AUTORITÉ
DE SÛRETÉ
NUCLÉAIRE

ASN REPORT

on the state of nuclear safety and radiation protection in France in 2023

The French Nuclear Safety Authority presents
its Report on the state of nuclear safety
and radiation protection in France in 2023.

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.

THE FRENCH NUCLEAR SAFETY AUTHORITY

2023

ROLES
OPERATIONS
KEY FIGURES
ASN ORGANISATION CHART

Created by the 13 June 2006 Nuclear Transparency and Security Act, ASN 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 license 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 Act of 17 August 2015 on energy transition for green growth, known as the "TECV Act", ASN's roles now include protecting ionising radioactive sources against malicious acts. Inspection is ASN's primary monitoring activity. In 2023, 1,790 inspections were thus performed by ASN 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.

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 set up around the nuclear installations.
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;
- 36 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.

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.

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(*).

Bernard DOROSZCZUK Chairman	Stéphanie GUÉNOT BRESSON (*) Commissioner	Géraldine PINA (*) Commissioner	Olivier DUBOIS (*) Commissioner	Jean-Luc LACHAUME (*) Commissioner
from 13 November 2018 to 12 November 2024	from 10 December 2023 to 9 December 2029	from 15 December 2020 to 9 December 2026	from 29 January 2024 to 9 December 2029	from 21 December 2018 to 9 December 2026
APPOINTED BY the President of the Republic	APPOINTED BY the President of the Republic	APPOINTED BY the President of the Republic	APPOINTED BY the President of the Senate	APPOINTED BY the President of the National Assembly

** 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.*

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 Parliament with the *ASN Report on the state of nuclear safety and radiation protection in France*. 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*(**) 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.*

ASN in 2023

PERSONNEL

521 staff members

48% women

86% management

307 inspectors

ASN ACTIONS

1,790 inspections

398
IRSN deliverables submitted to ASN, including 183 expert assessment opinions

26
plenary sessions of the Advisory Committees of Experts

1,940
individual licensing and registration resolutions issued

30,022
inspection follow-up letters available on *asn.fr* as at 31 December 2023

BUDGET

€71.62 M
budget for ASN (programme 181)

€85.1 M
IRSN budget devoted to expert assessment work on behalf of ASN

INFORMING

656 replies to queries from the public and the stakeholders

84
information notices

11
press conferences

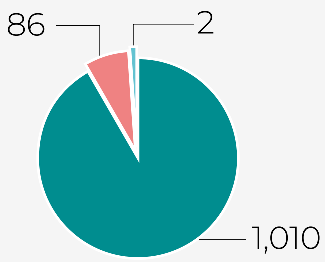
NUMBER OF SIGNIFICANT EVENTS IN 2023

RATED ON THE INES SCALE (*)

BASIC NUCLEAR INSTALLATIONS

1,098

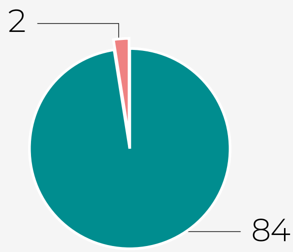
events



TRANSPORT OF RADIOACTIVE SUBSTANCES

86

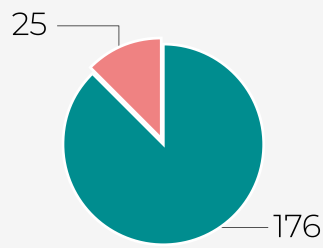
events



SMALL-SCALE NUCLEAR ACTIVITIES (medical and industry)

201

events



Level 0 Level 1 Level 2

** The INES scale (International Nuclear and Radiological Event Scale) was developed by the International Atomic Energy Agency (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.*

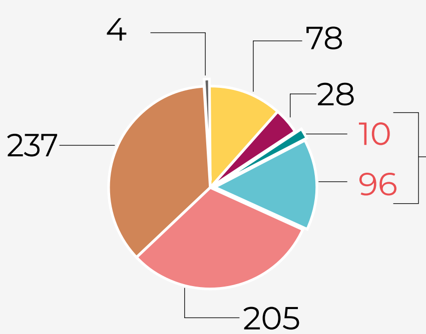
As it was pertinent to be able to inform the public of radiotherapy events, ASN – in close collaboration with the French Society for Radiotherapy and Oncology – developed a scale specific to radiotherapy events (ASN-SFRO scale).

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

IN THE MEDICAL FIELD

658

significant events per area of exposure

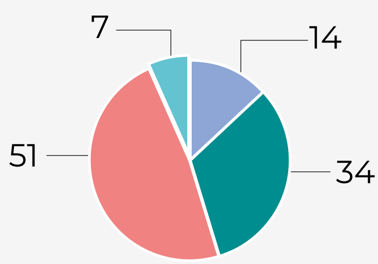


- BRACHYTHERAPY
- EXTERNAL-BEAM RADIOTHERAPY
- NUCLEAR MEDICINE
- COMPUTED TOMOGRAPHY
- DENTAL RADIOLOGY
- CONVENTIONAL RADIOLOGY
- FLUOROSCOPY-GUIDED INTERVENTIONAL PRACTICES

106

significant events in external beam radiotherapy and brachytherapy

according to the rating on the ASN-SFRO scale



Out of scale Level 0 Level 1 Level 2

Organisation Chart(*)

COMMISSION

CHAIRMAN
Bernard DOROSZCZUK

COMMISSIONERS
Olivier DUBOIS
Stéphanie GUÉNOT BRESSON
Jean-Luc LACHAUME
Géraldine PINA

HEAD OF PRIVATE OFFICE
Sylvie RODDE

ADMINISTRATIVE ENFORCEMENT COMMITTEE
CHAIRMAN
Maurice MÉDA

GENERAL DIRECTORATE

DIRECTOR GENERAL
Olivier GUPTA

DEPUTY DIRECTORS GENERAL
Pierre BOIS
Julien COLLET
Daniel DELALANDE

CHIEF INSPECTOR
Christophe QUINTIN

TECHNICAL ADVISER
Sylvie CADET-MERCIER

DIRECTOR OF PRIVATE OFFICE
Vincent CLOÎTRE

ETHICS OFFICER
Alain DORISON

INNOVATIVE REACTORS MISSION
Philippe DUPUY

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
Flavien SIMON

WASTE, RESEARCH FACILITIES AND FUEL CYCLE
Cédric MESSIER

TRANSPORT AND SOURCES
Fabien FÉRON

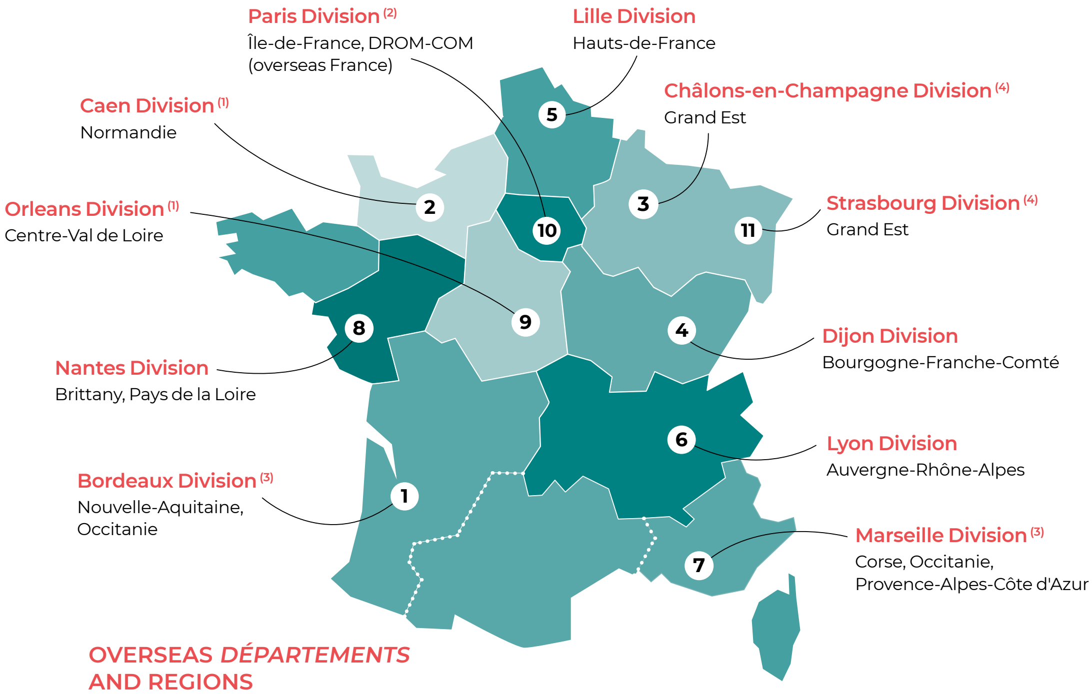
IONISING RADIATION AND HEALTH
Carole ROUSSE

ENVIRONMENT AND EMERGENCY SITUATIONS
Olivier RIVIÈRE

INTERNATIONAL RELATIONS
Luc CHANIAL

LEGAL AFFAIRS
Andy CONTESSO

INFORMATION, COMMUNICATION AND DIGITAL USAGES
Clémence PICART



OVERSEAS *DÉPARTEMENTS* AND REGIONS

(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
Vincent JECHOUX
REGIONAL HEAD
Paul de GUIBERT

2
CAEN
REGIONAL REPRESENTATIVE
Olivier MORZELLE
REGIONAL HEAD
Gaëtan LAFFORGUE

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

4
DIJON
REGIONAL REPRESENTATIVE
Olivier DAVID
REGIONAL HEAD
Marc CHAMPION

5
LILLE
REGIONAL REPRESENTATIVE
Julien LABIT
REGIONAL HEAD
Rémy ZMYSLONY

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

7
MARSEILLE
REGIONAL REPRESENTATIVE
Sébastien FOREST
REGIONAL HEAD
Mathieu RASSON

8
NANTES
REGIONAL REPRESENTATIVE
Anne BEAUVAL
REGIONAL HEAD
Émilie JAMBU

9
ORLÉANS
REGIONAL REPRESENTATIVE
Hervé BRÛLÉ
REGIONAL HEAD
Albane FONTAINE

10
PARIS
REGIONAL REPRESENTATIVE
Emmanuelle GAY
REGIONAL HEAD
Agathe BALTZER

11
STRASBOURG
REGIONAL REPRESENTATIVE
Hervé VANLAER
REGIONAL HEAD
Camille PERIER

*As at 1 March 2024.

Competence
Independence
Rigour
Transparency

asn.fr info@asn.fr

You can also follow ASN on social media

SUMMARY

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*, under the heading "L'ASN réglemente".

EDITORIAL BY
THE COMMISSION

2023, a key year marked by new nuclear ambitions

Montrouge, 1 March 2024

The safety level of the nuclear facilities was satisfactory in 2023, with less pressure on the "fuel cycle" facilities than in 2022 and with implementation by EDF of a strategy that ASN considered to be appropriate for dealing with and remedying the stress corrosion phenomenon that had appeared on some of its reactors. Radiation protection performance remained at a good level despite an increase in the number of level 2 significant events in the medical sector. This mixed picture recalls the importance of conducting radiotherapy risk assessments.

At a time of new nuclear ambitions, ASN underlines three topics that deserve particular attention:

1. The more ambitious aims by the licensees, for the continued operation of the existing nuclear facilities, requires that the measures to be implemented without delay in order to safely achieve these new objectives be identified. They also require that forward planning for the long-term issues regarding the reactors must be continued and reinforced with a view to operation beyond 60 years, in coordination with the new "fuel cycle" facilities being envisaged, while clarifying future reprocessing solutions.

2. The enthusiasm for the Small Modular Reactors (SMRs) and Advanced Modular Reactors (AMRs) which have potentially promising intrinsic safety characteristics, should not eclipse the technical and societal issues that they raise. These issues are notably linked to the preliminary work to be done to demonstrate their dependability, to all the safety/security and non-proliferation issues to be considered upstream, and to the acceptability of the siting of these reactors outside dedicated nuclear sites.

3. The numerous new nuclear projects require an exceptional effort in terms of expertise, project management and industrial rigour, which concerns the entire sector. Despite the progress made in technical expertise and management of activities, the checks carried out by ASN along the procurement chain for the equipment intended for nuclear facilities still highlight a recurring lack of industrial rigour. Over and above these shortfalls, against the backdrop of a significant increase in workload, preventing falsification and counterfeiting at all levels along the subcontracting chain must remain a major point of focus across the sector.

From left to right:
Stéphanie GUÉNOT BRESSON, Commissioner
Olivier DUBOIS, Commissioner
Géraldine PINA, Commissioner
Bernard DOROSZCZUK, Chairman
Jean-Luc LACHAUME, Commissioner

ANTICIPATING TECHNICAL QUESTIONS RAISED BY THE OPERATING LIFE OF THE REACTORS REMAINS A PRIORITY

The law requires that every ten years, following the periodic safety review, ASN issue a position statement regarding the conditions for the continued operation of the nuclear facilities. Concerning the reactors, the fourth periodic safety review for each individual reactor is underway for the 900 Megawatts electric (MWe) reactors, and the generic review phase for the 1,300 MWe reactors has been started.

