\text{year}$ , assuming the workers are present constantly, and then implement radiation protection measures if necessary according to the level of exposure of the workers.
- In some PAB, the radon management methods have been adjusted, more specifically with the inclusion of day-care facilities for children under 6 years of age and an obligation to inform the public by displaying the radon measurement results<sup>(11)</sup>. The type of action to be taken if the reference level of  $300 \text{ Bq}/\text{m}^3$  is exceeded is graded according to the measurement results: simple corrective actions for radon concentrations between 300 and  $1,000 \text{ Bq}/\text{m}^3$ , expert assessment and remediation work if the corrective actions do not reduce the radon concentration to below the reference level or if the measurement results equal  $1,000 \text{ Bq}/\text{m}^3$  or higher.

ASN issues the approvals to the organizations that measure radon in certain PAB. Fifty-two approvals were issued in 2022 (44 of level N1A and 8 of level N2), bringing the total number to 83. The list is available in the ASN *Official Bulletin* at [asn.fr](http://asn.fr).

The data transmitted to ASN each year by these organisations in their annual report concern the measurements taken in the PAB that are subject to monitoring of exposure of the public, defined in Article D. 1333-32 of the Public Health Code (level N1A approval). The analysis of the data over the last six measuring campaigns shows a gradual reduction in the number of buildings exceeding the reference level of  $300 \text{ Bq}/\text{m}^3$  and the level of  $1,000 \text{ Bq}/\text{m}^3$  under the initial and ten-yearly measurements, which means a reduction in the exposure of the public frequenting these buildings (see Diagram 3). During the last campaign of 2021-2022, the radon activity concentration was less than the reference level of  $300 \text{ Bq}/\text{m}^3$  in 84% of the teaching institutions measured, in 91%

11. Order of 26 February 2019 relative to the methods of managing radon in certain buildings open to the public and dissemination of information to the people frequenting these buildings.

in the care facilities for children under 6 years of age, 86% of the healthcare, social and medico-social facilities, in 50% of the spas and 89% of the penitentiaries.

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 six years shows improved effectiveness of these corrective actions and works, with a regular reduction in the measured values exceeding the reference level of 1,000 Bq/m<sup>3</sup> and a recent downward trend in the measured values exceeding the reference level of 300 Bq/m<sup>3</sup>. Thus, during the last campaign from 2021-2022<sup>(12)</sup>, more than half of the facilities managed to return to a level below the reference level of 300 Bq/m<sup>3</sup> (see Diagram 4).

Additional measurements are performed to identify radon sources, entry and transfer pathways in the buildings, which are carried out to support the expert assessment, particularly for building covering a large ground surface area with complex substructures. They correspond to level 2 of the approvals. Between 60 and 100 additional measurements were thus carried over the last three campaigns.

For the last six measuring campaigns, the categories of establishments measured are broken down as follows: 59% educational institutions (from nursery school to secondary high school), 29% healthcare, social and medico-social institutions, 11% care facilities for children under 6 years of age (new category introduced in 2018) and less than 1% spas and penitentiaries (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 plan for the 2020-2024 period was published in early 2021. It fits into the framework of the fourth 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 2018-2022, of which one action aims to reduce exposure to interior pollution. This action explicitly targets the effects of radon in the home: “over and beyond the sanitary aspects, it is question of promoting a living environment that fosters health and of reducing the effects of exposure in the home (chemical pollution, radon, etc.)”.

This plan follows on from the preceding plans (the assessment of the third 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 3 Results of the initial and ten-yearly measurements in public access buildings

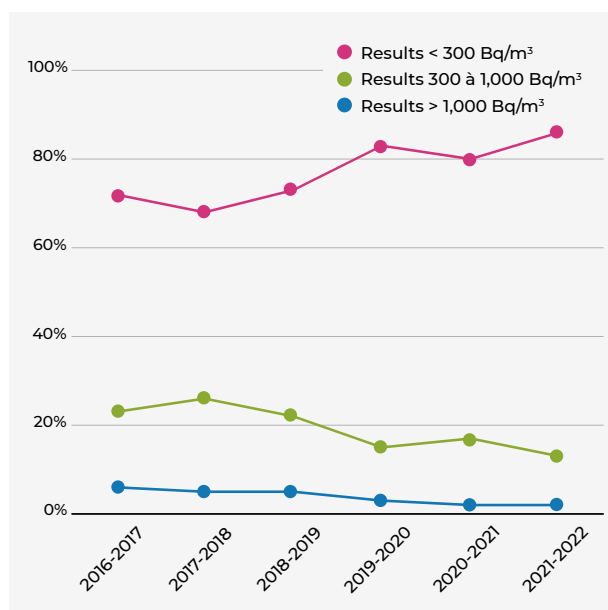
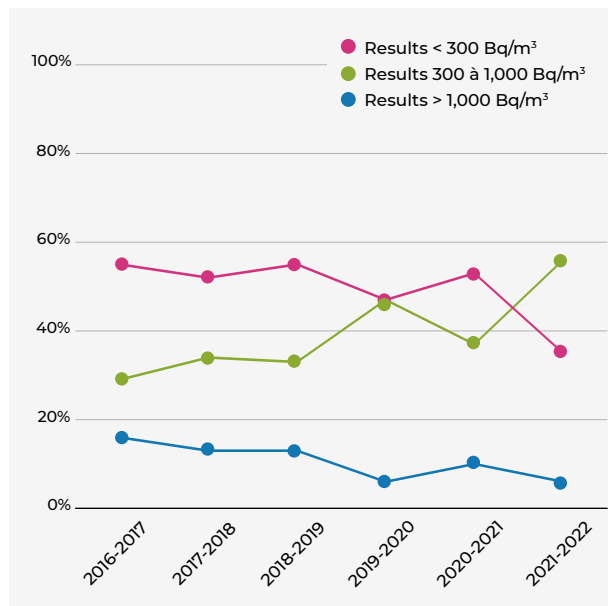


DIAGRAM 4 Measurements after corrective actions and works



**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 fourth 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

12. Order of 26 February 2019 relative to the methods of managing radon in certain buildings open to the public and dissemination of information to the people frequenting these buildings.

**MANAGEMENT OF THE RADON RISK, NEW ISSUE 2022, INTENDED FOR THE REGIONAL AUTHORITIES**

In 2022, in partnership with the DGS and the Scientific and Technical Centre for Building (CSTB), ASN updated the guide for the regional authorities entitled *Management of the Radon Risk*. As the radon regulations changed in 2018, particularly with regard to PAB and informing the public, the guide as a whole needed to be updated. The purpose of this guide is to assist the regional authorities in fulfilling their regulatory obligations regarding management of the radon risk, notably by giving the floor to the authorities involved in monitoring radon in PAB and residential buildings. The guide is divided into three parts corresponding to the different roles of the regional authorities as:

- owner or operator of the PAB subject to radon monitoring. This part details each step of the process: from the initial measurement to the corrective actions or works to be implemented and the verification of the effectiveness of these actions. The presentation of the regulations is supplemented by operational recommendations;
- municipality or agglomeration participating in informing the population about major risks;
- stakeholder of a proactive policy vis-à-vis the radon exposure risk. This part contains a wealth of advice on measures the authorities can take to encourage private individuals to measure the radon concentration in their home.

An appendix provides numerous links giving free access to further information, such as the webinars of the National Centre of the Regional Public Authorities (CNFPT), guides on prevention methods in new buildings and reduction of radon concentration in existing buildings, along with examples of remediation work.

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 complete the offering, a guide intended for professionals and private individuals will establish prevention recommendations for new constructions and remedial measures 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.

**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 is therefore raised for this specific population. It is worth pointing out that these patients are

**DIAGRAM 5 Distribution of NIA measurements per building category in the measuring campaigns from 2016-2017 to 2021-2022**

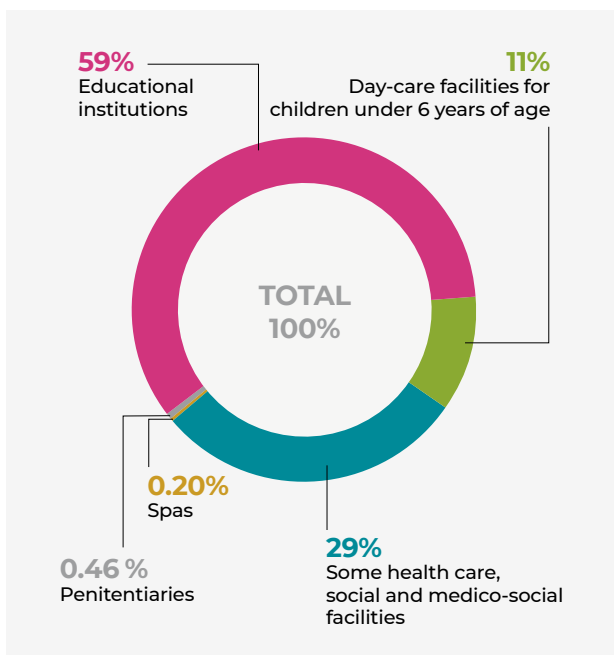


TABLE 5 Number of procedures and associated collective effective dose for each imaging method (rounded values) in France in 2017

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	11.3
Total	84,667,000	100.0	100.0

Source: IRSN 2020.

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). 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. The results of this 2nd action plan shall be assessed in early 2023 in collaboration with all the stakeholders, and the plan shall be updated.

### 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 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 with 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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## ASN ACTIONS TO PREVENT THE RADON RISK IN THE REGIONS

In 2022, the ASN regional divisions, along with the public authorities (Dreal<sup>(\*)</sup>, ARS, Dreets<sup>(\*\*)</sup>) and the partner organisations (Cerema, trade associations, local authorities, etc.), continued the actions to raise the awareness of elected officials, building trade professionals, employers, managers of PAB and the general public to the regulatory changes made since 2018 (see point 3.2.2). This awareness-raising is accompanied by inspection actions. For the PAB, these inspections target the major property managers in particular.

### AWARENESS-RAISING ACTIONS

#### AUVERGNE-RHÔNE-ALPES Lyon Division

- Participation in a **campaign to inform the companies of the region** about the radon risk, conducted as part of the Regional Occupational Health Plan No. 4 (PRST4).
- Participation in a **campaign to inform day-care facilities for young children** about the radon risk, conducted under the Regional Health Environment Plan (PRSE), in partnership with the ARS and the Dreal.

#### BOURGOGNE-FRANCHE-COMTÉ Lyon Division

- **Creation of a regional health/environment network** to lead the players involved in management of the radon risk and air quality inside buildings. It is based on the digital platform stemming from the Jurad-Bat project and will contribute to its development.

#### BRETAGNE / PAYS DE LA LOIRE Nantes Division

- Between 65% and 93% of the municipalities in the *départements* (Sarthe excluded) of these regions are situated in **zones with significant radon potential**.
- Co-financing in Pays de La Loire of **six new awareness-raising actions** targeting private individuals and **assistance in conducting voluntary campaigns to measure** radon in their home and participation in the kick-off meetings of some of these campaigns.

#### AUVERGNE-RHÔNE-ALPES Lyon Division

- **Performance of two inspections of the local authorities** (Departmental Councils of the Haute-Savoie and Cantal *départements*) responsible for educational institutions, two inspections of spas (Royat and Châteauneuf-les-Bains) and one inspection of the underground structure of the EDF hydroelectric power station of Les Bois in Chamonix, a designated radon-risk workplace.
- The situation **of the Cantal département is to be flagged in particular, as the inspectors have found establishments that have not been monitored since 2016 and still require remedial measures**. In particular, the presence of radon at concentrations above the reference level for the last 10 years in two lower secondary schools necessitates an expert assessment of the buildings concerned without delay.

- **Contribution to an assessment of the campaigns carried out between 2015 and 2021**: nearly 4,000 households in the Loire *département* have thus been able to measure the radon concentration in their home; the concentration is below the regulatory reference level in 84% of them.
- **Contribution to the actions concerning the evaluation of PRSE3 and the launching of PRSE4**.

#### CENTRE-VAL DE LOIRE Orléans Division

- Participation in an **awareness-raising operation with the ARS (Indre département delegation) and CAP Tronçais** with supply of radon screening kits to the persons interested.

#### NORMANDIE Caen Division

- **Participation in the preparatory work** for PRST4 with the Dreets and the ARS.

#### NOUVELLE-AQUITAINE / OCCITANIE Bordeaux Division

- Participation in the **creation of the “radon” action sheet of PRST4** for Nouvelle-Aquitaine and **setting up communication actions** targeting the region’s employers and Occupational Safety and Health (OHS) organisations
- Participation in the meetings to prepare the future PRSEs.

### OVERSIGHT ACTIONS

#### AUVERGNE-RHÔNE-ALPES Lyon Division

- With regard to the spas of Royat, ASN’s inspection was conducted jointly with the labour inspectorate services. **The constant presence of radon for more than 10 years necessitates an expert assessment of the buildings concerned without delay.**
- For the hydroelectric power station of Les Bois, the inspectors noted **good management of the radon risk**. Radon measurement campaigns have led the employer to consider the entire designated radon-risk workplace as a “radon zone”. The employer has also performed individual dosimetric assessments of the workers and provided passive radon dosimeters for the workers concerned.
- The inspectors have observed **rigorous management of the radon risk by the Departmental Council of the Aveyron département**. A number of situations in the Cantal *département* require expert assessments of buildings to be carried out without delay.

**BOURGOGNE-FRANCHE-COMTÉ** Dijon Division

- Performance of three **inspections aiming to track over time the actions taken** by the previously inspected Departmental Councils (Doubs, Haute-Saône, Territoire-de-Belfort *départements*): the requirements regarding the Public Health Code are duly taken into account in all the establishments concerned, especially the lower secondary schools. Difficulties in reducing the radon concentration below the thresholds are encountered in a few rare cases.
- Performance of four other inspections aiming to **contact owners or managers of PAB** in departments in which there was no obligation to measure radon before 2018 (Departmental Councils of the Côte-d'Or, Jura and Yonne *départements* and catholic institutions management body). These inspections showed that the initial radon measurement had been effectively carried out on the whole.
- Performance of an **inspection in designated radon-risk workplaces in basements**: the Grande Saline salt museum, a former salt production site in Salins-les-Bains and the well in Muyre that supplies the spa. This inspection revealed that the radon issue has been well assimilated by the town council departments that initiated the risks assessment procedure.

**BRETAGNE / PAYS DE LA LOIRE** Nantes Division

- Performance of five **inspections of organisations managing PAB**: town councils of Nantes, Angers, Cholet and catholic educational institutions of Loire-Atlantique and Côtes-d'Armor *départements* and one **inspection in the Mine Bleu slate mine** situated in Segré-en-Anjou. These inspections show that the **radon risk is duly taken into account in PAB by the large local authorities**. Improvements are expected in certain private educational institutions, and more generally in the organisation put in place for continuous monitoring of management of the radon risk.

**GRAND EST** Strasbourg and Châlons-en-Champagne Divisions

- After several years of awareness-raising, **three inspections were performed**: two inspections of PAB managers (Department Council of the Vosges with the ARS; town council of Saint-Dié) and one inspection in a designated radon-risk workplace (Maurice Lemaire tunnel).
- **Measurements were taken** inside PAB and in the workplaces.
- The finding for the Vosges Departmental Council was of **contrasts in the way the radon risk is taken into account**, with the initial screening performed relatively late, followed by remediation measures.

**NORMANDIE** Caen Division

- **Performance of three inspections**:
  - Bagnoles-de-l'Orne spas: further diagnoses are required, even though the previous ones were carried out when the spas were closed;
  - Departmental Council of the Manche: inspection giving highly satisfactory results for the PAB and the workers alike, diagnoses carried out in all the buildings concerned, remedial actions performed in the buildings where necessary and further diagnoses planned for this autumn;
  - underground quarry of Plaine de Caen: conclusion satisfactory, measurements taken in the quarry, the values are below the reference level of 300 Bq/m<sup>3</sup>. The galleries are ventilated mechanically.

**NOUVELLE-AQUITAINE / OCCITANIE** Bordeaux Division

- Performance of an inspection by **ASN, Dreets and the Labour Inspectorate** in the Betharram Grottos as a designated radon-risk workplace. Requests for information concerning notably the assessment of the risks and the individual assessment of exposure to radon were sent to the employer.
- **Inspection of the Regional Council of Nouvelle-Aquitaine and of the Departmental Councils of Corrèze and Haute-Vienne**, with the participation of the ARS and its departmental delegations, and one inspection of the Departmental Council of the Aveyron *département* in Occitanie. Several situations with concentrations persistently higher than the reference level threshold were identified and expert assessments of buildings must be undertaken.

**PROVENCE-ALPES-CÔTE D'AZUR / OCCITANIE**

## Marseille Division

- Inspection of the towns of Alès and Ajaccio with the ARS Occitanie and Corse: the **implementation of the radon regulations governing PAB is broadly satisfactory**.
- Inspection of a wine estate in the Var *département* with infrastructures situated 20 metres underground governed by the regulations for designated radon-risk workplaces. The enterprise was unaware of the regulations relative to radon.
- **Contact made with the Interregional Directorates of the Penitentiary Services (DISP)** South-East – Marseille and South – Toulouse with the ARS of the Occitanie and PACA regions.

As these are PAB managers overseen by the ASN regional divisions, the measuring campaigns in the establishments concerned are duly carried out in the majority of cases, but further efforts must be made in displaying information, periodic monitoring and management of threshold exceedances when expert assessments and works are necessary. With regard to management of the occupational risk however, the regulations are rarely applied.

With regard to the oversight by the ASN divisions in certain designated radon-risk workplaces under the Labour Code (spas, tunnels, etc.), the results are fairly contrasted. If some employers of these workplaces have assessed the radon risk and taken the regulatory measures required in cases where the reference level is exceeded, others have taken no action whatsoever, in the majority of cases due to ignorance of the risk and of the regulations.

The radiation protection inspections carried out in 2022 in medical or industrial facilities situated in municipalities with significant radon potential were moreover used by some ASN divisions as an opportunity to explain the regulatory obligations of employers in workplaces. The information sheet published by ASN *Prevention of the radon risk in the workplace* is given to the employers on this occasion.

In this respect, as in the preceding years, ASN found that radon is increasingly taken into account in the assessment of risks for workers.

The regional divisions moreover contributed to the inspection of organisations approved for taking radon measurements in PAB (14 inspections).

\* Regional directorate for environment, planning and housing.

\*\* Regional directorate for the economy, employment, labour and solidarity.



**RAPPORT DE L'ASN**  
sur l'état de la sûreté nucléaire  
et de la radioprotection en France en | 2021 |



# The principles of nuclear safety and radiation protection and the regulation and oversight stakeholders

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**N**uclear 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 for its part 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 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 Prefectures. 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, more particularly that provided by the Institute for Radiation Protection and Nuclear Safety (IRSN).

At the 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 Ecological Transition, which can draw on the services of 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 has constitutional value – 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, ten fundamental safety principles defined by the IAEA (see box page 122 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.

#### 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 fight against 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.



RESPONSIBILITY OF LICENSEES AND RESPONSIBILITY OF ASN



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.

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”.

This principle, referred to as the ALARA<sup>(1)</sup> 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. The ALARA (As Low As Reasonably Achievable) principle appeared for the first time in publication 26 of 1977 from the International Commission on Radiological Protection (ICRP) in 1977. It was the result of reflection around the principle of optimisation of radiation protection. Over the past thirty years, the acceptance and implementation of the ALARA principle have significantly changed in Europe, with considerable involvement by the European Commission which, in 1991, led to the creation of a European ALARA network.

## 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.

### 1.1.8 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. At the individual level it must be given expression by a rigorous and cautious approach and a questioning attitude making it possible to both obey rules and take initiatives. In operational terms, the concept underpins daily decisions and actions relating to activities.

### 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

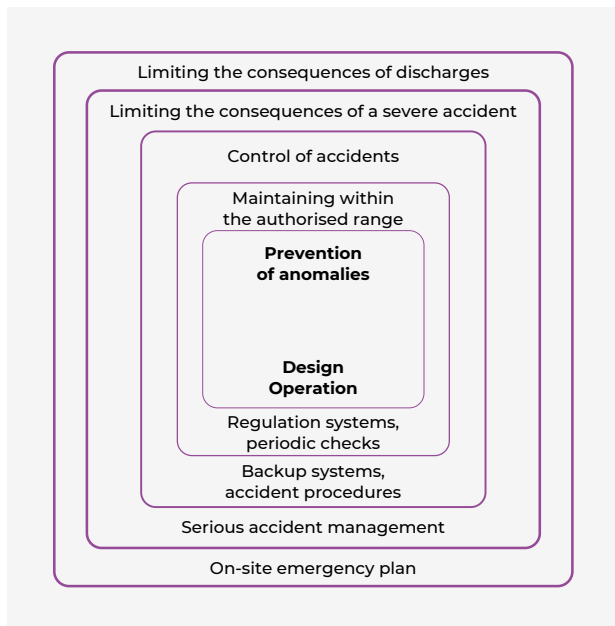
Regulation and governing systems must be designed, installed and operated such that the installation is kept within an operating range that is far below the safety limits. For example, if the temperature in a system increases, a cooling system starts up before the temperature reaches the authorised limit. 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

THE 5 LEVELS OF DEFENCE IN DEPTH



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.

**Level 5: Mitigation of the radiological consequences of significant releases**

This involves implementation of the measures set out in the contingency plans including population protection measures: 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 nuclear power plants, 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 failure (or the success) of the actions provided for in the reactor management procedures and the failure (or correct operation) of the reactor. 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.

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### 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 understanding 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.

ASN defines SHOF as being all the aspects of working situations and of the organisation which have an influence on the work done by the persons involved. 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. Therefore, ASN resolution 2014-DC-0420 of 13 February 2014 concerning physical modifications to BNIs requires that *“the design of the physical modification envisaged shall, when it is applied and put into operation, take account of the interactions between the modified or newly installed equipment on the one hand and the users and their needs on the other”*;
- 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 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 provisions mentioned in Article 7 and given adequate powers, expertise and financial and human resources to assume the responsibilities given to it” and “[...] takes appropriate steps to ensure effective separation between the functions of the regulatory body and those of any other body or organisation in charge of promoting or using 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.

### 2.1 Parliament

Parliament’s principal role in the field of nuclear safety and radiation protection is to make laws. Two major acts were therefore passed in 2006: Act 2006-686 of 13 June 2006, on Transparency and Security in the Nuclear field (TSN Act) and Programme Act 2006-739 of 28 June 2006, on the sustainable management of radioactive materials and waste.

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 reports regularly to the OPECST on its activities, notably by submitting its annual *Report on the State of Nuclear Safety and Radiation Protection* to it.

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. The Government can also call on consultative bodies 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, Employment and Integration. That concerning the radiation protection of patients is the responsibility of the Minister for Solidarity and Health.

The Ministers responsible for nuclear safety and for radiation protection approve the ASN internal regulations by means of an Interministerial Order. 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, 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

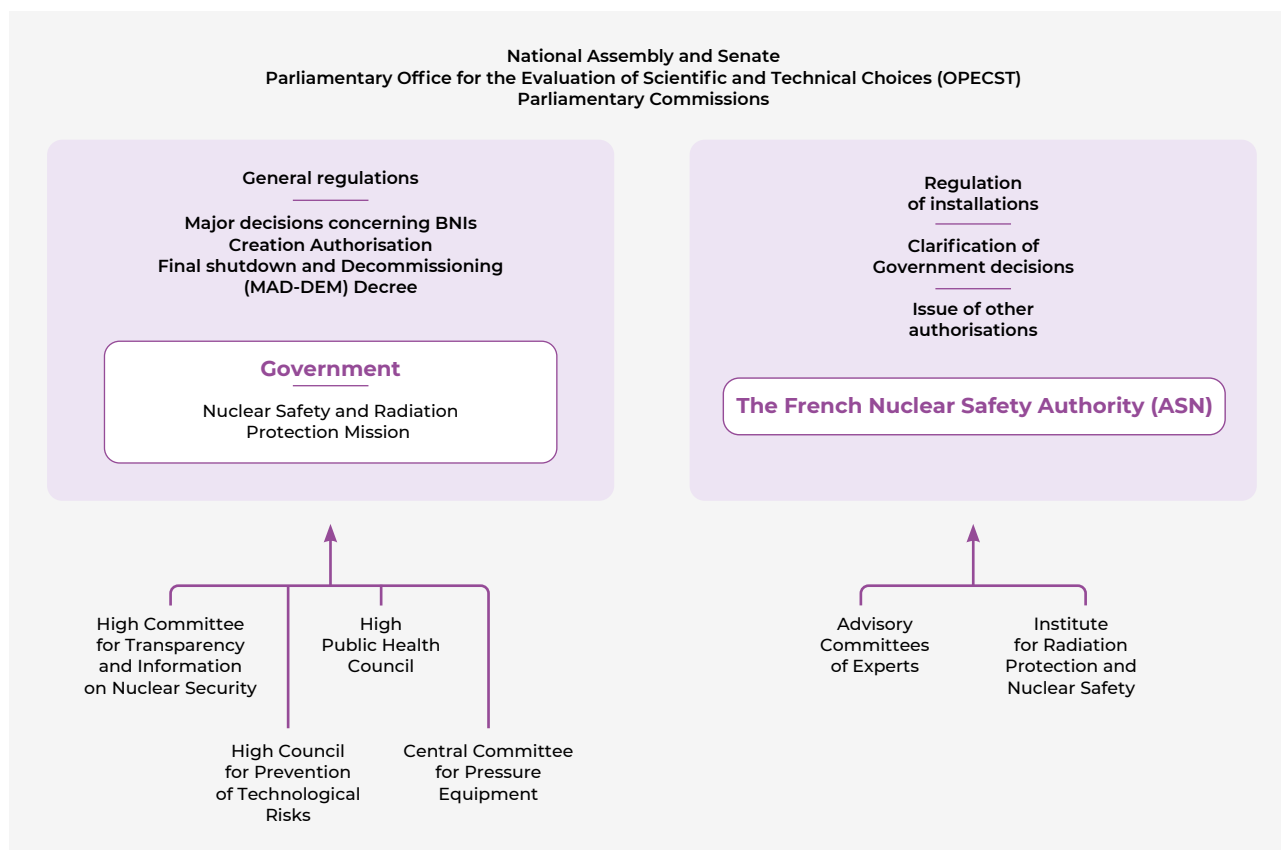
The purpose of nuclear security, in the strictest sense of the term (IAEA definition, less wide-ranging than that of Article L 591-1 of the Environment Code) is to protect and monitor nuclear materials, their facilities and their transportation. It aims to ensure protection of the population and environment 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 IRSN.

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.



REGULATION OF NUCLEAR SAFETY AND RADIATION PROTECTION IN FRANCE



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 Île-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 The French Nuclear Safety Authority

The French Nuclear Safety Authority (*Autorité de 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 roles are to

regulate, authorise, monitor and support the public authorities in the management of emergency situations and to contribute to information of the public and transparency within its fields of competence.

ASN is governed by a Commission comprising five Commissioners, including the ASN Chairman. They are appointed for a 6-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 below). For the purposes of technical analysis and assessment, it more particularly draws on the services of IRSN and the Advisory Committees of Experts (GPEs).

2.3.1 Role and duties

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 issue technical regulations to complete the implementing procedures for Decrees and Orders adopted in the nuclear safety or radiation protection field, 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 debated by its Commission are published in its *Official Bulletin* on its website *asn.fr*.

### Oversight

ASN verifies compliance with the general rules and specific requirements for nuclear safety and radiation protection applicable to BNIs, to the pressure equipment 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 enforcement 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 enforcement 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 takes part 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 concerning technical inquiries into accidents or incidents concerning a nuclear activity, ASN may carry out a technical inquiry.

### Information

ASN participates in informing the public in its areas of competence. 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), ASN issued three opinions on research needs in 2012, 2015 and 2018. Since then it regularly publishes its opinions and those of the scientific committee and continues to strengthen its relations with research organisations and institutions in charge of programming and financing research nationally and at a European level.

ASN takes part in the steering committee for the "Nuclear Safety and Radiation Protection Research" (RSNR) Call for Projects, launched in 2013 by the National Research Agency, under the Investing in the Future programme, for which funding should be completed in mid-2023. The evaluation of the corresponding projects will begin in the first quarter of 2023.

## 2.3.2 Organisation

### ASN Commission

The ASN Commission comprises five full-time Commissioners. Their mandate is for a period of six years and may not be renewed. 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. The Commission adopts the ASN internal rules of procedure which set out its organisation and working rules, as well as its ethical guidelines. The Commission's decisions and opinions are published in ASN's *Official Bulletin*.

In 2022, the ASN Commission met 62 times. It issued 21 opinions and 31 decisions.

### Administrative Enforcement Committee

"Nuclear" Ordinance 2016-128 of 10 February 2016 created the ASN Sanctions 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 will have the power to issue administrative fines on the licensees of BNIs, those responsible for the transport of radioactive substances, the operators of NPE, or indeed those

## THE MEMBERS OF THE EXECUTIVE COMMITTEE

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From left to right: V. Cloître, C. Quintin, O. Gupta, D. Delalande, J. Collet and P. Bois

responsible for nuclear activities 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 Court of Cassation. It also comprises alternate members. The duration of the members' mandate is 6 years.

At their first meeting, on 19 October 2021, the regular members elected Mr. Maurice Méda 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.

Annual information exchange meeting between the members of the Administrative Enforcement Committee, the ASN Commission and the ASN general management was held on 9 December 2022.

As set out by law, the Committee will meet exclusively when referred to 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 basic nuclear installations, one million euros for a breach of the provisions applicable to NPE, 30,000 euros in the field of transport of radioactive substances, and 15,000 euros 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.

### ASN head office departments

The ASN head office departments comprise an Executive Committee, a General Secretariat, a Management and Expertise Office, an Oversight Support Office 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 Plant Department (DCN) is responsible for regulating and monitoring the safety of the NPPs in operation, as well as the safety of future power generating reactor projects. It contributes to the development of regulation/oversight strategies and ASN actions on subjects such as facility ageing, reactor service life, assessment of NPP safety performance and harmonisation of nuclear safety in Europe. The DCN comprises six offices: "Hazards and Safety Reviews", "Equipment and Systems Monitoring", "Operation", "Core and Studies", "Radiation Protection, Environment and Labour Inspectorate" and "Regulation and New Facilities".
- The Nuclear Pressure Equipment Department (DEP) is responsible for monitoring the safety of PE installed in BNIs. It monitors the design, manufacture and operation of NPE and application of the regulations by the manufacturers and their subcontractors and by the nuclear licensees. It also monitors the approved organisations performing the regulation checks on this equipment. The DEP comprises three offices: "Evaluation of the conformity of new NPE", "In-service Monitoring" and "Relations with the Divisions and Interventions", plus two units: "Baseline Requirements, Quality Audits" and "Organisations Inspections Irregularities".
- The Transport and Radiation Sources Department (DTS) is responsible for monitoring activities relating to sources of ionising radiation in the non-medical sectors and to transport of radioactive substances. It contributes to the drafting of technical regulations, to monitoring their application and to managing authorisation procedures (installations and equipment emitting ionising radiation in non-medical sectors, suppliers of medical and non-medical sources, accreditation



## THE MEMBERS OF THE MANAGEMENT COMMITTEE



*From left to right: C. Silvestri, L. Chaniai, J. Husse, A. Clos, F. Feron, C. Rousse, J-P. Goudalle, C. Messier, O. Rivière (not in photo: O. Lahaye and R. Catteau)*

of packaging and of relevant organisations). It took charge of oversight of the security of radioactive sources. The DTS comprises two offices: “Transport Monitoring” and “Radiation Protection and Sources”, plus a “Source Security” section.

- The Waste, Research Facilities and Fuel Cycle Department (DRC) is responsible for monitoring “nuclear fuel cycle” facilities, research facilities, nuclear installations being decommissioned, contaminated sites and radioactive waste management. It takes part in monitoring the Meuse/Haute-Marne underground research laboratory and the research facilities covered by international conventions, such as the European Organisation for Nuclear Research (CERN) or the International Thermonuclear Experimental Reactor (ITER) project. The DRC comprises five Offices: “Radioactive Waste Management”, “Monitoring of Laboratories-plants-waste-decommissioning and research facilities”, “Monitoring of Fuel Cycle Facilities”, “Management of Reactor Decommissioning and the Cycle Front-end” and “Management of Cycle Back-end Decommissioning and Legacy Situations”.
- The Ionising Radiation and Health Department (DIS) is tasked with regulating medical applications of ionising radiation and – in collaboration with IRSN and the various health authorities – organising the scientific, health and medical watch with regard to the effects of ionising radiation on health. It contributes to the drafting of the regulations in the field of radiation protection, including with respect to natural ionising radiation, and the updating of health protection measures should a nuclear or radiological event take place. The DIS comprises two offices: “Exposure in the Medical Sector” and “Exposure of Workers and the Public”.
- The Environment and Emergency Department (DEU) is responsible for monitoring environmental protection and managing emergency situations. It establishes policy on nationwide radiological monitoring and on the provision of information to the public and helps to ensure that discharges from BNIs are as low as reasonably achievable, in particular by establishing general regulations. It contributes to defining the framework of the organisation of the public authorities and nuclear licensees in the management of emergency situations. The DEU comprises two Offices: “Safety and Preparedness for Emergency Situations” and “Environment and Prevention of Detrimental Effects”.
- The Legal Affairs Department (DAJ) provides consulting, analysis and assessment and assistance services on legal matters. It assists the various departments and the regional divisions with drafting ASN standards and analyses the consequences of new texts and new reforms on ASN’s actions. It takes part in drawing up ASN’s enforcement and sanctions doctrine. 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.
- The Information, Communication and Digital Usages Department (DIN) 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. The DIN comprises two offices: “Communication and Information” and “IT and Digital Usages”.
- The International Relations Department (DRI) coordinates ASN’s bilateral, European and multilateral actions on the international stage, 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 practices abroad. 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 DRI coordinates ASN representation in cooperative structures created under bilateral agreements or arrangements, but also within formal international bodies such as the European Union (European Nuclear Safety Regulators Group – ENSREG – which it chairs), the IAEA or the Nuclear Energy Agency (NEA). It ensures similar coordination in the more informal structures taking the form of associations (e.g.: Western European Nuclear Regulators Association – WENRA, International Nuclear Regulators Association – INRA, Heads of European Radiation Control Authorities – HERCA) or cooperative groups under multilateral State-based initiatives (e.g.: Nuclear Safety and Security Working Group – NSSG, under the G7).
- The General Secretariat (SG) 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

## THE REGIONAL DIVISION HEADS

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From left to right: R. Zmyslony, N. Khater, B. Lauras, G. Lafforgue-Marmet, M. Riquart, C. Perier, A. Neveu, S. Garnier and M. Champion (not in photo: E. Jambu et A. Baltzer)

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 SG comprises three offices: “Human Resources”, “Budget and Finance”, “Logistics and Real Estate”.

- The Management and Expertise Office (MEA) 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 MEA comprises eight members in charge of expert assessment, relations with IRSN, research, quality, archival and transmission of knowledge. The MEA is in charge of overseeing the research network and the quality network at ASN.
- The Oversight Support Office (MSC) ensures that the inspections carried out by ASN are pertinent, harmonised, 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 of the departments.

#### 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 nuclear activity managers 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 divisions contribute to ASN’s public information duty. They for example take part in the meetings of the Local Information Committees (CLIs) and maintain regular relations with the local media, elected officials, associations, licensees and local administrations.

#### 2.3.3 Operation

##### Human resources

As at 31 December 2022, ASN’s overall workforce stood at 516, distributed between the head office departments (297 staff), the regional divisions (217 staff) and various international organisations (2 staff).

This workforce can be further broken down as follows:

- 458 tenured or contract staff members;
- 58 staff members seconded by public establishments (National Radioactive Waste Management Agency – Andra, *Assistance publique – Hôpitaux de Paris*, Alternative Energies and Atomic Energy Commission – CEA, IRSN, Departmental Fire and Emergency Response Service).

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.

##### 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 Article 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



## THE REGIONAL REPRESENTATIVES (AS AT 31 DECEMBER 2022)



From left to right: H. Vanlaer, J-P. Deneuvy, S. Forest, H. Brûlé, A. Beauval, J-P. Lestoille, O. Morzelle, L. Tapadinhas (not in photo: A-A. Médard and E. Gay)

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 2022, ASN employed 329 nuclear safety or radiation protection inspectors holding at least one qualification, or nearly 64% of the 516 ASN staff.

Training re-engineering work to adapt the modules following the Covid-19 pandemic, led to optimisation of the training time. Thus in 2022, nearly 2,600 days of training were provided for the ASN staff over a wide variety of topics, representing 107 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.

### Social dialogue

As a State administration, ASN has three social dialogue bodies:

- the Social Dialogue Committee (SDC);
- the Joint Consultative Commission (CCP);
- the Health, Safety and Working Conditions Committee (CHSCT).

These three bodies allow wide-ranging and regular internal discussions on all subjects affecting the organisation, operations and the working environment of its personnel.

During the course of 2022, the ASN SDC met four times, once in an extraordinary session, to cover various subjects (organisation and working of the departments, training, budget/finances,

professional elections<sup>(2)</sup>, etc.). It issued opinions on texts presented by the administration (remote working agreement, single social report, draft decision creating a Social Dialogue Administration Committee – CSAP<sup>(3)</sup>, etc.).

For its part, the CHSCT met five times in 2022, including twice in extraordinary session. It focused on ensuring that occupational health and safety aspects were taken into account in ASN's organisational and operational changes and in the performance of its duties.

It issued opinions on the important relocation (Paris division) and premises redevelopment (head office) projects.

As is the case every year, the CHSCT also issued opinions on the annual report on the general Occupational Health and Safety (SST) situation at ASN, the SST results at CEA and the radiation protection results.

The CHSCT also carried out a visit to the Marseille division. In the same way as all the other entity visits at ASN, this visit was part of an overall goal to contribute to protecting the health of the staff and improving working conditions.

Finally, in consultation with the members of the CHSCT and with the assistance of the network of prevention assistants, the administration continued its actions to improve the prevention of occupational risks linked to remote-working and Covid-19 and updated the consolidated Occupational Risks Assessment Document (DUERP).

The CCP, which has competence for contract staff, met twice in 2022. The debates primarily concerned the situation of contract staff at ASN and the salary measures applicable to this population.

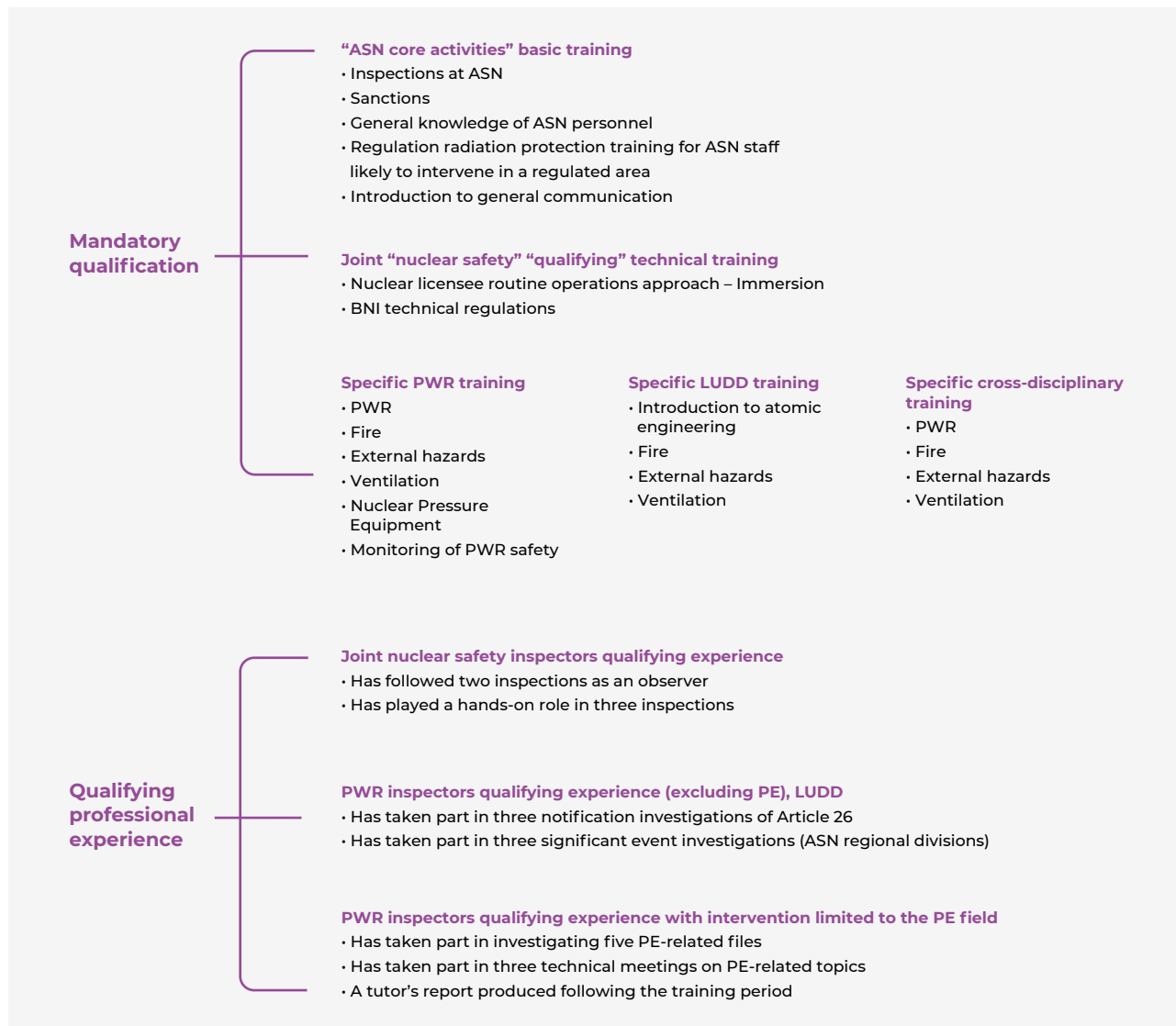
Finally, the social dialogue process involved regular meetings between the personnel representatives throughout the year. These meetings covered the management of the health situation and the corresponding measures to be taken.

2. Professional elections 2022: the professional elections to renew the personnel representative bodies were held at ASN electronically for the first time from Thursday 1 December to Thursday 8 December 2022. The 2022 vote was marked by the creation of a new social dialogue body, the CSAP. The level of participation in these elections was: 60.29% for the CCP vote and 54.92% for the CSAP vote.

3. The ASN CSAP is the result of a merger of the CTP and the CHSCT. ASN resolution 2022-DC-0722 of 2 June 2022 creating a CSAP for the ASN appeared in the ASN Official Bulletin on 13 June 2022. The ASN CSAP comprises eight regular members and eight alternates. As of January 2023, the CSAP is responsible for examining collective occupational questions at the level at which it is created: operation and organisation of the departments; strategic guidelines in human resources policies; management guidelines regarding mobility, promotion and career path enhancement; etc. As the ASN workforce exceeds 200, Specialist Health, Safety and Working Conditions Training (FSSCT) was set up within the CSAP. The eight regular specialist training representatives will be regular or alternates elected to the CSAP and the eight alternate representatives could be appointed from among the CSAP voting staff.

**“NUCLEAR SAFETY” INSPECTOR TRAINING PROGRAMME, PRESSURISED WATER REACTOR (PWR), LABORATORIES, PLANTS, DECOMMISSIONING AND WASTE (LUDD) AND CROSS-DISCIPLINARY QUALIFICATION**

02



**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 Advisory Committees (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-CLF-2012-033820 by the ASN Chairman applies the DPI requirements to the members of the Commission, the management committee and the Advisory Committee for Radiation Protection for Medical and Forensic Applications of Ionising Radiation (GPMED), now incorporated into the Advisory Committee for Radiation Protection (GPRP).

Until mid-July 2017, the DPI were posted on the *asn.fr*. The DPI are henceforth declared on the single on-line declaration site. About sixty 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 Director General, the Deputy Director Generals, and the General Secretariat 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 28 January 2020, the ASN Chairman appointed Alain Dorison as professional ethics officer.

He was also appointed as secularity coordinator and coordinator for internal alerts in this same decision.

A procedure for collecting and processing whistle-blower alerts from current or former staff, unsuccessful hiring candidates, external and occasional collaborators or co-contractors of ASN was set up 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 party concerned to submit an internal ethical alert and also to report information concerning a misdemeanour, threat or prejudice to the general interests, or a breach of a law of which they have personal knowledge or which was reported to them in the course of their professional activities.

In addition to the obligations recalled above, ASN defined a new internal monitoring procedure for staff wishing to work in the private sector or requesting permission to add a professional activity in order to create or take over a company, in accordance with Act 2019-828 of 6 August 2019 on the transformation of the civil service and Decree 2020-69 of 30 January 2020. Actions to raise personnel awareness in order to enhance the in-house ethics culture and prevent conflicts of interest were also carried out, such as placing practical documents on-line on the intranet (for example on the prevention of conflicts of interest and the role of ethical supervision in the event of departures to the private sector), the inclusion of a module on professional ethics rules applicable to ASN staff during training sessions held for new arrivals and a video interview in which the professional ethics coordinator uses a few examples to explain professional ethics and which professional activities require particular vigilance.

#### Financial resources

ASN’s financial resources are presented in point 3.

In its opinion 2022-AV-0401 of 10 May 2022 regarding the budget for the regulation and oversight of nuclear safety and radiation protection in France for the period 2023-2027, ASN notably requests a modification of the scope of its budget and the creation of a specific budget programme for the regulation and oversight of nuclear safety and radiation protection, in order to improve the management of and optimise the resource devoted to technical expert assessments (see point 3). ASN considers that the new nuclear challenges also require a strengthening of the technical support from IRSN.

#### ASN management tools

ASN’s management tools are more specifically evaluated during peer review missions (Integrated Regulatory review Service – IRRS), devoted to analysis of the French system of regulation and oversight of nuclear safety and radiation protection (see box next page).

#### The Multi-Year Strategic Plan

The Multi-year Strategic Plan (PSP), produced under the authority of the ASN Commission, develops ASN’s strategic lines for a period of several years. It is presented annually in an operational guidance document that sets the year’s priorities for ASN, and which is in turn adapted by each entity into an annual action plan that is subject to periodic monitoring. This three-level approach is an essential part of ASN’s organisation and management.

ASN produced a new PSP for the period 2023-2027, available on [asn.fr](http://asn.fr). This plan comes at a time of transition for the fleet of nuclear facilities and activities: the number of new facility projects is increasing and the question of continued operation will be posed for many of the existing facilities.

The period is also marked by a change in the international context and the expectations of society, with stronger demands in terms of dialogue and involvement in the decision-making process. The new PSP comprises the following four strategic points:

- state and share our short-, medium- and long-term vision of the issues relating to nuclear safety, radiation protection and environmental protection;
- enhance knowledge of the risks and, with the other players concerned, promote a culture of nuclear safety and radiation protection;
- adapt our oversight to a new context;
- make a success of the internal transformations to be more attractive and efficient.

#### The ASN internal management system

Within ASN, there are many forums for discussion, coordination and oversight.

These bodies, supplemented by the numerous cross-disciplinary structures, reinforce the safety culture of its staff through sharing of experience and the definition of coherent common positions.

#### 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.

### ASN INTERNATIONAL AUDITS (IRRS MISSIONS)

IAEA's Integrated Regulatory Review Service (IRRS) missions are designed to improve and reinforce the efficiency of national nuclear regulatory frameworks, while recognising the ultimate responsibility of each State to ensure safety in this field. These missions take account of the regulatory, technical and strategic aspects, make comparisons with the IAEA safety standards and, as applicable, take account of good practices observed in other countries.

**These audits are the result of the European Nuclear Safety Directive which requires a peer review mission every ten years.**

#### RECORD OF MISSIONS IN FRANCE

**2006:** ASN hosted the first IRRS mission concerning all the activities of a safety regulator.

**2009:** IRRS follow-up mission.

**2014:** new review mission extended to include management of security/safety interfaces.

**2017:** follow-up mission in October to assess the steps taken following the review carried out at the end of 2014, with the following findings and recommendations:

- implementation of measures to address 15 of the 16 recommendations;
- achievement of significant progress in improving its management system;
- drafting of general policy principles including safety culture aspects in training, self-evaluation and management;
- achievement of efficiency gains across all activities;
- need to continue improving resources management to ensure that they enable future challenges to be met, more particularly the periodic safety reviews, the NPP operating life extension, the graded approach to issues, plus new responsibilities, such as supervision of the supply chain and the security of radioactive sources.

The reports for the 2006, 2009, 2014 and 2017 IRRS missions are available for consultation on [asn.fr](http://asn.fr).

ASN considers that by contributing to the adoption of the best international practices, the IRRS missions constitute a tool for the continuous improvement of safety worldwide.

At the request of ASN, a further IRRS mission is scheduled in France for March 2024.

In addition, ASN experts took part in 2022 in IRRS missions in Slovenia, Argentina, Finland, Sweden and Bosnia and Herzegovina.

### 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 responsible for 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, the 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 CLIs for BNIs 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 communities 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 Local Information Committees and 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's technical support organisations

ASN benefits from the expertise of technical support organisations when preparing its decisions and resolutions. IRSN is the main one. 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

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. Since then, these texts have been modified, notably by Article 186 of the TECV Act and Decree 2016-283 of 10 March 2016 relating to the IRSN.

IRSN reports to the Ministers for the Environment, Defence, Energy, Research and Health respectively.

Article L. 592-45 of the Environment Code specifies that IRSN is a State public industrial and commercial institution which carries out expert analysis and assessment and research missions in the field of nuclear safety – excluding any responsibility as nuclear licensee. IRSN contributes to information of the public and publishes the opinions requested by a public authority or ASN, in consultation with them. It organises the publicity of scientific data resulting from the research programmes run at its initiative, with the exception of those relating to defence matters.

For the performance of its missions, ASN receives technical support from IRSN. As the ASN Chairman is a member of the IRSN Board, ASN contributes to setting the direction of IRSN's strategic planning.

IRSN conducts and implements 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. It is tasked with providing technical support for the public authorities with competence for safety, radiation protection and security, in both the civilian and defence sectors.

IRSN also has certain public service responsibilities, in particular monitoring of the environment and of populations exposed to ionising radiation.

IRSN manages national databases (national nuclear material accounting, national inventory of ionising radiation sources, file for monitoring worker exposure to ionising radiation, etc.), and thus contributes to information of the public concerning the risks linked to ionising radiation.

#### IRSN workforce

As at 31 December 2022, IRSN's overall workforce stood at 1,744 employees, of whom 433 are devoted to ASN technical support.

#### IRSN budget

The IRSN budget is presented in point 3.

A five-year agreement defines the principles and procedures for the technical support provided to ASN by the Institute. It was renewed at the end of 2021 for the period 2022-2026. This agreement is clarified on a yearly basis by a protocol identifying the actions to be performed by IRSN to support ASN.

#### TECV Act

This 17 August 2015 Act clarifies the organisation of the system built around ASN and IRSN:

- It enshrines the existence and duties of IRSN within a new section 6 of the Environment Code entitled “The Institute for Radiation Protection and Nuclear Safety” in Chapter 2

concerning “The French Nuclear Safety Authority (ASN)” of Title IX of Book V of the Environment Code.

- It recalls that ASN benefits from IRSN technical support, indicating that this support comprises expert analysis and assessment activities “supported by research”.
- It clarifies the relations between ASN and IRSN, indicating that ASN “guides IRSN's strategic programming concerning this technical support” and that the ASN Chairman is a member of the Board of the Institute.
- Finally, it also makes provision for the principle of the publication of IRSN opinions.

### 2.5.2 Advisory Committees of Experts

In preparing its decisions, ASN relies on the opinions and recommendations of seven Advisory Committees of Experts (GPEs). 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 GPEs every 4 years (see box next page). In 2022, they were broken down according to their areas of expertise:

- The Advisory Committee of Experts for Decommissioning (GPDEM) created in October 2018 for which the mandate expired on 31 October 2022;
- The Advisory Committee of Experts for Reactors (GPR) renewed in October 2018 for which the mandate expired on 31 October 2022 and was extended until 31 December 2022;
- the Advisory Committee of Experts for Laboratories and Plants (GPU) renewed in October 2018, for which the mandate expired on 31 October 2022;
- the Advisory Committee of Experts for Waste (GPD) renewed in October 2018, for which the mandate expired on 31 October 2022;
- the Advisory Committee of Experts for Transports (GPT) renewed in October 2018, for which the mandate expired on 31 October 2022;
- the Advisory Committee of Experts for Nuclear Pressure Equipment (GPESPN) renewed in October 2018, for which the mandate expired on 31 October 2022 and was extended until 31 December 2022;
- The Advisory Committee of Experts for 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 telluric radiation), as well as for the radiation protection of patients (GPRP) created in January 2022.

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 Advisory Committees 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 Advisory Committees 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 for Decommissioning (GPDEM)**

Chaired by Michèle Viala in 2022, the GPDEM comprises experts appointed for their competence in the field of BNI decommissioning. It did not meet in 2022. It comprises 33 members and since 1 January 2023 has been chaired by Chantal Mommaert.

#### **Advisory Committee for Waste (GPD)**

The GPD is chaired by Pierre Bérest in 2022 and comprises experts appointed for their competence in the nuclear, geological and mining fields. Since 1 January 2023, it comprises 36 members and is chaired by Marie-Pierre Comets.

#### **Advisory Committee for Nuclear Pressure Equipment (GPESPN)**

The GPESPN is chaired by Matthieu Schuler since 6 October 2018 and comprises experts appointed for their competence in the field of PE. It comprises 29 members.

#### **Advisory Committee 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 telluric radiation);
- radiation protection of patients.

In 2022, the GPRP drew up its programme of work which notably concerns the demarcation of areas applicable to working

equipment using pulsed fields, communication about risk, international work, artificial intelligence and digital innovation and its impact on radiation protection, as well – specifically for the medical field – as the Diagnostic Reference Levels (DRL) in mammography and the evaluation of radiation protection issues notably with respect to clinical trials for new radiopharmaceutical drugs.

In 2022, the GPRP held four plenary meetings.

Owing to the specific nature of the subjects regarding the radiation protection of patients, a specific Working Group for these questions (GTRPP) reports to the GPRP. The GTRPP is chaired by Mr Thierry Sarrazin and comprises 25 experts, nine of whom are shared with the GPRP.

In 2022, the GTRPP held three plenary sessions, including one shared with the GPRP.

#### **Advisory Committee for Nuclear Reactors (GPR)**

The GPR has been chaired by Thierry Charles since 2020 and comprises experts appointed for their competence in the field of nuclear reactors. Since 1 January 2023, it comprises 36 members.

#### **Advisory Committee for Transport (GPT)**

The GPT comprises experts appointed for their competence in the field of the transport of radioactive materials. Since 1 January 2023, it comprises 26 members and is chaired by Pierre Maleysis.

#### **Advisory Committee 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. Since 1 January 2023, it comprises 32 members.

### 2.5.3 Scientific Committee

ASN calls on the expertise of a Scientific Committee reporting to the 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. The ASN Commission appointed the current seven members of the Scientific Committee, on the basis of their expertise notably in the fields of research. Under the Chairmanship of Michel Schwarz, and until December 2023, the Committee will comprise Christophe Badie, Benoît De Boeck, Jean-Marc Cavedon, Catherine Luccioni, Philippe Maingon, Jean-Claude Micaelli and Marc Vannerem. The Scientific Committee held two annual plenary meetings in 2022. It continued with its meetings with research organisations, notably in the fields of ageing of the metal materials of nuclear power reactors and metrology on nuclear sites undergoing post-operational clean-out.

It also drafted an opinion, published on the ASN website, on the research to be carried out on the medical device based on microspheres labelled with yttrium-90.

### NEW MANDATE FOR THE EXPERTS OF THE ADVISORY COMMITTEES FOR NUCLEAR SAFETY

A new mandate for six GPEs began on 1 January 2023, that is:

- the Advisory Committee for Waste (GPD);
- the Advisory Committee for Decommissioning (GPDEM);
- the Advisory Committee for Nuclear Pressure Equipment (GPESPN);
- the Advisory Committee for Nuclear Reactors (GPR);
- the Advisory Committee for Transports (GPT);

- the Advisory Committee for Laboratories and Plants (GPU).

The call for candidates was issued in June 2022 and nearly 250 expert candidate applications were received. On the basis of the proposals from the selection committees, the Director General finalised the composition of these Advisory Committees on 16 December 2022.

These members were selected for their competence, whether cutting

across the nuclear safety or radiation protection fields, relative to certain types of facilities or activities, or specialising in a technical field. In addition to ensuring the complementarity of the skills present, the composition of these GPEs ensures the independence of the expertise on which ASN relies and the transparency of the process of drafting its resolutions and decisions.

TABLE 1 Advisory Committee meetings in 2022

GPE	DATE	MAIN TOPIC
GPD	1 February 2022	• Safety review of the Manche waste repository (BNI 66)
GPU	17 February 2022	• GP5 periodic safety review: NPH unit (BNI 117 – UP2-800 plant)
GPESPN	11 March 2022	• Information meeting on “Stress corrosion”
GPT	30 March 2022	• R85 package model approval application
GPRP/ GTRPP	1 April 2022	• Presentation of the composition and operation of the GPRP and the GTRPP • Summary of the three mandates of the GPRADE and the GP MED and subsequent action • Work programme for the GPRP and the GTRPP • International news: latest news from the ICRP
GPR	14 April 2022	• GPR working meeting
GPR	9 May 2022	• Information meeting: EPR2 project
GPD	10 to 12 May 2022	• Visit to the IRSN underground research laboratory in Tournemire
GTRPP	9 June 2022	• Summary of work resulting from the GP MED opinions • Review of radiation protection in the medical field • GTRPP working topics, prioritisation and working methodology
GPESPN	10 June 2022	• Information meeting “Stress relieving heat treatment”
GPR	16 June 2022	• Examination of OEF from operation of EDF’s PWRs in 2020
GPRP	5 July 2022	• International news: latest news about ICRP, IAEA and the European Commission • Discussions on the participation of GPRP experts in the GPR meeting of 16 June 2022 concerning analysis of OEF from PWR operations in 2020 • Summary of work resulting from the GPRADE and the GP MED opinions • GPRP work programme (work in progress, work to be initiated and prioritisation): state of progress of the referral regarding the demarcation of areas applicable to work equipment using pulsed fields and the think tank on risk communication
GPR	7 and 8 July 2022	• Examination of OEF for the period from 2010 to 2019, on the behaviour of fuel (fuel assemblies and clusters) used in EDF’s PWRs in France
GPR	12 July 2022	• Information meeting: progress of examinations prior to an ASN position statement regarding commissioning of the Flamanville EPR reactor
GPD	13 to 15 September 2022	• Meeting between the GPD and the German nuclear management commission ( <i>Deutsche Entsorgungskommission – ESK</i> ) followed by a visit of KTE ( <i>Kerntechnische Entsorgung Karlsruhe GmbH</i> ) and a nuclear fuels reprocessing facility
GTRPP	20 September 2022	• Presentation of referrals: new radiopharmaceutical drugs – draft opinion to the promoters for the purposes of the clinical trials or clinical investigations and diagnostic reference levels for mammography • Artificial intelligence in the medical world: what are the challenges? – Viewpoints of the notified organisations and medical devices industrial firms
GPESPN/ GPR	22 and 23 September 2022	• Opinions and recommendations regarding the stress corrosion cracks detected on the austenitic steel auxiliary lines of the main primary system of various PWRs of the EDF fleet
GPRP	7 October 2022	• International news: new concerning the NEA, the Committee on Radiological Protection and Public Health and HERCA • Presentation of the French National Network for environmental radioactivity monitoring and considerations regarding its modernisation • GPRP work programme (work in progress, work to be initiated and prioritisation): state of progress of the referral regarding the demarcation of areas applicable to work equipment using pulsed fields and the think tank on risk communication/presentation of the referral regarding the draft opinion for promoters for the purposes of clinical trials or clinical investigations • Review of radiation protection
GPESPN	30 November and 1 December 2022	• Information meeting: summary of closure of the examinations regarding the EPR • Information meeting: presentation of the EPR2 project and incorporation of OEF – NPE aspects
GPR	5 December 2022	• Discussion meeting concerning PWR safety between equivalent foreign entities
GPRP	16 December 2022	• International news: presentation of the World Health Organisation programme on ionising radiation • GPRP working programme: state of progress of the referral regarding the demarcation of areas applicable to work equipment using pulsed fields – presentation of the referral regarding risk communication • Presentation of the IRSN report concerning occupational exposure to ionising radiation – 2021 results • Presentation of the overhaul of Siseri (Siseri-2)

### 2.5.4 ASN's other technical support organisations

To diversify its expertise and benefit from other particular skills, ASN committed credits of about €200,000 in 2022.

ASN was thus able to finance the expert assessments needed to examine the safety analyses submitted by CEA regarding the Cabri nuclear facility. It also published a framework agreement designed to assist it with the definition and implementation of the oversight of complex projects at EDF, CEA and Andra.

## 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 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 drafting 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 at the Ministry for Energy Transition and by ASN.

This Working Group 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 14 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 a 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 16 experts appointed by ASN, from learned societies, along with representatives of the French health institutions. The sub-group of experts working on the ZAP-X self-shielded radiotherapy platform met on 31 May 2022. An opinion from the Canpri is currently being drafted. The sub-group working on flash radiotherapy met on 20 October and 10 November 2022. This group will continue its work in 2023.

### 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 purpose of the Cofsoh is on the one hand to allow exchanges between stakeholders on such a difficult subject as SHOF and, on the other, to draft documents proposing common positions by the various members of the Cofsoh on a given subject, as well as guidelines for studies to be taken to shed light on subjects for which there is a lack of data or need for clarity.

ASN also heads the national Committee in charge of monitoring the National Plan for the management of radon risks. In 2019 and 2020, the Committee drew up the fourth radon plan for the period 2020-2024, which was published in early 2021 (see chapter 1). The Committee met six times for this purpose. Within the framework of this plan, ASN has since 2018 been heading a working group in charge of coordinating communication measures regarding management of the radon risk.

## 2.7 The other stakeholders

As part of its mission 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 Medication and Health Products

The National Agency for the Safety of Medication 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 Agency and its activities are presented on its website [ansm.sante.fr](http://ansm.sante.fr). This agreement is currently being renewed.

### 2.7.2 French National Authority for Health

The essential role of the 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 Authority and its activities are presented on its website [has-sante.fr](http://has-sante.fr). 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.

TABLE 2 Status and activities of the main civil nuclear safety regulators<sup>(\*)</sup>

COUNTRY / REGULATOR	STATUS			ACTIVITIES						
	ADMINISTRATI- ON	GOVERNMENT AGENCY	INDEPEND- ENT AGENCY	SAFETY OF CIVIL FACILITIES	RADIATION PROTECTION			SECURITY (PROTECTION AGAINST MALICIOUS ACTS)		TRANSPORT SAFETY
					LARGE NUCLEAR INSTALLA- TIONS	OUTSIDE BNIs	PATIENTS	SOURCES	NUCLEAR MATERIALS	
<b>Europe</b>										
Germany/Bmub + Länder	■			■	■	■	■	■	■	■
Belgium/AFCN		■		■	■	■	■	■	■	■
Spain/CSN			■	■	■	■	■	■	■	■
Finland/STUK		■		■	■	■	■	■	■	■
France/ASN			■	■	■	■	■	■ (**)	■	■
United Kingdom/ ONR		■		■	■			■	■	■
Sweden/SSM		■		■	■	■	■	■	■	■
Switzerland/ENSI			■	■	■				■	■
<b>Other countries</b>										
Canada/CCSN			■	■	■	■	■	■	■	■
China/NNSA	■			■	■	■		■	■	■
Korea/NSSC		■		■	■	■		■	■	■
United States/ NRC			■	■	■	■	■	■	■	■ (***)
India/AERB		■		■	■	■	■	■	■	■
Japan/NRA		■	■	■	■	■	■	■	■	
Russia/ Rostekhnadzor	■	■		■	■			■	■	■
Ukraine/SNRIU	■	■		■	■	■		■	■	■

\* Schematic, 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.

### 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 €559.77 million in 2022. The proceeds go to the central State budget.

In addition, for certain BNIs, said Act also creates three additional taxes, known as “research”, “support” and “disposal”, respectively. The revenue from these taxes is allocated to funding economic development measures

and research into underground disposal and storage by the Andra. The revenue from these taxes represented €126.18 million in 2022, of which €3.30 million were paid in 2022 to the municipalities and the local public cooperation bodies situated around the disposal centre. 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 €80.7 million in 2022. 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 €61.09 million in 2022.

TABLE 3 Breakdown of licensee contributions

LICENSEE	AMOUNT FOR 2022 (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	18.00	6.20	4.00	5.42
CEA	4.51	18.34	13.70	7.08
Andra	5.41	3.30	-	0.40
Others	1.25	1.67	-	0.71
<b>Total</b>	<b>559.77</b>	<b>126.18</b>	<b>80.70</b>	<b>61.09<sup>(*)</sup></b>

\* The amount allocated to IRSN is capped at €61.09 million.

### 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 Institute and its activities are presented on its website *e-cancer.fr*. 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).

## 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 2022 Budget Act, the ASN budget (action 9 of programme 181 "Risk prevention") amounted to €68.30 million in payment credits. It included €50.67 million for personnel expenses and €17.63 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 and Regional Cohesion (programme 217) and the General Secretariat of the Government (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 2022 amounted for its part to €288 million, of which €83.5 million were devoted to the provision of technical support for ASN. IRSN credits for providing ASN with technical support come in part (€41.8 million) from programme 190 (see below). The rest (€41.7 million) comes from a contribution paid by the nuclear licensees. This contribution was put into place by the budget amendment Act of 29 December 2010.

In total, in 2022, the State's budget for transparency and the regulation of nuclear safety and radiation protection in France amounted to €300.34 million.

By way of comparison, the amount of taxes collected by ASN in 2022 amounted to €766.66 million:

- €559.77 million from BNI taxes (paid into the State's general budget);
- €126.18 million from additional "support", "disposal" and "research" taxes (allocated to various establishments, including Andra, municipalities and Public Interest Groupings (GIPs);
- €80.7 million from the special contribution for the management of radioactive waste (allocated to Andra).

This complex funding structure is detrimental to the overall clarity of the cost of regulation. It moreover leads to difficulties in terms of budgetary preparation, arbitration and implementation.



## 4. Outlook

The year 2023 will be the first year of implementation of ASN's new Multi-year Strategic Plan. In organisational terms, it will on the one hand renew the working organisation in order to take greater advantage of remote-working resources and, on the other hand, take full benefit from the cross-functionality between all the entities, in "project" formats appropriate for the situations where applicable. All the internal transformations will be part of an eco-friendly approach.

With regard to skills, ASN will adapt them to the new challenges in order to reinforce the oversight of organisational and human factors, project management and the industrial capacity of the licensees and their suppliers.

In budgetary and financial terms, work to consolidate the financing of both its operations and its expert assessment capacity will be continued.

In terms of expert assessments, 2023 will see the start of a new mandate, with a renewed composition, for six Advisory Committees of Experts (GPDEM, GPR, GPU, GPT, GPD and GPESPN) which should be called on more extensively in the coming years, given the rise in the volume of examination work with major implications. ASN will also reinforce its use of external expert assessments, in order to meet the specific needs of the examination work scheduled for the short and medium terms.

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**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 2021 AE (€M)	INITIAL BUDGET ACT 2021 CP (€M)	INITIAL BUDGET ACT 2022 AE (€M)	INITIAL BUDGET ACT 2022 CP (€M)	BNI TAX 2022 (€M)
Ministerial mission <b>Ecology, sustainable development and spatial planning</b>	Programme 181: Risk prevention	<b>Action 9:</b> Regulation of nuclear safety and radiation protection	Staff costs (including seconded employees)	49.41	49.41	50.67	50.67	
			Operating and intervention expenditure	59.73	17.73	12.93	17.63	
			<b>Total</b>	<b>109.14</b>	<b>67.14</b>	<b>63.60</b>	<b>68.30</b>	
		<b>Action 1:</b> 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	
			<b>Sub-total</b>	<b>109.29</b>	<b>67.29</b>	<b>63.75</b>	<b>68.45</b>	
Ministerial mission <b>Oversight of Government actions</b>	<b>Programme 217:</b> Management and coordination of policies for ecology, sustainable development and mobility <b>Programme 354:</b> 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				559.78
Interministerial mission <b>Management of public finances and human resources</b>	<b>Programme 218:</b> Implementation and coordination of economic and financial policies	-	Part of the shared operation of the ASN central services					
Interministerial mission <b>Research and higher education</b>	<b>Programme 190:</b> Research in the fields of energy and sustainable development and spatial planning	<b>Sub-action 11-2 (area 3):</b> French Institute for Radiation Protection and Nuclear Safety	IRSN technical support activities for ASN	41.80	41.80	41.80	41,80	
		<b>Sub-action 11-2 (3 other areas):</b> French Institute for Radiation Protection and Nuclear Safety	-	-	125.40	125.40	129.00	
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)			-	19.40	19.40	19.36	19.36	
Annual contribution on behalf of IRSN instituted by Article 96 of budget amendment Act 2010-1658 of 29 December 2010 dedicated to IRSN's technical support activities for ASN			-	41.90	41.90	41.73	41.73	
			<b>Sub-total</b>	<b>228.50</b>	<b>228.50</b>	<b>231.89</b>	<b>231.89</b>	<b>559.78</b>
<b>Grand Total (excluding IRSN and programmes 217, 218 and 354)</b>				<b>192.99</b>	<b>150.99</b>	<b>147.28</b>	<b>151.98</b>	<b>559.78</b>
<b>ASN and IRSN Grand Total (excluding programmes 217, 218 and 354)</b>				<b>337.79</b>	<b>295.79</b>	<b>295.64</b>	<b>300.34</b>	

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.

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# Regulation of nuclear activities and exposure to ionising radiation

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In France, the party responsible for a nuclear activity 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 a party responsible for a nuclear activity 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, binding requirements, inspection follow-up letters, plus penalties as applicable.

The oversight priorities are defined with regard to the risks inherent in the activities, the behaviour of those responsible for the activities and the means they deploy to control them. In the priority areas, ASN must reinforce its oversight. Conversely, for lower-risk areas, ASN must be able to explicitly scale-back 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 facilities:

- 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 proportionality 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).

### 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);
- those in charge of activities entailing a risk of exposure of individuals and workers to ionising radiation;
- those in charge of implementing ionising radiation exposure monitoring measures, such as 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. Chapter 10 details the ASN's particular actions in 2022 concerning the inspection of the NPPs procurement chain.

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.

*In this chapter, these persons or entities are called the "licensees".*

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. ASN carries out labour inspectorate 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 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 spot 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 entities and laboratories taking part in radioactivity measurements and radiation protection inspections, as well as qualification of pressure equipment monitoring organisations;
- presence in the field, also frequently outside actual inspections;
- dialogue with the professional organisations (trades unions, professional orders, learned societies, 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 the 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 implementation of 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 pressure equipment, 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.

The operation of pressure equipment is subject to regulatory oversight in particular covering in-service monitoring programmes, non-destructive testing, maintenance work, processing of anomalies affecting these systems and periodic requalifications.

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 monitoring 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 EPR reactor under construction at Flamanville 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:

- 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 8.20 Full-Time Equivalent of which 2 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 (CHSCT) and the Inter-company Committees on Safety and Working Conditions (CIESCT), 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 noteworthy 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 approved organisations and Laboratories is available on [asn.fr](http://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 premises open to the public;
- assessment of NPE conformity and inspection of PE in service.

TABLE 1 Methods of ASN regulation of the various radiation protection stakeholders

	EXAMINATION/AUTHORISATION	INSPECTION	COOPERATION
Users of sources of ionising radiation	<ul style="list-style-type: none"> <li>• Examination of the dossiers required by the Public Health Code (Articles R.1333-1 et seq.)</li> <li>• Pre-commissioning inspection, mainly in the medical field</li> <li>• Receipt of notification, registration or issue of authorisation (Article R. 1333 -8)</li> </ul>	<ul style="list-style-type: none"> <li>• Radiation protection inspection (Article L. 1333-29 of the Public Health Code)</li> </ul>	<ul style="list-style-type: none"> <li>• Jointly with the professional organisations, drafting of guides of good practices for users of ionising radiation</li> </ul>
Organisations approved for radiation protection checks	<ul style="list-style-type: none"> <li>• Examination of approval application files for performance of inspections required by Article R. 1333-172 of the Public Health Code</li> <li>• Organisation audit</li> <li>• Delivery of approval</li> </ul>	<ul style="list-style-type: none"> <li>• Second level inspection:                             <ul style="list-style-type: none"> <li>– in-depth inspections at head office and in the branches of the organisations</li> <li>– unannounced field supervision inspections</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Jointly with the professional organisations, drafting of rules of good practices for performance of radiation protection checks</li> </ul>

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.

In 2021, the Organisations Approved for Radiation Protection (OARP) verifications carried out 87,304 verifications, with the breakdown per type of source and per field being given in Table 2.

The reports of the verifications performed in each facility by the OARP verifications are at the disposal of and examined by ASN personnel on the occasion of:

- licence renewals or modifications requiring ASN authorisation;
- inspections.

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.

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).

The updated list of approvals issued by ASN is available on *asn.fr*.

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, 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 kg or more of uranium hexafluoride (UF<sub>6</sub>);
- 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 UF<sub>6</sub> packaging.

As at 31 December 2022, the following are approved or accredited by ASN:

- 23 organisations responsible for radiation protection verifications. Four approval renewals were delivered in 2022;
- 83 organisations tasked with measuring radon activity concentration in buildings. Fifteen of them are approved to identify sources and means of radon ingress into buildings. In 2022, ASN issued 52 new approvals or approval renewals;
- 4 organisations qualified for NPE inspections as part of the new NPE conformity assessment;
- 2 organisations qualified for NPE inspections as part of in-service monitoring;
- 3 organisations qualified for PE and simple pressure vessels within the perimeter of BNIs (in-service monitoring);
- 17 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 978 approvals, of which 139 are approvals or approval renewals delivered during 2022.

In 2022, the regulations on radon measurement in Public Access Buildings (PAB) changed:

- resolution 2022-DC-0743 of 13 October 2022 replaces resolution 2009-DC-0134 of 7 April 2009. The main modification corresponds to the removal of approval level 1 option B for radon screening, as well as the checks on the effectiveness and durability of the mitigation techniques in cavities and underground structures, because no PAB have been identified underground. The other changes or clarifications incorporated into the text are the following: details of approval and withdrawal of approval, extension of the maximum duration of the first approval, which is raised from one year to two years, simplification of the file to be provided when the organisation holds an accreditation, revision of the composition of the approval commission and updating of the content of the approval application file and the required content of the reports and report templates;
- resolution 2022-DC-0744 of 13 October 2022 replaces resolution 2009-DC-0136 of 7 April 2009. The drafting was revised with regard to the teaching objectives and level of competence to be acquired, expressed in terms of knowledge and know-how. The minimum duration of level 2 training is increased to 14 hours instead of one day, and the breakdown between theory and practical modules is specified;
- resolution 2022-DC-0745 of 13 October 2022 replaces resolution 2015-DC-0507 of 9 April 2015. The PAB health and environment information system (SISE-PAB) will be superseded by the *demarches-simplifiees.fr* application, which is simpler to use and creates a historical record of the results.

The three resolutions also update the current provisions, by incorporating the text and the new regulatory references of the Public Health Code derived from the 2018 Decree.

The ASN resolutions concerning the organisations approved for measurement of radon will also be updated in order to take account notably of the recent changes to the Labour Code because, since 1 January 2022, only accredited organisations can conduct the initial verification of workplaces mentioned in Article R. 4451-44 of the Labour Code.

In 2023, the regulations concerning the verifications performed and services provided by the Organisation Approved for Radiation Protection (OARP) will change.

Since 1 January 2023, the Order of 24 October 2022 relative to the procedures and frequencies of the checks on the rules put into place by the person responsible for a nuclear activity repealed ASN resolution 2010-DC-0175 of 4 February 2010 defining the procedures for verification of the OARP. This text modifies the scope of the OARP verifications. The Order applies to medical and industrial nuclear activities subject to the notification, registration and authorisation systems set out in the Public Health Code and when these activities generates 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 13-8 to the Public Health Code.

In 2023, an ASN resolution will supplement the rules that the person responsible for a nuclear activity is required to have checked by an OARP or by IRSN, specified in the Order of



**TABLE 2** Radiation protection verifications performed in 2021 by the organisations approved for radiation protection verifications

	MEDICAL	VETERINARY	RESEARCH/ TEACHING	INDUSTRY EXCLUDING BNIs	BNIs	TOTAL
Sealed sources	1,781	3	1,409	7,095	9,455	19,743
Unsealed sources	299	6	730	41,718	1,247	44,000
Mobile electrical generators of ionising radiation	2,585	191	43	719	7	3,545
Fixed electrical generators of ionising radiation	12,864	738	615	4,847	230	19,294
Particle accelerators	444	2	33	214	29	722
<b>Total</b>	<b>17,973</b>	<b>940</b>	<b>2,830</b>	<b>54,593</b>	<b>10,968</b>	<b>87,304</b>

24 October 2022. 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.

Moreover, resolution 2010-DC-0191 of 22 July 2010 will be replaced in 2023 by a new ASN resolution stipulating the conditions and procedures for the 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 adjusted 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 consequences.

##### 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 on a representative sample of other nuclear activities;
- inspections of approved organisations and laboratories.

The inspections may be unannounced or notified to the licensee a few weeks before the visit. 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;
- 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;
- in-depth inspections which take several days and cover several topics, involving 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<sup>(1)</sup>, 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 Health, Safety and Working Conditions Commissions, of Social and Economics Committees and the inter-company committees on safety and working conditions (EPR construction site);
- 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.

1. The intervention is the unit representative of the activity normally used by the labour inspectorate.



During the pandemic, ASN implemented remote-inspection measures. This type of inspection has become one of the tools available to the inspectors and is suitable for certain inspection topics. On-site inspection however remains the preferred method.

The implementation of remote inspection measures required ASN to modify the inspection indicators. For this type of inspection, the critical review of documents transmitted by a nuclear activity manager, 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 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 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 management of the means at their disposal.

In 2022, ASN finalised its work to update the text of its inspection follow-up letters. The main goal was to reinforce its graded approach and make it more legible. This work notably led to a new presentation of requests, findings and observations according to their potential consequences and to a reinforcement of the follow-up to the action taken further to the inspections for those subjects with the most serious implications. This revision was implemented as of mid-2022.

The follow-up letters are now structured as follows:

- a summary of the inspection, which presents the subjects examined, the inspection process and the inspectors' assessments. It can include the change observed with respect to a previous inspection;
- the inspection findings which, depending on their implications or their consequences, are either the subject of reasoned and prioritised requests, or are simply notified to the inspected entity without requiring any formal reply from it to ASN, in accordance with the following plan:
  - I. the requests for priority actions, the implications of which warrant reactive processing and more in-depth follow-up;

- II. the other requests: actions to be dealt with through an action plan with deadlines subject to ASN validation;
- III. findings and observations requiring no reply: findings of lesser importance made during the inspection, which require no formal reply from the inspected entity to ASN, but which it will nonetheless have to take into account, along with any observations the inspectors wish to make. In the event of a reoccurrence illustrating a systemic deficiency, these findings of lesser importance could be the subject of requests.

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 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 6).

Some inspections are carried out with the support of one or more IRSN representatives specialised in the facility 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 aids) to assist them in their inspections.

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 in-depth 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;

TABLE 3 Breakdown of inspectors per inspection field as at 31 December 2022

INSPECTOR CATEGORIES	DEPARTMENTS	DIVISIONS	TOTAL
Nuclear Safety Inspectors	135	123	258
<i>including nuclear safety inspectors for transport</i>	13	47	60
Radiation protection inspectors	39	108	147
Labour inspectors	2	18	20
Inspectors for all fields	157	172	329

TABLE 4 Number of inspections per field in 2022

BASIC NUCLEAR INSTALLATION (EXCLUDING PRESSURE EQUIPMENT)	PRESSURE EQUIPMENT	TRANSPORT OF RADIOACTIVE SUBSTANCES	SMALL-SCALE NUCLEAR ACTIVITIES	APPROVED ORGANISATIONS AND LABORATORIES	TOTAL
725	146	96	832	69	1,868

03

- 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 in at least one inspection performed in a different region. This rule was considerably relaxed in 2020 owing to the Covid-19 pandemic context and the need, at certain times, to avoid the spread of the virus between regions, but was restored in 2021.

Table 3 presents the headcount of inspectors, which stood at 329 on 31 December 2022. Some inspectors operate in several inspection areas, 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 52% of the ASN inspectors. The 157 inspectors assigned to the departments take part in ASN inspections within their field of competence; they represent 48% of the inspector headcount and carried out 18% of inspections in 2022, 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 2022, the ASN inspectors carried out a total of 1,868 inspections, representing 4,093 inspection man.days in the field. About 4% of the inspections were carried out remotely. The breakdown per field is given in Table 4.

### ASN inspections programme

To guarantee a distribution of the inspection resources that is proportionate to the safety and radiation protection implications of the various facilities and activities, ASN drafts a planned inspections schedule every year, taking account of the inspection issues (see point 3.1). This programme is not communicated to either the licensees or the nuclear activity managers.

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 2022, 2,439 inspector.days were devoted to the on-site field inspection of BNIs and NPE, corresponding to 850 inspections. Of these, 20% were unannounced. Furthermore, 21 inspections were conducted remotely.

Inspection work in the field can be broken down into 1,238 inspector.days in the NPPs (395 on-site inspections), 868 inspector.days in the other BNIs (320 on-site inspections), that is mainly the “fuel cycle” facilities, research facilities and installations undergoing decommissioning, and 333 for NPE (135 on-site inspections).

The remote inspections can be broken down as follows: 8 inspections for the nuclear power plants, 2 inspections for the other BNIs and 11 inspections for NPE.

TABLE 5 Breakdown of inspection days by topic in 2022

PER FIELD	NUMBER OF INSPECTOR DAYS	NUMBER OF INSPECTIONS PERFORMED
Basic Nuclear Installation /Pressurised Water Reactor	1,238	395
Basic Nuclear Installation/Laboratories Plants Waste and Decommissioning	868	320
Basic Nuclear Installation/Pressure Equipment	333	135
Small-scale nuclear activities/Industry	452	268
Small-scale nuclear activities/Medical	800	427
Small-scale nuclear activities/Natural radioactivity	26	24
Small-scale nuclear activities/Polluted sites and ground	5	3
Small-scale nuclear activities/Research	73	45
Small-scale nuclear activities/Veterinary	30	25
Small-scale nuclear activities/Other	6	7
Transport of radioactive substances	137	92
Approved Organisations/Approved laboratories	127	55
Total(*)	4,093	1,796

\* The fact that the various numbers are rounded off gives a total slightly different from the sum of each line.

Three joint inspections were performed in 2022 on the nuclear power plants of Saint-Laurent-des-Eaux and Penly, as well as on the La Hague site, corresponding to 118 inspector.days.

The ASN labour inspectors also carried out 450 interventions during the 128 inspection days in the NPPs.

### 3.1.4 Inspection of radioactive substances transport

In 2022, 137 inspector.days were devoted by ASN to on-site inspection of transport activities, corresponding to 92 on-site inspections. Of these, 26% were unannounced. 4 remote inspections were 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 2022, 1,392 inspector.days were devoted to on-site inspections of small-scale nuclear activities, corresponding to 799 on-site inspections, 8% of which were unannounced, plus 33 remote inspections. This inspection work was notably distributed among the medical, industrial, veterinary, research or natural 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 2022, 127 inspector.days were devoted to checking approved organisations and laboratories, corresponding to 55 inspections, 20% of which were unannounced, plus 14 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 PAB 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 PAB 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 methods used for these

checks take account of the recommendations issued by ASN and included in the circular from the General Directorate for Health 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 Analysis of 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 research and development 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 other matters, 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 an Advisory Committee of Experts, 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 that 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 the 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, as well as OEF. 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 concerns 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 approach

#### 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, radiation protection and environmental protection, 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 TSR 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, the nuclear licensees detect and analyse several hundred anomalies every year, for each EDF 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 reported 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 the 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 experience feedback about the event.

The purpose of this system is not to identify or penalise any individual person or party.

Moreover, the number and rating on the International Nuclear and Radiological Event scale (INES) 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 the 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 party responsible for a nuclear activity 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 notification time of two working days (four days for significant TSR events), mentioned in the ASN notification guides, does not



**PUBLIC CONSULTATION ON THE REVISION OF THE REPORTING PROCEDURES AND CRITERIA FOR SIGNIFICANT RADIATION PROTECTION EVENTS**

In 2018, the provisions of the Public Health Code and the Labour Code concerning the exposure of individuals to ionising radiation was modified following transposition of the European Directive laying down Basic Safety Standards for protection against the dangers arising from exposure to ionising radiation.

These modifications affect the obligations to report to ASN any Significant Radiation protection Events (ESR) affecting patients, the general public or the environment.

ASN thus started a revision of these ESR reporting criteria, with the main aims being to harmonise reporting practices between the BNI and small-scale nuclear activities sectors, and to improve these practices in the

light of the lessons learned from application of the existing guides. Regulatory changes were incorporated and the new ASN inspection practices, notably the graded approach adopted at the end of 2017, were taken into account.

This work led to the production of a draft resolution applying to all professionals subject to the obligations of the Public Health Code and the Labour Code, and falling within the scope of ASN regulation and oversight: those responsible for nuclear activities, including BNI licensees, health professionals, as well as employers whose employees can be exposed to ionising radiation. The draft resolution defines the criteria and the procedures for reporting ESR to ASN.

They will apply both to BNIs and to small-scale nuclear activities.

A draft ASN Guide has also been written. It clarifies the elements defined in the resolution, so that they are as operational as possible. This Guide will replace Guide No. 11 which concerns small-scale nuclear activities and Appendix 7 of the 2005 Guide applicable to BNIs. ASN Guide No. 31 relative to the procedures for reporting TSR events will also be modified in order to take account of resolution and Guide drafts concerning ESR.

These draft texts were submitted for public consultation on the *asn.fr* website in the second half of 2022. A summary of the observations received will be posted on-line.

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 happening again, 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 human measures taken by the licensee to maintain or bring the installation into a safe condition, and the pertinence of the submitted analysis.

**TABLE 6** Number of significant events rated on the INES scale between 2017 and 2022

		2017	2018	2019	2020	2021	2022
Basic Nuclear Installations	Level 0	949	989	1,057	1,033	1,068	985
	Level 1	87	103	112	107	103	97
	Level 2	4	0	3	2	1	0
	Level 3 and +	0	0	0	0	0	0
	<b>Total</b>	<b>1,040</b>	<b>1,092</b>	<b>1,172</b>	<b>1,142</b>	<b>1,172</b>	<b>1,082</b>
Small-scale nuclear activities (medical and industry)	Level 0	144	143	142	135	177 <sup>(*)</sup>	162
	Level 1	36	22	35	24	33 <sup>(*)</sup>	39
	Level 2	3	0	2	1	0	1
	Level 3 and +	0	0	0	0	0	0
	<b>Total</b>	<b>183</b>	<b>165</b>	<b>179</b>	<b>160</b>	<b>210</b>	<b>202</b>
Transport of radioactive substances	Level 0	64	88	85	71	80	76
	Level 1	2	3	4	4	4	12
	Level 2	0	0	0	0	0	0
	Level 3 and +	0	0	0	0	0	0
	<b>Total</b>	<b>66</b>	<b>91</b>	<b>89</b>	<b>75</b>	<b>84</b>	<b>88</b>
<b>Grand Total</b>	<b>1,289</b>	<b>1,348</b>	<b>1,440</b>	<b>1,377</b>	<b>1,466</b>	<b>1,372</b>	

\* 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).



ASN and IRSN also carry out a more wide-ranging examination of the OEF 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 for 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 2022, 1,989 significant events were reported to ASN:

- 1,161 significant events concerning nuclear safety, radiation protection, the environment and the on-site transport of hazardous materials within BNIs, 1,082 of which are rated on the INES scale (97 level 1 events). Of these events, 21 significant events were rated as “generic events”, in other words concerning several reactors, including 2 at level 1 on the INES scale;
- 88 significant events concerning the TSR on the public highway (12 events rated level 1 on the INES scale);
- 740 significant events concerning radiation protection in small-scale nuclear activities, including 202 rated on the INES scale (39 were level 1 events and 1 level 2).

Graphs 1 to 6 (see pages 158 and 159) describe in detail the significant events reported to ASN in 2022, differentiating between them according to the various notification criteria for each field of activity.

In 2022, one event was rated level 2 on the INES scale. It concerns the accidental exposure of a worker who was carrying out maintenance work close to an X-ray generator used to measure the thickness of steel sheets.

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 given in Table 6. 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<sup>(2)</sup> is specified in chapter 7.

Likewise, 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.

### 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 publishes “Avoiding accidents” sheets 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;
- the approvals and accreditations it issues or rejects;
- incident notices;
- reactor outage summaries;
- thematic publications.

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.

## 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 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 on 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 into three topics:

- prevention of pollution and management of detrimental effects;
- 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 accounted 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 page 161) are counted at the decision threshold level.

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.

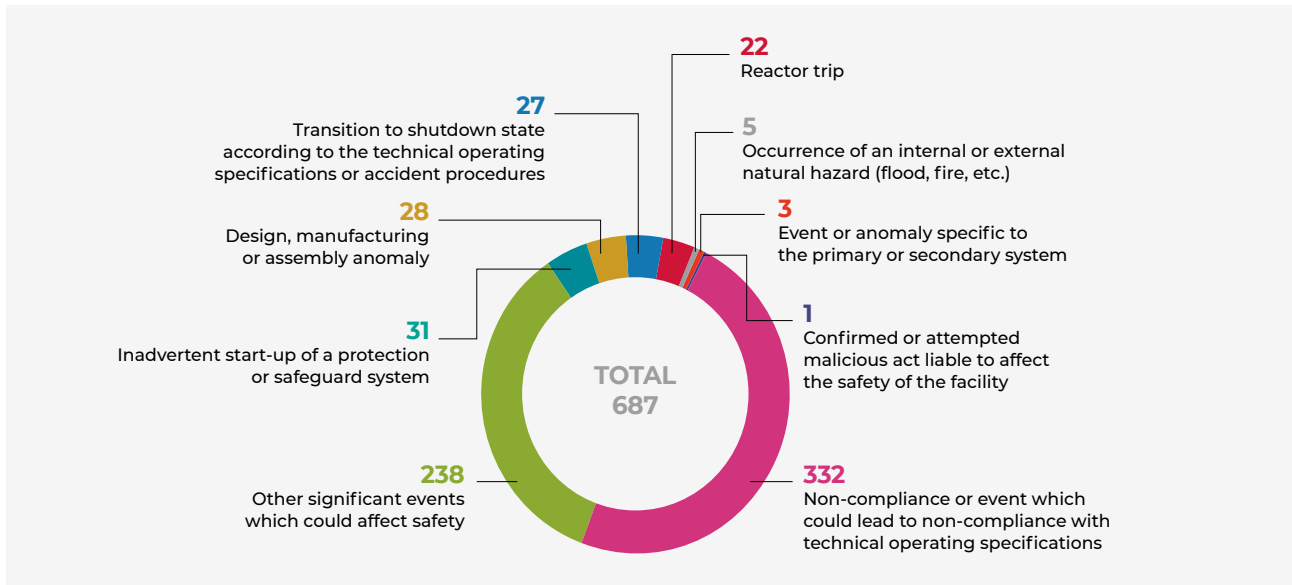
#### Monitoring discharges in the medical sector

Pursuant to ASN resolution 2008-DC-0095 of 29 January 2008, radioactivity measurements are taken on the effluents coming from the places that produce them. In hospitals that have a nuclear medicine department, these measurements chiefly concern iodine-131 and technetium-99m. In view of the difficulties encountered in putting in place the permits to discharge radionuclides into the public sewage networks, as provided for by the Public Health Code, ASN has created a working group involving administrations, “producers” (nuclear physicians, researchers) and sanitation professionals. The report from this working group formulating recommendations to improve the efficiency of the regulations was presented in October 2016 to the Advisory Committee for Radiation Protection of workers and the public (GPRADE, now called GPRP), for industrial and research applications of ionising radiation and the environment. ASN consulted the stakeholders in 2017 on this subject. The report from the working group and a circular letter intended for the professionals concerned and constituting the applicable doctrine on the subject were published on the ASN website on 14 June 2019.

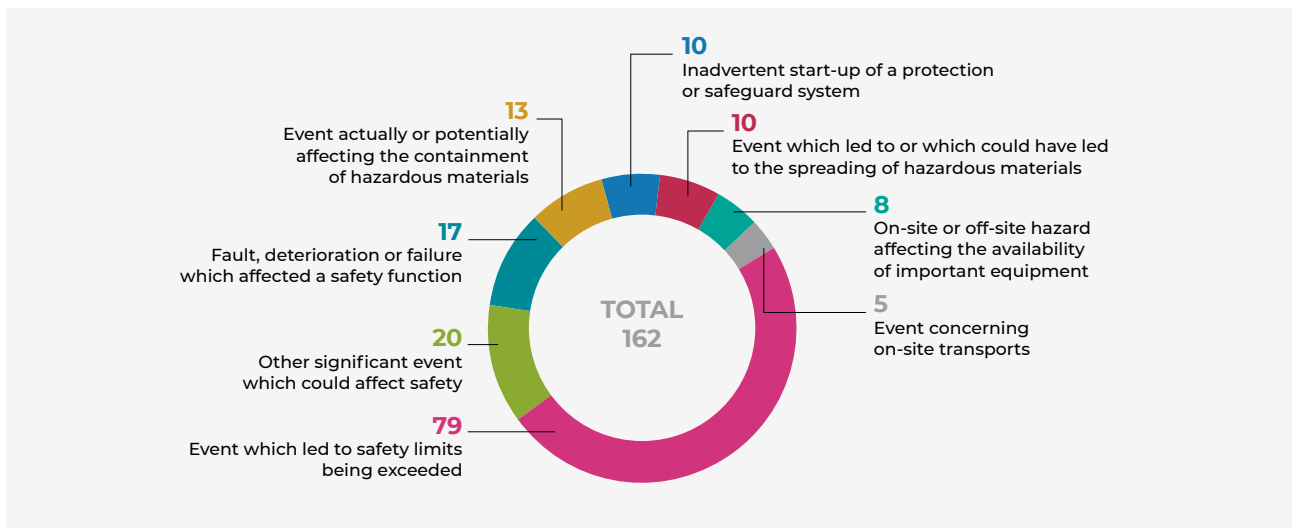
Since 2019, the CIDRRE tool (Calculation of the impact of radioactive spills into the networks) developed by IRSN, enables the licensees to evaluate the impact of their discharges. It is available on-line on the Internet. Moreover, additional work has been started concerning the use of new radiopharmaceutical drugs and their environmental impact, as well as the definition of guideline levels enabling the sewage network managers to regulate discharges into the sewage networks.

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.

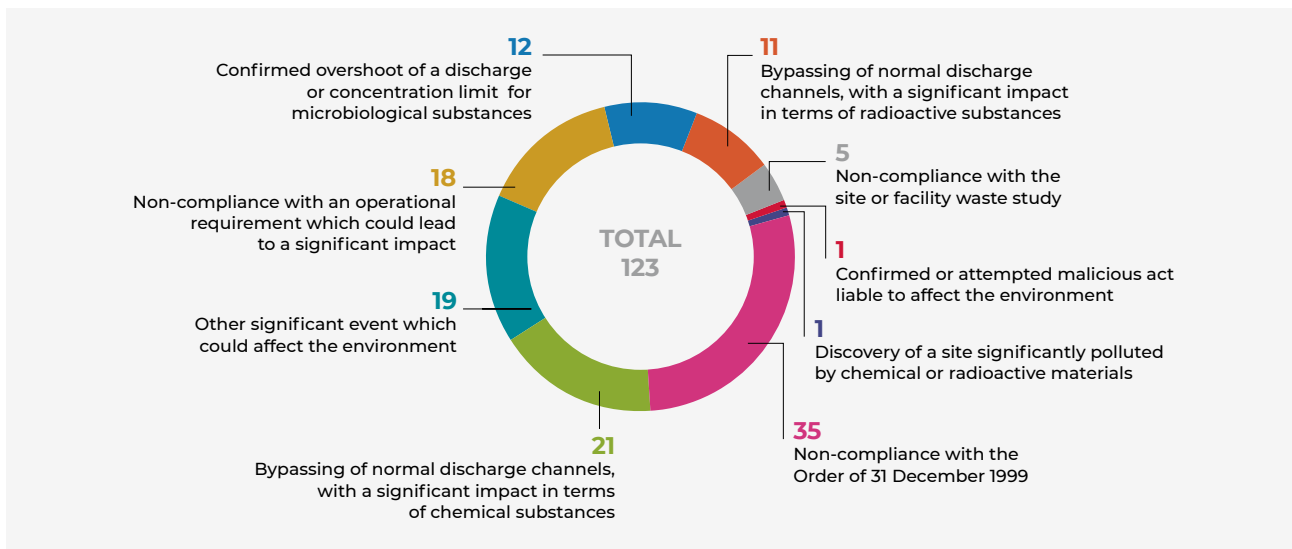
GRAPH 1 Events involving safety in the nuclear power plants reported in 2022



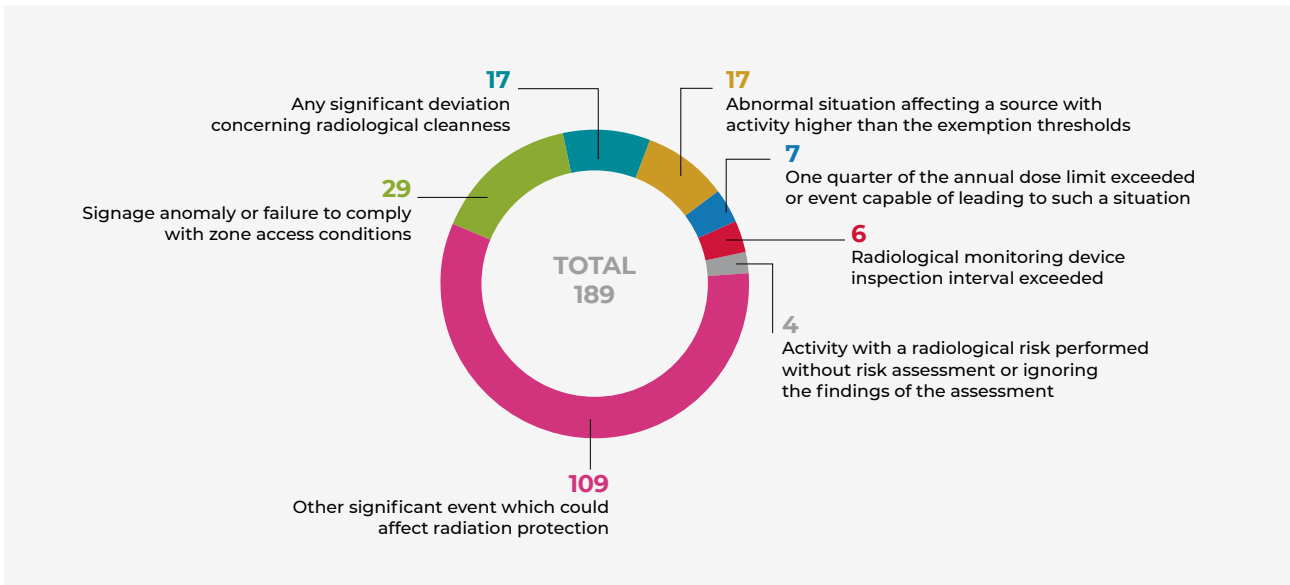
GRAPH 2 Events involving safety in BNIs other than nuclear power plants reported in 2022



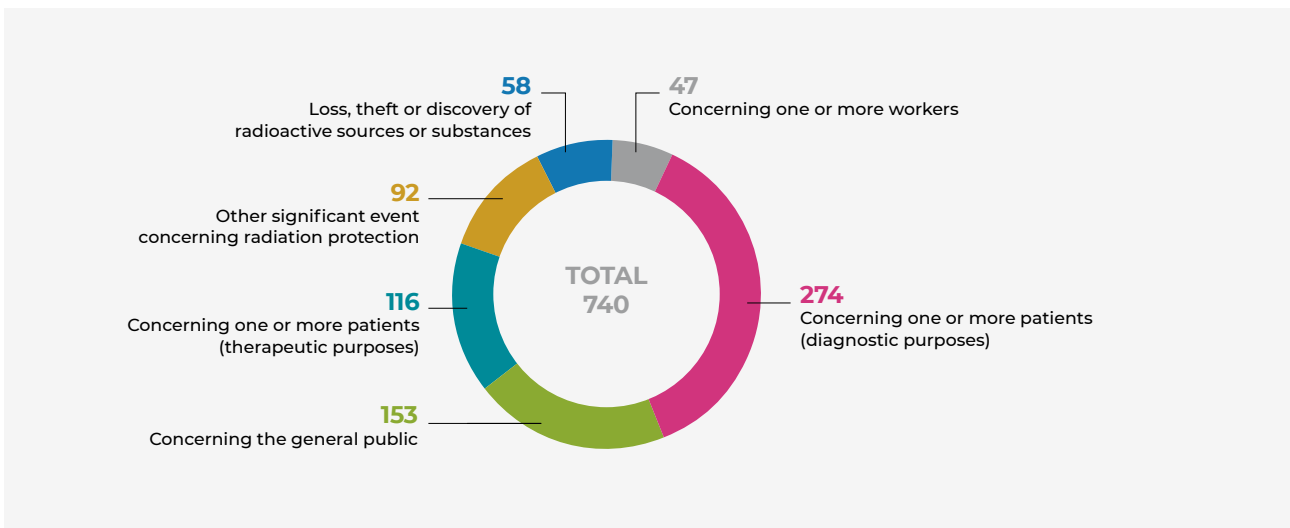
GRAPH 3 Significant environmental events in the BNIs reported in 2022



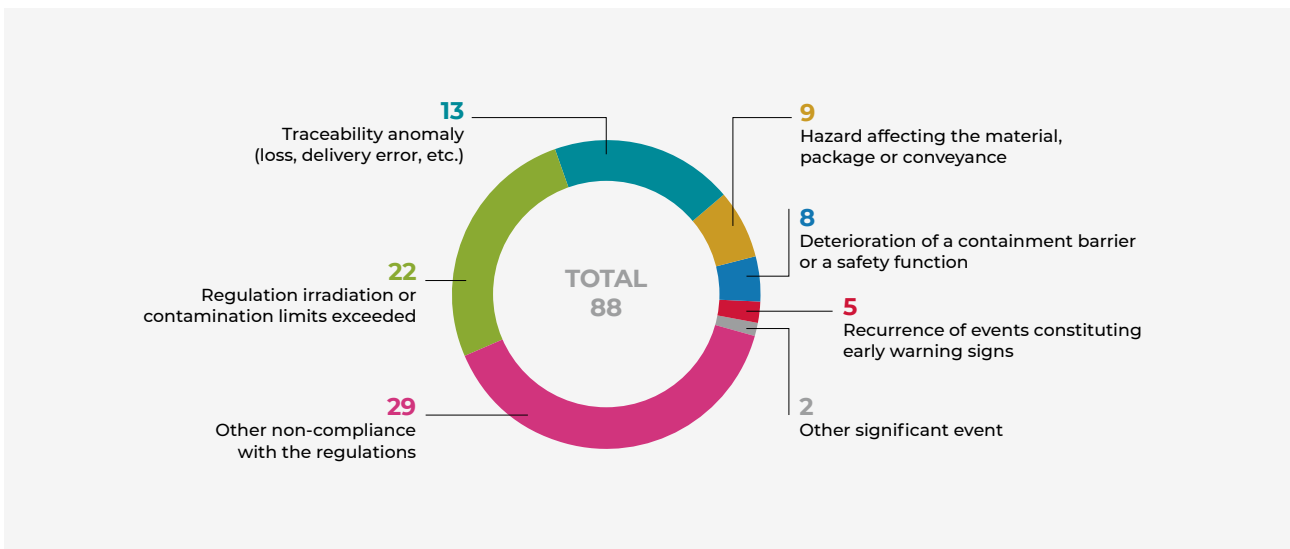
GRAPH 4 Events involving radiation protection in BNIs reported in 2022



GRAPH 5 Events involving radiation protection (other than BNIs and TSR) reported in 2022



GRAPH 6 Events involving the transport of radioactive substances reported in 2022



## 4.1.2 Evaluating the radiological impact of nuclear activities

### The radiological impact of effluents produced by medical activities

The radiological impact of the effluents or waste produced by the nuclear medicine departments underwent recent assessments, which concluded that these discharges represent a low dose impact for persons outside the health facility.

### 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 ASN resolution 2013-DC-0360 of 16 July 2013, amended, 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.

The estimate is made in relation to one or more identified reference groups. These are uniform groups of people (adults, children, infants) receiving the highest average dose out of the entire population exposed to a given installation, following realistic scenarios (taking into account the distance to the site, meteorological data, etc.). All of these parameters, specific to each site, explain most of the differences observed between sites and from one year to another.

The Table entitled “Radiological impact of BNIs since 2016” in chapter 1 presents an assessment of the doses due to BNIs calculated by the licensees for the most exposed reference groups.

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 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 European Commission has carried out the following verification inspections:

- the La Hague reprocessing plant and the Manche disposal facility of the French national radioactive waste management agency, in 1996;
- the Chooz NPP in 1999;
- the Belleville-sur-Loire NPP in 1994 and 2003;
- the La Hague reprocessing plant in 2005;
- the Pierrelatte nuclear site in 2008;
- the old uranium mines in the Limousin *département* in 2010;
- the CEA Cadarache site in 2011;
- the environmental radioactivity monitoring facilities in the Paris area in 2016;
- the La Hague reprocessing plant in 2018.

From 14 to 16 December 2021, ASN took part in the verification inspection by the European Commission on the environmental radioactivity monitoring system around the facilities operated by Orano at Malvési in the Aude *département*. The report on this visit was published in November 2022 on the website of the European Commission and confirms that the discharges and environment monitoring programme around the Malvési site is appropriate.

## 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 Ministry for Agriculture, for example);
- the approved air quality monitoring associations (local authorities), environmental protection associations and Local Information Committees (CLIs).



## 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, Ag-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).

The French National Network of Environmental Radioactivity Monitoring (RNM) brings all these players together. Its primary aim is to collect and make available to the public all the regulation environmental measurements taken on French territory, by means of a dedicated website (*mesure-radioactivite.fi*). The quality of these measurements is guaranteed by a laboratories approval procedure (see point 4.3).

The guidelines of 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, members of the CLIs, IRSN, ASN, etc.

### 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 Decree, discharge licensing orders or ASN resolutions), 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 there are no facility malfunctions, notably by analysing the ground water and checking licensees' compliance with the regulations;
- contributes to transparency and information of the public through the transmission of monitoring data to the RNM.

### 4.2.3 Content of monitoring

All the nuclear sites in France that produce discharges are subject to systematic environmental monitoring. This monitoring is proportionate 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 gives examples of the monitoring performed by the licensee of an NPP and of a research centre (or 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 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 radioactive state of the French environment*. The fourth edition of this summary, for the period 2018-2020, was published in December 2021.

Finally, between November 2020 and April 2021, IRSN carried out a campaign to measure tritium in the Loire river. This campaign, the results of which were published at the beginning of 2022, was unable to determine the origin of the atypical value of 310 becquerels per litre (Bq/L) observed in Saumur in January 2019 but did reveal significant differences in the concentrations measured at different points downstream of the discharges. Depending on the hydraulic conditions, the discharges from the site can take time to disperse uniformly across the width of the river. ASN thus questions the licensee EDF once again, through letters sent at both national and local levels, questioning the method used to monitor discharges downstream of the riverside NPPs, in particular the positioning of the stations located downstream of the environmental monitoring installations. Solutions to improve the representativeness of the samples and measurements taken downstream of the Chinon NPP are notably being studied.

#### 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 of 29 April 2008.

This network is being deployed for two main objectives:

- 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 of 29 April 2008.

In total, an approval covers about fifty measurements, for which there are as many Inter-laboratory Comparison Tests (ILT). 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 monitoring 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.

##### 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 ILT 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.

##### 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 ILT organised by IRSN. The ILT programme, which now operates on a five-yearly basis, 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 ILT. 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 2022, IRSN organised seven ILT and two cross-check tests. Since 2003, 102 ILT have been carried out, covering 59 types of approval. The most numerous approved laboratories (54) are in the field of monitoring of radioactivity in water. Between 30 and 45 laboratories are approved for measurement of biological matrices (fauna, flora, milk), atmospheric dust, air, or ambient gamma dosimetry. There are 29 laboratories for soils and sediments. Although most laboratories are competent to measure gamma

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 LA HAGUE FACILITY (ASN RESOLUTION 2015-DC-0535 OF 22 DECEMBER 2015)
Air at ground level	<ul style="list-style-type: none"> <li>4 stations continuously sampling atmospheric dust on a fixed filter with daily measurements of total <math>\beta</math> activity (<math>\beta</math>G):                             <ul style="list-style-type: none"> <li><math>\gamma</math> spectrometry if <math>\beta</math>G &gt; 2 mBq/m<sup>3</sup></li> <li>Monthly <math>\gamma</math> spectrometry on groups of filters per station</li> </ul> </li> <li>1 continuous sampling station downwind of the prevailing winds, with weekly measurement of atmospheric <sup>3</sup>H</li> </ul>	<ul style="list-style-type: none"> <li>5 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the total <math>\alpha</math> activity (<math>\alpha</math>G) and total <math>\beta</math> activity (<math>\beta</math>G):                             <ul style="list-style-type: none"> <li><math>\gamma</math> spectrometry if <math>\alpha</math>G or <math>\beta</math>G &gt; 1 mBq/m<sup>3</sup></li> <li>Monthly <math>\alpha</math> (Pu) spectrometry on grouped filters per station</li> </ul> </li> <li>5 continuous sampling stations for halogens on specific adsorbent with weekly <math>\gamma</math> spectrometry to measure iodines</li> <li>5 continuous sampling stations with weekly measurement of atmospheric <sup>3</sup>H</li> <li>5 continuous sampling stations with bi-monthly measurement of atmospheric <sup>14</sup>C</li> <li>5 continuous measurement stations for <sup>85</sup>Kr activity in the air</li> </ul>
Ambient $\gamma$ radiation	<ul style="list-style-type: none"> <li>Continuous measurement with recording:                             <ul style="list-style-type: none"> <li>4 detectors at 1 km</li> <li>10 detectors on the site boundary</li> <li>4 detectors at 5 km</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>5 detectors with continuous measurement and recording</li> <li>11 detectors with continuous measurement at the site fencing</li> </ul>
Rain	<ul style="list-style-type: none"> <li>1 continuous sampling station under the prevailing winds with bi-monthly measurement of <math>\beta</math>G and <sup>3</sup>H</li> </ul>	<ul style="list-style-type: none"> <li>2 continuous sampling stations including one under the prevailing winds with weekly measurement of <math>\alpha</math>G, <math>\beta</math>G and <sup>3</sup>H:                             <ul style="list-style-type: none"> <li><math>\gamma</math> spectrometry if significant <math>\alpha</math>G or <math>\beta</math>G</li> </ul> </li> </ul>
Environment receiving liquid discharge	<ul style="list-style-type: none"> <li>Sampling from the river upstream of the discharge point and in the good mixing area for each discharge:                             <ul style="list-style-type: none"> <li>Measurement of <math>\beta</math>G, potassium (K)<sup>(*)</sup> and <sup>3</sup>H</li> </ul> </li> <li>Continuous sampling in the river at the good mixing point:                             <ul style="list-style-type: none"> <li><sup>3</sup>H measurement (average daily mixture)</li> </ul> </li> <li>Annual sampling in aquatic sediments, fauna and flora upstream and downstream of the discharge point with <math>\gamma</math> spectrometry, free <sup>3</sup>H measurement and, on fish, organically bound <sup>14</sup>C and <sup>3</sup>H</li> <li>Periodic sampling from a stream and in the dam adjoining the site with measurements of <math>\beta</math>G, K, <sup>3</sup>H</li> </ul>	<ul style="list-style-type: none"> <li>Daily seawater samples from 2 points on the coast, with daily measurements (<math>\gamma</math> spectrometry, <sup>3</sup>H) at one of these points and for each of the 2 points, <math>\alpha</math> and <math>\gamma</math> spectrometry and <math>\beta</math>G, K, <sup>3</sup>H and <sup>90</sup>Sr measurements</li> <li>Quarterly seawater samples at 3 points offshore with <math>\gamma</math> spectrometry and <math>\beta</math>G, K, <sup>3</sup>H measurements</li> <li>Quarterly samples of beach sand, seaweed and limpets at 13 points with <math>\gamma</math> spectrometry + <sup>14</sup>C measurements and a spectrometry for the seaweed and limpets at 6 points</li> <li>Sampling of fish, crustaceans, shellfish and molluscs in 3 coastal zones of the Cotentin with <math>\alpha</math> and <math>\gamma</math> spectrometry and <sup>14</sup>C measurement</li> <li>Quarterly sampling of offshore marine sediments at 8 points with <math>\alpha</math> and <math>\gamma</math> spectrometry and <sup>90</sup>Sr measurement</li> <li>Weekly to six-monthly samples of water from 19 streams around the site, with <math>\alpha</math>G, <math>\beta</math>G, K and <sup>3</sup>H measurements</li> <li>Quarterly sampling of sediments from the 4 main streams adjacent to the site, with <math>\gamma</math> and <math>\alpha</math> spectrometry</li> <li>Quarterly samples of aquatic plants in 3 streams in the vicinity of the site with <math>\gamma</math> spectrometry and <sup>3</sup>H measurement</li> </ul>
Groundwater	<ul style="list-style-type: none"> <li>Monthly sampling at 4 points, bi-monthly at 1 point and quarterly at 4 points with <math>\beta</math>G, K and <sup>3</sup>H measurement</li> </ul>	<ul style="list-style-type: none"> <li>5 sampling points (monthly check) with <math>\alpha</math>G, <math>\beta</math>G, K and <sup>3</sup>H measurement</li> </ul>
Water for consumption	<ul style="list-style-type: none"> <li>Annual sampling of water intended for human consumption, with <math>\beta</math>G, K and <sup>3</sup>H measurements</li> </ul>	<ul style="list-style-type: none"> <li>Periodic sampling of water intended for human consumption at 15 points, with <math>\alpha</math>G, <math>\beta</math>G, K and <sup>3</sup>H measurements</li> </ul>
Soil	<ul style="list-style-type: none"> <li>1 annual sample of the topsoil with <math>\gamma</math> spectrometry</li> </ul>	<ul style="list-style-type: none"> <li>Quarterly samples at 7 points with <math>\gamma</math> spectrometry and <sup>14</sup>C measurement</li> </ul>
Vegetation	<ul style="list-style-type: none"> <li>2 grass sampling points, including one under the prevailing winds, monthly <math>\gamma</math> spectrometry and quarterly <sup>14</sup>C and C measurements</li> <li>Annual campaign for the main agricultural crops, with <math>\gamma</math> spectrometry, <sup>3</sup>H and <sup>14</sup>C measurements</li> </ul>	<ul style="list-style-type: none"> <li>Monthly grass sampling at 5 points and quarterly at 5 other points with <math>\gamma</math> spectrometry and <sup>3</sup>H and <sup>14</sup>C measurements                             <ul style="list-style-type: none"> <li>Annual <math>\alpha</math> spectrometry at each point</li> </ul> </li> <li>Annual campaign for the main agricultural crops, with <math>\alpha</math> and <math>\gamma</math> spectrometry, <sup>3</sup>H, <sup>14</sup>C and <sup>90</sup>Sr measurements</li> </ul>
Milk	<ul style="list-style-type: none"> <li>2 sampling points situated at 0 to 10 km from the installation, including one under the prevailing winds, with monthly <math>\gamma</math> spectrometry, quarterly <sup>14</sup>C measurement and annual <sup>90</sup>Sr and <sup>3</sup>H measurement</li> </ul>	<ul style="list-style-type: none"> <li>5 sampling points (monthly check) with <math>\gamma</math> spectrometry, K, <sup>3</sup>H, <sup>14</sup>C and <sup>90</sup>Sr measurement</li> </ul>

$\alpha$ G =  $\alpha$  total;  $\beta$ G =  $\beta$  total

\* Measurements of total concentration of potassium by spectrometry for <sup>40</sup>K.

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 2022, ASN issued 139 approvals or approval renewals and decided that 2 approvals would be maintained. As at 1 January 2023, the total number of approved laboratories stood at 67, which represents 978 approvals of all types currently valid.

The detailed list of approved laboratories and their scope of technical competence is available on [asn.fr](http://asn.fr).

## 03

## 5. Inspections concerning fraud and processing of reported cases

### 5.1 Monitoring of 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 is employed by ASN to cover any intentional modification, alteration or omission of certain information or data. An irregularity detected by ASN can be dealt with by a judge in a case of criminal fraud.

The number of confirmed or suspected cases only represents a very small proportion of the nuclear activities, but these cases show that neither the robustness of the monitoring and inspection chain, for which the manufacturers, suppliers and licensees have prime responsibility, nor the high level of quality required in the nuclear industry, have been able to totally rule out the risk of counterfeit, fraud and falsification. Not all of these cases were detected by the licensee's monitoring process, which must now be more adequately tailored to the prevention, detection, analysis and processing of cases of fraud.

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 led to changes in the ASN oversight methods, but it continues to be dealt with using the existing procedures.

ASN also reminded the BNI licensees and the main manufacturers of nuclear equipment that an irregularity is a deviation as defined by the BNI Order. The requirements of the BNI Order therefore apply to the prevention, detection and processing of cases that can be considered to be fraud. 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.

In 2022, the search for irregularities comparable to falsifications during routine inspections in the nuclear facilities continued, with such verifications being incorporated into the usual practices of the inspectors, who are now able to use new internal tools.

These inspections are of three types:

- inspections further to known subjects, resulting from irregularities 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;

- inspections with the purpose of raising awareness concerning the risks of fraud, notably during supplier inspections, where the risk of fraud in the subcontracting chain was dealt with.

About forty inspections were carried out in this way in 2022, excluding the inspections which carried out verifications but with no discovery of suspicious cases and for which there is no traceability. They mainly take 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 report or notification is sent to the Public Prosecutor's Office.

In addition, the question of data integrity, that is ensuring that they have not been modified or destroyed without authorisation, linked to the risk of fraud given that shortcomings in traceability can facilitate irregularities, is addressed frequently and forms the subject of requirements in certain inspection follow-up letters.

The detection of irregularities or suspicious cases is still very much a topical issue, both for the licensees themselves, within the context of their monitoring and internal checks, and for the ASN inspectors. Several cases were reported to ASN in 2022 and are being followed-up and processed in close collaboration with the licensees and manufacturers. The most striking case in 2022 is the discovery of irregularities committed by the Japanese manufacturer JSW, first of all reported as only affecting the non-nuclear sector and then, following investigations by a special committee, also detected on equipment intended for the nuclear industry. In 2023, ASN will continue to monitor the handling of this case by the licensees concerned.

ASN's actions to prevent, detect and process fraud type irregularities 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 discussions with foreign safety regulators, through an international exchange channel that it actively helped to set up.

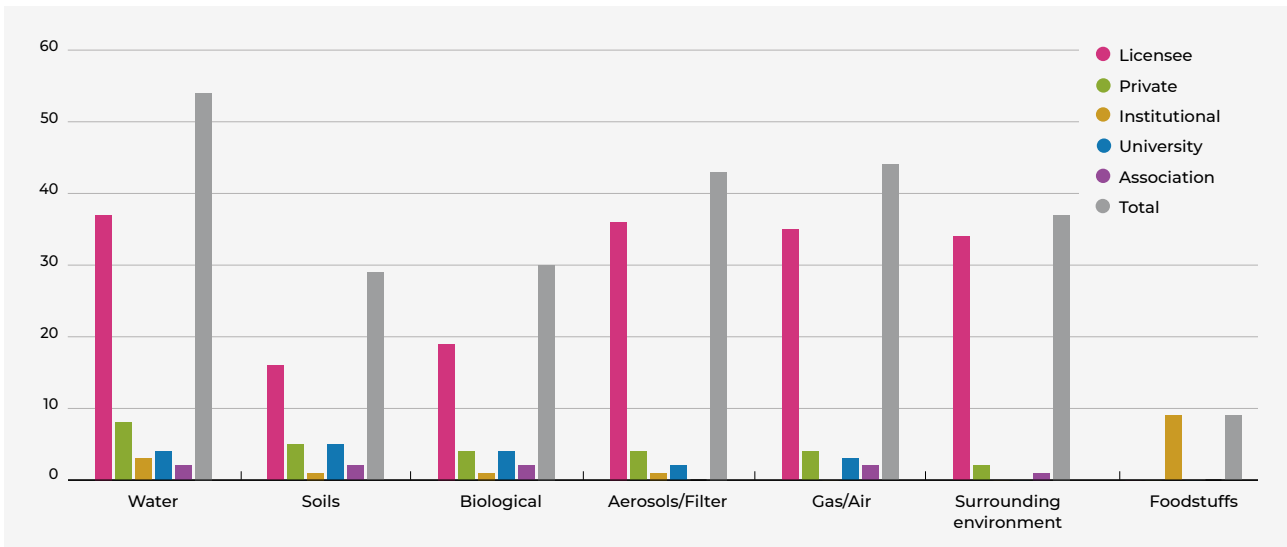
### 5.2 Processing of reported cases

At the end of November 2018, ASN set up an on-line portal to enable anyone wishing to report irregularities potentially affecting the protection of persons and the environment, potentially a whistle-blower, to do so.

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 not 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;

GRAPH 7 Breakdown of the number of approved laboratories for a given environmental matrix as at 1 January 2023



- contact them if clarification is required (this is frequently the case);
- inform them if action has been taken following their alert.

In 2022, 46 reports were sent to ASN: three-quarters (34) via the whistle-blower portal, the others by alternative means of transmission, mainly (8 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: just under one third concern BNIs, about one quarter the medical field;
- in their content: they can report deterioration in the organisation of the entity which could affect radiation protection, poorly performed work, etc.

Some reports are forwarded by ASN to other administrations when it is not competent to deal with them. All reports are examined and dealt with. This can lead to an inspection, a technical analysis, a request for information from a nuclear activity manager, 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.

Thirteen reports were verified during the course of inspections. The follow-up to these inspections is dealt with in the same way as routine inspections. One of them for example led to discussions with the Public Prosecutor’s Office owing to the potential gravity of the allegations contained in the report.

Few reports received in 2022 were anonymous (six), which make it easier to process them. Only one report could not be processed because its content was not detailed enough to allow this and its author could not be reached.

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 Act 2022-401 supplements these provisions by detailing the whistle-blowing report processing mechanisms. This Decree defined ASN as having competence to process whistle-blower alerts regarding radiation protection and nuclear safety.

The portal for submitting alerts to ASN and its internal procedures are being updated to take account of these changes.



## 6. Identifying and correcting deviations

ASN implements enforcement measures, making it possible to oblige a licensee or party responsible for a nuclear activity to restore compliance with the regulations, along with penalties.

In certain situations in which the actions of the licensee or party responsible for a nuclear activity 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, 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.

### 6.1 Enforcement measures and administrative sanctions

ASN has a range of tools at its disposal regarding the party responsible for a nuclear activity 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;
- have the work carried out without consulting the licensee or the party responsible for the nuclear activity and at its expense (any sums deposited beforehand can be used to pay for this work);
- 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 nuclear activity

manager 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 once again for its annual information meeting on 9 December 2022. The Act also provides for precautionary measures taken to safeguard public security, 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;
- prescribe at any time the assessments and implementation of the necessary measures in the event of a threat to the above-mentioned interests;
- take decisions to temporarily or definitively revoke the administrative title (authorisation and soon registration) issued to the party responsible for the nuclear activity, 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 2022, ASN sent out formal notice on three occasions: one for BNIs and two for small-scale nuclear activities.

Following an inspection during which shortcomings in the storage of gamma radiography equipment were noted, in breach of the obligations of protection against malicious acts, ASN limited the authorization to hold gamma radiography equipment.

### 6.2 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 infringements observed are written up in reports by the nuclear safety and radiation protection inspectors and transmitted to the Public Prosecutor’s Office, that decides on what subsequent action, if any, is to be taken.

The Environment Code makes provision for criminal penalties, a fine or even a term of imprisonment (up to €150,000 and 3 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. 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).

TABLE 8 Number of reports transmitted by the ASN inspectors between 2017 and 2022

	2017	2018	2019	2020	2021	2022
Report excluding labour inspection in the NPPs	13	14	8	4	2	3
Labour inspection report in the NPPs	5	2	4	8	0	2

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, notably provide for 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 2022, five violation reports were drawn up by the ASN inspectors. Table 8 shows the number of violation reports drawn up by the ASN inspectors between 2017 and 2022.

A person with their hair in a bun, wearing a grey jacket and a blue face mask, is seen from behind sitting at a desk. The desk has two computer monitors. The left monitor displays a dashboard with various charts and graphs. The right monitor displays a map with a red location marker. A red first aid kit is on the desk to the left. The word "ANTICIPATION" is printed in white on the back of the jacket.

ANTICIPATION

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# Radiological emergency and post-accident situations

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**N**uclear 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 notably aim to incorporate the lessons learned from the accident on the Fukushima Daiichi Nuclear Power Plant – NPP (Japan) and from national emergency exercises into 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 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 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 General Secretariat for Defence and National Security (SGDSN) and ASN is associated with this revision work.

#### b) Off-site Emergency Plan

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, in a radius of up to 20 km around the installations, the PPI provide for 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 (PUIs) 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. 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 on-site emergency plan, 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:

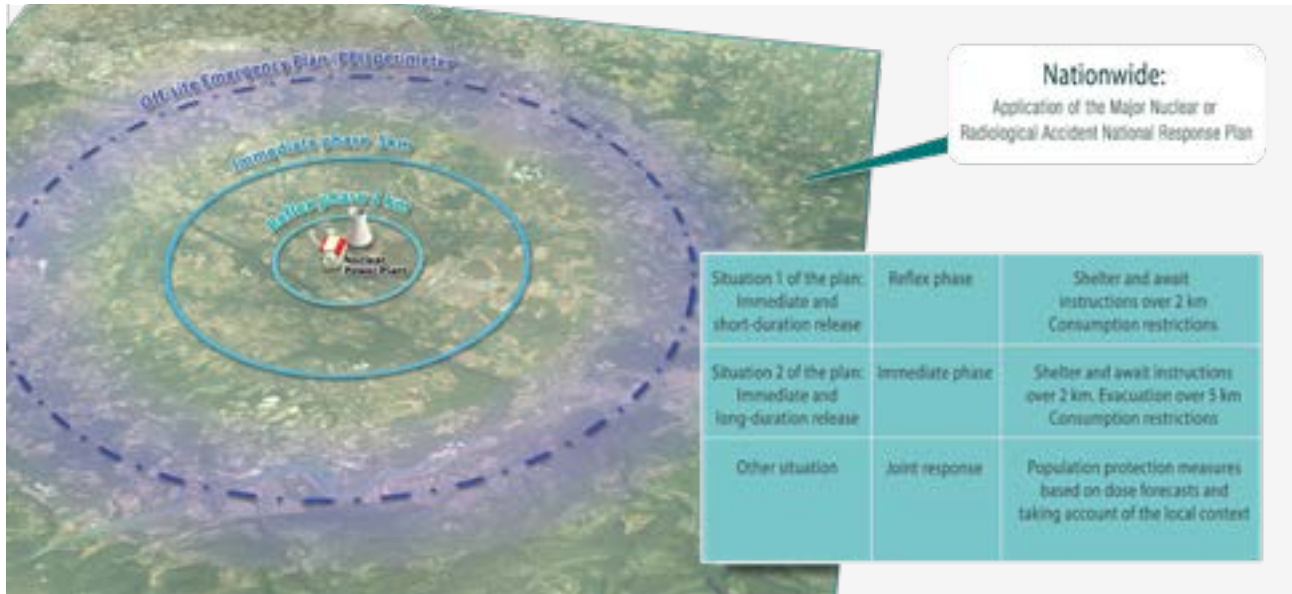
- during performance of a nuclear activity for medical, research or industrial purposes;
- in the event of intentional or inadvertent dispersal of radioactive substances into the environment;
- if radioactive sources are discovered in places where they are not supposed to be.

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.

DIAGRAM 1 Major nuclear or radiological accident national response plan



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### 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 Commissions and Committees (Ancli), 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 multi-faceted 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 assists the Prefect with managing the situation.
- 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, 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.

The Circular of 27 May 2009 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 requires that, as the party responsible for the safety of its facilities, the licensee finances the public information campaigns within the perimeter of the PPI and carries out permanent preventive distribution of the stable iodine tablets, free of charge, through the network of pharmacies.

An information and iodine tablet distribution campaign began in 2019 in a radius of 10 to 20 kilometres around the nuclear power plants further to the extension of the PPIs. It is complementary to the 2016-2017 campaign which concerned residents within a radius of 0-10 km.

Led by the Ministry of the Interior, this campaign involves the Ministries of Solidarities, and Health, and National Education, ASN, IRSN, pharmacists, general practitioners, Mayors, CLIs and EDF. The tablet collection campaign continued until January 2021 and was then ended, with tablets being sent by post in early 2021 to the homes of those people who had not collected them from a pharmacy, in the same way as for the previous campaigns in the 0-10 km zone.

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 in their *département*, relying in particular on the Mayors for this.

This arrangement is described in a Circular of 11 July 2011 concerning the storage and distribution of potassium iodide tablets outside the zones covered by a PPI. Pursuant to this

Circular, the Prefects implemented plans to distribute stable iodine tablets in a radiological emergency situation, which can involve exercises being held for the local implementation of the PNRANRM.

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 drafting of which was coordinated by ASN and which was published in 2008, accompanies Circular DHOS/HFD/DGSNR 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 methods for treating contamination, is currently being drafted.

## 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 Assistance.

### 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, which was 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 the 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. It is intended 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 a strategy 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.).

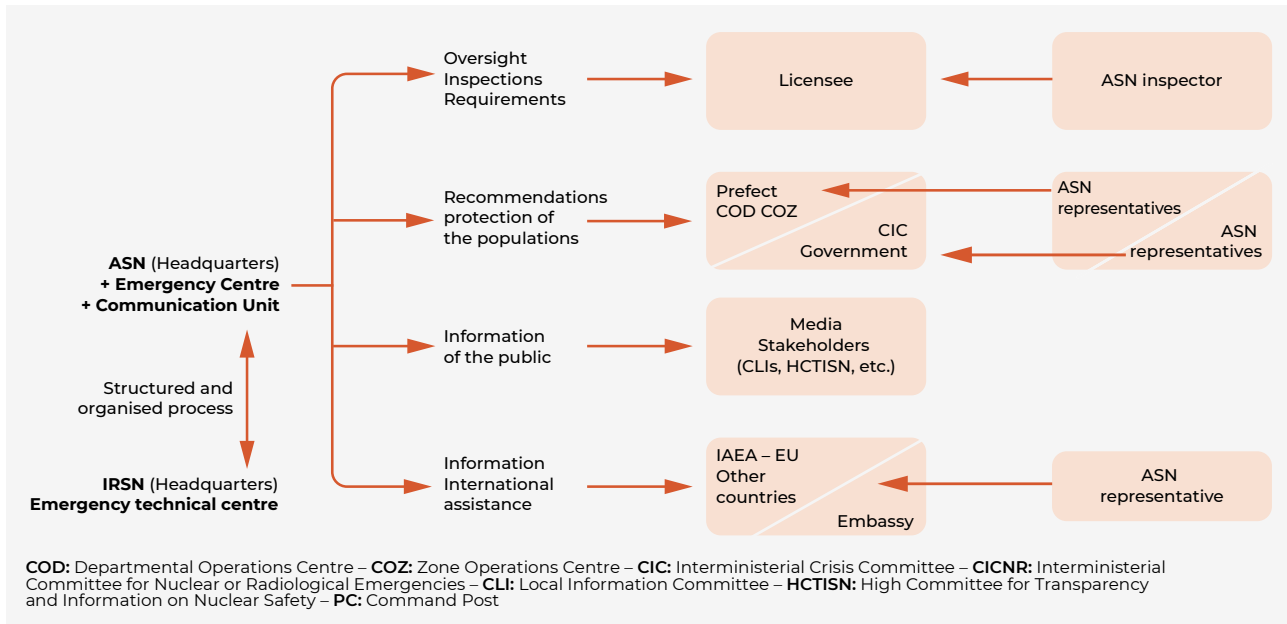
ASN is continuing its approach which is to include the population in the drafting of Codirpa's recommendations and, in the same way as the meetings held in 2021 and 2022, will be organising discussion sessions in 2023 to present the public with the results of the working groups regarding the consideration of accidents with the release of alpha emitters and the definition of strategies to reduce the contamination of an area affected by a radiological or nuclear accident and the management of the associated waste.

### 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.



DIAGRAM 2 The role of ASN in a nuclear emergency situation



### 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, CLIs, 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 and is activated for actual 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 2022, the ASN Emergency Centre was activated on 17 occasions for ten national exercises, two international exercises and five real situations.

Starting on 4 March, the situations on the Ukrainian sites of Zaporizhzhia and Chernobyl were monitored by the ASN teams, in particular with activation of the Emergency Centre when the Zaporizhzhia NPP was attacked on 4 March and following the total loss of electrical power to the Chernobyl NPP and its safety systems on 10 March. For these two events, the Emergency Centre remained in close contact with IRSN, the IAEA and the other European safety or radiation protection authorities, as well as with the monitoring units at the various Ministries, and coordinated replies to the numerous queries from the media.



## ASN EMERGENCY CENTRE: AN ESSENTIAL TOOL



In 2022, five events led to activation of the ASN Emergency Centre. On 4 and 10 March, to manage the Russian attack on the Zaporizhzhia NPP in Ukraine and the total loss of electrical power to

the Chernobyl site, on 31 March to deal with the intrusion by Greenpeace militants on EDF's Flamanville site in the Manche *département* (50), on 21 September for an outbreak of fire

in a room containing radioactive material in the Framatome facility at Romans-sur-Isère in the Drôme *département* (26) and finally, on 6 October after the presence of ammonia was detected in a room on EDF's Cattenom site in the Moselle *département* (57).

By means of its secure and redundant equipment in its Emergency Centre in Montrouge, the ASN teams were able to monitor the development of the situations, assess the potential consequences, and remain in permanent contact with the stakeholders (IRSN, Prefectures, licensees, etc.). To ensure that it is operational 24/7, the ASN Emergency Centre receives particular attention: periodic tests, documentary review, lessons learned from each emergency. In 2022, a new day-book supplements the arsenal of the tools already operational.

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On 31 March 2022 at 8h, as a result of several intruders penetrating the perimeter of the Reinforced Protected Area (ZPR) of EDF's Flamanville NPP in the Manche *département* (50), the on-call team was activated in the Montrouge Emergency Centre, to check with the licensee there were no safety consequences for the installations.

On 21 September 2022, ASN was informed of an outbreak of fire in a room containing radioactive materials in Framatome's facility at Romans-sur-Isère in the Drôme *département* (26). ASN activated its Emergency Centre to monitor the development of the situation and the steps taken by the licensee, and to advise the Prefect of the la Drôme *département*, who was in charge of the operations. The Emergency Centre was deactivated in the evening after verification that there had been no radioactive releases and that no radioactive material was in fact involved in the fire.

On 6 October 2022 at 9h21, EDF's Cattenom NPP triggered its PUI after the presence of ammonia was detected in a room on the site. ASN then followed the development of the situation from the Emergency Centre. After the leak was located and stopped by the site teams, the ASN teams were able to leave the Emergency Centre, after first ensuring that this event had no environmental consequences.

The ASN emergency response organisation was also partially activated on several occasions in 2022.

On 6 February 2022 at 12h15, ASN was informed of an outbreak of fire in a room outside the nuclear zone of the EDF plant at Cruas-Meysses (07). The on-call team was activated in order to monitor the development of the situation and prepare to activate the Emergency Centre if necessary.

On 23 November 2022 at 11h36, the Gravelines NPP (59) activated its PUI for a fire outside the controlled area, following a release of smoke being observed on a pump. The contacts between ASN and EDF led to the alert being rapidly cleared, as the release of smoke immediately stopped when this pump was shut down. The PUI was thus lifted at 12h30 with the approval of ASN.

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 the 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 Ministry for Ecological Transition and Regional Cohesion.

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.

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

TABLE 2 National nuclear and radiological emergency exercises conducted in 2022

NUCLEAR SITE	DATES OF EXERCISE	MAIN CHARACTERISTICS
EDF Cattenom NPP (57)	11 and 12 May	<ul style="list-style-type: none"> <li>• Decision-making process and simulated media pressure</li> <li>• ASN inspectors dispatched to the affected site</li> <li>• Exchange of information with neighbouring countries</li> </ul>
Avord air base (18)	8 and 9 June	<ul style="list-style-type: none"> <li>• Coordination with ASND</li> <li>• Recommendations for post-accident management</li> </ul>
EDF Dampierre-en Burly NPP (45)	14 and 15 September	<ul style="list-style-type: none"> <li>• Decision-making process</li> <li>• ASN inspectors dispatched to the affected site</li> </ul>
CEA's centre in Cadarache (13)	30 September	<ul style="list-style-type: none"> <li>• Decision-making process and simulated media pressure</li> <li>• ASN inspectors dispatched to the affected site</li> </ul>
EDF Paluel NPP (76)	12 and 13 October	<ul style="list-style-type: none"> <li>• Decision-making process and simulated media pressure</li> <li>• Actions related to the National Resilience Day</li> </ul>
EDF Cruas-Meyssse NPP (07)	20 and 21 October	<ul style="list-style-type: none"> <li>• Decision-making process</li> <li>• ASN inspectors dispatched to the affected site</li> <li>• Post-accident workshop</li> </ul>
Île Longue naval base (29)	23 and 24 November	<ul style="list-style-type: none"> <li>• Coordination with ASND</li> <li>• Post-accident workshop</li> </ul>
EDF Saint-Alban NPP (38)	25 November	<ul style="list-style-type: none"> <li>• Decision-making process</li> <li>• ASN inspectors dispatched to the affected site</li> </ul>
EDF Flamanville NPP (50)	13 and 14 December	<ul style="list-style-type: none"> <li>• Decision-making process</li> <li>• ASN inspectors dispatched to the affected site</li> </ul>

### 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 2022, concerning BNIs and the transport of radioactive substances. This programme was announced to the Prefects in the interministerial instruction of 28 January 2022.

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 2022.

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 2022, in addition to the general objectives of the exercises listed earlier, additional objectives were introduced into the schedule, taking account of lessons learned and the results of the exercises and experimental training carried out in 2021.

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 (Defence and Security High Official – HFDS – reporting to the Minister in charge of Energy) or for Defence-related facilities (ASND);

### THE CODIRPA PUBLISHES ITS NEW RECOMMENDATIONS FOR THE MANAGEMENT OF POST-ACCIDENT SITUATIONS

Following the publication of the first recommendations to the Government in 2012, the Codirpa continued its work to learn the lessons from the accident on the Fukushima Daiichi NPP and from national emergency



exercises, involving all the stakeholders (experts, State's services, CLIs, associations, licensees, etc.). The new *Codirpa recommendations for the management of the post-accident situations following a nuclear accident* were collated in a guide published in November 2022. The purpose of these proposals is to contribute to the next updates of national emergency planning.

- international bodies (IAEA, European Commission, Nuclear Energy Agency);
- 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.

### CITIZEN PANELS TO BUILD POST-ACCIDENT DOCTRINE TOGETHER: AND THEN THERE WERE FOUR!

After Golfech and Tricastin in 2021, ASN and the CLIs once again got together for a public debate on the subject of the Codirpa's proposals for managing the consequences of a nuclear accident, notably regarding fresh food produced locally (vegetable gardens, orchards) and produce from hunting, fishing and gathering. The main goal is to check that the citizens understand and accept the envisaged protection measures. These two additional panels were held in January and February 2022 in Paluel-Penly (76) and Dampierre-en-Burly (45) and led to intense discussions between ASN and the population in these areas. This approach, which aims to anticipate the consequences of a major accident, reflects the desire to reinforce the safety and radiation protection culture at the stakeholders concerned (population, elected officials,



associations, etc.); it is a crucial area for progress, as proven by recent emergencies (Lubrizol accident,

Covid-19 pandemic). The citizens panel experience will be repeated in 2023 on other subjects.

These assessment meetings enable the players to share their experience through a participative approach. They more specifically revealed:

- the importance of having scenarios that are as realistic as possible, in real meteorological conditions and that are 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.

#### 4. Outlook

The year 2022 saw a return to a normal rhythm for preparation and training for emergency management. The exercises and real situations managed by the ASN emergency teams in 2022, and the implementation of revised training and practice procedures, reinforced their competence and their experience.

The exercises and inspections with situational exercises carried out by ASN, verified the ability of the licensees to manage an emergency. Certain areas for improvement were identified and will be rapidly implemented.

In the post-accident field, work on the preparation for and management of the consequences of a nuclear accident were continued and intensified, notably with the publication of new recommendations from the Codirpa to the Government which supplement the lessons learned from the accident at the Fukushima Daiichi NPP (see box previous page). A report reviewing the safety and radiation culture around the nuclear installations was also published by the Codirpa. Further to the recommendations of this report, several members of the Codirpa

were actively involved in preparing and organising the national day for resilience to natural and technological risks, the first edition of which was held on 13 October 2022.

In 2023, ASN will continue with its active involvement in the preparation, performance and OEF from the various national emergency exercises carried out with the Prefectures. Transboundary coordination will also be given particularly close attention, through the work done with neighbouring countries.

With regard to post-accident management, the work of the Codirpa will continue, notably with proposals being awaited regarding the strategy for waste management following an accident. ASN will make efforts to involve the population in this process, notably by proposing new panels of citizens.

Finally, in 2023, the tools of the emergency centre will also be reinforced, for simpler and more practical access to the State’s mapping tools.

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# Informing the public

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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. Therefore, to fulfil its duty to inform, the French Nuclear Safety Authority (ASN) deploys efforts proactively and responsively.

In a proactive approach, the *asn.fr* website gives access to the inspection follow-up letters, significant event notices, information notices, press releases and the ASN resolutions.

Its news is communicated through the social networks and its *Lettre de l'Autorité de sûreté nucléaire* (ASN newsletter). ASN also develops educational aids: videos, computer graphics, travelling exhibition, etc.

In addition, ASN translates information notices, press releases and content concerning important issues. These publications in English support ASN's action on the international bodies.

Lastly, ASN engages in specific actions with the professionals (guides, conferences, seminars) in order to promote the regulations and enhance their awareness of the safety and radiation protection issues.

The ASN spokespersons respond to numerous queries from the media. Each year ASN is given a hearing before the Parliament on its activities and high-stake issues. ASN also contributes to the work of the Local Information Committees (CLIS).

Lastly, ASN is contacted by its stakeholders (Non-governmental Organisations – NGOs, professionals, local authorities, etc.) to obtain documents or to find out about its position on technical, environmental and regulatory subjects and on nuclear safety and radiation protection.

## 1. Developing relations with the various audiences

### 1.1 The general public

ASN works to ensure that citizens have reliable information on the nuclear risk and that they develop the right 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). To this end, ASN develops relations with its stakeholders and uses diverse vectors: printed or digital publications, website, social networks, etc.

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, it is designed to make for easy reading. The *Cahiers de l'ASN* are distributed to nearly 10,000 subscribers and are available at *asn.fr*. Four *Cahiers de l'ASN* have been published since 2018.



*Cahier de l'ASN* published in June 2022

The first, entitled *The issues of the fourth periodic safety review of the 900 MWe nuclear power reactors*.

The second, entitled *Nuclear power plants beyond 40 years: what are the conditions for the continued operation of EDF's 900 MWe reactors?*

The third, entitled *10 years after Fukushima: what safety improvements for nuclear facilities in France?*

In 2022, a *Cahier de l'ASN* concerning the decommissioning issues was published to answer the questions of the public on this key stage in the life of a nuclear installation.

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 nearly 45,000 visits per month on average, the website *asn.fr* is the focal point of the system for informing the various audiences. It posts the draft opinions and resolutions that represent the most important issues for consultation.

The website is also a reference source of information for the more informed audiences: expert citizens, members of environmental associations and professionals. In all, more than 1.6 million pages of the website were viewed in 2022.

The aim of putting a new version of the ASN website on line in 2021 was to facilitate access to the 20,000-odd pages it devotes 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 condition 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 of 7 October 2016.

A higher-performance search engine and a map of the facilities (nuclear power, industrial and medical) provide for a faster and more precise browsing experience.

The *asn.fr* 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.

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. ASN has stepped up the fraud prevention and detection measures further to the irregularities discovered at the Creusot Forge plant in 2016. In 2022, 34 reports were filed on *asn.fr*.

### 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 Twitter, Facebook 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 news is followed and passed on by more than 16,700 subscribers on Twitter, 38,000 on LinkedIn and 4,800 on Facebook.

### 1.1.3 The ASN/IRSN exhibition

As part of their duty to inform the public, ASN and the Institute for Radiation Protection and Nuclear Safety (IRSN) have created educational content intended for high school pupils, students, employees, hospital personnel, patients, etc. and the citizens more broadly. Comprising more than 80 display boards covering eleven themes, the exhibition is designed to provide information on radioactivity – whether natural or artificial –, its uses, its implications and its effects on humans and the environment.

The exhibition was hosted in 15 places in 2022: high schools, CLIS, centres for scientific culture, the Day of Resilience, the Science Fair, and hospitals during the patient safety week.

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 pages 184 and 185).

### 1.1.4 The ASN Information Centre

Any citizen can address information requests to ASN, either on-line (*info@asn.fr*), by letter or by telephone. In 2022, the on-line information centre responded to more than 600 requests on diverse subjects (technical questions, requests for transmission of administrative documents, information relative to the environment, publications, documentary searches, etc.).

## 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 the safety of Basic Nuclear Installations (BNIs). Over the last few years it has thus undertaken a major overhaul of the technical and general regulations applicable to 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 where they can find forms and regulatory texts, along with publications aiming to provide explanations or assistance in the application of the regulations.

In 2022, ASN published a series of medical sector inspection results for 2021 (radiotherapy, brachytherapy and Fluoroscopy-Guided Interventional Practices – FGIPs).

#### 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 methods and good practices resulting from lessons learned from significant events. ASN conducted a public consultation in 2022 on the revised versions of three guides to be issued in 2023: a Guide entitled “Quality management system applicable to the transport of radioactive substances”, dating from 2005; Guide No. 29, “Radiation protection in radioactive substance transport activities”, Guide No. 11, “Reporting significant radiation protection events”.

After meeting the main high-activity sources holders in the regions in 2020 and 2021, ASN published a brochure in 2022 to raise the awareness of the other heads of nuclear activities to the protection of sources of ionising radiation against malicious acts.

ASN met with radiographers during the Scientific Days of the French Association of Radiographers (AFPPE) in May in Nancy, radiology professionals at the French Radiology Days (JFR) in October in Paris and radiation protection experts-officers in November in Lyon. During these events, ASN presented the changes in the regulations, particularly the new registration system and the verifications in the form of a quiz and practical sheets.

ASN is also the initiator of thematic professional seminars. On 29 March 2022, 160 radiographers and companies from the Grand Est region took part in a webinar organised by ASN’s Châlons-en-Champagne and Strasbourg regional divisions and the Dreets<sup>(1)</sup> on radiation protection risks in industrial radiography.

1. Regional Directorates for the Economy, Employment, Labour and Solidarity.



# "RADIOACTIVITÉ DÉCOUVRIR & COMPRENDRE"



05



## 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.

**11**  
SEQUENCES

**85**  
DISPLAY  
BOARDS

  
MODULAR







## The eleven sequences have individual colour codes and logos

In 2022, the exhibition content was updated in 2022 and the graphics overhauled.



**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**

## Organise the exhibition to meet your specific need



The exhibition comprises more than 80 display boards divided into eleven thematic sequences which can be combined to form the exhibition that best corresponds to 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:**  
[asn.fr/l-asn-informe/exposition-asn-irsn](https://asn.fr/l-asn-informe/exposition-asn-irsn)





Patient safety newsletters published in September and October 2021

05

On 25 October 2022, the ASN regional division of Lyon brought together about a hundred therapeutic radiotherapy and nuclear medicine professionals for a day of discussions on team work and safe treatment of patients in a context of change (of organisation, equipment and techniques).

### 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 the culture of safety. Twelve declaration and notification forms were already available (including the declarations for possessing devices and sources and reporting events in the transport of dangerous goods). As of 1 July 2021, entry into effect of the new simplified authorisation system – the registration system – has been accompanied by the placing on line of 12 new registration application forms available to nuclear activity supervisors in the industrial, medical, veterinary and research sectors. ASN was thus able to introduce a dematerialised procedure as soon as the new regulations came into effect.

### 1.2.3 A bulletin 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 to FGIPs. Produced by multidisciplinary working groups coordinated by ASN, the newsletter offers a thematic presentation of the good practices of medical departments and the recommendations developed by the learned societies of the discipline concerned and the health and radiation protection institutions.

An error in the calibration of a linear particle accelerator formed the subject of an *Experience Feedback* report in April 2022.

A bulletin is to be published in March 2023 on the control of medical interventional radiology devices.

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

year 2022 was marked primarily by the debates concerning the nuclear policy in France and the state of safety of the nuclear fleet: the stress corrosion problems, the continued operation of the reactors and the management of radioactive waste. 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 state of nuclear safety and radiation protection in France*, ASN meets regional press journalists. In 2022, due to the pandemic, ASN held regional video conferences between late May and mid-September which brought together 80 journalists.

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<sup>(2)</sup>. In order to prepare for this, ASN staff receive specific training and take part in emergency 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). Since 2011, the social media have been integrated in the "media pressure simulation" of the emergency exercises.

## 1.4 Elected officials and institutional bodies

Each year, ASN presents its annual *Report on the state 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 learned societies, etc.

### THE SUBJECTS THAT FOCUS MEDIA ATTENTION

A number of subjects received particular attention from the media and the public opinion in 2022: the stress corrosion cracks detected on a number of reactors, the Flamanville Evolutionary Power Reactor (EPR) construction site and the problems of welds, the fourth periodic safety review of the 900 Megawatts electric (MWe) reactors, the revival of nuclear power and the continued operation of the Nuclear Power Plants (NPPs) the projects to build new reactors, the needs for skills in the nuclear sector, the management of waste, thermal discharges from certain NPPs during heatwave periods, the safety of nuclear installations in wartime, linked to the Ukrainian situation.

The incidents that occurred on certain nuclear sites (Chooz, Civaux) also interested the local media.

With regard to current events in the medical sector, the press focused more particularly on dose optimisation, especially in the area of nuclear medicine, and exposure to radon.

2. In accordance with Article L. 592-32 of the Environment Code.

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 contact with the national and local elected officials, advising and assisting them at their request.

## 2. Reinforcing the right to information and participation of 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. ASN also ensures they are applied by the licensees under its oversight, and it endeavours to facilitate interchanges between the 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 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 by law (more specifically, communication of the requested information must not jeopardise: national defence secrecy, State security, public safety, research and prevention of violations of any sort by the competent services, business secrecy which includes the secrecy of processes, economic and financial information and commercial or industrial strategies).

### 1.5 International cooperation

ASN invests itself on the international scene to promote experience feedback and the sharing of best practices in informing the public. ASN participates in the transparency working group of the European Nuclear Safety Regulators Group (ENSREG); it takes part in the work of the International Atomic Energy Agency (IAEA) and the working group on public communication of the Nuclear Energy Agency (NEA).

### 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 of participation of any citizen in the framing 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 regulations

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 considered as having an impact on the environment and are therefore 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, although they are not of a statutory nature, ASN applies this same procedure to certain draft guides and draft opinions. Sixteen consultations held in 2022 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 regulation on the ASN website for at least 21 days in order to give people time to make their comments.

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*.

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.

### 2.3.2 Consultation of the public on draft individual resolutions

The individual resolutions<sup>(3)</sup> 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<sup>(4)</sup>. 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 makes the “measures proposed by the licensees during the safety reviews beyond the 35th year of operation of a nuclear power reactor” subject to public inquiry. This is a special provision since the public inquiry does not focus on the continued operation of a nuclear power reactor as such, but on the adequacy of all the “measures proposed by the licensee” of which the end-purpose must aim to reduce the impacts of the facility on the environment with a view to its continued operation. Articles R. 593-62-2 and 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.

#### 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 2022, 68 consultations concerned draft individual resolutions.

### 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. 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 actors in the area of information

### 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 produces 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.

In 2022, the two HCTISN groups, one devoted to the consultation on the fourth periodic safety review of the 900 MWe nuclear power reactors, the other to the consultation for the *Cigéo* project, continued their work.

3. Resolution that applies to a licensee for a given installation.

4. In application of the provisions of Article L. 593-8 or L. 593-28 of the Environment Code.

## THE FUNCTIONAL FRAMEWORK OF THE LOCAL INFORMATION COMMITTEES AND THE SITE MONITORING COMMITTEES

The CLIS, whose creation is incumbent upon the President of the Departmental Council, comprise various categories of members: representatives of departmental General Councils, of the municipal councils or of the deliberative assemblies of the groups of communities and the Regional Councils concerned, members of Parliament elected in the *département*\*\*<sup>5</sup>, representatives of environmental protection associations or of economic interests and representatives of employee trade union and medical profession union organisations, and qualified personalities. The representatives of State services, including ASN, and of the licensee have an automatic right to participate in the work of a CLI in an advisory capacity. The TECV Act provides for the participation of foreign members in the CLIS of border *départements*. The CLIS are chaired by the President of the Departmental Council or

by an elected official from the *département* designated by the President for this purpose. They receive the information they need to fulfil their functions from the licensee, from ASN and from other State services. They may request expert assessments or have measurements taken on the installation's discharges into the environment. All BNI sites have a CLI, except for the Ionisos facility in Dagneux in the Ain *département*. The CLIS are funded by the regional authorities, and by ASN which devotes about 1.25 million euros per year to the financial support of the CLIS and their national federation, the National Association of Local Information Commissions and Committees (Anccli). Within the framework of its reflections on the financing of the oversight of nuclear safety and radiation protection, ASN regularly suggests to the Government the application of the provision of the TSN Act of 13 June 2006, to add to the budget of the CLIS with association status

(there are about ten of them) with a matching contribution of funds drawn from the BNI Tax.

In application of the Decree of 7 February 2012<sup>6</sup>, Site Monitoring Commissions (CSS) are gradually replacing the Local Information and Monitoring Committees (CLIS) for the former nuclear sites, research laboratories and waste treatment sites. Providing frameworks for discussion and information concerning the actions of the licensees of the targeted installations, they promote the informing of the public. They are, for example, kept informed of the incidents and accidents affecting the installations – and even of installation's creation, extension or modification projects.

ASN is invited to the meetings of the monitoring committees for defence sites and former mining sites.

<sup>5</sup> Issued in application of Article L. 125-2-1 of the Environment Code.

<sup>6</sup> Administrative region headed by a Prefect.

### 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 ("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 request. On subjects of concern 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.

Alongside this, each year IRSN makes public the results of its research and development programs, with the exception of those concerning national Defence.

In the context of a referral from ASN and with ASN consent, IRSN can request the participation of informed audiences, neighbourhood residents, or even the public at large. IRSN in this case provides them with information that is complete and understandable, and in return notes their subjects of concern and their questions in order to integrate them in the expert assessment work carried out for ASN.

### 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 on people and the environment of the nuclear activities of the facilities on the sites around which the CLIs have been set up<sup>5</sup>.

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, 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<sup>6</sup>. 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. On 10 November 2022, it participated in a webinar on the phenomenon of stress corrosion

5. 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.

6. 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.





Workshop on “Measuring and understanding radioactivity” at the 34th CLI Conference in Tours, 15 November 2022

affecting certain reactors in France. Some CLIs call upon external service providers to advise them concerning technical files on which they wish to take a stance.

#### 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 34th CLI conference

With the aim of highlighting the regional anchoring of the CLIs and their role as local information relays, the 34th CLI Conference was held for the first time at a regional venue, the *Palais des Congrès* (conference centre) of Tours, in the Val de Loire region, on 15 November 2022.

After the traditional morning overview of the major topical nuclear issues, the 160 participants were invited to attend collaborative workshops on the radiation protection culture. Four workshops provided the opportunity to share good practices and come up with ideas regarding the “Major Risks Resilience Day” and the measurement of radioactivity. As for the elected officials, they received coaching in addressing the media and experienced a post-nuclear accident simulation exercise.

The workshops were debriefed after holding a roundtable entitled “Transmitting and mobilising the memory of the CLIs to shed light on the future challenges”.

The Chairs of ASN and Anccli hailed the success of this regional-venue conference, which witnessed rich discussions between the CLI members and licensees, experts and representatives of the public authorities.

#### 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. The National Association of Local Information Committees and Commissions (Anccli) brings together the 34 French CLIs and the 34 committees put in place for the defence-related installations. The 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 interchanges with ASN very regularly and participates in several of its permanent or occasional working groups. Anccli fosters the enhancing of the technical competence of CLI members by organising thematic seminars with IRSN in the context of its expert assessment work carried out for ASN. Anccli, with ASN and IRSN, maintains a technical dialogue on the high-stake issues and takes part in the public consultations on nuclear questions. Each year, ASN organises the national conference of CLIs in cooperation with Anccli.

#### The activity of Anccli

Anccli runs the network of CLIs that it represents. By ensuring a regular watch and issuing clarifications and information that can be readily understood by the general public, Anccli helps give the CLIs the means to fulfil their duties to inform the various audiences. 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.



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Abstracts  
ASN REPORT

Les extraits  
RAPPORT

ASN  
**THE FRENCH NUCLEAR SAFETY AUTHORITY**

Roles  
Operations  
Key figures

**A**SN was created by the 13 June 2006 Nuclear Security and Transparency Act. It is an independent administrative authority responsible for regulating civil nuclear activities in France.

On behalf of the State, ASN ensures the oversight of nuclear safety and radiation protection to protect people and the environment. It informs the public and contributes to enlightened societal choices.

ASN decides and acts with rigour and discernment. It is to exercise oversight that is recognised by citizens and regarded internationally as a benchmark for good practice.

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# International relations

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**T**hrough a range of bilateral, European and multilateral cooperation frameworks, in which it participates, the French Nuclear Safety Authority (ASN) aims to promote the adoption of ambitious international baseline requirements. Within these frameworks, ASN also ensures that the French positions and doctrines are made known and advantage is taken of international best practices 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 frameworks.

## 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.

ASN's objectives internationally 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 regulations or oversight. These exchanges are an opportunity for ASN to share its experience and compare its positions and practices in order to progress. 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 emergency situations.

For ASN, Europe is one of the priority areas for its international actions. ASN's goal is to contribute to the sharing, harmonisation and improvement of nuclear safety and radiation protection. Within European associative or community circles, ASN's aim is to share its vision of the priority safety issues, to compare its analyses and to conduct discussions on the practices of its counterparts, in order to help establish and maintain a high level of stringency in nuclear safety and radiation protection at the European level, which can be based on harmonised baseline requirements and doctrines established together.

ASN is working to develop the sharing of good practices and radiation protection outside Europe. On this point, it aims to ensure that European doctrine, which promotes the highest levels of requirements, 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 therefore works within three main cooperative frameworks. 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.



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## 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, allowing the harmonised development of provisions allowing a strict regime of oversight for nuclear safety and security and radiation protection. The European Union (EU) Court of Justice, considering that the fields of nuclear safety and radiation protection form an inseparable whole, recognised the principle of the existence of community competence in the field of safety, as in the field of management of radioactive waste and spent fuel.

ASN experts participate in the work of the EURATOM Treaty committees and working groups:

- group of experts specified in Article 31 (Basic Radiation Protection Standards);
- group of experts specified in Article 35 (verification and monitoring of radioactivity in the environment);
- group of experts specified in Article 36 (information concerning the monitoring of radioactivity in the environment);
- group of experts specified in Article 37 (notifications relative to radioactive effluent discharges).

The group of experts of Article 31 met twice in 2022, remotely in May and physically in November. It was informed of the work of the European Commission notably with regard to:

- the SAMIRA (Strategic Agenda for Medical Ionising Radiation Applications) strategy and thus validated the QuADRANT report currently being published and entitled “*Current status and Recommendations for Improving Clinical Audit Uptake and Implementation*”;
- the ongoing studies concerning construction materials, the national radon plans and environmental monitoring.

A scientific seminar was also organised in November 2022 to review radiation protection issues for fusion reactors. The proceedings of the 2021 seminar on innovations in the field of

dosimetry “*Advances/Innovations in individual dosimetry*” were published in November 2022.

The group of experts for Articles 35 and 36 of the EURATOM Treaty met in October 2022, notably to discuss the current state and planned changes to the tools used by the European Commission to provide the public with monitoring data on discharges from nuclear installations and their environment.

### 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 Nuclear Power Plant – 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 the entire EU (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.