As the fifth periodic safety review is too far into the future for any fundamental operating lifetime hypotheses to be incorporated into the energy policy for the 2040 time-frame and beyond, ASN asked EDF to conduct preliminary analyses of the ability of the reactors to continue to function beyond 50 years. At the Government's request, ASN issued an opinion on June 2023 on the conclusions of EDF's analysis, underlining the major technical subjects associated with an operating life of up to 60 years, along with the subjects to be addressed as priorities.

Finally, going beyond this time-frame and on the basis of the work initiated by EDF, the main technical subjects requiring particular analysis, or even research and development, ahead of the periodic safety reviews, were identified in 2023, enabling continued reactor operations beyond 60 years to be envisaged. In 2026, ASN will issue a position statement on the conclusions of these EDF analyses which are expected at the end of 2024.

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SATISFACTORY DEPLOYMENT OF THE STRESS CORROSION TREATMENT STRATEGY

Following the discovery of stress corrosion cracking on the safety injection system of the main primary systems of some reactors at the end of 2021, EDF proposed a strategy involving the systematic replacement in 2023 of the lines considered to be susceptible to the phenomenon on those reactors liable to be the most severely affected, with inspection of all reactors by 2025.

In 2023, EDF implemented the proposed replacement strategy. The inspections carried out revealed the fact that certain weld repair processes during manufacturing were a factor liable to influence the appearance of stress corrosion, even on lines considered not to be susceptible to the problem. This enabled EDF to revise its inspection strategy, giving priority to the welds which had been repaired during manufacturing. EDF also decided to extend its spot-check inspection programme to all stainless steel lines connected to the primary system.

ASN considered this strategy to be appropriate, while pointing out that it might need to be revised in the light of the lessons learned from the ongoing programme of investigations. ASN also asked EDF to already take account of these lessons in the design of new reactors.

ASN is working in close collaboration with its foreign counterparts on this subject. Following the presentation of the findings made in France on the EDF fleet, the Western European Nuclear Regulators' Association (WENRA) issued recommendations concerning monitoring of the stress corrosion phenomenon for the reactors in operation, along with prevention of this phenomenon at the design stage.

PRESSURE ON THE "FUEL CYCLE" FACILITIES IS EASING BUT THIS SHOULD NOT MASK THE NEED TO PREPARE FOR THE FUTURE

The pressure identified in recent years in the "fuel cycle" eased in 2023, in particular due to improved Melox plant production.

These improvements and the prospect of a new Multi-year Energy Programme (PPE) could lead to the saturation time-frame for the Orano pools at La Hague being reconsidered. ASN nonetheless considers that new safe storage capacity will eventually be needed, in compliance with current standards, to ensure margins to deal with any contingencies affecting the facilities.

Generally speaking, ASN considers that the entire chain of back-end fuel management facilities and units must urgently be made more resilient so that the 2040 target set in the current PPE can be reached in safe conditions. This entails measures to be implemented without delay in order to meet this target, such as consolidation of MOX fuel production, developing interoperability between the reprocessing lines, the performance of considerable renovation and safety improvement works identified during the periodic safety reviews. The work undertaken on densification of the existing pools at the La Hague plant, along with dry storage, as means of dealing with the saturation risk, shall be continued.

ASN FINALISES THE TECHNICAL EXAMINATION PROCESS AND CHECKS THE LICENSEE'S PREPAREDNESS FOR EPR COMMISSIONING

The year 2023 was devoted to finalising the examination of technical subjects still open (design of primary system safety valves and performance of the internal water tank filtration system in particular), incorporating the latest modifications, and the performance of hot tests to ensure the overall qualification of the installation.

In May 2023, ASN carried out an in-depth inspection involving a large number of inspectors and experts, to check the licensee's preparedness for commissioning of the installation. ASN noted that the overall level of preparedness was good but it did underline that significant work was still required to ensure that the operational documentation was available and had been assimilated by the operating and maintenance personnel.

In 2023, ASN continued with its technical examination of certain topics, notably those linked to Operating Experience Feedback (OEF) from EPR reactors abroad, as well as the conformity assessments of the nuclear pressure equipment.

THE EPR 2 PROGRAMME MUST TAKE ADVANTAGE OF LESSONS LEARNED FROM THE EPR

In August 2023, EDF submitted the creation authorisation application for two EPR 2 reactors in Penly, for which the safety options had been the subject of an ASN opinion in 2019. The Penly reactors are the first ones in the EPR 2 programme, the aim of which is to incorporate the lessons learned from the design, construction and operation of the EPR reactors in France and abroad, along with feedback from operation of the existing reactors.

The lessons learned by ASN and the French Institute for Radiation Protection and Nuclear Safety (IRSN) on the Flamanville EPR project led to reinforced oversight being adopted for the examination of the creation authorisation application. ASN and the IRSN defined their examination strategy, identifying the schedule, the milestones and the deliverables required of EDF. ASN underlined the points requiring particular attention in the light of the operating lifetime envisaged for these new reactors, such as taking into account the effects of climate change between now and the end of the century.

ASN STRESSES THE ISSUES RELATED TO THE SMR AND AMR PROJECTS AND TAKES INITIATIVES TO ANTICIPATE THE EXAMINATION PROCESS

In the context of decarbonised industrial production targets, there is considerable enthusiasm for SMRs and AMRs and many start-ups are developing such projects. This will lead to the arrival of new players, new reactor technologies and new uses for nuclear power (production of steam, heat, or hydrogen) which will entail siting of reactors near the user industrial installations, potentially close to densely populated areas. For ASN, this means that the safety objectives associated with these reactors will have to be adapted in order to guarantee negligible releases, even in the event of a major accident.

In 2023, ASN expanded its discussions with several French companies developing these projects. Faced with these innovations, ASN modified its organisation and its working methods, notably with new types of technical dialogue, which are more interactive than at present and better-suited to the needs of start-ups while their projects are maturing and the envisaged technological options are being validated. ASN thus defined project maturity criteria to be met before entering the pre-authorisation process, in order to optimise its resources.

ASN recalls how important it is for project sponsors to develop a systemic approach including the industrial chain, the supply of nuclear fuel, spent fuel management, management of the risks of malicious acts and the proliferation of nuclear materials. Mitigating the consequences of accidents within the perimeter around these reactors and the management of waste will be essential pre-conditions for the deployment of these new reactors and for their acceptability.

In 2023, the French, Finnish and Czech nuclear regulators concluded the preliminary examination of the main safety options of the Nuward project sponsored by EDF. This examination enabled the regulators to identify the safety advantages of SMRs, as well as some issues they raise, while helping the project sponsor identify ways of developing a more standardised design. It also enabled the various requirements, practices and experiences of the regulators to be compared. In 2024, the joint review of the Nuward reactor project will continue and cover new topics, expanding it to include three other European safety regulators (Netherlands, Poland, Sweden). This initiative confirms ASN's position regarding the benefits to be gained from multilateral cooperation when reviewing sufficiently mature reactor projects, in an international context of standardisation.

INDUSTRIAL RIGOUR IS STILL A CHALLENGE FOR THE NUCLEAR INDUSTRY'S SUPPLY CHAIN

France's nuclear ambitions, both for reactors and for the "cycle" industry and waste management, will require an exceptional effort in terms of skills, industrial rigour and project management.

ASN considers that it will take at least a generation to address the sector's attractiveness challenge, notably given the dwindling interest in France for technological and scientific training and for the industrial professions. This challenge also concerns the nuclear safety and radiation protection inspection professions.

The difficulties and the occurrences of non-quality observed in the projects over the past twenty years are mainly the result of a lack of experience and professional rigour. The steps taken by the French Nuclear Energy Industry Players Group (GIFEN) and the deployment of EDF's nuclear sector Excellence plan (EXCELL) reflect active collective mobilisation around these challenges, with the aim of "getting it right first time". ASN considers that these are steps in the right direction and are to be encouraged.

From the safety viewpoint, and as of the moment of project launch, the ordering customers must ensure that the chain of contractors is competent to manage the technical, regulatory, standards-based and contractual requirements resulting from the detailed design studies.

In this context, ASN has in recent years strengthened its oversight of the procurement chain for equipment intended for nuclear facilities, through inspections of suppliers and of their subcontractors. The lessons learned from these inspections were sent out to the licensees in mid-2023. On the whole, the inspections demonstrated technical competence in the activities carried out by the suppliers, but revealed recurring shortfalls in industrial rigour across the nuclear sector, which must be corrected. These shortfalls primarily result from supplier unfamiliarity with requirements specified as being important for safety, competence in certain special processes, and monitoring rigour and performance.

Over and above these shortfalls, it also appears that the lessons learned from irregularities detected in the nuclear sector and in its supply chain in France and

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abroad, need to be better taken into account. ASN considers this situation to be unacceptable. At a time of an unprecedented increase in workload, the sector must meet a major challenge in the fight against falsification and counterfeiting, at all levels along the subcontracting chain, involving prevention, detection and dealing with the cases identified.

RADIATION PROTECTION CULTURE MUST BE MAINTAINED IN THE MEDICAL SECTOR

In 2023, the level of radiation protection in this sector is satisfactory, but prior weaknesses still persist with no notable improvement.

For a number of years now, ASN has observed that the radiation protection culture for fluoroscopy-guided interventional practices in the operating theatre has been improving too slowly. In 2023, this led ASN to enforce measures to ensure the compliance of premises and the radiation protection training of personnel. ASN notes the efforts made by the professionals to provide training appropriate to the specific issues of each discipline, which must continue to guarantee that skills further improve and that these issues are correctly understood.

In addition, and even if the radiation protection culture appears to be mature, implementation of the quality assurance approach needs to be re-examined and fully taken on board. This is the case in radiotherapy, where an unprecedented number of undesirable target error events occurred in 2023 (wrong-side or positioning errors). ASN recalls the importance of an advance risk assessment, evaluation of the effectiveness of the barriers put in place and consideration of both local and national OEF. In this respect, the principles of a risk assessment methodology were presented in the "Patient safety" bulletin in October 2023.

ASN also observes weak signals which, although not directly linked to significant or serious undesirable events, indicate conditions that are prejudicial to radiation protection.

By means of inspections and the whistle-blower system, ASN thus notes an increase in reports of internal conflict situations. The "radiation safety culture trait talk" in medicine proposed by the International Atomic Energy Agency (IAEA) include a respectful work environment, that is necessary for effective communication and guaranteeing that all personnel are able to report their concerns, question a decision or organisation and thus exercise their individual responsibility.

Furthermore, the lack of resources, shortness of staff and resorting to temporary workers or outside contractors, the rising use of teleradiology, or the sharing of resources, against a backdrop of healthcare authorisation reforms, are leading to new and often complex organisations, which can result in a certain dilution of responsibilities. In the face of these organisational changes, ASN is remaining attentive – whether during oversight activity, inspections or the issue of licenses and authorisations – to compliance with the regulatory obligations. It draws the attention of the decision-makers to the need to evaluate the impact of these changes on the organisation and on the work of individuals and the need for a precise definition of the roles and responsibilities of all players in order to guarantee that the radiation protection culture is maintained and indeed developed.

THE PROTECTION OF RADIOACTIVE SOURCES AGAINST MALICIOUS ACTS NEEDS TO BE IMPROVED

The protection of radioactive sources against malicious acts was an unregulated subject in France just a few years ago. Increased awareness of this aspect is required on the part of all those concerned.

It also requires the adoption of technical, organisational and human measures designed to protect sources of ionising radiation, but also the "sensitive information" concerning them.

In addition to these specific means, this above all implies that their potentially malicious use must be considered, which is sometimes hard to reconcile with the culture of establishments that are public access and/or devoted to health care.

ASN has been monitoring source security since 2019, and in 2023 it reviewed the results achieved. These results show that the level of competence of the players and implementation of the measures have progressed but remain insufficient. Many challenges are still to be met in order to guarantee the security of sources, in particular when they are being moved, which can then create points of vulnerability at the interfaces. ASN recalls the importance of progress in the security culture, which implies better information, especially in distributing OEF to the users (increased threat awareness, dissemination of event reports, participation in anti-malicious acts networks, etc.).

THE QUESTION OF WASTE, WHICH LIES AT THE HEART OF PUBLIC CONCERNS, IS THE SUBJECT OF SPECIFIC DISCUSSIONS

Radioactive waste management remains the most controversial subject with regard to risk management, as shown by the latest survey conducted in 2023 by the Kantar company, at ASN's request. At present, there is a management solution for 90% of the volume of the waste, although this represents only 10% of the radioactivity contained. Pending the arrival of dedicated management routes, this means that there must be safe storage solutions for significant periods of time.

Radioactive waste management in France does however benefit from internationally recognised advantages such as the National Radioactive Materials and Waste Management Plan (PNGMDR), an agency dedicated to waste management (Andra), well-operated disposal facilities and the *Cigéo* geological disposal project, now recognised as being in the public interest.

For the purposes of examining this project, ASN launched a specific and voluntary consultation process in 2023, designed to ensure participation by the stakeholders. Two workshops were thus held in preparation for referral to the IRSN and then to the advisory committee, in order to enrich the content of these referrals and structure the public information process.

ASN RAMPS UP ITS INTERNATIONAL ACTIVITIES

At a time of renewed enthusiasm for nuclear energy, international relations are continuing at a steady pace, leading to the signing of a large number of cooperation agreements between ASN and its counterparts, leading to the development of exchange programmes on high-stakes issues. This intense international activity was also an opportunity to go into greater depth on subjects of common interest for the safety regulators, such as the continued operation of reactors beyond their envisaged design lifetimes, or the management of radioactive waste.

This intensification also allowed the definition of common international positions. For example, various initiatives were launched internationally to promote the standardisation and harmonisation of regulatory approaches for the SMRs. ASN participates actively in this, notably by promoting cooperation between regulators. ASN considers that international harmonisation of the authorisation processes, often underlined by the developers of these projects as a pre-requisite for the deployment of SMRs, is in fact an illusion, given the specific nature of each country. On the other hand, ASN does consider that the joint review by several regulators of the design options for a given project, upstream of the authorisation process, would be such as to facilitate the development of a standardised design.

The conflict in Ukraine, which is one of the topics dealt with by WENRA and by the Heads of the European Radiological Protection Competent Authorities (HERCA), remains a subject of concern and of particular vigilance for the regulators. In this respect, WENRA issued a position statement in June 2023 indicating that the destruction of the Khakovka dam did not represent a threat to the safety of the reactors of the Zaporizhzhia Nuclear Power Plant (NPP). HERCA continued its work to harmonise the population protection measures for Ukraine's European neighbours in the event of an accident in the Zaporizhzhia NPP.

ASN is also continuing its involvement in the international bodies. It is acting as HERCA Chair for three years, with the aim of helping to achieve a high level of radiation protection in Europe. ■

EDITORIAL BY
THE DIRECTOR GENERAL

Maintaining a high level of regulation and oversight in an unprecedented context

Montrouge, 1 March 2024

The context in which ASN performs its regulation and oversight is unprecedented in more than one respect. The combination of continued operation of older installations and the construction of new installations at a pace not seen for several decades is creating pressure on the resources available in the nuclear industry. The medical nuclear sector is also experiencing pressure on its workforce. Finally, innovations are emerging, both in the industrial field, with Advanced Modular Reactors (AMRs) and in the medical use of ionising radiation with new treatment techniques.

ASN is preparing to deal with this new context: it is maintaining a high level of oversight, adapting it to the priority issues; it is preparing to support a significant workload on a long-term basis; it is relying on its in-house culture to ensure the robustness of its examination work and the pertinence of its oversight and decisions. At the same time, further to the Government's submission of a bill reforming the organisation of regulation and oversight, ASN – together with the French Institute for Radiation Protection and Nuclear Safety (IRSN) – has initiated preparatory work to ensure the implementation of this bill if enacted.

Olivier GUPTA

The lessons learned from the building of the Flamanville EPR also highlighted these construction quality issues. To address this situation, ASN has in recent years reinforced its oversight of the procurement chain for equipment intended for nuclear facilities: 53 inspections were thus performed on this topic in 2023. These inspections will be increased in the coming years, to keep pace with the development of new nuclear projects.

MAINTAINING A HIGH LEVEL OF OVERSIGHT

Throughout the year 2023, the ASN teams remained fully mobilised in the performance of their duties to protect people and the environment. They maintained both the level of rigour and the level of oversight, while adapting priorities. ASN identifies and reassesses its regulation and oversight priorities on the basis of the challenges defined on the one hand by the risks for people and the environment inherent in nuclear activities and, on the other, by the behaviour of those in charge of the activities, in particular through the means they deploy to manage these risks. The following example illustrates this point.

The present context of the nuclear industry is characterised by pressure on the energy markets, by the need for investment in infrastructure and thus large-scale financing, and by the fact that the nuclear sector needs to further consolidate its ability to support the needed revival process. This context is a challenge for the licensees and industrial firms, with the resulting increased risk regarding the quality of project performance.

HANDLING A GROWING WORKLOAD

The nuclear sector revival is resulting in an increasing number of new projects on which ASN must adopt a stance, with the support of the IRSN, as well as in the appearance of new players. Examination of the creation authorisation applications for the three pairs of EPR 2 planned for Penly, Gravelines and Bugey, monitoring of the manufacture of their large components (reactor vessel, steam generators, piping, etc.) and then oversight of the corresponding worksites will thus gradually increase ASN's workload in the coming years. To this can be added the projects to replace or expand the fuel fabrication and reprocessing plants, as well as the technical questions raised by the continued operation of the existing installations and the corresponding periodic safety reviews. Finally, technical dialogue with the sponsors of AMR projects, some of which include projects for specific fuel plants, is intensifying and will continue to do so in the coming years. This will demand far more resources than are currently available.

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To be able to handle this workload, ASN has received authorisation to increase its workforce by 12 staff for 2024, and is also relying on internal redeployments that will be made possible by the end of construction of the Flamanville EPR. Further increases in staffing and budget will nonetheless still be needed in the coming years.

In the medical nuclear sector, the persistence of events – with seven events rated level 2 on the ASN-SFRO scale in 2023 – underlines the fact that the challenges remain high and justifies maintaining ASN's level of oversight. The development of innovative high-stakes medical techniques, for nuclear medicine, or flash radiotherapy, is extensively mobilising the ASN teams in contact with the departments sponsoring the projects.

PROMOTING AND DEVELOPING ASN'S SAFETY CULTURE

The competence of the ASN personnel, as well as the rigour and collective nature of its decision-making process, are key factors in enabling ASN to correctly carry out its duties and are the focus of permanent attention. However, the pertinence of oversight is also heavily dependent on the "safety culture".

In 2023, ASN started work to identify which practices, which working and organisational methods and which attitudes enable ASN to effectively monitor nuclear safety and radiation protection, and then subsequently enhance and develop them. This work, entrusted to a researcher, consists in identifying the formal frameworks governing oversight actions and the managerial communications guiding these actions and then in observing the practices actually implemented, in order to determine the fundamental principles which encourage or impede the correct exercise of oversight aimed at protecting people and the environment.

The interim results highlight a number of key aspects of ASN's internal culture, which promote correct prioritisation and appropriate handling of high-stakes nuclear safety and radiation protection subjects: the importance of the collective, the benefits of comparing well-argumented opinions, respect for the responsibilities and scope of the duties of each party, intellectual curiosity, listening to different points of view, the sense of public service and rigour. The robustness of the examination process and the pertinence of oversight and decisions owe more to these practices and attitudes than to organisational methods. This culture thus constitutes a solid foundation for meeting the current challenges and it must be promoted and developed.

PREPARING FOR A POSSIBLE GRAND AUTHORITY

The Government has decided to change how the governance of nuclear safety and radiation protection is organised, by merging ASN and most of the IRSN in a new authority, which would then have its own expert assessment capability, as well as the research roles that underpin it. The two organisational options, with or without integrated technical support, are possible and have proven themselves. It is now up to Parliament to make a decision regarding the corresponding Bill.

The responsibility of the teams at ASN and IRSN is to perform their duties within the specified framework, both before and after the date on which the new group is created, if such is the decision. They have therefore started working together to define the possible functioning and organisation of the future authority, in which the personnel will become involved as and when the general frameworks are defined. This work is being carried out with the common goal of ensuring that the new group works, that the personnel find their place in it and that the future authority makes the most of the potential created by the merger, with a more efficient and more attractive organisation preserving the values of excellence and transparency of the two existing entities. In addition, a specific social dialogue body bringing together the management and trades union organisations of ASN and IRSN is holding monthly meetings.

To make time for the preparation and then implementation of the oversight organisation reforms, if passed, while preserving the resources assigned to operational duties, ASN has postponed those actions which can be put off and which do not affect its core duties.

*

Whatever the regulatory organisation finally chosen, the personnel at ASN 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 2023

The safety challenges for the new nuclear programme

Launching a new large-scale nuclear programme is a challenge for the French nuclear industry, which needs to rebuild its capacity, notably in terms of skills and expertise. ASN draws attention to the need to control the quality of construction and manufacturing given the rapid start-up of the EPR 2 nuclear power programme and takes account of this in its regulation and oversight.

At the same time, Small Modular Reactor (SMR) projects are multiplying, with ambitious objectives, including with regard to nuclear safety. Most of these innovative reactor projects, sponsored by new players, require the construction of experimental mock-ups before an industrial product can be envisaged. It will also be necessary to design new "fuel cycle" facilities, suited to the needs of these new technologies. Given the number and diversity of these projects, which raise new questions or require a fresh look at the safety doctrines currently in force, ASN is adapting, without in any way reducing its demands in terms of safety, and has set up procedures for exchanges and for work appropriate to these new players.

THE EPR 2 PROGRAMME

The design of the EPR 2 reactor differs from that of the EPR, with a number of simplifications to facilitate construction and operation. With regard to safety, it is a third-generation pressurised water reactor, which takes account of Operating Experience Feedback (OEF) from the EPR.

The plan is for these reactors still to be in service at the end of the 21st century, a time-frame by when the effects of climate change should be far more significant than today. Major uncertainties persist, notably regarding the temperatures to be considered when designing the equipment. Given this situation, ASN considers that quite apart from ambitious climatic resilience objectives, a certain level of adaptability should be designed into the facilities, so that certain critical equipment can be resized if necessary.

Controlling the quality of construction and manufacturing remains the main challenge EDF has to face. The EPR 2 programme is starting at the rate of one pair of reactors every three years. This situation is creating considerable pressure on the industrial stakeholders, with the risk being that faced with unrealistic objectives, deadlines compliance takes precedence over quality.

ASN observes that for several years now, the sector has been preparing for the arrival of this new nuclear power programme. The question of skills, considered by ASN to be primordial, is the subject of multiple actions together with the State and the regional authorities.

In this context, ASN adapts its oversight to these new challenges. Since 2016, legislation has expanded its competence to activities performed outside nuclear installations, in particular in the plants of the suppliers and subcontractors. ASN is gradually expanding its checks beyond the manufacture of Nuclear Steam Supply System (NSSS) equipment alone, with 53 supplier inspections performed in 2023.

ASN observes that although the tier 1 suppliers are closely involved, considerable work remains to be done with regard to

Penly (Seine-Maritime département[1]) site on which EDF intends to build two EPR 2 type reactors.

their subcontractors. ASN regularly finds situations in which these latter are unaware of the applicable requirements, or even that their product is intended for use in the nuclear industry. ASN will shortly be issuing an educational brochure intended for these stakeholders, so that they can gain a clearer understanding of the regulatory requirements applicable to their activities. It also shared the findings of its inspections with the main ordering customers, who it asked to improve their management of the procurement chains.

ASN regulation and oversight entered a new phase when in the summer of 2023, EDF submitted its creation authorisation application for two reactors in Penly. ASN is conducting the technical examination of this file on behalf of the Government, with a view to creation authorisation towards the end of 2026.

SMALL MODULAR REACTORS

Following the call for proposals issued by the Government for innovative reactors, new designers of SMRs of a few tens to a few hundred megawatts emerged, banking on the fact that a significant reduction in power will drastically reduce their complexity and enhance the mass production effect through manufacturing in the factory.

The term "SMR" covers a variety of technologies and applications. A number of projects to supply energy directly in the form of heat at temperatures of several hundred degrees thus represent an alternative to fossil fuels for many industrial processes.

In terms of technology, even if some reactor projects opt for light water, the same technology as that used in the reactors currently in operation in France, the vast majority of the new players have chosen to develop reactors using different technologies.

In 2015, the French Institute for Radiation Protection and Nuclear Safety (IRSN) had examined the level of maturity of the various reactor technologies and concluded that usable OEF only existed for Sodium Fast Reactors (SFR) and High-temperature Gas-cooled Reactors (HTGRs). For each technology, IRSN had also identified the additional scientific and technical knowledge that needed to be acquired before being able to envisage industrial demonstrators. Most of the technologies still require considerable development work.

Initial discussions with a project sponsor allow a review to be made of their technological choices, as well as their research and test programme leading to the definition and justification of the safety case for an industrial reactor or a first experimental prototype.

Over and above the technical aspects specific to the development of each project, SMRs raise new questions or lead to a fresh look at certain practices. In this respect, ASN participates in several international working groups for discussions with its foreign counterparts aiming to promote the creation of ambitious international baseline requirements.

The first subject concerns the definition of safety objectives for these SMRs. The project sponsors for these new reactors are looking to deploy them on a large number of industrial sites which could be located close to urban areas. ASN thus set up a pluralistic working group to consider the safety objectives to be defined before envisaging such siting choices.

Given the large number of emerging projects, ASN defined appropriate methods for discussions and work with these new stakeholders, so that on the one hand the mobilisation of its resources and those of IRSN can be tailored to the level of maturity of the projects and, on the other, so that it can adapt to the reactivity of the project sponsors. The exchanges during the first phases are in particular more informative and iterative, in order to provide rapid feedback on questions or problems arising from the envisaged design choices.

A few projects should be entering a new phase in 2024, with examination of the first files stipulated by the regulations (ASN opinion on the safety options or creation authorisation application).

THE "FUEL CYCLE" FACILITIES

The development of a new-technology reactor is not a stand-alone project. It is necessarily part of a whole range of inter-dependent projects for new nuclear facilities, with a front-end for producing its specific nuclear fuel, and a back-end for managing its spent fuel and operating waste and, eventually, its decommissioning.