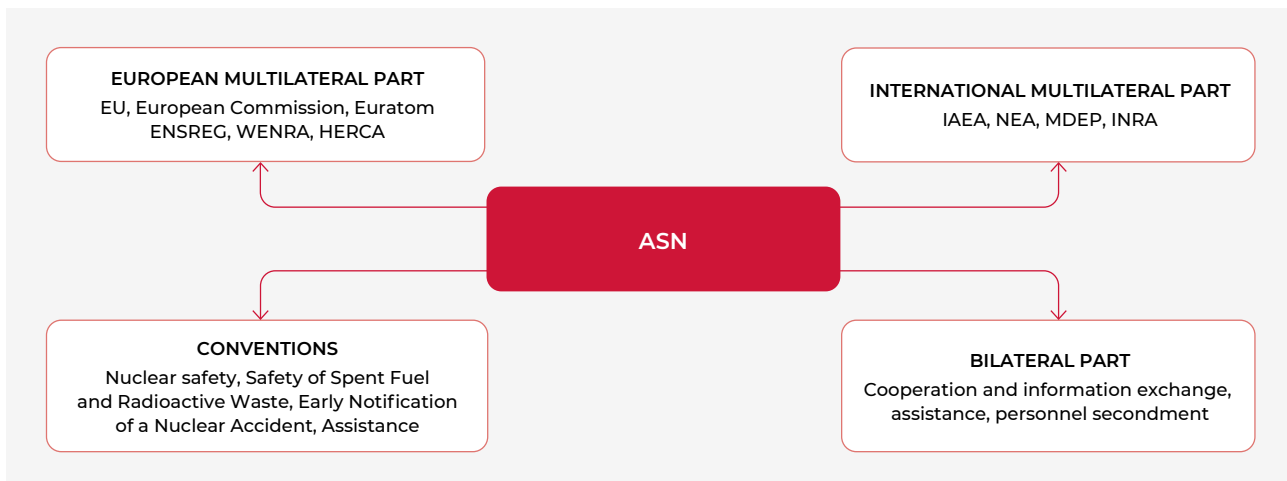
This Directive is transposed into French law.

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). The adoption of this Directive contributes to reinforcing safety within the EU, by making the Member States more accountable for the management of their spent fuels and their radioactive waste.

#### ASN ACTION ON THE INTERNATIONAL STAGE





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 (TECV 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 Materials and Construction Materials – NORM). 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 was created in 2008 and brings together experts delegated by the Member States of the EU, with the aim of supporting the European Commission 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 concerned the management of ageing of the nuclear reactors. Each of the participating countries first of all drafted a national report, which was then examined in 2018 by experts appointed by the Member States. This examination led to the drafting of a report on the generic results and a report on the specific results per country. On this basis, the national action plans drawn up by the countries were submitted in September 2019 and subsequently updated. The national report, the national action plan and the closing report for France are available on *asn.fr*, in both French and English.

The work on the second thematic peer review, chaired by an ASN Commissioner, concerning the protection of nuclear installations against fire hazards, initiated by the Member States in 2020, was completed with the 2022 publication of the terms of reference that frame the peer review and the technical specifications which provide guidelines for countries performing their self-evaluation. In 2022, the Member States thus began the process of drafting their national self-assessment reports, with publication being expected in October 2023.

## 2.6 The European Community Urgent Radiological Information Exchange system (ECURIE)

ECURIE is one of the rapid action systems set up by the European Commission, 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 radioactive emergency or major nuclear accident.

This system was put into place in 1987 by a Decision of the Council of the EU of 14 December 1987, notably in the wake of the Chernobyl (Ukraine) accident in 1986. This Decision came into force on 21 March 1988 and was ratified by all the Member States of the EU and a certain number of third-party countries, such as Switzerland and Turkey.

## 2.7 The Western European Nuclear Regulators' Association (WENRA)

WENRA was created in 1999 at the initiative of ASN and its current members are the 18 heads of the safety regulators of the European countries with experience in electricity generating reactors. It is open to 14 other countries with associate member or observer status.

WENRA has been chaired by the ASN Director General, Olivier Gupta since 2019.

Considering that the national safety regulators, in the light of their experience and their practical knowledge of the installations, are better placed than the European Commission 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 member countries, aiming for the highest level of safety that is reasonably achievable. Within this context, WENRA developed an original methodology which consists in defining “safety reference levels” for each technical topic, based on the most recent standards from IAEA and on the strictest safety approaches adopted in the EU. 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 actual procedures to implement these reference levels in the nuclear installations.



Plenary meeting of WENRA in Bonn (Germany) – April 2022

To do this, 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).

The work done by WENRA in 2022 led to a number of significant advances, in particular:

- completion of the drafting of the technical specifications for the second thematic peer review, devoted to protecting nuclear installations against fire hazards;
- definition of the criteria for expanding the association to other countries and to changing the status from observer member to associate member;
- the adoption of a joint declaration recalling the importance of nuclear safety in the current energy crisis context;
- coordination of the position of the WENRA members on several subjects currently under discussion at the European or international level. The WENRA members in particular

confirmed that the various international initiatives on the subject of Small Modular Reactors (SMR) should enable the nuclear safety authorities to assume their national responsibilities.

In 2022, the WENRA Chairman also took part in various conferences held by the WENRA stakeholders. With respect to the joint declaration mentioned above, he stressed the fact that the current renewed interest in nuclear power demands collective vigilance to maintain a high level of safety yet should be considered as an opportunity to achieve new progress in the field of safety, thanks to work being done on innovative technologies.

Finally, against the backdrop of the war in Ukraine, WENRA set up a group specifically to regularly send out information to its members on the situation of the nuclear installations and tasked with making public joint positions on events liable to have safety consequences, as well as to conduct simulations of accident scenarios in order to anticipate the deployment of coordinated measures by the WENRA members, were an accident to occur on a Ukrainian nuclear installation.

### WAR IN UKRAINE: WENRA TAKES ACTION

As of the beginning of the conflict, the entire international community of nuclear safety authorities took action. Whether at the national, European or international levels, various initiatives were carried out to recall the international principles of nuclear law, produce situation briefings, share preoccupations and provide the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU) and the Ukrainian Government with material or human assistance.

In addition to several discussions held during the plenary meetings of WENRA or extraordinary meetings devoted to the crisis in Ukraine, WENRA set up a group of experts. This group, which is chaired by ASN, comprises technical

support from WENRA members and representatives of the European Commission.

This expert group produced technical analyses of situations with particular safety implications and published its resulting position statements. After publishing an initial joint position statement with HERCA on 9 March, it drafted three position statements concerning the Chernobyl site (11 March) and the Zaporizhzhia NPP (24 March and 10 August). These position statements, focusing on the technical aspects of the situation in Ukraine, express a common view by the regulators about situations which could have a major potential impact on safety.

This group of experts also conducted comparative evaluations of source terms emitted into the atmosphere following a jointly selected specific core melt accident. The work that it did confirmed their mutual understanding and their knowledge of the tools, hypotheses and codes used by the various organisations to produce their models. They demonstrated that several organisations in Europe, even if few in number, are able to calculate the source terms in real-time and with coherent results. The hypotheses which need to be adjusted to more accurately reflect reality were also identified, thus reinforcing the implementation of a coordinated Europe-wide response in the event of an accident.

For 2023, one of WENRA's priorities will be to compare how the reference levels are implemented in the various European nuclear power plants, thus enabling it to complete the work to harmonise regulations through verification of the concrete measures actually adopted.

## 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, including the 27 members of the EU, Iceland, Norway, the United Kingdom, Serbia and Switzerland. In 2022 its technical secretariat was the responsibility of ASN and was recently handed over to the Swedish nuclear safety authority (SSM), which currently chairs the association with the assistance of two vice-chairs, one from the Luxembourg Ministry of Health, and the other being an ASN Commissioner.

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.

In 2022, the association met in Budapest in May, and then in Athens in December. The major decisions and actions include:

- implementation of the new HERCA strategy, which was defined with a significant contribution from ASN, with its main focus being reinforced cooperation between the radiation protection competent authorities and the development of cross-inspections;
- active participation by HERCA in the project to overhaul the recommendations of the International Commission on Radiological Protection (ICRP), with the publication of HERCA's "*Reflections on the Revision of the System of Radiological Protection*".

HERCA also organised several seminars in 2022, notably concerning implementation of the national radon risk management plans or clinical audits in the medical sector.

In response to the events in Ukraine, HERCA also mobilised a group of experts in 2022 to reinforce and prepare for transboundary cooperation in the event of an accident. ASN contributed to this work, which notably led to the publication of a guide intended to help Ukraine, the neighbouring countries and the other countries to manage an accident situation. Coordination meetings between these various circles of countries were also held at the initiative of this group of experts, with a view to reinforcing the effectiveness and the coordination of the measures to be taken to protect the population.

## 2.9 The European Commission's assistance programmes

Between 2007 and 2022, the actions of the EU with regard to assistance and cooperation for third-party countries in the field of nuclear safety continued under the Instrument for Nuclear Safety Cooperation (INSC), a system offering an administrative, technical and financial framework for those countries seeking such assistance.

A new European Instrument concerning assistance and cooperation in the field of Nuclear Safety (EINS) was approved by the European Parliament on 27 May 2021 and replaced the former INSC instrument. Between the date of approval and 31 December 2027, a budget envelope of 300 million euros is planned to support the various projects selected.

The goals of the new EINS instrument concern:

- the promotion and implementation of the strictest nuclear safety and radiation protection standards in nuclear facilities and for radiological practices in third-party countries;
- the implementation of frameworks and methods for application of effective checks on nuclear materials in third-party countries;
- the drafting and implementation of responsible strategies for the disposal of spent fuel, for waste management, for delicensing of facilities and for clean-out of former nuclear sites.

In 2022, ASN's Marseille regional division welcomed two inspectors from Morocco, who took part in inspections in the medical field as part of the EU support for the Moroccan nuclear safety authority (AMSSNuR).

The EINS instrument is supplemented by other international technical assistance programmes that respond 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 two 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 173 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 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 uses 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 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: the Nuclear Safety Standards Committee (NUSSC) for the safety of reactors, the Radiation Safety Standards Committee (RASSC) for radiation protection, the Transport Safety Standards Committee (TRANSSC) for the safety of radioactive substances transport, the Waste Safety Standards Committee (WASSC) for the safe management of radioactive waste and the Emergency Preparedness and Response Standards Committee (EPReSC) 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. In 2021, the IAEA made significant efforts to shorten the time taken to publish its standards. Prioritisation of the safety standards to be revised or produced over the period 2022-2027 is currently ongoing. Work is also being done to identify any adaptations to the body of standards required in order to take account of the issues related to SMR.

##### Peer review missions

The IAEA proposes peer review missions in the field of safety to the Member States. These services consist of expert missions organised by the IAEA in countries which ask for them. Each team of auditors consists of experts from other Member States and from the IAEA. These audits are produced on the basis of the IAEA's baseline safety standards. Several types of audit are proposed, notably the Integrated Regulatory Review Service (IRRS) missions devoted to the national regulatory framework for nuclear

safety and the working of the safety regulator, the Operational Safety Review Team (OSART) missions, devoted to the safety of NPPs in operation and, finally, the ARTEMIS 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 and also recognise 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.

A large number of IRRS missions took place in 2022 in order to make up for the delays accumulated during the Covid-19 pandemic. ASN experts took part in missions in Portugal, Slovenia, Argentina, Sweden and Bosnia-Herzegovina. In addition, an ASN Commissioner held the position of team leader during the mission to Finland.

ASN will also be welcoming an IRRS mission to France in March 2024.

##### OSART Missions

In France, the performance of OSART missions devoted to the safety of NPP operation, is requested from the IAEA by ASN, in coordination with EDF, the licensee of the NPPs.

Two OSART missions took place in France in 2022, in the Civaux (follow-up mission) and Tricastin NPPs respectively.

##### 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 the IAEA, ASN is also involved 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 2022, in addition to a detailed review of the situation of the safety authorities in Bangladesh, Egypt, Ghana and Poland, the RCF reinforced its cooperation with the EU (EINS) and with "regional" safety regulator forums.



### Harmonisation of communication tools

ASN takes part in the INES consultative committee, a body comprising experts in the evaluation of the significance of radiation protection and nuclear safety events, tasked with advising the IAEA and the INES national representatives of the member countries on the use of the International Nuclear and Radiological Event Scale (INES) and its updates. In this respect it was closely involved in the work to revise the INES scale manual recently published by the IAEA, the previous version of which was about ten years old. In addition to the updates to take account of advances in scientific knowledge, this revision also includes guidelines for communication in how to use the scale as well on how to apply it in a crisis.

Generally speaking, ASN is closely involved in the various actions carried out by the IAEA, providing significant support for certain initiatives, notably those which were developed following the Fukushima Daiichi NPP accident.

### 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 2022, ASN took part in one ConvEx-2 type 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 to 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.

The various NEA committees coordinate working groups of experts from the member countries. Within the CNRA, ASN contributes to the working groups on inspection practices, acquired operating experience, the regulation of new reactors, safety culture, codes and standards, as well as public communication by safety regulators. In 2022, the CNRA was restructured around its priorities for the coming five years, with the creation of a small number of new working groups.

ASN took part in setting up these working groups and will participate in overseeing and coordinating some of them.

### 3.3 The Multinational Design Evaluation Program (MDEP) for new reactor models

The MDEP is an association of safety regulators created in 2006 by ASN and the NRC, the format of which has changed significantly since 1 January 2022. The MDEP aimed to share experience and approaches in the regulatory evaluation of new reactor models, in order to contribute to the harmonisation of safety standards and their implementation. Until the end of 2021, the MDEP comprised the safety regulators of 16 countries interested in pooling their safety evaluation practices for third-generation nuclear reactor models.

#### Closure of the programme in its current format

In 2022, having noted the end of the work being done on several reactor models, the 16 programme members and its technical secretariat, NEA, organised the transition towards a scaled down format of the MDEP. Eight of the sixteen members, including ASN, withdrew from the MDEP in 2021. The procedures for continued international cooperation as of 2023 in the field of operation of EPR reactors will continue between the safety regulators concerned, within a framework as yet to be defined.

### 3.4 The International Nuclear Regulators' Association (INRA)

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 2022. The first, held in Japan, discussed regulatory changes and the challenges faced by each member of the association, notably in the light of climate issues and their potential consequences on NPP operations, the various bilateral or multilateral initiatives concerning SMR and the Japanese Government's project to discharge into the sea the reprocessed water currently stored on the site of the Fukushima Daiichi NPP. During the second meeting, held on the margins of the IAEA General Conference, the IAEA's initiative for harmonisation and standardisation of regulatory processes applicable to SMR, the situation of the Ukrainian NPPs, in particular that at Zaporizhzhia, and the conditions for public participation in the management of radioactive waste, were extensively covered.



## 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). 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 The Convention on Nuclear Safety

The Convention on Nuclear Safety is 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 sets a certain number of nuclear safety objectives and defines the measures which aim to achieve them. The Convention on Nuclear Safety was signed by France in 1994 and entered into force on 24 October 1996. It has 91 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 precise and 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.

Owing to the Covid-19 pandemic, the review meeting could not be held in March 2020 and was postponed to 2023 in the form of a review meeting common to the 8th and 9th cycles. In 2022, the national reports were submitted and the peer review began: each contracting party can ask questions about these reports and answers will be submitted in writing prior to the review meeting. The France report is available on *asn.fr*, in both French and English. In 2022, ASN analysed 59 reports submitted by foreign countries.

### 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.

There were 87 contracting parties to this Convention at the end of 2021. In the same way as the Convention on Nuclear Safety, it is based on a peer review mechanism comprising the submission of a national report by each contracting party every three years, which undergoes review by the other contracting parties, as well as a contracting parties peer review meeting.

The French report, the production of which is coordinated by ASN, was submitted to the AIEA in October 2020 and is available on the ASN website. In 2021, this work consisted in analysing foreign reports in order to prepare for France's participation in the 7th review meeting of the Joint Convention.

Owing to the Covid-19 pandemic, the Joint Convention's 7th review meeting scheduled for May 2021, was postponed to the summer of 2022.

### 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 131 contracting parties at the end of 2022.

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 without delay to the international institutions, 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 The 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 124 contracting parties at the end of 2022.

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 have already provided treatment for the victims of such accidents.

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## 5. The bilateral framework for ASN's international relations

ASN collaborates with about twenty foreign safety regulators under bilateral agreements. Most of these agreements are bilateral administrative arrangements, but they are sometimes part of broader Governmental agreements (as is the case with Germany, Switzerland, Belgium and Luxembourg).

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, modular reactors, management of emergency situations and the transformation of the regulators.

### 5.1 Bilateral cooperation between ASN and its foreign counterparts

#### SOUTH AFRICA

On **3 June 2022** a remote technical meeting was held by ASN and its South African counterpart (National Nuclear Regulator – NNR) on the continued operation of reactors and notably the ability of the civil engineering and certain equipment to withstand ageing. Following these discussions, an ASN delegation went to Cape Town on **21 November 2022** for a bilateral meeting with the NRR and a visit to the Koeberg NPP. These discussions reaffirmed the importance of the cooperation between the two authorities and confirmed the principle of a mission to exchange inspectors between the ASN's Lyon regional division and the NNR concerning the periodic safety reviews of the 900 Megawatts electric (MWe) reactors.

#### 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.

In 2022, the Commission and its working groups met on **8 and 9 June**, on **26 and 27 September** face to face and on **26 October** remotely. The plenary meeting of the Commission was an opportunity for discussion of several topical subjects which, for France, included the 4th periodic safety review of the 900 MWe reactors, the situation of the NPPs near the Franco-German border and the situation of the Flamanville Evolutionary Power Reactor (EPR).

On **21 July 2022**, ASN's Strasbourg regional division organised a cross-inspection in France, with participation by a member of the German authority, on the Fessenheim NPP primary system decontamination worksite. This was an opportunity to share inspection practices in France and Germany and share the experience acquired on this specific technical subject in Germany.

#### BELGIUM

ASN conducts discussions on all subjects within its field of competence with its Belgian counterpart the *Agence Fédérale de Contrôle Nucléaire* (AFCN). This leads to cooperation both nationally and locally, with certain of ASN's regional divisions. The Franco-Belgian steering committee met on **16 May 2022** at the AFCN headquarters in Brussels. The two delegations notably discussed the impact of the energy orientations of their respective countries on NPP operations. Stress corrosion phenomena affecting certain nuclear power reactors operated by EDF were also covered. The technical meeting on NPP safety was held remotely on **18 March 2022**.

#### CANADA

The Country Specific Safety Culture Forum was held in Ottawa on **7 and 8 September 2022**. This international forum, at which Canadian operators and several nuclear safety authorities, including ASN, took part, was jointly organised by the NEA, the World Association of Nuclear Operators (WANO) and the Canadian Nuclear Safety Commission (CNSC). It was an opportunity to compare the various approaches to safety culture and to share experience.

#### CHINA

In 2022, exchanges with ASN's Chinese counterpart (National Nuclear Safety Administration – NNSA) covered Operating Experience Feedback (OEF) from operation of the Taishan NPP in Guangdong province in southern China, which contains the first two EPR type reactors to have been commissioned anywhere in the world.

These exchanges primarily aimed to examine to what extent the OEF from the anomalies which affected the core of the Taishan reactors could be used in the examination of the current commissioning application for the Flamanville EPR.

#### SOUTH KOREA

The ASN Chairman met his counterpart from the Korean Nuclear Safety and Security Commission (NSSC) on **27 September 2022**, in the margins of the IAEA General Conference. This interview was an opportunity to sign the extension of the cooperation agreement which has bound the two authorities for more than ten years and to confirm the mutual desire of the two Chairmen to continue discussions between ASN and the NSSC through bilateral meetings.

A bilateral meeting between the two authorities was thus held in Seoul on **19 December 2022**. The subjects covered concerned the management of radioactive waste, stress corrosion affecting certain reactors operated by EDF and the SMR authorisation processes. During this meeting, ASN and the NSSC decided that in 2023 they would continue to share experience on the SMR authorisation process and organise bilateral exchanges, including a technical visit, between ASN's Bordeaux regional division and its Kori counterpart.

#### SPAIN

The bilateral meeting between ASN and its Spanish counterpart (*Consejo de Seguridad Nuclear – CSN*) was held on **24 June 2022** in Montrouge. The discussions notably concerned topical national and regulatory subjects in the two countries, the stress corrosion affecting certain reactors operated by EDF, the management of radioactive waste, OEF about how certain inspections are outsourced and revision of the licensing process in the medical field. During this meeting, ASN and the CSN decided to pursue their exchanges on the continued operation of the NPPs and analysis of radiotherapy risks and to set up a system of short personnel secondments.



Signing of cooperation agreements between ASN and its counterparts. From left to right: PAA (Poland), NSSC (South Korea) and CNCAN (Romania)

Two inspectors from ASN's Bordeaux regional division also took part in the inspection of industrial radiography activities carried out at the headquarters of a transboundary company located close to Madrid (Ajalvir). This cross-inspection allowed discussions regarding inspection practices, with comparison of the safety measures in place in the two countries for this type of activity.

#### UNITED STATES

An international video-conference meeting was held by expert groups on **5 December 2022**. At the initiative of the American Advisory Committee on Reactor Safeguards (ACRS) from the Nuclear Regulatory Commission (NRC), this meeting led to an exchange of good practices, with sharing of experience to improve the operation of the consultative groups. France was represented by the Advisory Committee for Nuclear Reactors (GPR).

#### IRELAND

A remote bilateral meeting was held on **21 September 2022** by ASN and its Irish counterpart (Environmental Protection Agency – EPA) in charge of radiation protection. This meeting led to exchanges on the topics of post-accident management in France and recent changes to radiation protection regulations in Ireland.

#### ISRAEL

A remote technical meeting was held on **4 July 2022** between ASN and its Israeli counterpart (Israel Atomic Energy Commission – IAEC) on regulations regarding the radon risk and relations between the safety authorities and their respective technical support organisations (Institute for Radiation Protection and Nuclear Safety – IRSN – for ASN).

#### JAPAN

On **28 and 29 November 2022** an ASN Commissioner took part in the international conference held to mark the tenth anniversary of the accident at the Fukushima Daiichi NPP and also took part in a visit to this site. An ASN Commissioner is also taking part in the high-level experts mission organised by the IAEA on the discharge of reprocessed waters at Fukushima. Finally, discussions were held so that cooperation could resume normally in 2023, in particular with the holding of a bilateral meeting in Tokyo and the resumption of field activities between inspectors.

#### LUXEMBOURG

The Franco-Luxembourg joint Commission on nuclear safety held its 20th meeting on **10 June 2022** in Luxembourg. The Commission comprises the national and Prefect level competent authorities and the Ministries of Foreign Affairs. It discussed recent developments in the two countries in the fields of nuclear safety and radiation protection, including the 2021 results for the Cattenom NPP, latest news in the medical fields (graded approach and radiotherapy inspections), periodic safety reviews on the French nuclear reactors, and the preparation for and management of emergency situations.

#### POLAND

A bilateral meeting was held in Montrouge on **6 and 7 July 2022** between the Polish nuclear safety authority (*Państwowa Agencja Atomistyki* – PAA) and ASN. The meeting led to discussions on topical items in both countries, the role of the PAA in the future Polish nuclear programme, SMR projects and the role of ASN's Caen regional division in the regulation and oversight of the Flamanville EPR reactor. A visit to the Flamanville EPR site was organised. The meeting was an opportunity to reaffirm the desire of the two authorities to continue with their cooperation, which led to the signing of their updated cooperation agreement.

#### ROMANIA

On **28 September 2022**, a cooperation agreement between ASN and its Romanian counterpart, the *Comisia Națională pentru Controlul Activităților Nucleare* (CNCAN) was signed in the margins of the IAEA General Conference in Vienna. The subjects which could be the subject of future exchanges notably concern waste management and the regulation of small electricity generating reactors.

#### SWITZERLAND

The Franco-Swiss Commission was created as an inter-governmental body and involves several competent authorities at both national and local levels. This Commission met on **13 and 14 April 2022**. With regard to ASN, this Commission involves both the head office departments and the Lyon and Strasbourg regional divisions. On **27 September 2022**, ASN monitored an emergency exercise in the Leibstadt NPP together with its Swiss counterpart, the *Inspection fédérale de la sécurité nucléaire* (IFSN), in order to reinforce information exchanges in the event of an accident.

#### TURKEY

On **20 and 21 October 2022**, ASN – in cooperation with the IRSN – organised technical discussions with the Turkish nuclear safety authority (*Nükleer Düzenleme Kurumu* – NDK). The purpose of this meeting was to share experience on preparedness and response in the event of a nuclear and radiological emergency. On this point, the Turkish delegation observed the emergency exercise in the Cruas-Meysse NPP.

The NDK also indicated that in 2023 it wished to establish a formal framework for exchanges and initiate close bilateral relations with ASN.

## 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 (EINS) 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.

ASN considers that developing an appropriate safety infrastructure requires a minimum of fifteen years before a nuclear power reactor can begin to operate in good conditions. For these countries, the goal is to set up a legislative framework and an independent and competent safety regulator with the financial and human resources it needs to perform its duties and to develop skills in terms of safety, safety culture and oversight as well as in radiological emergency management. In 2022, ASN finalised its mission under the INSC project that it was coordinating on behalf of NDK, the Turkish nuclear safety authority.

## 6. Outlook

In 2022, the more favourable health context than in the past two years enabled ASN to maintain regular exchanges with several of its counterparts, whether bilaterally or multilaterally. This momentum will be maintained in 2023 notably with the planned resumption of face to face meetings with the United Kingdom, Sweden, Finland and Japan.

In addition, new bilateral relations should appear with several other authorities, such as those of India, the Netherlands, the Czech Republic, Romania and Turkey, with whom agreements were recently signed or are being drawn up.

## 5.3 Personnel secondments between ASN and its foreign counterparts

Understanding the working and practices of foreign nuclear safety and radiation protection regulators enables pertinent lessons to be learned for the working of ASN and the training of its personnel to be enhanced. One of the means used to achieve this goal is personnel secondments, generally for a period of one to three years, but also for shorter periods through missions on specific subjects. This immersion in the activities and working of the counterpart safety regulator is a unique means of assimilating subjects of common interest. Between January 2018 and August 2021, an ASN staff member was thus seconded to the NRC for a period of three and a half years. Since 1 January 2019, an ASN senior inspector has been seconded to the British Office for Nuclear Regulation (ONR).

In 2022, short missions were set up between ASN and the CNSC. A Canadian inspector was thus welcomed by several ASN entities (Paris and Nantes regional divisions, as well as the ionising radiation and health department – DIS – and the waste, research installations and fuel cycle department – DRC) for three months, to look at radiation protection in the medical field, while an ASN inspector completed a two-week mission at the CNSC on SMR authorisation processes.

Important international milestones should also be reached in 2023: in March, France will present its national report for the Convention on Nuclear Safety. In October, France will also publish its national report for the second thematic peer review concerning the protection of nuclear facilities against fire risks.

In a nuclear context faced with new challenges, notably linked to the energy crisis, climate change, the war in Ukraine and the growing interest in new technologies and innovation, ASN will work to promote collective vigilance internationally with a view to maintaining a high level of safety, and to consider these challenges as opportunities to enhance safety even further.

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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 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) and Internal Targeted

Radiotherapy (ITR), 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), which bring the risks associated with waste and effluent management. The fast expansion of Fluoroscopy-Guided Interventional Procedures/Practices (FGIPs) carried out using increasingly sophisticated devices can lead to significant exposure of the patient and 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, 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 nuclear activities for diagnostic purposes such as computed tomography, conventional radiology, dental radiology and diagnostic nuclear medicine, interventional practices using ionising radiation (FGIPs), which bring together different techniques used primarily for invasive medical or surgical procedures for diagnostic, preventive or therapeutic purposes, and activities for therapeutic purposes, most of which are dedicated to cancer treatment, such as external-beam radiotherapy, brachytherapy and ITR<sup>1</sup>.

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 (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 2021 by Institute for Radiation Protection and Nuclear Safety (IRSN), the medical and veterinary sectors account for the majority of the people monitored: 60%, i.e. 234,284 persons were subject to dosimetric monitoring of their exposure. The average annual individual

dose is 0.27 millisievert (mSv). This figure remained relatively stable between 2015-2021, with the exception of 2020, when it dropped by 17% due to the Covid-19 pandemic. The analysis of the breakdown of the persons according to their level of exposure shows that the very large majority of workers (75% all sectors combined) received no dose above the detection threshold.

The largest proportion (48%) of exposed medical personnel is involved in radiology activities (diagnostic radiology and interventional radiology), with an average annual individual dose of 0.20 mSv. Nuclear medicine represents 3% of the personnel but with a significantly higher average annual individual whole body dose, estimated at 0.84 mSv.

The medical and veterinary activity sectors account for the majority of exposures of the extremities, with nearly 61% of the workers subject to this monitoring in 2020 and 2021. Altogether, 17,252 people were subject to dosimetry of the extremities, with an average dose of 14.9 mSv compared with 14.7 mSv in 2020. Nuclear medicine and interventional practices are the sectors that make the greatest use of ring dosimeters and contribute the most to exposures of the extremities (68% and 16% respectively of the total dose recorded for the medical and veterinary activity sectors). 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. For the first time since 2013, no exceeding of the regulatory limit for the equivalent dose to the extremities (500 mSv) was recorded in the medical sector in 2021.

1. Internal Targeted Radiotherapy (ITR) aims to administer a RadioPharmaceutical Drug (RPD) emitting ionising radiation which will deliver a high dose to a target organ for curative or palliative purposes.

Lastly, nearly 87% of the personnel monitored for exposure to the lens of the eye work in the medical and veterinary sectors, and represent 5,219 workers with an average individual dose of 1.72 mSv. Nearly two-thirds of the personnel monitored for lens of the eye dosimetry work in the FGIP sector which accounts for 59% of the total dose in the medical and veterinary sectors.

### 1.2.2 Exposure of patients

In medical applications for diagnostic purposes, optimisation of exposure to ionising radiation allows delivery of the minimum dose that produces the relevant diagnostic information or allows performance of the planned interventional procedure. With therapeutic applications, the highest dose possible must be delivered in order to destroy the targeted tumoral 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 responsible for health and the health professionals (see chapter 1, point 3.3). The action plan of 2018 will be updated in 2023 after reviewing the situation 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 (As Low As Reasonably Achievable) principle, has led to the introduction, in the area of medical imaging using ionising radiation, of the concept of “Diagnostic Reference Levels” (DRL). These DRL, which must not be considered to be “dose limits” or “optimum doses”, are established for standard examinations and typical patients. DRL are therefore dosimetric indicators of the quality of practices, intended to identify the examinations on which optimisation efforts must be focused in priority. They should not be exceeded in standard procedures without justification. 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 DRL. In 2022, ASN asked IRSN to propose new DRL values for Digital Radiography (DR) mammography and for tomosynthesis mammography. The ASN Advisory Committee for Radiation Protection (see chapter 2) was asked to give its opinion on these values with a view to updating ASN resolution 2019-DC-0667 of 18 April 2019 in 2023.

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. On the whole 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 are close to facilities that emit ionising radiation;
- sewage network and wastewater treatment plant personnel who could be exposed to effluents or wastes produced by nuclear medicine departments;
- patients’ family, carers and comforters.

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 ( $\mu\text{Sv}$ ) per year for the most exposed people, primarily the personnel working in the 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”), which enables nuclear medicine departments and research laboratories to estimate, with reasonably penalising assumptions, conservative dose values for the sewage system workers based on the activities administered by the departments. In the case of an examination performed on a pregnant woman, the embryo or foetus exposed *in utero* is considered to be a member of the public and therefore subject to the dose limits for the public.

Pregnant women unaware of their pregnancy represent one third of the Significant Radiation Protection Events (ESRs) reported annually to ASN, that is to say about 200 cases per year (see point 2.7). The doses delivered to the uterus by imaging examinations are usually less than 100 mGy, a value below which no increase in malformations or reduction in intellectual quotient has been detected to date in comparison with spontaneous risks (estimated at 3%)<sup>(2)</sup>.

In nuclear medicine, a radionuclide source is administered to the patient, who can then emit ionising radiation and expose the persons around them. To control this type of exposure, the regulations have introduced the notion of “dose constraints”. To verify compliance with these dose constraints, equivalent ambient dose rate measurements can be taken before discharging a patient who has received a nuclear medicine treatment or examination. 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 ( $\mu\text{Sv/h}$ ) at a distance of 1 m (recommendations of the Advisory Group for Radiation Protection in Medical Applications – Oct. 2017). It is usually necessary to hospitalise the patient in a radiation-proof room while waiting for the activity to decay.

### 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 the physical-chemical properties of the sources) 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 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

2. 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.



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 (chapter 3). The environmental gamma radiation does not reveal any exposure exceeding 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 state 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 bibliographical study conducted by IRSN<sup>(3)</sup> in 2021 reveals that the estimated radiological impact on the population of radioactive discharges from nuclear medicine departments into sewage systems is low (doses evaluated at below 1 µSv/year for people living in the vicinity of wastewater treatment plants).

## 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. 4451-135).

In order to protect the public and the workers, the facilities that use medical devices emitting ionising radiation must also satisfy the technical rules defined in the ASN resolutions (see technical rules described in point 2).

The monitoring of sources (radioactive sources including RadioPharmaceutical Drugs (RPD), 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) which concern the acquisition, distribution, import, export, sale, transfer and recovery and disposal of the sources. More specifically, the sources must be declared, registered or licensed if they are not exempted, they must be inventoried, recovered when expired/disused, and be subject to financial guarantees of recovery.

### 1.3.2 Medical devices and radiopharmaceuticals

The radionuclides used in nuclear medicine can be classified in two categories:

- the RPD, subject to obtaining a Marketing Authorisation (MA), issued by either the French Health Products Safety Agency (ANSM) or the European Medicines Agency (EMA);
- medical devices, which are required to obtain the “CE” marking (for example, implantable medical devices, such as microspheres marked with yttrium-90).

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.

Medical Devices (MD) emitting ionising radiation (electrical devices and particle accelerators) used in nuclear-based medical activities must meet the essential requirements defined in the Public Health Code (Articles 5211-12 to R 5211-24). 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 medical devices has been modified to reinforce the provisions concerning the display of the dose during imaging procedures. In addition, the new European regulation EU 2017/745 entered into application on 26 May 2021 and its implementation is planned for 2028. This new European regulation reinforces patient safety, through a better clinical assessment of the MDs, and improves transparency, thanks to the European Database on Medical Devices – EUDAMED), also accessible to the general public, which helps to improve collaboration between the competent European authorities. 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”, conditional on the deployment of a clinical study to confirm the substantial health benefit of the new technology.

The clinical assessments conducted for putting onto the market MDs, RPD or derogation processes allowing patients to receive an innovative treatment are determining factors in the application of the justification principle (see point 1.3.4).

On 8 July 2019, in order to plan ahead for the radiation protection risks associated with the introduction of new techniques and emerging practices using ionising radiation, ASN created “Canpri”, a Committee for analysing new techniques and practices using ionising radiation (see chapter 2). Chaired by ASN and comprising 16 experts and representatives of French health institutions, 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 with regard to patient and worker radiation protection. Its work focuses on intraoperative radiotherapy, the ZAP-X® gyrosopic platform for stereotactic intracranial radiotherapy and radiosurgery, the new radionuclides in nuclear medicine and Flash therapies. The Canpri will issue its first opinion, which will concern the ZAP-X®. gyrosopic platform, in 2023.

### 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 particularly suited to the nuclear activities that present the lowest risks for people, 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. Registration also involves the submission of documents for examination, but fewer in number.

Thus, since 1 July 2021, the ASN On-line services portal allows persons/entities responsible for nuclear activities to register their

3. 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.



TABLE 1 Classification of nuclear-based medical activities according to the radiation protection 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

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. Conventional radiology and dental radiology will continue to come under the notification system. The licensing system is maintained for external-beam radiotherapy, brachytherapy and diagnostic and therapeutic nuclear medicine.

### 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 (Art. 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). ASN updated and specified the necessary qualifications in October 2020. This aim of the updating is to adapt the regulatory provisions to the developments in the techniques and conditions of practise. ASN resolution 2020-DC-0694 of 8 October 2020, approved by Order of 5 July 2021, entered into effect in July 2021. It repeals the resolution of 23 August 2011 (2021-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, and for the physicians appointed to coordinate a medical nuclear activity or who 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 persons/entities responsible for nuclear activities 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 head of the nuclear activity, with requirements proportionate to the radiation protection risks, to formalise the processes, procedures and work instructions associated with the operational implementation of the two general principles of radiation protection, namely justification for the procedures and dose optimisation, and those concerning the lessons learned from the events, the training of professionals and, for therapeutic procedures, the prospective risk analysis. ASN 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.

*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 2017-DC-0585 of 8 January 2015 amended, further to discussions with all the National Professional Councils (CNP) concerned in order to clarify and reinforce the teaching objectives concerning justification, to integrate new players and to foster links with the other continuous training instruments. Since this resolution entered into application, some twenty professional guides have been produced by the learned societies, validated by ASN and put on line on *asn.fr*. To monitor the practical implementation of this new framework, a qualitative and quantitative assessment was initiated at the end of 2021, involving all the players. An inventory of the training offerings has been drawn up to identify the main players (health facilities, learned societies, 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 will be presented in 2023 to the committee that monitors the national plan for controlling imaging doses.

## THE SETTING UP OF CLINICAL PEER REVIEWS

In order to transpose Council Directive 2013/59/Euratom of 5 December 2013, the work on setting up clinical peer reviews, which began following publication of the Directive, was relaunched in 2022 by the Ministry responsible for health, which is coordinating drafting of the texts.

The ongoing work aims to determine the procedures for conducting these audits (recruiting auditors, training, funding, etc.) and to draw up the baselines on which the auditors can found their work. Work on imaging and radiotherapy is in progress, with contributions from the national professional councils of radiologists and radiotherapists. ASN is involved in the discussions on these two themes.

Several institutions are involved in the procedure (General Health Directorate – DGS, General Healthcare Directorate – DGOS, HAS, INCa, ASN), as the successful implementation of these clinical peer reviews is partly dependent on them fitting in well with the existing systems, such as HAS certification and ASN oversight.

ASN encourages an approach that is graded according to the radiation protection risks by focusing the clinical peer reviews on the areas of radiotherapy, therapeutic nuclear medicine, FGIPs and computed

tomography, the latter being the technique that makes by far the greatest contribution to exposure of the French population.

ASN will ensure compliance with the framework of the directive, and:

- provide input for the procedure based on European work (QUADRANT project and EU-JUST-CT project);
- participate actively on the steering committee that the Ministry responsible for health wishes to set up to evaluate the system and propose guidelines concerning any necessary changes;
- target these audits on clinical practices;
- link the system with the two ASN resolutions on the quality assurance obligations (ASN resolution 2019-DC-0660 of 15 January 2019 in medical imaging – nuclear medicine for diagnostic purposes, dental and conventional radiology, computed tomography and FGIPs, and ASN resolution 2021-DC-0708 of 6 April 2021 for therapeutic procedures (radiotherapy, radiosurgery and nuclear medicine for therapeutic purposes), being careful to maintain what has been achieved (formalising of change management, of subcontracted operations and of specific work task qualifications in particular);

- promote an approach graded according to the risks, prioritising putting in place computed tomography audits targeting implementation of the principle of justification and when deploying new radiotherapy techniques and practices.

Holding clinical peer reviews should improve the justification of procedures, which is why ASN is making it a priority action (justification/clinical peer reviews) of the National plan for controlling imaging doses. ASN cannot act alone on this subject because its scope of competence only enables it to verify implementation of the principles of justification during its inspections in a “quality management system process” approach (formalisation of the process, recording of the elements of proof of the justification process). This why ASN will endeavour to continue mobilising all the institutional players and learned societies on the subject of clinical audits, in particular through the framework agreements it has signed with these entities.

Alongside this work, ASN will continue its field inspection activity to monitor the deployment and the impact of the clinical peer reviews.

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### 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 reported 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 oversight must focus in priority on external-beam radiotherapy, brachytherapy, nuclear medicine and FGIPs. The inspection frequencies have been adapted and enable all the radiation-risk activities to be inspected over a period of 3 to 5 years, depending on the sectors. As from 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 worker 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 2022 were:

- in radiotherapy and brachytherapy: risk management, management of skills and training, mastery of the equipment and the security of high-activity sealed sources;
- in nuclear medicine: the experience feedback process for reported internal or external events (ESRs);
- in FGIPs: implementation of the optimisation approach.

For the routine inspections, ASN has defined an inspection frequency per inspected nuclear activity (Table 2) based on a graded approach to the radiation protection risks. 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.

TABLE 2 Inspection frequency by area of 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	Every 5 years
Computed tomography (emergencies or paediatrics)	Sampling: about twenty facilities per year

### 1.5 Significant radiation protection events

It is mandatory to report ESRs to ASN in application of the Public Health Code (Articles L. 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 reported to ASN since 2007. Reporting these events makes it possible, after analysing them, to give feedback to the medical professionals with a view to continuous improvement of radiation protection.

The on-line *Teleservices* portal at *asn.fr* has been provided to enable all the medical professionals to file reports on line. This portal is integrated in the “one-stop vigilance portal” managed by the Ministry responsible for health. Depending on the type of event reported, the notification is sent automatically to ASN (regional division), to the Regional Health Agency (ARS) for all events concerning the patient, while events relating to medical devices vigilance or drug safety monitoring (RPD) are sent to the ANSM.

A draft ASN resolution on “Procedures for reporting significant events and codifying the reporting criteria” was submitted for public consultation in 2022, along with the updated Guide No. 11 for the medical sectors, which details the event reporting procedures. The resolution and guide should be published in

the course of 2023. 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).

Moreover, the incident notices are published on *asn.fr*.

To encourage sharing of the lessons learned from experience feedback from medical professionals, ASN publishes the newsletter *Patient safety – Paving the way for progress*, first issued in March 2011, sheets on *Experience feedback* from ESRs, and circular letters addressed to the heads of nuclear activities. Produced by multidisciplinary working groups coordinated by ASN, the newsletter offers a thematic deciphering, good practices by medical departments and the recommendations developed by the learned societies of the discipline concerned and the health and radiation protection institutions. The “*Experience feedback*” sheet, for its part, draws attention to a specific ESR reported to ASN to prevent it from occurring in another centre.

## 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 non-malignant cells. The ionising radiation necessary for the treatments is produced by an electric generator or emitted by radionuclides in sealed sources. We distinguish external-beam radiotherapy, where the source of radiation (particle accelerator or a radioactive source such as Gamma knife®) is external to the patient, from brachytherapy, where the source is placed as close as possible to the cancerous lesion.

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 volumes 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 could occur. Implementation of the treatment quality and safety management system, skills management, mastery of the equipment, ESR recording and follow-up are the focal points of the ASN inspections. As technical, organisational and human changes have been identified as 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* (Record), 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 techniques 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. This technique consists in irradiating a target volume by continuous irradiation rotating around the patient.

**Helical radiotherapy, or tomotherapy**, enables radiation treatment to be delivered by combining the continuous rotation of an electron 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 with 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. The term radiosurgery is used to designate treatments carried out in a single session. This technique demands great precision in defining the target volume to irradiate, following the shape of the tumour as closely as possible, and uses specific identification techniques in order to locate the lesions with millimetric accuracy.

This therapeutic technique chiefly uses three specific types of equipment, such as:

- Gamma Knife®, which uses more than 190 cobalt-60 sources. It acts like a veritable scalpel over an extremely precise and delimited zone;
- robotic stereotactic radiotherapy; CyberKnife® is a miniaturised linear accelerator mounted on a robotic arm;
- multi-purpose linear accelerators equipped with additional collimation means (mini-collimators, localisers) that can produce mini-beams.

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 an X-ray generator using low-energy beams which are particularly suited to the treatment of skin cancers because the delivered dose decreases rapidly with depth.

**Intraoperative radiotherapy** combines surgery and radiotherapy, with the radiation dose being delivered in the operating theatre to the tumour bed during surgical intervention. This technique is used primarily for treating small cancers of the breast. In April 2016, the HAS published the results of the assessment of this practice and concluded that the conditions necessary to propose coverage by the state health insurance scheme were not satisfied at the time. It considers that the clinical and medico-economic studies must be continued in order to have clinical data over the longer term. Nevertheless, some **intraoperative**

**electron radiotherapy** devices, with the “CE” marking, have been put on the market. They allow optimal irradiation of the tumour while preserving the surrounding healthy tissues to the maximum possible extent. This innovative technique is currently being discussed by the Canpri.

**Hadron therapy** is a treatment technique based on the use of beams of charged particles (protons and carbon nuclei), which can deliver the dose in a highly localised manner during treatments, thereby drastically reducing the volume of healthy tissue irradiated. According to its advocates, hadron therapy with carbon nuclei 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.

## 2.1.2 Technical rules applicable to external-beam radiotherapy facilities

On account of the high dose rate 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 was 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. 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. The ZAP-X® gyroscopic platform, a new medical device which obtained the “CE” marking in January 2021, presents the innovative characteristic of being self-shielded. A first machine of this type is currently being installed in France and is planned to start operating in 2023. As part of ASN’s examination of the application for a licence to possess and use this device, it has been put before IRSN and the Canpri will give its opinion on this new technique at the beginning of 2023.

## 2.1.3 Radiation protection situation in external-beam radiotherapy

The installed base of external-beam radiotherapy facilities in 2022 comprises 592 particle accelerators installed in 174 radiotherapy centres subject to ASN licensing (see Graph 1).



More than 200,000 patients<sup>(4)</sup> are treated each year, which represents nearly 4.2 million radiation sessions. The French radiotherapy observatory (French National Cancer Institute – INCa), lists 901 radiation oncologists in 2021. ASN issued 115 licenses in 2022, which represents a 35% increase on 2021. These applications are either for new facilities (about 15%) or changes of devices (accelerators or simulation scanners). As the installed base of accelerators is aging (age > 10 years) and can represent 20 to 30% of the base in certain regions, licence renewal applications could increase in the coming years.

ASN moreover observes a rise in numbers of stereotactic treatments in radiotherapy departments across the country, with an increase in extra-cranial stereotactic indications (lung, liver, spine, bones, ENT). This activity presents radiation protection risks and requires skills of a high standard and greater control of the doses delivered.

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. The inspection programme for the 2020-2023 period places 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 approach to inspection:

- 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 48 inspections in 2022, representing 25% of the French centres. Out of the 48 inspections, 9 were conducted in combined mode, that is to say both on site and remotely. This results from the experience acquired over the previous two years where inspections were conducted remotely on account of the Covid-19 pandemic. By analysing documents and general points at their desk, inspectors can devote more time when on site to visiting the facility and interviewing the personnel.

### 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 2022 reveal no difficulties in this sector:

- radiation protection advisors have been designated in all the centres inspected;
- all the radiation protection technical controls have been carried out at the required regulatory frequency.

### 2.1.3.2 Radiation protection of radiotherapy patients

The assessment of the radiation protection of radiotherapy patients is based on the inspections focusing on implementation of the treatment quality and safety management system, 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, and in particular the presence of the medical physicist and the internal organisation procedures

for tracking and analysing adverse events – or malfunctions – recorded by the radiotherapy centres.

A medical physicist is effectively present during the treatments in 100% of the inspected centres. All the centres have a medical physics organisation plan, but the quality of the plans varies from one centre to another.

The ASN inspectors observe that the authorisation process is being deployed, but with disparities between the medical and paramedical personnel, given that it is applied to a greater extent for the paramedical staff. ASN was invited to give a presentation of ASN resolution 2021-DC-0708 of 6 April 2021 on personnel authorisation at a day event organised by the AFCOR<sup>(5)</sup> in September 2022.

Furthermore, the analysis of compliance with regulatory requirements concerning the management of events over the 2018-2022 shows that a constant proportion of departments complied with the regulations over the last 3 years, 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 80% and 88% over the period in question.
- The analysis of adverse events, the defining of corrective actions and building on the lessons learned, seem to be stabilising after an initial phase of progress, with about 74% of the inspected centres carrying out these steps satisfactorily over the period in question.
- The improvement in practices resulting from Incident Learning Systems (ILS's) and assessing the effectiveness of the corrective actions still represent the weak spot of these events analysis procedures, with the percentage of satisfactory situations remaining stationary at between 27% and 36% for the 2018-2022 period, with no dynamic for progress in this respect (see Graph 2). These procedures must involve representatives of all the staff contributing to the treatment of patients, but the lack of personnel availability, especially medical personnel, limits their effectiveness. 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 above-mentioned resolution 2021-DC-0708 of 6 April 2021, are vital in order to improve treatment quality and safety. In effect, the only way of testing the long-term robustness of the measures taken is to assess the corrective actions. The addition of check points, for example, can constitute a “false security” if they cannot be implemented by the professionals for various reasons. Moreover, the analysis of events can reveal that the safety barriers in place have not been effective, like those for ascertaining that the treatment has been delivered to the correct side, which should lead to a review of the prospective risk analysis and a team reflection to find more effective protection measures.

The ability of a centre to deploy a risk management procedure was again subject to specific investigations in 2022. These investigations reveal that:

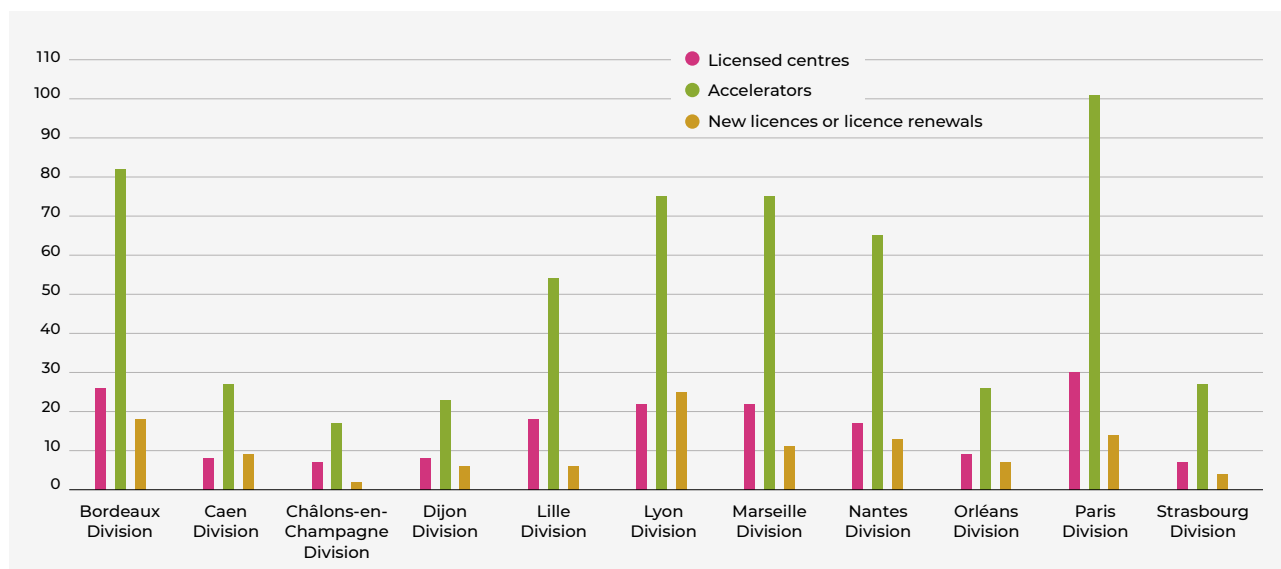
- Although the requirements for quality and safety management in radiotherapy departments are satisfied in the majority of cases, there are still disparities between centres. Thus, the prospective risk analysis is only complete or updated in half the inspected centres, mainly due to lack of training or resources, or to a change in the operational quality manager.

4. In 2020, 204,062 people with cancer were treated by radiotherapy in 4,093,819 sessions (source: INCa Observatory).

5. Association of continuous training in oncology.



GRAPH 1 Breakdown, by ASN regional division, of the number of centres and external-beam radiotherapy accelerators inspected and the number of new licenses or license renewals issued by ASN in 2022



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This incompleteness concerns, for example, the failure to take into account experience feedback (that of other centres for example, disseminated the ASN publications – *Patient safety* newsletter and *Experience feedback* sheets) or new practices or the organisation of the centre if there is a change in the technical platform.

- More generally, ASN considers that the risk management procedure is only implemented satisfactorily in half of the inspected centres. These are the centres in which management has defined a policy with shared, assessable and assessed operational objectives, has communicated on the results of this policy and allocated the necessary resources, in particular, to the operational quality manager. 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 implementation of management reviews and internal audits is also observed but remains highly dependent on an internal dynamic and the availability of the operational quality managers. ASN has also noted during its inspections that some centres have initiated peer review procedures in medical physics, particularly when replacing their accelerators. These voluntary initiatives fully converge with the reflections on clinical peer reviews conducted by the Ministry responsible for health (see point 1.3.4).

ASN again observes that the impact of an organisational or technical change on the operators' activity is 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. It is vital in this respect to call into question the prospective risk analysis in order to supplement it, if necessary, from the moment new work processes are put in place or to verify that the existing defence barriers are still appropriate. The now obligatory formalisation of the change management process is not always properly carried out in the centres concerned by recent or ongoing changes.

The lessons from the inspections in 2022 effectively show that when a new technique is put in place, the change management procedure is considered satisfactory in only half of the centres, a proportion that remains constant for the 2018-2022 period. ASN more particularly draws the attention of medical professionals

to high-risk situations, such as a relocation combined with an activity extension (new rooms, new machines) which necessitate not only considerable efforts on the part of the personnel in place but also the recruitment and integration of additional personnel made necessary by the new acquisitions. Moreover, ASN observes that the functioning of the centres can be suddenly disrupted further to the buying out of private centres or a mass departure of personnel (radiotherapists or medical physicists). This situation arose in summer 2022 at the Ris-Orangis radiotherapy centre (see box next page).

Project mode change management (appointment of a leader, project planning, training of teams, organisation of routine work continuity during project implementation, updating of documents) is not yet well established in the departments. 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*. ASN organised a day of discussions with the professionals in Lyon on 25 October 2022 on change management and managing changes in project mode. The centres that have deployed this procedure underline that is a way of improving team dynamics.

### 2.1.3.3 Significant events in external-beam radiotherapy

In 2022, 102 ESRs were reported in radiotherapy under criterion 2.1 (exposure of patients for therapeutic purposes). Among these events, 70 were rated level-1 on the ASN-SFRO scale, *i.e.* 68% of the total, and three were rated level 2. The latter three concerned:

- an error in dose or volume having led to exposure exceeding the planned dose for one of the organs targeted by the treatment as well as a neighbouring organ, and exposure of less than the planned dose for another organ targeted by the radiotherapy treatment;
- a fractionation error having resulted in exposure exceeding the planned dose to the organs at risk;
- a calibration error that led to six patients receiving an overdose during external-beam radiotherapy treatment.

Two ESRs rated level 1 on the ASN-SFRO scale concerned cohorts of patients as a result of:

- a calibration error for more than 5,800 patients. This calibration error resulted from incorrect use of barometric data, leading to

## RIS-ORANGIS RADIOTHERAPY CENTRE (CRRO): MANAGEMENT OF AN EMERGENCY SITUATION

An inspection of the CRRO, concomitant with that of the ARS of Île-de-France, was carried out in August 2022, following the publication of articles in the mainstream press mentioning the departure of 4 of the centre's radiotherapists after terminating their contract two years earlier, in a situation of private law conflict between CRRO senior management and the radiotherapists. With the new medical team arriving on 1 September 2022, the centre had to put in place a temporary organisation to ensure treatment

continuity during the month of August 2022. It also had to plan for a period of skills build-up for the various medical teams.

Further to this inspection, ASN made requests – which the centre has taken into account – concerning:

- the completeness of the prospective risks mapping, more specifically by indicating certain barriers and the associated preventive or corrective actions and the continuation of its enrichment in view of the arrival of the new medical team as of September 2022;

- the revival of the ILS approach, particularly the detection and reporting of adverse events;
- monitoring of the new radiotherapists on arrival with the organisation of medical monitoring reinforced by occupational medicine for classified workers and training in occupational radiation protection appropriate for the practices of the department, dispensed by the radiation protection advisor.

A follow-up inspection is scheduled in early 2023 to track the progress of the centre's commitments.

## CALIBRATION ERRORS: LESSONS LEARNED FROM THE EVENT REPORTED IN 2022

### Saint-Jean de Saint-Doulchard Oncology and Radiotherapy Centre (Corrèze département)

On 30 May 2022, the Saint-Jean de Saint-Doulchard Oncology and Radiotherapy Centre (Corrèze département)<sup>(\*)</sup> reported to ASN a significant event that occurred in its radiotherapy department of Moulins (Allier département), linked to an error in dose calibration under the reference conditions, as a result of an error in setting the parameters of a barometer.

This incorrect parameter setting induced an overdosing of about 3%, with no expected clinical consequences, for all the patients treated between November 2010 and May 2022, which represents a cohort of about 5,800 patients.

Following detection of this event, the department immediately checked the barometers and corrected the calibration of the doses of all the accelerator beams.

However, this event adds on to another event in the same centre reported on 23 March 2022, which also led to overdosing of the ionising radiation delivered to five patients, with an error of 7.5% for one of them. Although such a difference is not likely to result in any clinical consequences, the patients' follow-up consultations with their referring doctor(s) were brought forward.

In response to ASN's request, the centre has drawn up a retrospective clinical study protocol to look for any unexpected secondary effects in a representative sample from the cohort of patients concerned. The conclusions of this study have not yet been communicated to ASN.

ASN rated this event level 1 on the ASN-SFRO scale of radiotherapy events, graded from 0 to 7 in increasing order of severity.

### Léon Bérard Centre in Lyon (Rhône département)

On 19 December 2022, the Léon Bérard Centre (CLB) in Lyon reported a significant event that occurred in its external-beam radiotherapy department concerning six patients who received higher-than-expected Total Body Irradiation (TBI) during treatments of malignant hemopathies.

TBI is an external-beam radiotherapy treatment used mainly in preparation for an allogenic bone marrow transplant in patients suffering from blood cell cancers and their precursors (leukaemias, lymphomas, myelomas, etc.).

In September 2022, after finding a drift in the calibration of the device delivering the prescribed dose to the patient, the centre's medical physics team conducted a retrospective analysis of the impact of this drift on the treatment plans of the patients treated using this technique. For six patients, the doses delivered per treatment session were higher than expected. The CLB evaluated the dose to the lungs (sensitive organs) of these patients in priority. The estimated doses received at the lungs of all six patients remained below the doses considered to be associated with an increased toxicity risk.

Following this event, the centre informed the patients concerned and put in place corrective actions. The practices for checking the doses delivered to the patients have been modified and stepped up. Furthermore, the use of a new measuring system with an ionisation chamber positioned directly on the patient during the treatment sessions is envisaged.

In view of the confirmed overexposure of patients and the potential consequences, and after consulting the SFRO, ASN rated this event level 2+

on the ASN-SFRO scale of radiotherapy events, graded from 0 to 7 in increasing order of severity.

ASN has examined the corrective measures proposed and considers that they will limit the risks of a similar event occurring. Taking into account the SFRO's recommendations, ASN has asked that the six patients concerned be subject to pulmonary monitoring every three months for 18 months.

More generally, ASN underlines that the calibration of medical devices is critical for treatment safety and urges radiotherapy departments to question their practices by referring to the ASN publications drawn up on the basis of lessons learned from the analyses of several events associated with calibration errors.

ASN points out that:

- a circular letter of 19 May 2016 was sent to all the radiotherapy departments giving recommendations on the conditions for determining the absorbed dose, notably by using calibrated measuring instruments to measure the atmospheric pressure used to correct the response of the ionisation chamber;
- an *Experience feedback* sheet published on 25 April 2022 concerning particle accelerator calibration errors sets out one centre's analysis and its tips for reducing the risk of errors when calibrating an accelerator.

*\* At the beginning of 2022, the Saint-Jean Oncology and Radiotherapy Centre (Corrèze département) took over responsibility for the radiotherapy nuclear activity previously exercised by the Hospital Centre of Moulins (Allier département).*

an incorrect atmospheric pressure value discovered during the machine quality controls. ASN had already alerted the centres to this type of error by circular letter of 19 May 2016, and drawn up recommendations for calibrating the treatment beams;

- an error in the computer modelling of the treatment table led to a position error situated at the head of the patient in the computerised dosimetric planning system; 134 patients were concerned.

Most of the events reported in 2022 concern patient radiation protection, and the majority of them are not expected to have any clinical consequences.

As in the preceding years, these events always highlight organisational weaknesses concerning:

- the management of movements of patients' files;
- the validation steps, which are not explicit enough;
- the keeping of patients' files in a manner that provides an overall view and gives access to the required information at the right time.

Variations in practices within a given centre, frequent task interruptions, a high and uncontrolled workload affecting the length of working hours, or the deployment of a new technique or practice, all constitute situations that disrupt work activities and weaken the safety measures defined in the quality management system. It is therefore essential to assess these measures regularly and to draw lessons from the malfunctions that occur.

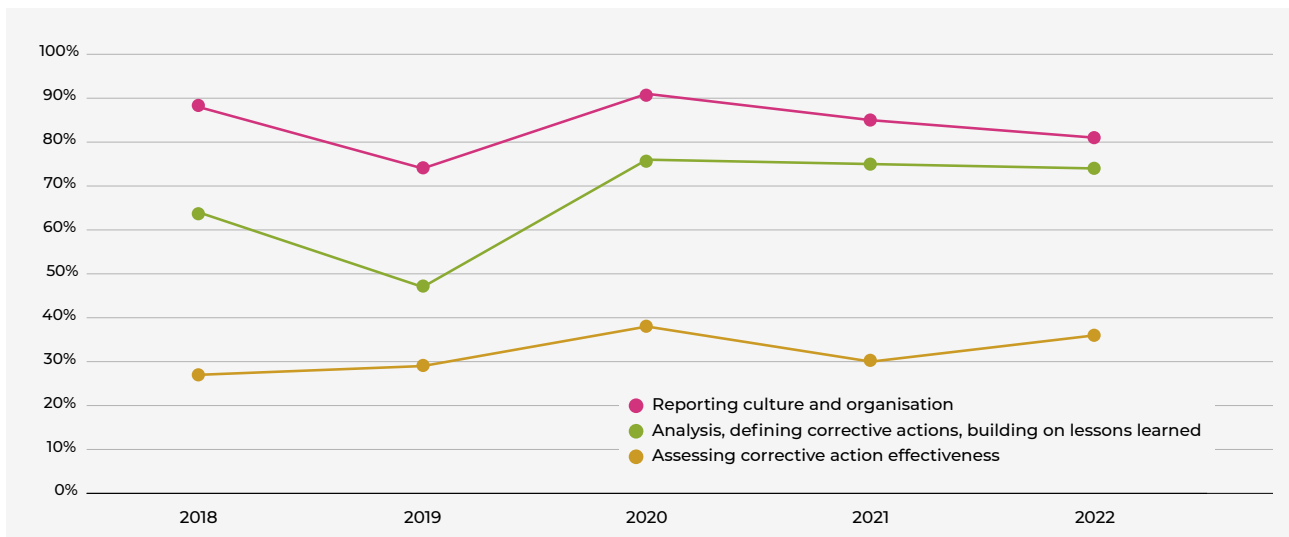
ASN has noted a significant and regular drop in ESR notifications in radiotherapy since 2015 (see point 2.7 Graph 12). This drop can probably be partly attributed to the setting up of organisations that have rendered treatment preparation smoother and safer (complete dematerialisation with lists of "record and verify" tasks, harmonisation of medical protocols, delineation assistance software, automatic application of dosimetry shifts, monitoring of preparation times, etc.), and the integration of lessons learned from events. The setting up of audits to assess the performance of the radiotherapy treatment process (auditing of files, tracking times), observance of the identity monitoring rules or the effectiveness of an improvement measure can also explain this drop in ESR reporting, even if these procedures are still far from being widely implemented.

However, at the same time the ASN inspectors observe a drop in the ESR reporting culture with a reduction in the number of internally recorded adverse events that are analysed (fewer feedback analysis committee meetings organised) and more analyses of superficial events but rarely investigating their root causes. The inspectors also note a lack of integration of the lessons learned from the analysis of reported events at national level and shortcomings in communication, which is top-down only in some centres. The drop in reported ESRs in radiotherapy is one of the themes of a seminar organised by ASN for 15 March 2023 entitled "Quality-safety approach in radiotherapy: what lessons have been learned after more than 15 years of application?"

Among the adverse events declared in 2022 is a growing number of cyber attacks (3 radiotherapy centres, 1 in 2021 and 2 in 2022, and 1 nuclear medicine centre in 2022). These attacks paralyse the computer system and cause serious disruptions in the organisation of treatments. In view of the risks of reduced chances of success for patients whose treatments are interrupted or errors in treatment delivery due to potential data losses, these cyberattacks generate stress for the treatment teams and the patients alike. Although cyber security does not fall under the competence of ASN, these situations are nevertheless brought to ASN's attention and form the subject of a report if they cause an ESR. These cyber attacks call into question current practices of "all-electronic" patient records. The SFRO has just initiated a reflection, in which ASN is involved, with the aim of issuing recommendations to anticipate and limit the risks associated with cyber attacks in a context of growing digitisation of data (relevance of keeping paper documents, reviewing backup procedures in the event of loss of digital data, etc.).

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GRAPH 2 Percentage conformity of external-beam radiotherapy facilities in the management of events in 2022



## SUMMARY

In radiotherapy, the inspections carried out by ASN in nearly one quarter of the radiotherapy units in 2022, considered alongside those carried out over the period 2018-2021, enabling all the departments to be covered, confirm that the safety fundamentals are in place: organisation of medical physics, equipment verifications, training in the radiation protection of patients, deployment of quality assurance procedures, recording and analysis of events. However, the analysis of the 2018-2022 period confirms that assessing the effectiveness of corrective actions is still the weak point of the ILS procedures and is struggling to become more widely adopted. Although the preliminary risk assessments are inadequately updated prior to an organisational or technical change or following the analysis of events, ASN views positively the voluntary development of peer review practices in medical physics, when new equipment is installed. ASN underlines that the buy-outs of centres are situations entailing considerable disruptions that lead to risks if the impact on the working activity of the professionals is not analysed and if these changes are not prepared for with all the teams. ASN also observes that the formalisation of the specific work tasks authorisation procedures, which have been mandatory since August 2021, is being deployed with differences between the professional categories. Finally, the occurrence of events such as patient identification errors, delineation of organs at risk and/or target organs, and once again calibration, still reveals organisational weaknesses and the need to regularly assess practices. ASN moreover observes a loss of memory of lessons learned from past ESRs and a steady reduction in the number of ESRs reported to ASN since 2015. Although this can be partly attributed to greater treatment safety, a regression in the culture of reporting internal events is noticeable, with the events analysis committees meeting less frequently and conducting less detailed analyses. Furthermore, the occurrence of cyber attacks also underlines the new challenges facing radiotherapy professionals in a context of increasing digitisation of data. Finally, the new techniques and practices, which are constantly evolving, are not always sufficiently evaluated to allow an assessment of the long-term radiation induced effects (adaptive radiotherapy, hypofractionation, flash-radiotherapy, etc.).

## 2.2 Brachytherapy

Brachytherapy can be used to treat cancerous tumours either specifically or as a complement to another treatment technique.

This technique consists in placing sealed radionuclide 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, which differ more specifically in the dose rate applied (details below) according to the indications.

As with radiotherapy, the radiation protection risks 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 reported to ASN, and the security of the sources, constitute specific issues 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 or interrupting the treatment when the sources are stored in the afterloader. On the other hand, it is necessary to make provision 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.

**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 gigabecquerels (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) brachytherapy** is carried out using high-activity (about 370 GBq) sealed sources of iridium-192 or cobalt-60. The dose rates are higher than 12 Gy/h. The treatment is performed using an afterloader containing the source, and the treatments are delivered on an out-patient basis in one or more sessions lasting a few minutes, spread over several days.

### 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 shall be enforceable as from 1 July 2022.



### 2.2.3 Radiation protection situation in brachytherapy

ASN has licensed 60 brachytherapy centres, 52 of which use the HDR technique. In 2022, 18 licenses were updated (see Graph 3).

The brachytherapy activity is stable. The INCa observatory has recorded 500 to 600 LDR treatments per year using iodine-125 seeds, 650 to 800 PDR treatments per year for gynaecological cancers, and about 3,000 HDR treatments per year.

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 2020-2023 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 source management, appropriate measures to prevent unauthorised access to the sources, source inventory, protection against malicious acts and management of sensitive information).

In 2022, 14 inspections were carried, representing a quarter of the licensed departments; three of these inspections were conducted in combined mode (remotely and on-site).

#### 2.2.3.1 Management of sources

The management of brachytherapy sources is considered satisfactory. Thus, all the centres inspected in 2022 record the tracking of source movements, transmit the source inventory to IRSN and store the sources waiting to be loaded or collected in a suitable place. The organisational measures in place enable the category of each source or batch of sources to be identified in all the inspected centres and in three-quarters of the centres the personnel have been issued with the necessary authorisations to access the high-activity sealed sources. Furthermore, 75% of the inspected centres have put in place appropriate measures to prevent unauthorised access to these sources.

ASN observes that deployment of the new requirements concerning safeguarding access to high-activity sources continues to progress, but some departments are having difficulties due to the cost of the necessary compliance work.

#### 2.2.3.2 Emergency situations and management of malfunctions

Malfunctions of brachytherapy devices which can result in jams or incorrect positioning of the source can lead to overexposure – sometimes serious – of staff or patients. 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 2022 by the brachytherapy departments were considered satisfactory. Out of the 16 inspected centres possessing high-activity sources, 88% have put in place enhanced training in emergency situations and have organised situational exercises, particularly for managing situations linked to source jamming. ASN considers that these efforts must be continued in order to reinforce the radiation protection training of medical professionals where high-activity sources are held.

#### 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 quality and safety management system.

The presence of medical physicists in sufficient numbers for the activity was observed in all the centres inspected. A medical physics organisation plan is also available in all the centres inspected.

#### 2.2.3.5 The treatment quality and safety management system

The qualitative result of the inspections carried out in 2022 has shown that the majority of brachytherapy departments inspected have deployed the quality management system, with the support of the external-beam radiotherapy departments.

A review of the inspections carried out over the 2018-2022 period and covering all the departments reveals the following trends:

- the reporting culture and the organisation for managing reported events are deemed satisfactory for all the departments over the last two years, and the level was already good in 2018 with 85% satisfaction;
- the analysis, the defining of corrective actions and building on the lessons learned are considered satisfactory in about two-thirds of the departments (between 60 and 66%), a level that varies little from one year to the next;
- the assessment of corrective action effectiveness has been progressing since 2018 but there is still room for improvement. Only a quarter of the departments assessed the effectiveness of corrective actions in 2018, whereas half the inspected centres did so in 2022.

*Maintenance and quality controls* – The majority of the centres have an inventory of the medical devices 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 learned societies. Guide of the *European Society Radiation Oncology (ESTRO) Booklet No. 81* and Guide No. 36 of the French Society of Medical Physics (SFPMP).

*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.

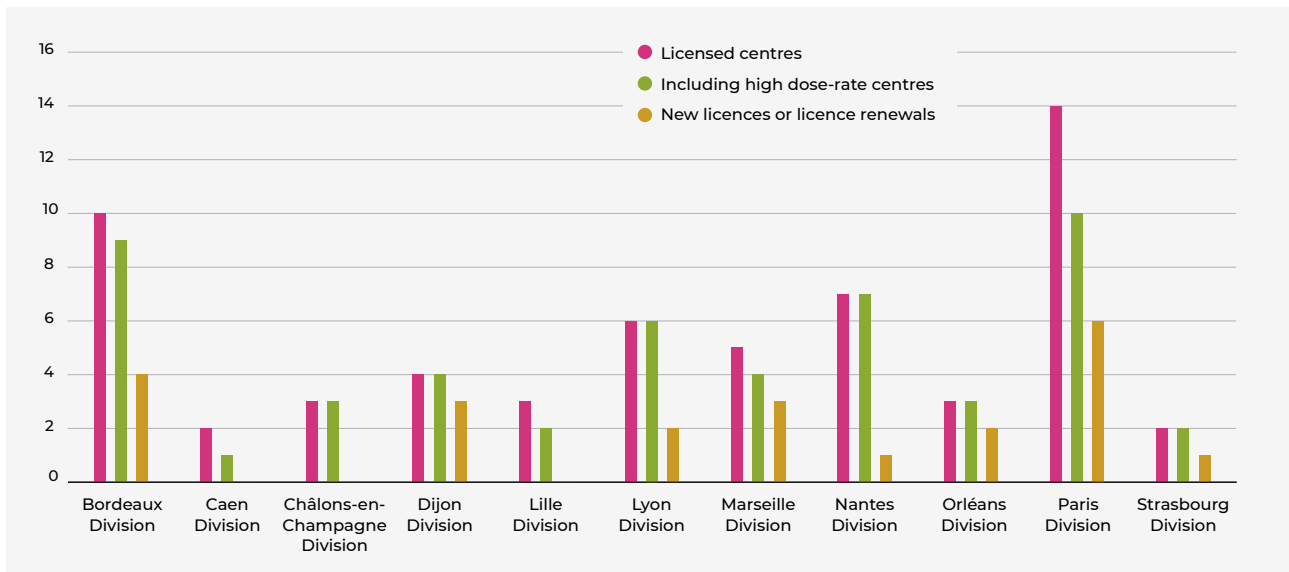
ASN notes that the verifications performed by the departments can sometimes prove insufficient when a new device is received, and draws attention to the need to clearly define these verifications taking into account the manufacturer's requirements, particularly for HDR brachytherapy. As the doses delivered 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 reported in brachytherapy

Four ESRs were reported in brachytherapy in 2022 under criterion 2.1 (exposure of patients for therapeutic purposes), one rated level 2 on the ASN-SFRO scale concerning a dose delivery error due to the use of an inappropriate afterloader in an HDR brachytherapy treatment. One event is linked to the chance discovery of a lost passive dosimeter in a treatment room with a PDR brachytherapy afterloader; the person assigned this dosimeter had retired when it was discovered.



GRAPH 3 Breakdown of the number of brachytherapy centres, high dose-rate brachytherapy centres and new licenses or license renewals in 2022, by ASN regional division



The analysis of these events underlines that the control of risks in brachytherapy must be based on appropriate quality controls and

the implementation of organisational measures to better manage informing of the patient, the sources and emergency situations.

### SUMMARY

In brachytherapy, the inspections carried out in 2022 in nearly one quarter of the brachytherapy units, considered alongside those carried out over the period 2018-2021, enabling all the departments to be covered, reveal no breach of the radiation protection rules. The radiation protection of medical staff and the management of high-activity sealed sources are thus considered satisfactory. The training effort for professionals in possession of a high-level source must be maintained and reinforced for certain centres. ASN observes that deployment of the new requirements concerning safeguarding access to high-activity sources, which came fully into force in 2022, continues to progress, in particular regarding measures to prevent unauthorised access to these sources. However, some centres are faced with difficulties when bringing into compliance necessitates major works. The events reported in 2022 underline the importance of having an active events recording system so that malfunctions can be identified as rapidly as possible, equipment quality controls can be formalised, performed and recorded, while ensuring that these latter comply with professional standards and the manufacturer's recommendations.

## 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).

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.

Nuclear medicine forms part of ASN's inspection priorities. The main radiation protection risks are linked in particular 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 radioactive substance called a 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. The imaging techniques depend on the type of radionuclide used: Single Photon Emission Computed Tomography (SPECT), sometimes called "gamma-camera", uses radionuclides emitting gamma radiation, while Positron Emission Tomography (PET) uses radionuclides emitting positrons.

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 computed tomography 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 marked 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 RPD 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.

ITR treatments can be administered either by mouth (e.g. capsule of iodine-131) or by systemic route (intravenous injection or 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.

45 nuclear medicine departments have a combined total of 167 ITR rooms for therapeutic purposes (see Graph 4).

**Medical dispensaries**

When a medical dispensary is authorised in a health care centre, the room in the nuclear medicine department in which RPD are prepared, called the “nuclear pharmacy” or “radiopharmacy”, is part of the medical dispensary. In 2019, there were 128 nuclear pharmacies in the nuclear medicine departments in public health care institutions and non-profit private health care 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 2022, which will come into effect 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 preparation units are also used for the preparation of fluorine-18 labelled RPD, along with automated injection units.

**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.

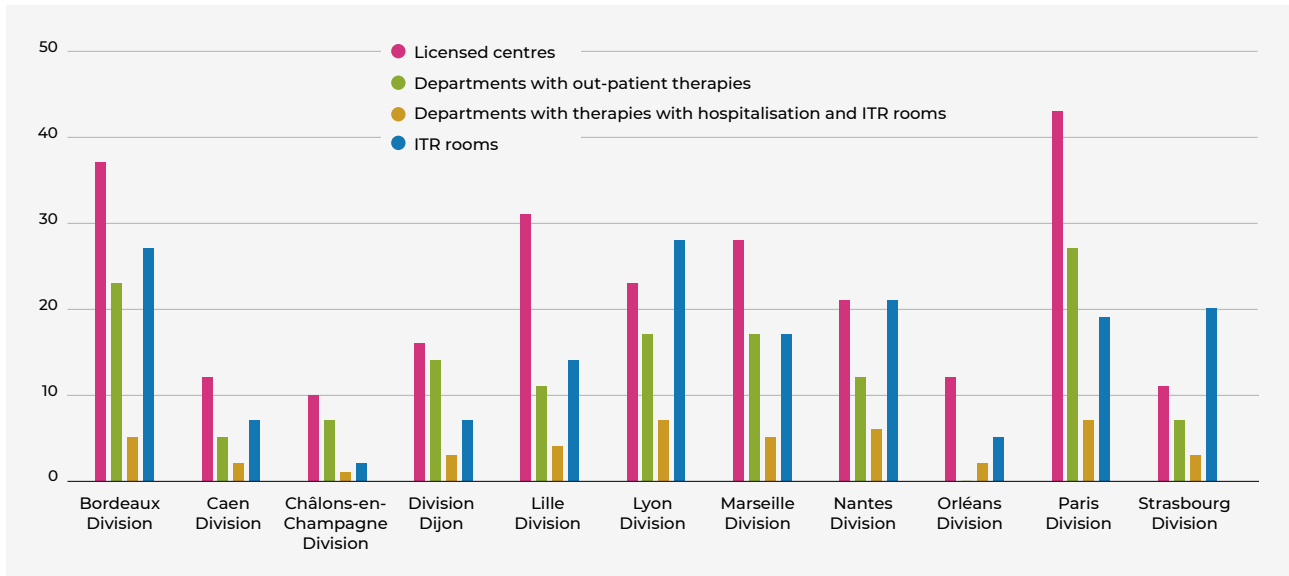
**Management of waste and effluents from nuclear medicine departments**

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

TABLE 3 Main radionuclides used in diverse *in vivo* nuclear medicine examinations

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	Fluorine-18, technetium-99m
Renal exploration	Technetium-99m
Oncology – search for metastases	Fluorine-18, gallium-68, technetium-99m
Neurology	Fluorine-18, technetium-99m

**GRAPH 4 Breakdown by ASN regional division of the nuclear medicine facilities, the number of departments with out-patient therapies and departments with hospitalisation rooms dedicated to internal targeted radiotherapy in 2022**



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” 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 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 managers. IRSN’s recommendations are expected in 2023.

### 2.3.3 The radiation protection situation in nuclear medicine

The nuclear medicine facilities base in 2022 comprises 244 licensed nuclear medicine departments, of which 45 practice high-activity ITR requiring hospitalisation in an ITR room, 140 practice moderate-activity ITR on an out-patient basis, and 59 only carry out diagnostic examinations.

119 nuclear medicine licenses were delivered during 2022, most of which concerned changes of cameras or license extensions to allow the use of new radionuclides, increases in the activity of radioisotopes already used and licences for performing clinical studies with new RPD (such as actinium-225).

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). Consequently, about a quarter of the French nuclear medicine base is inspected each year, that is to say about 15 of the 45 departments performing complex therapies, 34 of the 140 departments performing diagnostic examinations and out-patient therapies, and 11 of the 59 departments only performing examinations for diagnostic purposes.

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 DRL, quality control of medical devices, control of dispensing of RPD) and source management (circuit followed by unsealed sources, from delivery to disposal, such as the delivery reception premises, storage tanks and effluent discharges).

In 2022, 79 nuclear medicine departments were inspected, representing 32% of the facilities.

#### 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 RPD, and a risk of internal exposure through accidental intake of radioactive substances.

The results concerning radiation protection of professionals (see Graph 5) show that the radiation protection measures implemented by nuclear medicine departments are generally satisfactory with regard to the appointing of a Radiation Protection Expert-Officer (RPE-O) dedicated to this activity (valid certificate issued by the employer in all the inspected departments), the analysis of the dosimetric results of the medical staff, and the consistency between the delimiting of restricted areas and the results of the working environment verifications. These results remain relatively stable over an observation period allowing the entire nuclear medicine base to be covered (2019-2022), even if the inspected centres differ from one year to the next.

Two areas for improvement come back as a matter of course each year. The first concerns the updating of personnel training in occupational radiation protection (in 64%, in 2022 of the departments all the staff concerned received their training less than three years ago), a requirements for which ASN notes a slight regression over the last two years. The second area for improvement, also recurrent, is the coordination of the prevention measures with outside contractors, with about one-third of the nuclear medicine departments having drawn up a prevention plan with all their outside contractors (35% in 2022).

Alongside this, the radiation protection technical verifications were carried out at the required regulatory frequency for all the sources and devices in 86% of the departments inspected in 2022, a percentage that remains relatively constant from one year to the next. The same goes for the periodic verifications of radiation measurement and monitoring devices which are compliant in 87% of the departments inspected in 2022.

### 2.3.3.2 Radiation protection of nuclear medicine patients

Since resolution 2019-DC-0667 of 18 April 2019 on the Diagnostic Reference Levels<sup>6</sup> came into effect, ASN assesses the new requirements concerning the quality of dose recording, analysis and optimisation, if this proves necessary. The inspections carried out show better results for the last two years with more than 70% of the departments implementing a complete optimisation process (see Graph 6). Only 12% of the departments in 2022 had not optimised their practices even though this was necessary (exposure levels significantly higher than the DRL).

Management of the external quality controls of medical devices has also been improving steadily over the last few years. In 2022, 95% of the departments carried out the quality controls of all their medical devices at the required regulatory frequency, and the identified nonconformities have been remedied (see Graph 6).

The organisation in place to allow the involvement of a medical physicist, identify their duties and quantify the time of presence on site is also found to be better defined in the last two years and deemed satisfactory in more than 80% of the departments (82% in 2022 – see Graph 6). However, in 10% of cases, the Medical Physics Organisation Plan (POPM) was incomplete and the medical physics organisation described in the POPM was considered inadequate in 2022. In 8% of the centres inspected, the medical physics resources were found inappropriate with regard to the risks associated with the activity, and tasks such as dose recording and analysis for the CT scanner were not carried out.

Lastly, further to the publication of two ASN resolutions 2019-DC-660 and 2021-DC-0708 setting the quality assurance obligations in medical imaging and for therapeutic procedures respectively, ASN observes a high level of commitment and investment on the part of the medicine departments in the deployment of the quality management systems and notes that the events-reporting culture is present in the majority of the services inspected but must be further developed.

### 2.3.3.3 Protection of the public and the environment

Compliance with the requirements concerning protection of the general public and the environment was checked in all the inspected centres.

More than 90% of the departments (92% in 2022) have a dedicated and protected deliveries area (see Graph 7) that complies with the requirements of ASN resolution 2014-DC-0463 of 23 October 2014. About 20% the departments inspected each year (18% in 2022) have difficulties in meeting the regulatory

limits set for the activity concentration of effluents discharged after letting the effluents decay (10 becquerels per litre – Bq/L – for contaminated effluents after storage, or 100 Bq/L for effluents from the rooms of patients treated with iodine-131 - see Graph 7). Improvements have been observed these last two years in the verification of the storage tank leak detectors in the retention trays and in the formalising of checks, with more than 80% complying with the regulations (81% in 2022). In 5% of the cases, documentation tracking (registers) must be improved; the frequencies defined in the EWMP are not observed and the traceability of checks is insufficient. Four departments inspected in 2022 were found deficient in the inspection of the leak detectors.

Lastly, ASN notes an improvement over the last two years in the performance of the contamination checks at the end of therapeutic procedures when carried out outside the nuclear medicine departments; the checks are performed satisfactorily by 90% of the services inspected (96% in 2022).

### 2.3.3.4 Significant events reported in nuclear medicine

Out of the 79 departments inspected, 73% have a system for recording adverse events. These latter departments analysed the events and reported them to ASN when necessary. However, 20% of the inspected departments had not reported their ESRs to ASN, primarily due to the personnel's lack of awareness of events reporting (ESRs not recorded or not reported).

After dropping for the last two years in succession, the number of ESRs reported in 2022 totalled 191, a figure that has been gradually increasing over the last 10 years.

As in the preceding years, most of the reported events (>70%) concerned patients who had undergone a nuclear medicine procedure. The majority of the reported events have no expected clinical consequences, in view of the activities injected (see Graph 8).

#### Significant events concerning patients (140 ESRs, or >70% of the reported ESRs)

The large majority of ESRs concerning nuclear medicine patients occurred in the course of diagnostic procedures (> 90%). Most of these ESRs result from injection errors (wrong RPD, wrong activity injected) or identity monitoring errors (RPD administered to the wrong patient), and result from organisational and human malfunctions, usually in high workload situations. Although most of the departments have put in place events recording systems in application of ASN resolution 2019-DC-0660, the experience feedback procedures need to be improved in the large majority of the departments, particularly to further the analyses and to assess the robustness of the corrective actions.

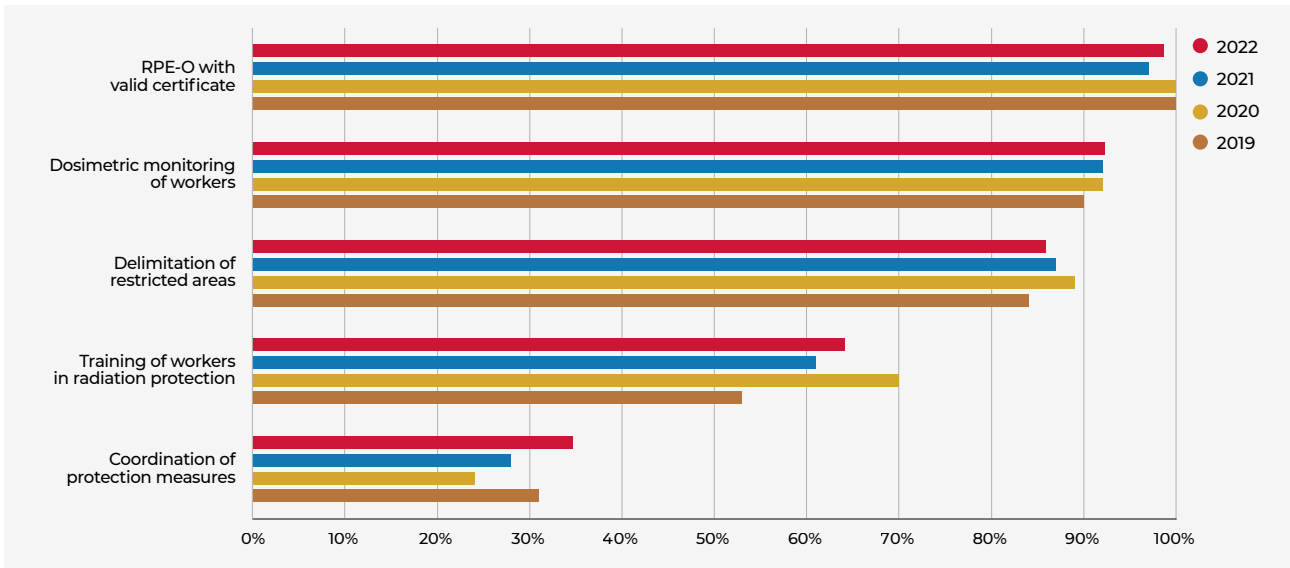
In 2022, 11 ESRs that occurred during therapeutic procedures were reported, five linked to complications associated with the use of yttrium-90 microspheres, the others concerning errors in the handling or injection of RPD (lutetium-177 and iodine-131).

#### Significant events concerning medical professionals (10 ESRs, i.e. 5% of the reported ESRs)

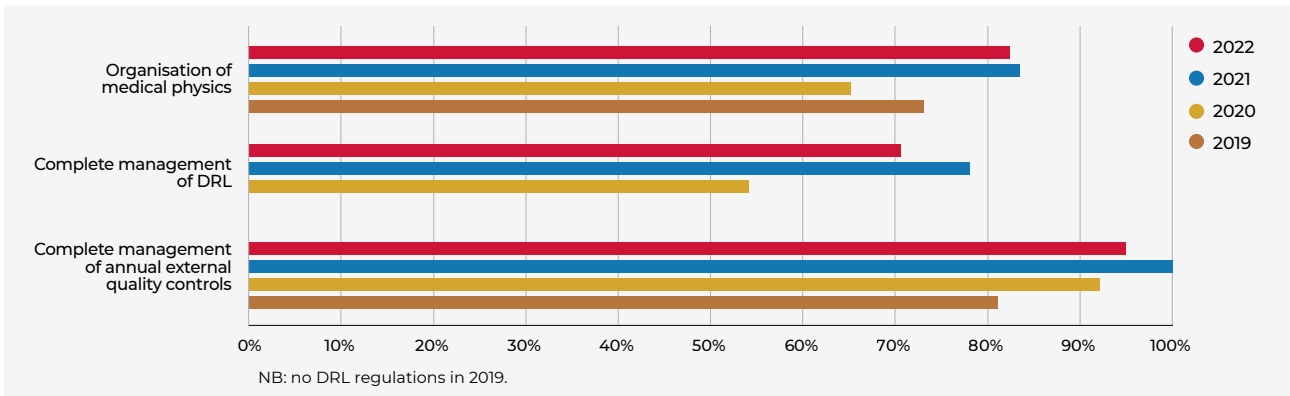
Ten events concerning nuclear medicine professionals were reported in 2022. They result from contaminations that led to internal exposures due to the malfunctioning of an extraction hood, and external exposures (surface contaminations as a result of handling errors or reception of a broken vial). One event concerned the irradiation of a radiographer when X-ray emission was triggered accidentally at the same time as the contrast agent was injected.

6. Order of 23 May 2019 approving ASN resolution 2019-DC-0667 of 18 April 2019 concerning the methods for evaluating ionising radiation doses delivered to patients during a radiology procedure, fluoroscopy-guided interventional or nuclear medicine practices, and the updating of the corresponding diagnostic reference levels.

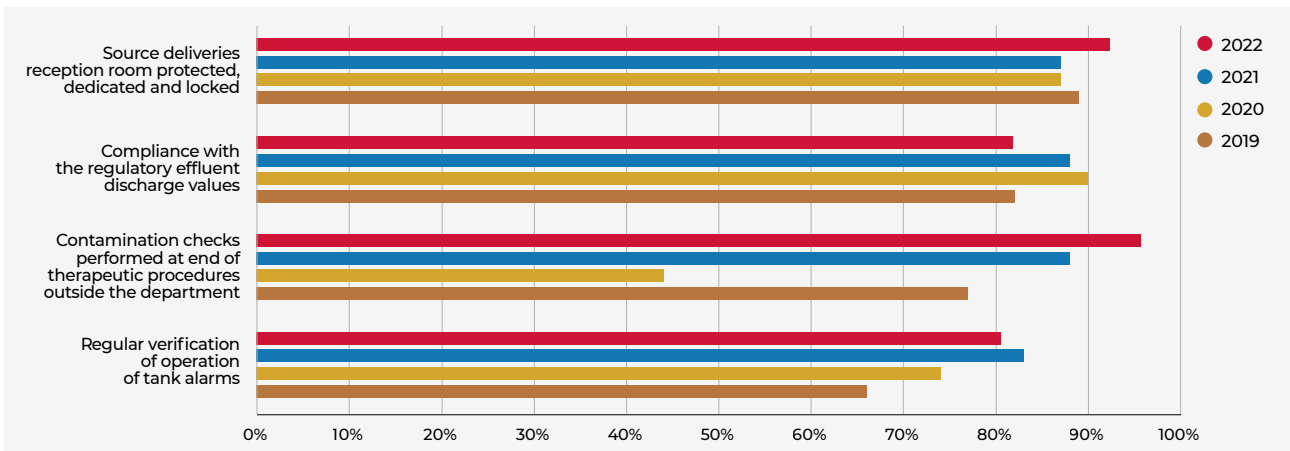
GRAPH 5 Development of nuclear medicine department compliance with occupational radiation protection regulations between 2019 and 2022



GRAPH 6 Development of nuclear medicine department compliance with patient radiation protection regulations between 2019 and 2022

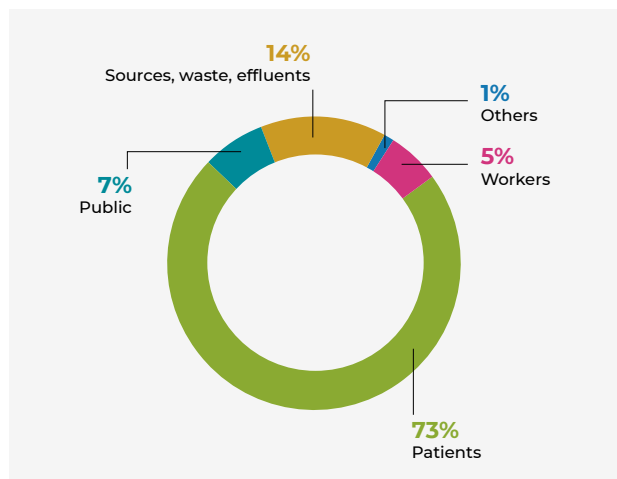


GRAPH 7 Development of nuclear medicine department compliance with protection of the public and the environment between 2019 and 2022





GRAPH 8 Breakdown of ESRs in nuclear medicine in 2022



#### Significant events concerning the public (15 ESRs, i.e. <10% of the reported ESRs)

All the events concerning the public except one result from exposure of the foetus in women unaware of their pregnancy. The doses received had no consequences for the child to be born (source: ICRP, 2007). A *Patient safety* newsletter published in 2021 was devoted to this type of event (see point 2.7). The last ESR involving the public concerned the exposure of people who entered a building contaminated by former nuclear medicine activities (malicious act).

#### Significant events concerning radioactive sources, waste and effluents (26 ESRs, i.e. 14% of the reported ESRs)

These ESR are mostly related to source losses/discoveries, the dispersion of radionuclides (resulting from overflows of radioactive effluent tanks), deliveries that do not comply with the licenses and unauthorised discharges of effluents into the environment (emptying of tanks, etc.).

### SUMMARY

In nuclear medicine, the inspections in 2022, considered alongside those performed over the period 2018-2021, enabling all the departments to be covered, reveal that radiation protection is correctly taken into account in the vast majority of the departments, with improvements observed for those departments inspected in the past two years, in particular for radiation protection of patients. Improvements are nevertheless required in three recurrent areas: in effluent management in order to control discharges into the sewage networks, in formalising the coordination of prevention measures with outside contractors (for maintenance, upkeep of the premises, the intervention of private practitioners, etc.) and the training of professionals. Similarly, the organisation of medical physics was considered inadequate in 20% of the departments inspected in 2022, particularly with regard to the radiation protection risks associated with the therapeutic treatments, and constitutes an area for progress in a context where new RPD-based therapies are being deployed. The engagement of the nuclear medicine departments in the deployment of quality management systems is continuing and ASN notes progress in formalising the specific work tasks qualification for medical staff. Even if the adverse events reporting culture is present in most of the departments inspected in 2022, it must be further developed. The reported events again reveal that the drug administration process must be regularly evaluated in order to control it, particularly for therapeutic procedures, due to the potentially serious consequences of a drug administration error.

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## 2.4 Fluoroscopy-guided interventional practices

Fluoroscopy-Guided Interventional Practices (FGIPs) group all the imaging techniques using ionising radiation to perform invasive medical or surgical procedures for diagnostic, preventive and/or therapeutic purposes, and surgical and medical procedures using ionising radiation for the purpose of guidance or verification.

These practices are constantly evolving, with continuing diversification of their indications. They can be carried out in imaging departments dedicated to interventional imaging or in the operating theatre. 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. The surgeons and physicians from different disciplines who work in these departments do not always master the use of ionising radiation with increasingly sophisticated medical devices.

FGIPs, especially when conducted in operating theatres, are part of ASN's national inspection priorities, due firstly to a weaker radiation protection culture, and secondly to the exposure levels involved, as much for the patients as for the practitioners who can be required to work close to the radiation beams.

### 2.4.1 Description of the techniques

#### The health care centres

According to the codes of the common classification of medical procedures and the activity data reported by the health care 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 a defibrillator, angioplasty, etc.), interventional neurology (embolization of arteriovenous malformation), vascular radiology (embolization of the coeliac artery), or uterine embolization. Graph 9 shows the breakdown of the number of centres by FGIP category for the centres having declared the FGIPs<sup>(7)</sup> 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

7. 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)".

operating theatres in several surgical specialities such as vascular surgery, gastroenterology, orthopaedics and urology.

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 high-resolution spatial images. Practitioners can also use the subtraction method to obtain images, after injecting a contrast agent.

The centres practising FGIPs are equipped with evermore 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. If used without specific dose-reduction technology and without mastering the principles of radiation protection, these devices can expose the patient and the medical staff – who most often work in the immediate vicinity of the patient – to higher dose levels than during other interventional practices. In these conditions, given the exposure risks for both the operator and the patient, practices must be optimised to reduce doses and ensure the radiation protection of operators and patients alike.

#### 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 in particular. 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.

#### 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 is low compared with the number of procedures performed. In the course of its inspections, ASN finds that the medical professionals lack knowledge of the criteria for reporting significant events, even though the doses administered in some centres are high (for diagnostic activities) and sometimes exceed the dose 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. Concerning patients, particular attention is paid to the optimisation of doses delivered to the patient (putting in place DRL and dose analysis), personnel training in patient radiation protection and the use of the medical devices. Application of resolution 2019-DC-0660 of 15 January 2019 setting the quality assurance requirements for medical imaging procedures that use ionising radiation helps the centres to manage the risk associated with 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 5 years.

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), the radiation protection culture of the teams and the situational factors (ESRs, vulnerabilities identified in previously inspected centres). Some 150 to 200 inspections are carried out each year.

In 2022, the operating theatre complexes of the university hospital centres and the largest hospital centres, and the departments licensed by the ARS (licensed for treatments in cardiac rhythmology, interventional cardiology and neuroradiology) were prioritised. One hundred and thirty-four centres were thus inspected, representing a total of 209 departments performing FGIPs. 60% of the inspections in 2022 were carried out in operating theatre departments. Since 2018, ASN prioritises its inspections in the operating theatres where the radiation protection culture is the poorest.

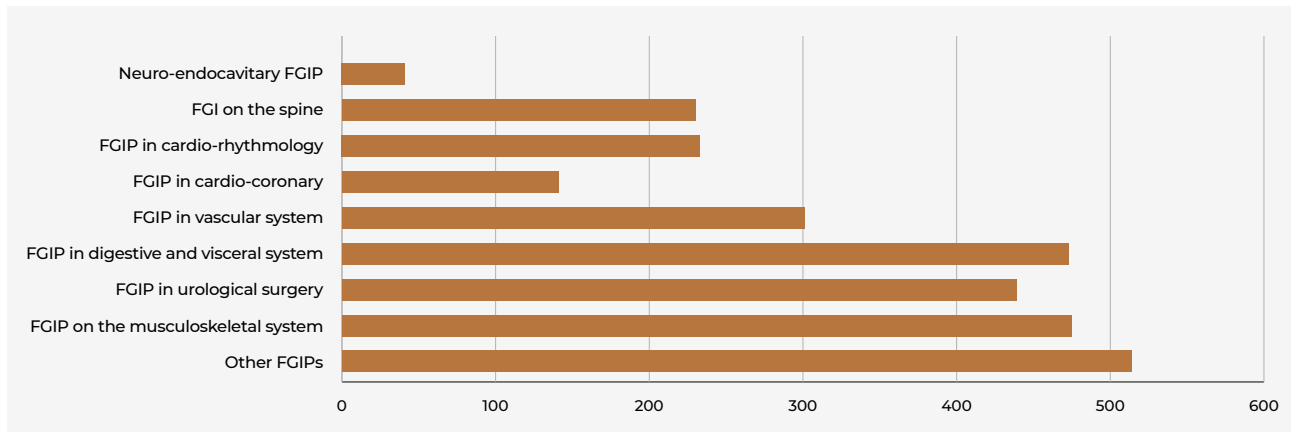
#### Characteristics of the inspected departments

The 209 departments having undergone an inspection in 2022 can be broken down as follows:

- the 83 interventional imaging departments inspected comprise 25 coronary angiography departments, 29 cardiac rhythmology departments, 23 interventional vascular and osteoarticular radiology departments and 6 neuroradiology departments. 56 had at least one fixed C-arm, 14 had mobile C-arms and 4 had fixed CT scanners;
- of the 126 operating theatre departments inspected in 2022, 109 had at least one mobile C-arm, 8 had fixed arms and 2 had a mobile CT scanner.

In 2022, 56% of the interventional radiology departments and 39% of the operating theatres have rooms conforming to the requirements of 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 four years. The centres must cope with financial difficulties, and bringing the operating theatre rooms into conformity still comes up against technical difficulties in meeting the requirements for lighted signalling of restricted areas.

GRAPH 9 Breakdown of the number of centres by category of fluoroscopy-guided interventional practices in 2022



2.4.3.1 Radiation protection of medical professionals

**In interventional imaging departments and in operating theatres**

The radiation protection of the professionals is deemed satisfactory as regards the appointment of an RPE-O (92% of the inspected departments) and the implementation of radiological zoning in the facilities (86% of the inspected departments). These findings have been stable for the last four years. The majority of the shortcomings observed in 2022 are due to noncompliance with the Order of 18 December 2019 amended concerning the RPE-O training procedures which enabled RPE-Os holding a valid certificate issued between 1 July 2016 and 31 December 2019 to assert their right to a temporary certificate under Article 23 of the 2019 Order. The application had to be made before 1 January 2022 in order to keep the certificate issued pursuant to the Order of 6 December 2013.

The lack of training of medical professionals in occupational radiation protection has been a recurrent finding in inspections over the last four years. The situation in 2022 is even less satisfactory, as much in the operating theatres as in the interventional imaging departments and for the medical personnel in particular. In effect, for the operating theatre, only 10% of the departments have trained all their medical personal and 24% have trained all their paramedical personnel; for interventional imaging departments these figures are 20% and 25% respectively. The departments inspected in 2022 reveal poorer compliance with the requirements concerning occupational radiation protection training compared with previous years. The deterioration in this situation is undoubtedly partly due to the difficulty in catching up the training backlogs stemming from the Covid-19 pandemic, and the workload of the RPE-Os who do not always have sufficient resources to fully accomplish their duties. Yet this training is essential to get a full grasp of the radiation protection risks and identify the risk situations, in order to be capable of implementing prevention measures to ensure personnel safety, such as positioning the equipment such that exposure levels are limited, putting in place or wearing collective and personal protective equipment respectively, wearing of dosimetry devices, etc.

Coordinating prevention measures with outside contractors, including private practitioners, is also an areas for progress in interventional imaging departments and operating theatres alike. The percentage of inspected departments having formalised prevention measures with all their service providers through a prevention plan varies between 17 and 28% for the 2018-2022 period. In 2022, only 17% of the inspected centres had formalised these measures, compared with 28% in 2021. 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 one's own radiation protection and that of other professionals.

In 67% of the inspected departments, the operating theatre staff have dosimetric monitoring devices available in sufficient quantity and appropriate for their type of exposure risk. This figure has remained relatively stable over the last four years with an average of 70%. ASN notes that the situation in the interventional imaging departments is worse in 2022 than in 2021, with only 69% of the departments providing appropriate dosimetric monitoring devices in sufficient numbers, particularly for the extremities and the lens of the eye, compared with 80% in 2021. Moreover, the effective wearing of passive and active dosimeters remains an area for improvement in many centres, as it has been for several years now.

ASN does however observe that the analysis of dosimetric results by the RPE-Os in order to identify and correct bad practices has been improving over the last four years; the percentage of departments analysing dosimetric results for the operating theatres has increased from de 58% in 2018 to 73% in 2022.

**Radiation protection technical verifications**

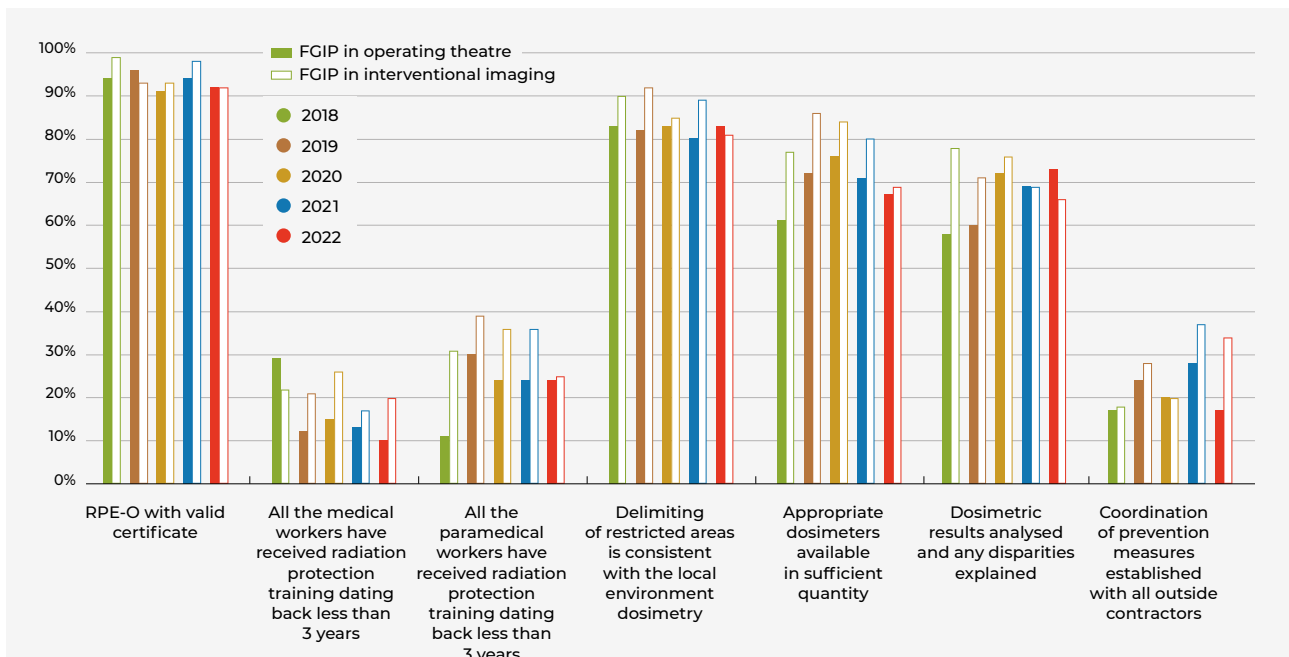
ASN notes that radiation protection technical verifications were carried out at the required frequency in 81% of the interventional imaging departments and 61% of the operating theatres in 2022. When nonconformities had been identified, they had been corrected or were in the course of being corrected on the date of inspection in 81% of the cases. These findings have been stable for the last four years.

2.4.3.2 Radiation protection of patients

The inspection findings concerning the radiation protection of patients over the last four years do not reveal any distinct trends.

Of the departments performing FGIPs inspected in 2022, 66% 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; the figure for 2021 was 68%. This figure has remained relatively stable over the 2018-2022 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.

GRAPH 10 Development of the compliance of FGIP facilities inspected on the theme of medical staff radiation protection in 2022 (operating theatres and interventional departments)



**In interventional imaging departments and in operating theatres**

The training of physicians in patient radiation protection is a recurrent weak point, with about 15% of the operating theatres having trained all the physicians. Although the medical personnel are better trained in the interventional radiology departments, ASN observes a deterioration in the situation since 2018. 24% of the departments inspected in 2022 have trained all the physicians compared with 37% in 2018.

In the course of the last four years, 30% of the interventional departments on average have recorded, analysed and optimised the doses, whereas only 14% of the operating theatres have done so. The corresponding figures for 2022 are 24% for the interventional imaging departments and 15% for the operating theatres respectively. ASN makes the same finding of weakness in applying the procedures optimisation principle as concerns setting the machine parameters and optimising the protocols used. The staff training time is insufficient and the shortage of paramedical personnel, partly as a result of the Covid-19 crisis, does not facilitate the following of training courses; the time dedicated to training often comes on top of the effective working time. 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. The patient dose archiving and analysis systems currently being deployed facilitate the development of local reference levels and alert levels per machine and per 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 to the patient.

For the first time, patient monitoring in the event of exceeding the skin exposure threshold defined by the HAS<sup>(8)</sup> is formalised to a greater extent in the operating theatres (90%) inspected in 2022 than in the interventional imaging departments (70%) which

are more frequently concerned by procedures leading to such exposure levels.

The External (third-party) Quality Controls (EQC) of the medical devices are generally carried out at the right frequency and on the day of the inspection any previously detected nonconformities had been or were being corrected, equally well in the operating theatres as in the interventional imaging departments.

**2.4.3.3 Significant events reported in relation with fluoroscopy-guided interventional practices**

An events recording system is in place in more than 74% of the inspected sites performing FGIPs. In 2022, 25 significant events were reported in this area:

- 15 events concerned overexposure of patients, some having led to tissue effects (one case of radiodermatitis);
- 8 concerned exposure of medical professionals;
- 2 concerned pregnant women exposed during a fluoroscopy-guided interventional examination; these women were unaware of their pregnancy at the time of exposure.

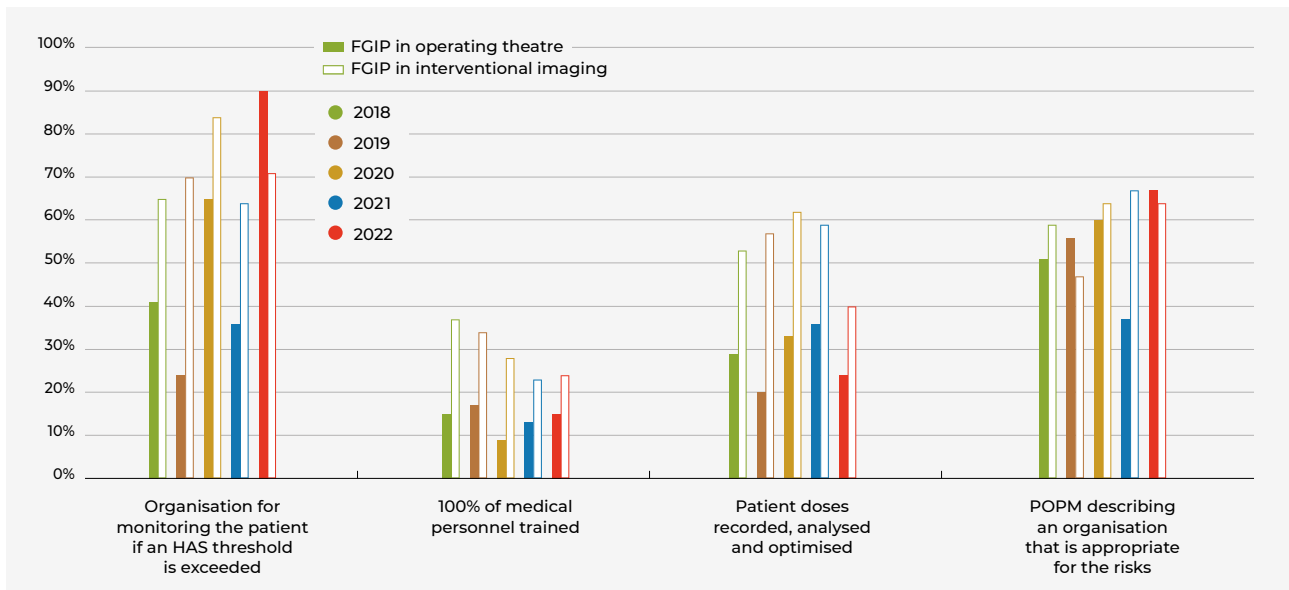
Among these ESRs, four were linked to a medical device malfunction (malfunction of pedals or machine) and were reported as part of medical devices vigilance. Some of these events are linked to noncompliance with the obligatory quality controls of medical devices.

The majority of patient exposures are due to long and complex procedures (in interventional neuroradiology and in cardiology) and for some patients to overexposures resulting from successive procedures with a very high accumulation of doses.

Analysis of the events reveals a lack of protocol optimisation, inappropriate utilisation of the devices by the operators, the use of inappropriate protocols or the absence of protocols revealing deficiencies in operator training and the importance of implementing a specific work task qualification procedure. These weak spots constitute areas for improvement.

8. Improving patient monitoring in interventional radiology and fluoroscopy-guided procedures – reducing the risk of deterministic effects of 21 May 2014.

GRAPH 11 Development of the compliance of FGIP facilities inspected on the theme of patient radiation protection in 2022 (operating theatres and interventional departments)



The ESRs concerning the professionals, all of which occurred in the operating theatre, result from accidental exposures without exceeding regulatory dose limits. The events analysis also reveals a lack of training of various employees required to work in operating theatres (hospital service employees, nursing auxiliaries, State-registered nurse anaesthetists, State-registered nurses).

Lastly, events were reported 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* newsletter published in 2021 addressed the lessons learned specifically from this type of event (see point 2.7).

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**SUMMARY**

In the area of FGIPs, the inspections of 2022, considered alongside those performed over the period 2018-2021, allowing coverage of all the facilities considered to have radiation exposure risks, highlight the fact that radiation protection makes little progress from one year to the next, that the situation is always better in the interventional procedure rooms than in the operating theatres, and there are persistent weaknesses. Thus, 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 medical devices 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. Although the use of medical physicists and formalising of the POPMs is gaining ground, further progress must be made in implementation of the optimisation procedure, particularly in the operating theatres where doses are still insufficiently analysed and findings of inappropriate or non-existent protocols subsist. The reporting culture, however, has been spreading in the past five years, with the deployment of events recording systems. The reporting 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 computed tomography 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. A guide intended for general practitioners (*Guide to good medical imaging examination practices*) indicates the most appropriate examinations to request according to the clinical situations.



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), 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). Only planar imaging, which functions at low voltage and offers high definition and high contrast, is at present approved by the HAS for breast cancer screening. ASN participates in a working group coordinated by the HAS which is assessing 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 should be published in 2023.

The use of these devices is subject to quality controls defined by the ANSM. The planar imaging (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 EQCs for the tomosynthesis devices.

#### Computed tomography

Computed tomography (CT) scanners use a beam of X-rays emitted by a tube which moves in a spiral around the body of the patient (helical CT scanner). These scanners produce a three-dimensional reconstruction of the organs with very much better image quality than that of conventional radiology devices. The number of rows of detectors (multidetector-row CT scanner, also known as a multislice or volumetry CT scanner) has been increased in recent machines, enabling thinner slices to be produced. An examination can comprise several helical image acquisitions of a specific anatomical region (with or without injection of a contrasting agent) or of 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 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<sup>9</sup>. 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. ASN notes the emerging trend to equip ambulances with CT scanners in order to perform CT scans on stroke patients.

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). Technical progress has nevertheless brought a new mode of image reconstruction in the form of iterative reconstruction. Computed tomography can thus provide consistent image quality at reduced doses. The devices can also be equipped with dose-reduction tools.

#### Teleradiology

Teleradiology provides the possibility of performing and remotely interpreting radiological examinations. The interchanges must be carried out in strict application of the regulations (relating to radiation protection and the quality of image production and transfer in particular) and professional ethics. Essentially two interchange methods are used:

- Telediagnosis, which enables a doctor on the scene (*e.g.* an emergency doctor), who is not a radiologist, to perform the radiological examination and then send the results to a radiologist in order to obtain an interpretation of the images. If necessary the radiologist can guide the radiological operator during the examination and imaging process. In this case, the doctor on the scene is considered to be the doctor performing the procedure and assumes responsibility for it.
- Tele-expertise, which is an exchange of opinions between two radiologists, where one asks the other – the “expert radiologist” (teleradiologist) – for a remote confirmation or contradiction of a diagnosis, to determine a therapeutic orientation or to guide a remote examination. The data transmissions are protected and preserve medical secrecy and image quality.

Teleradiology involves multiple responsibilities, which must be specified in the agreement binding the doctor performing the procedure to the teleradiologist. The teleradiology procedure is a medical procedure in its own right, like all other imaging procedures, and cannot be reduced to a simple remote interpretation of images. Teleradiology therefore fits into the general healthcare organisation governed by the Public Health Code and obeys the rules of professional ethics in effect.

The Teleradiology Charter published by the French professional council of radiology (G4) was re-updated in 2020. It details the organisation of the two parts of teleradiology (telediagnosis and tele-expertise). In addition, a guide to good practices concerning the quality and safety of teleimaging procedures was published in May 2019 by the HAS. In this guide the HAS makes important clarifications concerning the proper use of “medical imaging examinations with remote interpretation”. It has the particularity of also addressing nuclear telemedicine, deployed with the aim of providing uniform coverage across the country. This guide does not consider mammography, which cannot be done by

9. 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.

teleradiology because it necessitates clinical examination of the patient, including palpation.

### 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

Cone-beam computed tomography (3D) 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). 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.

### 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 computed tomography 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 person or entity responsible for the nuclear activity.

#### Portable electrical devices generating X-rays

ASN and the Dental Radiation Protection Commission (CRD) 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 Heads of the European Radiological protection Competent Authorities – 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).

### 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 and 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 the population concerned.

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 ASN resolution 2019-DC-0660 of 15 January 2019 relative to quality assurance in medical imaging, especially the justification of the examinations and optimisation of the procedures. The majority of the inspected departments moreover have recourse to teleradiology to ensure Out-Of-Hours (OOH) service. The activity carried out in this context also enters into the checks performed in inspections. In 2022, ASN carried out 19 inspections in the area of computed tomography.

Despite gradual implementation of the requirements of ASN resolution 2019-DC-660 of 15 January 2019, improvements are expected in applying quality assurance methods to the justification principle for patients at risk (vulnerable patients, children, pregnant women, etc.) in order to improve the traceability of examination referral verifications at the various stages (reception, preliminary analysis, validation, alternative non-irradiating procedure, non-performance of procedure) and in formalising the specific work task qualification for medical staff.

Alongside this, the ASN inspectors observe that departments are turning increasingly to teleradiology, sometimes leading to organisational difficulties (communication between software applications, delegation of tasks).

Furthermore, 27 of the 219 ESRs in computed tomography reported to ASN (> 10%) occurred in teleradiology situations and were linked to communication problems between the medical professionals on-site and those working remotely. An analysis of events of this type will be conducted in 2023.

### 2.5.4 Significant events reported in medical and dental radiodiagnosis

In 2022, 288 ESRs were reported in medical and dental radiodiagnosis:

- 66 in conventional radiology, of which 25 concerned women unaware of their pregnancy;
- 219 in computed tomography, of which 94 concerned women unaware of their pregnancy;
- 3 in dental radiology (of which 1 concerned a woman unaware of her pregnancy).

The ESRs primarily concern women unaware of their pregnancy (120), failings in the patient management process (identity monitoring error, protocol errors, etc.) and situations of inappropriate exposure of professionals (20). The steps taken by medical staff to check for possible pregnancy in patients must be further increased. A specific *Patient safety* newsletter was published in September 2021 to improve the organisational measures to reduce the number of events of this type (see point 2.7).

#### SUMMARY

ASN oversight in computed tomography mainly concerns checking implementation of the requirements of ASN resolution 2019-DC-660 of 15 January 2019 more specifically regarding formalising of the justification principle in order to avoid delivering unnecessary doses to patients, along with the specific work tasks qualification for medical staff. During its inspections in 2022, ASN again observed contrasting deployment of the quality assurance system concerning the traceability of examination justification in the centres, with practices that are satisfactory in some units and far less so in others. Progress is also required in formalising the specific work tasks qualification for medical staff.

## 2.6 Blood product irradiators

### 2.6.1 Description

The irradiation of blood products is used 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, source irradiators have been gradually replaced by X-ray generators, which have been subject to notification to ASN since 2015. In 2019, the inventory stood at 29 irradiator 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.

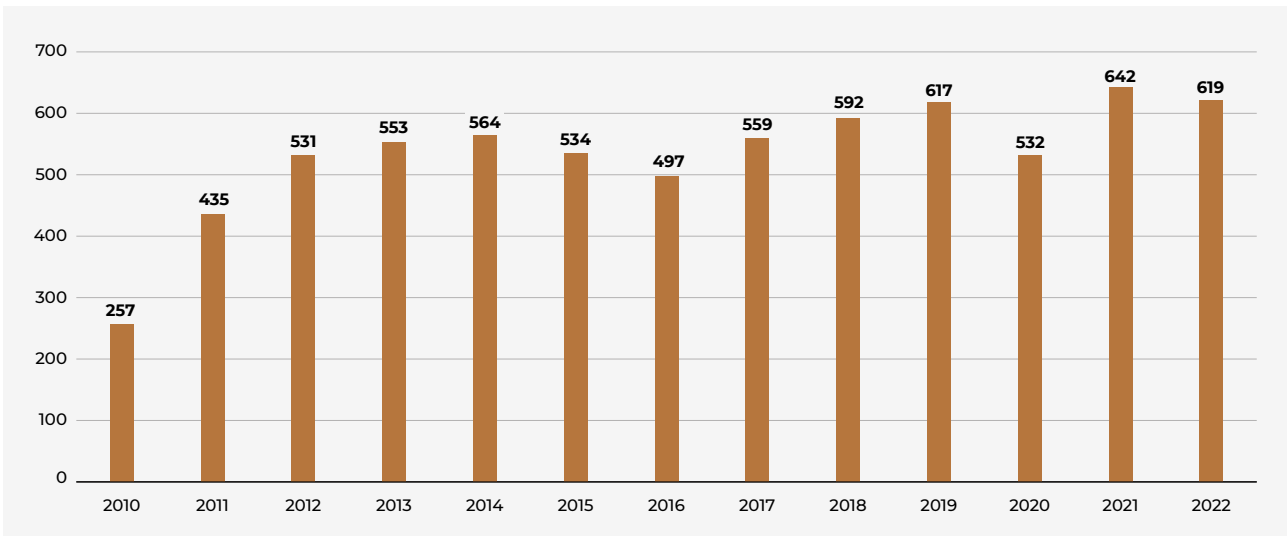
## 2.7 Significant radiation protection events

The number of ESRs in the medical field reported to ASN in 2022 (619) is similar the numbers for the last five years, with the exception of 2020, when fewer events were reported to ASN, probably on account of the Covid-19 pandemic. ASN underlines the importance of reporting ESRs in order to share ILS's and improve radiation protection.

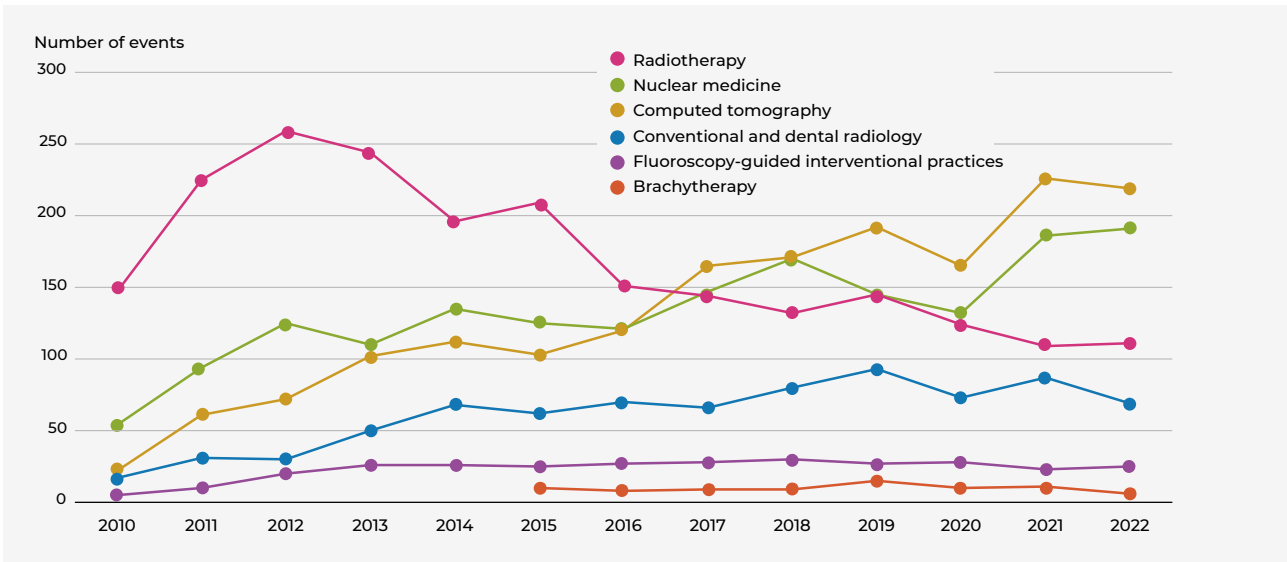
Graphs 12 and 13 illustrate how the number of ESRs has evolved by activity category since 2011. Graphs 14 and 15 illustrate the breakdown of the number of ESRs in 2022 by area of exposure (environmental impact, exposure of the general public, exposure of patients, exposure of professionals) and by category of activity.

In the light of the events reported to ASN in 2022, the most significant findings from the patient radiation protection aspect occurred in radiotherapy (see point 2.1.3.3) and brachytherapy (see point 2.2.3.5) and reveal that lessons learned from past ESRs have been forgotten.

GRAPH 12 Evolution of the number of annual ESR reports from 2010 to 2022

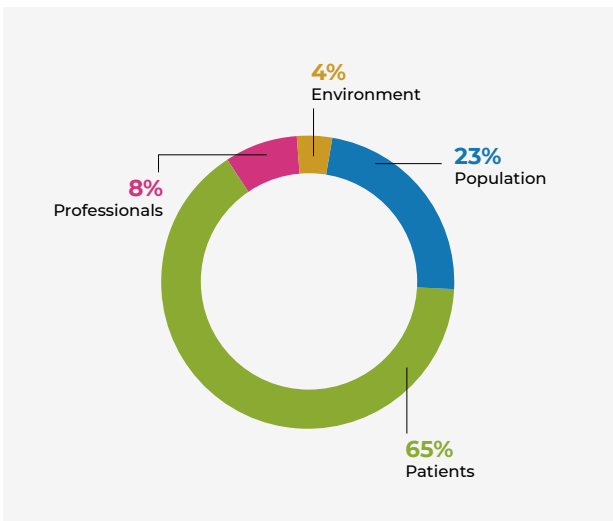


GRAPH 13 Number of ESRs by activity category during the 2010-2022 period

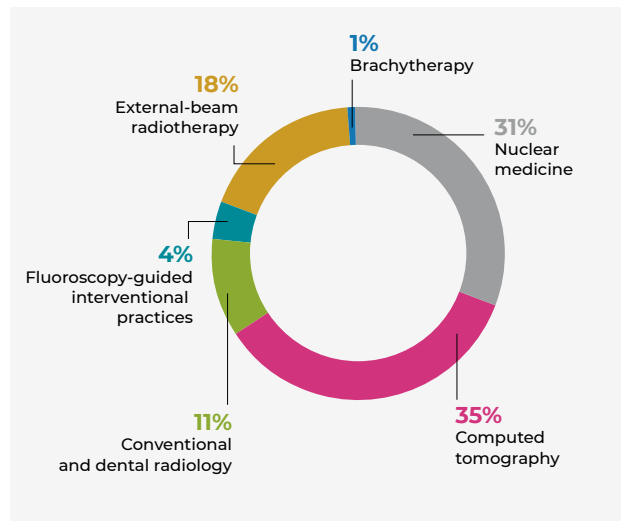


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GRAPH 14 Breakdown of ESRs by exposure category in 2022



GRAPH 15 Breakdown of ESRs by activity category concerned in 2022



### 3. Synthesis and prospects

On the basis of the inspections carried out in 2022 and an analysis of the period 2018-2022 enabling the entire base of facilities to be covered, ASN considers that the state of radiation protection in the medical sector is being maintained at a good level, relatively comparable from one year to the next, although with a number of persistent shortcomings.

In nuclear medicine and for FGIPs, deviations persist as the years go by in terms of radiation protection training of the professionals and the coordination of prevention measures during concomitant activities, notably during interventions by private practitioners. In radiotherapy, the evaluation of the effectiveness of the corrective measures taken is still the weak point of the ILS approaches and the preliminary risk assessments are still insufficiently updated prior to an organisational or technical change, or after the analysis of events that have occurred in the profession. In the area of FGIPs, and more particularly in the operating theatre, work to bring the premises into conformity with the technical design rules and steps to optimise the doses received by workers and patients alike are progressing too slowly, and raising the awareness of non-specialists in ionising radiation, such as surgeons, remains necessary to ensure a clearer perception of the risks and enhance the assimilation of radiation protection measures. Although the quality assurance fundamentals are today well-established in the radiotherapy departments, they are still being deployed too slowly in the other sectors, in particular concerning the requirements for internal reporting of events and formalisation of the procedures for qualifying professionals for the particular positions.

The events reported to ASN underline that the training of professionals, the management of maintenance work and the implementation of technical barriers controlling the use of medical devices, which constitute the fundamental basis of safety, need to be improved in order to make practices safer. ASN also

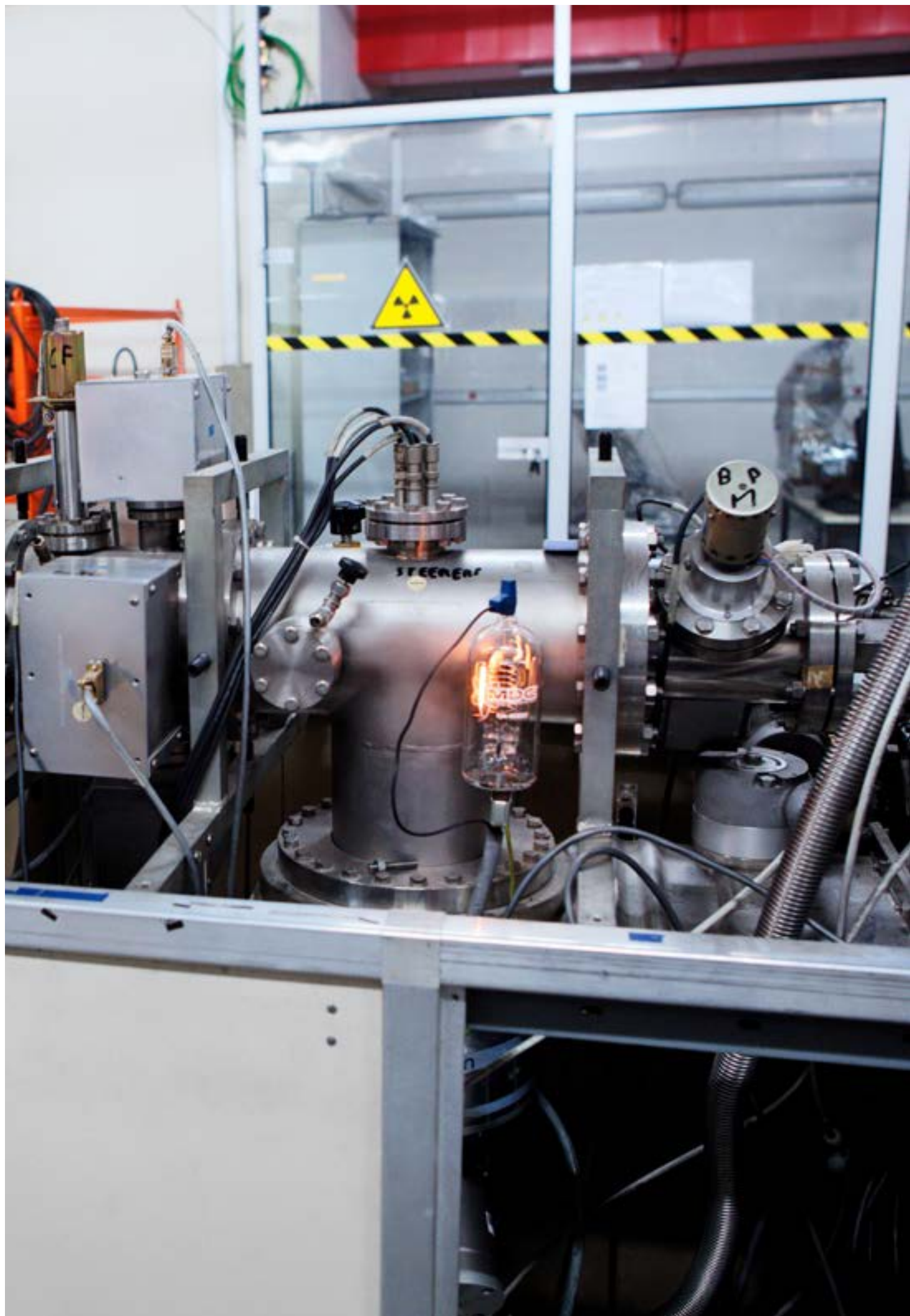
observes that the lessons learned from past event reports are forgotten.

In 2023, ASN will continue its inspections in the radiotherapy, nuclear medicine, FGIP and computer tomography sectors, following on from the checks carried out in 2022, paying particular attention to the weak points identified in 2022, as well as to the implementation of the quality assurance obligations.

From the regulatory viewpoint, ASN will in 2023 continue revising resolution 2008-DC-0095 of 29 January 2008 setting out the technical rules for the elimination of effluents and waste contaminated by radionuclides. ASN will also continue to contribute to the regulatory work conducted by the Ministry responsible for health concerning the organisation of medical physics and the deployment of clinical audits, which could be a pertinent means of ensuring progress with regard to the justification of procedures.

Finally, ASN will maintain its commitment to subjects linked to the spread of new techniques and practices, jointly with the various institutional players in the health sector and the learned societies, while calling on its expert groups, in particular the Canpri, in order to promote and facilitate safe working frameworks and improve the evaluation of long-term radiation induced effects for therapeutic procedures. As part of the 2nd National imaging dose management plan (2018-2022), ASN will aim to encourage all actions to promote implementation of the justification principle, access to the least irradiating imaging techniques and the automated collection and analysis of doses for the purpose of optimising and monitoring exposure from medical imaging in the French population.





# Sources of ionising radiation and their industrial, veterinary and research applications

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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 ensure that workers, the public and the environment are properly protected. 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 ongoing 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”.

In 2022, to complete the comprehensive overhaul of the system regulating these nuclear activities, ASN (the French Nuclear Safety Authority) started work revising resolutions setting the content of the licence application to be submitted by the licensees.

## 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:

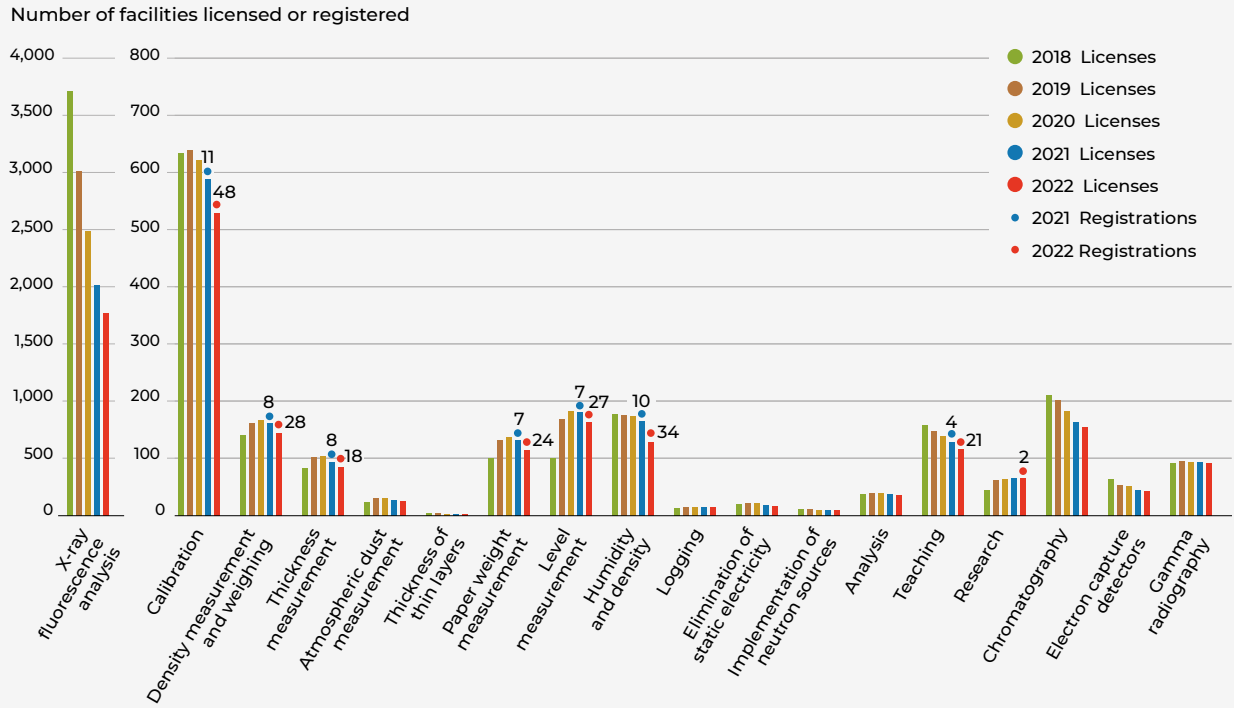
- Atmospheric dust measurement: the air is permanently filtered through a tape placed between the source and detector and running at a controlled speed. The intensity of radiation received by the detector depends on the amount of dust on the filter, which enables this amount to be determined. The most 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 plants.

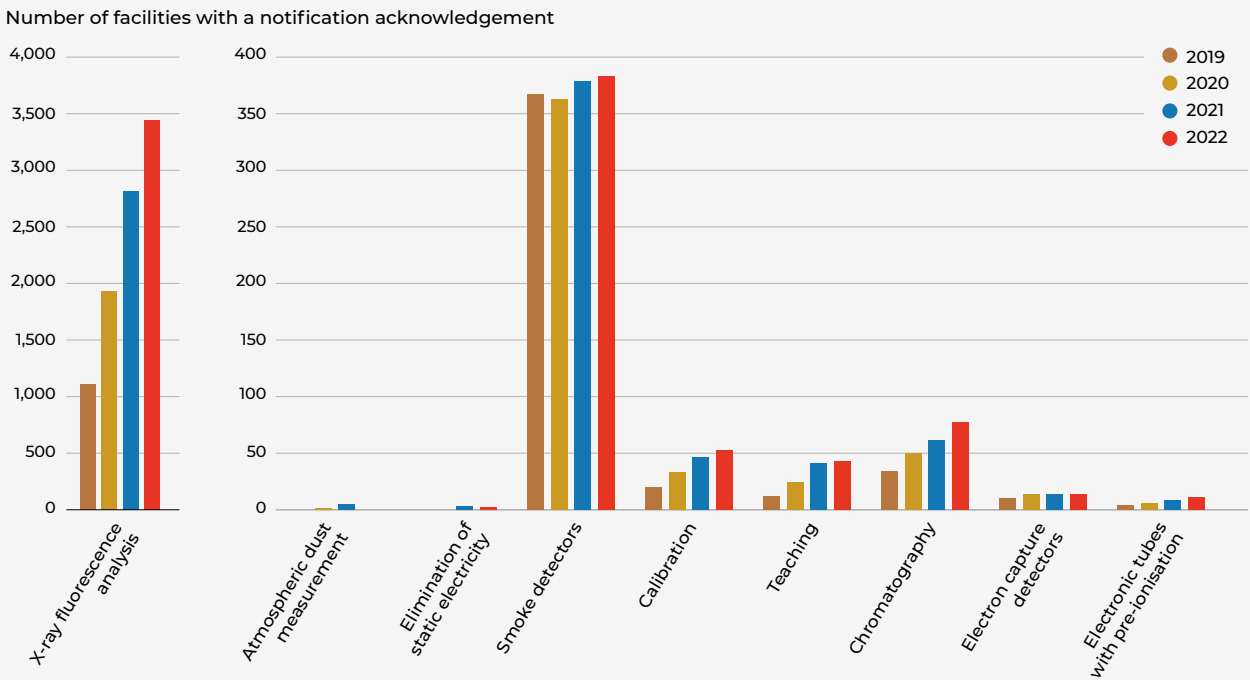
- Paper weight measurement: a beam of beta radiation passes through the paper and hits a detector situated opposite. The signal attenuation on this detector indicates the density of the paper, and therefore its weight per unit area. The sources used are generally krypton-85 or promethium-147, with activities 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. 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.

USE OF SEALED RADIOACTIVE SOURCES BY END-PURPOSE

GRAPH 1A Breakdown of licenses or registrations for sealed radioactive sources



GRAPH 1B Breakdown of sealed radioactive source notifications



- 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. 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:

- industrial irradiation, used for sterilisation in particular (see point 3.2.1);
- gamma radiography, which is a non-destructive inspection method (see point 3.3.1);
- 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, will extend through to 31 December 2023 (see point 2.4.2) and until 1 July 2026 (see point 2.4.3) for those subject to registration since 1 July 2021.

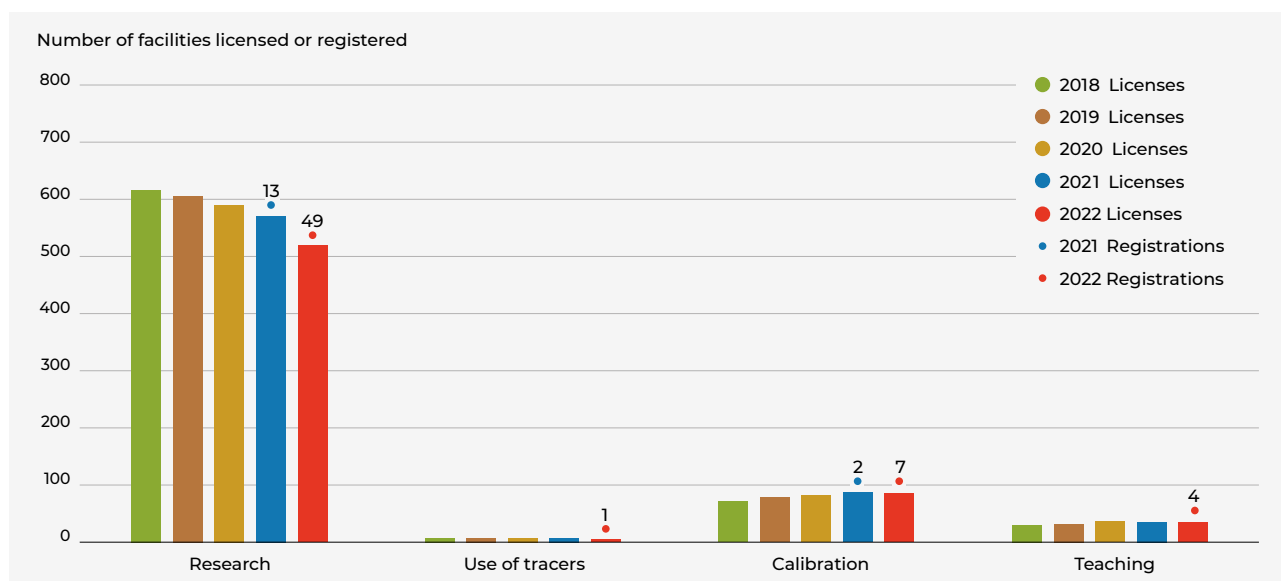
### 1.2 Uses of unsealed radioactive sources

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 2022, 643 facilities were authorised to use unsealed radioactive sources (to which can be added 61 registered 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.

GRAPH 2 Use of unsealed radioactive sources by end-purpose

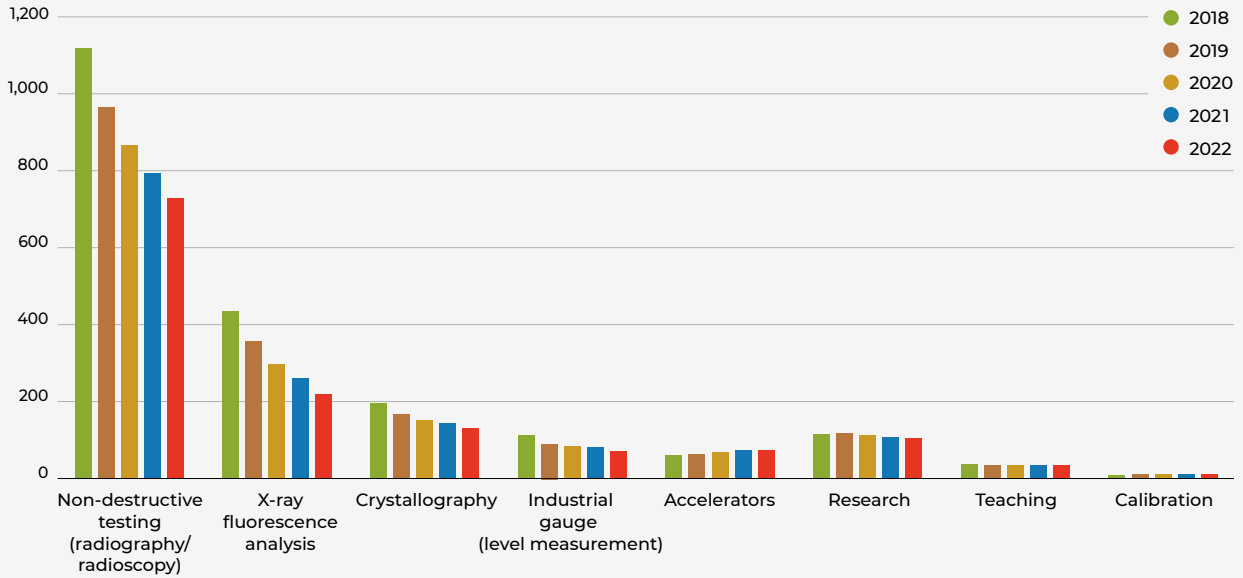




USE OF ELECTRICAL DEVICES GENERATING IONISING RADIATION BY END-PURPOSE  
(VETERINARY SECTOR EXCLUDED)

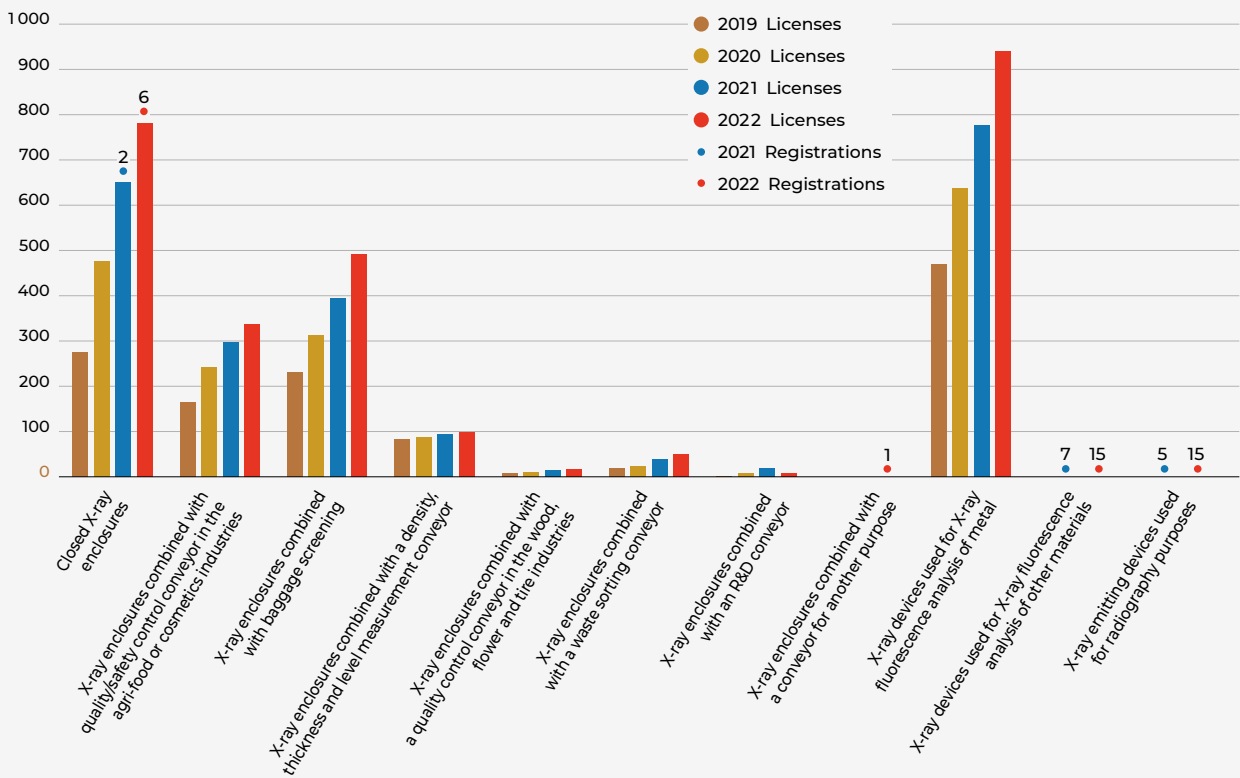
GRAPH 3A Breakdown of licenses for electrical devices emitting ionising radiation

Number of facilities licensed



GRAPH 3B Breakdown of notifications or registrations of electrical devices emitting ionising radiation

Number of facilities with a notification acknowledgement or registered



### 1.3 The uses of 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 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 2.4.3), 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).

These devices, which work using the principle of X-ray attenuation, are also used as industrial gauges (measurement of drum filling, thickness measurement, etc.), inspection of goods containers or luggage, as well as 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 currently not 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 2022, the profession counted 20,197 veterinary surgeons, some 13,300 non-veterinarian employees (counted in full-time equivalents) and 6,538 veterinary facilities. 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 one hundred 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.

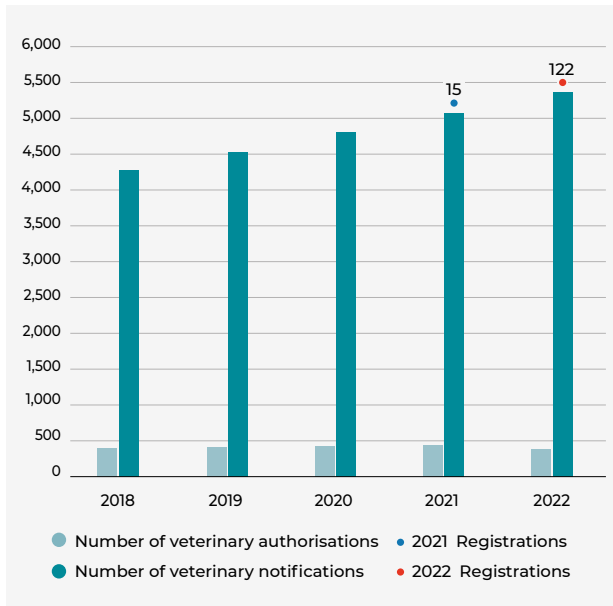
The treatment of large animals (mainly horses) requires the use of more powerful devices installed in specially equipped premises (radiography of the pelvis, for example) and portable X-ray generators, used indoors – whether in dedicated premises or not – or outdoors.

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 2.4.3), 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 will still be 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.

**GRAPH 4 Use of electrical devices generating ionising radiation for veterinary activities**



With regard to veterinary facilities, the administrative situation has been continuously improving for a number of years now. At the end of 2022, ASN counted 5,900 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:

- the presence of in-house Radiation Protection Expert-Officers (RPE-Os) in the most of the facilities;
- 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.

There are also some (rare) cases of veterinary facilities in which the radiation protection organisation is highly unsatisfactory. These shortcomings can oblige ASN to take more stringent or even enforcement measures, if a “soft” approach has no effect.

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 contacts with the profession’s national bodies (more particularly the veterinary radiation protection commission).

### 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. Regulation of 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 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.

Since the publication of Decree 2014-996 of 2 September 2014 amending the nomenclature of the ICPEs, some facilities previously licensed by Prefectoral Order under the Environment Code for the possession and use of sealed radioactive sources are now regulated by ASN, under the Public Health Code. The requirements applicable to these installations are now those of the Public Health Code. The provision of Article 4 of the above-mentioned Decree, which provided that the license or notification issued under the former section 1715 continued to be deemed a license or notification under the Public Health Code, on condition that no change was made to the nuclear activity, for a maximum period of five years, that is to say until 4 September 2019 at the latest, has now ended. These facilities must therefore have a license, a registration or a notification acknowledgement issued 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 (m<sup>3</sup>) 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 analyser is based on a different technology to that used in the Lafarge-Holcim group cement works, namely the use of an accelerator rather than a sealed radioactive source.

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 energy transition,

for solidarities and health, and for 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 Security (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 (ICSD) from approximately 300,000 sites over 10 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 2022, ASN had issued 383 acknowledgements of notification and 11 national licenses (issued to industrial groups with a total of 125 agencies) for ICSD removal activities. Among these companies, five are authorised to perform ICSD decommissioning operations, thereby guaranteeing a disposal route for all the existing detectors.



In order to keep track of the pool of ICSD, the French Institute for Radiation Protection and Nuclear Safety (IRSN) set up in 2105, 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 allow a conclusive assessment.

Although the removal operations have progressed over the last few years, not all the ICSD 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 ICSD are still installed. 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 ICSD 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 drive to remove the ionic detectors to continue, which remains the desired aim.

ASN maintains 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 the French National Agency for Radioactive Waste Management (Andra). The removal and disposal plan is being gradually implemented and should be 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.

### 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 has been estimated at 40,000. Slightly more than 11,000 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 devices, 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 replaces 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. In 2021 and 2022, ASN thus continued its 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 continued and revealed the need to strengthen their link with the existing European framework.

### 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 in the Nuclear Security Series 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 the application of 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 facilities where nuclear activities take place.

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 those responsible for nuclear activities 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 those 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.

Some 260 facilities in the civil sector in France hold around 5,500 radioactive sources presenting such security risks. These sources are used essentially for industrial purposes (irradiation, radiography, measurements, etc.) or medical purposes (such as teletherapy 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 (Article R. 1333-14 of the Public Health Code);
- the prompt notification to 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 documents that could facilitate malicious acts by separate, specially identified mail (R. 1333-130);
- the nominative and written authorisations to be delivered 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. It entered into force on 1 January 2020 for the sites not licensed on its date of publication (nor being examined on that same date).

For already licensed sites, entry into force takes place in two stages which were postponed due to the pandemic. The first was set for 1 January 2021 and concerned the organisational and human provisions; the second, set for 1 July 2022, chiefly concerns the systems providing physical protection against malicious acts. These two dates were therefore pushed back six months by the

Order of 24 June 2020, on which ASN issued an opinion (opinion 2020-AV-0353 of 11 June 2020).

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 on this topic;
- 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 nuclear activity licensees concerned.

ASN had also accompanied the publishing of the Order by actions in the regions at professional events or by holding *ad hoc* meetings with professionals concerned. This initiative had been suspended due to the Covid-19 pandemic. It was resumed during 2021 and by spring 2022 all the regions had been able to organise a presentation of this type.

To facilitate the application of this Order, a working group had started, at the same time as drafting the Order of 29 November 2019 amended, preparing a joint guide to be issued by ASN/SHFDS (Service of the Defence and Security High Official) of the MTE, for persons/entities responsible for nuclear activities and for the ASN and SHFDS inspectors. This guide should provide for a common understanding of the requirements of the Order by the professionals and inspectors alike.

It provides recommendations and numerous examples. Detailing certain elements of the appendices of the Order, it is subject to targeted and controlled distribution (dispatch in double envelope with acknowledgement of receipt).

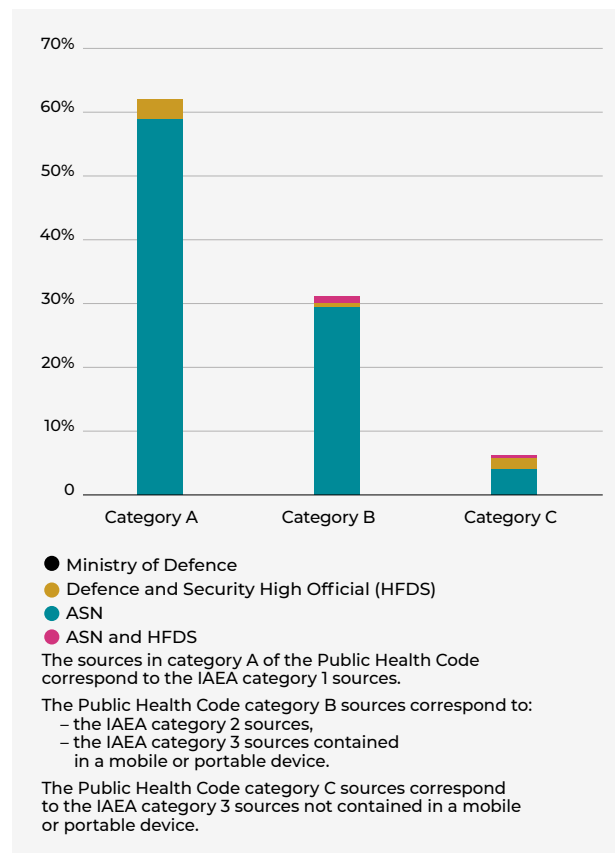
To supplement the information for professionals, a brochure intended for persons/entities responsible for nuclear activities who are in possession of category D sources only (for which the number of regulatory obligations is limited) has been prepared and made available in each of the ASN regional divisions. This brochure is also available on [asn.fr](http://asn.fr).

### 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 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.

GRAPH 5 Breakdown of high-activity sealed sources according to their category and their oversight authority for protection against malicious acts



## 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 person responsible for the nuclear activity, 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 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: this 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 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

### INTERNATIONAL WORKING 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 has, along with the National Nuclear Security Administration (United States), initiated an informal think tank involving several countries working on the subject of replacing 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. At the group meetings ASN has presented, for example, the operations conducted by the French blood transfusion agency to replace – in application of the principle of justification – its irradiators that use radioactive sources by electric irradiators emitting X-rays. ASN has also enabled the French Confederation for Non-Destructive Testing to present the progress of its work to replace gamma radiography by other non-destructive testing technologies.

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 think tank was underlined.

After a break in 2020 due to the Covid-19 pandemic, the annual meetings of the working group resumed in 2021 and 2022. The 2022 meeting organised as an on-line event brought together more than 200 participants. This meeting provided the opportunity to review the prospects of bypassing the use of radioactive sources in diagraphy (well logging) and to discuss applications (medical, industrial and research alike) for which the particle accelerators can be used effectively.

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.

## PRACTICAL ILLUSTRATION OF THE ENTRY INTO EFFECT OF PROVISIONS CONCERNING THE PHYSICAL PROTECTION OF RADIOACTIVE SOURCES: “OPENABLE ELEMENTS” GUIDE

With the entry into effect, on 1 July 2022, of the appendices of the Order of 29 November 2019 amended, in addition to the implementation of a few organisational measures complementary to those already in effect, the installation of physical systems contributing to protection of the site is required:

- the resistance of walls and openable elements (door or window leaves, locks, hinges);
- access control (identification and authentication) by badge with or without contact or by biometric recognition;
- detection (peripheral and perimetric) which can use various technologies (opening detectors, impact or seismic detectors, movement detectors using infrared, microwave or ultrasound waves);
- surveillance by fixed or mobile cameras;
- alarms (luminous and audio);
- transmission and processing of information to lift any uncertainty.

As far as the resistance of wall and openable elements is concerned, the Order appendices could not stipulate extremely precise requirements as the facilities were built at a time when the protection of sources against malicious acts was not a major concern. Furthermore, the Order sets objectives rather than imposing means.

The practical application of the requirements by persons/entities responsible for nuclear activities should therefore be acceptable to the inspector (ASN or MTE-SHFDS). Moreover, the chosen criteria had to have the same level of stringency in all the facilities.

IRSN, which has an office specialised in physical protection, was mandated by ASN in late 2021 and early 2022 to visit some facilities and establish a field report on the provisions already in place and what could be required, in practical terms for the openable elements (essentially doors and windows). This procedure was undertaken before the Order

appendices came into effect. Interviews with professionals, law enforcement authorities and the National Centre for Prevention and Protection (CNPP) allowed a better assessment of the minimum level of requirements that could be adopted.

Following this field report a guide was drafted. It attributes points according to the various elements characterising the openable element (leaf, hinge, lock), enabling the element to be assigned a score. This score determines whether the openable element can be deemed to meet the essential requirements of the appendices or not. A draft was tested during ASN inspections in spring before its final validation, jointly with the MTE-SHFDS and IRSN.

ASN has issued this guide to persons/entities responsible for nuclear activities in a controlled manner as it contains sensitive information, asking them to undertake a self-assessment which can be subsequently examined during an inspection.

list the documents that must be enclosed with the application. All the other documents listed in the appendix to ASN resolution 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.

To further the implementation of a graded approach in the oversight of the nuclear activities coming under the Public Health Code, ASN started revising the above-mentioned resolution in 2022 in order to adapt and simplify the content of applications. This will complete the work started in 2018 which has already led to revising of the notification system and creation of the registration system (see below).

### The notification system

As part of the overhaul of the classification of nuclear activities into the three administrative systems introduced by the above-mentioned 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, those responsible for a nuclear activity 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 approved on 21 November 2018, ASN has extended the list of activities subject to notification. The notification system extension should concern about 6,000 companies or individuals which were previously subject to the licensing system. However,

the exact number of cases will not be quantifiable until after five years (31 December 2023). This is because, in accordance with the principle of grandfathering, the licenses issued before 1 January 2019 act as notification acknowledgements until the license reaches term, on condition that in the interim there is no change in the nuclear activity. This means that a number of nuclear activities, though now subject to notification, are still regulated by a license.