The question is that the existing "fuel cycle" facilities were designed to meet the needs of a nuclear fleet consisting of reactors of the same technology, using relatively similar fuels. These facilities were also commissioned several decades ago and their continued operation for the medium or even long term, beyond 2040, as had previously been envisaged, implies major safety issues which must be examined in the light of the most recent standards. The decision to build new facilities must thus be made rapidly, so that they can be designed and built in controlled conditions of safety and radiation protection. Given the needs involved in the fabrication, and possibly the reprocessing of the fuels needed for the reactors of a new nuclear programme or for SMRs, ASN stresses the fact that these future facilities must have the necessary capacity margins and use technologies that are ambitious enough to achieve them in the best conditions of safety and management of the inventories of radioactive materials and waste. With the same goal, forward planning is also required concerning the necessary storage facilities and means of transport. ■

1. *Administrative region headed by a Prefect.*

Flamanville EPR reactor

Conclusion of examination of the commissioning authorisation application

Major difficulties affected the construction of the Flamanville EPR reactor, which began in 2007. Throughout the project, ASN carried out its oversight duties, sometimes requiring that EDF modify the planned provisions. Based on the steps taken by EDF, ASN considers that the reactor can be commissioned in good conditions of safety. As at the time of approving this report, ASN is preparing to conclude the final examinations prior to issuing the reactor commissioning authorisation.

A DESIGN CAPABLE OF ACHIEVING AMBITIOUS SAFETY GOALS

ASN examined the design of the installation and its safety case. Discussions were held with EDF throughout the construction of the reactor. Between 2007 and 2023, ASN convened its Advisory Committees of Experts (GPEs) 28 times and asked the Institute for Radiation Protection and Nuclear Safety (IRSN) for more than a hundred opinions, in order to complete its examination. This regularly drew on data from the oversight and inspections on the site, in the supplier plants or within the EDF engineering bodies. As a result of this examination, EDF sometimes had to modify the design of its installation and reinforce its safety case.

Throughout the project, ASN maintained close ties with its foreign counterparts also overseeing an EPR reactor project. These discussions were used to share the conclusions of safety assessments and the lessons learned from each project. That was particularly the case regarding the various anomalies found on the cores of the Taishan reactors (China), including the fuel cladding bursts observed in 2021. As a result of these anomalies, EDF notably modified the fuel assemblies.

The design of the Flamanville EPR reactor enables the ambitious safety objectives set for the third-generation reactors to be met. By comparison with the second-generation reactors, it results in a significant reduction in the probability of core melt and radioactive releases in the event of an accident. 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 Nuclear Power Plant (NPP – Japan).

DIFFICULTIES ENCOUNTERED DURING MANUFACTURE OF EQUIPMENT AND CONSTRUCTION OF THE REACTOR

ASN carried out nearly 600 inspections during construction of the EPR reactor. These inspections were primarily carried out on the Flamanville site, within the EDF head office departments and in the manufacturing plants.

ASN thus checked the activities involved in civil engineering, manufacturing and equipment assembly, installation testing and preparation for operations. ASN also carried out labour inspectorate duties on the construction site.

Throughout the project, ASN carried out its oversight duties and sometimes required that EDF modify its project when the safety issues so warranted.

In 2008, a series of anomalies found during concrete pouring and rebar installation led ASN to tell EDF to suspend concrete pouring operations for the safety-important structures. Similarly, in 2011, ASN told EDF to suspend concrete pouring activities on the inner containment as a result of pre-stressing duct positioning anomalies.

Between 2015 and 2018, ASN asked EDF for in-depth justification data concerning the reactor vessel, for which there was a manufacturing anomaly in the steel of the bottom head and closure head. Following its examination, ASN considered that this anomaly was not such as to compromise the commissioning of the reactor pressure vessel, provided that specific checks are carried out during operation of the installation. Owing to the difficulties involved in performing these checks on the vessel head, ASN decided to limit its service life and it will have to be replaced.

In 2019, ASN considered that the nature and the particularly large number of deviations that occurred at the design stage and during manufacture of the main steam line welds on the containment penetrations represented a major obstacle to maintaining these welds "as is", and that their repair before commissioning of the reactor should be the reference solution. Finally, a large number of welds on the main secondary system lines had to be repaired.

Various irregularities were also brought to light in the equipment manufacturing plants during the course of the project, both in France and abroad. This situation shows that neither the monitoring and inspection chain, nor the high level of quality demanded in the nuclear industry, were able to completely rule out the risk of counterfeit, fraud and falsification. It is notably at the urging of ASN that Framatome, called Areva NP at the time, brought irregularities to light in its Creusot Forge plant in 2016.

Each irregularity detected requires that specific investigations be carried out by EDF and its subcontractors. ASN checks the robustness of these investigations by means of technical exchanges and inspections, while sometimes calling in qualified organisations for the purpose of inspections. These verifications concern the causes, the identification of the scope of the irregularities, the action plans implemented, as well as the consequences for equipment conformity and the safety of the facility. ASN oversight is carried out in parallel with any legal action being taken.

More generally, ASN asked EDF to carry out an overall review of the quality of the reactor equipment, notably by means of additional checks on the main equipment items with safety implications.

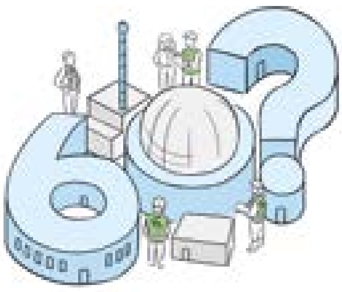
The commissioning authorisation will enable EDF to initiate fuel loading into the reactor. EDF will then conduct a programme of tests to verify the reactor's safety and performance. This is scheduled to last about eight months. This programme was examined by ASN with the support of IRSN. ASN will monitor the performance of the programme, as it will do throughout the operating life of the reactor.

Many lessons were learned from the construction of the Flamanville EPR reactor, by both EDF and its suppliers. For its part, ASN adapted its oversight methods for the construction of future reactors (see notable event "The safety challenges for the new nuclear programme"). ■

NOTABLE EVENTS
2023

Prospects for continued operation of EDF's nuclear reactors

ASN considers that the continued operation of EDF's existing reactors must be planned well in advance, so that it can be envisaged with no compromises on safety and so that it does not constitute a variable in the adjustment of energy policy. ASN therefore asked EDF to provide advance justification of the hypothetical continued operation of the current reactors up to and beyond 60 years.

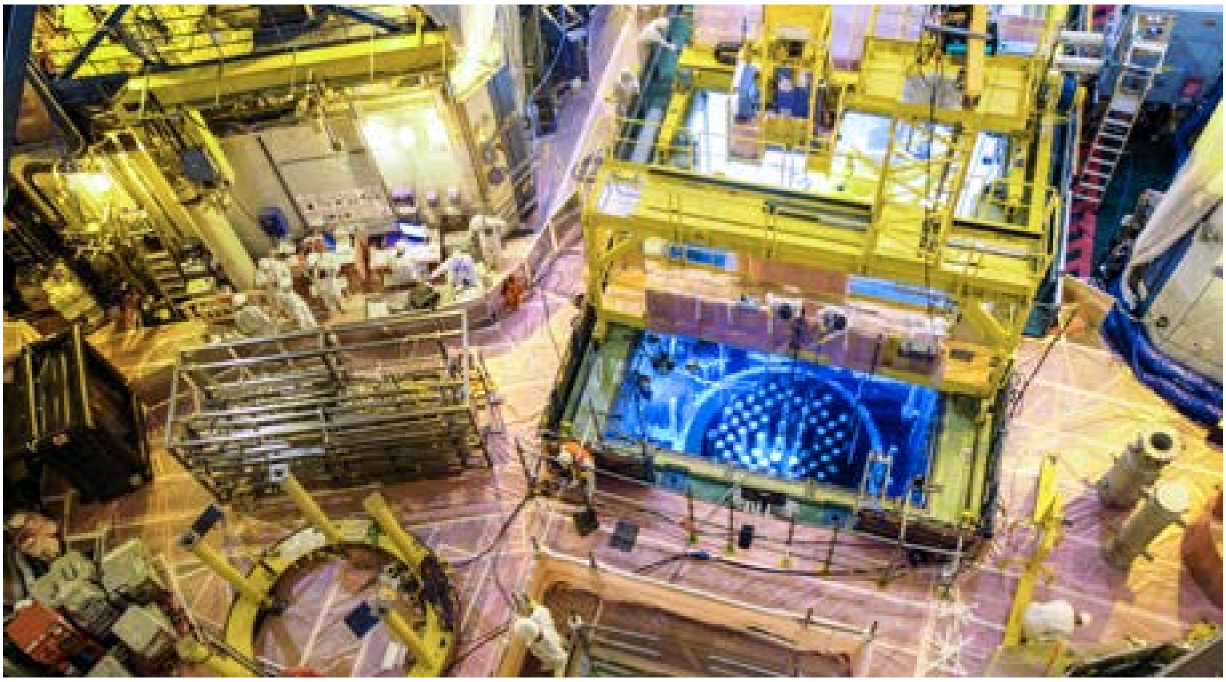


The French nuclear power reactors were commissioned to a very tight schedule, mainly in the 1980s. Despite the specific aspect of each reactor, this situation could lead to them all being shut down for ageing-related reasons, over a relatively short period of time. Given the time needed to build new electrical production capacity, scheduling their final shutdown takes on particular importance.

ASN therefore asked EDF to provide advance justification of the hypothetical continued operation of the current reactors up to and beyond 60 years, by the end of 2024, to allow an in-depth examination leading to an ASN position statement by the end of 2026.

Without waiting for this deadline and at the request of the Government, ASN issued an opinion on 13 June 2023 concerning the prospects for the continued operation of EDF's nuclear reactors up to their 60th year.

This opinion covers a preliminary analysis by EDF of the ability of its reactors to continue to function beyond 50 years, along with the corresponding technical issues and challenges.



Check on fuel assemblies in the reactor building. Golfech NPP.

In this opinion, which does not pre-empt the position that ASN will adopt on the occasion of their fifth periodic safety review, regarding the conditions for continued operation of the reactors beyond 50 years, ASN identifies two subjects requiring priority analysis by EDF:

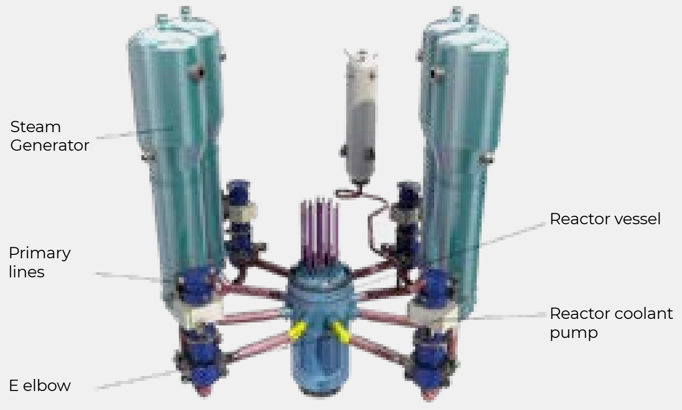
- the mechanical strength of certain portions of the primary system main lines of several reactors, called "E elbows" (see opposite);
- for the reactors of the Cruas-Meysse Nuclear Power Plant (NPP), taking account of the lessons learned from the earthquake that occurred in Le Teil on 11 November 2019 (see box below).

In addition to these two technical subjects, other factors such as considering the expected effects of climate change, or the functioning of the "fuel cycle" facilities in satisfactory conditions of safety, must also be given particular attention with a view to possible operation up to 60 years.

Finally, the extensive standardisation of the French NPP fleet, which is a particularity of the French electrical grid, implies the risk of a serious generic defect leading to simultaneous suspension of operation by several reactors, as was recently the case when stress corrosion cracks were discovered on the auxiliary lines of the primary system of several reactors. ASN considers that the possible occurrence of this type of event must be taken into account when checking compliance with security of electricity supply criteria.

MECHANICAL STRENGTH OF THE E ELBOWS

The E elbows are a part of the main primary systems of the reactors. They are shown in yellow on the figure below.



Position of E elbows on the reactor primary system

The E elbows for the older reactors (900 and 1,300 Megawatts electric – MWe) are manufactured from cast stainless steel. They are considered by EDF to be very hard to replace, because often located in a zone subjected to levels of irradiation making human intervention difficult.

There are particular problems with the steel used in the elbows. On the one hand, the casting process for these elbows is liable to generate manufacturing flaws. On the other, it is subject to a thermal ageing phenomenon. The mechanical strength of the cast elbows on the primary system must thus be demonstrated, taking account of the presence of potential flaws and the reduced tensile strength as a result of ageing.

For most of these elbows, EDF demonstrated that their lifetime is greater than 60 years and considers that operation up to 80 years is possible. However, the analyses on the E elbows of five reactors at the time of drafting of the ASN opinion, could not demonstrate continued operation up to 60 years.

EDF presented possible avenues to supplement these analyses. ASN considers that the various avenues studied by EDF to operate the elbows up to 60 years are credible, but that they still require work in order to lead to acceptable demonstrations and be implemented.