### 2.4.3 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),



## 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.

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, as is the case with the notification system, the number will not be able to be accurately quantified until a 5-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.

(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, 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 above).

08

### 2.4.4 Statistics for the year 2022

#### 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 2022, 98 radioactive source supply license applications or license renewal applications were reviewed by ASN, and 37 inspections were carried out (all ionising radiation sources combined).

#### Users

##### The case of radioactive sources

In 2022, ASN examined and issued 9 new licences, 206 license renewals or updates, 60 license cancellations, and 133 registration decisions. ASN also issued 661 notification acknowledgements for sealed radioactive sources in 2022. Graph 6 shows the regulatory acts issued by ASN for radioactive sources in 2022 and, where applicable, their development over the last five years. The entry into effect of ASN resolution 2018-DC-0649 of 18 October 2018

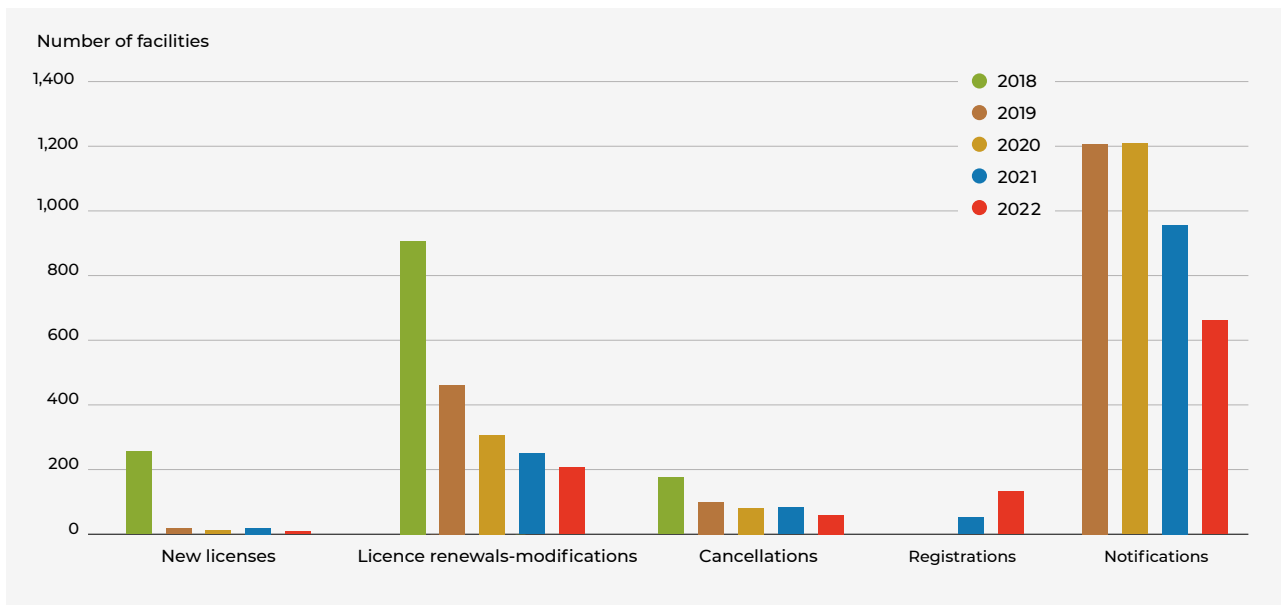
##### The case of electrical generators of ionising radiation

ASN has been responsible for the oversight of these devices since 2002, devices for which numerous administrative compliance actions are still required. In 2022 it granted 22 new licenses, 130 license renewals or updates and issued 141 registration decisions for the use of electrical devices emitting X-rays. ASN also delivered 722 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 above-mentioned ASN resolutions 2018-DC-0649 of 18 October 2018 and 2021-DC-0703 of 4 February 2021.

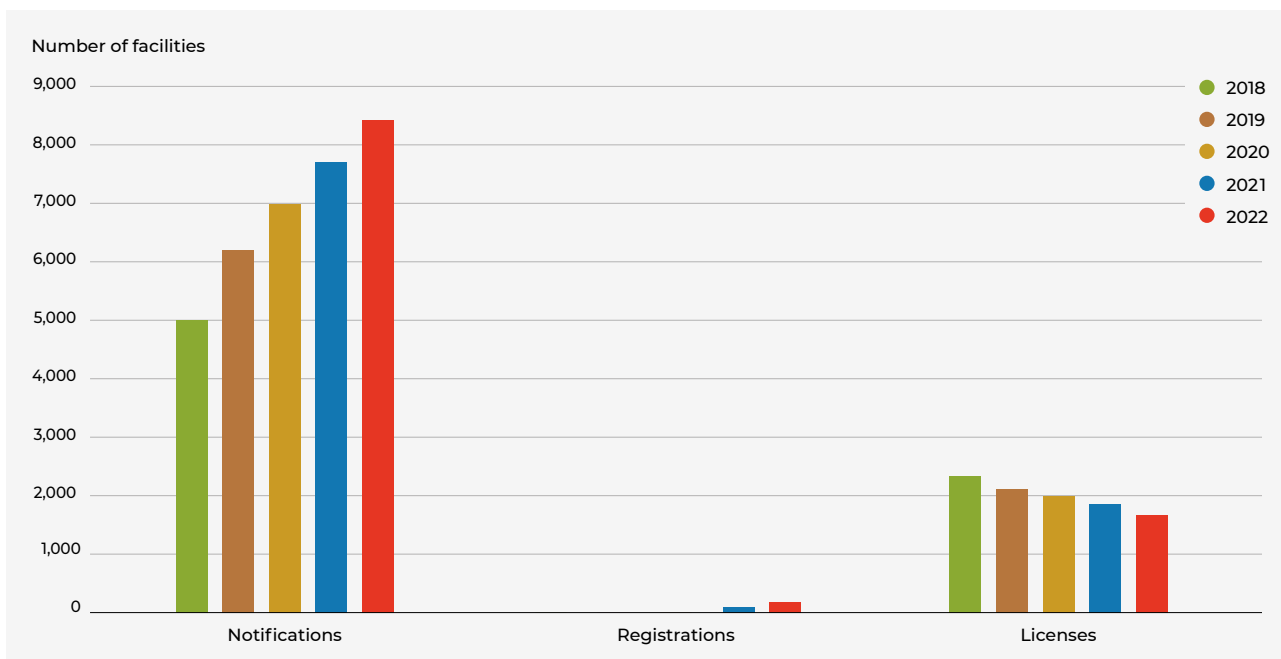
Altogether, 1,673 licences, 178 registrations and 8,420 notification acknowledgements have been issued for electrical devices emitting ionising radiation since 2002. Graph 7 illustrates the development over the last few years.



GRAPH 6 “User” licenses, registrations and notifications for radioactive sources issued each year



GRAPH 7 “User” licenses, registrations and notifications for electrical generators of ionising radiation in effect over the last five 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 with radiation protection rules, or operating incidents. Furthermore, these gamma radiography activities are 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). This is therefore 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 worksite 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 radiation protection

Industrial radiography activities are high-risk activities which have been an inspection priority for ASN for several years now.

In 2022, ASN conducted 144 inspections in this area, a number that is stable with respect to the three preceding years. Among these inspections, 60 were unannounced inspections on worksites which also include night work.

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 finds that the large majority of companies maintained the necessary rigour to meet the regulatory requirements with respect to the appointing of a radiation protection advisor, worker dose monitoring and radiological zoning of their facilities (less than 10% noncompliance observed). Furthermore, the inspectors noted that the frequency of maintenance of gamma radiography devices on the whole complies with regulations (no non-compliance found for projectors, 7% non-compliance found 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 3 cases of noncompliance observed, all concerning use in a facility).

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 more than 91% of the inspected facilities concerned in 2022.

Furthermore, although the inspections found only one non-compliance with the licences issued by ASN concerning 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.

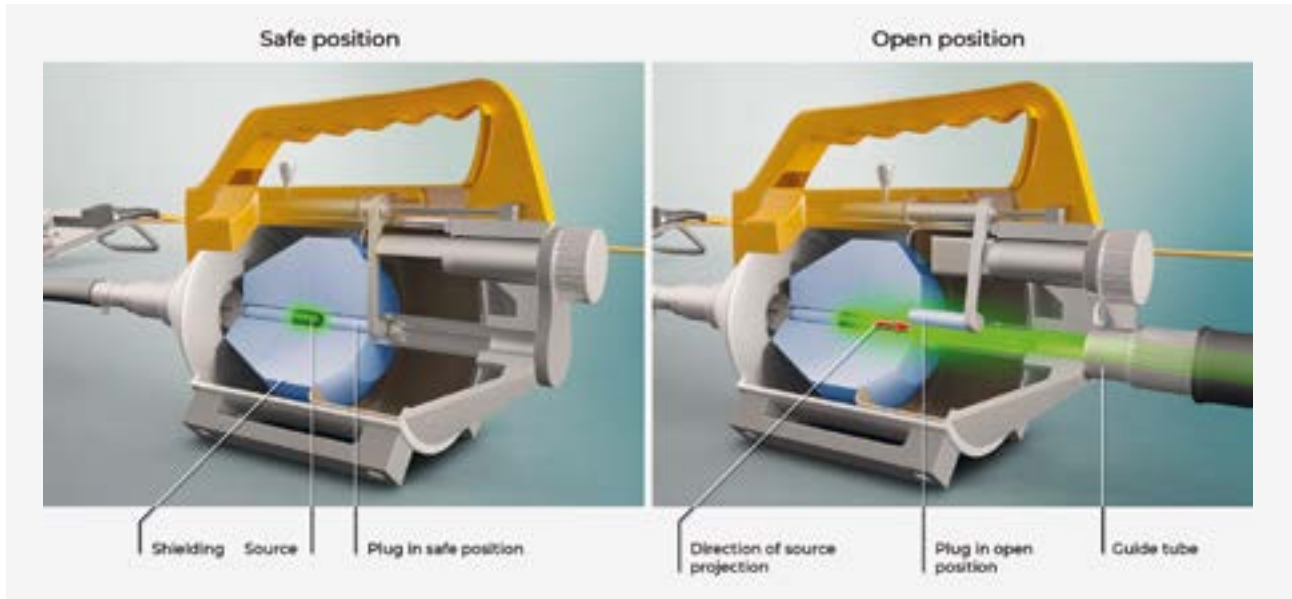
ASN still considers that the deviations observed in cordoning off the work zones on worksites (found in virtually one inspection in three) give cause for concern. ASN underlines that the lack of preparation and cooperation between the ordering customers and the radiography contractors before starting temporary worksites (particularly the failure to draw up a precise prevention plan) is one of the causes of these deviations.

ASN points out that the work area must be cordoned off before the work begins and, in all events, before the radiography 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 to take at one or more measurements and to record the results. Zoning and cordoning off effectively constitute the main safety barrier in worksite conditions, 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 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 non-conformities

**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 (mSv) per hour and per terabecquerel (TBq) one metre from the selenium-75 source, as opposed to 130 millisieverts per hour

per terabecquerel 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 20% of the devices are equipped with selenium-75 sources. The use of selenium-75 has stagnated in recent years. 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, diverse procurement routes have been set up by the source suppliers in the last few years, and new ones are being explored. ASN therefore still encourages the use of selenium-75 whenever possible.

ASN considers 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. The figures in 2022 stand at:

- 96 licensed gamma radiography facilities (36 gamma radiography facilities and 60 combined facilities, that is to say which can accommodate either gamma ray projectors or electrical devices emitting X-rays);
- 493 licensed X-ray radiography facilities (421 facilities using electrical devices, 60 combined facilities and 12 facilities using accelerators).

This network thus enables 83% of the professionals to propose industrial radiography services within facilities (57% 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 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 2022 as in the last few years, no cases of overexposure of industrial radiography operators were reported to ASN, even if

## 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, examples brought to ASN's attention confirming the risks to which operators can be exposed as a result of inappropriate actions, include:

- 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 millisieverts (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 equipped with 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 INES scale.
- 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.
- In 2020, in the United States, a radiographer and two assistant-radiographers performing non-destructive tests in an asphalt production unit were exposed to whole body doses of 636, 104 and 26 mSv respectively while attempting to reintroduce the source into the gamma ray projector after the guide tube had been crushed by a support which fell from a storage tank. The event was rated level 2 on the INES scale.
- In 2019, in Spain, an employee of a non-destructive testing company was exposed to about 200 mSv (whole body) by entering a gamma radiography bunker when the iridium-192 source was not in the safe position. The door-opening slaving system for prohibiting access to the bunker during the emission of ionising radiation, did not function due to the failure of the dose rate measuring system. The event was rated level 2 on the INES scale. A similar accident happened the same year in Germany: two employees were exposed to 100 and 30 mSv respectively (whole body) when they entered a gamma radiography bunker when the iridium-192 source was not in the safe position and the radiological environment had not been checked. The event was rated level 2 on the INES scale.

The data from before 2019 can be consulted in the previous issues of this annual report. The issues are available at [asn.fr](http://asn.fr), under the headings "ASN informs", "Publications", "ASN's annual reports".

08

several significant events linked to loss of source control (source "jamming") did occur during the use of gamma ray projectors. Nevertheless, and contrary to the previous years, the majority of these significant events involved inappropriate or prohibited actions by the operators leading to unnecessary exposure but without exceeding regulatory limits. Moreover, these actions complicate the subsequent operations 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.

ASN remains particularly attentive to the management of these 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. Penal enforcement actions have already been proposed for serious breaches, and will continue to be so.

## 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 12). In many sectors, X-ray generators are gradually replacing high-activity sealed sources for the irradiation of products (see point 1.3.1).

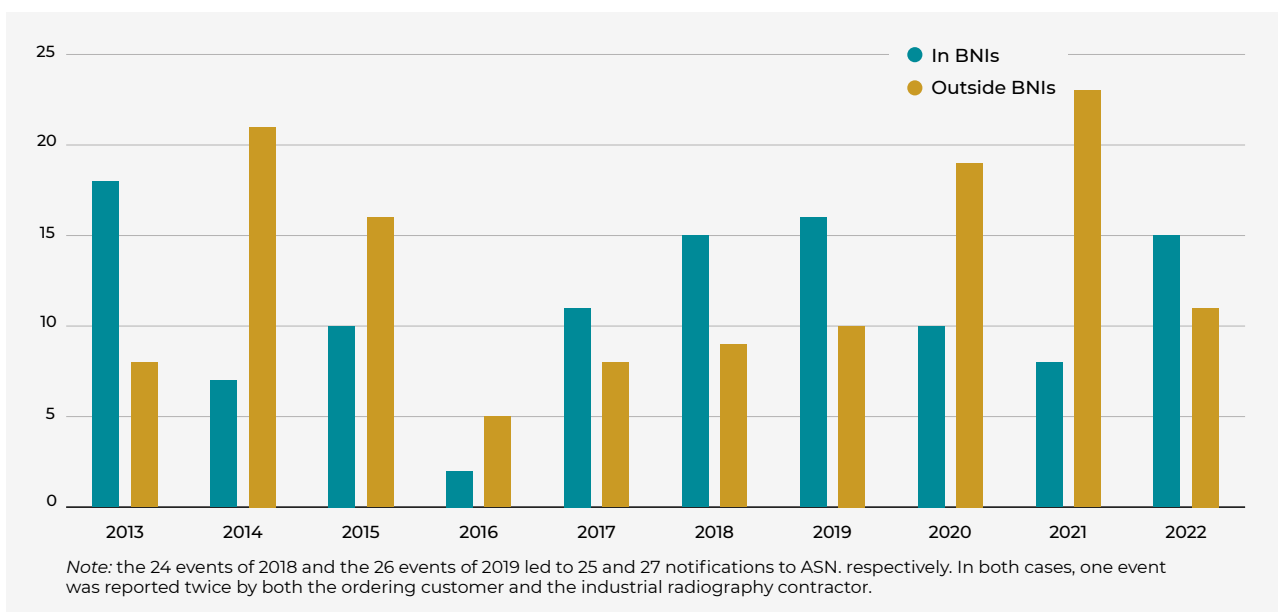
### LOSS OF CONTROL OF THE SOURCE IN GAMMA RADIOGRAPHY

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:

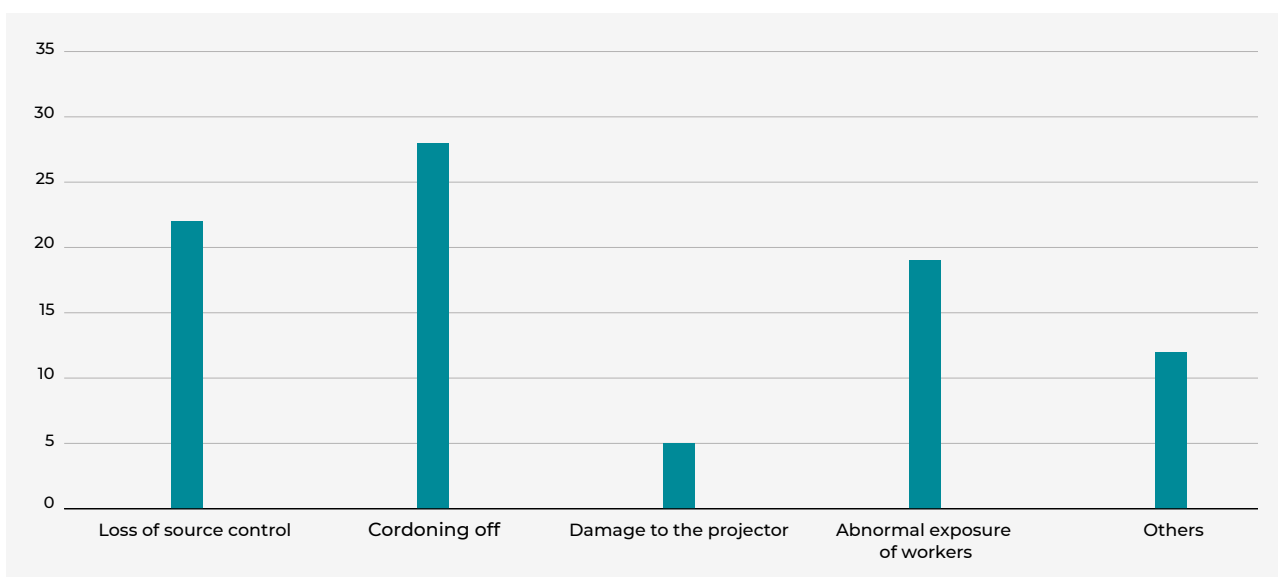
- The radioactive source remains jammed in its guide tube. The cause of the blockage is often the presence of foreign bodies in the tube, or deterioration of the tube itself.
- The front of the projector is not fully blanked due to either the presence of foreign bodies in the channel preventing full 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.

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 2020-2022 period





## 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 and the implementation of national monitoring indicators.

With gradual entry into effect of the requirements of the Order of 29 November 2019 amended, the monitoring was adjusted accordingly on 1 January 2021 (organisational provisions) and 1 January 2022 (technical systems). The number of inspection items that are verified systematically and consistently during the inspections as a whole therefore gradually increased from 4 to 6, then to above 10 on 1 January 2022 (the technical systems are more numerous for the sources or batches in category A or B than in category C; moreover, certain inspection items address transport vehicles which the majority of persons/entities responsible for nuclear activities do not possess, as they prefer to subcontract transport operations).

### Notes:

*1° Out of all the inspection points, four concern questionnaires stemming from obligations figuring in the non-published appendices of the Order of 29 November 2019 amended. Consequently, they cannot be addressed in a publication.*

*2° The changes indicated in the medical sector must be taken with caution as the number of inspections dedicated to malicious acts is relatively small.*

*3° The aggregate of the responses since 2019 gives some hindsight, but this only concerns the first two indicators as the others were put in place later.*

### Classification of radioactive sources or batches of sources

This criterion and the one following it have been monitored since 2019. The findings of 2022 can therefore be compared with the aggregated result for the years 2019-2021.

In 2022, 80% of the inspections performed in industrial facilities raised no comment on this point. This good result for 2022 is an improvement of about 30% on the findings made over the 2019-2021 period. Out of the remaining facilities, about 10% have taken no action.

Likewise, 90% of the medical centres inspected have classified their sources.

The increase in compliant situations in 2022 compared with the previous three years is more than 30%.

The situation of the sites which have not yet carried out this classification obligatorily leads to nonconformities, since this evaluation is the basis for determining the technical provisions of the protection plan against malicious acts which is applicable since 1 July 2022.

### Nominative authorisations

These are delivered by the nuclear activity licensee 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 2022, more than 60% duly issued the necessary authorisations. This represents an increase of 60% on the findings for 2019-2021. The percentage of situations without any authorisation is now marginal (less than 5%). The situation can nevertheless be further improved in nearly 25% of the cases for 2022.

The situation in the medical sector is similar (even if the indicator is less representative given that fewer inspections are carried out here than in the industrial sector) with 50% of findings compliant. This nevertheless represents just under a two-fold increase in compliant situations compared with the aggregate for 2019-2021.

### Policy of protection against malicious acts

This indicator (and the following one) was not put in place until 2021 since a general statement of management's commitment regarding protection against malicious acts and its distribution was not required by the regulations until 1 January 2021. This provision contributes to establishing a corporate security culture, including in terms of cyber security, which is a long process by nature. It is not sufficient, but it should provide some impetus for the organisation to address the question of malicious acts.

In the industrial sector, although such a policy exists in 70% of the licensees inspected in 2022, 15% need more appropriate dissemination. The number of cases that raised no comments during inspection has increased by 30% compared with last year.

In the medical sector, the proportion of inspected facilities that have a management commitment statement has increased with respect to last years.

However, the proportion of situations where the inspection found communication to be inadequate increased to 50% in 2022, a significant increase on the previous year.

### Identification and control of sensitive information

In 2022, nearly 60% of the industrial facilities inspected had a duly applied procedure on this matter, which is an improvement on last year. In slightly less than 20% of the situations, there was no document.

In the medical sector, 50% of the facilities had no document addressing this question, the same figure as in 2021.

### Principle of barriers

This inspection item concerns the basic provisions with regard to resistance to forced entry, based on criteria which are now more precise and therefore more stringent than before. This indicator, and the subsequent ones, were put in place to track the requirements that came into effect in 2022, therefore they cannot be compared with the previous years.

Slightly less than 40% of the industrial sites inspected are considered to have "barriers" that are clearly identified and suitably resistant. In the medical sector, this figure increases to above 50%, but one centre has still not taken this aspect of the order into consideration.

There is therefore still room for improvement.

### 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 equipment requires maintenance to prevent failures. It is therefore vital to have a verifications programme.

Such a programme exists in the industrial sector but is only implemented by 30% of the companies inspected in 2022. In the same percentage of situations the subject is not addressed at all. The remaining cases correspond to situations where a programme exists but is poorly applied or is inappropriate.

In the medical sector the number of inspected sites with a maintenance plan is slightly lower, standing at 25%, but in nearly 60% of the cases the issue has not been addressed. The remaining 15% of inspected facilities have a plan that is inappropriate or poorly applied.

### 3.2.2 The radiation protection situation

BNI excluded, ASN carried out 16 inspections from 2019 to 2022 (of which 3 were in 2022) in this sector, out of the 25 facilities currently licensed. These inspections show that the radiation protection organisation (in particular the appointing of a Radiation Protection Advisor – RPA), the radiological zoning put in place on the inspected licensees' premises, the informing of new employees and the renewal of verifications are satisfactory, as no significant deviations from the regulations have been 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 has found in about one in four 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 be 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 a device or installation in which electrically charged particles undergo acceleration, emitting ionising radiation at an energy level in excess of 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 66 licensed facilities<sup>1)</sup> (excluding cyclotrons – see point 4.2 – and BNIs), possessing slightly more than one hundred particle accelerators, 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 European Synchrotron Radiation Facility (ESRF) in Grenoble, and the Optimised Source of Intermediate Energy Light of the Lure Laboratory (Soleil) synchrotron in Gif-sur-Yvette.

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 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 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 2019 and 2022, 55 facilities equipped with these devices were inspected by ASN, 17 of them in 2022.

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 non-conformities detected during these checks;
- 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 availability of radiation monitoring devices in sufficient quantities for the operators who access these rooms and keeping these devices in good working order.

Lastly, with regard to experience feedback, no Significant Radiation Protection Event (ESR) was reported to ASN in 2022, apart from the recurrent events associated with the use of particle accelerators in shipment security checks. When conducting these checks, the customs services take precautions (such as broadcasting information messages in several languages) to avoid

1. To which can be added seven licenses to use an accelerator, either under worksite conditions, or for the shared use of a device of which possession is regulated by the other party's license.

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 2022, ASN counted 565 licenses and about 70 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. X-ray generators are also used for X-ray fluorescence or X-ray diffraction spectrum analysis. Particle accelerators are used for research into matter or for the production of radionuclides.

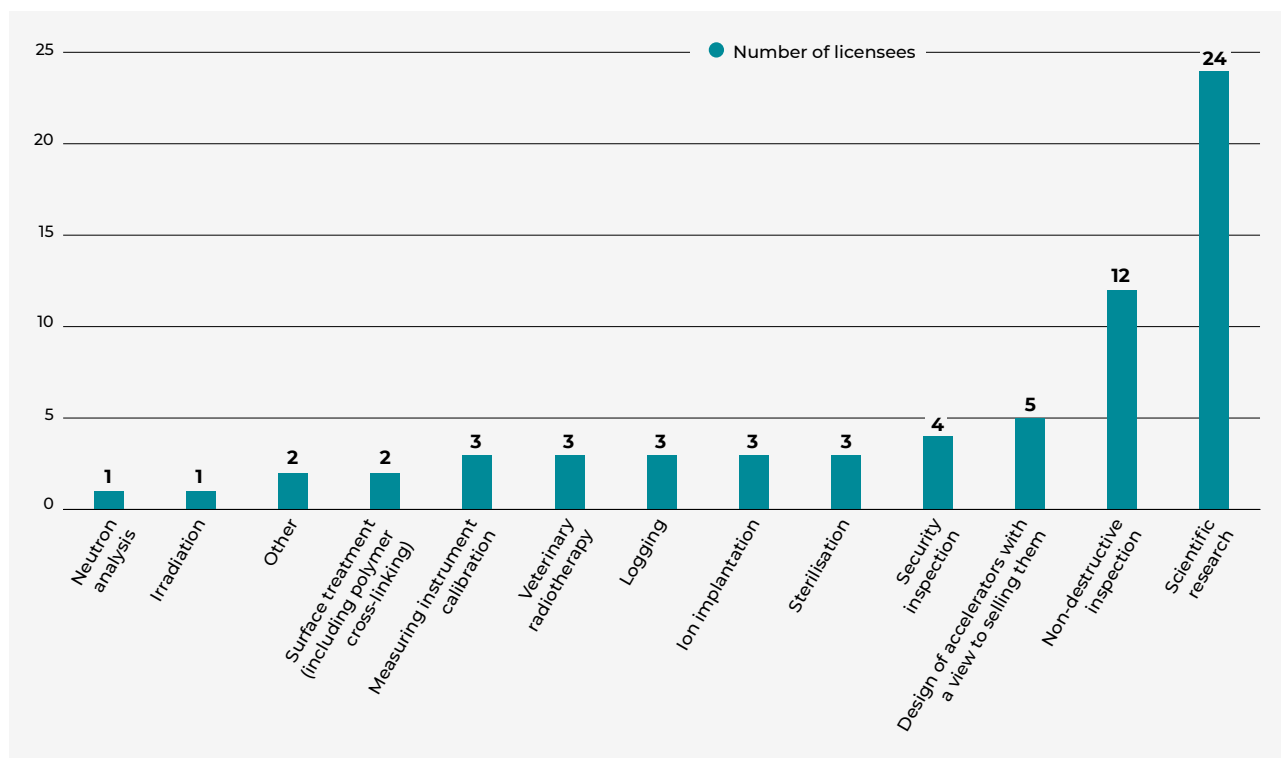
#### 3.4.2 The radiation protection situation

In 2022, ASN carried out 43 inspections in this sector<sup>(2)</sup> (compared with 51 inspections per year on average over the 2020-2022 period<sup>(3)</sup>). Broadly speaking, the actions undertaken over the last few years have brought improvements in the implementation of radiation protection within research laboratories thanks to a growing overall awareness of the radiation exposure risks.

Among the areas of progress observed in 2022, ASN underlines the strong involvement of the RPAs due in particular to the allocation of dedicated means and their interaction with the research teams, thereby allowing better integration of radiation protection.

On the other hand, ASN has identified areas for progress that will receive particular attention in future inspections, particularly in the conditions of interim storage of radioactive waste and in the performance and traceability of the inspections before final waste removal. The inspections in 2022 also highlighted the need for the licensees to comply more strictly with the stipulations of their licences, particularly regarding the maximum activity held. The maximum activity is sometimes exceeded, due either to the discovery of “legacy” radioactive sources which add to those whose possession is effectively authorised, or because the inventory of sources held on the sites is incomplete.

GRAPH 10 Breakdown of particle accelerators by end-purpose in 2022



2. Among these inspections, nine focused exclusively on the use of sealed radioactive sources or X-ray emitting devices.

3. There was a significant rise in the number of inspections between 2020 and 2021 due to the postponing to 2021 of inspections that could not be held in 2020 because of the Covid-19 pandemic.

### 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 higher-activity 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.

ASN therefore considers that the conditions of storage and removal of sealed radioactive sources at end of life and of radioactive waste and effluents remain the main difficulties encountered by the research units. This situation is particularly pronounced in universities which have historically stored their expired/disused sealed radioactive sources and their waste contaminated by radionuclides, sometimes over very long periods of time rather than disposing of them regularly, which today poses two main problems:

- in view of their diversity, the radioactive waste and expired/disused radioactive sources cannot be further managed without first being precisely identified and characterised;
- this disposition, to which must be added prior characterisation where applicable, represents a significant financial cost which has often been neither foreseen nor budgeted for.

The technical, economic and regulatory difficulties concerning the disposal of old sealed sources persist.

In 2022, faced with the persistent failure of one university to characterise and seek appropriate disposal routes for its sealed radioactive sources at end of life and for its waste, ASN issued a

compliance notice; the university has now started the procedures necessary to remedy this legacy situation.

At the same time, ASN has put in place tightened monitoring of certain research units with regard to management of sources and waste or the compliance with their licenses.

With regard to occupational radiation protection, the Order of 23 October 2020 on the radiation protection verifications of equipment and workplaces gives more responsibilities to the radiation protection advisors in this respect. A few deviations are to be noted concerning the failure to fully apply the periodic verifications programme (verifications incomplete or lacking) or to carry out the verifications; the situation has nevertheless been improving since 2021. Particular attention shall continue to be paid to this point in future inspections.

Lastly, in nearly 85% of the sites inspected, the periodic verification of the calibration of the radiation protection instrumentation is carried out at the proper frequency and the instrumentation is in good working order.

76% of the inspected sites have systems for recording and analysing adverse events and ESR. In 2022, ASN registered 29 ESRs concerning research activities (see Graph 12), of which only one was rated level 1 on the INES scale.

Three-quarters of the reported ESRs are essentially of two types:

- discovery of sources (59%);
- slight contamination of the work environment during the handling of sources (24%).

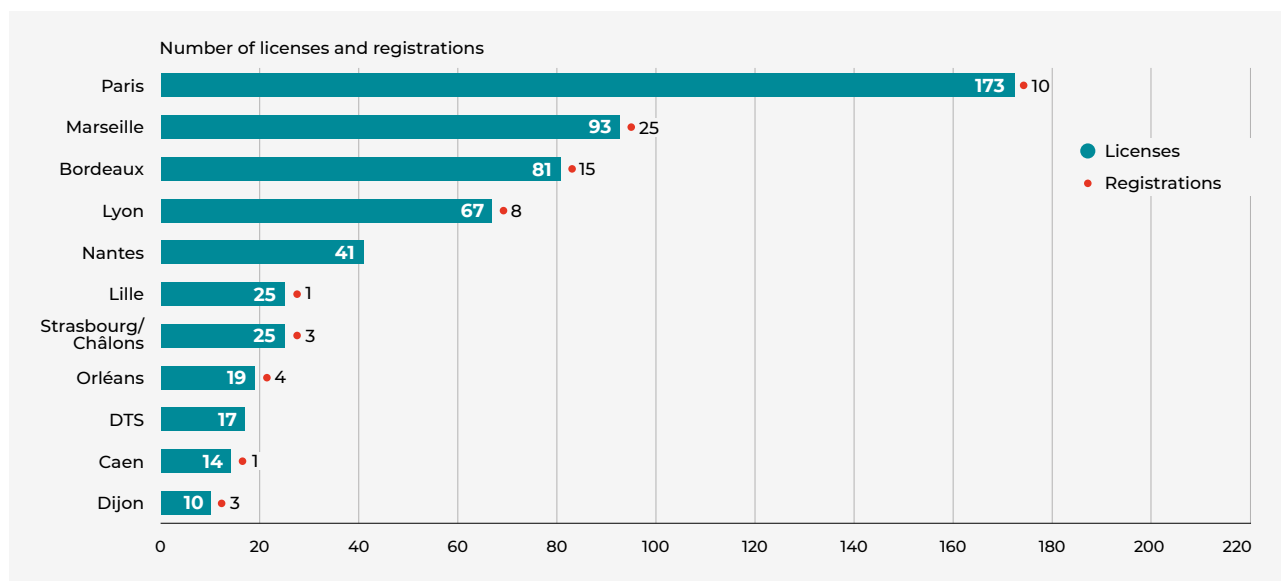
The five other reported events are of diverse origins (loss or theft of sources, jamming of source in a gamma ray projector (see point 3.1.1) used for research purposes, contamination of a dosimeter due to incorrect stowage and possessing radionuclides without a license).

The discoveries of sources can be explained in particular by poor overall traceability: this often results from the failure to take action to dispose of them when laboratories cease their activity, or from irregular and incomplete keeping of source inventories, as mentioned above. These chance discoveries occurred most often during fitting out works in basement rooms or rooms which have not been used for several years.

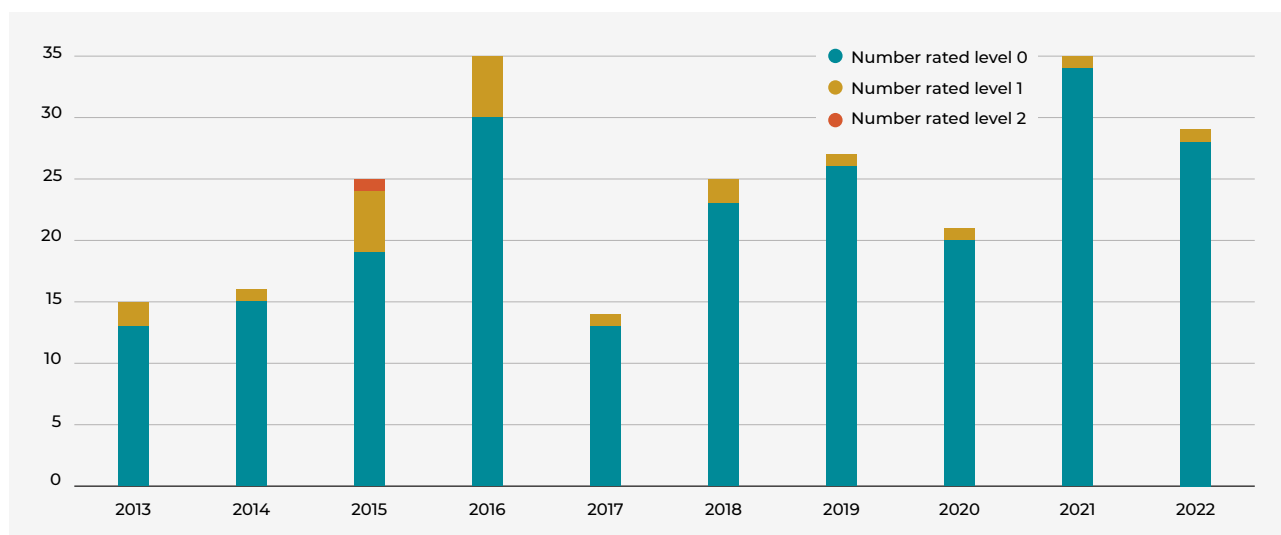
With regard to the cases of work environment contamination, the main identified causes are linked to the presence of contamination on the ground as a result of manipulations of unsealed sources, the malfunctioning of a liquid effluent management system and the loss of integrity of a sealed radioactive source.

ASN is also continuing its collaboration with the General Inspectorate of the National Education and Research Administration, which has competence for labour inspection in the public research sector. An agreement signed in 2014 provides for mutual information sharing to improve the effectiveness and complementarity of the inspections.

GRAPH 11 Distribution 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 2022



GRAPH 12 Trends in the number of events reported to ASN in the research sector from 2013 to 2022



08

## 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 around 115 suppliers with safety-significant business, including 36 low and medium-energy cyclotrons which are currently licensed under the Public Health Code in France.

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.

### 4.2 Cyclotrons

#### Operation

As at 31 December 2022, 4 cyclotrons were “on standby” and 32 cyclotrons were in service. Among the 32 cyclotrons in routine operation, 25 are used to produce radiopharmaceuticals intended at least for *in vivo* diagnosis, sometimes with medical or non-medical research as an additional end-purpose, five produce radionuclides for medical or non-medical research purposes, and two produce radionuclides exclusively for non-medical research.



The commissioning of three new cyclotrons is scheduled for the years 2023 and 2024.

### The assessment 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 standards, in particular standard NF M 62-105 “Industrial accelerators: installations”, ISO 10648-2 “Containment enclosures” and ISO 17873 “Ventilation systems for nuclear installations”, guarantees safe use of the equipment and 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. Some licensees have also installed – 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.

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 that began in 2016, with IRSN support, on the gaseous discharges from the cyclotrons resulted in 2018 in a doctrine, of which the key principles, will be used to draft a regulatory text. Alongside this, 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. As a complement, 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.

During 2022, ASN and IRSN explored jointly, with the participation of the cyclotron licensees, options 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. Nine sites were inspected in 2022, including one where

the inspection targeted a new reprocessing plant for water both enriched with oxygen-18 (used in the pharmaceutical production process) and contaminated more particularly with tritium during the cyclotron irradiation phases. 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 the aspects 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. In the eight radiopharmaceutical production facilities, the organisation of radiation protection is satisfactory since at least one person holding the CAMARI certificate is appointed, except on one site where the RPA’s training was not up to date. The exposed workers are trained and are all subject to appropriate dose monitoring. With the exception of two sites, the periodic verifications, including the presence and correct functioning of the safety and alarm devices and maintenance operations, are carried out exhaustively. Lastly, in all the inspected facilities the waste and contaminated effluents are properly managed and checked before disposal or discharge.

Lastly, national action plans are put into place by the licensees of the two major French radiopharmaceutical production groups and are monitored annually by ASN to ensure continuous improvement of radiation protection and safety in these facilities.

Six ESR were reported by the cyclotron licensees in 2022. None of these events led to significant exposure of workers or the public.

Three ESR were related to delivery errors (two involved the delivery of an activity exceeding the customer’s maximum authorised activity, while the third concerned the delivery a day early when the customer had not placed an order for that day). Two other events concerned in one case the contamination (with no radiological consequences) of the face of a female operator who was splashed with micro-droplets when handling a pipette of fluorine-18, and in the other, exceeding by a few gigabecquerels the maximum activity handled in an enclosure.

Lastly, one facility reported one exceedance its annual limit for discharges of radioactive gaseous effluents. Further verifications of both the measurements and the calculations established that the discharges were actually below the authorised maximum value. This event had led to an incident notice published on the ASN website and was rated level 1 on the International Nuclear and Radiological Event Scale (INES).

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 will continue in 2023 in order to create a single regulatory baseline for the whole sector. 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 licenses.

### 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 which is activated and produces radionuclides.

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 <sup>18</sup>F-FDG (fluorodeoxyglucose marked by fluorine-18), which is an industrially manufactured injectable drug, commonly used for early diagnosis of certain cancers.

Other radiopharmaceutical drugs manufactured from fluorine-18 have also been developed in recent years, such as <sup>18</sup>F-Choline, <sup>18</sup>F-Na, <sup>18</sup>F-DOPA, along with other 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.

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.

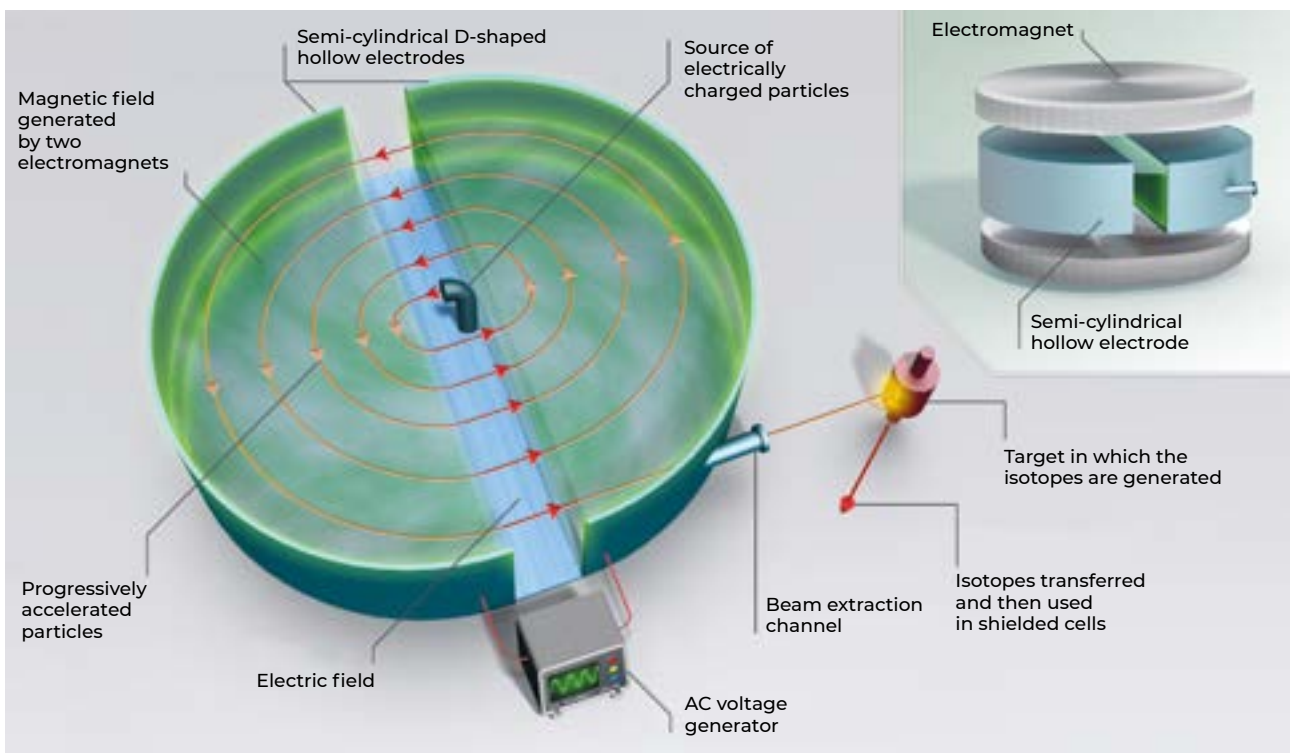
### 4.3 The other suppliers of sources

#### Evaluation of radiation protection

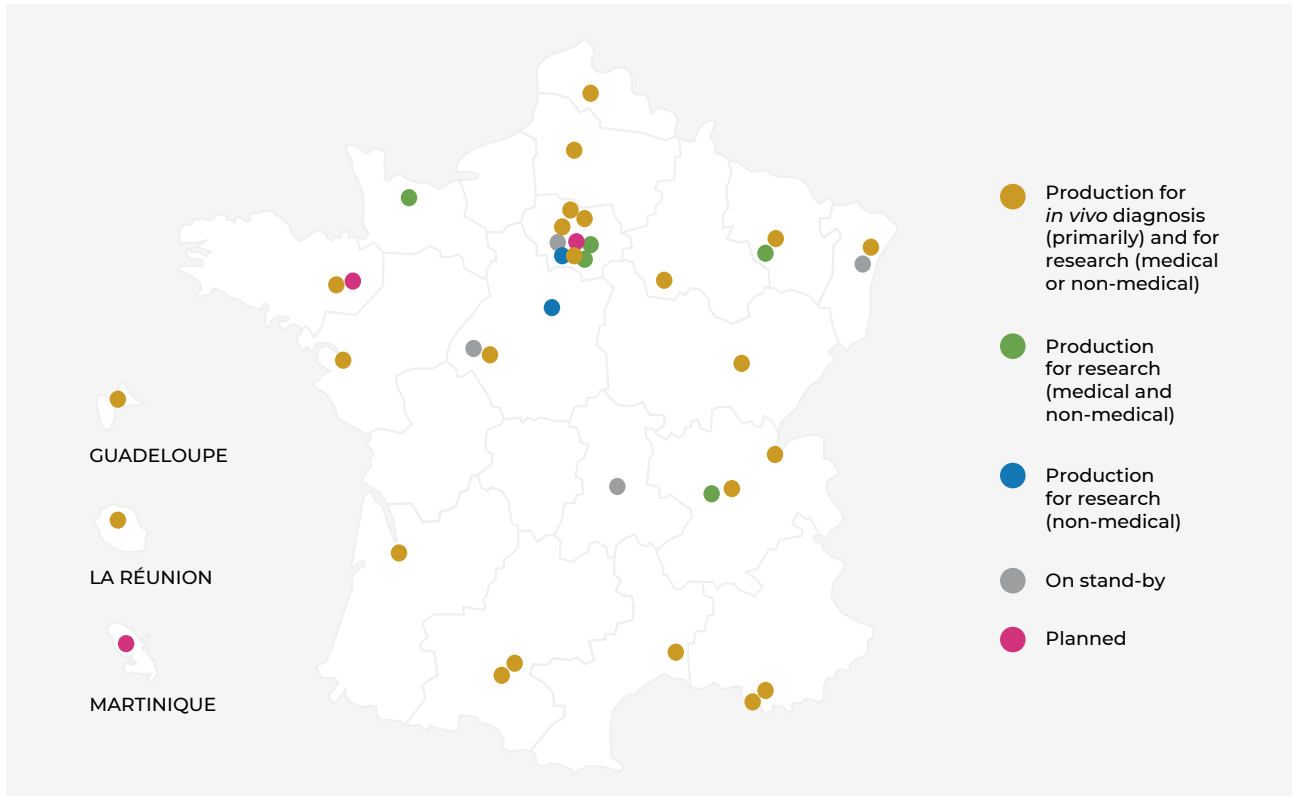
Suppliers of radioactive sources, cyclotrons excluded, propose technical solutions for the industrial, medical and research sectors. Suppliers may be manufacturers of “bare” sources or of devices containing sealed radioactive sources, manufacturers of unsealed sources, or distributors who import sources from other countries. Whatever the case, ASN examines the license application files for the sources these suppliers wish to distribute in France.

In 2022, excluding cyclotrons, 28 inspections were carried at manufacturers/distributors of sealed and unsealed sources, companies removing surge suppressors, and those manufacturing, installing or maintaining X-ray generators or particle accelerators (although they are not yet subject to a distribution licence, the utilisation of these devices is regulated, thereby including the commissioning and maintenance operations carried out by the companies that sell them). As a complement to what was done until now, five of the 28 inspections focused on priority themes other than the supply of radioactive sources (protection of sources against malicious acts, maintenance of electrical devices emitting ionising radiation, removal of surge suppressors). Lastly, one of these inspections concerned a foreign company distributing ionising radiation sources in France.

#### SIMPLIFIED DIAGRAM OF THE OPERATION OF A CYCLOTRON



LOCATION OF CYCLOTRONS IN FRANCE



These inspections have covered about a quarter of the suppliers with safety-significant business, checking specific inspection indicators, 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 distribution 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, tool for tracking the delivered sources or devices, setting up the source recovery streams, transmission of information to IRSN). These inspections also provided the opportunity to increase the source suppliers' awareness of regulatory changes, particularly those concerning the measurements and the application of the Initial Verifications (IV) and Periodic Verifications (PV) systems which replace the former third-party and internal "technical controls". Moreover, the defining of the conditions of recovery of sealed radioactive sources prior to their delivery between the suppliers and customers has improved with respect to 2021, thereby enabling the user to better understand the obligations and conditions of recovery of expired sealed sources (ten years counting from the first registration date figuring on the supply form).

Nevertheless, these inspections and the analysis of significant event reports have also revealed points requiring particular attention, notably the fact that all the pre-delivery verifications are not always carried out by all the suppliers. 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.

Lastly, four ESRs were rated level 1 on the INES scale in 2022. These incidents concerned the discovery of sealed radioactive sources on land reassigned for public use, the discovery of an area of limited contamination on a radionuclide production site, the jamming of gamma radiography source (see point 3.1.1) during measuring system calibration operations having led to inappropriate actions by the operator, and the unjustified exposure of a worker to a freight inspection scanner. The consequences on the environment and the workers concerned nevertheless remained limited.

## 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. For the actual entry into effect of this new system, ASN has developed an on-line registration service on its website, allowing application files to be submitted on line, and widely disseminated information to the professionals.

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 will continue in 2023.

ASN will continue, in collaboration with the DGT, its 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.

Lastly, ASN aims to finalise the draft resolution regulating the design and operations of the facilities using a cyclotron.

### 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. Publication of the above-mentioned Decree brought into effect the first provisions in this respect in mid-2018: those responsible for nuclear activities 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 to protect sources against malicious acts 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 (just like the cyber security associated with it, from the moment it concerns information necessary for the protection of sources) 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 person responsible for the nuclear activity. This person must be assigned the necessary resources and have the requisite skills (assisted if necessary by a person trained in this areas) 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. As information is planned to be shared, 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 and framed.

On 1 July 2022 the Order entered fully into effect and the technical provisions for the physical protection of sources must 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 greater emphasis. Inspections devoted entirely to this question began in limited numbers in 2021 and will reach “cruising speed” as of 2023.

Likewise, when examining the nuclear activity licensing applications, ASN ensures that the necessary organisation and material provisions have been put in place. The required content of the application files has therefore also evolved in recent years to include protection of radioactive sources. The application forms have been revised accordingly.

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 examination matrices, question-and-answer sheets, networks of regional correspondents).

To conclude, a number of tangible effects of the Order of 29 November 2019 amended can already be perceived: reduction in the stock of sealed radioactive sources held by the licensees, significant rise in groupings of industrial radiography agencies or equipping of vehicles in 2022.

ASN has already started identifying potential changes to the Order that might prove useful; it would be more a question of providing clarifications and relaxing certain provisions than of adding requirements. A proposal to this effect will be made to the Minister responsible for the energy transition in 2023. The year shall be used to continue, through the inspections, the information and awareness-raising actions, particular with regard to the “cyber” risks and risks related to transport operations.

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# Transport of radioactive substances

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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 regulation and

oversight of the safety of radioactive substance transports cover a wide range of activities in the industrial, medical and research sectors. This is based on strict international regulations.

## 1. Radioactive substance 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, etc. materials). 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: non-nuclear industry, medical sector and nuclear industry (see Graph 1).

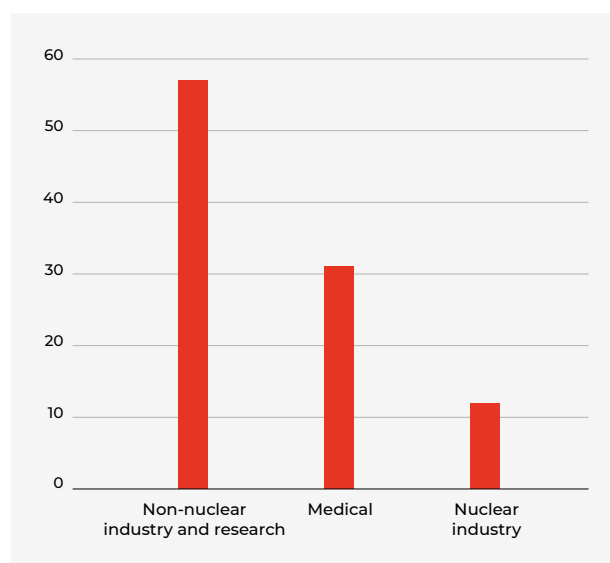
Most of the packages transported are intended for the non-nuclear industry, or for non-nuclear research: this mainly involves devices containing radioactive sources which are not used in a single location and which therefore need to be transported with considerable frequency. For example, these could 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.

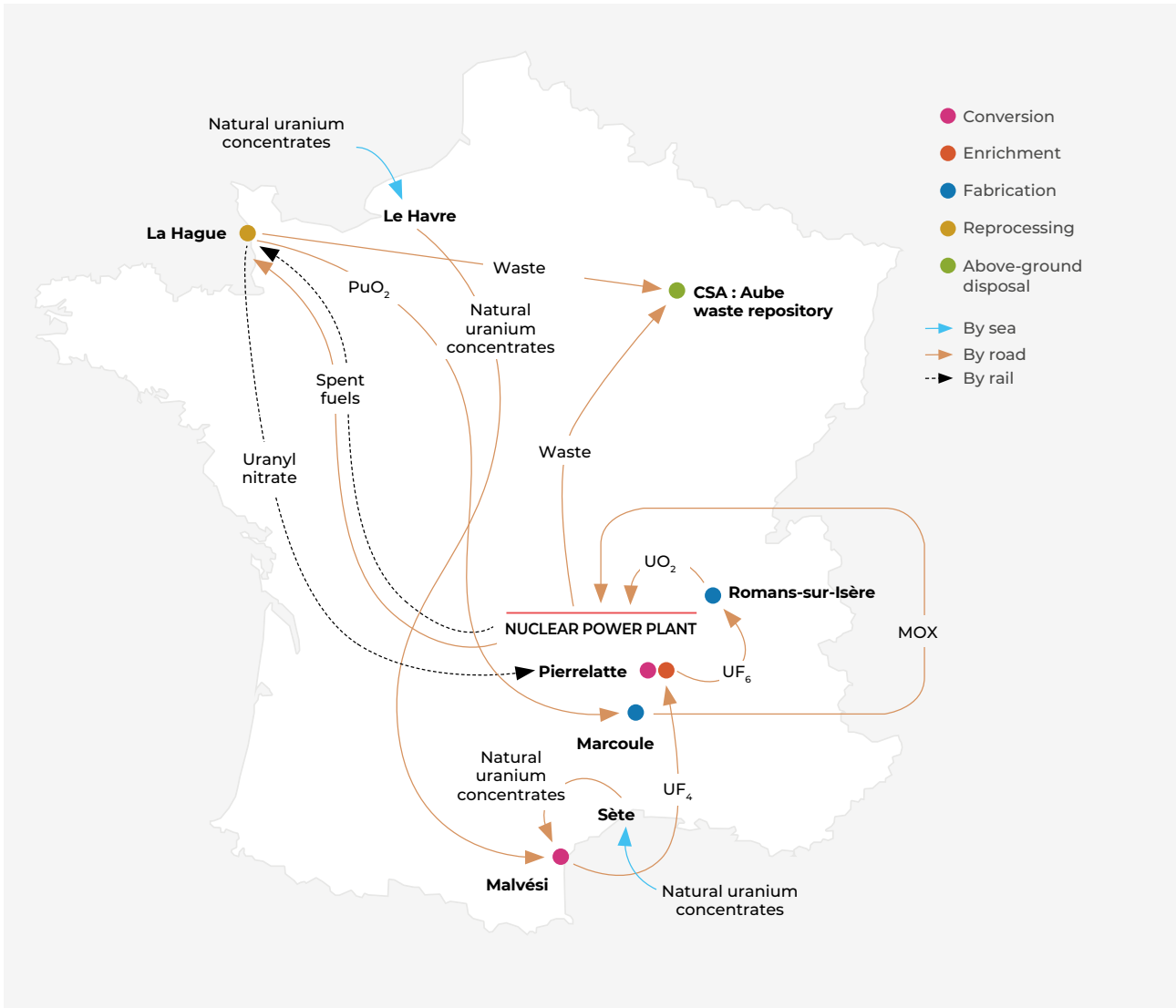
Finally, 12% of the packages shipped in France are for the nuclear industry. This represents about 19,000 shipments annually, involving 114,000 packages. These shipments are required to ensure the working of the “fuel cycle”, owing to the distribution of the various facilities and Nuclear Power Plants (NPPs) around the country (see map below). 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 (UF<sub>6</sub>) whether or not enriched (dangerous more specifically owing to the toxic and corrosive properties of the hydrogen fluoride formed by UF<sub>6</sub> 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 nuclear power plants 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 UF<sub>6</sub> used for fuel fabrication;
- 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).

GRAPH 1 Proportion of packages transported per field of activity in %



TRANSPORT OPERATIONS RELATING TO THE “FUEL CYCLE” IN FRANCE



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](http://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 (rounded figures)

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, UF<sub>6</sub>, used in the manufacture of fuels for NPPs 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 physicochemical 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 UF<sub>6</sub> 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.

TABLE 2 Breakdown of transported packages by type

TYPE OF PACKAGE		APPROXIMATE SHARE OF PACKAGES TRANSPORTED ANNUALLY
Packages approved by ASN	Type B packages, packages containing fissile materials and packages containing UF <sub>6</sub>	2%
Packages not requiring approval by ASN	Type A package not containing fissile radioactive substances	32%
	Industrial package not containing fissile radioactive substances	8%
	Excepted packages	58%



### 2.3.2 Type A packages and industrial packages containing non-fissile substances

Type A packages can, for example, be used to transport radio-nuclides for medical purposes commonly used in nuclear medicine departments, such as technetium generators. The total activity which 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 manageable, 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 9m 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 9m free-fall test, the package reaches the target at about 50 kilometres per hour (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

UF<sub>6</sub> is used in the “fuel cycle”. This is the form in which the uranium is enriched. UF<sub>6</sub> 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, UF<sub>6</sub> also presents a significant chemical risk. The regulations thus set out particular prescriptions for packages of UF<sub>6</sub>. 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 UF<sub>6</sub>, are also subject to the prescriptions previously presented (see point 2.3.3).

The UF<sub>6</sub> is transported in type 48Y or 30B metal cylinders. In the case of enriched UF<sub>6</sub>, 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 UF<sub>6</sub> 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 mSv. Moreover, the justification and optimisation principles applicable to all nuclear activities also apply to the transport of radioactive substances (see chapter 2).

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”<sup>(1)</sup> 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)<sup>(2)</sup> 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.

On 29 March 2018, ASN published Guide No. 29 to help carriers meet their regulatory obligations relative to the radiation protection of workers and the general public. ASN will be updating this Guide in 2023, to take account of the new provisions of the Labour Code and the Health Code, and their implementing texts, for example the Order of 23 October 2020 (see box), resulting from Directive 2013/59/Euratom (known as the “BSS” Directive).

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 result of a process of reflection on the principle of optimising radiological protection.

### PREVENTION OF RISKS OF EXPOSURE TO IONISING RADIATION

The joint ASN and Ministry for Labour instruction DGT/ASN/2018/229 of 2 October 2018, concerning the prevention of risks of exposure to ionising radiation, broadened the scope of application of the notion of “zoning” – which aims to limit worker and public exposure – to the transfer of radioactive substances within a facility, its annexes or worksites.

Thus, the phases of package loading or unloading on a conveyance, modification of a shipment, transshipment or temporary parking within the perimeter of a facility or its annexes can lead to the creation of a “monitored” or “controlled” zone, depending on the characteristics of the packages carried.

In addition, specific actions are provided for in the Order of 23 October 2020 regarding measurements taken for the assessment of risks and checks on the effectiveness of the prevention means put into place for the protection of workers against the risks from ionising radiation. It notably requires that the periodic checks on vehicles used to carry radioactive substances are performed or supervised by the radiation protection advisor. Whereas the first check is carried out before a vehicle is used for carriage of radioactive substances, to ensure the radiological cleanness of the vehicle, the subsequent checks are carried out to ensure that there is no contamination of the vehicle. These checks are conducted at a frequency defined by the employer, taking account of the frequency of shipments and the radiological issues, as well as after each transport operation for which a contamination risk has been identified. In any case, the time between two checks may not exceed three months.

In 2023, it will continue with measures to increase the awareness of professionals, dealing more specifically with changes to the regulations.

### 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 personnel working in proximity to the packages are thus visually informed of those which lead to 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 or fissile packages containing UF<sub>6</sub>.
- 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 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.

In 2023, ASN will be updating its 2005 Guide intended for professionals involved in radioactive substances transport operations and which specifies ASN’s requirements regarding the contents of a quality management system. It will notably emphasise, 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<sup>(3)</sup> 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 2022, 1,423 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.

3. [teleservices.asn.fr](https://teleservices.asn.fr)

ASN Guide No. 17 presents 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 be the entire responsibility of the first responder emergency services. The orange-coloured plates and the trefoil symbols on the vehicles thus indicate 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. Once its national emergency centre has been activated, 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.

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 certain nuclear 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.

ASN will continue in 2023 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.

Finally, ASN intends to update the guide on the performance of risk assessments required for transport installations or infrastructures (marshalling yards, ports, etc.) which could accommodate dangerous goods. The purpose of this guide is to ensure that the risks linked to radioactive substances are adequately assessed, to enable the licensees to define any relevant measures needed to reduce them, under the supervision of the Prefect.

### 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.

## 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 with 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.

Finally, in 2020, ASN extended the on-line notification and on-line transmission functions to deal with requests for noteworthy changes to on-site transports as set out in Articles R. 593-59 and R. 593-56 of the Environment Code.



### 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 safety and the radiation protection of transports of radioactive substance 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, is 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 duty is defined by the Order of 18 August 2010 relative to the protection and regulation of nuclear materials during transport. 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 18 August 2010.

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 soil. 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 entity 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 High Council for the Prevention of Technological Risks), 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.

#### 25TH ANNIVERSARY OF THE REGULATION OF RADIOACTIVE SUBSTANCES TRANSPORTS BY ASN

In 1961, within the scope of its statutory powers and in accordance with the recommendations issued by the United Nations Economic and Social Council, the IAEA published the first safety regulations for the national and international transport of radioactive materials on the public highway, whatever the conveyance used. These requirements were published under the title “*Regulations for the Safe Transport of Radioactive Material*”, Safety Standard Series No. 6, 1961 edition. Since then, these regulations have been revised repeatedly, most recently in the editions of 1985, 1985 revised in 1990, 1996, 1996 revised in 2003, 2005, 2009, 2012, and the current 2018 edition, called “Revision 1” of the SSR-6.

It was on the occasion of a change in Government in June 1997, modifying the ministerial powers, that competence for regulatory oversight of class 7 and its regulation was transferred from the Minister responsible for transports to the Ministers responsible for industry and the environment, at the time

jointly in charge of nuclear safety, and under whose authority the Directorate for the Safety of Nuclear Installations (DSIN) was working (formerly the General Directorate for Nuclear Safety and Radiation Protection – DGSNR, formerly ASN).

Thus, on 12 June 1997, the ASN mandate was extended to include the radioactive material transport regulations and the oversight of their application. The first years were devoted to bringing the organisation of transport oversight closer into line with that for the safety of nuclear facilities, with the assistance of the Institute of Nuclear Safety and Protection (IPSN), which in 2022 became the Institute for Radiation Protection and Nuclear Safety (IRSN). A system of transport inspections was then set up nationwide, with training of the ASN inspectors assigned to regional divisions.

With regard to expert assessment, the close cooperation with the IRSN was supplemented in 1998 by the setting up of an Advisory Committee of Experts for the Transport of radioactive

materials (GPT), which now meets at the request of ASN.

Since 2000, ASN has played an active role in drafting IAEA regulations and regularly cooperates with its foreign counterparts (see point 4.3.1).

In recent years, ASN has contributed to supplementing general international regulations on the safety of transport, through specific national provisions to clarify and reinforce the requirements in France relative to radiation protection, the management of emergency situations, or the security of certain transport operations with particular implications (notably by publishing Guides available on *asn.fr*).

ASN has also dematerialised most of its administrative procedures with the creation of an on-line service to facilitate:

- the notification of carrier activities;
- the notification of transport events and event reports;
- the application for authorisation of a noteworthy modification to the general operating rules for on-site transports.



## 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<sub>6</sub> must be covered by an ASN approval certificate in order to be transported. 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 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 in order to improve the safety case.

In some cases the IRSN expert assessment is supplemented by a meeting of the ASN GPT. The opinions of the Advisory Committees are always 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 safety checks (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 9m 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 thus 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 2022, 30 approval applications were submitted to ASN by the designers or operators.

ASN issued 37 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 2022, ASN carried out 108 inspections in the field of radioactive substances transport (all sectors considered). The follow-up letters to these inspections are available on *asn.fr*.

#### 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 2022, ASN carried out four 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.

#### EXTENSION OF THE MX6 PACKAGE APPROVAL TO TRANSPORT MOX

As part of its multi-year energy programme, EDF intends to use "MOX" fuel for some of its 1,300 Megawatts electric (MWe) reactors.

As the characteristics of the MOX assemblies intended for the 1,300 MWe reactors are different from those of the MOX assemblies currently in use in the 900 MWe reactors, their transportation is not covered by any approval currently in force in France.

Orano NPS therefore submitted an application to ASN to extend the approval of the MX6 package model, so that these new MOX assemblies could be transported to the 1,300 MWe reactors.

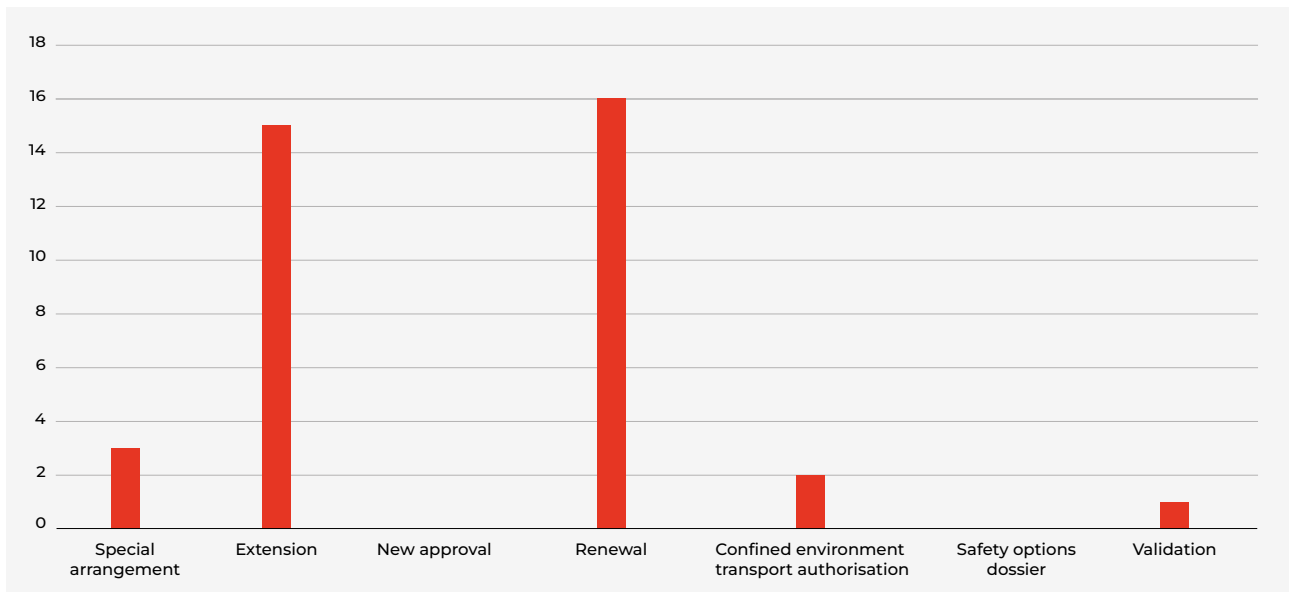
Following the review of the application, especially the review of the safety case for this package model with this new content, ASN issued the B(U) approval certificate for this MX6 package model on 23 September 2022.

Issue of this approval however in no way prejudices the other authorisations needed to use MOX fuel in EDF's 1,300 MWe reactors.

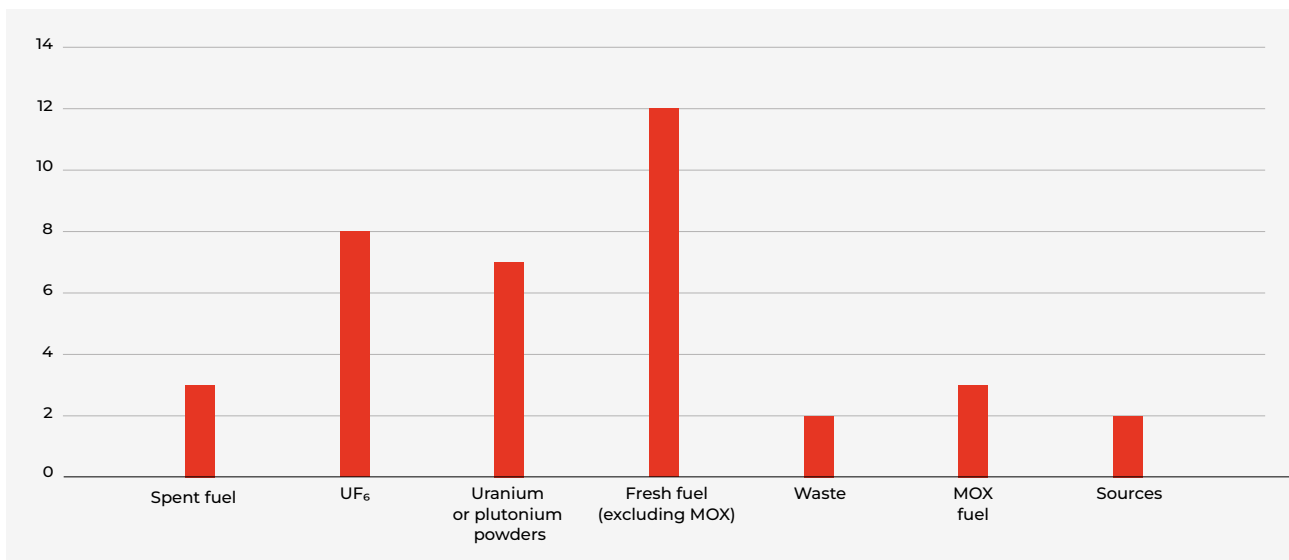
TABLE 3 Administrations responsible for regulating the mode of transport and the packages

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.

GRAPH 2 Breakdown of number of approvals according to type, issued in 2022



GRAPH 3 Breakdown of number of approvals according to content carried, issued in 2022



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 2023, ASN intends to continue spot-check inspections of transport packaging manufacturing. This is because the irregularities detected in 2016 at the Framatome Le Creusot plant, which notably affected certain transport packagings, as well as the 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 still finds 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

### REFUSAL TO VALIDATE A GERMAN CERTIFICATE

Pursuant to Article R. 595-1 of the Environment Code, Framatome Advanced Nuclear Fuels (ANF) GmbH submitted an application to ASN for French validation of approval D/430/IF-96 (revision 11) issued by the German competent authority for the ANF-10 package model loaded with fresh fuel assemblies, on the basis of a Safety Options Dossier.

This validation request concerns two contents consisting of fresh fuel assemblies based on uranium oxide, intended for Boiling Water Reactors (BWRs), and one content consisting of two tubes transporting non-irradiated fuel rods in unspecified quantities, for BWRs or Pressurised Water Reactors (PWRs).

The purpose of this application is to be able to resume transport operations by road, rail or sea on French territory with the ANF-10 package, as an IP-2 type industrial package for fissile materials. This package is used more specifically for transport operations between the Framatome Lingen plant in Germany and the Cofrentes NPP in Spain.

The transport of ANF-10 packages on French territory was authorised for the last time in France in 2005, under a special arrangement shipment approval, which expired on 31 July 2005. This authorisation had been delivered subject to the implementation of compensatory measures for the transport of the ANF-10 package. This special arrangement had been issued

because, for ASN, this package model already at the time failed to meet all the requirements of the previous international transport regulations. In particular, the regulation package drop test had not been performed in the most penalising conditions; in addition the demonstrations that the package safety functions were guaranteed at -40°C and that safety-criticality was controlled were also insufficient under standardised transport accident conditions.

The new review showed that the safety case for the package model was still not satisfactory with regard to maintaining sub-criticality. ASN therefore refused to validate the German certificate for the third consecutive time.

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 stowage 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 they 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 OEF 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.

#### Events notified in 2022

In 2022, in the field of radioactive substances transport, ASN was notified of 76 events rated level 0 on the International Nuclear and Radiological Event Scale (INES) and 12 events rated level 1. A slight drop in the number of level 0 events is observed by comparison with 2021, whereas the number of level 1 events tripled. Graph 4 shows the variations in the number of significant events notified since 2005.

ASN was also notified of 52 Events of Interest for the safety of Transports (EIT), a figure which is identical to 2021. 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 EIT and can detect any recurrence or trends which could be indicative of a problem.

Finally, five transport events, occurring within nuclear installations, rated level 0 on the INES scale were notified in 2022. This figure, which has almost doubled in one year, indicates an improvement in the safety culture and the notification of transport events to ASN.

#### Sectors concerned by these events

As was the case last year, most of the significant events notified concern the nuclear industry. Only 15% relate to transports for the non-nuclear industry. However, by comparison with 2021, the number of transport events involving pharmaceutical products increased quite significantly: they account for 38% of significant events (as opposed to 11% in 2021).

As for the events rated level 1 on the INES scale:

- five of them concern regulatory nonconformities observed during road and air transport of industrial gamma ray projectors (transport of a gamma ray projector from Chad without its transport case and without the appropriate regulation labelling/markings, transport of a gamma ray projector from Tunisia without its appropriate transport case and stowing, rupture of a plug detected during a transport operation in France, absence of labelling and maintenance carried out more than one year previously, problem with closure of a package from Algeria and absence of seal). The foreign competent authorities concerned

#### INSPECTIONS OF ON-SITE TRANSPORTS AT EDF NUCLEAR POWER PLANTS

The last 2022 inspections on on-site transports in the Saint-Laurent-des-Eaux and Flamanville NPPs show that EDF needs to update the list of authorised packages and the corresponding safety requirements. These inspections also revealed insufficient compliance with the EDF internal requirements for on-site transports. Finally, the lack of any designated staff for the safety of on-site transports for periods of several months was observed.

In 2023, ASN will continue its inspections of EDF's on-site transports.



were informed by ASN of the breaches of the regulations, and corrective measures were taken by the consignors to prevent such events from happening again;

- four other events concerned the same carrier which, over the space of four months, delivered radiopharmaceutical packages to the wrong hospitals. An ASN inspection recorded shortcomings in the company's organisation, with possible human factors underlying the repeated delivery errors. ASN expects effective corrective measures to be taken and their actual implementation will be verified during an upcoming inspection;
- the discovery, by a service company, of an empty package in the basement of a building was rated level 1 on the INES scale, owing to a lack of radiation protection culture;
- the penultimate event rated level 1 concerns non-compliance with a criticality control rule in a rail shipment;
- and finally, the last event rated level 1 on the INES scale concerns incorrect tightening of one or two screws participating in the closure system for FCC transport packages loaded with fresh fuel, detected at reception in the NPPs.

None of these 12 level 1 events on the INES scale had any consequences for the workers, population, or environment.

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 2022 include the following:

- non-conformities affecting a package: they mainly concern dose rate measurement errors, leading to under-evaluation of the package category, or labelling faults (error or omission). These events had no actual consequences for safety or radiation protection;
- surface contamination spots exceeding the regulation limits, detected mainly on conveyances which have been used to transport spent fuel packages, or inside containers or packagings. These events had very little impact on radiation protection of the public, who cannot have access to the contaminated areas;
- 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.

The EIT reported to ASN are primarily deviations relating to incorrect labelling (loss or error) of packages and stowage faults.

With regard to significant events occurring during transport within nuclear installations, these concern the transport of a drum containing a sample of radioactive materials, even though it was supposed to be empty, the failure to perform a ten-yearly inspection of a cylinder participating in a truck fire-fighting system, a transport documents error and the use of screws specific to another packaging configuration.

The significant on-site transport events concern non-compliance with a package transport authorisation and the detection of contamination on the transport system carrier vehicle.

### 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 about sixty modification proposals to the IAEA in 2023.

#### 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 High Council for the Prevention of Technological Risks, 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.

### 4.4 Contributing to public information

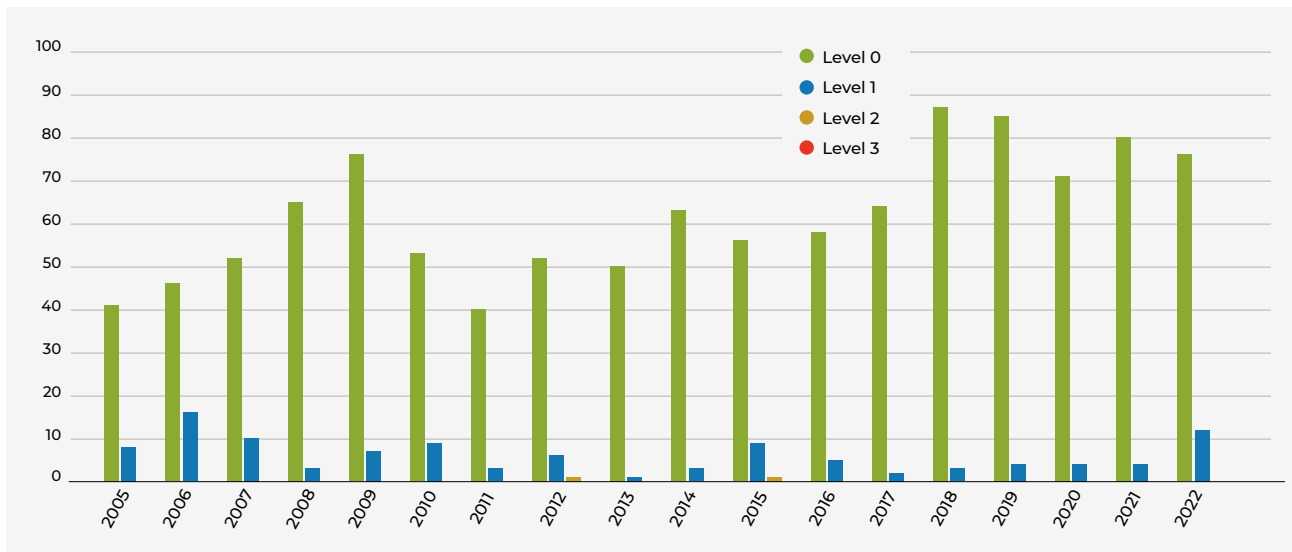
Ordinance 2012-6 of 5 January 2012, modifying Books I and V of the Environment Code, extends the obligations for public information to the persons responsible for nuclear activities. Article L. 125-10 of the Environment Code sets the thresholds beyond which the person responsible for transport must communicate 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



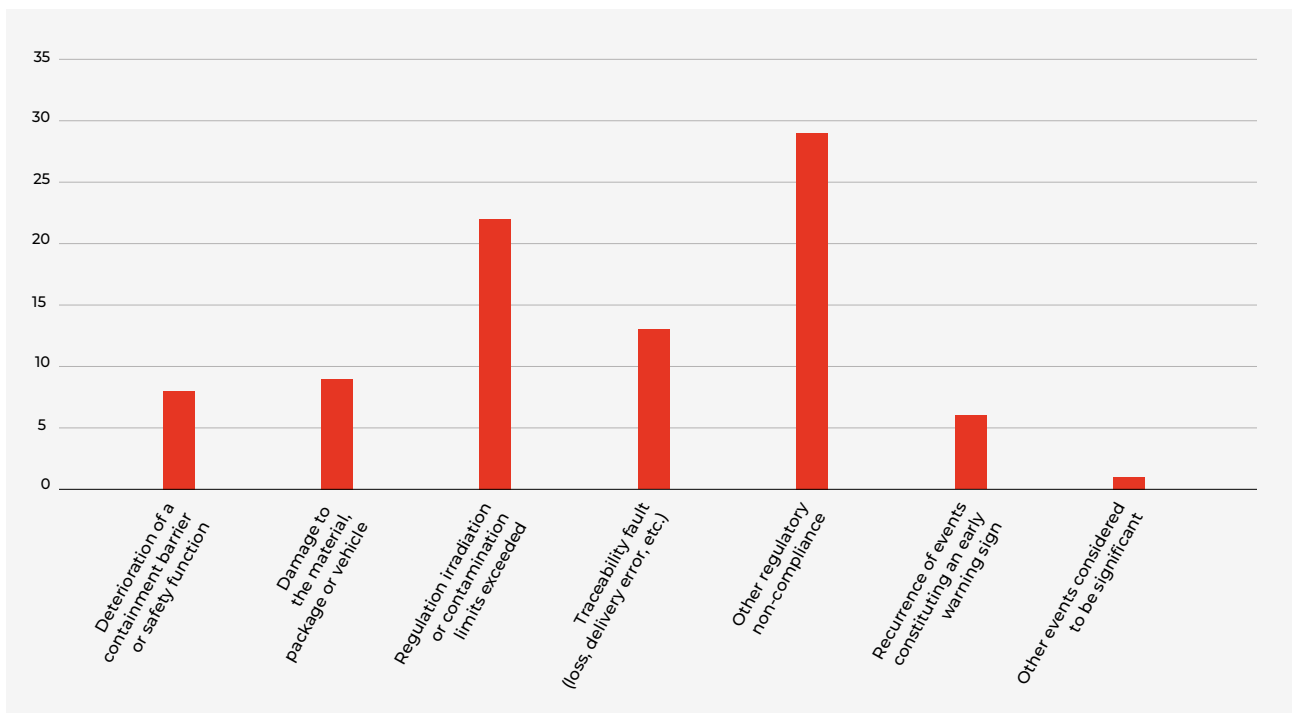
Participants in the IAEA TRANSSC Committee No. 45 – 2 December 2022



GRAPH 4 Trend in the number of significant events affecting the transport of radioactive substances notified between 2005 and 2022



GRAPH 5 Breakdown of significant events notified in 2022 by notification criterion



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.