Lessons learned from the earthquake at Le Teil (Ardèche *département*) on 11 November 2019

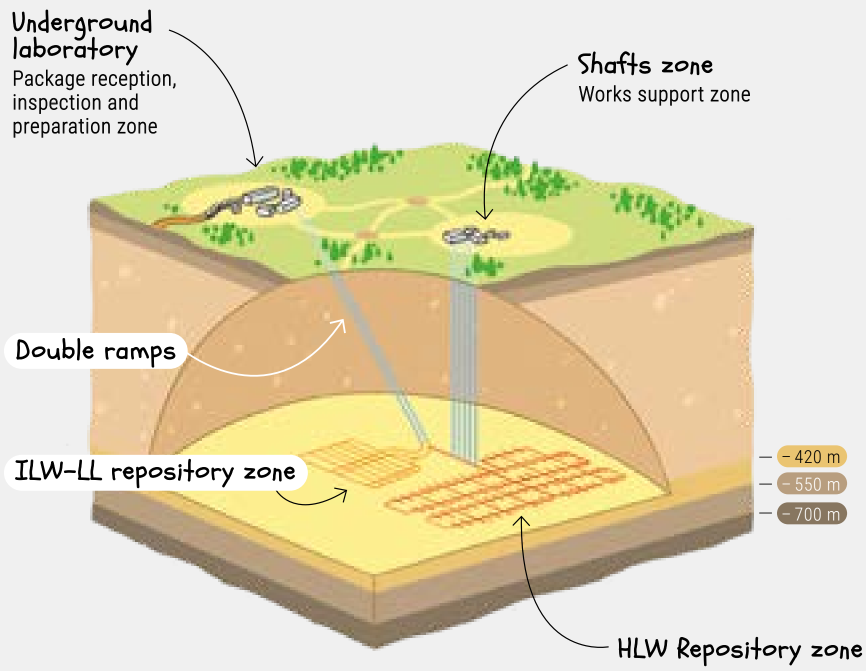
The fault that caused this earthquake led to a surface fracture over several kilometres, with soil uplift and shift of several centimetres.

This phenomenon is extremely rare in mainland France. Work is in progress to characterise the scope of the network of faults. If the existence of a fault capable of leading to a surface fracture were to be confirmed under the Cruas-Meysse site, it would then be complicated to produce the safety case for this NPP. It could require significant work, or even compromise the continued operation of its reactors.

Cigéo

A review involving all the stakeholders

In order to address society's strong desire to take part in the radioactive waste deep geological disposal facility project, and consistently with the measures stipulated in this respect by the 5th National Radioactive Materials and Waste Management Plan (PNGMDR), ASN is implementing an unprecedented system of consultation and discussion around the technical review process.



The Bure (Meuse *département*) underground laboratory, situated at a depth of 490 metres, is a unique research tool for the *Cigéo* project.

Its underground drifts allow *in-situ* study of a layer of clay 160 million years old, along with various concepts and techniques that could be used to construct the *Cigéo* facility.

Following several decades of research and development, the National Radioactive Waste Management Agency (Andra) submitted a creation authorisation application file in January 2023 for a deep geological waste disposal facility. This facility, called "Cigéo" is intended for the disposal of high-level waste (HLW) and intermediate-level, long-lived waste (ILW-LL).

Before this major step, Andra had submitted a Safety Options Dossier (DOS) for this facility in April 2016, which signalled the start of a process governed by regulatory requirements. Following review of this dossier, ASN considered that the project as a whole had reached a satisfactory level of technical maturity and that it represented a significant step forward in relation to the previous dossiers on which ASN had issued an opinion. ASN also made recommendations regarding the safety options, such as to prevent or mitigate the risks in the envisaged facility, and asked Andra for additional studies and justifications on subjects such as corrosion phenomena, low pH concretes, the representative nature of the hydrogeological model or the monitoring strategy.

Review of the *Cigéo* DOS also highlighted several important subjects such as the choice of the repository architecture, the definition of contingencies and post-accident management. The facility's creation authorisation application file submitted in January 2023 was produced taking account of the requests and recommendations made by ASN.

ASN was tasked by the Ministry for Energy Transition with conducting the technical review of this creation authorisation application and, after considering the file to be acceptable, began its examination in 2023. In so doing, it called on the expertise of

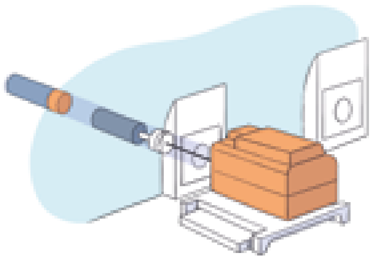
ASN visit during the excavation of the network of drifts in the Bure underground laboratory.

the Institute for Radiation Protection and Nuclear Safety (IRSN) and on its Advisory Committees of Experts (GPEs), more particularly that devoted to the topic of radioactive waste (GPD). This technical review, the duration of which is estimated at about three years, is built around the assessment of three topics: the basic data adopted for the *Cigéo* safety assessment, notably regarding the choice of the site, the safety of the surface and underground installations during the operational phase, and the long-term safety after closure. Following the technical review, ASN will issue an opinion on the application submitted by Andra, as stipulated by Article L. 542-10-1 of the Environment Code. At the same time, the National Review Board (CNE2) will submit an opinion on the scientific underpinnings of the file as compared with the state of the art. The duration of the entire authorisation process is estimated at about five years. Apart from the technical review phase, it includes a consultation phase (local authorities, Environmental Authority, etc.), as well as a public inquiry, prior to starting the drafting of any decree to finalise the procedure.

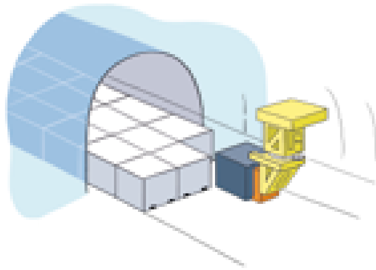
In order to address society's strong desire to take part in the *Cigéo* project, and consistently with the measures stipulated in this respect by the 5th PNGMDR, ASN is implementing an unprecedented system of consultation and discussion around the technical review process. Various stakeholders (about twenty organisations, including Local Information Committees (CLIs), the National Association of Local Information Committees and Commissions (Anccli), and environmental protection associations) were thus consulted as part of IRSN's review of the *Cigéo* creation authorisation application, with the aim of identifying their expectations and concerns as related to nuclear safety and radiation protection, so that they could be taken into account when framing the assessment of the file.

Following this exercise, the IRSN referral project was modified, for example, to incorporate aspects related to addressing climate change issues. To guarantee the continuity of participation by society throughout the technical review process, consultation measures will also be taken when drafting the GPE referrals on the three previously mentioned topics, and the public will be regularly informed, notably after each meeting of these GPEs, the first of which is scheduled for April 2024. This information, which is structured consistently with the referrals, will provide answers to the expectations and questions incorporated therein. ■

Cigéo project disposal vaults



HLW waste packages will be emplaced in vaults about a hundred metres long and about 70 cm in diameter, with a metal liner.



ILW-LL waste packages will be emplaced in horizontal disposal vaults a few hundred metres long and a few tens of metres in diameter.

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 operation of the Nuclear Power Plants (NPPs) remained satisfactory in 2023.

2023 was marked by the restart, following lengthy outages, of a large number of reactors in which certain lines, affected by stress corrosion cracking, had to be replaced.

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 EDF's engineering capacity. At EDF's request, which highlighted considerable pressure on its engineering teams, changes to reactor outage scheduling and the safety benefits to be gained from limiting the number of different reactor configurations, ASN in 2023 adjusted the deadlines for the requirements it issued in 2021 following the generic phase of the fourth periodic safety review of the 900 Megawatts electric (MWe) reactors.

ASN considers that EDF must take steps to ensure that the implementation and operation of the modifications can be guaranteed in good conditions despite the considerable workload on the engineering teams and the sometimes short amount of time the operating teams have in which to assimilate these modifications. Attention must also be given to right training of the parties concerned, so that they can correctly operate the new systems and maintain them.

In this context, ASN takes a positive view of the action taken by the in-house inspection bodies set up by EDF for the design of the noteworthy modifications to its installations.

THE CONFORMITY OF THE FACILITIES

As in previous years, ASN considers that EDF must continue the targeted inspection actions it has been deploying over the last few years. 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 the deviations detected has improved in recent years and is 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.

MAINTENANCE

As a general rule, the organisation in the NPPs for large-scale maintenance operations was again relatively satisfactory in 2023.

However, in 2023 as in previous years, ASN found certain points needed to be improved, such as the coordination between the disciplines and the projects, or within the maintenance departments, the quality of the documentation made available to the parties concerned, or 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.

Improvements were observed in 2023 regarding management of the quality of subcontracted activities, notably thanks to the provision of a growing number of spaces for preparation on mock-ups of the work to be done, and increased monitoring by EDF of the technical procedures. EDF's monitoring of manufacturing operations for safety-important equipment in supplier plants is however unsatisfactory.

OPERATION

In terms of reactor operation and control, ASN considers that performance improved in 2023. The actions plans covering operational rigour initiated in recent years by certain NPPs are appearing to bear fruit. However, the number of significant events related to control room monitoring faults further increased this year. This subject must be a priority for EDF in the coming years.

In 2023, ASN observed improvements in the working of the operating teams training departments. Persistent weaknesses in the skills acquisition process for operating personnel were however still observed during the inspections or during analysis of significant events, which raises questions regarding the effectiveness and scope of the training.

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. With regard to firefighting, and at the request of ASN, EDF has been working for several years on the deployment of a new organisation on its sites and on improving its response capacities, together with the Departmental Fire and Emergency Services (SDIS).

The ASN inspections focusing on the emergency organisation and resources confirmed that the organisation, preparedness and management principles for emergency situations have been correctly assimilated. EDF must nonetheless continue with its efforts to maintain the operational condition of certain resources that could be called on in an emergency situation and must increase its vigilance regarding work done in the emergency management rooms or close to equipment needed for emergency management.

The analyses carried out by the sites following significant events are generally pertinent, but must go further in identifying human failures, and in investigating the work situations and organisational processes involved. The assessment of corrective action effectiveness must also progress.

Finally, ASN again observed a shortage of personnel in the teams in charge of conducting independent evaluations of reactor safety in certain NPPs. EDF intends to remedy this situation by increasing the staff numbers dedicated to this activity.

ENVIRONMENTAL PROTECTION

ASN considers that the management of intakes and discharges into the environment of the various NPPs is on the whole satisfactory. Certain events however reflect the weaknesses indicative of operating faults or ageing of certain equipment, which can have consequences in terms of availability and the effectiveness of treatment prior to discharge.

In 2023, the inspections carried out by ASN showed that EDF is improving its management of non-radiological hazards with potential consequences outside the sites, a subject for which the inspections conducted in 2022 had revealed a situation that was unsatisfactory.

ASN considers that waste management is also continuing to improve. Progress is however still needed, notably with regard to duration of storage, inventory-keeping and the conformity of storage facilities.

WORKER RADIATION PROTECTION AND OCCUPATIONAL SAFETY

ASN considers that the radiation protection expertise centres created at the end of 2022 are functioning satisfactorily. The approach used in preparing for work and optimising doses is also considered to be satisfactory on most of the NPPs. However, on several sites, ASN found deviations in compliance with reinforced rules specific to apprentices under 18 years of age and personnel on fixed-term contracts, which EDF must remedy. ASN also notes the persistence of problems with management of industrial radiography worksites observed in 2022.

With regard to occupational health and safety, the number of accidents with time lost is up on 2022. Progress is needed to improve the management of situations presenting risks for the workers, notably with regard to lifting work, asbestos and electrical hazards.

Individual nuclear power plant assessments

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

With regard to safety, the NPPs at Chinon and Tricastin stood out positively in 2023. The NPP at Dampierre-en-Burly and, to a lesser extent that of Le Blayais, under-performed by comparison with the other NPPs operated by EDF.

With regard to radiation protection, the Penly NPP stands out positively. ASN considers that the NPPs of Cattenom, Gravelines, Saint-Laurent-des-Eaux and, to a lesser extent, Bugey, under-performed.

With regard to environmental protection, the NPPs of Chooz B, Civaux, Penly and Saint-Laurent-des-Eaux stood out positively. On the other hand, the Bugey NPP under-performed.

New reactor projects

In 2023, EDF completed the hot requalification tests of the Flamanville EPR reactor and prepared for its commissioning.

The work to repair the secondary system welds was carried out rigorously, with a good level of monitoring by EDF, leading to confidence that a high level of production quality will be achieved. More generally, ASN considers that significant work has been done in recent years to obtain a satisfactory level of completion of the installation.

In 2023, EDF submitted the creation authorisation application for two EPR 2 reactors on the Penly site. ASN considers that the design of the EPR 2 reactor is more advanced than the Flamanville EPR reactor at the same stage, which is a positive point.

EDF also sent ASN a safety options file for its Nuward Small Modular Reactor (SMR) project.

Nuclear power plants being decommissioned and waste management facilities

INSTALLATIONS SHUT DOWN OR UNDERGOING DECOMMISSIONING

The reactors finally shut down or undergoing decommissioning operated by EDF (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 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 2023 for these installations, notably with completion of the decontamination of the primary system of Fessenheim NPP reactor 2 and finalisation of the operations in preparation for the dismantling of installation EL4-D (Brennilis NPP).

ASN will be vigilant with respect to the decommissioning of EDF's reactors, notably the operations involved in cutting up the reactor vessel of the Chooz A NPP, from which Operating Experience Feedback (OEF) should help to determine similar operations for decommissioning of the Fessenheim NPP.