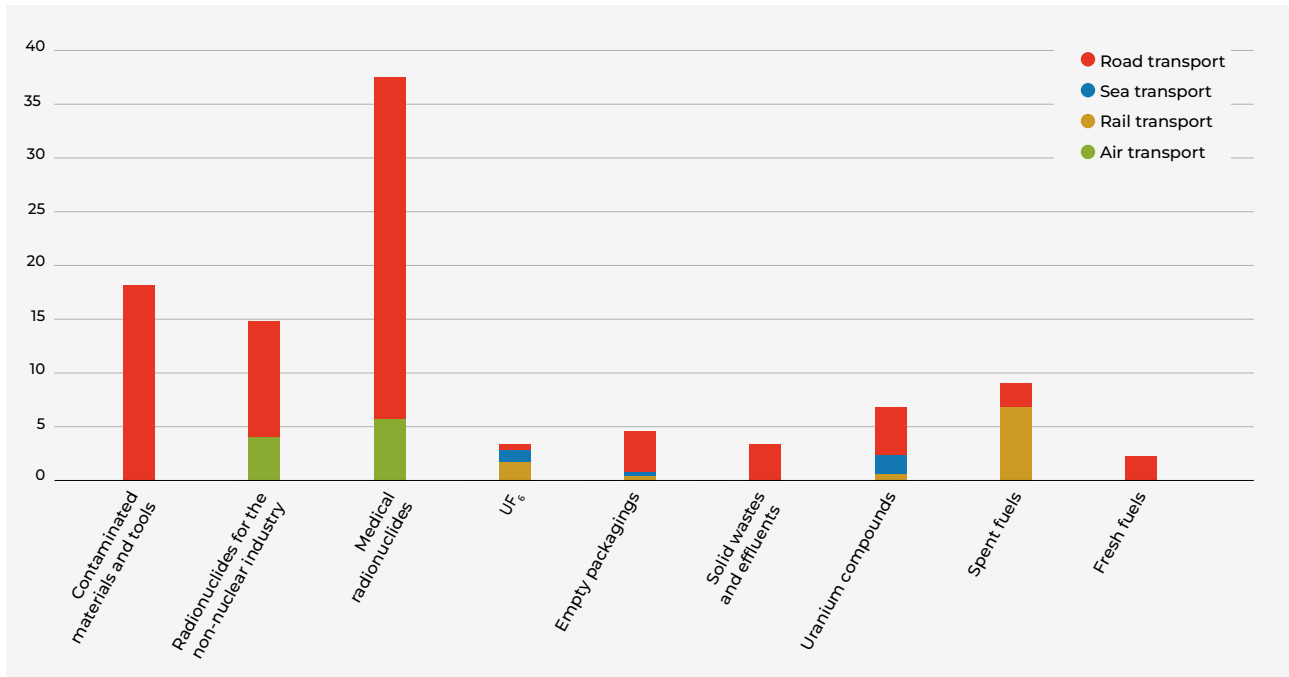
#### 4.5 Participation in international relations in the transport sector

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 counterparts in other States.

#### 4.5.1 Work of the European Association of Competent Authorities on transport

A 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 OEF 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.

GRAPH 6 Breakdown of notified transport events by content and mode of transport in 2022



#### 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 Germany, Belgium, the United Kingdom and Switzerland.

##### Germany

In 2016, the French and German Authorities decided to meet regularly to discuss a range of technical subjects. ASN also participates in the Franco-German technical committees concerning the programme for returning German spent nuclear fuel reprocessing waste.

##### Belgium

For the production of nuclear electrical power in Belgium, French-designed packagings are sometimes used for “fuel cycle” 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 for French package models for which 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.

### SCHEDULED REPLACEMENT OF UX-30 OVERPACKS BY DN-30 OVERPACKS

The UX-30 is an overpack that surrounds a 30B cylinder filled with enriched UF<sub>6</sub>, in order to provide mechanical and thermal protection during the regulation tests.

The UX-30 is the subject of an American certificate that expires on 31 December 2024, which was validated by ASN in November 2019 and then again in December 2020. Approvals F/538/AF-96 (w) and F/538/AF-96 (x) issued by ASN expired on 15 November 2022.

The Orano NPS company undertook to replace all UF<sub>6</sub> shipments with UX-30 overpacks by shipments with DN-30 overpacks, no later than 31 December 2024, as the latter's design is more recent and has also obtained the required approval certificate.

Orano NPS asked ASN for a final validation extension for the UX-30 packaging approval for an additional two years, to allow a transition between the UX-30 overpack and the DN-30 overpack, to ensure that a sufficient number of DN-30 can be manufactured.

The validity of the two French approvals F/538/AF-96 (w) and F/538/AF-96 (x) was issued on 29 April 2022, with the addition of the following compensatory measures proposed by the licensees and accepted by the authorities of the European countries using the UX-30 overpack:

- two 6 kg powder or CO<sub>2</sub> extinguishers are positioned on each side of the conveyance;

- the drivers of the conveyance are trained in firefighting techniques, with training refresher courses at intervals of no more than two years;
- the tunnels restriction code is B;
- the conveyance is equipped with a geopositioning device, or a member of the crew is regularly able to communicate their position to the consignor and, as necessary, to the emergency services.

The English, Belgian, Dutch and German competent authorities also adopted these compensatory measures in their approval renewal processes.



# 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, dispose of the waste from the 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 the 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 therefore demands considerable reactivity on the part of EDF and extreme rigorosity in the analysis of the generic nature of these flaws and their consequences for the protection of humans and the environment, as well as in their processing.

ASN exercises extremely stringent oversight of safety, environmental protection and radiation protection measures in the NPPs and continuously adapts it in the light of Operating Experience Feedback (OEF).

ASN develops an integrated approach to the oversight of the facilities. 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 3-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.

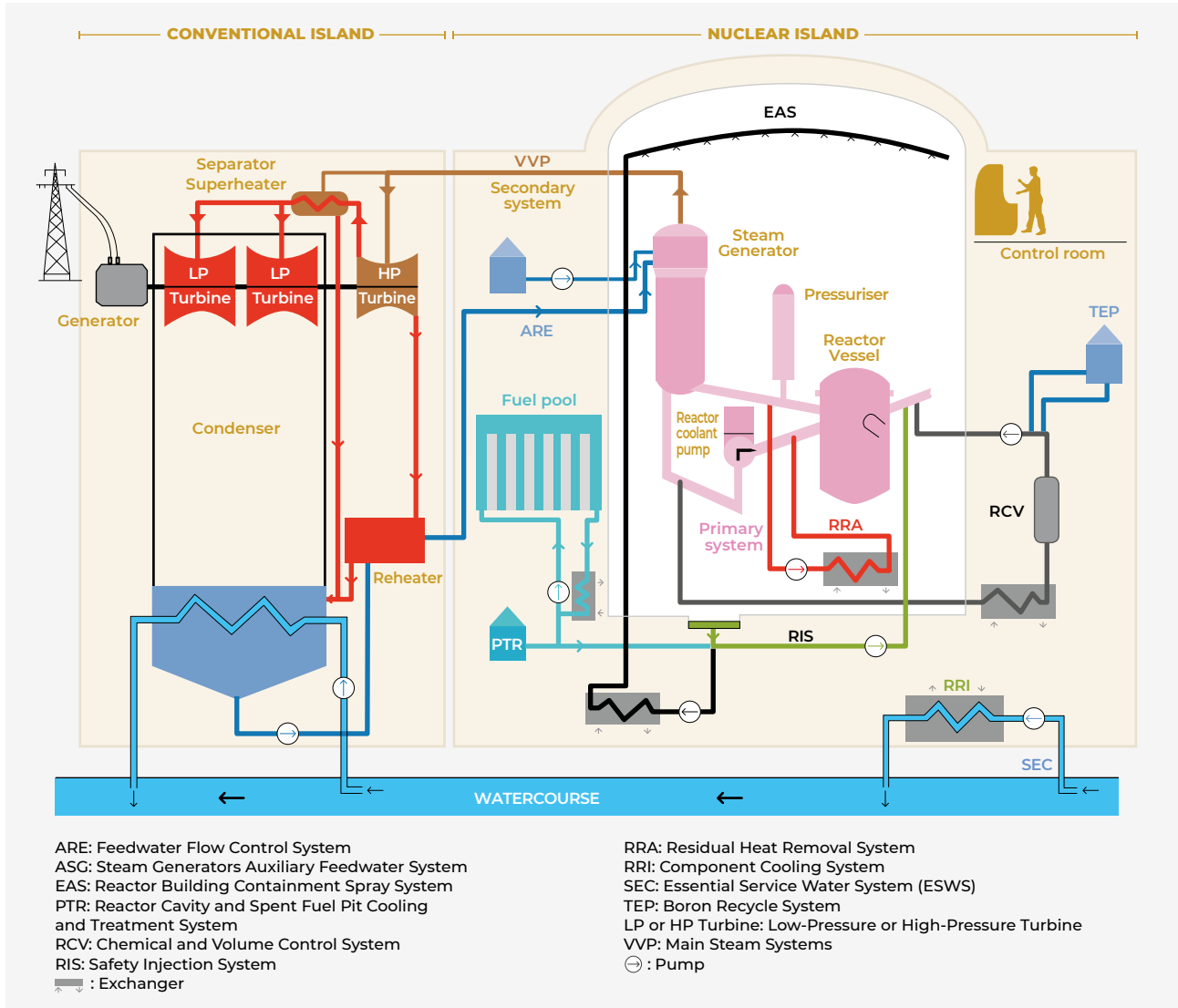
Each reactor comprises a nuclear island, a conventional island, water intake and discharge structures and possibly a cooling tower.

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.

PRESSURISED WATER REACTOR OPERATING PRINCIPLE



## 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.

Radioactive substances are contained by the positioning of three containment barriers between these substances and the outside environment:

- the cladding around the fuel rods retains the radioactive products contained in the fuel pellets;

- 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 during the cycle according to the gradual depletion of the fissile elements in the fuel;
- 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 (UO<sub>2</sub>) based fuels enriched with uranium-235 to a maximum of 4.2% by mass. These fuels are fabricated in several French and foreign plants, by Framatome and Westinghouse;
- fuels consisting of a mixture of depleted 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 UO<sub>2</sub> 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 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

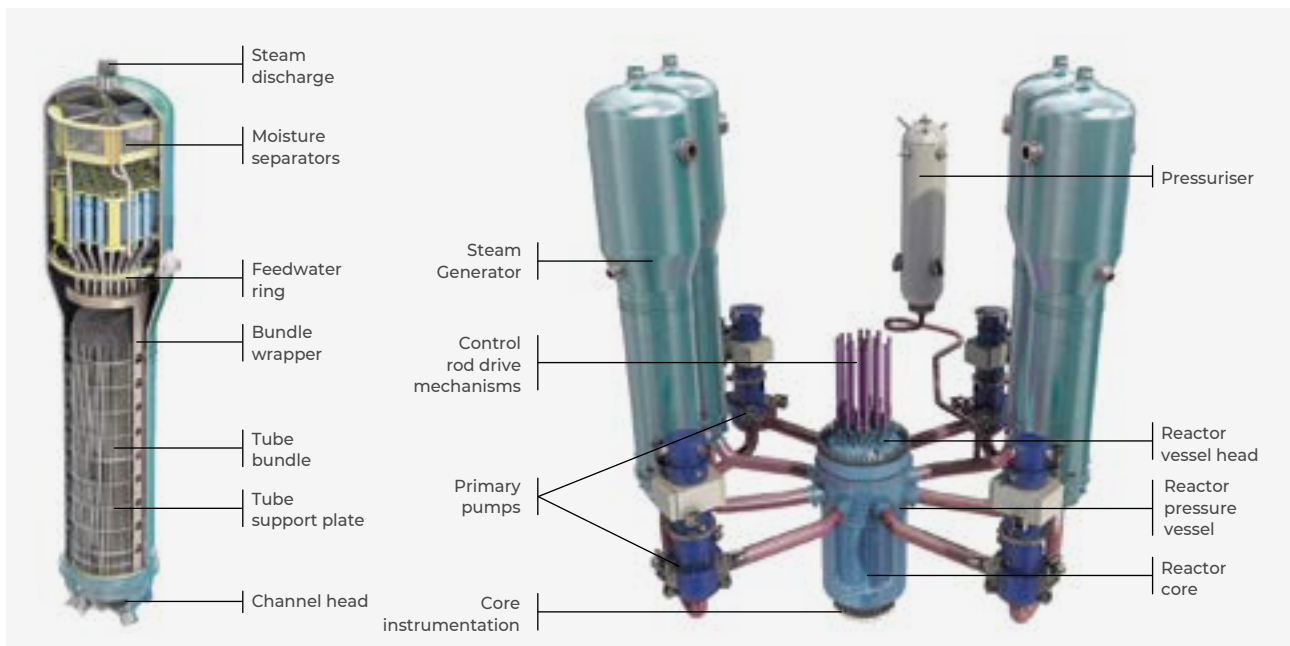
The primary system and the secondary systems transport the energy given off by the core in the form of heat to a turbine generator set which produces electricity.

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, 1,450 MWe or 1,650 MWe Evolutionary Power Reactor (EPR) 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.

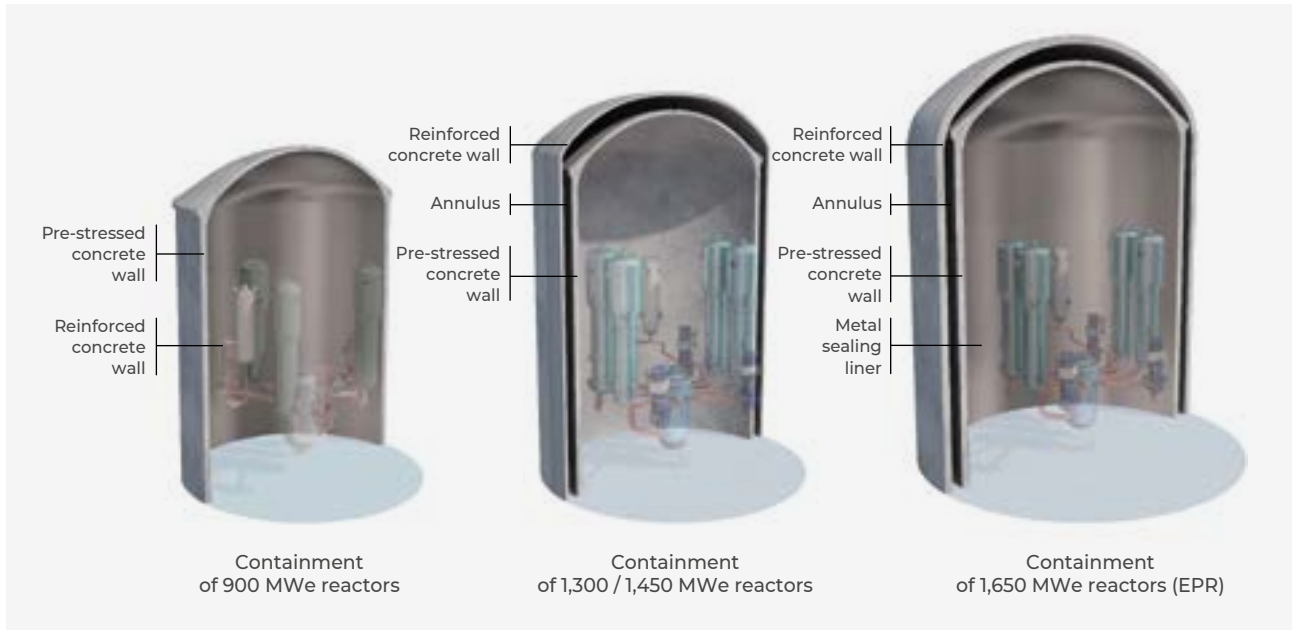
The primary system coolant transfers its heat to the water of the secondary systems in the SGs. The SGs are heat exchangers which contain from 3,500 to 6,000 tubes, depending on the model, through which the primary reactor coolant water circulates. These tubes are immersed in the secondary system water, 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.

A STEAM GENERATOR AND A MAIN PRIMARY SYSTEM FOR A 1,300 MWE REACTOR



REACTOR CONTAINMENTS



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 heats up in the condenser and is then either discharged into the environment (once-through circuit) or, if the river discharge is too low or the heating too great for the sensitivity of the environment, is 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.

1.6 The containment

The PWR 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 Flamanville EPR consists of two concrete walls and a metal liner covering the entire internal face of the inner wall.

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 (SIS), 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 (Japan) 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 NPPs 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.

## 2. Oversight of nuclear safety of the reactors in operation

The year 2022 was marked by the prolonged outage of a significant number of reactors, notably as a result of stress corrosion being discovered on certain lines connected to the primary system (see “Notable events” in the introduction to this report).

These unusual prolonged outages had an impact on the regulation and the assessment of the safety of the reactors, as certain topics could not be inspected in the same way on the reactors shut down and those in operation. The trends and developments highlighted in this chapter take account of this context.

### 2.1 Fuel

#### 2.1.1 Fuel and its management 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 and its management in the reactor

In 2022, all the NPPs satisfactorily managed the integrity of the first barrier, that is the fuel rod cladding.

The number of reactors with fuel leakage faults was lower than in 2021. This improvement is notably the result of the gradual incorporation of fuel assemblies fabricated by Framatome, for which the mixing grid springs have been heat treated, thereby increasing their strength.

The technical discussions on the subject of the generalised corrosion of certain M5 alloy fuel claddings detected in February 2021, enabled the operational compensatory measures defined by EDF and implemented on the 900 and 1,300 MWe reactors, to be lifted.

An investigation is currently under way to determine whether or not to lift some or all of these measures for the 1,450 MWe reactors. In addition, since 2022, in order to control the corrosion risk, the iron content of the M5 alloy fabrication specification has been increased. The industrial manufacturing capability with increased iron contents was inspected by ASN, which made no subsequent requests.

Finally, the production difficulties encountered in the Melox plant once again led EDF in 2022 repeatedly to refuel with fewer MOX assemblies than usual for its 900 MWe reactors. For the same reactor, ASN thus authorised EDF to repeat refuelling without fresh MOX fuel or to use a series of atypical refuelling loads consecutively. In 2022, under EDF surveillance, Orano qualified a MOX fuel fabrication process which should eventually restore a level of production quality enabling standard MOX fuel refuelling loads to be obtained.



## 2.2 Nuclear Pressure Equipment

### 2.2.1 Design and manufacturing of Nuclear Pressure Equipment

The manufacturer of the Nuclear Pressure Equipment (NPE) is responsible for the conformity of this equipment with the applicable safety requirements in order to guarantee that there will be no failures during its operation. These requirements are defined by a European Pressure Equipment (PE) Directive and are supplemented by specific NPE requirements, which take account of their importance for the safety of the installation. The manufacturer defines and applies the rules that enable it to prove compliance with these requirements.

As of 2015, the industrial firms, EDF and Framatome in particular, took fundamental measures to change their rules and bring them into line with the regulatory requirements. Most of these actions were carried out within the framework of the “NPE programme” of the French Association for Nuclear Steam Supply System Design (NSSS), Construction and Monitoring Rules (AFCEN), which involves the majority of the profession. The work done, led to the AFCEN issuing methodology guides and several revisions of the RCC-M code (design and construction rules for mechanical equipment of PWR nuclear islands), on which ASN issues a position statement. The work to update the RCC-M will continue beyond 2022. It shall enable this code and the associated guides to be kept up to date according to progress in techniques and practices, and to OEF.

ASN asked that AFCEN’s 2019-2022 programme address the methodology for managing deviations and the OEF acquired with regard to welding. A methodology guide was thus drafted, which in particular promotes the principle of the priority given to restoring conformity or repair, rather than keeping as-is. This principle, supported by ASN, was regularly recalled during the recent events, in particular with regard to the main steam line welds on the Flamanville EPR reactor. This guide also highlights good practices in terms of reporting of deviations and taking account of OEF with a view to ensuring continuous improvement. With regard to welding, the discussions in 2022 concerned the work still to be done and tangible assimilation of OEF for the EPR2 project.

### 2.2.2 Assessment of the design and manufacturing of Nuclear Pressure Equipment

ASN assesses the regulatory compliance of the NPEs most important for safety, referred to as “level N1”, corresponding to the reactor pressure vessel, the SGs, the pressuriser, the reactor coolant pumps, the piping, notably that of the Main Primary (MPS) and Secondary (MSS) Systems, as well as the safety valves.

This conformity assessment concerns the equipment intended for the new nuclear facilities (more than 200 equipment items are concerned on the Flamanville EPR reactor) and the spare equipment intended for nuclear facilities already in service (notably the replacement SGs). ASN can be assisted in this task by organisations that it approves. These latter can be mandated by ASN with performance of some of the inspections on the “level N1” equipment and are tasked with assessing the regulatory compliance of the NPE less important for safety, said to be “level N2 or N3”. The oversight by ASN and the approved organisations is carried out at the different stages of the design

and manufacture of the NPEs. 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. Four 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.

In 2022, with regard to NPE design and manufacture, the approved organisations carried out about 3,700 inspections on the NPE intended for the Flamanville EPR reactor and about 3,500 inspections on the replacement NPE intended for the NPP reactors in operation. These inspections are performed under ASN supervision.

With the support of the approved organisations and the Institute for Radiation Protection and Nuclear Safety (IRSN), ASN examined all the steps taken by the manufacturers and by EDF to address the problems associated with post-weld heat treatment<sup>(1)</sup>. ASN concluded that these measures, which could in certain cases require strengthened in-service monitoring provisions, ensure that the safety of the equipment concerned by these problems is maintained.

In particular, during the investigations carried out by Framatome following the discovery in 2019 of a deviation concerning the use of post-weld heat treatment, a new problem linked to high residual stresses generated during the cooling of these post-weld heat treatments was brought to light. This problem was addressed by Framatome and by the other SG manufacturers (Westinghouse and Mitsubishi Heavy Industry) by optimising the use of their processes to reduce the residual stress levels liable to be generated during cooling.

Framatome continued its quality improvement actions at its three plants. EDF in particular improved the skills management and deviations prevention and handling processes, by deploying monitoring of the most sensitive industrial processes, such as the welding and heat treatment processes, along with supplier approval, evaluation and surveillance. Through its inspections, ASN evaluates the results of these actions, which apply to the manufacture of spare equipment for the NPPs and to the future manufacture of equipment for the EPR2 reactors. It thus underlines the quality and pertinence of the actions taken, which should lead to improved quality of manufacturing. For several years, ASN has in particular maintained its involvement in monitoring the steps defined to ensure that a long-term, robust and efficient organisation tailored to the safety issues is maintained within the Framatome Le Creusot plant.

The manufacturer Westinghouse continued to apply its improvement plan in its SG manufacturing plant in Italy, with regard to the internal quality and monitoring system. The pre-conditions for lifting the reinforced surveillance currently in place were defined and ASN, with the involvement of the organisation it mandated, is examining the progress being made in correcting the significant manufacturing deviations.

ASN finds that the approved organisations, the manufacturers and the licensees are developing an organisation and the corresponding resources within their own structures, in order to prevent and detect the risk of fraud. Although progress has been observed, improvements are still needed in the implementation of the technical procedures.

1. The purpose of the post-weld heat treatment is to release the residual welding stresses and obtain the appropriate mechanical characteristics. The technical baseline requirements for fabrication sets the required temperature range for this operation according to the materials used.

### 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 MSS of PWRs. These systems are thus the subject of monitoring and periodic maintenance by EDF.

These systems are subject to periodic re-qualification every ten years, which comprises a complete inspection of the systems involving non-destructive examinations, pressurised hydro-testing and verification of the good condition and good operation of the over-pressure protection accessories.

The licensee is 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.

The safety implications of some 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 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 two reasons:

- The vessel is a component for which replacement is not envisaged, owing to both technical feasibility and cost.
- Monitoring 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.

#### Cast elbow assemblies

The MPS of a reactor comprises several austenitic-ferritic stainless steel cast elbow assemblies. The ferritic phase experiences ageing under the effect of temperature. Certain alloy elements present in the material 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.

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.

#### LEAK DURING HYDRO-TESTING OF CIVAUX REACTOR 1

During the ten-yearly outages, the primary system undergoes periodic requalification which notably includes a hydrostatic pressure test.

During the hydrostatic pressure test on Civaux reactor 1 on 2 November 2022, a major event occurred at 190 bar and 98°C during the pressure rise. Rapid depressurisation was observed, with a loss of 40 bar in just one second, followed by a drop of more than 10 bar per minute.

This situation was caused by the ejection of a removable tube from the In-core Instrumentation System (RIC). An element of the retaining device specifically installed for the hydro-tests was missing from this tube.

This event led EDF to reinforce its checks and its monitoring, to safeguard the next hydro-tests on the reactor primary systems. Reactor safety was not compromised by this leak. This is because, during the hydro-test, no fuel assemblies were present in the reactor vessel.

#### Nickel-based alloy zones

Several parts of the PWRs are made of nickel-based alloys, owing to its generalised or pitting corrosion resistance. However, in the reactor operating conditions, one of the alloys chosen, Inconel 600, has proven to be susceptible to stress corrosion. This particular phenomenon occurs in the presence of significant mechanical stresses. It can lead to the appearance of cracks, as observed on certain SG tubes in the early 1980s or, more recently in 2011, on a vessel bottom head penetration in Gravelines NPP reactor 1 and in 2016 on a vessel bottom head penetration in Cattenom NPP reactor 3. These cracks led EDF to repair the zones concerned or isolate the part of the system concerned.

At the request of ASN, EDF adopted an overall approach to monitoring and maintenance for the zones concerned. Several zones of the main primary system made of Inconel 600 alloy are thus subject to specific monitoring. For each of them, the in-service monitoring programme, defined and updated annually by EDF, is submitted to ASN, which checks that the performance and frequency of the checks carried out are satisfactory and able to detect the deteriorations in question.

#### 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. Rupture of one of the tube bundles 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 by EDF and periodically revised 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 prevent the free circulation of the water-steam mixture (clogging), which creates a risk of damage to the tubes and the internal structures and which can degrade the overall operation of the SG.

To minimise this fouling, various solutions can be implemented to limit metal deposits: preventive chemical cleaning or remedial mechanical cleaning (using hydraulic jets), replacement of material (brass by stainless steel or titanium alloy, which are more corrosion-resistant) in certain secondary system exchanger tube bundles, modification of the chemical products used for conditioning of the systems and an increase in the pH of the secondary system. Some of these operations must be authorised beforehand, because they imply discharges of some of the products used.

Some chemical cleaning processes are still being tested to confirm that the chemical products utilised are harmless.

Since the 1990s, EDF has been running a programme to replace the SGs with the most severely degraded tube bundles.

The SG replacement campaign for 26 reactors with non-heat treated Inconel 600 alloy tube bundles has been completed. It is continuing with replacement of SGs on the 26 reactors in which the tube bundle is made of heat treated Inconel 600.

## 2.2.4 Assessment of Nuclear Pressure Equipment in operation

### The reactor pressure vessels

ASN issues reports following the inspections made during each ten-yearly outage on the primary systems, the reactor pressure vessels in particular, which undergo numerous checks and a hydro-test during these outages.

During the generic phase of the fourth periodic review of the 900 MWe reactors, EDF justified the in-service strength of the reactor vessels up to their fifth periodic safety review. The generic approach adopted by EDF consists in conservatively considering the mechanical properties of the vessel experiencing the worst-case irradiation embrittlement. EDF carried out fast fracture resistance studies taking account of the changes in the properties of the materials and is carrying out inspections to check there are no prejudicial defects in the steel during the ten-yearly outage of each reactor.

This generic approach was submitted to the Advisory Committee for Nuclear Pressure Equipment (GPESPN) for its opinion on 20 November 2018, 15 October 2019 and 8 September 2020. The GPESPN examination concerned the defects analysed, the estimated irradiation ageing of the metal of the vessel, the thermomechanical analyses, the studies assessing the margins

### THE PRINCIPLES OF THE REACTOR VESSELS IN-SERVICE STRENGTH DEMONSTRATION

The regulations in force require in particular that the licensee:

- identify the operating situations with an impact on the vessel;
- take measures to understand the effect of ageing on the properties of the materials;
- deploy resources to enable it to ensure sufficiently early detection of defects prejudicial to the integrity of the structure;
- eliminate all cracks detected or, if this is impossible, provide appropriate specific justification for retaining such a type of defect as-is.

with respect to fast fracture, the classification of small primary break transients and justification of the level of residual stresses in the circumferential welds of the core shells.

The studies carried out and the additional information provided at the request of GPESPN lead to a favourable conclusion regarding the ability of the reactor pressure vessels to function for a further ten years, subject to the result of the examinations performed on the occasion of the fourth ten-yearly outages of the reactors concerned.

### Cast elbow assemblies

The dossier produced by EDF was examined by ASN with production of an opinion from the GPESPN on 23 May 2019. Following this analysis, ASN sent EDF requests for additional substantiation of the predicted behaviour of the aged material, identification of the flaws present in the cast elbow assemblies, analysis of the fast fracture margins and in-service monitoring of these components.

EDF has provided substantiating documents for certain types of elbow assemblies and the replacement strategy envisaged for others. The situation of certain elbow assemblies it would be hard to replace has led to technical developments in the fields of non-destructive testing. Restoring the mechanical properties of these elbow assemblies via thermal regeneration has been studied in recent months, although no industrial process has yet been determined.

### IN-SERVICE MONITORING DEFICIENCIES CONCERNING THE SELF-BLOCKING DEVICES ON THE MAIN PRIMARY SYSTEM LINES

The self-blocking devices are items placed between the civil engineering anchors and a line or component. These devices are designed to limit unwanted sudden movements. They thus allow slow movements of the secured components, offering no resistance to movement of thermal origin, for example when returning the reactor to service. However, they block accidental rapid movements such as those linked to an earthquake, opening of a valve, or a rupture. The self-blocking devices require regular checks, to ensure that they are in good condition and are not locked

or incorrectly adjusted, which could mean they might not play their role when called on, or degrade the components in normal operation. During an inspection on the Saint-Laurent-des-Eaux site, the ASN inspectors found that the settings of numerous self-blocking devices mounted on the primary system lines were outside the tolerance values, without this having been identified by EDF. ASN then decided to conduct a nationwide review to check whether this equipment was correctly monitored. This revealed

that non-conformities were widespread, with major shortcomings in the monitoring of the self-blocking devices. ASN asked EDF to take the necessary measures to rapidly correct the deviations identified and implement an action plan to improve the monitoring of this equipment. EDF reported a generic significant event as a result of these inspections. In the event of seismic loading or a dynamic transient, these non-conformities could lead to stresses on the components and, in the worst case, a break on the lines concerned.

### Nickel-based alloy zones

In 2018, EDF updated its analysis of the nickel-based alloy zones by reviewing the design, evaluating the risk of initiation of stress corrosion, analysing national and international OEF, reviewing mechanical analyses and safety studies, listing available repair and inspection procedures, and updating its maintenance strategy.

This dossier was examined jointly by ASN and IRSN and then presented to the GPESPN during its session of 26 November 2020.

The update work carried out by EDF is satisfactory. However, EDF must provide greater guarantees regarding the ability of the non-destructive examinations to detect any damage early on, in particular for the vessel bottom head penetrations. On this point, EDF transmitted technical data in response to this request and in particular began to develop a new non-destructive examination which should be in use starting in 2026.

### The Steam Generators

For ASN, the SGs remains a point warranting particular attention in 2022.

The significant fouling levels observed in certain SGs, liable to impair their operating safety, has led to scheduling of a preventive cleaning programme in 2023 and in the subsequent years. Maintenance in order to guarantee a satisfactory level of cleanness has been insufficient in the past and must be a priority. The monitoring strategy for the secondary part of the SGs deployed by EDF was revised in mid-2020 to better prevent these situations.

SG replacement operations are scheduled at the rate of one reactor per year over the coming years, starting in 2024.

The regular perforation of SG tubes, which are the subject of a multi-year inspection and plugging strategy by EDF, confirms the need to adapt the degree of stringency of the in-service monitoring. In addition, the adoption of repairs in a “thimble” tube of an SG of Nogent-sur-Seine reactor 1, following the detection of a boiler effect, illustrates the need for forward planning of the development of repair processes.

### Main Primary System auxiliary lines

Numerous stress corrosion cracks have been discovered, 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. They led to a very large number of destructive assessments and repairs. An inspection and repair programme is scheduled for the coming years (see “Notable events” in the introduction to this report).

## 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 Order of 7 February 2012, setting the general rules concerning Basic Nuclear Installations – BNIs (BNI Order).

Other equipment takes part in the containment function, such as the points of access to the interior of the containment (airlocks

and equipment hatch), the circuit depressurising the annulus between the double-wall containments or the control room ventilation system. Since 2014, EDF has also 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 condition of the equipment and ducts. As necessary, EDF carries out repairs and improvements and adjusts the ventilation flow rates.

### 2.3.2 Assessment of the containments

#### Overall management of the containment function

EDF’s management of the containment function is on the whole relatively satisfactory. ASN however observes occasional but recurring unavailabilities affecting certain equipment participating in the containment function. These unavailabilities notably concern the containment’s leaktightness and monitoring system and the control room ventilation system. These unavailabilities were discussed with EDF in 2022 in order to identify the root causes. These discussions will continue in 2023 in order to verify the pertinence of the measures envisaged by EDF to mitigate these unavailabilities.

EDF launched a national action plan in 2014 to ensure that the ventilation flowrates are compliant with the required safety flowrates, and to make appropriate modifications if necessary. The final phase of this national action plan includes a programme to ensure the lasting nature of the adjustments made. An examination of the pertinence of this programme by ASN is ongoing and will lead to a position statement being issued.

#### 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.

The leaktightness of the Bugey NPP reactor 5 containment was however the subject of particular attention. The containment of this reactor had to be repaired, following damage to the tightness of its metal liner at the lower part of the reactor building, observed in 2015. This containment was tested in 2021 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 prestressing 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.

ASN remains vigilant with regard to changes in the leaktightness of these containments and to maintaining the long-term effectiveness of the coatings.



## 2.4 Risk prevention and management

### 2.4.1 The General Operating Rules

The RGEs cover the operation of nuclear power generating reactors. These are drafted by the licensee and are the operational implementation of the hypotheses and conclusions of the safety assessments constituting the nuclear safety case. They set the limits and conditions for operation of the installation.

Depending on their significance, RGE modifications that could affect safety require either submission of an authorisation application to ASN or notification to ASN before they are implemented.

#### Normal operation

##### Operating Technical Specifications

The Operating Technical Specifications (STE), which are part of the RGEs, define the normal operating conditions based on the facility's design and sizing hypotheses and identify the systems needed to maintain the safety functions, in particular the integrity of the radioactive substances containment barriers and the monitoring of these functions in the event of an incident or accident. They also stipulate the action to be taken in the event of temporary failure of a required system or if a limit is exceeded, situations which constitute "degraded mode" operation.

EDF regularly updates the STEs to incorporate the lessons learned from their application and the modifications made to the reactors. The licensee can amend them temporarily on an *ad hoc* basis, for example to carry out an operation in conditions that differ from those initially considered in the nuclear safety case. The licensee must then demonstrate the relevance of this temporary modification and define adequate compensatory measures to control the associated risks.

#### Periodic tests

The Protection Important Component (PIC) of persons and the environment undergo qualification to guarantee their ability to perform their assigned functions in the situations where they are needed. They must be tested in order to verify the long-term validity of their qualification. The periodic test rules for equipment important for safety are incorporated into the RGEs. They set the nature of the technical checks to be performed, their frequency and the criteria for determining the satisfactory nature of these checks.

#### Core physics tests

The purpose of core physics tests is, on the one hand, to confirm that the core in operation is compliant with the design baseline requirements and the safety case and, on the other, to calibrate the automatic control and protection systems. These tests, prescribed in the RGEs, are performed periodically.

The physics tests at restart are comparable to requalification tests following reloading of the core. The physics tests during a cycle and a cycle extension guarantee the availability and representativeness of the instrumentation as well as the characteristics of the core in operation.

#### Operating rules in the event of an incident or accident

##### Operation in the event of an incident or accident

The RGEs also deal with the reactor operating procedures in an incident or accident situation. They specify the operations to be performed by the shift crew when the reactor experiences an incident or accident situation; these operations aim to restore the reactor to normal operation or, for accident situations, to mitigate the consequences. The control teams are regularly trained in the use of these procedures.

EDF is updating these procedures to take account of experience feedback from incidents and accidents, to correct the anomalies detected during their application or to take account of modifications made to the facilities, in particular those resulting from the periodic safety reviews.

#### Operation in a severe accident situation

Following an incident or 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 unlikely 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. These teams draw on the On-site Emergency Plan (PUI) plus the severe accident intervention guide and the emergency teams action guides in particular.

### 2.4.2 Assessment of reactor operations

ASN checks the content of the RGEs during their examination prior to implementation, and monitors application of the RGEs during inspections.

More broadly, it ensures that the measures planned and taken by EDF for operation of the reactors, are appropriate to the risks created by this operation.

#### Normal operation

During its NPP inspections, ASN notably verifies that the licensee complies with the STEs and, if applicable, the compensatory measures associated with any temporary modifications. It also checks the consistency between the modifications made to the facilities and those made to the documents used by the reactor control teams, such as operational control instructions and alarm sheets. 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 STEs. Finally, it is attentive to the good understanding and good application of these various documents by the control teams and the correct management of sensitive activities, which are often the cause of anomalies.

Failures to comply with the STE 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.

The situations in which the reactors were operated outside the specified limits were fewer in number in 2022 than in 2021. The steps taken by EDF on this subject would appear to paying off.

However, ASN finds that the quality of surveillance in the control room deteriorated in 2022. This situation sometimes led to belated identification of equipment unavailability, which could lead to non-compliance with the STEs.

In addition, the number of significant events linked to system configuration faults reached a noticeably higher level than in 2021. Most of the sites are concerned by this increase. These faults can be caused by failure to comply with procedures or by incomplete procedures. In 2023, ASN will reinforce its inspections on these topics.

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 when RGE modification authorisation applications are submitted. 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 periodic tests were the origin of several significant events. The main causes of these significant events are incorrect specification of the test rules in the operating documents, errors in application of the test rule when performing tests, inconsistent uncertainty values between the operating documents and methodology guides, the use of a test procedure associated with an inappropriate reference document, or periodic test programming errors.

With regard 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.

### The Independent Safety Organisation

During its inspections, ASN examines the actions of the Independent Safety Organisation – FIS (see box opposite) and checks that its opinions are correctly taken into account by the operational departments. The inspectors were able to observe the competence, good working and independence of the FIS in 2022. On several sites, it did however find too few safety engineers in place; EDF must take steps to ensure a sufficient number of safety engineers, so that they can perform their independent verification of reactor safety in optimal conditions.

### 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 2022 on the organisational and technical arrangements made by EDF to deal with an incident and accident situation. These inspections almost always include a situational exercise for the facility's control teams in the room or on a simulator, to check the application of instructions and intervention and communication practices within these teams. In 2022, ASN thus carried out reactive inspections on the sites where the control of the installations had been disrupted by operating contingencies; these inspections aimed to verify compliance with the applicable procedures in the management of these contingencies.

Following these inspections, ASN considered the implementation of the incident or accident operating provisions to be satisfactory. Nonetheless, ASN found that the operating documents still contain errors and imprecisions, despite the considerable work done by EDF's national engineering teams to correct them. ASN will remain attentive to ensuring correct implementation of the processes to verify the operating documents and process the anomalies detected.

### Emergency organisation

When the situation in the facility 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 2022, three NPPs activated their emergency organisation, described in the PUI. In February, the PUI was activated by the Cruas-Meysses NPP following a fire outside the limited access area. In October, the Cattenom NPP activated its PUI following a localised ammonia release on the site. Finally, in November, the PUI was activated by the Gravelines NPP following a fire outside the limited access area. These three situations did not require any population protection measures.

In 2022, six national exercises, notably involving ASN, were held in certain NPPs (Cattenom, Dampierre-en-Burly, Cruas-Meysses, Paluel, Saint-Alban and Flamanville). These were able to test the emergency organisation on these sites, as well as the exchanges with the authorities.

## THE INDEPENDENT SAFETY ORGANISATION

At EDF, the 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 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, in particular the general inspector reporting to the Chairman of the EDF group, assisted by a team of inspectors, represents the highest level of independent verification of nuclear safety within the EDF group.

ASN also carried out several inspections on the emergency organisation and resources, some of which entailed an unannounced situational exercise leading to activation of the site's emergency organisation. These inspections were an opportunity to test the operational nature of the NPPs' emergency organisation on specific topics (resilience of the organisation, equipment used by the teams during emergency situations, documentation, training, etc.). Overall, these exercises and inspections demonstrated that the EDF sites have assimilated the principles of organisation, preparation 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 true professionalism and considerable motivation of the on-call personnel mobilised. However, EDF must continue with its training efforts concerning adoption of the "incremental" method, which should enable it to perform its duties with fewer personnel, as a result of problems with accessing the site following a hazard of extreme intensity. Finally, the through life support for a certain number of emergency rooms and certain resources deployed in an emergency situation must also be reinforced.

### 2.4.3 Maintenance of the facilities

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 equipment important for safety but also 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 a new 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 a new phase of its project to control the volume of maintenance.

Moreover, in response to the ASN request in 2019, EDF submitted an authorisation application at the end of 2021 to add a new chapter to the RGEs, devoted to maintenance.

#### 2.4.4 Assessment of maintenance

Maintenance is an important topic, regularly checked by ASN during its inspections in the NPPs. The organisation employed by the NPPs to carry out large-scale maintenance work was relatively satisfactory in 2022, especially given the impact of the management of stress corrosion on the handling of the outages.

In this respect, ASN's inspections in 2022 found that the various sites did on the whole deploy the maintenance policy changes initiated by EDF as of 2016 (see box below). However, ASN still regularly finds points to be improved, such as addressing various hazards, preparing activities and reinforcing the monitoring of activities entrusted to outside contractors.

The procurement of non-conforming spare parts once again in 2022 led to faults in the management of the activities. Incorrectly applied national EDF documents or incorrect operational documents are also the cause of inappropriate maintenance operations or maintenance quality defects.

Similarly, ASN revealed several anomalies concerning extensive inspection programmes performed for maintenance (self-blocking devices, anchors). These anomalies sometimes led the NPPs to undertake new complete inspection programmes.

Finally, despite an observed improvement in the technical oversight of the work and contractor monitoring between 2019 and 2020, particularly through the use of computer tools recently deployed in the NPPs (see point 2.6.2), there were still numerous significant events arising from maintenance non-quality, undetected by monitoring or by the first level analyses. In this respect, ASN observes that the requalification tests are not always able to detect equipment defects following maintenance or modification work.

In the context of the fourth periodic safety reviews on the reactors, and the “major overhaul” programme, ASN considers that it is important for EDF to continue with its efforts to remedy the difficulties encountered and improve the quality of its maintenance activities.

#### 2.4.5 Protection against internal and external hazards

##### 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 “Defence in Depth” principle built around three levels, that is the design of the facilities, fire prevention 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 spreading to two redundant equipment items performing a fundamental safety function.

Prevention primarily consists in:

- ensuring that the nature and quantity of combustible material in the premises remains below the hypotheses adopted for fire sectorisation;
- identifying and analysing the fire risks in order to take steps such as to avoid them. More specifically, for all the work liable to generate a fire, a “fire permit” must be issued and protective measures taken.

### 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 means 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 refuelling outages can be of several types:

- Refuelling Outage and Maintenance Outage: these outages, which last a few weeks, 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 major operations such as a complete inspection and hydro-testing of the primary system, hydro-testing 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 shutdowns and restarts of pressurised water reactors, the monitoring performed by ASN primarily concerns:

- during the outage preparation phase, the content of the outage

programme drawn up by the licensee. As necessary, ASN may ask for additions to this programme;

- during the outage, through regular briefings and inspections, the implementation of the programme and the handling of any unforeseen circumstances;
- at the end of the outage, the condition of the reactor and its suitability for restart. It is after this inspection that ASN may or may not approve reactor restart;
- after reactor restart, the results of all the tests performed during the outage and in the restart phase.

Since 2020, ASN has reduced the volume of its documentary examinations for reactor outages and has increased its field inspections. These new oversight methods enable ASN's resources to be targeted on the activities with the highest risks and this oversight to be made more efficient.

## CAMPAIGN OF MAINTENANCE-RELATED INSPECTIONS

In 2021 and 2022, ASN ran a campaign of 14 inspections on the organisation of the maintenance departments in the NPPs, in order to check EDF's deployment of its new maintenance strategy.

The inspections revealed an organisation of the departments in charge of maintenance that was on the whole satisfactory, with a good level of deployment of the new tools. This is particularly the case with the performance of the function reviews, which enable each NPP to identify the technical problems – with an integrated vision per function – that could affect equipment and systems, along with the associated areas for improvement, and monitoring of trends, with the aim to be able to detect equipment performance degradation early on.

Finally, the detection of an outbreak of fire and fire-fighting measures should enable a fire to be brought under control and then extinguished within a time compatible with the fire resistance duration of the sectorisation elements.

### 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 facility against explosions.

### 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.).

### External flooding risks

Following the partial flooding of the Blayais NPP in December 1999, the licensees, under the supervision of ASN, reassessed the safety of their facilities in the face of this risk, in conditions that were more severe than before, and made numerous safety improvements, according to a schedule defined according to the risks. In accordance with the ASN requirements, EDF completed the required work on all its nuclear power reactors in 2014.

At the same time, to ensure more exhaustive and more robust integration of the flooding risk, as of the facilities design stage, ASN published Guide No. 13 in 2013 concerning BNI protection against external flooding.

Following the stress tests performed in the wake of the Fukushima Daiichi NPP accident, ASN considered that with regard to flooding protection, the requirements resulting from the complete reassessment carried out following the flooding of the Blayais NPP in 1999 would be able to provide the NPPs with a high level of protection against the external flooding risk. However, ASN issued several resolutions in June 2012 asking the licensees:

- to reinforce NPP protection against certain hazards, such as intense rainfall and earthquake-induced flooding;
- to define and implement a “hardened safety core” of material and organisational measures to control the fundamental safety functions in extreme situations and in particular in the case of flooding beyond the design-basis safety requirements.

### Seismic risks

Although seismic activity in France is moderate or slight, 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 and changes to the regulations, 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 (except for radioactive waste long-term disposal facilities).

This RFS is supplemented by ASN Guide 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 about the methods for assessing the seismic behaviour of elements of the facility. The lessons learned from international experience feedback are also analysed and integrated into this framework.

Following the Fukushima Daiichi NPP accident, ASN asked EDF to define and implement a “hardened safety core” of material and organisational measures to control the fundamental safety functions in extreme situations comparable, in the French context, to that which occurred in Japan on 11 March 2011. This “hardened safety core” shall notably be designed to withstand an earthquake of an exceptional level, exceeding those adopted in the design or periodic safety review of the installations.

In order to define this exceptional level earthquake, ASN asked EDF to supplement the deterministic approach to defining the seismic hazard with a probabilistic approach, in order to take account of international best practices.

### Heatwave and drought risks

During the heat waves in recent decades, 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 OEF and initiated reassessments of the operation of its facilities in air and water temperature conditions more severe than those initially included in the design. In parallel with development of these “extreme heat” baseline safety requirements, EDF initiated the deployment of a number of priority modifications (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.

For the periodic safety review of its reactors, EDF has initiated a modifications programme on its facilities designed to provide protection against heat wave situations. 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 for the other hazards, ASN asks EDF to learn the lessons from the various heatwave events, along with their effects on the installations.

#### Other hazards

The safety case for the EDF NPPs also takes account of other hazards such as high winds, snow, tornados, lightning, cold air temperatures, man-made hazards (transport of dangerous goods, industrial facilities, airplane crashes, etc.), and hazards affecting the heatsink.

#### 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 steps taken to mitigate the risks linked to hazards are regularly inspected by ASN.

The Fukushima Daiichi NPP accident led EDF to reinforce its organisation for the management of risks relating to extreme hazards. More specifically, networks of coordinators were set up for 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 needed on most of the sites to improve how hazard risks are dealt with, in particular with regard to:

- the maintenance of the necessary equipment (sluice gates, fire doors, sensors, floor drains, etc.);
- risk assessments during maintenance operations and in the event an equipment malfunction is detected;
- the compliance with the corrective action deadlines identified by the annual reviews;
- the training of the coordinators and awareness-raising among the EDF and contractor personnel.

#### Fire risks

The fire risks are significant. ASN thus reminded EDF in 2016 that, for the purposes of the fourth periodic safety review of the 900 MWe reactors, it expected a well-structured and robust safety case based on a "Defence in Depth" approach. ASN examined the justification methods produced by EDF, along with the corresponding modifications, and obtained the opinion of the Advisory Committee for Nuclear Reactors (GPR) in 2019. This examination shows that the changes proposed by EDF represented considerable improvements to the fire risk safety case (for example, sectorisation resistance studies, account taken of the effect of smoke). In addition, the new methods adopted identified sectorisation aspects for which correct working is particularly important. For example, the fire doors which are required to be closed were identified and will be subject to specific monitoring. These methods will also be implemented during the fourth periodic safety review of the 1,300 MWe reactors

On the sites, ASN sees no significant change with regard to control of fire risks, with a level that remains lower than that expected. The number of outbreaks of fire and significant fire-related events is slightly down in 2022 by comparison with 2021. Two outbreaks of fire occurred in 2022 outside the limited access areas and led to activation of the PUI on the site concerned.

ASN has observed certain improvements in the management of this risk in the NPPs. However, the tightened inspections campaign (see box next page) shows that improvements are needed for better control of this risk. Fire detection management and personnel training are in general satisfactory and, since the end of 2021, ASN notes that the alarm verification officers in all the NPPs have been working in pairs. EDF also continued with its measures to improve management of the fire risks in the premises identified as being particularly sensitive to this hazard in the light of the potential consequences for safety. However, progress is required in application of the rules in the field.

ASN thus considers that the efforts made by the NPPs to take corrective measures must continue and the personnel must receive greater support in this respect and be given the time needed to perform the required actions.

Finally, further to an ASN request made in 2019, EDF presented ASN in 2022 with the strategy to be deployed as of 2024 regarding the organisation of fire-fighting. Changes are planned with regard to protection equipment, personnel training, but also the links with the *département* level fire and emergency services.

#### Explosion risks

ASN checks the explosion risk prevention and monitoring measures, paying particular attention to ensuring that it is taken into account in EDF's baseline safety requirements and organisation. ASN also ensures compliance with the "EXplosive ATmospheres" (ATEX) regulations to ensure worker protection.

The management of explosion risks is not yet satisfactory for all the sites. Certain maintenance and inspection work required by EDF's internal doctrine is not always carried out satisfactorily, notably with regard to the risks related to the presence of hydrogen in the installations. Furthermore, ASN observes that the integration of OEF and the processing of certain deviations are sometimes postponed and this is not always justified given the potential safety consequences. During inspections, ASN is particularly vigilant with regard to the inspections and corrective measures taken by EDF to guarantee the compatibility of the electrical equipment with use in rooms where an explosive atmosphere is liable to form. The management of the gas storage yards is also the subject of particularly close attention during the inspections.

ASN notes the efforts made by EDF to reduce these deviations, notably through the implementation of reinforced monitoring and the deployment of action plans leading to equipment replacement. ASN considers that EDF must continue to pay particular attention to this subject and ensure that the explosion risk prevention approach is implemented with all necessary rigour on all the sites.

#### Internal flooding risks

In 2019, ASN asked EDF to supplement its approach in order to better control the internal flooding risk, ensure correct operation of the floor drains, reinforce its 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.

Finally, for the fourth periodic safety review of the 900 MWe and 1,300 MWe reactors, EDF has updated its safety case regarding



internal flooding risks, notably by considering several possible water flow routes, and has defined additional provisions to mitigate the risks. In 2022, ASN examined the new methodology proposed and asked EDF for adjustments.

#### Seismic risks

The inspection programmes implemented by EDF lead it to regularly report significant safety events 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 (Ardèche *département*). It led EDF to implement the operating procedure required in the event of an earthquake on the Cruas-Meysses NPP. This was because the seismic motion detected on this site reached the level requiring shutdown of the reactors so that checks could be carried out. An inspection programme was then defined and carried out before the reactors were restarted. 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 field investigations, EDF defined a new design response spectrum for the Cruas-Meysses site.

This spectrum will be used to initiate the seismic re-evaluation studies associated with the fourth periodic safety review of this 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.

#### 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, which led to corrective action requests.

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 is to confirm the qualification demonstration of this equipment.

During the heatwaves of the summer of 2022 (see "Notable events" in the introduction to this report), the maximum temperatures recorded on the sites did not reach the temperatures considered in the safety case. In the same way as during the previous heatwave episodes, ASN asked EDF to produce OEF.

#### 2.4.7 Monitoring facilities compliance 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 OEF, 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.

### INSPECTION CAMPAIGN ON THE CONTROL OF FIRE RISKS

In 2022, ASN completed the campaign of in-depth inspections on the control of fire risks, which began in 2021.

These inspections notably concerned the monitoring and control of sectorisation and the fire loads and fire-fighting resources. For some of the NPPs, these inspections were accompanied by a situational exercise involving the response teams.

ASN made improvement requests for the management of equipment temporary storage sites and warehouses, which have significant calorific potential, as well as for detection and rapid handling of sectorisation anomalies. EDF must also improve the condition of the fire-fighting means, notably the fire hydrants and associated water networks.

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 persons 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 deviations already known, 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 persons and the environment for the coming production cycle.

#### Ten-yearly verifications: conformity checks

EDF carries out periodic safety reviews of the nuclear reactors every ten years, in accordance with the regulations (see point 2.9.2). 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 the parts of the facility which are not covered by a 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, with regard 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.

#### Information of ASN and the public

When a deviation is detected, and in the same way as any BNI licensee, EDF is required to assess the impacts on nuclear safety, radiation protection and protection of the environment. If necessary, EDF then sends ASN a significant event notification report. In addition, when the most noteworthy significant events occur, EDF informs the public by publishing notices on the website of the NPPs concerned, or in its external newsletter.



For its part, ASN informs the public on *asn.fr* of significant events rated level 1 or more on the INES scale (International Nuclear and Radiological Event Scale, graded from 0 to 7 in increasing order of severity).

#### ASN requirements concerning repairs

ASN published its Guide No. 21 on 6 January 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 principle of proportionality. 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.

#### 2.4.8 Assessment of facilities compliance with the applicable requirements

In the past, ASN has found that the organisational measures taken by EDF to deal with deviations were unsatisfactory 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 proportional to the safety implications. In 2022, ASN observed that the steps taken by EDF enabled the deviations to be corrected within the required time in most situations. 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 2022 following the detection of conformity deviations; some of these deviations date back to the construction of the reactors, while others arose when making modifications to or performing maintenance on the facilities.

ASN will continue to be particularly attentive to the conformity of the facilities in 2023 and will in this respect continue its inspections of the condition of equipment and systems.

ASN observes that certain systems linked to the "support", "reactivity control" and "cooling" safety functions are subject to recurring unscheduled unavailability, in the same way as in 2020 and 2021. This is notably the case with the reactor component cooling systems, post-accident monitoring, reactor nuclear power measurement and rod cluster control, or the 48V direct current electrical production and distribution systems.

Discussions with EDF will continue in 2023 in order to identify the root causes of the unavailability of these systems and check the pertinence of the measures envisaged by EDF to reduce their number.

#### Notification of significant events by EDF

Pursuant to the rules for the notification of significant events (see chapter 3, point 3.3), ASN received 687 Significant Safety Event (ESS) reports from EDF in 2022, along with 136 Significant Radiation Protection Event (ESR) reports and 56 Significant Environmental Protection Event (ESE) reports. The number of significant events fell by about 9.7 % in 2022 by comparison with the previous year, in particular the ESS (746 in 2019, 740 in 2020, 762 in 2021).

Graph 1 shows the trend since 2012 in the number of significant events reported by EDF and rated on the INES scale.

### REINFORCED OVERSIGHT OF SUPPLIERS OF EQUIPMENT IMPORTANT FOR NUCLEAR SAFETY

In 2022, ASN continued to reinforce its oversight of the EDF procurement chain for equipment important for safety intended for NPPs. In 2022, ASN therefore carried out 48 inspections, most of them in manufacturing plants.

During these inspections, ASN examined compliance with the regulatory requirements during manufacturing operations, the ability of the suppliers to manufacture equipment meeting the safety requirements and how the risk of fraud is addressed. ASN also checked EDF's monitoring of its suppliers and their subcontractors. ASN also inspected the purchasing process put into place by EDF, to ensure that the safety issues are correctly addressed when EDF places contracts with its suppliers, as well as throughout the execution of the contracts.

Finally, in 2022, ASN continued to exchange with its counterparts on the subject of supply chains, notably within the Committee on Nuclear Regulatory Activities (CNRA), which offers a forum for sharing the conclusions of the inspections performed in the various factories around the world.

Graph 2 shows the trend since 2012 in the number of significant events according to the notification field: ESS, ESR and ESE. Events not rated on the INES scale are also taken into account.

Significant events affecting several nuclear reactors are grouped under the term generic significant events. In 2022, 21 events of this type were reported in the field of nuclear safety (29 in 2019, 26 in 2020, 31 in 2021).

## 2.5 Prevention and management of environmental and health impacts and non-radiological risks

### 2.5.1 Discharges, waste management and health impacts

#### Limiting water intake and environmental discharges

NPPs discharge liquid and gaseous effluents. These effluents, which can be radioactive or chemical, are created by the actual operation of the reactor, primarily the operations designed to ensure the radiochemical quality of the MPS system, the chemical conditioning of the systems in order to contribute to their good condition, the production of demineralised water to supply certain systems, biocidal treatments and effluents from the site's wastewater treatment plant.

For each site, ASN sets the limit values for water intake and discharge of effluents on the basis of the best available technologies in technically and economically acceptable conditions, taking into consideration the characteristics of the installation, its location and the local environmental conditions.

ASN also sets the rules concerning the management of detrimental effects and the impact on health and the environment of the reactors. These requirements 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 setting these requirements, ASN uses OEF from all the reactors as the basis, while also taking account of operational changes (change in conditioning of systems, anti-scaling treatment, biocidal treatment, etc.) and changes to the general regulations.

In 2022, the resolutions governing the intake, consumption of water and discharges into the environment and the limits on effluent discharges from the Bugey and Dampierre-en-Burly NPPs were updated by ASN.

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 may have, and any significant events which have occurred.

**The impact of thermal discharges from the NPPs**

NPPs discharge hot 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. Thermal discharges from NPPs lead to a temperature rise between the points upstream and downstream of the discharge which,

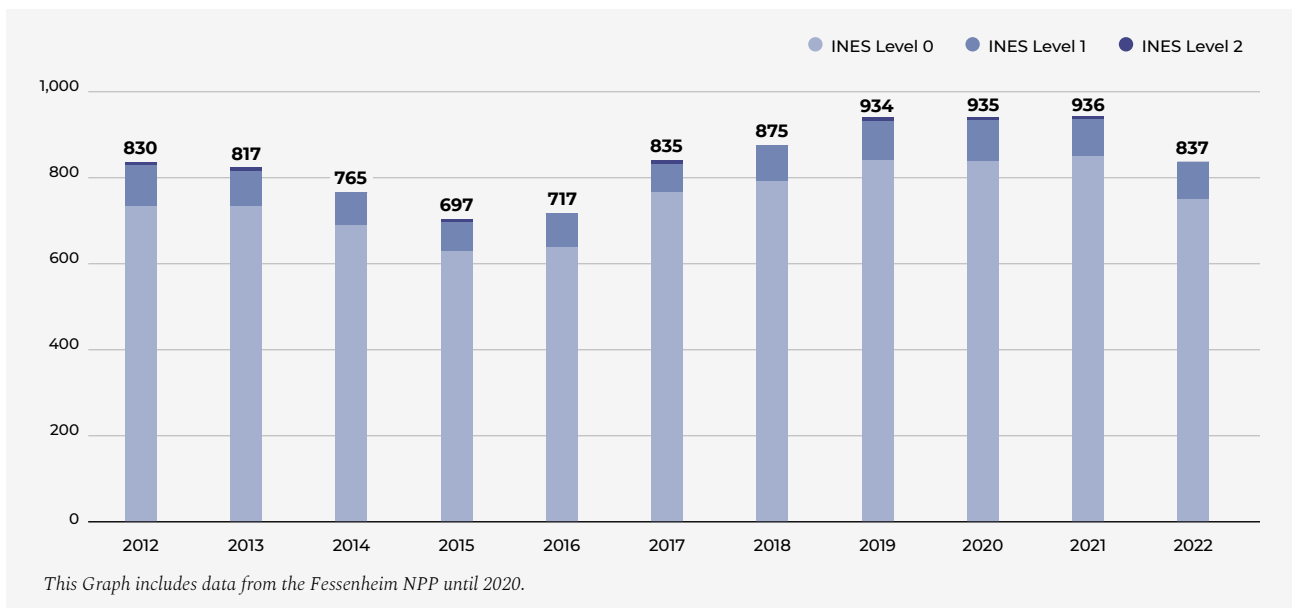
depending on the reactors, can range from a few tenths of a degree to several degrees. These thermal discharges are regulated by ASN resolutions.

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 watercourse. These special provisions are however only applicable if the security of the electricity grid is at stake.

**Waste management**

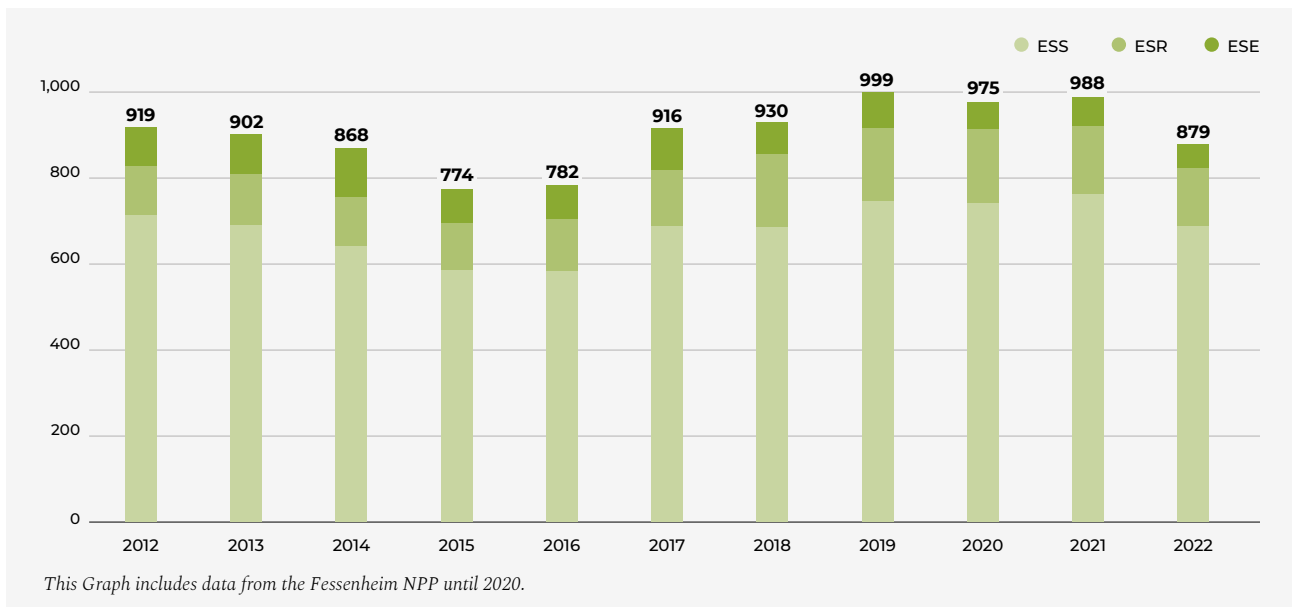
In compliance with the provisions of the Environment Code, EDF carries out waste sorting at source, differentiating in particular between waste from nuclear zones and other waste. For each installation, EDF produces a summary of the management of this waste, in particular presenting a description of the operations which are the cause of production of the waste, the characteristics

**GRAPH 1** Trend in the number of significant events rated on the INES scale in the EDF Nuclear Power Plants between 2012 and 2022



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**GRAPH 2** Trend in the number of significant events by domain in the EDF Nuclear Power Plants between 2012 and 2022



### CAMPAIGN OF INSPECTIONS ON THE ULTIMATE BACK-UP DIESEL GENERATOR SETS

The “Ultimate back-up” DUS are electrical power sources installed in response to the technical prescriptions issued by ASN following the accident at the Fukushima Daiichi NPP. Their role is to provide electricity to the “hardened safety core” systems, enabling the basic safety functions to be controlled in extreme situations.

The inspections performed by ASN show that operator training and familiarisation with this new equipment could be improved.

The commissioning of the DUS was also marked by the outbreak of fire on some of the DUS for the 1,300 MWe reactors. Following these outbreaks of fire, EDF defined an action plan to remedy these situations. The provisions of this action plan are being examined and closely monitored by ASN, which will continue in 2023.

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 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 system.

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.

#### 2.5.2 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 all the accidents which can arise from the release of hazard potentials not specific to the nuclear activity, insofar as they not concern radioactive substances. These hazard potentials, which can also be present in other industries such as Installations Classified for Protection of the Environment (ICPEs), are associated with storage facilities and processes using gaseous or liquid chemical substances.

Through a specific study, known as the non-radiological risks assessment, these non-radiological accidents are taken into account in the nuclear safety case in accordance with the provisions of Title III of the Order of 7 February 2012. This study is drawn up, pursuant to II of Article 3.7 of the Order of 7 February 2012, with the methodology applicable to ICPEs. The purpose of this study is to justify the thermal, toxic, missile 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 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 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 CLP (Classification, Labelling, Packaging) 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, soil).

For several years and at the request of ASN, EDF has 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.

#### 2.5.3 Assessment of control of environmental and health impacts and non-radiological hazards

ASN monitors the organisational and material measures put into place by EDF, on the one hand to prevent non-radiological risks and liquid pollution resulting from the dangerous substances present in its installations, and on the other, to guarantee control of the detrimental effects arising from the operation of the installations, such as water intake, effluent discharge into the natural environment, and waste. As each year, ASN carried out inspections on these measures in 2022: Two inspection campaigns – described in detail below – were in particular carried out.

ASN also conducted a campaign of inspections on seven NPPs with regard to the organisation adopted for the management of non-radiological risks. During these inspections, which were primarily focused on field inspections, ASN carried out unannounced situational exercises to check the licensee’s organisation in the event of a non-radiological accident which could be the cause of potential effects off the site. These inspections revealed the fact that although these NPPs do have an organisation and resources to deal with non-radiological accident scenarios, this organisation could be improved. These inspections were thus able to identify areas for improvement, such as updating of the operational documentation relative to the organisation to be implemented in the event of a non-radiological accident, or reinforcement of the specific material and organisational

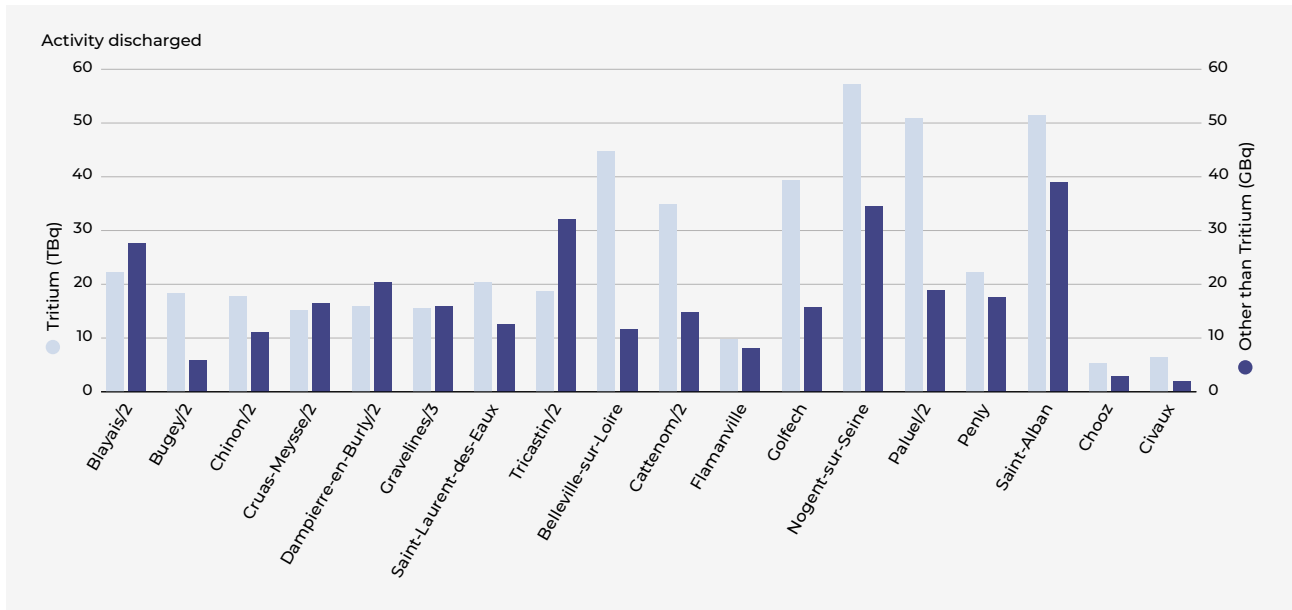
measures for preventing or limiting the effects of these accidents. ASN will monitor the implementation of these improvements, notably required during the periodic safety reviews of the NPPs.

ASN also carried out a campaign of tightened inspections on the Bugey, Nogent-sur-Seine and Tricastin NPPs, which are currently engaged in the periodic safety review of one of their reactors. The inspectors therefore carried out conformity inspections, including in the field, and inspections to reassess the provisions for controlling the detrimental effects created by the installation. This campaign shows that, even if the general organisation implemented by the NPPs concerned is satisfactory, improvements are still required on assimilation of OEF and analysis of the best available techniques.

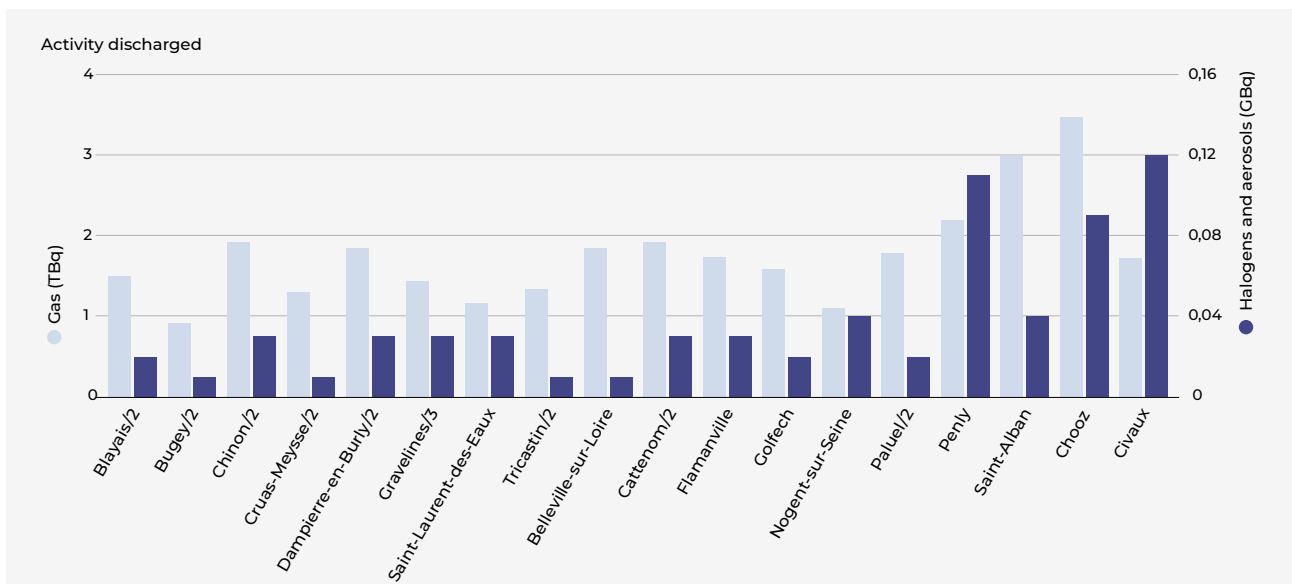
This campaign will be carried over into 2023 on three other NPPs. The lessons learned from these campaigns are exploited in the reactor periodic safety reviews.

With regard to waste management, the inspections carried out by ASN reveal that operational management of waste needs to be further improved. During its inspections, ASN finds non-conforming signage and cases of non-compliance with the operating baseline requirements, notably regarding storage durations, inventory keeping and traceability.

GRAPH 3 Liquid radioactive discharges for the NPPs in 2022 (per pair of reactors)



GRAPH 4 Gaseous radioactive discharges for the NPPs in 2022 (per pair of reactors)



As there can be a different number of reactors on each site, the results are given "per pair of reactors", to enable a comparison to be made from one site to another. This for example entails: keeping the results as they are for the Golfech site, which has two reactors; dividing by two those of Chinon, which has four reactors (Chinon/2); dividing by three those of Gravelines, which has six reactors (Gravelines/3). Moreover, the discharge data for each site, sent to ASN by EDF, are not representative of the operating time of the facilities or activities.

In 2022, as in previous years, ASN observed that discharges are well managed on most of the sites. However, certain events are indicative of isolated weaknesses reflecting operating defects in certain equipment such as the oil removers.

Finally, the exceptional heatwave episodes in the summer of 2022 led to the warming of some of the watercourses used to cool the NPPs. To guarantee the security of the electricity grid and save the natural gas reserves and the water in the hydroelectric dams, ASN temporarily modified its prescriptions relating to thermal discharges from the Blayais, Bugey, Golfech, Saint-Alban and Tricastin NPPs (see “Notable events” in the introduction to this report).

## 2.6 The contribution of man and organisations to safety

The contribution of people and organisations to the safety of NPPs is a decisive factor in all steps of the plant lifecycle (design, construction, commissioning, operation, decommissioning).

### 2.6.1 The operation of organisations

#### The Integrated Management System

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 the protection of interests 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.

#### Management of subcontracted activities

Maintenance and modification activities on the reactors are to a large extent subcontracted by EDF to outside contractors. EDF justifies the use of subcontracting by the need to call on 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 carry out its responsibility as licensee with regard to the protection of persons 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.

### 2.6.2 Assessment of the operation of the organisations and control of activities

ASN focuses on the conditions which are favourable or prejudicial to the contribution to NPP safety by the operators and worker groups. It defines the Human and Organisational Factors (HOF) as being all the aspects of working situations and the organisation which will have an influence on the work done by the operators.

ASN oversight of the working of the organisations set up by EDF aims to check the IMS implementation procedures. More specifically, ASN ensures that the design or modification approaches implemented by the engineering centres at the moment of the design of a new facility or modification of an existing one take

account of the needs of the users and organisations that will be operating it.

More broadly, ASN monitors the organisation put into place by EDF to manage the resources needed to perform these activities.

The comments expressed during the inspections are the subject of requests for improvement actions.

#### The overall organisation

The organisation set up by EDF to control risks is on the whole satisfactory but could still be improved in a few NPPs. Maintenance and operational non-quality remained at a high level, despite a larger number of reactor outages in 2022, and some of them were the cause of significant events. The inspections and event analyses carried out by ASN notably reveal a significant uptick in deviations during lock-out and line connection activities. Certain weak points in the organisational provisions, notably inadequately managed scheduling, do not enable absolute priority to be given to the activity preparation phases, which leads to programming errors, failures in the risk assessments performed upstream or insufficient assimilation of OEF. The ASN inspections highlight improvements in the performance of the pre-job briefings, by comparison with 2021. The involvement of the first-line managers on this subject would appear to be producing tangible results.

During its inspection campaign (see box page 307), ASN encountered difficulties with the distribution of roles and with communications within the control teams. ASN also notes that there are still coordination problems with the other disciplines and project teams. With regard to maintenance activities, problems of coordination between the various departments were found on a number of sites, with under-performing organisations for the management of several activities at the same time.

The NPPs were able to implement an efficient organisation for forward planning of the deployment of the modifications associated with the fourth periodic safety review of the 900 MWe reactors, with the adoption of extensive supporting information work and an oversight body for integration of the modifications.

Finally, in 2022, the organisational and professional practices changes that EDF had adopted during the acute phases of the Covid-19 pandemic were terminated. However, OEF from implementation of these changes was initiated by EDF and will continue in 2023.

#### Skills management

Skills management among the control teams was the subject of an inspection campaign in 2022 (see box page 307). With regard to the maintenance activities, ASN is continuing to find that the explicit underlying cause is errors in tutoring and training and therefore ultimately insufficient skills, which notably manifests itself in an inadequate perception of the safety issues by the parties involved.

Finally, ASN also observes a persistent lack of tutoring and training in 2022, with regard to material modifications to the installations. These shortcomings can be attributed to various organisational failures (lack of resources, insufficient forward planning for training, lack of coordination between the disciplines during the final phase of deployment of a modification, etc.).

#### Management of subcontracted activities

ASN checks the conditions surrounding the preparation for (schedule, required human 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 were observed in 2022 in the field of subcontracted activities quality control, notably through the use of a new tool used to monitor the contractors. 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.).

ASN's inspections also show a very positive move within the NPPs to improve the skills of the contractors and tangible measures such as the increase in the provision of spaces for preparation work on a mock-up.

#### Management of operational documentation

As in 2021, the significant event reports regularly point the finger at insufficient documentation quality. This is an underlying problem which has been a recurring one for a number of years. The difficulties identified are of various types (documentation not concise enough, not explicit, incomplete, or even non-existent). This has consequences for a wide range of activities, including control activities (periodic tests, lock-outs and administrative closures, line connections) and maintenance work (technical inspections, maintenance work on equipment, requalifications, local control actions).

These documentation deviations remain to a large extent related to organisational malfunctions in the documentation creation and update process and they potentially compromise the documentary support line of defence.

#### The Operating Experience Feedback process

The quality and availability of the human resources assigned to the in-depth analyses of significant events are satisfactory on all the sites. The involvement of HOF skills in the analysis phase is tending to improve on most sites, which is a very positive point.

ASN however finds that EDF often limits its analysis to the situations and systems involved in the events and does not learn the lessons adequately with respect to similar situations or systems. Moreover, reports presenting criteria for measuring the effectiveness and the conditions for closure of the proposed corrective measures are still rare.

## 2.7 Personnel radiation protection

### 2.7.1 Exposure of personnel 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,  $\alpha$ ,  $\beta$  and  $\gamma$ ), with a risk of internal and external exposure. In practice, more than 90% of the doses received come from external exposure to  $\beta$  and  $\gamma$  radiation. Exposure is primarily linked to maintenance operations during reactor outages.

Despite a year 2022 marked by the work concerning the stress corrosion problem, the average collective dosimetry on all the reactors (see Graph 5), and the average dose received by the workers for one hour of work in the limited access area (see Graph 6) was down in 2022 by comparison with 2021.

Graph 7 shows the breakdown of the workers according to whole body external dosimetry. In 2022, the share of workers for whom the dosimetry was below one millisievert (mSv) rose slightly (77% in 2021 as against 75% in 2021). The annual regulation limit for whole body external dosimetry (20 mSv) was exceeded on no occasion in 2022.

Graph 8 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, the most exposed workers are the personnel responsible for heat insulation, for whom the average individual dose rose in 2022.

The other categories of disciplines most exposed also remain unchanged: welders, personnel in charge of inspection, mechanical and ancillary activities. For these latter discipline categories, the average individual dose however fell in 2022.

#### Significant contamination events

EDF reported six significant contamination events concerning workers in the NPPs in 2022.

For the workers concerned, these events led to exposure to a level higher than one quarter of the annual regulation limit per square centimetre of skin, and were rated level 1 on the INES scale. Unlike in 2021, no event led to exposure higher than the regulation limit for the skin.

The workers concerned by these events were given care and the radioactive particles responsible for their contamination were removed, in accordance with the procedure applied by EDF.

### 2.7.2 Assessment of personnel 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 during inspections once or twice per year and per NPP, specifically on the topic of radiation protection, or during reactor outages, as well as following significant events, or more occasionally in the EDF head office departments and engineering centres. It is also carried out during examination of the worker radiation protection files (significant event reports, design, maintenance or modification files, documents implementing the regulations and produced by EDF, etc.).

During inspections carried out in 2022, ASN found progress in the prevention of dissemination of radioactive contamination outside the installations. ASN also examined the procedures for treatment of contaminated personnel, in order to check that the time taken to initiate treatment enables the exposure time of the workers to be reduced. On several inspected sites, this subject was considered to be satisfactory.

Nonetheless, during inspections on worksites in limited access areas, the ASN inspectors continue to observe faults in the implementation of containment resources. In addition, the inspection findings and several significant events reported show difficulties with managing the processes involved in industrial radiography work and in access to the operations area. ASN will be remaining vigilant on these issues during the course of 2023.

### 2.7.3 The organisation of radiation protection in the Nuclear Power Plants

The Order of 28 June 2021 relative to the radiation protection expertise centres requires that as of 2 January 2022, the NPP "Radiation Protection Adviser" duties of the licensees of NPPs and of the employer are no longer performed by the "Radiation Protection Expert-Officer" (RPE-O) but by the radiation protection expertise centres mentioned by the Environment Code and the Labour Code. These centres comprise persons with the skills and qualifications needed to provide advice and support on subjects concerning protection of the population and the environment from ionising radiation, as well as worker radiation protection.

The Order also states that these centres require ASN approval by 2 January 2023. Pending this approval, the EDF NPPs had set up provisional expertise centres during the course of 2022.

During ASN's examination of the organisation of the expertise centres set up by EDF, specific inspections were performed on all the NPPs during the course of 2022. Following these inspections and based on the OEF from the operation of the provisional centres, ASN considered that the radiation protection organisation put into place is able to meet the regulatory requirements of the Order of 28 June 2021, which led to the approval of the expertise centres for all the NPPs.

## 2.8 Labour Law in the Nuclear Power Plants

### 2.8.1 Oversight of Labour Law in the Nuclear Power Plants

ASN is responsible for labour inspectorate duties in the 18 NPPs, the EPR reactor under construction at Flamanville and 11 other installations, most of which are reactors undergoing decommissioning. 800 to 1,400 EDF employees work in each NPP consisting of two to four reactors, and nearly 2,000 EDF employees in the Gravelines NPP, which has six reactors. About 23,000 EDF employees and 10,000 employees from permanent 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.

### Oversight of occupational health and safety regulations

Following on from the action taken in 2021, the labour inspectors carried out checks in all the NPPs on the exhaustiveness of the verifications of the electrical installations EDF is required to perform in accordance with the Labour Code.

In addition, in 2022 ASN extended its checks to the field of electrical lock-outs prior to maintenance work on equipment, as well as to the regulations applicable to measures to prevent asbestos-related risks during work on the installations.

In 2022, the labour inspectors therefore monitored and checked the worksites being carried out in the NPPs, notably during reactor outages and the removal and reinstallation of sections of auxiliary piping affected by stress corrosion, in particular as relating to the waivers requested by the employers with regard to the maximum working times and the safety of workers during maintenance operations.

At the same time, monitoring continued on worksites with risks relating to the non-conformity of the work equipment and more specially of lifting gear.

Finally, the labour inspectors followed up events relating to occupational safety which occurred on the sites, systematically opening inquiries in the event of serious accidents or "near accidents". They were also called on to deal with subjects relating to psychosocial and working hours risks.

### CAMPAIGN OF INSPECTIONS ON THE SKILLS AND TRAINING OF THE TEAMS IN CHARGE OF REACTOR OPERATION

Following a number of significant events directly implicating the competence of the teams in charge of reactor operations, ASN conducted inspections in 2021 on the EDF head office departments, to check how the national training programme for these teams is drawn up.

Following these inspections, ASN decided to conduct an inspection campaign in 2022 in all the NPPs, with the aim of checking the local adoption of the national skills management process, along with concrete implementation in the field. The inspectors carried out situational exercises, on a control simulator, and at the same time held a series of explanatory interviews with the control staff and skills management players.

During the situational exercises on the simulator, the control teams were faced with scenarios built around recent unforeseen technical events which occurred in the EDF NPPs. The inspectors verified the ability of the teams to run the installation in compliance with the baseline safety requirements.

Following this campaign of inspections, ASN considers that the skills management process for the control



staff is well applied in most of the NPPs. However, its correct implementation depends directly on the organisation adopted by each NPP and the human and material resources devoted to it. The inspectors were in particular able to see too few training personnel in certain NPP, vacant training correspondent positions or insufficient equipment in the training spaces. In addition, identification of the training needs could be improved in certain NPPs and the effectiveness of the

training is on the whole insufficiently measured.

Moreover, during the situational exercises on the simulator, ASN sometimes observed a lack of communication within the control teams, insufficient implementation of certain practices to reduce errors and problems with the distribution of roles within the teams.

After each of these inspections ASN sent improvement requests to EDF.

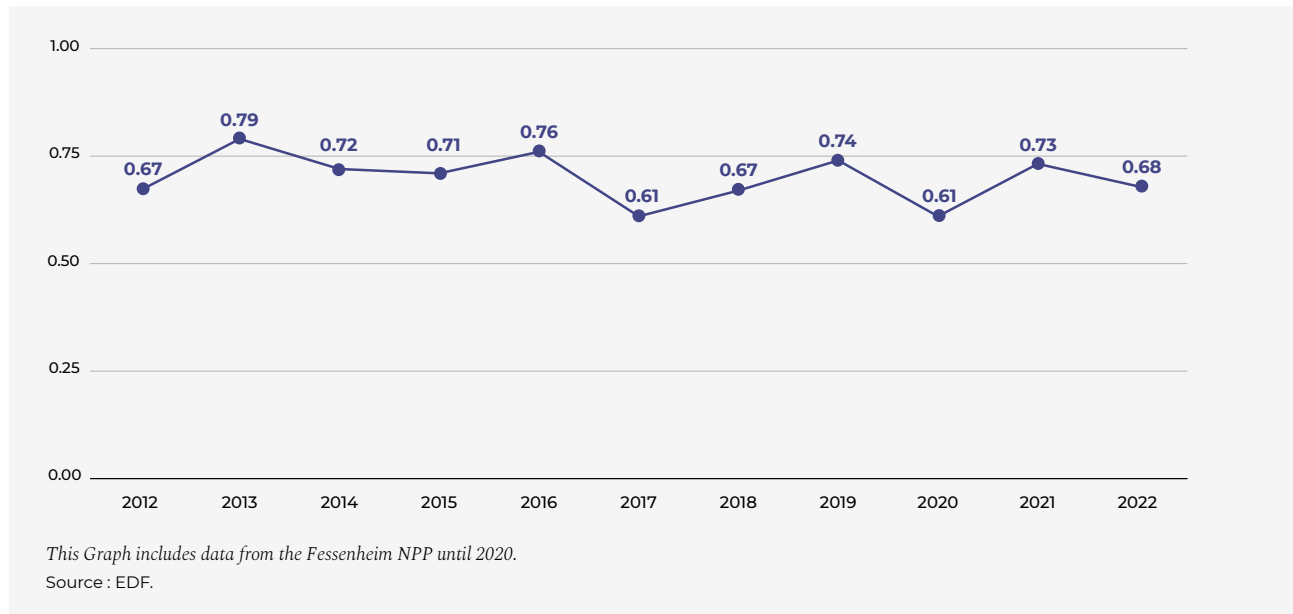
## 2.8.2 Assessment of health and safety, professional relations and quality of employment in the Nuclear Power Plants

Certain occupational risk situations, such as those relating to work equipment (lifting gear in particular), exposure to asbestos, or electrical risks, must be improved further. In addition, the various inspections carried out by the labour inspectors brought to light weaknesses in the organisation on the sites for the correct performance of electrical checks or for coordination of these checks between the various EDF entities. In 2023, ASN will continue its oversight of these fields.

In 2022, the social climate deteriorated, notably within the outside contractors, leading the labour inspectorate to intervene in the settlement of disputes, whether individual or collective. The NPPs were also affected by local labour movements in response to the calls from national trades union organisations, notably driven by requests for increased wages.

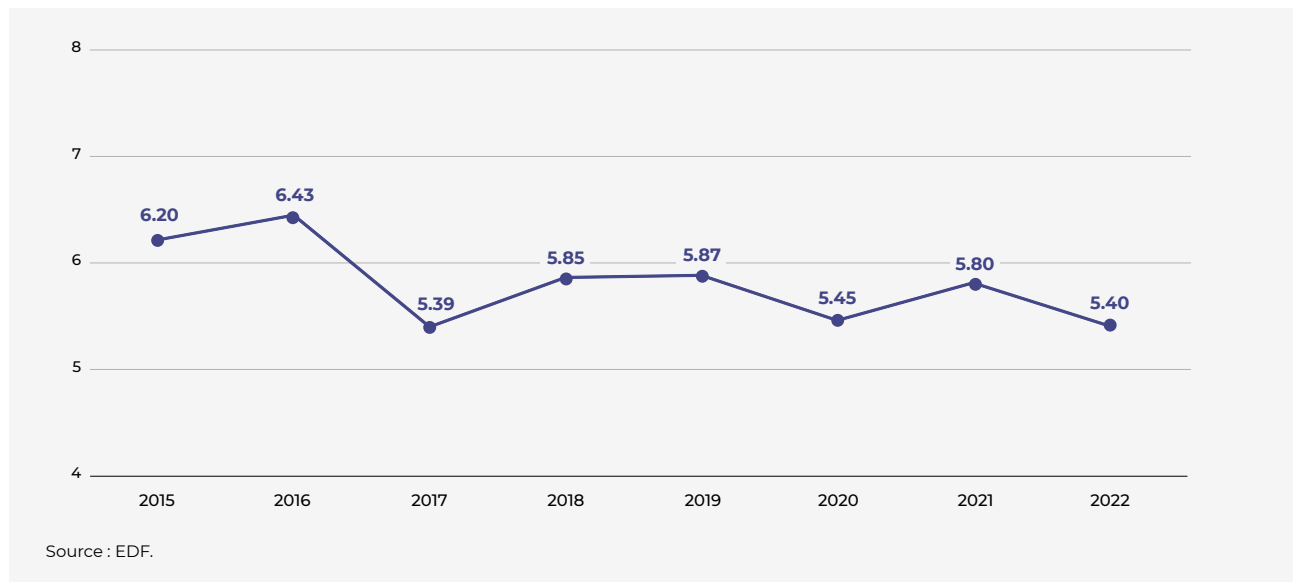
ASN observes that the total number of occupational accidents in the NPPs, affecting EDF employees and the employees of outside contractors, is up in 2022. However, the number of accidents with time lost is down by comparison with 2021. 63% of the accidents concern outside contractors. More than half of the “near accidents” concern critical risks: 21% concern lifting operations, 18% electrical risks and 14% falls from height. Moreover, the labour inspectors observe numerous “near accidents”, with an analysis of the causes revealing errors in risk assessment, problems with understanding the risks, or a lack of expertise in equipment electrical lock-outs. Progress is still required in 2023 in the field of joint contractor management (quality of prevention plans in particular) and the use of subcontracting. Work by outside contractors in the NPPs will be given particularly close attention by the ASN labour inspectors in 2023.

GRAPH 5 Mean collective dose per reactor (Man.Sv/reactor)



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GRAPH 6 Collective dose for one hour of work in a controlled area (in µSv)



The labour inspectors also issued reminders regarding work on 1 May and compliance with maximum working hours. In 2022, an administrative enforcement procedure on maximum working hours problems was initiated by a labour inspector and sent to the regional directorate for the economy, employment, labour and solidarity, which has competence for issuing penalties.

Finally, a labour inspector was requisitioned on two occasions by the Public Prosecutor's Office. He thus took part with the judicial police officers in an inquiry following occupational accidents.

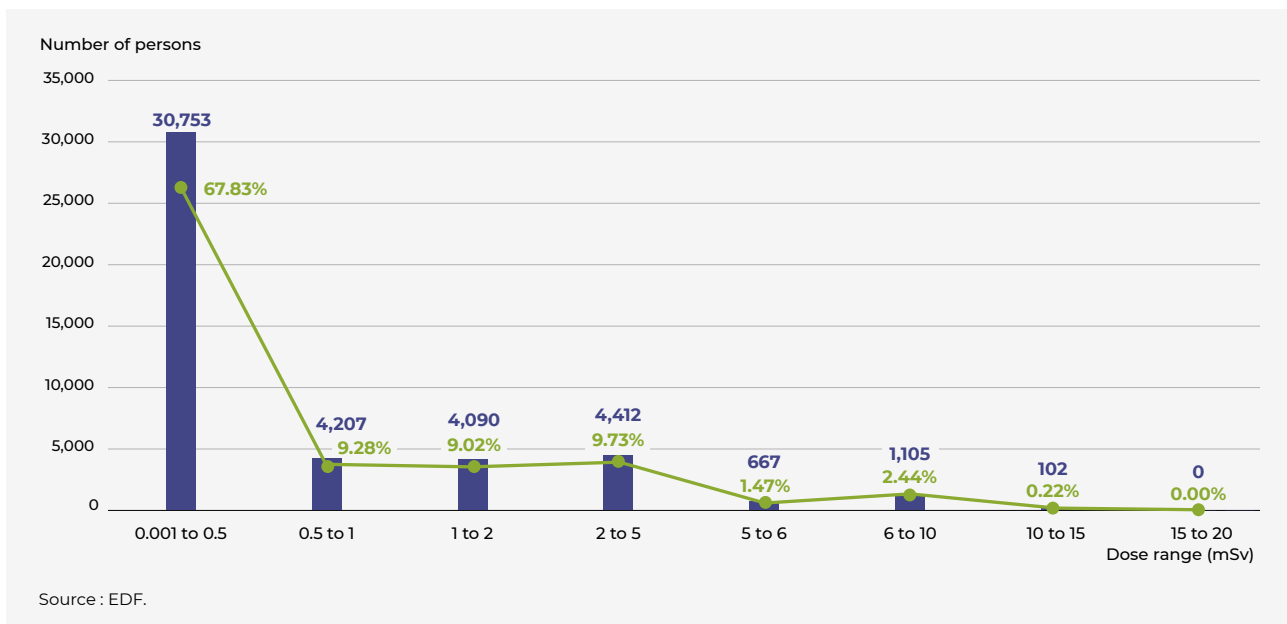
## 2.9 Continued operation of the Nuclear Power Plants

### 2.9.1 The age of Nuclear Power Plants

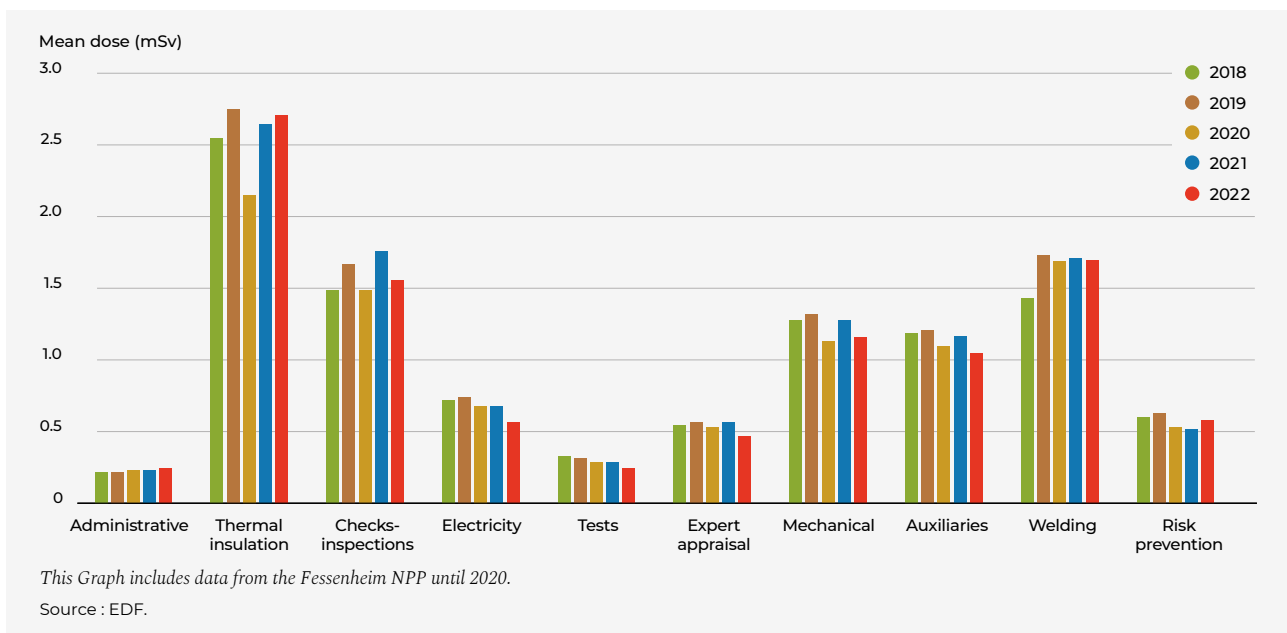
The NPPs currently in service in France were built over a relatively short period of time: 45 nuclear power reactors representing nearly 50,000 MWe, or three-quarters of the power output by all the French nuclear power reactors, were commissioned between 1980 and 1990, and seven reactors, representing 10,000 MWe, between 1991 and 2000. In December 2022, the average age of the 56 reactors in operation, calculated from the dates of first divergence, can be broken down as follows:

- 40 years for the 32 nuclear power reactors of 900 MWe;
- 35 years for the 20 nuclear power reactors of 1,300 MWe;
- 25 years for the four nuclear power reactors of 1,450 MWe.

GRAPH 7 Number and percentage of workers per dose range (in mSv) for 2022



GRAPH 8 Trend in mean individual dosimetry according to the categories of trades of the workers in the NPPs





### CAMPAIGN OF IN-DEPTH RADIATION PROTECTION INSPECTIONS

Every year, ASN runs a campaign of in-depth inspections on the topic of radiation protection in several EDF NPPs. These campaigns are a means of identifying good practices and points needing improvement that could potentially be transposed to all the NPPs.

The 2022 campaign was held in the Gravelines, Flamanville and Paluel NPPs and concerned the organisation and management of radiation protection, control of worksites in controlled areas, notably during radiography work, application of the Optimisation Principle, control of the risk of the dissemination of contamination within installations and management of radioactive sources. The inspections focused primarily on field checks and measurements. The inspectors also carried out situational exercises for treating contaminated persons.

The inspectors found a good general organisation, but also observed the unsatisfactory state of a number of premises (site laundries, zones used to extract contaminated equipment, etc.) in terms of control of worker radiation protection and radiological cleanliness. They also noted that not all the sites inspected showed the required level regarding the applicable requirements in terms of marking out and signage of radiographic inspection worksites.

After each of these inspections ASN sent improvement requests to EDF.



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## 2.9.2 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, as well as 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 generic studies programme for a given type of reactor (900 MWe, 1,300 MWe or 1,450 MWe reactors). The results of this programme are then applied to each nuclear power reactor 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 installation 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 assessment 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 the periodic safety review concluding report for each reactor, ASN communicates its analysis to the Ministry responsible for nuclear safety. It can issue new requirements governing its continued operation.

The Energy Transition for Green Growth Act 2015-992 of 17 August 2015 supplemented the framework applicable to the periodic safety reviews on nuclear power reactors. It more specifically requires ASN authorisation, following a public inquiry, of the provisions proposed by the licensee during the periodic safety reviews beyond the 35th year of operation of a nuclear power reactor. Five years after submitting the periodic safety review report, the licensee also submits an interim report on the condition of these equipment items, in the light of which ASN may supplement its prescriptions.

## 2.9.3 Ongoing periodic safety reviews in the Nuclear Power Plants

### The fourth periodic safety review

#### A high-stakes review

EDF's 32 reactors of 900 MWe in operation were commissioned between 1978 and 1987. The first ones 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 will 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, in other words, 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 Advisory Committees, 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 prescribed by itself, combined with those planned by EDF open the prospect of continued operation of these reactors for the ten years following their fourth periodic safety review.

#### **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 2022, EDF had carried out or initiated eleven 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.

#### **Involving the public at each step**

For the purposes of this periodic safety review, ASN has been involving the public since 2016 in the drafting of its position statement regarding the objectives proposed by EDF. This approach continued in 2018, under the aegis of the High Committee for Transparency and Information on Nuclear Safety (HCTISN), in the form of a consultation on the measures planned by EDF to meet these objectives. At the end of 2020, ASN also consulted the public on its draft resolution specifying the conditions for continued operation of these reactors. Pursuant to the law, a public inquiry is then held, reactor by reactor, after submission of the periodic safety review concluding report for each reactor.

The public inquiry on Tricastin NPP reactor 1 took place at the beginning of 2022. The conclusions of this inquiry were taken into account by ASN, which asked EDF to improve the presentation of its dossier for the public inquiries for the next reactors.

#### **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 30 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 equipment important for safety 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 2024.

##### **The fourth periodic safety review**

In July 2017, EDF presented a file giving the approaches 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 orientations, after involvement of the public and consultation of the GPR on 22 May 2019. ASN considers that the general objectives set by EDF for this review are acceptable in principle. They aim more specifically to avoid the need to implement population protection measures for design-basis accidents, and in the case of severe accidents, to try to have population protection measures that are limited in space and time. 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.

In 2022, ASN continued with the examinations performed for the generic phase of this periodic safety review. Its examinations have focused in particular on the methods that will be used in this review to analyse certain accidents and to assess the hazard robustness of the installations. EDF has also continued the studies needed to update the regulation reference files for the main primary and secondary systems; this update is particular in that the design hypotheses were initially produced for 40 years of operation.

EDF will begin the first ten-yearly outage associated with this periodic safety review at the end of 2025.

#### **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 orientations 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 in 2022 on this generic phase. It underlined the significant safety improvements made to the reactors on the occasion of this periodic safety review.

Chooz NPP reactors B1 and B2 carried out their second ten-yearly outages in 2019 and 2020. As at the end of 2022, the ten-yearly outages for the Civaux NPP reactors 1 and 2 are ongoing.

##### **The third periodic safety review**

In 2022, EDF transmitted the envisaged guidelines for the generic phase study programme for the third periodic safety review of the 1,450 MWe reactors.

In 2023, ASN will issue a position statement on these guidelines, following consultation of the GPR. The ASN position statement will also be submitted to the public for consultation.

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TIME-LINE OF FIRST CRITICALITY OF THE FRENCH NUCLEAR POWER REACTORS

Date of 1st criticality									Total power	
1978	Bugey 2	Bugey 3							1,800 MWe	
1979	Bugey 4	Bugey 5							1,800 MWe	
1980	Tricastin 1	Gravelines 1	Tricastin 2	Tricastin 3	Gravelines 2	Dampierre 1	Gravelines 3	Saint-Laurent B1	7,200 MWe	
1981	Dampierre 2	Saint-Laurent B2	Blayais 1	Dampierre 3	Tricastin 4	Gravelines 4	Dampierre 4			6,300 MWe
1982	Blayais 2	Chinon B1							1,800 MWe	
1983	Cruas 1	Blayais 4	Blayais 3	Chinon B2					3,600 MWe	
1984	Cruas 3	Paluel 1		Cruas 2	Paluel 2		Gravelines 5	Cruas 4	6,200 MWe	
1985	Saint-Alban 1		Paluel 3		Gravelines 6	Flamanville 1				4,800 MWe
1986	Paluel 4		Saint-Alban 2		Flamanville 2		Chinon B3	Cattenom 1		6,100 MWe
1987	Cattenom 2		Nogent 1		Belleville 1		Chinon B4		4,800 MWe	
1988	Belleville 2		Nogent 2						2,600 MWe	
1990	Cattenom 3		Penly 1		Golfech 1					3,900 MWe
1991	Cattenom 4								1,300 MWe	
1992	Penly 2								1,300 MWe	
1993	Golfech 2								1,300 MWe	
1996	Chooz B1								1,450 MWe	
1997	Chooz B2		Civaux 1						2,900 MWe	
1999	Civaux 2								1,450 MWe	

● 900 MWe ● 1,300 MWe ● 1,450 MWe  
Source: ASN.

3. Regulation and oversight of the safety of the Flamanville EPR reactor

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The EPR is a PWR using a design that has evolved from that of the reactors currently in operation in France. It meets reinforced safety objectives: reduction in the number of significant events, 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 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 1,650 MWe on the Flamanville site, which was already home to two 1,300 MWe reactors.

The Government authorised its creation through Decree 2007-534 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 Creation Authorisation Decree 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.

EDF plans to load fuel and start up the reactor in the first quarter of 2024. This schedule takes account of the time needed on the one hand to repair certain main primary system welds and, on the other, for the end of the assembly and testing operations.

3.1 Examination of the authorisation applications

Examination of the commissioning authorisation application

In March 2015, EDF sent ASN its commissioning authorisation application for the installation, including the safety analysis report, the RGEs, a study of the installation’s waste management, the PUI, the decommissioning plan and an update of the installation’s impact assessment. Following a preliminary examination, ASN considered that all the documents required by the regulations were officially present, but it decided that additional justifications were needed if ASN was to be able to reach a final decision on the commissioning authorisation application. ASN began the technical examination of the subjects for which most of the information was available, although it did submit some requests on certain points.

In June 2017, ASN received updated versions of the commissioning authorisation files and in 2018 made requests for additional information, notably concerning the RGEs.

ASN obtained the opinion of the GPR on 4 and 5 July 2018 concerning the safety analysis report for the Flamanville EPR reactor. This meeting was devoted in particular to the action taken following the previous GPR sessions devoted to this reactor since 2015. The Advisory Committee considered that the reactor’s safety case is on the whole satisfactory and points out that some additional information is still required concerning how the fire risk is addressed and the behaviour of the fuel rods which have

## THE AGEING OF NUCLEAR POWER PLANTS 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, equipment important for safety 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 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.

experienced a boiling crisis. The GPR also considered that the design and dimensioning of the back-up systems and auxiliary safety systems are on the whole satisfactory and observed that additional information was still required concerning the breaks liable to affect the fuel storage pool cooling system. In 2019 and 2020, in the light of this opinion and the conclusions of its technical examinations, ASN submitted requests for supplements to the safety case that are needed for it to make a final decision on the commissioning authorisation application.

In June 2021, EDF sent ASN a new commissioning authorisation application. This application replaces the initial application of March 2015 and contains a complete update of the file appended to the initial application, incorporating certain additions requested and the conclusions of the examinations conducted since 2015.

### Partial commissioning authorisation for arrival of the fuel

On 8 October 2020, ASN authorised partial commissioning of the installation for arrival of the fuel on the site. This authorisation enabled EDF to receive fuel assemblies and store them in the fuel storage pool, for use in the first fuelling of the reactor. This partial commissioning is one of the steps prior to commissioning of the Flamanville EPR reactor, but in no way prejudices this commissioning, which is the subject of a separate examination.

## 3.2 Construction, start-up tests and preparation for operation

ASN is faced with numerous challenges concerning oversight of the construction, start-up tests and preparation for operation of the Flamanville EPR reactor. These are:

- checking the quality of equipment manufacturing and installation construction, in order to be able to issue a position statement on the ability of the installation to meet the defined requirements;
- ensuring that the start-up tests programme is satisfactory, that the tests are correctly performed and that the required results are obtained;
- ensuring that the various stakeholders learn the lessons from the construction phase and the performance of the start-up tests, including the upstream phases (selection and monitoring of contractors, construction, procurement, etc.) which will enable the as-built installation to comply with the safety case for the duration of the project;
- ensuring that the licensee takes the necessary steps so that the teams in charge of operating the installation after commissioning are well-prepared.

To do this, ASN has set binding requirements regarding the design, construction and start-up tests for the Flamanville EPR reactor and for operation of the existing two Flamanville 1 and 2 reactors close to the construction site.

As this is a nuclear power reactor, ASN is also responsible for labour inspection on the construction site. Lastly, ASN ensures oversight of the manufacture of the NPE that will be part of the primary and secondary systems of the nuclear steam supply system.

In 2022, EDF continued with work to complete the installation, to make modifications to certain equipment and to draw up the various documents needed for operation. EDF also continued to analyse and remedy deviations, notably those affecting the MSS welds as well as three main primary system nozzles. EDF implemented a programme of additional inspections as part of the quality review requested by ASN owing to significant shortcomings observed in the monitoring of its contractors. EDF also continued to conduct the reactor start-up test programme and initiated preparations for the equipment requalification phase, scheduled in 2023 in preparation for commissioning.

## 3.3 Assessment of design, construction, start-up tests and preparation for operation of the Flamanville EPR reactor

### The examinations in progress

ASN considers that the design of the Flamanville EPR reactor should be able to achieve the ambitious safety objectives set for the third generation reactors. It should also lead to a significant reduction in the probability of core melt and radioactive releases in the event of an accident, by comparison with the second generation reactors. The EPR reactor design in particular includes systems for managing severe accidents and is able to withstand extreme external hazards. This design only required very minor changes to take account of the lessons learned from the accident at the Fukushima Daiichi NPP.

In 2022, EDF continued with the examinations linked to the commissioning authorisation application. A number of important technical subjects are still being examined. This is in particular the case with the design of the primary system safety valves, I&C upgrades, the performance of the containment internal water tank filtration system, the RGEs that will be applicable as of commissioning and incorporation of the lessons learned from the commissioning of the first EPR reactors abroad, in particular the various anomalies found on the cores of the EPR reactors in Taishan (China), including the fuel clad perforations observed in 2021.

## CAMPAIGN OF INSPECTIONS 10 YEARS AFTER THE FUKUSHIMA DAIICHI NPP ACCIDENT

Following the accident that struck the Fukushima Daiichi NPP on 11 March 2011, ASN asked EDF to carry out stress tests on its installations. These stress tests led, on 26 June 2012, to ASN adopting technical prescriptions applicable to each of the NPPs, in order to regulate the required safety improvements.

Ten years after the adoption of these prescriptions, ASN conducted an inspection campaign in 2022 with the aim of checking the deployment of the safety improvements. Each NPP was thus inspected, along with

the four regional bases of the Nuclear Rapid Intervention Force (FARN).

The inspectors notably checked the installation of additional water and compressed air supplies, the new provisions and reinforcements in the event of an earthquake, the new back-up electrical power sources, the new provisions improving the safety of the fuel pool and the new mobile resources to monitor the environment in an emergency situation.

The inspectors found that deployment of the safety improvements was on the

whole as required with generally correct application of the technical prescriptions adopted in 2012. However, these inspections also demonstrated that the documentary baseline on the sites was not always up to date with all the safety improvements deployed. In addition, an occasional lack of rigorousness in the follow-up of the new equipment was recorded, along with shortcomings in the identification of certain new provisions needed for correct implementation of this equipment. After each of these inspections ASN sent improvement requests to EDF.

### Assessment of nuclear pressure equipment conformity

The NPE of the Flamanville reactor includes that making up the main primary and secondary systems presented in point 2.2 (reactor pressure vessel, SG, pressuriser, reactor coolant pumps, piping, safety valves) but also that constituting other parts of the NSSS.

During the course of 2022, ASN continued to assess the conformity of the NPE design of the MPS and MSS. As in 2021, it in particular checked performance of the operations to repair the main steam lines subject to the break preclusion requirements, as well as the operations performed on the other lines not subject to this requirement, with more extensive involvement of the *Bureau Veritas Exploitation* organisation.

ASN also continued to analyse the deviations which affected the post-weld heat treatment of the connection welds on the SG and pressuriser components carried out in Framatome's Saint-Marcel plant, as well as on the main secondary system lines carried out on the Flamanville site, where a high level of activity will continue in 2023. EDF and Framatome intend to carry out repairs when this can be envisaged or, failing which, to demonstrate that the conformity of the equipment is not compromised.

In 2022, ASN also continued to assess the conformity of the main steam lines with the break preclusion requirements, as well as the quality of the welds on three main system nozzles, around which EDF has decided to install a retaining collar. In the event of rupture of the nozzle set-in weld, this collar would limit the size of the resulting break. The consequences of this break would then be covered by the reactor's existing safety studies. ASN considers that the solution proposed by EDF is acceptable. The examination of the justification of the production quality of these three nozzles has yet to be finalised.

### Oversight of construction, start-up tests and preparation for operation

Oversight of construction has repeatedly revealed faults in construction quality, requiring corrective measures. EDF carried out additional verifications which were the subject of discussions with ASN. In 2022, ASN continued to examine the programme of additional inspections and the results of the review carried out by EDF. In 2023, EDF should be issuing the results of these actions and draw up the corresponding conclusions.

ASN considers that EDF's equipment conservation strategy is satisfactory, provided that EDF carries out additional maintenance to prevent ageing of the equipment and sets up an equipment inspection programme at the end of the conservation phase, to check the effectiveness of the steps taken and detect any latent defects. The conservation activities were inspected on-site by ASN.

In 2022, ASN initiated a campaign of inspections (3 in 2022) on completion of the installation, in order to check that EDF is fully cognizant of the activities still to be carried out (end of assembly, modifications, tests, deviations, etc.) and has scheduled them prior to commissioning of the reactor. ASN also continued its oversight of preparation for operation and in 2023 intends to conduct an in-depth inspection of several days, to obtain a more exhaustive picture of the preparations of the future licensee, before commissioning of the reactor. This in-depth inspection will notably concern the definition and implementation of the operational organisations, the management and assimilation of the required skills, and the drafting and operational nature of the operating documentation.

In June 2020, EDF sent ASN a first version of the results of the installation start-up tests. These results are updated as and when the remaining tests are performed. ASN continued with examination of this document and its updates transmitted, in order to verify that the as-built installation complies with the hypotheses contained in the safety case. This examination will continue in 2023. In addition, during its inspections, ASN ensures that EDF has taken sufficient measures either to guarantee that the work carried out after the start-up tests does not compromise the results obtained during these tests, or to identify the tests to be repeated following this work.

In 2022, ASN carried out 15 inspections of EDF on the Flamanville site, including a campaign of 4 inspections on MSS repairs and two inspections in the engineering departments. ASN also carried out labour inspections. The conclusions of these inspections are presented in the Regional Overview in the introduction to this report.



## WELDS ON LINES OF THE MAIN SECONDARY SYSTEMS OF THE FLAMANVILLE EPR REACTOR

Major repairs are required to the welds on the lines of the main secondary systems of the Flamanville EPR reactor. The majority of these welds are located on the main steam lines, and are subject to a “break preclusion” approach: they thus require mechanical properties and a level of manufacturing quality that are particularly high.

Eight of these welds are located in the annulus between the two containment walls of the reactor building. The difficult access conditions required the development of special intervention means and the qualification of specific welding, inspection and heat treatment processes. After examining these intervention means and the qualification of the processes in 2020, ASN inspected the production of these eight welds in 2021. The post-weld heat treatment and final weld inspections were performed in 2022. These welds comply with the break preclusion requirements.



Implementation of the orbital TIG process – weld on the main secondary system

Most of the other welds on the main steam lines which are to be repaired, of which there are about 50, are located in an environment with no access difficulties. In 2022, as in 2021, ASN continued to assess the conditions for their repair and to monitor the weld repair operations. EDF was attentive to ensuring that the number of repairs made at the same time is compatible with the organisation of worksite

surveillance. This work should continue in 2023, in particular with regard to the post-weld heat treatment and non-destructive inspection activities.

At the same time, EDF analysed the quality of other welds, in particular those on the SG feedwater lines. This work led EDF to decide to repair ten or so additional welds. EDF's treatment strategy was considered by ASN to be appropriate.

## 4. Regulation and oversight of reactor projects

### The EPR2 reactor

EDF is developing a new reactor, called “EPR2”. It aims to incorporate the lessons learned from the design, construction and commissioning of the EPR reactors and OEF from operation of existing reactors. As with the EPR reactors, this project aims to meet the general safety objectives of 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 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. On 16 July 2019, ASN thus published its opinion on the proposed safety options. ASN considers that the general safety objectives, the baseline safety requirements and the main design options are on the whole satisfactory. ASN's opinion identifies the subjects to be considered in greater depth prior to submitting a reactor creation authorisation application. Additional justifications were in particular needed on the break preclusion approach for the main primary and secondary piping, the approach for dealing with hazards, fire and explosion in particular, and the design choices for certain safety systems. The justifications required were specified by ASN in a letter sent to EDF in July 2021.

Further to ASN's opinion, EDF changed its break preclusion approach for the main primary and secondary systems piping. EDF intends to make a number of design, manufacturing and organisational changes to enhance safety. These changes will more particularly concern the choice of materials and manufacturing

and inspection techniques. Furthermore, even though EDF applies a break preclusion approach, it also intends to add certain devices to mitigate the consequences of any break, such as separating walls, whip-restraint devices and steam evacuation vents.

ASN considers that, given the additional measures, using a break preclusion approach for the main lines of the primary and secondary systems of the EPR2 reactor project is acceptable. This position statement, issued in September 2021, supplements ASN's 2019 opinion on the safety options for this reactor project.

In April 2021, ASN also issued a position statement on the additional information provided by EDF regarding a military aircraft crash. ASN considers that the EDF approach would be able to achieve safety objectives for the EPR2 reactor identical to those of the Flamanville EPR reactor.

In February 2021, EDF sent ASN a preliminary version of the safety analysis report for advance examination, were a construction programme for new reactors actually to be launched. A file examination programme was drawn up jointly with IRSN.

ASN is also examining the safety options dossiers for the main nuclear pressure equipment. ASN issued opinions concerning the reactor vessel in 2021 and the SGs in 2022.

In 2022, with the support of the IRSN, ASN also examined the baseline requirements for application of the break preclusion approach, which concerns equipment said to be “non-rupturable components” (vessel, SG, pressuriser, reactor coolant pump volutes) as well as the EPR2 reactor main primary and secondary system lines. Examination of the break preclusion baseline requirements continued in 2022 and will be presented to the GPESPN for its opinion in 2023.



### Small Modular Reactors

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

The characteristics of the SMR, in particular their low power and compactness, contribute to their safety. ASN considers that the designers should take advantage of these characteristics to propose reactors aiming for more ambitious safety objectives than the existing high-power reactors.

In 2022, ASN continued exchanges with several French companies developing SMRs, in order to familiarise itself with the technical characteristics of these projects, present the applicable regulatory framework and clarify the technical elements needed in order to begin discussions in greater depth. The degree of progress of these projects varies.

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 OEF from its counterparts.

### PRELIMINARY ASSESSMENT OF THE MAIN SAFETY OPTIONS OF THE NUWARD PROJECT

Nuward is a pressurised water SMR developed by EDF and its partners (Alternative Energies and Atomic Energy Commission – CEA, Naval Group, TechnicAtome, Framatome and Tractebel), consisting of two modules of 170 MWe each, housed in the same building.

In the first quarter of 2022, ASN and its Czech and Finnish counterparts, with the support of IRSN, conducted a preliminary assessment of the main safety options for the Nuward project. This initiative should notably be able to use a concrete case to examine the safety issues raised by the small modular reactors. It is also an opportunity for the regulators to use a concrete case to discuss their approaches and the national implementation of safety requirements. The conclusions of this preliminary assessment will be shared with its counterparts within the framework of the ongoing international work being done on SMR.

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# “Nuclear fuel cycle” facilities

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The “nuclear fuel cycle” begins with the extraction of uranium ore and ends with the conditioning of the radioactive wastes from spent fuel 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 monitors the overall consistency of the industrial choices made with regard to fuel management and which could have consequences for safety.

In 2022, Orano commissioned new storage capacity for the materials and waste resulting from the reprocessing of spent fuels (FLEUR facility on the Tricastin site, standard vitrified waste package (CSD-V) storage pit on the La Hague site), and increased the storage capacity for plutonium-bearing materials made necessary by production difficulties at the Melox plant. ASN considers that these new capacities contribute to improving the management of materials and waste. However, the countermeasures required to prevent saturation of the storage pools have yet to be deployed. ASN therefore sees that the margins are extremely slight in operation of the “fuel cycle”. It repeats its request that the licensees significantly reinforce their forward planning and take the steps necessary to deal with the risk of situations that could block the “cycle” and thus the production of nuclear electricity.

With regard to the performance of the sites in 2022 and the steps taken by their licensees to improve it, ASN considers that the operation of the “fuel cycle” as a whole remains fragile.

## 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<sub>6</sub>) through a series of 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<sub>6</sub> enrichment between 3% and 6% is carried out by ultracentrifuges in the Georges Besse II (GB II) plant in Tricastin.

This enriched UF<sub>6</sub> 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 inserted into the reactor core, where they deliver energy, notably by fission of uranium-235 nuclei. Before it is used in the reactors, fresh nuclear fuel can be stored in one of the two Inter-Regional fuel Stores (MIR) operated by EDF in Bugey and Chinon.

After a period of use of about three to four 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 then separated from the fission products and other transuranic elements<sup>1)</sup>. The uranium and plutonium are packaged and then stored for subsequent re-use. With regard to the reprocessed uranium, EDF had announced its intention to resume its use by 2023, after re-enrichment of the reprocessed uranium in Russia.

The plutonium resulting from the reprocessing of uranium oxide fuels is used in the “Melox” plant operated by Orano in Marcoule, to fabricate MOX fuel (Mixture of uranium and plutonium OXides) which is used in certain 900 Megawatts electric (MWe) nuclear power 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.

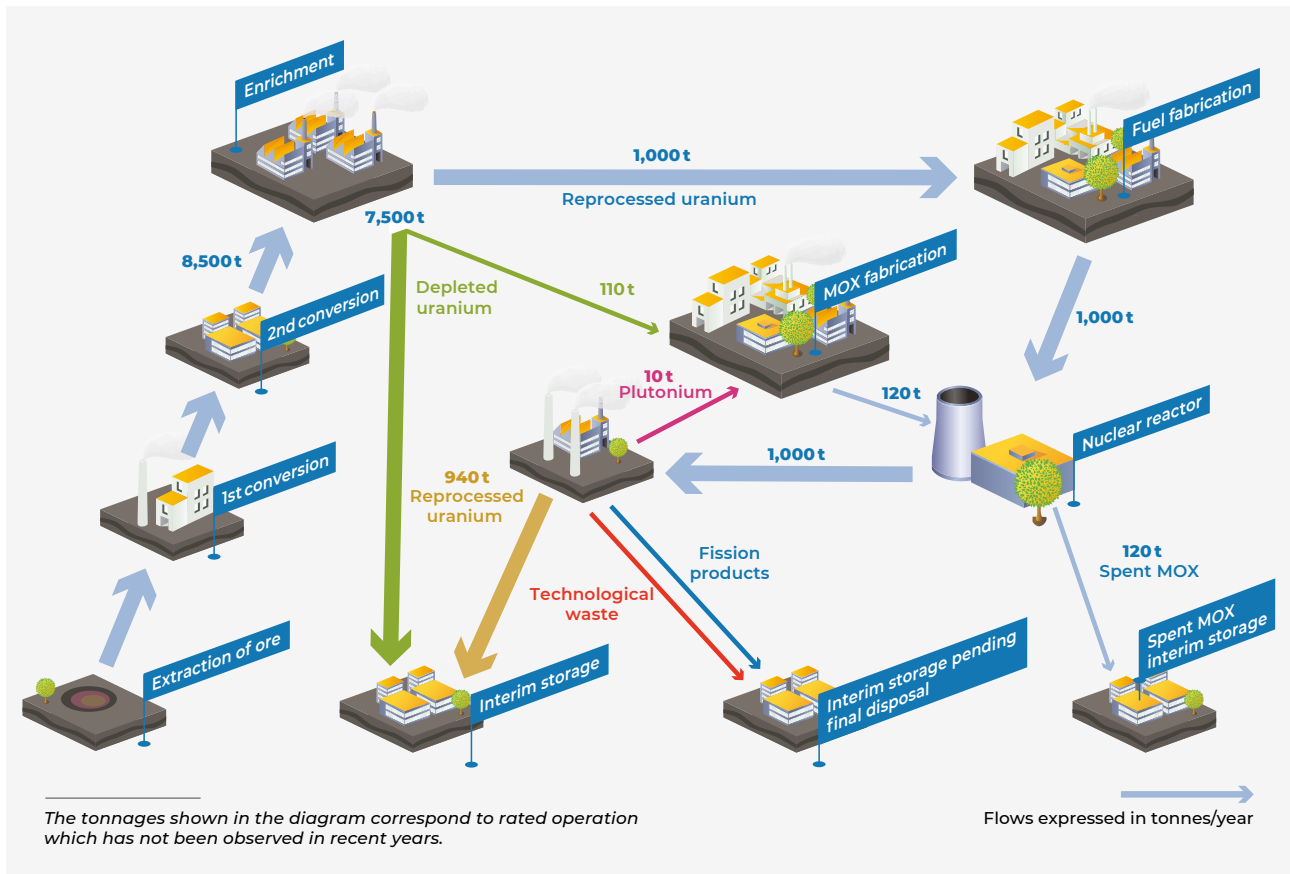
1. Transuranic elements are chemical elements heavier than uranium (atomic number 92). The main ones are neptunium (93), plutonium (94), americium (95), curium (96). In a reactor, they are derived from uranium during secondary reactions other than fission.



TABLE 1 "Fuel cycle" industry movements in 2022

INSTALLATION	PRODUCT PROCESSED			PRODUCT OBTAINED		PRODUCT SHIPPED	
	ORIGIN	PRODUCT PROCESSED	TONNAGE	PRODUCT OBTAINED	TONNAGE	DESTINATION	TONNAGE
Orano Tricastin Conversion	Orano Malvési	UF <sub>4</sub>	12,248	UF <sub>6</sub>	13,107	Orano storage areas Tricastin	13,107
Orano Tricastin TUS Unit	Orano La Hague	Uranyl nitrate	3,610	U <sub>3</sub> O <sub>8</sub>	1,078	Orano storage areas Tricastin	1,078
Orano Tricastin W plant	Orano Tricastin GB II	UF <sub>6</sub> depleted	9,537	U <sub>3</sub> O <sub>8</sub>	7,604	Orano storage areas Tricastin	7,604
Orano Tricastin GB II	Orano Tricastin Conversion	UF <sub>6</sub>	10,430	UF <sub>6</sub> depleted	8,878	Orano Tricastin Plant W	8,878
				UF <sub>6</sub> enriched	1,369	Fuel fabrication plants	1,369
Framatome Romans	Orano Tricastin GB II	UF <sub>6</sub> enriched	550	Fuel assemblies	709	EDF	583
	Urenco (Netherlands, Germany and United Kingdom)		90			Taishan (China)	44
	Tenex (Russia)		40			Tihange (Belgium)	30
	ANF Lingen (Germany)	Gadolinium rods	20	UO <sub>2</sub> and U <sub>3</sub> O <sub>8</sub> powder	3	CEA	3
	Framatome Richland (États-Unis)		2			Framatome Richland (United States)	2
Orano Melox Marcoule	Framatome Lingen (Germany)	UO <sub>2</sub> depleted	5	MOX fuel elements	54	EDF	47
	WSE Vasteras (Sweden)		73				
	Orano La Hague	PuO <sub>2</sub>	5			Kansai (Japan)	7
Orano La Hague	Fuels reprocessed in the La Hague plant						
	EDF and other licensees	UOX and MOX	925	Uranyl nitrate	953	Orano Tricastin	902
				PuO <sub>2</sub>	12	Melox Marcoule	6
	Fuels stored in the La Hague plant pools						
EDF and other licensees	Irradiated fuel elements	10,071	-	-	-	-	

“FUEL CYCLE” DIAGRAM



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 “fuel cycle” front end

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  $UO_2(NO_3)_2$  produced by reprocessing spent fuel at La Hague into uranium sesquioxide ( $U_3O_8$ );
- 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  $UF_6$  ultra-centrifuge enrichment plant (BNI 168);
- the Atlas analysis laboratory (BNI 176);
- areas for the storage of uranium and thorium in various forms (BNIs 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 of uranium per year, enabling it to reprocess all the  $UO_2(NO_3)_2$  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 13).

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 tonnes 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”, licensed 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.

Enrichment of the uranium resulting from reprocessing, which would require prior authorisation from ASN, is not currently implemented in this plant.

In 2022, Orano referred to the National Commission for Public Debate (CNDP) pursuant to Article L. 121-12 of the Environment Code, about the project to increase the capacity of the GB II plant by around 30%. The CNDP decided to hold a prior consultation because substantial changes to the circumstances which justified the plant’s capacity extension project had occurred since the first public debate which ended in 2004.

#### 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.

#### 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.

#### 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 2022-391 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 consists of two buildings and could eventually contain up to four buildings.

#### 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

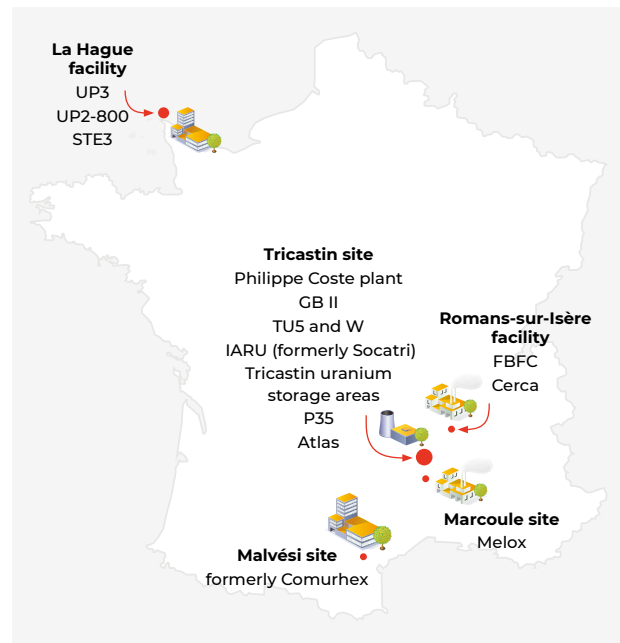
The fabrication of fuel for electricity generating reactors involves the transformation of UF<sub>6</sub> into uranium oxide powder. The pellets fabricated from this powder in the Framatome “FBFC” plant in Romans-sur-Isère are placed in zirconium metal cladding to constitute the fuel rods, which are 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.

The MOX fuel is fabricated in BNI 151 – Melox – operated by Orano and located on the Marcoule nuclear site, by mixing and pelletisation of uranium oxide and plutonium oxide powders,

### THE “FUEL CYCLE” FACILITIES IN SERVICE



which are then placed in cladding and assemblies of the same geometry as those produced by FBFC.

### 1.3 The “fuel cycle” back-end – 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 UP3-A (BNI 116) and UP2-800 (BNI 117) plants and of the STE3 (BNI 118) Effluent Treatment Station were commissioned from 1986 (reception and storage of spent fuel assemblies) to 2002 (R4 plutonium reprocessing facility), with most of the process facilities entering service 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 control procedures for the discharge into the sea of eleven chemical substances, detected by the licensee in small quantities in the discharges during a regulations 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 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 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, 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 as uranyl nitrate  $UO_2(NO_3)_2$ . It will then be converted into a solid compound ( $U_3O_8$ ) called “reprocessed uranium” in the TU5 facility on the Tricastin site.

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 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 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 14) 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 14). 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 System”, was approved by the Order of the Minister responsible for energy of 2 October 2008.

#### **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.

On 18 October 2018, ASN issued its opinion 2018-AV-0316 on the “2016 Cycle Impact” 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 (MEP), 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 December 2020, together with Framatome, Orano and Andra, EDF updated its “fuel cycle” outlook according to energy mix scenarios consistent with the Multi-year Energy Programme published in April 2020. In the light of this outlook, saturation of spent fuel storage capacity could be reached in 2030, or even 2029. EDF also announced in 2020 a postponement of the commissioning of its centralised storage pool project, now scheduled for 2034, which means that countermeasures are needed to deal with the delay in this project: these countermeasures are the densification of the storage pools at La Hague, dry storage of spent fuels and greater use of MOX fuel in the reactors. ASN recalls that none of these countermeasures has the same safety advantages as the centralised storage pool project, which to date remains the reference solution with no alternative equivalent in terms of safety.

After the malfunctions concerning certain steps in the “fuel cycle”, which had appeared and became worse in 2021, the situation in 2022 remains fragile:

- The Melox plant is still experiencing difficulties in producing MOX fuel of the required quality and quantities expected. These difficulties are leading to the production of a large quantity of radioactive materials containing plutonium unsuitable for use as fuel in reactors, qualified as “MOX scrap”, which is then stored in the La Hague plant, either in powder form, or in the form of fuel assemblies.
- An action plan has been implemented by Orano since 2019 to overcome the production difficulties at Melox. The use of depleted uranium powder, produced by the “wet process approach” was qualified in September 2022. Output by the Melox plant was thus slightly higher than in 2021, when it was very low. The production of MOX scrap was also kept down. The use of this powder prevents the situation from being further degraded, pending the use of a “wet process” uranium powder from a new unit called “New Wet Process” (NVH) in Orano’s Malvési plant. This unit is currently under construction, with a view to the “wet process” production of depleted uranium at the end of 2023.

- The malfunctions with Melox are still causing 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 and a second is currently being examined by ASN.
- The capacity situation of the La Hague evaporators, used for the concentration of nitric acid solutions of fission and transuranic products, remains a subject requiring particular attention:
  - as part of the replacement of the UP3 evaporation capacity (“NCPF” programme), the fission products evaporator-concentrators of the UP3 plant were definitively shut down in September 2022. Their replacement by three new evaporators is now being completed, with testing under way since September 2022 and start-up scheduled for March 2023;
  - the malfunctions with the evaporation capacity in the R7 unit led Orano to ask for a fourth extension for use of the evaporators in the UP2-400 plant in order to carry out the reprocessing and vitrification programmes of the UP2-800 plant in accordance with the forecasts.
- The authorisation application file for densification of the pools at La Hague was submitted at the end of December 2022, with deployment planned for mid-2024 at best. This project, which consists in replacing the baskets currently used in pools C, D and E by more compact baskets, in compliance with the limits set by the creation authorisation decrees of BNIs 116 and 117, constitutes one of the countermeasures identified to deal with the delay in commissioning of a centralised storage pool.
- The commissioning of two of the four uranium storage buildings in the new FLEUR BNI on the Tricastin site, as well as the commissioning in September 2022 of a new CSD-V waste storage pit at La Hague means that additional storage capacity is now available for reprocessed uranium and high level, long-lived waste (HLW-LL) from the reprocessing of spent fuels.

## 1.5 Outlook: planned facilities

### “New Concentration of Fission Products” (NCPF) project on the La Hague site

In order to replace the fission products evaporator-concentrators at La Hague, which are suffering from a more advanced stage of corrosion than imagined in the design, Orano is building new units, called “NCPF”, comprising six new evaporators. This particularly complex project required several authorisations and was the subject of an ASN resolution in 2022 concerning the commissioning of three of these evaporators (NCPF T2) with start-up planned for March 2023. The commissioning authorisation for the three other evaporators (NCPF R2) is envisaged for some time in 2023.

### Construction of new storage capacity for waste packages

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 to the CSD-C storage facility was also authorised by the Decree of 27 November 2020; ASN had issued a favourable opinion regarding this draft text on 8 September 2020. Construction is under way and the introduction of radioactive substances into this extension for the first time will require authorisation from ASN.

In 2023, Orano envisages submitting an application for a substantial modification of the Creation Authorisation Decree 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.

### The special fuels reprocessing unit project

In order to receive and reprocess the special fuels irradiated in the Phénix reactor or other research reactors, Orano transmitted the Safety Options Dossier (DOS) in 2016 for a new special fuels reprocessing unit, on which ASN issued an opinion in March 2017. The licensee submitted new safety options for this project in January 2020. ASN issued its observations on this Dossier on 9 December 2020. In 2022, Orano informed ASN that this project had been abandoned owing to the failure to reach a financing agreement with those in possession of the fuels to be reprocessed. Orano is now envisaging reprocessing by means of the future renewal of the dissolution units at La Hague.

### EDF centralised storage pool project

During the public debate held in 2019, prior to the fifth edition of the National Radioactive Materials and Waste Management Plan (PNGMDR), EDF reaffirmed that the strategy to increase the 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 is about a century. In 2017, EDF transmitted a DOS for this project. In July 2019, ASN issued its opinion on the safety options presented by EDF for such a facility and considers that the general safety objectives and the design options adopted are satisfactory.

In 2020, EDF indicated a delay in this storage pool project, which is to be installed on the La Hague site but will not be in service before 2034. In 2021, EDF referred this project to the CNDP and a prior consultation under the auspices of the CNDP was organised by EDF from 22 November 2021 to 8 July 2022, with a suspension running from 2 February to 20 June 2022. The guarantors appointed by the CNDP submitted the results of the consultation on 8 August 2022, to which EDF replied on 7 October 2022, stating that they wished to continue with the project and prepare submission of the creation authorisation application for the installation by the end of 2023.

ASN recalls the importance of obtaining new spent fuels storage capacity meeting the most recent safety standards as soon as possible, in order to address the problem of saturation of the existing capacity, for which there is no alternative equivalent to the centralised storage pool.

As of 2018, ASN had asked EDF to present the countermeasures it envisaged for this situation, given the possible saturation of French spent fuel storage capacity by the time of this commissioning.

The countermeasures envisaged by EDF, together with Orano, are to increase the density in the La Hague pools, increase the use of MOX fuels in the reactors, subject to return to nominal operation by the Melox plant, and use dry storage of spent fuels.

### La Hague pools densification project

In November 2020, Orano submitted a DOS. In order to promote technical discussions on this dossier, ASN created a pluralistic working sub-group at the beginning of 2021 to take part in the proceedings of the PNGMDR working group, to which the members of the La Hague Local Information Committee (CLI) had been invited. ASN issued a position statement on this dossier on February 2022. In a letter of 14 February 2022, ASN considers that the safety options presented by the licensee



are on the whole satisfactory. Observations have been made and additional information was requested. The noteworthy modification authorisation application was transmitted by the licensee at the end of 2022 and will be the subject of an ASN position statement in 2024.

## 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 dangerous substances, 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. In this respect, Orano submitted applications for a change of licensee concerning all its BNIs, in February 2020. The “PEARL” project was authorised by the Decrees 2020-1593 and 2020-1594 of 15 December 2020. This project separated

### Spent fuel dry storage project

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. Orano intends to transmit a new dossier in 2023.

the group’s activities into three separate subsidiaries dealing with the “cycle” front-end, the “cycle” back-end and decommissioning. ASN’s examination of this application showed that it led to a change in organisation in the operation of the Orano group BNIs undergoing decommissioning, liable to compromise the principle set out in the regulations, whereby operational responsibility for a BNI lies with its nuclear licensee (III of Article R. 593-10 of the Environment Code). Orano thus submitted a request for a waiver to this principle. ASN granted this waiver in resolution 2022-DC-0746 of 6 December 2022, considering that it was necessary for activities notably characterised by particular technical complexity, such as process control, which require monitoring, surveillance or adjustment of parameters in real time, or when incident management or making equipment safe require a sequence of specific operations for which operators are specially qualified. This waiver concerns operation of the “HAPP” unit in BNI 33 of and silo 130 in BNI 38, located on the La Hague site.

### 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.

The first reviews on facilities in the cycle concerned BNIs 151 (Melox) and 138 (IARU, formerly Socatri) and identified numerous points on which these facilities could be reinforced. Most of this work is now being carried out.

Examination of these periodic safety reviews confirmed the pertinence of an upstream definition, in what is known as the “orientation” phase, of the priority subjects for examination by the licensee during the periodic safety review, along with the associated methodologies. In addition, probabilistic analyses must be added to the safety cases for all the BNIs. The periodic safety review of plant UP2-800 (BNI 117) is nearing completion, with finalisation of the examination of the improvement proposals concerning the NPH unit by the Advisory Committee of Experts for Laboratories and Plants (GPU) in February 2022. In 2023, ASN will regulate the continued operation of this BNI by means of prescriptions. For plant UP3-A (BNI 116), Orano transmitted its review concluding report at the end of 2020, and it will be examined by the GPU during the course of several meetings scheduled between 2023 and 2025. 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

is currently being examined by ASN, with a view to it being examined by the GPU in 2024. The upcoming periodic safety review of the FBFC and Cerca plants, combined in a single BNI (63-U) by the Decree of 23 December 2021, shall be submitted by Framatome in June 2023.

In October 2021, following the examination of the review concluding report for TU5 (BNI 155), ASN validated continued operation of BNI 155.

The periodic safety reviews show the importance of an *in situ* verification of the conformity of the Protection Important Component (PIC) that is as exhaustive as possible, or as representative as possible of the PIC 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.

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# Nuclear research and miscellaneous industrial facilities

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**N**uclear 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 International Thermonuclear Experimental Reactor – ITER 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<sup>(1)</sup> 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 recovered and is in fact a “by-product” 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 certain research reactors.

#### Neutron beam reactors

The irradiation reactors are pool type. 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.

After consultation of the public and in the light of the conclusions of its third periodic safety review, ASN (the French Nuclear Safety Authority) made the continued operation of this facility dependent on compliance with the prescriptions set out in the resolution of 28 July 2022, notably the improvements to the provisions for the prevention of fire and explosion risks and risks linked to handling operations.

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

“Test” reactors are pool type. 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: 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, after major renovation work, ASN authorised the first active experimental test of the facility’s pressurised water loop.

#### Irradiation reactors

The irradiation reactors are pool type. 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 characterise the effects of irradiation. They are thus an important tool for the qualification of materials subjected to a neutron flux.

These research reactors are also significant sources for the production of certain radionuclides for medical uses.

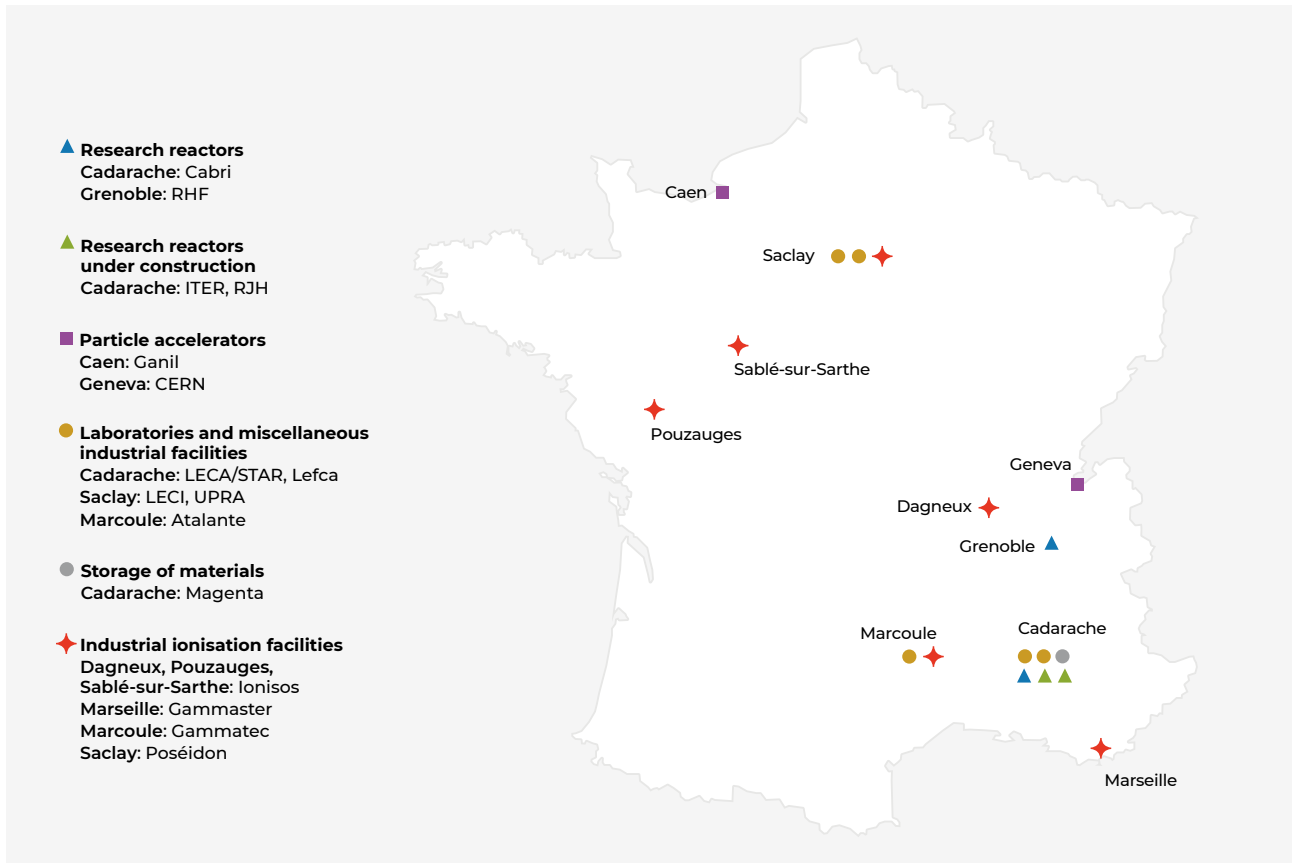
The power of these reactors varies from a few tens to a hundred MWth. These reactors operate in cycles of about 20 to 30 days.

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 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.

1. The use of radionuclides offers medical analysis and treatment possibilities: to diagnose cancers by scintigraphy and tomography, allowing detailed examination of functioning organs, or to treat tumours with radiotherapy, which uses radiation from the radionuclides to destroy the cancer cells (see chapter 7).



RESEARCH FACILITIES IN FRANCE



The Jules Horowitz reactor (RJH – BNI 172), which is intended to replace Osiris, is under construction at Cadarache. Commissioning of the facility, which comprises a number of milestones, is currently being examined by ASN.

**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 s).

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.

Owing to a certain number of installation design subjects still open and technical problems encountered on the construction site, ASN considered that the hold point linked to tokamak assembly could not yet be lifted. Assembly of the tokamak could not therefore begin.

**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 by strict instructions regarding the handling, storage and monitoring of the materials being studied. 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 four main risks.

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### 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 transuranian elements analysis and reprocessing studies (Atalante – BNI 148), situated in Marcoule and operated by CEA, provides Orano Cycle with technical support for optimising the operation of 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.

In the light of the issues associated with certain accident scenarios, ASN considered that a strict schedule needed to be applied to the implementation of certain provisions, notably those concerning improvements to the measures for prevention of fire and flooding risks following an earthquake and that the waste stored in the facility should be reprocessed or removed within a reasonable time-frame. Continued operation of BNI 148 following the conclusions of its periodic safety review is therefore subject to the prescriptions defined in the ASN resolution of 19 April 2022.

### 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 will also be the subject of an opinion from the Advisory Committee of Experts for Laboratories and Plants (GPU).

### 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.

#### The CERN

The European Organization for Nuclear Research (CERN) is an international organisation situated between France and Switzerland, whose role is to carry out purely scientific 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, the CERN is subject to particular verifications by the French and Swiss Authorities.

### 1.2.3 Industrial ionisation installations

Industrial ionisation installations, 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 placed in the lowered position, stored in a pool under a layer of water which protects the workers, or are placed in the raised position 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, agrifood 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 objective 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;
- the CEA, which operates the Poséidon irradiator (BNI 77) on the Saclay site.

### 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 activity enables the laboratories (Atalante, Lefca, etc.) to be supplied according to the needs of the experiments being conducted. 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 (glovebox, shielded cell) 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.

### 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 notably replacing the Central Fissile Material Warehouse (MCMF – BNI 53), which was finally shut down at the end of 2017.

## 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 2022, ASN completed examination of the periodic safety reviews of the Atalante (BNI 148) and Chicade (BNI 156) installations operated by CEA, as well as of the RHF (BNI 67) operated by the ILL and the irradiator in Sablé-sur-Sarthe (BNI 154), operated by Ionisos. ASN considered that the steps taken or planned by the licensees of these installations were on the whole satisfactory and it made no objection to their continued operation, which it regulated by means of technical prescriptions.

Several other periodic safety reviews are currently being examined by ASN, which – as part of its analyses – is continuing with the on-site inspections devoted specifically to the periodic safety review.





# Decommissioning of Basic Nuclear Installations

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The term decommissioning covers all the technical and administrative activities carried out after the final shutdown of a nuclear installation, on completion of which the installation can be delicensed, that is to say it can be removed from the list of Basic Nuclear Installations (BNIs). These activities include removal of the radioactive materials and waste still present in the installation and disassembly of the equipment, components and facilities used during operation, and the clean-up of the premises, remediation of the soils, and possibly the destruction of civil engineering structures.

The aim of the decommissioning and clean-out operations is to achieve a predetermined final state that allows the 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 the French Nuclear Safety Authority (ASN). This phase in the life cycle of the installations is characterised by a succession of operations which are sometimes highly complex, are long and costly, produce large amounts of waste, and which must be optimally planned for – especially given that they must be carried out in 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.

In 2022, 35 nuclear installations of all types (power and research reactors, laboratories, fuel reprocessing plants, waste treatment facilities, etc.) were either shut down or undergoing decommissioning, which represents more than a quarter of the BNIs in operation.

## 1. Technical and legal framework for decommissioning

### 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 choice of immediate dismantling in France obliges the licensees to carry out their decommissioning operations in the shortest time frame possible under economically acceptable conditions (see point 1.2).

Decommissioning is characterised by a succession of operations which tend to gradually reduce the quantity of radioactive substances present in the facility, therefore the risk levels evolve. 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 protection 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 very large volumes of waste produced, which are usually very much greater than the volumes produced during its operation. Decommissioning of the CEA's old installations and Orano's first-generation plants (especially the plants that played a role in the French deterrence policy, such as the gaseous diffusion plants of the Pierrelatte Defence Basic Nuclear Installation (DBNI) at Tricastin and the UP1 plant of the

Marcoule DBNI) is going to produce extremely large quantities 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 in as short a time frame as possible.

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, with due caution, organise 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 14).

ASN considers that management of the waste resulting from decommissioning operations is crucial for the smooth running of the decommissioning programmes (availability of disposal routes, management of waste streams). This subject is addressed with particular attention during the assessment of the decommissioning and waste management strategies established by the Alternative Energies and Atomic Energy Commission (CEA) EDF and Orano (see point 4).

## 1.2 The ASN decommissioning doctrine

At the international scale, 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. Consequently, practices and regulations differ from one country to another.

### 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 strategy adopted 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 financial resources to finance decommissioning, covering its anticipated expenses by dedicated assets.
- The decommissioning operations are carried out in as short a time as possible after shutting down the installation, a time 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 prepare and plan ahead for decommissioning as best possible. Since 2007, this document has been required as from commissioning of the facility, and is then updated regularly during its lifetime. It capitalises on the operating experience feedback 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 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 with its subsequent withdrawal from the list of BNI. 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 to deploy POCO practices that integrate the best available scientific and technical knowledge 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. In such cases ASN examines the scenarios proposed by the licensee and ensures that the POCO will be taken as far as reasonably possible.

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.

### DELICENSING OF THE ULYSSE REACTOR

BNI 18, named “Ulysse”, was commissioned in 1961. This research reactor with a nominal power of 100 kilowatts thermal (kWth) was operated by the CEA on its Saclay site for 47 years for the purpose of training and experimental activities.

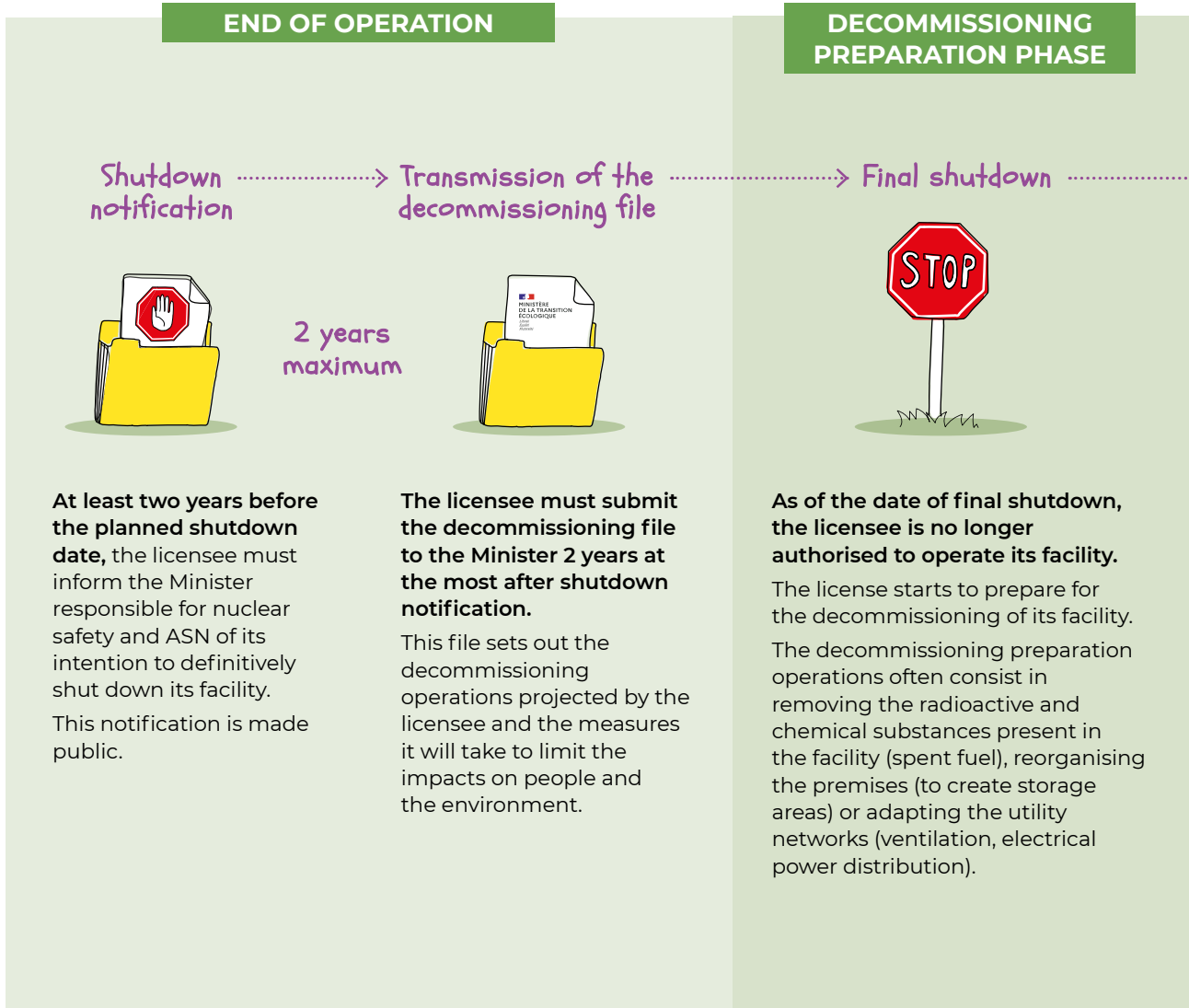
The reactor was definitively shut down in 2007. Following decommissioning preparation operations, including in particular removal of the spent fuel, the decommissioning operations began in 2014 after publication of the decommissioning decree.

Decommissioning was organised in three stages spanning five years, with a first phase of conventional work, followed by a second phase of nuclear work and finally a clean-out phase.

In February 2021, the CEA filed a BNI delicensing application, including a presentation of the post-decommissioning state of the site and the prospects for its future use. After analysing the file and the conclusions of the consultations, ASN considered that BNI 18 could be delicensed without active institutional

controls. The CEA was able to demonstrate that it had performed a complete post-operational clean-out in accordance with the ASN doctrine and the clean-out methodology approved by ASN in 2017. After conducting all the decommissioning operations, the land on which the facility was located is now compatible with all the potential future uses. Consequently, ASN delicensed the Ulysse reactor through a resolution of 24 June 2022. BNI 18 has thus been removed from the list of BNIs.

PHASES IN THE LIFE OF A BASIC NUCLEAR INSTALLATION



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 principle<sup>(1)</sup>). 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.

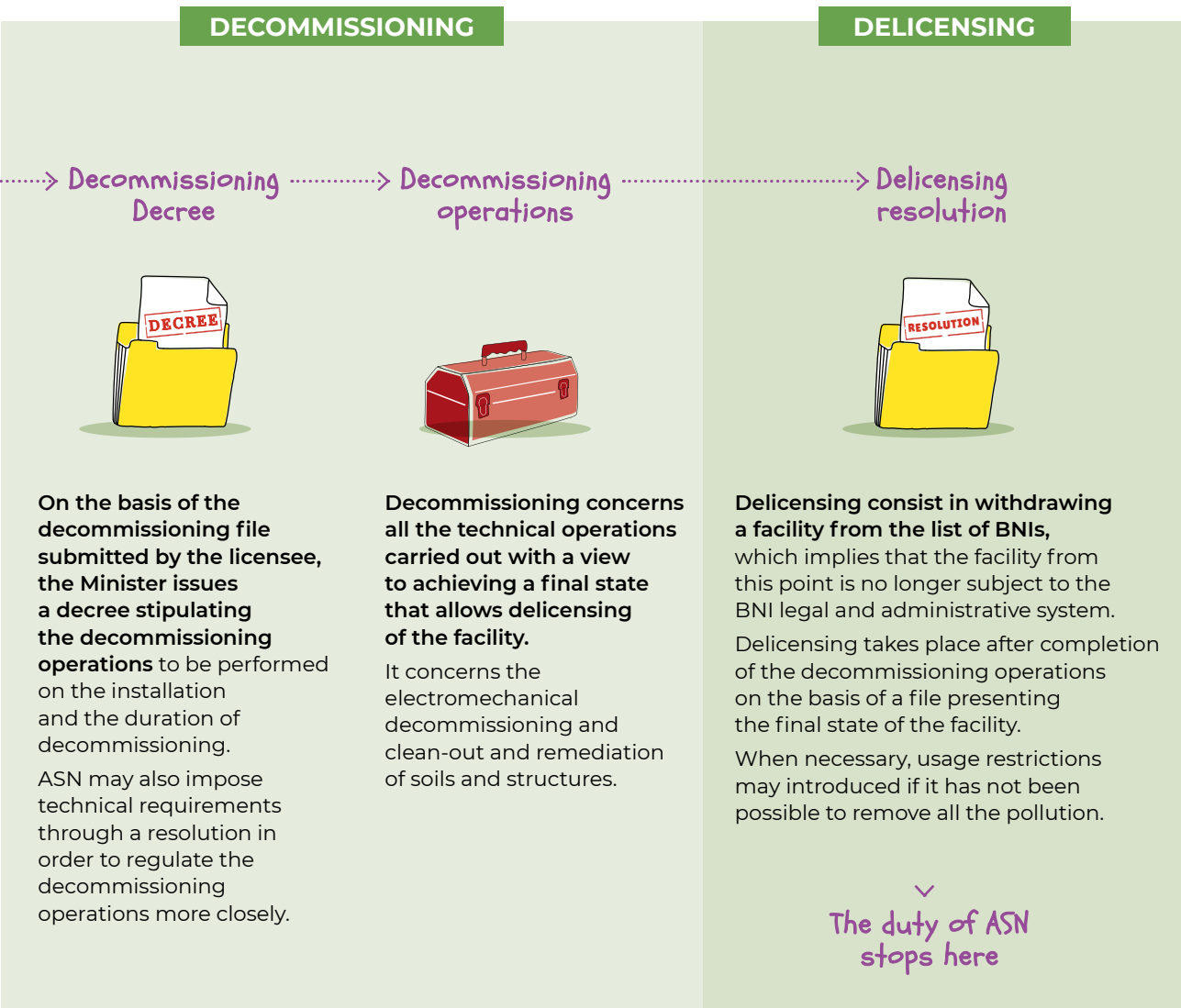
The doctrine implemented by ASN is set out in the guides relative to the structure clean-up operations (Guide No. 14, available at [asn.fr](http://asn.fr)), and the management of polluted soils in nuclear installations (Guide No. 24, available at [asn.fr](http://asn.fr)). The provisions of these guides 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 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 Creation Authorisation Decree. The decommissioning of a nuclear installation is prescribed by a new decree issued on the basis of an opinion from ASN. This decree sets out, among other things, 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

1. ALARA principle (As Low As Reasonably Achievable).



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 Committees (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.

Given that installation decommissioning operations are often very long, the decommissioning decree can stipulate that some steps will be subject to prior approval by ASN on the basis of specific safety analysis files.

The above Diagram 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 (including the fuel of a nuclear reactor) as well as preparing for 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 mappings, analysis of the operating history), which are vital for establishing the targeted POCO scenarios.

The Environment Code requires – as is the case for all other BNIs – that the safety of a facility undergoing decommissioning be reviewed periodically and at least every 10 years. 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 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.).