With regard to the GCRs, EDF continued "out of vessel" decommissioning work in 2023 on the reactors of Saint-Laurent A, Bugey 1 and Chinon A3 in satisfactory conditions of safety, more specifically completing the decommissioning work on the heat exchangers of Chinon A3. However, the progress of these projects is significantly slower and the completion deadlines for the decommissioning operations envisaged by EDF remain a subject of concern for ASN. During the 2024 examination of the decommissioning files for these reactors, ASN will pay particular attention to the robustness of the graphite waste management strategy.

During its examination of the modifications to the operating baseline requirements of EDF's installations, ASN noted in 2023 that these documents were sometimes overly generic. ASN will thus be vigilant in ensuring that the specific aspects of each installation are taken into account in these baseline requirements.

THE SPENT FUEL AND RADIOACTIVE WASTE MANAGEMENT FACILITIES

With regard to its facilities in operation, EDF is carrying out numerous equipment upgrades in the Superphénix spent fuel storage unit (Apec), which is satisfactory. ASN is particularly attentive to implementation of EDF's action plan for managing the obsolescence of certain equipment important for protection, adopting regular and joint monitoring with the licensee.

Improvements are however required in waste management in the Activated waste conditioning and interim storage installation (Iceda).

ORANO

In 2023, Orano continued its work to enhance the security of the management of radioactive materials and waste on the La Hague and Tricastin sites. In addition, the wide-ranging action plan designed to overcome the production difficulties at the Melox plant is beginning to bear fruit, with a significant improvement in the quantity of MOX (Mixed OXides) fuel fabricated and the volume of waste generated. ASN considers that these factors are helping to stabilise the "fuel cycle", even if this still offers little margin for contingencies and the countermeasures to be put into place to counter the risk of saturation of the spent fuel storage pool are yet to be deployed.

ASN also considers that Orano must continue and intensify the work to review the issues related to the ageing of all the facilities at La Hague, in terms of both the 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, in the light of ambitious safety standards. This issue is all the more important in the current context, in which current thinking on the future of the "cycle" does not rule out operation of these facilities well beyond the 2040 time-frame previously defined.

Installations in operation

ASN considers that the La Hague site operates its various functioning facilities in a satisfactory manner. With regard to nuclear safety, ASN notes good management of control and operations, as well as the involvement of the personnel in the organisational and operational changes implemented on the site since 2022 ("Convergence" project).

ASN considers that the level of safety of the Orano site at Tricastin, where the main facilities are considerably more recent than those of the La Hague site, is satisfactory.

With regard to the Melox plant, ASN considers that its level of safety is satisfactory, and sees in a positive light the efforts made by the licensee to catch up on required maintenance work. The new emergency management building was commissioned in June 2023, in accordance with ASN's requirement.

PERSONNEL RADIATION PROTECTION

With regard to radiation protection, the radiation protection centres of expertise were created in a satisfactory manner in early 2023, even if a number of documentary and operational adjustments still need to be finalised.

The modernisation work carried out by Orano, notably with changes to the dosimetry system, dematerialisation and increased robustness of the controlled zone access systems, is beginning to bear fruit, with the number of Significant Radiation Protection Events (ESRs) down in 2023. These measures must be continued.

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

ENVIRONMENTAL PROTECTION

ASN welcomes the action taken by the La Hague site to ensure regulatory conformity of the facilities and the operational implementation of the requirements governing discharges from the plant, as set out by ASN in June 2022 and applicable as from 1 January 2023.

In 2023, ASN continued to monitor the steps taken by the Tricastin site to reduce the releases of coolant fluids into the atmosphere and notes the efforts made by the licensee to mitigate these losses resulting from mechanical failures.

The safety reassessments of the facilities

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

Generally speaking, 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. ASN stresses the need for greater forward planning for equipment repair or replacement as a result of ageing, in order to avoid the risk of situations that could block operations, or of long-term outage of the facilities. ASN underlines that Orano must also examine the medium and long-term prospects for operation of its various units in the light of the most ambitious safety standards.

Facilities planned or under construction

ASN considers that the commissioning of the New Fission Products Concentration (NCPF) units in the T2 facility on the La Hague site, to replace the existing equipment which was more severely corroded than anticipated in the design, is a significant step forward. The project was deployed on-schedule and the operational results from the new units following commissioning are as expected.

On 19 June 2023, Orano submitted an application for modification of the creation decree in order to increase the production capacity of the Georges Besse II plant (Basic Nuclear Installation – BNI 168) by about 30%. The application is currently being examined by ASN and will be the subject of a public inquiry in 2024. ASN underlines the quality of the file submitted by Orano and of the technical discussions during the course of its examination. Orano shall ensure that the resources committed to the new projects, such as this one, shall not be to the detriment of other projects to improve support functions or process legacy radioactive substances stored on the site, which are just as high priority.

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

Large quantities of legacy waste at La Hague are not stored in accordance with current safety standards and present major risks. The Legacy Waste Retrieval and Conditioning (WRC) is a key step in the progress of decommissioning of definitively shut down plants. ASN therefore welcomes Orano's decision at the beginning of 2023 to build new silos to significantly improve the storage conditions for the sludges from the former effluent treatment station (BNI 38) without waiting for a final conditioning process for these sludges.

With regard to the organisation and management of these complex projects, ASN notes the progress made, such as acceptance of the objectives of immediate dismantling, the use of project maturity assessments, or the development of project progress management tools. ASN considers that Orano must make progress concerning the robustness of the waste retrieval and processing scenarios and in ensuring the reliability of the operational waste retrieval processes, in order to guarantee the schedules for the various WRC and dismantling projects announced

Individual facility assessments

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

CEA

Most French nuclear research facilities have been historically operated by the Alternative Energies and Atomic Energy Commission (CEA). Although some are still contributing to CEA's scientific and technical research programmes, a good number of them have been shut down and CEA is faced with major challenges in order to decommission them and manage the legacy waste satisfactorily. ASN considers that the safety of the facilities operated by CEA is still under control but that the results of the decommissioning and WRC projects differ widely and are still exposed to major contingencies.

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

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

CEA's decommissioning and materials and waste management strategy

In order to keep track of the progress of the projects with the highest priority for safety, the authorities and CEA set up regular and high-level reporting of the deadlines with the greatest safety implications; ASN underlines the commitment by the CEA managers in the oversight and monitoring of these milestones. In 2023, CEA notably continued with the removal of a certain number of radioactive substances (effluents and spent fuels) from its facilities that had been definitively shut down, which helped substantially reduce the residual risks. ASN nonetheless finds that, despite CEA's clear intention to carry out facilities decommissioning and WRC operations, this licensee is experiencing major difficulties in meeting the deadlines initially set.

These delays are notably caused by technical or contractual difficulties. ASN also regularly draws CEA's attention to certain shortcomings in its waste and effluent management strategy. This is to large extent based on unique facilities, for which there is no operational alternative, and which therefore determine the satisfactory performance of the numerous projects using them. Moreover, for several of these facilities, there are serious risks in terms of the time required for commissioning (Diadem), for refurbishment (BNI 37-A) or for storage capacity extension (Cedra), which all constitute risks for the project that depend on them.

Facilities in operation

ASN considers that the safety of the facilities in operation is satisfactory. During the course of the inspections carried out in 2023, 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, organisational and human factors, as well as the prevention of pollution and management of detrimental effects.

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

RISK CONTROL AND EMERGENCY MANAGEMENT

The significant delays in constructing more robust emergency management buildings, taking account of the lessons learned from the accident at the Fukushima Daiichi NPP (Japan), are undermining emergency management in several centres. With regard to the new emergency management premises on the Saclay site, ASN set a new deadline for commissioning the emergency management premises of 31 December 2024. Concerning the Marcoule centre, additional justifications are required regarding the operability and accessibility of the emergency management building. A number of emergency exercises carried out in 2023 jointly with the public authorities, also revealed that CEA needs to supplement its organisation in order to provide an effective response to operational requirements, notably regarding the exchange of information with the other emergency management players.

PERSONNEL RADIATION PROTECTION

The organisation put into place by CEA for radiation protection of workers is satisfactory. ASN has no remarks concerning the working of the CEA radiation protection expertise centres. The inspections performed by ASN in 2023 on the CEA sites revealed radiological zoning anomalies that CEA will have to correct. ASN will be vigilant on this point, as well as on monitoring of outside contractors in terms of radiation protection.

The number of ESRs reported by CEA is slightly down in 2023. However, more than one third are linked to failure to wear dosimeters (whether passive or active), mostly by outside contractors. CEA must take steps to raise the awareness of these personnel and ensure that this is effective. This will then be checked by ASN.

ENVIRONMENTAL PROTECTION

For the year 2023, 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 Protection Events – ESEs) in 2023 is of the same order of magnitude as in previous years, with no notable events (only events rated level 0 on the International Nuclear and Radiological Event Scale – INES, 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 bringing the network of piezometers back into compliance, the positioning of sampling devices in the gaseous discharge outlets and, more generally, management of the discharges continuous monitoring devices, notably with regard to pollution of soil and groundwater.

Performing consolidated impact assessments, for those centres that are home to several facilities operated primarily by CEA but also by other licensees (such as Marcoule or Cadarache) should enable the main risks to be better identified, with subsequent prioritisation of the corresponding applicable requirements.

SAFETY REASSESSMENT OF FACILITIES

ASN considers that the organisation put into place by CEA to evaluate the conformity of its facilities and reassess their safety during the periodic safety reviews, is appropriate. The inspections carried out by ASN on the topic of the periodic safety reviews identified some points for improvement which must be addressed by CEA, notably concerning monitoring of the action plan as a result of the periodic safety review. CEA will also have to continue its efforts in the coming years in order to comply with the schedule for implementation of the compliance and safety improvement work defined by these periodic safety reviews, so that in all cases a new review can be started once the deployment of the action plan from the previous review has been completed.

Individual facility assessments

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

ANDRA

2023 was marked by the start of the examination of the creation authorisation application for the *Cigéo* deep geological repository, submitted on 16 January 2023.

Cigéo project

Following the acceptability analysis of the *Cigéo* creation authorisation application file, ASN began its technical examination in June 2023. ASN notes a positive dynamic within the project owner's team and correct working by the governance bodies set up to identify, prioritise and rule on the most important technical choices regarding the project. These points confirm the demonstration that the French National Radioactive Waste Management Agency (Andra) has the technical capabilities needed to successfully complete the *Cigéo* project.

Operation of Andra's existing facilities

ASN considers that operating conditions in Andra's facilities remained satisfactory in the areas of nuclear safety, radiation protection and environmental protection in 2023. It also underlines the good quality of the safety assessments produced by Andra and the fact that the periodic safety reviews of the disposal facilities are carried out satisfactorily. The evaluation of the long-term impacts of the radiological and chemical substances in the disposal facilities on the flora and fauna nonetheless remains a subject for which management must be consolidated by Andra.

ASN assessments **by activity sector**

THE MEDICAL SECTOR

On the basis of the inspections carried out in 2023 and an analysis of the period 2019-2023 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 satisfactory level, relatively comparable from one year to the next, although with a number of persistent shortcomings which in 2023 led to an enforcement approach being adopted in the field of Fluoroscopy-Guided Interventional Practices (FGIPs).

It underlines the advances made in the field of clinical audits, with the first experiments launched in 2023 in radiotherapy and radiology, but is urging that they be extended to higher-risk activities, radiosurgery in particular, as well as to therapeutic nuclear medicine.

However, ASN identifies a number of signals which could indicate that the current situation could deteriorate:
- a finding that resources are on the whole shrinking, with pressure on Medical Electroradiology Manipulator (MERM), medical practitioner, medical physician staffing levels, with the expansion of temporary work and the postponement of tasks;
- in imaging, the use of insufficiently well-understood services to assist the Radiation Protection Experts-Officers (RPE-Os) and the medical physicians in the plants, liable to lead to a loss of radiation protection expertise and a lack of flexibility in implementing the regulation radiation protection requirements (training, verifications, etc.);
- the emergence of mobile radiology and constant growth in teleradiology with the technical and organisational constraints linked to this organisation method that are under-estimated by the facilities (communication problem, software interfacing);
- increasingly complex organisations, with sharing of resources and the risk of dilution of responsibilities, against a backdrop of health care authorisation reforms and buy-out of centres;
- conflict situations in a context of pressure on human resources or organisational changes of which it became aware during inspections or through the whistle-blower reporting system.

In this context, ASN draws the decision-makers' attention to the need to assess the impact of these changes on the organisations and on the work of the participants and to precisely define the roles and responsibilities of all parties involved, so that the radiation protection requirements are met.

In radiotherapy, even if the safety fundamentals are in place, the OEF process is running out of steam and less detailed ESR analyses and less frequent OEF committee meetings underline the need to restore some meaning to this approach in order to maintain the interest of the professionals and retain a collective dynamic attitude. The repetition of target errors (in particular wrong-side or positioning errors), reported in 2023, once again recalls the need for regular evaluation of the barriers put into place, taking greater advantage of national OEF. ASN stresses the importance of the advance risk assessment when technical and organisational changes are made. In this respect, ASN shared a risk assessment methodology in its "Patient safety" bulletin of September 2023.

In brachytherapy, the inspections confirm that the radiation protection rules are well taken into account, but the enhanced training effort for emergency situations in the event of a source blockage must be maintained on a long-term basis. ASN underlines the challenges in the coming years linked to maintaining the resources and skills needed for this activity.