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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. As part of its delicensing application, the licensee must provide a file containing a description of the state of the site after decommissioning (analysis of the state of the soils, remaining buildings or facilities, etc.) and demonstrating that the planned final state has been reached. Depending on the final state reached, ASN may require the implementation of active institutional controls\* as a condition of delicensing the BNI in question. These may set a number of restrictions on the use of the site and buildings (use limited to industrial applications for example) or precautionary measures (radiological measurements to be taken in the event of excavations <sup>(2)</sup>, etc.). Some twenty facilities, most of them old research reactors, have been decommissioned and delicensed to date.

As at 31 December 2022, ASN was examining 22 decommissioning files for definitively shut down facilities whose decommissioning has not yet been prescribed or whose decommissioning conditions have substantially changed. The examination of the delicensing files of the last two BNIs of the CEA Grenoble centre is completed.

## 2. Situation of nuclear facilities undergoing decommissioning: specific challenges

At the end of 2022, 35 nuclear facilities in France are definitively shut down or undergoing decommissioning, that is to say about a quarter of the BNIs (see map page 342). These facilities are varied (nuclear power reactors, research reactors, fuel cycle facilities, support facilities, etc.) and the decommissioning challenges can differ greatly 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 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 is the case in particular with the Orano former spent fuel reprocessing plants and the CEA's old storage facilities. Furthermore, 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

The decommissioning of Pressurized Water Reactors (PWRs) 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.

### 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 cover the costs of decommissioning nuclear facilities and managing the spent fuel and radioactive waste. This system is clarified by the Order of 21 March 2007 relative to securing 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 triennial reports 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 the each licensee and can prescribe the necessary measures should it be found to be insufficient or inadequate. The General Directorate of the Treasury (DGT) 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.

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 Nuclear Power Plant (NPP) was definitively shut down in 2020. Its two reactors, which are representative of the fleet of reactors currently operated by EDF, will be first 900 Megawatts electric (MWe) reactors to be decommissioned in France. Decommissioning of the Fessenheim reactors with 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 breeder 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 perspective 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.

2. Excavation means the intentional digging of a plot of land by soil extraction to conduct works (for example, digging the foundations of a construction).



As with the PWRs, decommissioning begins with the removal of the nuclear fuel, which removes 99% of the radioactivity present in the installation. As the 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 the graphite bricks, representing some 15,000 tonnes of waste that will be produced, for which disposal appropriate for low-level long-lived nuclear waste (LLW-LL) is envisaged.

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 up and running and the reactor building decommissioning scenario is established, decommissioning of the installation should start again in the coming years.

Decommissioning of the sodium-cooled reactors (Phénix and Superphénix) has met with no major technological obstacles. The specific challenges lie chiefly in the control of the fire risk due to the presence of sodium and the safety of its treatment processes.

## 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 intermediated-level, long-lived waste (ILW-LL) and waste without a management route (such as non-incinerable oils and organic liquids, or waste containing potentially water-soluble mercury). 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 in final shutdown status at the end of 2022: Rapsodie (sodium-cooled fast neutron reactor), Masurca, Éole and Minerve (critical mock-ups), Phébus (experimental reactor), Osiris and Orphée (“pool” type reactors) and Isis (training reactors). The training reactor Ulysse 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 VLL waste, which must be stored then disposed of 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<sup>3</sup>), the Strasbourg University Reactor – RUS, Ulysse) and abroad. Their decommissioning usually spans about ten years, but the large number of installations to decommission simultaneously may lead to significantly longer prospective decommissioning durations for some of the 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

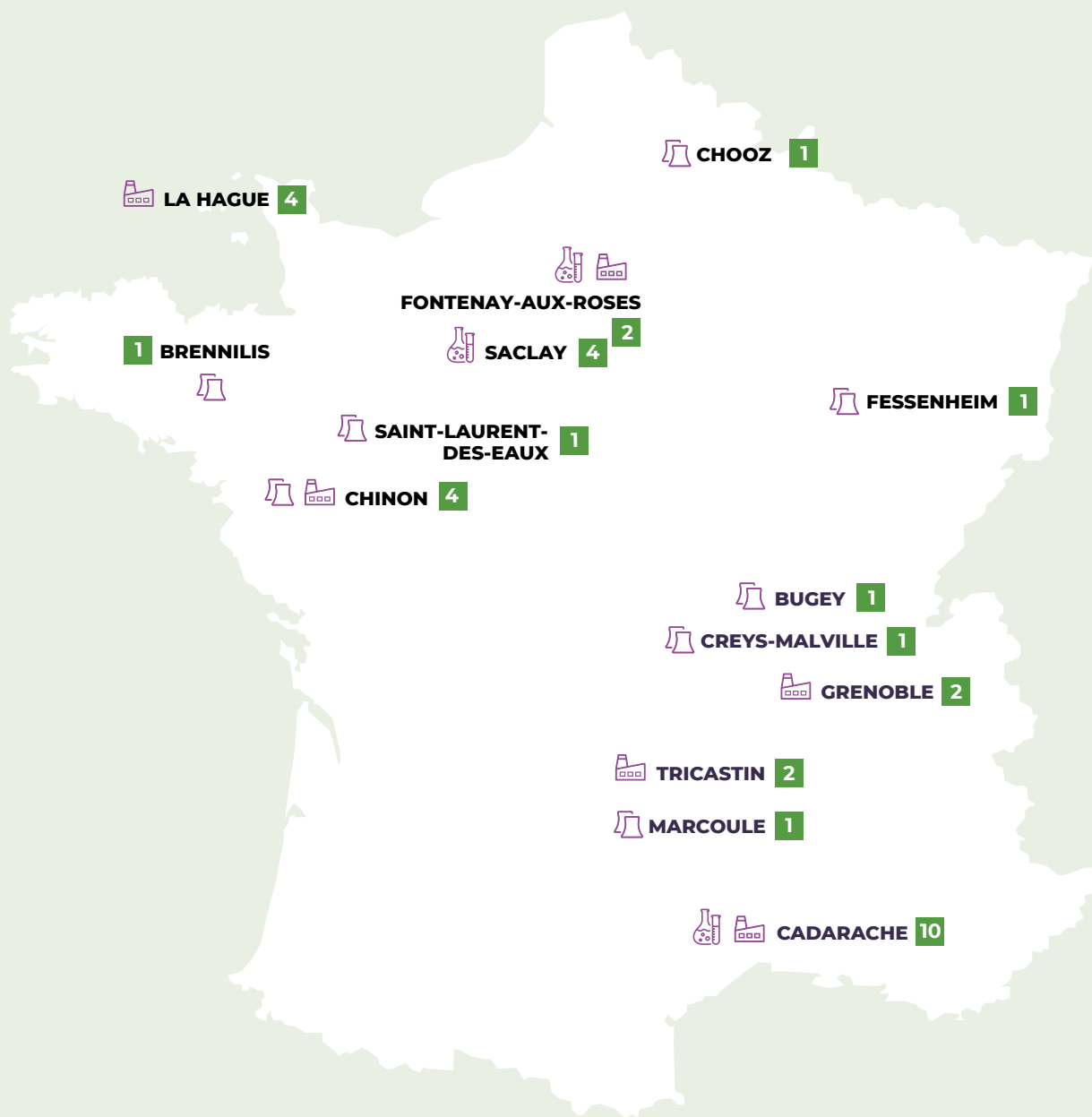
Two front-end “nuclear fuel cycle” facilities are undergoing decommissioning. They are located on the Tricastin site, one specialising in uranium enrichment by gaseous diffusion (George-Besse I plant – BNI 93), the other in uranium conversion (former Comurhex plant – BNI 105).

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 exposure risks are therefore largely 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, and 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.).

3. Triton was one of the first very compact and very flexible pool type research reactors called “MTR” (Material Test Reactor). Triton (6.5 MWth) was installed in Fontenay-aux-Roses in 1959.

# 35 NUCLEAR FACILITIES DEFINITELY SHUT DOWN OR IN THE PROCESS OF DECOMMISSIONING AS AT 31 DECEMBER 2022



KEY



Reactor



Plant



Research laboratory and reactor

### BRENNILIS

REACTOR EDF

- BNI 162 • EL4-D**  
 ● Commissioned: 1967  
 ● Decommissioning in progress

### BUGEY

REACTOR EDF

- BNI 45 • Bugey 1**  
 ● Commissioned: 1972  
 ● Decommissioning in progress

### CADARACHE

RESEARCH REACTORS CEA

- BNI 25 • Rapsodie**  
 ● Commissioned: 1967  
 ● Final shutdown

- BNI 39 • Masurca**  
 ● Commissioned: 1966  
 ● Final shutdown

- BNI 42 • Éole**  
 ● Commissioned: 1965  
 ● Final shutdown

- BNI 92 • Phébus**  
 ● Commissioned: 1978  
 ● Final shutdown

- BNI 95 • Minerve**  
 ● Commissioned: 1977  
 ● Final shutdown

MANUFACTURE, TRANSFORMATION OR STORAGE OF RADIOACTIVE SUBSTANCES CEA

- BNI 32 • Plutonium technology facility – ATPu**  
 ● Commissioned: 1962  
 ● Decommissioning in progress

- BNI 52 • Enriched uranium processing facility – ATUe**  
 ● Commissioned: 1963  
 ● Decommissioning in progress

- BNI 37-B • Effluent Treatment Station – STE**  
 ● Commissioned: 2015<sup>(\*)</sup>  
 ● Final shutdown

- BNI 53 • Central Fissile Material Warehouse – MCMF**  
 ● Commissioned: 1966  
 ● Final shutdown

- BNI 54 • Chemical Purification Laboratory – LPC**  
 ● Commissioned: 1966  
 ● Decommissioning in progress

### CHINON

UTILISATION OF RADIOACTIVE SUBSTANCES CEA

- BNI 94 • Irradiated Materials Facility – AMI**  
 ● Commissioned: 1964  
 ● 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

### CHOOZ

REACTOR EDF

- BNI 163 • Chooz A**  
 ● Commissioned: 1967  
 ● Decommissioning in progress

### CREYS-MALVILLE

REACTOR EDF

- BNI 91 • Superphénix**  
 ● Commissioned: 1985  
 ● Decommissioning in progress

### FESSENHEIM

REACTORS EDF

- BNI 75 • Fessenheim 1 – 2**  
 ● Commissioned: 1977  
 ● Final shutdown

### FONTENAY-AUX-ROSES

RESEARCH FACILITY CEA

- BNI 165 • Procédé**  
 ● Commissioned: 2006<sup>(\*\*)</sup>  
 ● Decommissioning in progress

EFFLUENT REPROCESSING AND WASTE STORAGE FACILITY

- BNI 166 • Support**  
 ● Commissioned: 2006<sup>(\*\*)</sup>  
 ● Decommissioning in progress

### GRENOBLE

TRANSFORMATION OF RADIOACTIVE SUBSTANCES CEA

- BNI 36 • Effluent and Solid Waste Treatment Station – STED**  
 ● Commissioned: 1964  
 ● Decommissioning in progress

- BNI 79 • High-level waste storage unit**  
 ● Commissioned: 1972  
 ● 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

### MARCOULE

REACTOR CEA

- BNI 71 • Phénix**  
 ● Commissioned: 1973  
 ● Decommissioning in progress

### SACLAY

RESEARCH REACTORS CEA

- BNI 40 • Osiris-Isis**  
 ● Commissioned: 1966  
 ● Final shutdown

- BNI 101 • Orphée**  
 ● Commissioned: 1980  
 ● Final shutdown

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

### SAINT-LAURENT-DES-EAUX

REACTORS EDF

- BNI 46 • Saint-Laurent A1 – A2**  
 ● Commissioned: 1969 et 1971  
 ● Decommissioning in progress

### TRICASTIN

TRANSFORMATION OF RADIOACTIVE SUBSTANCES Orano Chimie Enrichissement

- BNI 105 • Comurhex uranium hexafluoride preparation plant**  
 ● Commissioned: 1978  
 ● Decommissioning in progress

- BNI 93 • Georges Besse plant for separating uranium isotopes by gaseous diffusion**  
 ● Commissioned: 1979  
 ● Decommissioning in progress

\* This date results from 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 PROJECTS

Given the large number of their facilities in final shutdown status or undergoing decommissioning, the 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 process based on technologies that are not yet tried and tested, or putting in place management routes for radioactive waste for which there is no disposal solution at present.

Making specific efforts to identify the short and medium-term milestones contributes to the successful management of these projects.

The scale of these projects and the particular difficulties they can present has led the CEA and Orano to prioritise those presenting the greatest challenges, 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.

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 PHASES	DEADLINE <sup>(*)</sup>	ASN OBSERVATIONS
BNI 22	<b>Decommissioning of Pégase facility</b>	Safety of storage pool with respect to a seismic hazard  Limitation of dependency of Cascad in terms of active institutional controls	<ul style="list-style-type: none"> <li>Retrieval and packaging of araldite-encapsulated fuels from the Pégase facility (planned to start in 2025).</li> <li>Decoupling of Pégase and Cascad facilities (envisaged from 2030 to 2035).</li> </ul>	2065	In 2022, ASN authorised the "DECAP" process (a French acronym for "removal of araldite-encapsulated fuels from Pégase"), permitting the repackaging of the cans of araldite-encapsulated fuels for storage in the Cascad facility.  The decoupling work is planned for 2030.
BNI 37B	<b>Retrieval and packaging of all the residues in the facility's tanks</b>	Safety of the pits containing waste with respect to a seismic hazard and a fire	<ul style="list-style-type: none"> <li>Construction of a new building and putting into service an entirely automated retrieval process requiring substantial preliminary operations.</li> <li>Defining of the definitive packaging process</li> </ul>	To be defined	Commissioning of the residue treatment facility allowing retrieval of the residues from the facility's tanks is planned for 2052.  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.

\* 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 PHASES	DEADLINE (*)	ASN OBSERVATIONS
BNI 54	<b>Decommissioning of the cryogenic treatment facility</b> 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	<ul style="list-style-type: none"> <li>Decommissioning of the cryogenic treatment process chambers.</li> <li>Characterisation of the soils under the facility.</li> </ul>	06/03/2024	<p>This priority operation in the CEA's "decom/waste" strategy began in 2021.</p> <p>A decommissioning decree modification request is expected in the first half of 2023.</p>
BNI 56	<b>Retrieval and packaging of the waste</b> stored in the trenches	Risk of flooding by water table upwelling	<ul style="list-style-type: none"> <li>Develop packaging routes for certain particular types of waste.</li> <li>Design automated means of retrieval.</li> </ul>	To be defined	The retrieval scenario for the waste in the trenches is to be transmitted to ASN at the end of 2023.
	<b>Retrieval and packaging of all the intermediate level bulk waste</b> present in the old pits ("vrac MI" (bulk IL) project)	Safety of the pits containing waste with respect to a seismic hazard	<ul style="list-style-type: none"> <li>Construction of a new buildings and putting into service an entirely automated retrieval process requiring substantial preliminary operations</li> </ul>	To be defined	ASN is currently examining the decommissioning file.
	<b>Retrieval and packaging of all the waste</b> present under the hangars ("ATC" project)	Safety of the hangars containing waste with respect to a seismic hazard	<ul style="list-style-type: none"> <li>Defining the definitive packaging processes</li> </ul>	To be defined	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 PHASES	DEADLINE (*)	ASN OBSERVATIONS
BNI 165	<b>Packaging of the ILW-LL waste</b> in PETRUS drums and characterisation of the waste from the decommissioning of the PETRUS unit	Access to the contaminated silos under the PETRUS unit	<ul style="list-style-type: none"> <li>Construction of the new waste transfer and packaging enclosure (ETCB).</li> <li>Development work in order to accept and remove the waste drums from decommissioning of the equipment of building 18 (EDB).</li> </ul>	01/07/2017	<p>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.</p> <p>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.</p>
BNI 166	<b>Retrieval of waste</b> 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.	01/07/2018	

\* 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 PHASES	DEADLINE (*)	ASN OBSERVATIONS
BNI 71	<b>Sodium treatment</b>	Risk of fire, pyrophoricity, explosion	<ul style="list-style-type: none"> <li>Commissioning of the sodium treatment facility Noah.</li> <li>Removal of the fuel.</li> </ul>	2037	Treating the sodium is a prerequisite for decommissioning the facility and significantly reduces the risks it represents.
				2025	Completion of fuel removal will be pushed back a few years.

\* 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 PHASES	DEADLINE (*)	ASN OBSERVATIONS
BNI 35	<b>Emptying of tanks</b> 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, planned for end of 2026.	To be defined	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.
	<b>Clean-out</b> of pit 99		Emptying tank-bottom contents present in the pit.		ASN is currently examining a licence application for the emptying of tank 40/4, considered to be a priority.
	<b>Treatment of the sludges</b> of tanks MA501 to MA507		Characterisation of effluents and clean-out strategy to consolidate.		ASN considers tank MA507 a priority.
BNI 72	<b>Retrieval and packaging of drums</b> containing a mixture of waste and fuel fragments ("EPOC" project, a French acronym for "Removal of fuel bins")	Safety of the storage areas with respect to containment and a seismic hazard	<ul style="list-style-type: none"> <li>Construction of retrieval equipment.</li> <li>Adaptation of the retrieval equipment, whatever the envisaged state of the waste.</li> <li>Entry into service of the EPOC processes.</li> </ul>	2029	The process sizing studies are completed; the next stage is the construction of the equipment. Commissioning was initially planned for 2023. This deadline was pushed back to 2029 due to numerous technical and organisational difficulties.
	<b>Retrieval and packaging</b> of all the solid waste, fuels, irradiated fuels and radioactive sources		Removal of the stored content from the pool and emptying of the pool	31/12/2024	The removal operations are in progress. Given the numerous technical and organisational difficulties, the initial deadlines have been pushed back by several years.
	40 pits zone – Removal of stored irradiating waste.		31/12/2030		
	Removal of stored content from blocks 108 and 116.		Completed in 2022		
	Removal of stored sources from building 116.	31/12/2025			

\* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

EDF

	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY PHASES	DEADLINE (*)	ASN OBSERVATIONS
BNI Chinon A2	<b>Decommissioning of reactor pressure vessel</b>	Pilot project for the decommissioning of the other GCRs	<ul style="list-style-type: none"> <li>Opening of RPV and setting up of the decommissioning platform.</li> <li>Decommissioning of the graphite stack.</li> </ul>	To be defined	<p>Removal of the fuel from the facility has significantly reduced the risks. The facility has moreover already been partly decommissioned.</p> <p>ASN will issue a position statement on the time frames proposed by EDF for decommissioning its GCRs as part of the examination of the decommissioning files submitted at end of 2022.</p>
	<b>Retrieval and packaging of the graphite sleeves</b>	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 examination of the decommissioning file submitted in 2022.

\* 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 PHASES	DEADLINE (*)	ASN OBSERVATIONS
BNI 33	<b>Decommissioning of the "High-Activity Dissolution Extraction" unit (HADE)</b>	Short-term safety with respect to the earthquake hazard	Entry into active services of the DFG building (French acronym for "fine granulometry waste") for retrieval of decladding waste, planned for 2028.	31/12/2046	The decommissioning priority for this facility, whose decommissioning decree sets completion for 2046, is given to the expeditious retrieval of the legacy waste, which represents a major risk for safety given the large radiological inventory and the vulnerabilities in the waste storage conditions.
	<b>Decommissioning of the "High-Activity Fission Product" unit (HAPF)</b>		Rinsing and effluent treatment operations on the HAPF unit solvent tanks; completion is planned for 2031 but could be pushed back to about 2035 in the event of technical difficulties.		
	<b>Decommissioning of the "Medium Activity Plutonium" unit (MAPu)</b>	Short-term safety of neighbouring units with respect to the earthquake hazard	Dismantling of upper storeys to limit risks to the units in operation, planned before end of 2028.		

\* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

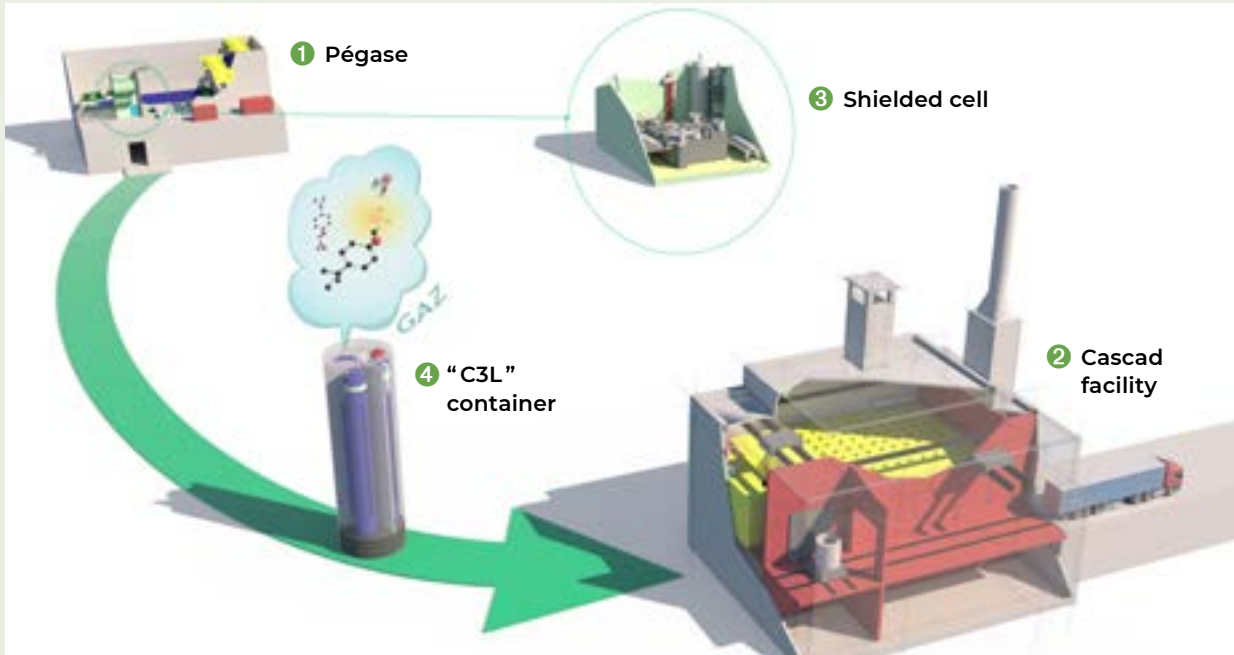
## Orano La Hague

	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY PHASES	DEADLINE (*)	ASN OBSERVATIONS
BNI 38	<b>Retrieval and packaging of waste</b> from silo 130	<p>Short-term safety of the silo with respect to containment or a seismic hazard</p> <p>Packaging within time frames compatible with commissioning of the deep geological repository <i>Cigéo</i></p>	<ul style="list-style-type: none"> <li>End of retrieval of solid GCR waste (intermediate-level long-lived waste – ILW-LL).</li> <li>End of retrieval of active effluents and sludge.</li> <li>End of packaging of ILW-LL waste.</li> </ul>	31/12/2025	<p>Retrieval began in February 2020, but technical malfunctions require technical developments in order to achieve industrial output rates.</p> <p>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.</p> <p>The end-of-retrieval deadlines are therefore pushed back by a few years.</p> <p>Packaging in definitive packages that meet the acceptance criteria for a deep geological repository is pushed back by several decades (**).</p>
	<b>Retrieval and packaging of the sludge</b> stored in the silos of the Effluent Treatment Station No.2 – STE2 (“Sludge Retrieval and Packaging” project) (RCB)	<p>Safety of the silos with respect to containment and a seismic hazard</p>	<ul style="list-style-type: none"> <li>Defining of the sludge retrieval scenario (direct packaging or construction of a new storage facility).</li> <li>Defining of the sludge encapsulation matrix, development then commissioning of the sludge treatment process.</li> <li>Defining of the definitive packaging process.</li> </ul>	31/12/2030	<p>The new sludge retrieval and management strategy was revised in 2022. Orano is to submit a file presenting the planned options for improving the robustness of the sludge storage conditions.</p> <p>The time frames for the start and end of retrieval are therefore pushed back significantly.</p> <p>The packaging in definitive packages acceptable in a deep geological repository will be pushed back by several decades(**).</p>
BNI 80	<b>Retrieval and packaging of the waste</b> from the “High Activity Oxide” (HAO) silo and the Organised hull storage (SOC) pools	<p>Safety of the silo with respect to containment, a seismic hazard or resistance to an aircraft crash</p> <p>Packaging within time frames compatible with commissioning of the <i>Cigéo</i> deep geological repository</p>	<ul style="list-style-type: none"> <li>Commissioning of the ILW-LL solid waste and active effluents retrieval unit.</li> <li>End of packaging of the waste.</li> </ul>	31/12/2022	<p>In view of the difficulties associated with operation and maintenance of the planned process, the retrieval scenario was updated in 2021. ASN is examining the applications for authorisation to put the equipment into active service. The first tests are planned in the next few years. Start of retrieval is now pushed back to 2027. The end-of-packaging deadline is pushed back significantly.</p>
	<b>Partial dismantling of the filtration building</b> at the end of decommissioning	<p>Reduction of the interactions with the pools of the spent fuel elements unloading and storage facility (NPH), in the event of an earthquake</p>	<ul style="list-style-type: none"> <li>Clean-out of the “900 cells”.</li> <li>Dismantling of the upper storeys.</li> </ul>	To be defined	<p>Completion of dismantling of the filtration building is forecast between 2031 et 2036, and clean-out of the “900 cells” around 2050; these time frames must nevertheless be supported by additional files to be submitted in the coming years.</p>

\* 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.

**THE “DECAP” PROJECT**



By a resolution of 18 August 2022, ASN authorised implementation of the “DECAP” process (French acronym for “Removal of araldite-encapsulated fuels from Pégase”) in the CEA’s BNI 22 called “Pégase”.

The “araldite-encapsulated” cans are sealed metal containers in which are placed spent fuel assemblies coated in a hardenable resin which sets them. This resin can react with the nuclear material by radiolysis, creating gases which can ultimately deform the cans.

The DECAP process, currently being set up in the Pégase ① facility, will consist in repackaging in a shielded cell ③, all the araldite-encapsulated cans stored at present in the facility’s pool, and transferring them to the Cascad ② facility for storage.

This will involve several operations:

- piercing the wall of the outer can to evacuate any built-up gases,
- cutting away the outer can,
- extracting the inner can,
- piercing the wall of the inner can to evacuate any built-up gases,
- transferring the inner can to a container baptised “C3L” ④. The “C3L” container, similar to those used on the Cascad facility, features a system for monitoring any build-up of gases.

It is to be noted that further to the last periodic safety review of the Pégase facility, ASN required the repackaging operations to begin by the end of 2024 at the latest. The DECAP process will enable this requirement to be met. In this context, the CEA has set the target of finalising the repackaging of the Pégase pool cans by the end of 2030.

**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 are operated by Orano and 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, namely the effluent treatment station STE2 and the spent fuel reprocessing facility AT1 (BNI 38), the radioactive source fabrication facility ELAN IIB (BNI 47) and the “High Activity Oxide” facility (HAO), built for reprocessing the fuels from the “light water” reactors (BNI 80). Some of these facilities suffered accidents which led to contamination of the premises and their near environment, such as the 1981 fire in silo 130 which is part of BNI 38.

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 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 processing of radioactive effluents and waste)**

Many of these facilities, most of which were commissioned in the 1960’s and whose level of safety did 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 Saint-Laurent-des-Eaux silos (BNI 74), the pits, trenches and hangars of

BNI 56 and the pits of BNI 72 and BNI 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 projected or in the course of construction.

The Effluent Treatment Stations (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 station STE2 of the La Hague plan (BNI 38). The difficulties associated with decommissioning of the effluent treatment stations 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 old stored waste and of the sludge or present in certain tanks. 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 effect, 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 and carrying out the operations under conditions ensuring a satisfactory level of safety and radiation protection 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.

### 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. 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 borne by 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.

In 2022, ASN examined the periodic safety review reports of 17 facilities in final shutdown status. Inspections focusing on the periodic safety review were conducted in 2022 on four facilities undergoing decommissioning. 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.

In 2022, ASN rendered public its conclusions on the periodic safety review of the Solid Radioactive Waste Management Zone (ZGDSw BNI 72) and Chooz A (BNI 163).

#### 3.3 Financing decommissioning: ASN's opinion on the triennial 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 licensees' triennial reports of 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 triennial 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 show reasonable caution 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 the 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 priority 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 14.

### 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, which may also be revised if it turns out in the coming decades that this scenario can be optimised in view of acquired experience. This decommissioning strategy for the GCRs is governed by two ASN resolutions, 2020-DC-0686 and CODEP-CLG-2020-021253, published on 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, 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. EDF also commissioned its graphite industrial demonstrator at Chinon in 2022.

ASN considers that it is appropriate for EDF to develop an industrial demonstrator 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 decommissioning 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.

### 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, individual facilities of the DBNI at Pierrelatte, etc.). Implementation of decommissioning is closely linked to the 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 the new waste resulting from the 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 governs 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 inventory of radioactive substances present and the age of the facilities in which they are stored, which do not 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 at 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 foresee and address any blocking situations and determine practical measures to put in place to accomplish the WRP and decommissioning operations in the shortest time frame possible.

In June 2016, at the request of ASN and the Defence Nuclear Safety Authority (ASND), Orano submitted its decommissioning and waste management strategy. The file also includes the application of this strategy on the La Hague and Tricastin sites. In its position statement letter of 14 February 2022, ASN underlined the licensee's progress in assimilating the objectives of immediate dismantling, in tracking the governance of complex projects, the progress of the operations of several Tricastin facilities, and the defining of the definitive waste packaging processes for the La Hague site. ASN nevertheless considers that Orano should prioritise the implementation of its decommissioning and waste management strategy according to the risks, and more specifically better manage its WRP strategy in order to reduce the “dispersible radiological inventory”<sup>(4)</sup> as early as possible. ASN also considers that Orano should improve its knowledge of the current state of the facilities with a view to their future post-operational clean-out and progressing in the management of complex projects.

4. 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.

**RESULTS OF THE EXPLORATORY APPROACH TO THE OVERSIGHT OF COMPLEX PROJECTS CONDUCTED WITH THE CEA IN 2021 AND 2022**

In 2021 and 2022, CEA voluntarily embarked on the implementation of an exploratory approach to the oversight of complex projects by ASN. The aim of this approach is to develop effective oversight of the nuclear licensees' control of complex projects, of which the smooth running and compliance with the deadlines determine the risks for nuclear safety.

ASN performed a joint inspection of the BNI 37-B<sup>(\*)</sup> decommissioning project from 4 to 8 July 2022. This inspection was carried out with the DGEC competent for checking the financial issues associated with complex project control, with the Institute for Radiation

Protection and Nuclear Safety (IRSN), and a consultancy firm with expertise in complex project management.

It emerges from this inspection that the CEA has assets to succeed with this decommissioning, chiefly the personnel commitment and skills, the appropriate technical choices for the decommissioning scenario and initiatives on the part of the central services for improving certain project management practices. The inspectors identify five areas for improvement, namely:

- ensuring consistency with the project baseline reference<sup>(\*\*)</sup>,
- project control discipline,

- improving project maturity,
- contract management,
- safety management.

*\* BNI No. 37-B is the former Radioactive Liquid Effluents Treatment Station (STEL) of the Cadarache centre, which functioned from 1965 to 2013.*

*\*\* The baseline reference is the reference scheduling meeting, the reference budget and the reference technical scenario. It constitutes the integrated reference against which project progress is measured, which allows early detection and analysis of deviations in deadlines, costs or technical modifications, and therefore to foresee the corrective measures to take to maintain project control. This is the purpose of the project control discipline.*

**4.3 Assessment of the CEA's decommissioning strategy**

Given the number and complexity of the operations to be carried out for all the nuclear facilities concerned, the 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. The two Authorities have since observed changes in the WRP schedules presented by the CEA, particularly the pushing back of waste management deadlines, including for operations considered to be priorities. ASN, ASND and the CEA have agreed to set up regular monitoring of these operations, through progress indicators in particular.

As concerns facilities classified as lower priority, ASN and ASND have also noted significant push-backs of some of the decommissioning deadlines announced by the licensee since 2016. The two authorities will rule on the CEA's justifications for these schedule push-backs on reception of the facilities' decommissioning files.

## Appendix

**BNI** ● List of Basic Nuclear Installations undergoing decommissioning or delicensed as at 31 December 2022

INSTALLATION LOCATION	BNI No.	TYPE OF INSTALLATION	COMMIS- SIONED	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	Decommissioned 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 list of BNIs and classified as ICPE	Partially decommissioned, remaining parts confined
Ulysse (Saclay)	(Former BNI 18)	Reactor (100 kWth)	1967	2007		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 – passive institutional controls <sup>(*)</sup>
Silhouette (Grenoble)	(Former BNI 21)	Reactor (100 kWth)	1964	2002	2007: Removed from BNI list	Decommissioned – passive institutional controls <sup>(*)</sup>
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 at Marcoule, 1964 at 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 of solid and liquid waste	Before 1964	2006	2006: Removed from BNI list	Integrated in BNI 166
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	Destruction of the ancillaries building
ALI (Saclay)	(Former BNI 43)	Accelerator	1958	1996	2006: Removed from BNI list	Decommissioned – passive institutional controls <sup>(*)</sup>
Strasbourg University reactor	(Former BNI 44)	Reactor (100 kWth)	1967	1997	2012: Removed from BNI list	Decommissioned – passive institutional controls <sup>(*)</sup>
Saturne (Saclay)	(Former BNI 48)	Accelerator	1966	1997	2005: Removed from BNI list	Decommissioned – passive institutional controls <sup>(*)</sup>
Attila <sup>(*)</sup> (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 laboratory	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

INSTALLATION LOCATION	BNI No.	TYPE OF INSTALLATION	COMMIS- SIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
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	Buildings demolished, active institutional controls
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 – passive institutional controls <sup>(*)</sup>
IRCA (Cadarache)	(Former BNI 121)	Irradiator	1983	1996	2006: Removed from BNI list	Decommissioned – passive institutional controls <sup>(*)</sup>
FBFC (Pierrelatte)	(Former BNI 131)	Fabrication of fuel	1990	1998	2003: Removed from BNI list	Decommissioned – passive institutional controls <sup>(*)</sup>
Uranium warehouse (Miramas)	(Former BNI 134)	Uranium-bearing materials warehouse	1964	2004	2007: Removed from BNI list	Decommissioned – passive institutional controls <sup>(*)</sup>
SNCS (Osmanville)	(Former BNI 152)	Ioniser	1983	1995	2002: Removed from BNI list	Decommissioned – passive institutional controls <sup>(*)</sup>
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	Partial decommissioning in progress
STED and high-level waste storage unit (Grenoble)	36 and 79	Waste treatment and storage plant	1964/1972	2008	2008: Final Shutdown and 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 (Cadarache)	42	Reactor (1 kWth)	1965	2017		Preparation for decommissioning
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
ÉLAN 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		Preparation for decommissioning
LPC (Cadarache)	54	Laboratory	1966	2003	2009: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Phénix (Marcoule)	71	Reactor (536 MWth)	1973	2009	2016: Decommissioning Decree	Decommissioning in progress

INSTALLATION LOCATION	BNI No.	TYPE OF INSTALLATION	COMMIS-SIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
ZGDS (Saclay)	72	Transformation of radioactive substances	1971	2022	2022: Decommissioning Decree	Preparation for decommissioning
Fessenheim NPP (Fessenheim)	75	Reactors (each of 2,660 MWth)	1977	2020		Preparation for decommissioning
HAO (High Activity Oxide) 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		Preparation for decommissioning
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
Minerve (Fontenay-aux-Roses)	95	Reactor (100 Wth)	1977	2017		Preparation for decommissioning
Orphée (Saclay)	101	Reactor (14 MWth)	1980	2019		Preparation for decommissioning
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 A2D	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	Partial decommissioning in progress Preparation for complete decommissioning
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 (BNI 57 and 59) concerning reprocessing processes	2006	2006	2006: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Support (Fontenay-aux-Roses)	166	Grouping of former installations (BNI 34 and 73) for packaging and treating waste and effluents	2006	2006	2006: Final Shutdown and Decommissioning Decree	Decommissioning in progress

\* Attila: reprocessing pilot located in a unit of BNI 57

\*\* Passive institutional controls.

\*\*\* Active institutional controls





# Radioactive waste and contaminated sites and soils

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**T**his chapter presents the role and actions of the French Nuclear Safety Authority (ASN), 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 administrative authority. 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 ensures that the waste resulting from contaminated site clean-up operations are directed to appropriate management routes.

The French Governments' National Radioactive Materials and Waste Management Plan (PNGMDR), enshrined by the Act of 28 June 2006 on the sustainable management of radioactive materials and waste, constitutes a tool of choice for the sustainable management of radioactive materials and wastes, in compliance with protection of the human health, safety and the environment. In 2021 and 2022, as part of the preparation for the 5th PNGMDR covering the 2022-2026<sup>(1)</sup> period, which was published at the end of 2022, ASN issued several opinions.

In the context of its oversight of the decommissioning and waste management strategies implemented by the major licensees, ASN made a position statement on Orano's strategy in early 2022. It moreover continued its monitoring of the strategy implemented by the Alternative Energies and Atomic Energy Commission (CEA).

Lastly, on 16 January 2023 the French National Agency for Radioactive Waste Management (Andra) submitted the Creation Authorisation Application (DAC) for *Cigéo*, the deep geological disposal facility project for the most highly radioactive waste.

## 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 their 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 (ICPE), which are placed under the oversight of the Prefects.

1. The initial PNGMDR draft concerned the 2021-2025 period.



TABLE 1 Classification of radioactive waste<sup>(2)</sup>

		VERY SHORT LIVED WASTE CONTAINING RADIONUCLIDES WITH A HALF-LIFE OF < 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 <sup>(*)</sup>		<b>Management by radioactive decay on production site then disposal via disposal routes dedicated to conventional waste</b>	<b>Recycling or dedicated surface disposal</b> (disposal facility of the industrial centre for collection, storage and disposal – Cires – in the Aube département)	
HUNDREDS Bq/g <sup>(*)</sup>			<b>Surface disposal</b> (Aube waste disposal repository)	<b>Near-surface disposal</b> (being studied pursuant to the Act of 28 June 2006)
MILLIONS Bq/g <sup>(*)</sup>				
BILLIONS Bq/g <sup>(*)</sup>		<b>High-level (HL)</b>	<b>Deep geological disposal</b> (planned pursuant to the Act of 28 June 2006)	

\* Becquerel per gramme (Bq/g).

\*\* There is no such thing as high-level, very short-lived.

### 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.

First, the nuclear power sector, with 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, and the technological waste, and the waste from the treatment of effluents such as the bituminised sludge. Furthermore, decommissioning of the facilities produces a large volume of radioactive waste.

Second, the research sector, which includes civil nuclear research, in particular the CEA’s laboratory and reactor research activities, 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<sup>(3)</sup> 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 regulate the management of the waste produced by these activities.

#### Management of disused sealed sources considered as waste

Sealed sources<sup>(4)</sup> are used in 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.). Consequently, NORM waste, for which there is no planned or envisaged use, is now considered as 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 above-mentioned exemption thresholds is directed to conventional waste management routes.

2. 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.

3. Source for which the presentation and the normal conditions of use are unable to prevent all dispersion of the radioactive substance.

4. Source for which the structure or packaging prevents all dispersion of radioactive substances into the ambient environment, in normal use.

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 conditions stipulated in the Circular of 25 July 2006<sup>5</sup> relative to waste storage facilities, coming under sections 2760 of the ICPE classification are satisfied;
- in the industrial centre for grouping storage and disposal (Cires<sup>6</sup>) intended for the disposal of very low-level radioactive waste.

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

Radioactive waste management falls within the general waste management framework defined in Book V, Part IV, Chapter I of the Environment Code and its implementing decrees. Particular provisions concerning radioactive waste were introduced first by Act 91-1381 of 30 December 1991 on research into the management of radioactive waste, and then by Planning Act 2006-739 of 28 June 2006 on sustainable management of radioactive materials and waste, called the “Waste Act”, which gives a legislative framework to the management of all radioactive materials and waste. A large part of the provisions of these Acts are codified in Book V, Part IV, Chapter II of the Environment Code.

The Act of 28 June 2006 more specifically sets a calendar for research into high and intermediate-level, long-lived (HL and IL-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 preparation of the PNGMDR, which aims to carry out a periodic assessment and define the prospects for the radioactive substance management policy. It also consolidates the missions of the French National Radioactive Waste Management Agency (Andra), notably by entrusting it with a public service mission for the management of waste 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, 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. In 2021, 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).

This framework was amended in 2016 with the publication of the 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 high-level and intermediate-level long-lived (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 Part 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 (RGE) 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.

5. Circular of 25 July 2006 relative to classified installations – Acceptance of technologically enhanced or concentrated natural radioactivity in the waste disposal centres.

6. French acronym standing for “Industrial centre for grouping, storage and disposal”, name given in October 2012. It was commissioned in 2003 under the name CSTFA, standing for “Very low level waste disposal facility”, a facility licensed under section 2797 of the ICPE System.



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 amended ASN resolution 2015-DC-0508 of 21 April 2015 to take into account this regulatory change.

### 1.2.2 Legal framework for the management of radioactive waste produced by activities governed by the Public Health Code

Article R. 1333-16<sup>(7)</sup> 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 specified.

#### 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 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 above-mentioned Article L. 542-12 and that they must be continued.

Nevertheless, the tritiated solid waste must be managed with the waste from ITER in a storage facility operated by the CEA (called

the “Intermed project” at present). The delays in the ITER project schedule are impacting the Intermed project schedule and the management strategy for tritiated waste from small producers. In its report provided in response to Article 61 of the Order of 23 February 2017, Andra proposes storing this waste on the CEA Valduc site pending commissioning of the above-mentioned storage facilities.

In its opinion 2021-AV-0379 of 11 May 2021, ASN gave a reminder that the storage of tritiated waste from small producers in a Defence Basic Nuclear Installation (DBNI) was not justified by a possible need to protect information for the purpose defence. As the commissioning of Intermed in about ten years' time has become improbable due to the delays in its dimensioning and detailed design, ASN recommends that Andra puts in place, as soon as possible, the necessary storage capacities for the acceptance of highly tritiated waste and sources containing tritium from small producers, prior to their definitive management in a disposal facility or their possible subsequent storage in Intermed.

### 1.2.3 The National Inventory of radioactive materials and wastes

Article L. 542-12 of the Environment Code assigns Andra the task of establishing, updating every three years and publishing the National Inventory of radioactive materials and waste.

The last update was published in 2018. 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 2016. A prospective exercise, more detailed than for the 2015 edition, was also conducted considering four contrasting scenarios for France's energy policy, as envisaged in 2017. These scenarios were updated in 2021 and will be used for the next update of the National Inventory, planned to be published in 2023.

This Inventory constitutes an input database for preparing the PNGMDR. In its opinion 2020-AV-0363 of 8 October 2020, ASN considers it necessary to plan ahead for the consequences of possible changes in the energy policy regarding the management of materials and waste, and points out that these projections must be based on various long-term hypotheses, consistent with the forecasts of the Multi-year Energy Programme (MEP) adopted by Decree of 21 April 2020.

### 1.2.4 The National Radioactive Material and Waste Management Plan

Article L. 542-1-2 of the Environment Code, amended by the above-mentioned Ordinance 2016-128 of 10 February 2016, defines the objectives of the PNGMDR:

- 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;
- organises 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.

7. Formerly Article R. 1333-12.

## 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 of Ecological Transition.

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.

ASN also publishes on its website the PNGMDR, its synthesis, the minutes of the above-mentioned working group's meetings, the studies required by the plan and the opinions it has issued on these studies.

## PUBLICATION OF THE 5TH NATIONAL RADIOACTIVE MATERIALS AND WASTE MANAGEMENT PLAN (PNGMDR)

Radioactive materials and wastes must be managed sustainably and responsibly, to protect individual health, safety and the environment, including in the long and very-long term.

Instituted by the Act of 28 June 2006 on the sustainable management of radioactive materials and waste, the PNGMDR is a management tool of choice for the sustainable implementation of these principles. The PNGMDR covers the ultimate waste and the reusable radioactive materials alike, the existing management routes and those that are planned, under development or to be defined; it also concerns all categories of radioactive waste, whatever their origin. The PNGMDR takes account of the French energy policy and the management solutions it sets out are compatible with the Multi-year Energy Programme (MEP).

For the first time ever, the preparation of the 5th PNGMDR was preceded by a public debate held in 2019. On 21 February 2020, further to this public debate, the Ministry for Energy Transition (MTE) and ASN published a joint resolution setting out the broad lines of the plan. In 2020 and 2021, ASN subsequently issued seven technical opinions on the management of radioactive materials and waste with a view to drafting the 5th PNGMDR.

In the course of preparation of the 5th plan by the MTE, ASN issued general opinions 2021-AV-0390 and 2022-AV-0403 on 9 November 2021 and 23 June 2022 respectively.

ASN issued a favourable opinion on the draft PNGMDR 2022-2026 and the associated draft decree and order, subject to some reservations concerning the consideration in particular of:

- pessimistic operating scenarios for the "fuel cycle" and the forecast dates of saturation of the spent fuel storage capacities;
- the required forward planning of the actions associated with a decision to either stop or continue reprocessing spent fuels beyond 2040;
- its opinion of 19 March 2021 on the safety of management of HL/ILW-LL waste;
- the continuation of the work to establish specific management routes for certain types of waste, and in particular those containing tritium, disused sealed sources, organic oils and liquids and activated waste from small producers (hospital, laboratories, etc.).

Alongside this, ASN has insisted on the need to assess the recyclable nature of radioactive materials taking into account the quantities in question

and the time frames for the possible development of industrial processes that could use these materials – failing which the administrative authority will have to requalify them for management as waste.

Decree 2022-1547 of 9 December 2022 provided for by Article L. 542-1-2 of the Environment Code and establishing the requirements of the PNGMDR and the Order issued in application of the said Decree were published in the *Official Journal of the French Republic* on 10 December 2022.

The MTE took ASN's recommendations concerning prevention of saturation of the spent fuel storage areas, the management of tritiated waste and of activated waste from the accelerators, and ensuring the reliability of the LLW-LL into account in the final versions of the said Decree and Order. Some recommendations however were not retained, such as that concerning the assessment of the radioactive waste recyclability.

ASN considers that the PNGMDR 2022-2026 and the associated regulatory texts must allow the necessary decisions to be made, before it reaches term, so that safe management routes are operational in the 15 to 20 years to come for all types of radioactive waste.

In view of the conclusions of the public debate of 2019, ASN and the DGEC have decided to change the governance of the PNGMDR. The 5th PNGMDR is prepared by the Ministry of Ecological Transition, 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 very low level – 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 then followed up at periodic meetings of the PNGMDR working group jointly chaired by ASN and the DGEC.

In 2020 and 2021, ASN assessed the studies submitted for 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 draft PNGMDR 2021-2025, 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.

### 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 becquerels per gram (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 2022, Cires held 429,869 m<sup>3</sup> of VLL waste, which represents 66% of its authorised 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 m<sup>3</sup>. According to current forecasts, the facility could be filled to maximum capacity around 2029. Andra is currently working on the Acaci project, which aims to increase the facility’s authorised capacity to more than 900,000 m<sup>3</sup>, without changing its ground surface area (compared with the 650,000 m<sup>3</sup> currently authorised).

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 the foundations of VLL waste management must be based on the place of origin of the waste and guarantee its traceability 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 more specifically continuation of the project for a metal materials recycling facility, with the setting up of a specific regulatory framework for 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 authorising, as a waiver, the recycling of weakly radioactive metal substances after melting and decontamination. This type of waiver will be granted by Ministerial Order.

In addition, ASN considers it necessary for all the stakeholders, especially the representatives of the localities actually or likely to be concerned, to be more actively involved in defining LLW 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 above-mentioned 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 residual 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 363,000 m<sup>3</sup> at the end of 2021, which represents 36% of the facility’s maximum authorised capacity. Added to this quantity is the waste emplaced in the Manche repository, which represents 527,225 m<sup>3</sup>. The total quantity of LL/ILW-SL waste emplaced in the Andra facilities is therefore 890,225 m<sup>3</sup>, to be compared with the quantity of 971,000 m<sup>3</sup> produced at the end of 2020. According to the data of the national inventory drawn up by Andra, this waste will represent a maximum volume of 2,000,000 m<sup>3</sup> 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

The LLW-SL waste initially comprised two main types: graphite waste resulting from the operation of the Gas-Cooled Reactor (GCR) nuclear power plants, 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 Orano Malvési plant (*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 drafted 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 outcropping 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-SL 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 was examined in an Advisory Committee of Experts (GPE) meeting 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. This work will continue in 2023.

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 Malvési site (baptised “RTCU”), currently stored in the Écrin facility (BNI 175). Various disposal concepts are envisaged.

- 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 as yet to be built.

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.

On 2 September 2019, ASN issued its opinion on the studies required by Article 7 of the Decree of 27 December 2013 relative to the implementation of a final management solution for the Malvési legacy waste in a near-surface repository. Orano’s responses are currently being examined.

With the 5th edition of the PNGMDR 2022-2026 in view, ASN issued its opinion 2020-AV-0357 of 6 August 2020 which details the work focuses it recommends for the management of LLW-LL waste.

It more particularly urges continuation of the work engaged, such as the consolidation of the inventories of the various families of LLW-LL waste and the periodic reassessment of storage needs, notably in order to allow the decommissioning of the nuclear facilities. As at 31 December 2019, the producers and holders of LLW-LL waste indicated that their storage capacities for this type of waste were sufficient for the next 30 years.

ASN considers that, on the basis of a multi-criteria analysis, Andra should submit the outlines of various technical and safety options for the near-surface disposal facilities for LLW-LL waste, comparing the health and environmental effects of the various options envisaged. All of the stakeholders concerned, in particular the representatives of the localities actually or liable to be concerned, must be involved more actively in defining the LLW-LL waste management solutions.



ASN also recommends setting time milestones for Andra's next design stages (preliminary design study and then Safety Options Dossier – DOS), for a near-surface disposal project for LLW-LL waste in the Vendeuve-Soulaines municipality federation, which will be incorporated into this general strategy.

ASN considers that the legacy RTCU waste, as a conservative measure, and the RTCU waste produced as from 1 January 2019 must, in application of Article 63 of the Order of 23 February 2017, be registered in the LLW-LL category and be better integrated in the current work on the LLW-LL waste management scenarios.

ASN recommends that the studies of a near-surface RTCU waste disposal facility, under reworked cover (either in the pit of the former open-cast mine, or in a new pit yet to be built), be continued, involving the representatives of the localities actually or liable to be concerned.

The 5th edition of the PNGMDR is intended, during its implementation, to clarify the possible management scenarios for all LLW-LL waste and to analyse them applying several criteria in order to stabilise an overall management strategy. The main question is to define the scope of the waste that could be emplaced in the facility planned to be set up on the site of the municipal federation of Vendeuve-Soulaines and to identify the additional needs for disposal sites, sites whose locations shall be sought under regulated conditions.

### 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 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 portion 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 planned 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 law 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 operation 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 high-level waste and situated in BNI 116. This extension comprises two pits: 30 and 40, commissioned in 2015 and 2017 respectively.

Within the framework of the PNGMDR 2013-2015, and after presenting the inventory of HLW and ILW-LL waste packages intended for *Cigéo* as 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.



In its opinion 2020-AV-0369 of 1 December 2020 on the studies into the management of HL and ILW-LL waste, ASN observed that the waste producers had generally well identified the saturation dates of the existing storage facilities and the future storage needs for the next twenty years. It did however indicate that the storage capacity estimates should be consolidated by all the producers by integrating margins to allow for any contingencies affecting the waste management routes concerned.

#### 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, integrating 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.

Article 52 of the Order of 23 February 2017 requires Andra to substantiate the reasons that led it to reject the option of designing near-surface storage facilities. In response to this requirement, in 2018 Andra submitted a comparative study of the different types of storage it has studied.

In its opinion 2020-AV-0369 of 1 December 2020, ASN confirms that near-surface storage facilities have no decisive advantage in terms of nuclear safety and radiation protection over surface storage facilities.

The PNGMDR 2016-2018 sets out several guidelines for the design of HL and ILW-LL waste storage facilities (significant design margins, simple and modular architecture favouring passive systems, provisions for controlling the ambient storage conditions in normal, incident and accident situations, provisions for monitoring and surveillance and deviation management defined at 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*.

#### Reversible deep geological disposal

Deep geological disposal is called out by Article L. 542-1-2 of the Environment Code, which stipulates 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 Act of 28 June 2006 assigns Andra the task of devising a project for a deep geological disposal facility which shall be a BNI, governed by the regulations specific to this type of installation, and as such shall be subject to ASN oversight.

#### 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 1991, ASN published Basic Safety Rule RFS III-2-f defining the objectives to be set in the design and works phases for final disposal of radioactive waste in deep geological formations, in order to ensure safety after the operational life of the repository. In 2008 it published an update of this document in the form of a safety Guide relative to radioactive waste disposal in deep geological formations (ASN Guide No. 1).

The conditions of creation of a reversible deep geological repository for HL and ILW-LL radioactive waste were specified by the Act of 25 July 2016, which defines the principle of reversibility, introduces the industrial pilot phase before complete commissioning of *Cigéo* and brings schedule adaptations concerning the deployment of *Cigéo*.

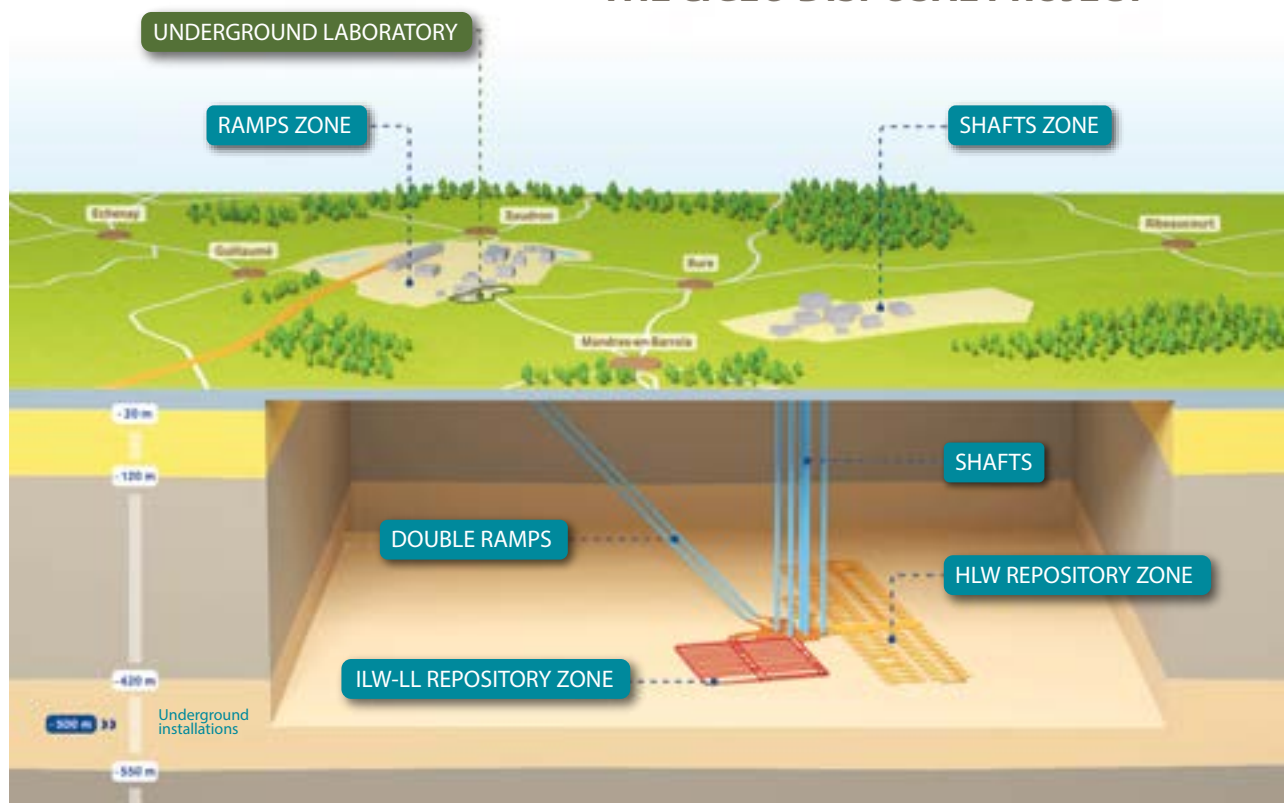
This Act defines reversibility as “*the ability, for successive generations, to either continue the construction and then the operation of successive sections of a disposal facility, or to reassess previous choices and change the management solutions. Reversibility is materialised by the progressive 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 23 February 2017 relative to the provisions of the PNGMDR details certain principles applicable to *Cigéo*, and more particularly in Articles D. 542-88 to D. 542-96 of the Environment Code. Article D. 542-90 stipulates in particular that “*The inventory to be considered by the French National Agency for Radioactive Waste Management (Andra) for the studies and research conducted for the design of the repository provided for in Article L. 542-10-1 shall comprise a reference inventory and a reserve inventory. The reserve inventory shall take into account the uncertainties associated more specifically with putting in place new waste management routes or changes in energy policy. The repository is designed to accept waste from the reference inventory. It shall also be designed by Andra, in consultation with the owners of the substances of the reserve inventory, to be capable of accommodating the substances figuring in that inventory, provided that changes in its design can be implemented if necessary during operation of the repository at an economically acceptable cost*”.

## SCHEMATIC DIAGRAM OF THE CIGÉO REPOSITORY SHOWING THE SURFACE AND UNDERGROUND FACILITIES

## THE CIGÉO DISPOSAL PROJECT

**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 ascertains by random sampling during follow-up inspections that they are carried out using processes that guarantee the quality of the results.

**Technical instructions**

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 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 of 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.

**The *Cigéo* Safety Options Dossier (DOS)**

The filing of a DOS marks the start of a regulatory process<sup>(8)</sup>. ASN received the DOS for *Cigéo* in April 2016. At the end of the technical examination phase, the ASN draft opinion underwent public consultation, which took place from 1 August to 15 September 2017. After analysing the resulting contributions, 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 take into account the suggestions and comments received through the public consultation.

The examination of the *Cigéo* DOS highlighted several issues relating to specific aspects (architecture, defining of hazards, post-accident management, etc.). Among these issues, ASN pointed out that the management of bituminised waste required special attention.

8. 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 DAC. It can set a validity period for its opinion. This opinion is communicated to the applicant and to the Minister responsible for nuclear safety”.

### Particular case of bituminised waste

The management of bituminised waste is moreover monitored under the PNGMDR, which demands several studies relative to the characterisation of these packages, their conditions of transport and the treatment possibilities (Articles 46, 47 and 48 of the Order of 23 February 2017).

In 2019, ASN made additional information requests<sup>9)</sup> to the waste producers and to Andra further to the examination of the study submitted under Article 46. 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 to the working group tasked with monitoring the PNGMDR in September 2019. ASN considers in this respect in its opinion 2020-AV-0369 of 1 December 2020 that in view of the conclusions of the third-party review of the management of bituminised waste and the studies on the changes in design of the *Cigéo* ILW-LL waste disposal cells, which highlight new technical factors since the publication of the opinion of 11 January 2018, it is essential for the waste producers to conduct an ambitious programme to characterise the bituminised waste packages in order to demonstrate that all or part of these packages could be emplaced with a high level of safety in the projected *Cigéo* facility 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 launching in 2021 of a new “quadripartite” studies programme (grouping Andra and the three major licensees), aiming to enrich reflections on the methods of managing bituminised waste by contributing elements stemming from the research and development work. ASN welcomed this initiative, on which it made remarks in 2022, and will follow the progress of this programme which will span five years.

### From the Safety Options Dossier to the creation authorisation application

At present, Andra is continuing the *Cigéo* project design and preparing the requisite authorisation applications. Andra filed a Declaration of Public Utility (DUP) application in August 2020. On completion of examination of the dossier, which included a public inquiry from 15 September to 23 October 2021, and after obtaining the opinion of the Council of State in March 2022, the *Cigéo* project was declared of public utility by Decree 2022-993 of 7 July 2022, published in the *Official Journal* on 8 July 2022. During this process, ASN answered questions from the inquiry commissioners concerning certain technical aspects of the *Cigéo* project. Andra will acquire the status of *Cigéo* nuclear licensee as soon as the DAC is filed. In 2022, ASN and IRSN continued their discussions with Andra on the question of defining the in-service seismic hazard level, and started discussions with a view to preparing the examination of the DAC. Andra must also integrate the results of the bituminised waste review in its DAC file, particularly with regard to the architecture of the ILW-LL waste disposal cells.

In the public debate relative to the fifth edition of the PNGMDR, the question of *Cigéo* governance was identified as requiring closer examination, particularly with regard to the implementation of reversibility and the objectives of the industrial pilot phase.

The resolution of 21 February 2020 of the Minister responsible for energy and the ASN Chairman further to the public debate provides that the PNGMDR 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. It also specifies that the PNGMDR shall define 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 of involving the public in the decisive development steps of the *Cigéo* project. Provisions that meet the requirements set out in this opinion have been integrated in the draft PNGMDR 2021-2025.

### The authorisation process for the Creation Authorisation Application filed in early 2023

Further to the filing of the *Cigéo* DAC on 16 January 2023, ASN initiated the DAC examination process for this deep geological disposal facility, which is regulated in particular 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.

### Consultation actions

In 2022, as part of the implementation of the 5th PNGMDR, ASN began looking into the consultation and information campaigns it would conduct during its examination of the DAC. The implementation of consultations on the *Cigéo* project, whether by ASN or the other stakeholders, is carried out in collaboration with the *Cigéo* project consultations monitoring committee, placed under the auspices of the French High Committee for Transparency and Information on Nuclear Safety (HCTISN).

### The cost of the project

On 15 January 2016, 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 Order also specifies that the cost must be updated regularly and at least at the key stages of project development (creation authorisation, commissioning, end of “industrial pilot phase”, periodic safety reviews).

9. 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”.

## 2. Nuclear safety in waste management support facilities, role of ASN and waste management strategies of the major nuclear licensees

### 2.1 Nature of ASN oversight and actions

#### 2.1.1 The graded approach

With regard to radioactive waste management, ASN’s oversight aims at verifying on the one hand correct application of the waste management regulations on the production sites (for example with respect to waste zoning, packaging or the controls performed by the licensee), and on the other hand 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 of this report.

#### 2.1.2 Radioactive waste management support facilities

##### Treatment

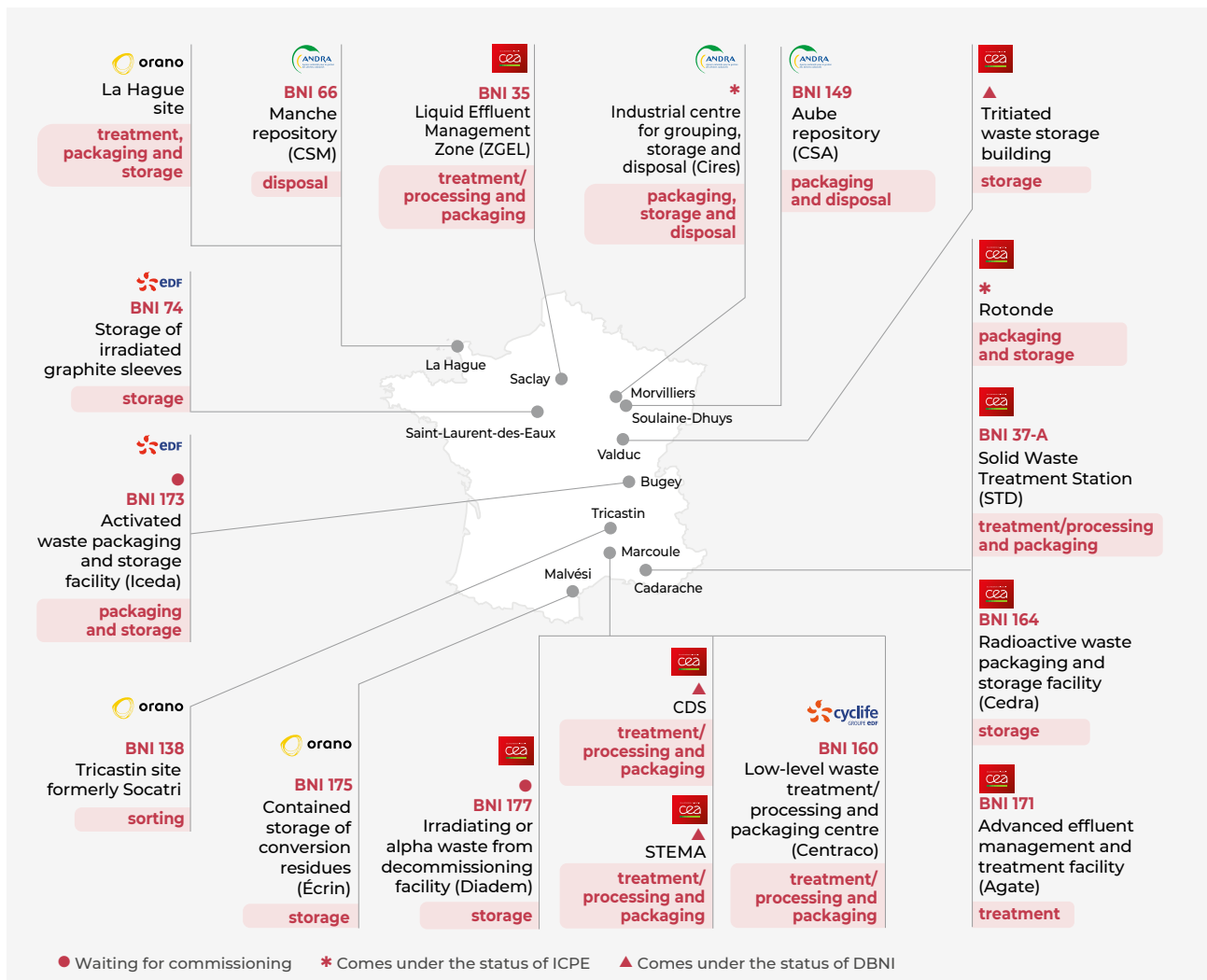
Treatment is a fundamental step in the radioactive waste management process. This operation serves to separate the waste into different categories to facilitate its subsequent management and to significantly reduce the volume of waste.

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, 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, and a melting unit in which metal waste is melted down.

The radioactive effluents can also be concentrated by evaporation, like the operations carried out in Agate, the effluent advanced management and processing facility (Agathe – BNI 171), with this same aim of volume reduction.

#### THE MAIN SUPPORT FACILITIES FOR RADIOACTIVE WASTE MANAGEMENT





## Packaging

Radioactive waste packaging consists in placing the waste in a package which provides a first containment barrier preventing radioactive substances being dispersed in the environment. The techniques used depend on the physical-chemical characteristic of the waste and their typology, which explains the large variety of packages used. These packages are subject to approvals 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 waste packages are sometimes packaged in the facilities in which they are to be stored, which will be the case for the ILW-SL waste packages in the Iceda facility, or directly in a disposal facility, such as Cires and CSA, which carry out these operations on a portion of the incoming 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 below) are specifically dedicated to the storage of radioactive waste, such as Ecrin, commissioned in 2018, and Cedra and Iceda, commissioned in 2020. This will also be the case with Diadem once this facility is commissioned around 2024. 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 planned for 2035.

## 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 the CEA on the Cadarache site conducts research and development work in low-level and intermediate-level 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 therefore cannot 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 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 also avoids delaying Waste Retrieval and Packaging (WRP) operations.

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*, which will be presented when the DAC for this facility is filed.

## Checks and inspections

Alongside Andra's surveillance of approved packages, ASN checks the measures taken by the licensee to correctly implement the requirements of the authorisation 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 issued packaging approvals.

ASN also ensures through inspections that Andra takes the necessary measures 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 Drafting of recommendations and prescriptions for sustainable waste management

ASN issues opinions on the studies submitted under the PNGMDR. Between June 2020 and May 2021, ASN issued seven opinions on the radioactive material and waste management routes, for the preparation of the 5th PNGMDR. ASN also issued an opinion 2021-AV-0390 of 9 November 2021 on the draft 5th plan produced by the Ministry responsible for energy.

### 2.1.5 Developing the regulatory framework and issuing prescriptions to the licensees

ASN can issue regulations. 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. This resolution has been applicable since 1 July 2018. Moreover, to ensure a consistent approach to the management of waste in BNIs and Defence BNIs (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.

### 2.1.6 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 13 (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, taking into account, more specifically, 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 six safety reviews of radioactive waste management facilities. They concern:

- two BNIs operated by the CEA: the treatment and packaging facility (BNI 35) on the Saclay site and the waste treatment station (BNI 37-A) on the Cadarache site;
- one BNI operated by Orano: BNI 118, the waste treatment, packaging and waste package storage facility on the La Hague site;

- one BNI operated by Andra: the Manche radioactive waste disposal centre (BNI 66);
- one BNI operated by EDF: BNI 74 comprising the Saint-Laurent-des-Eaux storage silos;
- one BNI operated by Cyclife France: the Centraco facility for waste treatment by melting or incineration (BNI 160).

### 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 in the case of BNI 118) 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 issued its conclusions on the periodic safety review of the Cedra storage facility on 3 December 2021 and those for the Chicade safety review on 29 August 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, while examination of the second safety review of the CSM is currently in progress, following a review of this file by the Advisory Committee on Radioactive Waste on 1 February 2022.

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 the CEA

The 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.

The CEA also carries out numerous decommissioning operations.

Consequently, the types of waste produced by the 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.

The 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 in Marcoule or the solid waste treatment station in Cadarache.

### The issues and challenges

The main issues for the 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 the CEA's waste management strategy

In response to a request from ASN and ASND dating from 2012, the 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 the 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. It appears acceptable for the CEA to envisage staggering the decommissioning operations in view of the resources allocated by the State and the large number of facilities undergoing decommissioning, for which waste retrieval and storage capacities will have to be built.

With regard to the material and waste management strategy, the two Authorities observe several vulnerabilities due in particular to the envisaged sharing of resources between centres, for the management of liquid radioactive effluents or solid radioactive waste for example, which means that for some operations, only a single facility will be available. The two Authorities also note uncertainties concerning the management of spent fuels or irradiated materials, which will have to be clarified.

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 the 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 the CEA have agreed to set up regular monitoring of these operations, through progress indicators in particular.

### Monitoring implementation of the CEA waste management strategy

ASN has engaged regular interchanges with the DGEC, ASND and the CEA to reinforce progress monitoring on the priority projects. ASN has observed the difficulty the CEA has 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. ASN notes that the deadlines for priority projects have changed since the file was submitted in 2016. 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 the 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 to ASN and ASND a file, 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 this strategy on 14 February 2022, requiring Orano to improve it in the following four areas:

- implementation of the decommissioning and waste management strategy must be prioritised according to the risks that each operation of the project represents;
- implementation of the clean-out strategy must be based on a sufficiently good level of knowledge of the current state of the facilities;
- control of the implementation of the WRP strategy and reduction of the dispersible inventory as early as possible;
- complex project management.

### 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, conditioning and storage have to be designed, built and then

commissioned. These complex projects meet with technical difficulties which can make it necessary to adjust deadlines set by ASN (see chapter 13). 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 defining of solutions for waste packaging, in particular the legacy waste. The methods of packaging the radioactive waste require the prior approval of ASN in accordance with 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 programmes to demonstrate the feasibility of the chosen packaging processes and to identify sufficiently early the risks that could significantly affect the 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 counter-action that could jeopardise final packaging. For information, Article L. 542-1-3 of the Environment Code requires that the ILW-LL waste produced before 2015 be packaged by the end of 2030 at the latest.

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 plants (*Gard département*) 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 1.3.2). 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.

Lastly, the spent control rod cluster guide tubes of the EDF fleet could be either:

- processed by Cyclife France in the Centraco facility with the aim of reducing the waste volume;
- or emplaced directly in the CSA.

EDF is studying both options.

### 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. This report is being examined 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 11) 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 11).

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### 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 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 2016-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-0374 of 4 February 2021 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 was finalised and published on 30 January 2023. This report must be taken into consideration by Orano in order to update its assessments of the stability of its structures encircling the mining residue disposal sites.
- Management of the water from the former uranium mining sites. In 2022, the dedicated technical working group continued development of the multi-criteria multi-player analysis methodology, by testing it on a site, and has also started drawing up a methodological guide.

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). Setting up of the group has been pushed back to 2023, priority having been given to the work of the two working groups mentioned above.

The PNGMDR 2022-2026 plans for continuation of these actions concerning the long-term environmental and health impact of the management of the former uranium mines. It will result in the defining of a detailed work programme in 2023. This programme will take into consideration more specifically the 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 specified above.



### 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.

## 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 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 three years and comprises the sites identified as contaminated by radioactive substances (the 2018 edition is available on *andra.fr*, as is the publication of the National Inventory Essentials 2022) 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 CNAR comprises:

- “members by right”: representatives of the Ministries responsible for the environment and energy, of Andra, the French Environment and Energy Management Agency (Ademe), IRSN, the 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).

By Order of 21 March 2019, the mandated members have been appointed to the CNAR. The Commission met 5 times during 2022, in particular 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.

With regard to the management of radioactive contaminated sites coming under the ICPE System and the Public Health Code, when the responsible entity is solvent or defaulting, the Prefect uses the opinions of the classified installations inspectorate, of ASN and the Regional Health Agency (ARS) to validate the site rehabilitation project and supervises the implementation of the rehabilitation measures by Prefectural Order. 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.



# Overview of the Basic Nuclear Installations as at 31 December 2022

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To ensure the oversight of all the civil nuclear activities and installations in France, the French Nuclear Safety Authority (ASN) 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 (BNI) in the Bretagne (Brittany) and Île-de-France regions respectively. The Paris division is responsible for oversight of the overseas regions and the *département* 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 entry thresholds 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:

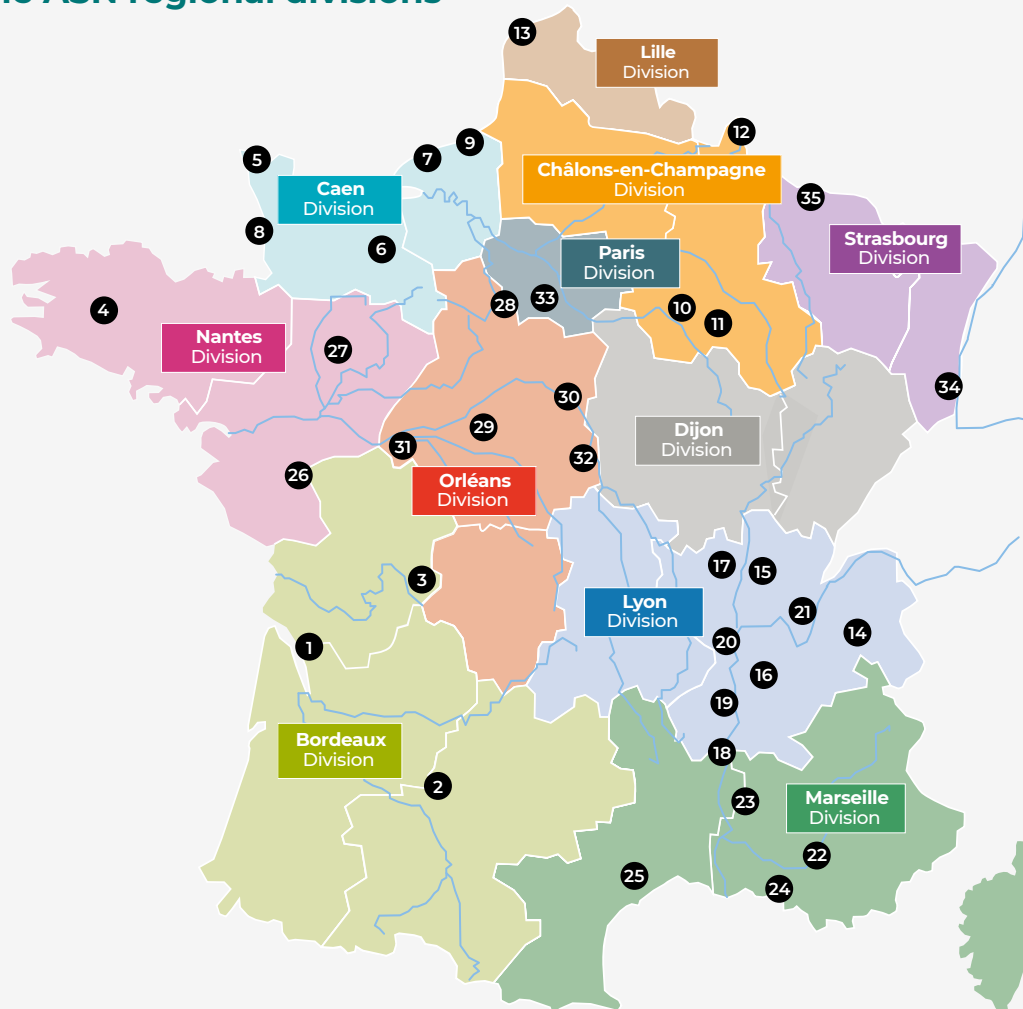
- installations under construction, if they have formed the subject of a Creation Authorisation Decree (DAC);
- installations in operation;
- installations that are shut down or undergoing decommissioning, until they are delicensed by an ASN resolution.

As at 31 December 2022, the number of BNIs (in the sense of legal entities) stood at 123.

Notified BNIs are those which existed prior to publication of Decree 63-1228 of 11 December 1963 concerning nuclear installations which neither the said Decree nor the Environment Code subjected to licensing but simply to notification on the basis of the acquired rights (see Articles L. 593-35 and L. 593-36 of the Environment Code).

The missing BNI numbers correspond to installations that figured in the previous issues of the list but which are no longer BNIs, having been either delicensed (see chapter 13) or licensed as new BNIs (for example, further to the merging of BNIs 63 and 98 into a single BNI 63-U, the numbers 63 and 98 have been removed from the list and number 63-U has been added).

## Facilities overseen by the ASN regional divisions



### 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 Soulaines-Dhuys
- ⑫ Chooz

### LILLE

- ⑬ Gravelines

### LYON

- ⑭ Grenoble
- ⑮ Bugey
- ⑯ Romans-sur-Isère
- ⑰ Dagneux
- ⑱ Tricastin
- ⑲ Cruas-Meysse
- 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 installation

- Nuclear power plants
- Plants
- Research installations
- Waste storage
- Others

• APPENDIX •

Overview of the Basic Nuclear Installations as at 31 December 2022

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF FACILITY	No.
<b>BORDEAUX DIVISION</b>				
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
<b>CAEN DIVISION</b>				
4 Brennilis	MONTS 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) (La Hague) 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 ORDINARY WATER NUCLEAR REACTORS (UP3A) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	116
5 La Hague	PLANT FOR REPROCESSING SPENT FUEL ELEMENTS FROM ORDINARY WATER NUCLEAR REACTORS (UP2800) 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
<b>CHÂLONS-EN-CHAMPAGNE DIVISION</b>				
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 Soulaïnes-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

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Overview of the Basic Nuclear Installations as at 31 December 2022

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF FACILITY	No.
<b>LILLE DIVISION</b>				
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
<b>LYON DIVISION</b>				
14 Grenoble	RADIOACTIVE EFFLUENT AND SOLID WASTE TREATMENT STATIONS (STEDs) 38041 Grenoble Cedex (Isère)	CEA	Transformation of radioactive substances	36
14 Grenoble	HIGH-FLUX REACTOR (RHF) 38041 Grenoble Cedex (Isère)	Max Von Laue Paul Langevin Institute (ILL)	Reactor	67
14 Grenoble	DECAY STORAGE FACILITY (STD) 38041 Grenoble Cedex (Isère)	CEA	Storage of radioactive substances	79
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactor 1) BP 60120 - 01150 Saint-Vulbas (Ain)	EDF	Reactor	45
15 Bugey	LE BUGEY NUCLEAR POWER PLANT (reactors 2 and 3) BP 60120 - 01150 Saint-Vulbas (Ain)	EDF	Reactors	78
15 Bugey	LE 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 3 and 4) 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

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Overview of the Basic Nuclear Installations as at 31 December 2022

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF FACILITY	No.
<b>MARSEILLE DIVISION</b>				
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 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	42
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	MINERVE 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	95
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 (RJH) 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	Research, development and actinide 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 Malvésí	CONTAINED STORAGE OF CONVERSION RESIDUES (ÉCRIN) 11100 Narbonne (Aude)	Orano Chimie-Enrichissement	Storage of radioactive substances	175



• APPENDIX •

Overview of the Basic Nuclear Installations as at 31 December 2022

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF FACILITY	No.
<b>NANTES DIVISION</b>				
26 Pouzauges	POUZAUGES IONISATION FACILITY Z.I. de Monlifant 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
<b>ORLÉANS DIVISION</b>				
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
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### **ASN Report on the state of nuclear safety and radiation protection in France in 2022**

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