In nuclear medicine, the inspections show that radiation protection is satisfactorily addressed, while underlining the need to deploy quality assurance procedures to secure the drugs administration process, in particular for therapeutic procedures as well as for those concerning children, in the light of the ESRs reported. In addition, formalised coordination of prevention measures with outside contractors (for maintenance, upkeep of the premises, the intervention of private practitioners, etc.), personnel training and analysis of the Diagnostic Reference Levels (DRL) are still areas in which progress could be made.

In the field of FGIPs and more particularly in the operating theatre, regulatory nonconformities persist as the years go by, whether the technical rules for the layout of installations, radiation protection training requirements (worker and patient training) and coordination of prevention measures during concomitant activities, notably for interventions by private practitioners. As a result of these deviations, ASN served formal notice on one facility requiring that they comply with the rules regarding radiation protection of professionals and the layout of rooms in which interventional procedures are carried out. ASN also observed that the centres are increasingly calling on Radiation Protection Organisations (OCR), either as specialists for internal RPE support missions, or as Radiation Protection Adviser (RPA), and that if insufficiently well managed, this subcontracting leads to a dilution of the responsibilities of the person/entity Responsible for a Nuclear Activity (RNA) with less consideration for and even deterioration of radiation protection.

In 2024, ASN will continue its inspections in the priority sectors such as radiotherapy, radiosurgery, nuclear medicine, FGIP and computed tomography, following on from the checks carried out in 2023. Particular attention will be paid to the weak signals previously mentioned and to the weak points identified in 2023 (training, OEF approach and lessons learned from reported ESRs, coordination of prevention measures during concomitant activities, work to ensure compliance of installations with layout rules, maintenance), as well as implementation of the quality assurance and change management obligations. If necessary, unannounced inspections will be carried out.

In radiotherapy and in nuclear medicine, on the basis of the lessons learned from the ESRs reported in recent years, specific inspections will be carried out by ASN in 2024 on the accelerators calibration programme and verification of non-contamination, in collaboration with the French Institute for Radiation Protection and Nuclear Safety (IRSN). With regard to FGIPs, ASN will carry out targeted inspections on the private practice physicians who, although not RNA, and not owners of the equipment on which they work, do have radiation protection obligations both for themselves and as an employer of personnel classified in terms of exposure to ionising radiation.

In regulatory terms, ASN will in 2024 revise resolution 2019-DC-0667 of 18 April 2019 setting DRL values to update the values for mammography procedures and will continue the work to prepare for revision of resolution 2008-DC-0095 of 29 January 2008 setting the technical rules to be met for elimination of effluents and wastes contaminated by radionuclides.

Finally, the deployment of new techniques and practices in therapy (radiotherapy, Internal Targeted Radiotherapy – ITR) remains a subject of particular attention for ASN, which will aim to promote all actions designed to improve assessment of the radiation protection issues and allow a better demonstration of their advantages over the existing techniques. On this point, ASN will continue its work with the various institutional players in the health field and the learned societies, and will call on the Advisory Committees of Experts (GPEs), in particular the Committee for the analysis of new techniques and practices using ionising radiation (Canpri), notably flash radiotherapy and adaptive radiotherapy.

In nuclear medicine, against the backdrop of the emergence of new vectors and radionuclides for therapeutic purposes, and the projected growth in the number of patients eligible for these new treatments, with limited out-patient treatment resources and infrastructures, ASN underlines the importance of anticipating the radiation protection issues for the patient and their entourage, the workers, as well as in terms of layout of the facilities and effluent and waste management. To this end, it referred the matter to the Advisory Committee for Radiation Protection (GPRP), and is following European work being done under the SimpleRad[1] project and maintains dialogue with the nuclear medicine players to recall the regulatory framework and examine that it is keeping pace with the changes made.

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

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 rigorousness to meet the regulatory obligations concerning the organisation of radiation protection, training and dosimetric monitoring of the workers, the use of operators holding the required Certificate of proficiency in handling industrial radiology devices (CAMARI) and maintaining gamma radiography devices. However, significant efforts are still required on the part of many companies to correctly define the programme of verifications required by the Labour Code, implement it, correct any nonconformities found on this occasion and ensure the traceability of the corrections made. If the risk of incidents and the doses received by the workers are on the whole well managed by the licensees when this activity is performed in a bunker in accordance with the applicable regulations, ASN is still concerned by the observed shortcomings in the signalling of the operations area during on-site work, even if a slight improvement in relation to 2022 is observed. ASN underlines that the lack of preparation and cooperation ahead of the work, between the ordering customers and the radiography contractors, is frequently one of the causes of these nonconformities. Progress is in particular needed regarding the content of the prevention plans, and familiarity with and implementation of the provisions contained in them. More generally, ASN considers that the ordering parties should, whenever possible, give priority to industrial radiography services in bunkers and not on the worksite.

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 advance preparations for the expiry of the sources administrative recovery period (which by default is ten years), information for the purchasers regarding future source recovery procedures, and the checks prior to delivery of a source to a customer, are areas in which practices progressed by comparison with 2022, but still need to improve further. As for the distributors of accelerators or X-ray emitting devices, the monitoring tools that they put into place to identify the devices distributed and who acquired them often need to be reinforced, to avoid compromising any recall or OEF processes.

The actions carried out by the licensees in recent years are continuing to improve radiation protection within the **research laboratories**. This is to a large extent based on the involvement of the RPAs and depends on the resources placed at their disposal. It should be recalled that the radiation protection issues in many research laboratories tend to be small or are decreasing owing to the use of techniques other than those using ionising radiation.

The conditions for the storage and elimination of waste and effluent remain the primary difficulties encountered by the research units or universities, including with regard to the performance and traceability of checks prior to elimination, the recovery of "legacy" unused sealed radioactive sources or the regular elimination of stored radioactive waste. On these latter points, the lack of forward planning for the funding needed to manage "legacy" sources or waste and their prior characterisation if necessary, is often observed. Finally, the facilities are also still experiencing difficulties in taking on board and correctly implementing checks on equipment, workplaces and instrumentation, as a result of changes to the Labour Code and Public Health Code in 2018, in particular in the case of joint research units.

With regard to the **veterinary uses of ionising radiation**, ASN can see the results of the efforts made by veterinary bodies over the past few years to comply with the regulations, notably in conventional radiology activities on pets. For practices concerning large animals such as horses, or performed outside veterinary facilities, ASN considers that the implementation of radiological zoning and the radiation protection of people 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, on the basis of the inspections performed in 2023:

- source categorisation, an essential step in identifying the applicable requirements and implementing an approach proportionate to the risks, was carried out by the vast majority of facilities;
- in half of the industrial facilities and one third of the medical facilities, ASN has no comments regarding the source protection policy, supported by the facility's general management and promoting the concrete measures to be taken;
- if all the facilities inspected have taken steps to protect the sources, about one third of them had not formally identified the physical barriers guaranteeing this protection, or demonstrated that they offered adequate intrusion resistance;
- in half of the cases, no preventive maintenance programme is defined for the equipment designed to detect intrusions;
- the issue of nominative permits for access to sources has barely progressed by comparison with 2022 and still needs to be implemented in nearly half the facilities;
- half of the facilities do not take steps to identify and protect sensitive information concerning source security.

ASN therefore considers that considerable progress is still needed.

In 2024, 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 2023, 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 events affecting TSR on the public highway is stable by comparison with 2022, with a handful of events rated level 1 on the INES scale, which is an appreciable fall in relation to 2022. The events chiefly consist of:

- material nonconformities 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 BNIs, ASN finds that the licensees carry out numerous checks and are therefore better able to detect any deviations. For BNIs performing research programmes, 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, notably when this demonstration is carried out by a third-party company. An incident involving non-compliance with a criticality risk control limit, rated level 1 on the INES scale, during on-site transport operations, recalls the importance of such provisions.

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, remains a point warranting particular attention.

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

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

Regulatory News

The year 2023 was marked by the publication of Act 2023-491 of 22 June 2023 concerning the acceleration of the procedures linked to the construction of new nuclear facilities close to existing nuclear sites and to the operation of the existing facilities. It also saw the completion of a certain number of important texts, in particular those concerning protection against ionising risks and nuclear security.

This year also saw continuing 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

● **Act 2023-491 of 22 June 2023 relative to the acceleration of the procedures linked to the construction of new nuclear facilities close to existing nuclear sites and to the operation of the existing facilities**

This Act is in line with the President of the Republic's speech in Belfort on 10 February 2022, which underlined the need to move away from fossil fuels by lowering energy consumption, combined with a massive acceleration in the production of decarbonised energy, electrical energy in particular: renewable energies, which are the subject of a specific Act, and nuclear energy, notably with the creation of six new pressurised water reactors (Evolutionary Power Reactor – EPR) by 2035.

This concern comes against the backdrop of a climate emergency threatening ecosystems and future generations, on the one hand, and a crisis of energy sovereignty and security of supply in 2022 following the Ukraine conflict, on the other.

The more precise aim of the Act is to simplify and accelerate construction projects for new nuclear power reactors in France, close to existing nuclear sites, by clarifying the interfaces between the various procedures (urban planning, nuclear power reactor creation authorisation and environmental permit), while guaranteeing protection of all the interests mentioned in Article L. 593-1 of the Environment Code (public health and safety, protection of nature and the environment) and full compliance with the principle of public participation enshrined in the *Charte de l'environnement* (Environment Charter).

During the Parliamentary debate, provisions regarding energy policy were added to the bill. Parliament also asked that several reports be submitted to it by the Government in the coming months or years.

The Act also enabled the procedures for periodic safety review of nuclear power reactors in operation for 35 years or more to be clarified, and the management of extended outages of the Basic Nuclear Installations (BNIs) to be improved. These measures help to provide a secure legal framework for the long-term operation of the nuclear power plant fleet.

Some provisions of the Act require implementing decrees, which are either being drafted or have already been published.

Decrees and Orders

● **Decree 2023-489 of 21 June 2023 relative to the protection of workers against ionising radiation risks**

This Decree draws the consequences of the modifications introduced by Act 2021-1018 of 2 August 2021 aiming to reinforce occupational health prevention. The provisions of the text mainly concern the skills of the occupational health professionals carrying out reinforced individual monitoring of workers exposed to ionising radiation, under the authority of the occupational physician, and their access to the Ionising radiation monitoring information system (Siseri). The text adapts the conditions of training and delivery of the certificate of proficiency in handling industrial radiological equipment to the new professional training framework. It reforms the certification of external contractors working in areas where there are significant risks of exposure to ionising radiation, using the graded approach. It takes account of the observations of the European Commission (EC) on the transposition of Directive 2013/59/Euratom of 5 December 2013 concerning the continuity of service by radiation protection experts and the training of occupational health professionals. It classifies as category A those workers exposed to a dose to the eye lens higher than 15 millisieverts (mSv) over 12 consecutive months. Finally, it clarifies the procedures for application of certain rules, notably those concerning the dose constraints, the use of operational dosimeters, periodic checks on means of transport or on measuring instruments.

● Decree 2023-722 of 3 August 2023 relative to Installations Classified for Protection of the Environment (ICPEs) operating on the basis of acquired rights and subject to Directive 2010/75/EU of the European Parliament and Council of 24 November 2010 concerning industrial emissions (integrated pollution prevention and control)

This Decree is in response to the formal notice served on France by the EC, reference INFR(2022)2057 C (2022)3978 relative to "vested rights" with respect to ICPEs, in which the EC considered that for installations benefiting from acquired rights, French regulations did not stipulate that they required a permit with prescriptions compliant with the requirements of the Directive.

● Decree 2023-1104 of 28 November 2023 containing various provisions regarding the periodic safety reviews of nuclear power reactors and shutdown of Basic Nuclear Installations (BNIs)

The purpose of this Decree is to improve access to information by the public and by foreign States during the periodic safety review of a nuclear power reactor after the 35th year of operation and to enable the licensee to postpone transmission of the data associated with this process for all the periodic safety reviews in the event of difficulties with performing some of the planned activities. It also updates the provisions concerning the final shutdown of an installation in the light of the changes introduced by the Act of 22 June 2023 concerning the acceleration of the procedures linked to the construction of new nuclear facilities close to existing nuclear sites and to the operation of the existing facilities.

● Order of 16 January 2023 amending the Order of 12 January 2017 defining the template form for the "case by case examination request" pursuant to Article R. 122-3-1 of the Environment Code

This Order modifies the form for the "case by case examination request" as part of the environmental assessment system.

● Order of 28 February 2023 relative to activities subject to authorisation set out in Article R. 1333-4 of the Defence Code, concerning category III nuclear materials in installations or which are imported and exported, outside a point of vital importance designated under the energy sector national security Directive (civil nuclear sub-sector) and Order of 13 April 2023 with regard to activities subject to authorisation set out in Article R. 1333-4 of the Defence Code, concerning category I and II nuclear materials in installations, which are imported and exported, or present in a point of vital importance designated under the energy sector national security Directive (civil nuclear sub-sector)

These two Orders specify the nuclear security obligations for the persons concerned (those carrying out an activity, except for transport, associated with nuclear materials in the stated categories).

They supplement two Orders published at the end of 2022: the Order of 27 December 2022 relative to activities subject to authorisation set out in Article R. 1333-4 of the Defence Code concerning category IV nuclear materials in installations or which are imported and exported, outside a point of vital importance in the energy sector (civil nuclear sub-sector) and the Order of 27 December 2022 relative to physical monitoring, nuclear materials accounting, implementing Articles R. 1333-3-2 and R. 1333-11 of the Defence Code, for activities not subject to authorisation set out in Article R. 1333-4 of the same Code.

● Order of 16 June 2023 defining the national template for the environmental permit application

This Order modifies the national template for the environmental permit application set out in the Order of 28 March 2019.

● Order of 20 June 2023 relative to the analysis of per- and polyfluoroalkyl substances (PFAS) in aqueous discharges from Installations Classified for Protection of the Environment (ICPEs) subject to the authorisation system

This Order defines the procedures for a campaign to identify and analyse the PFAS substances to be found in the aqueous discharges of certain ICPEs subject to authorisation. Twenty PFAS substances targeted by the European Directive on waters intended for human consumption will have to be analysed. It should be noted that other substances that could be analysed are also mentioned. In order to adapt the conduct of the analysis campaigns to the availability of the laboratories, they will be staggered over a period of time according to the activity sectors and the corresponding number of installations in them.

● Order of 23 June 2023 relative to the procedures for registration and access to the "Siseri" ionising radiation exposure monitoring information system and amending the Order of 26 June 2019 relative to the individual monitoring of worker exposure to ionising radiation

This Order defines the new procedures for registration and access to "Siseri" by authorised persons (workers, occupational physicians and occupational health professionals, radiation protection advisers, inspectors or inspection staff). It repeals the relevant Articles of the Order of 26 June 2019 (Art. 2 to 8, 10 to 15 and 19 to 22). The other provisions of the Order of 26 June 2019 remain in force.

The main modifications made concern:
- **direct access by the worker to "Siseri"** *via* the *France Connect+* web portal as of 1 July 2024 (option added to the existing possibility of a direct request to the French Institute for Radiation Protection and Nuclear Safety – IRSN);
- **on 1 July 2024, extension of access to "Siseri" to the other health professionals** liable to intervene, under the responsibility of the occupational physician, as part of the reinforced individual monitoring of an exposed worker;
- **the period for retention of the various data** by the accredited organisations and by IRSN, in accordance with the proportionality principle defined by the European General Data Protection Regulation (GDPR);
- clarification of **access to the results of individual dosimetric monitoring** in "Siseri" by prevention engineers, intervening in support of the labour inspectorate system's inspection staff.

● **Order of 26 June 2023 containing procedures for the approval of laboratories performing analysis of water and aquatic environments pursuant to the Environment Code**

This Order defines the conditions in which a laboratory performing physico-chemical, chemical, hydrobiological or ecotoxicological analyses of water, sediments, or biota in water and aquatic environments can be approved by the Minister for the Environment.

● **Order of 30 June 2023 relative to restriction measures – during periods of drought – on the intake of water and water consumption by Installations Classified for Protection of the Environment (ICPEs)**

This Order defines the restriction measures on water intake and consumption by industrial sites, as well as the exemption conditions for certain installations. It applies consistently with the catchment area guideline Orders, the departmental and inter-departmental framework Orders as well as with the prefectural Orders applicable to ICPEs. When the local context so warrants, these Orders may notably stipulate any provisions more restrictive than those set out in this present Order, in order to protect the interests mentioned in Article L. 511-1 of the Environment Code. These Orders may also be revised in order to take account of the provisions of this Order.

● **Order of 16 November 2023 defining the methods for calculating effective doses and equivalent doses resulting from human exposure to ionising radiation**

This Order sets the methods for calculating effective doses and equivalent doses resulting from human exposure to ionising radiation pursuant to Article R. 1333-24 of the Public Health Code. It is applicable as of 1 January 2024 and on this date repeals the Order of 1 September 2003 (same title):
- for the calculation of effective doses, the tissue and radiological weighting factors take account of publication 103 from the International Commission on Radiological Protection (ICRP);
- for workers, the effective dose coefficients per unit of activity ingested or inhaled are taken from ICRP publications 134, 137, 141, 151.

The coefficients for the public, taken from publication 119, are maintained, except for radon.

With regard to workers, two radon coefficients are proposed:
- for indoor workplaces in which the activity of the workers is primarily **sedentary** (service sector, offices, etc.): 3 $Sv/m.d.m^{-3}$;
- for indoor workplaces in which the activity of the workers is primarily **non-sedentary** (significant physical activity: works, maintenance, servicing, etc.): 6 $Sv/m.d.m^{-3}$.

● **Modification of the Order of 7 February 2012 setting the general rules concerning Basic Nuclear Installations ("BNI Order"): the work to revise this Order continued in 2023.**

ASN resolutions

Resolutions issued pursuant to the Public Health Code

● **Resolution CODEP-DIS-2023-014569 from the ASN Chairman of 16 March 2023 approving the Guide for continuing training in radiation protection of persons exposed to ionising radiation for medical purposes, intended for neurosurgeons performing intra-cranial radiosurgery procedures in stereotactic conditions**

In accordance with Decree 2018-434 of 4 June 2018, ASN determines the objectives of continuing training in the radiation protection of patients and, along with the health professionals, establishes the programmes, teaching methods and evaluation procedures. The guides, approved by ASN, are then published. All the guides are available on *asn.fr*.

Summary of two resolutions issued in 2022 (included in the 2022 Annual Report), but approved in 2023:

● **ASN resolution 2022-DC-0747 of 6 December 2022 setting the rules to be verified by the party responsible for the nuclear activity pursuant to Article R. 1333-172 of the Public Health Code *(approved by the Order of 18 January 2023 approving ASN resolution 2022-DC-0747 of 6 December 2022 setting the rules to be verified by the party responsible for the nuclear activity pursuant to Article R. 1333-172 of the Public Health Code)***

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, implementing 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.

● **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 *(approved by the Order of 18 January 2023 approving 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)***

Resolution 2022-DC-0748 is in response to Article R. 1333-174 of the Public Health Code, which requires 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.

Basic Nuclear Installations

● **ASN resolution 2023-DC-0770 of 7 November modifying ASN resolution 2017-DC-0616 of 30 November 2017 concerning noteworthy modifications to Basic Nuclear Installations – BNIs *(approved by the Order of 9 February 2024 approving ASN resolution 2023-DC-0770 of 7 November modifying ASN resolution 2017-DC-0616 of 30 November 2017 relative to noteworthy modifications to Basic Nuclear Installations)***

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

This resolution in particular defines the list of modifications requiring notification during the construction phase and those requiring authorisation by ASN. It also adapts certain criteria for activating the notification system, to take account of the lessons learned from application of resolution 2017-DC-0616 since it entered force on 1 July 2019.

Summary of a resolution issued in 2022 (included in the 2022 Annual Report), but approved in 2023:

● **ASN resolution 2022-DC-0749 of 29 November 2022 amending ASN resolution 2015-DC-0508 of 21 April 2015 relative to the waste management study and the inventory of waste produced in the Basic Nuclear Installations (BNIs) and ASN resolution 2017-DC-0616 of 30 November 2017 relative to noteworthy modifications to Basic Nuclear Installations *(approved by an Order of 16 February 2023 approving 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 Basic Nuclear Installations and ASN resolution 2017-DC-0616 of 30 November 2017 relative to noteworthy modifications to Basic Nuclear Installations)***

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 noteworthy modifications to BNIs.

The modifications made are of several types:

Firstly, the resolution divides 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 optimisation 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.

REGIONAL OVERVIEW
of nuclear safety and radiation protection

ASN, the French Nuclear Safety Authority, has **11 regional divisions** through which it carries out its regulatory duties throughout metropolitan France and in the French overseas *départements* and regions. Several ASN regional divisions can be required to coordinate their work in a given administrative region. As at 31 December 2023, the ASN regional divisions totalled 218 employees, of whom 157 are inspectors.

Under the authority of the regional representatives (see chapter 2), the ASN regional divisions carry out on-the-ground inspections of the Basic Nuclear Installations (BNIs), of radioactive substance transport (TSR) operations and of small-scale nuclear activities; they examine the majority of the licensing applications submitted to ASN by the persons/entities Responsible for Nuclear Activities (RNA) 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*[1], who is responsible for protection of the population.

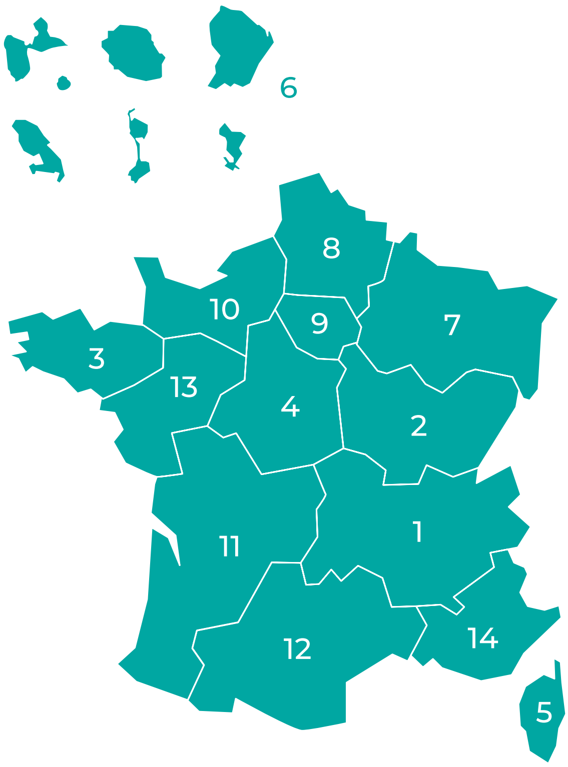
To ensure emergency situation preparedness, they help draw up the emergency plans established by the Prefects and take part in the periodic exercises.

The ASN regional divisions contribute to the mission of informing the public. 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 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.*



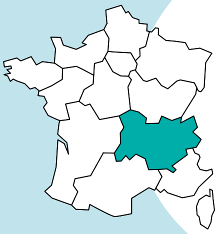
IMPORTANT

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 2023, ASN carried out 309 inspections in the Auvergne-Rhône-Alpes region, comprising 111 in the Bugey, Saint-Alban, Cruas-Meysse and Tricastin Nuclear Power Plants (NPPs), 96 in plants and installations undergoing decommissioning, 90 in small-scale nuclear activities and 12 in the Radioactive Substance Transport (TSR) sector.

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

In 2023, ASN was notified of 24 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale), of which 21 occurred in Basic Nuclear Installations (BNIs) and one in TSR and two in small-scale nuclear activities.

Furthermore, two events were rated level 2 on the ASN-SFRO scale (scale specific to radiation protection events affecting patients undergoing a radiotherapy procedure).

Lastly, in the context of their oversight duties, the ASN inspectors issued two violation reports.

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.

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

BUGEY NUCLEAR POWER PLANT

Reactors 2, 3, 4 and 5 in operation

ASN considers that the performance of the Bugey NPP with regard to nuclear safety and, to a lesser extent, radiation protection, is in line with ASN's general assessment of the EDF plants. Its environmental protection performance however is considered to be below the average for the EDF plants.

With regard to nuclear safety, ASN considers that the NPP's performance has improved slightly, but in an industrial context with lower workloads than in the preceding years. Configuring the systems and managing the periodic tests and requalification tests are still areas displaying weaknesses. In addition, ASN expects to see improvements in the control of fire risks, having noted breaks in sectorisation and unauthorised storage of fire loads during its inspections.

There are improvements in maintaining the first barrier, that is to say the fuel cladding, in good condition, but shortcomings are still observed in the management of the risk of introducing foreign objects into the systems. Lastly, ASN is waiting for EDF to analyse the causes and potential consequences of the two internal floods of the site's underground galleries which occurred in autumn 2023 and to take appropriate measures to prevent this recurring.

With regard to radiation protection, although occupational exposure is well managed, ASN notes persistent weaknesses in the culture of worker radiation protection, radiological cleanliness of the installations and containment on work sites with contamination dispersion risks. During the tightened inspection it carried out in 2023, ASN noted deviations in the upkeep of the installations, in the management of controlled zones and the personal radiation monitoring devices.

Concerning environmental protection, several events and problems of retention structure leakages in 2023 led to bypassing of the normal discharge routes, without harming the environment. ASN considers that the overall standard of waste management remains satisfactory.

With regard to health and safety at work, ASN considers that appropriate measures have been put in place reactively to take account of the accident levels, particularly in lifting operations. Nevertheless, measures must be taken with outside contractors to improve the management of storage areas and the upkeep of work sites, particularly during reactor outages.

Reactor 1 undergoing decommissioning

Bugey 1 is a Gas-Cooled Reactor (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.

ASN considers that the Bugey 1 reactor decommissioning and vessel characterisation operations are proceeding with a satisfactory level of safety.

ACTIVATED WASTE CONDITIONING AND INTERIM STORAGE FACILITY

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

- 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 Radioactive Waste Management Agency (Andra).

The installations and activities to regulate comprise:

- **Nuclear Power Plants operated by EDF:**
  - Bugey (4 reactors of 900 MWe),
  - Cruas-Meysse (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 Tricastin Operational Hot Unit (BCOT) of EDF, undergoing decommissioning;**
- **the High Flux Reactor (RHF) operated by the Laue-Langevin Institute in Grenoble;**
- **the Activated waste conditioning and storage facility (Iceda) on the Bugey nuclear site and the Bugey Inter-Regional Warehouse (MIR) for fuel storage operated by EDF;**
- **reactor 1 undergoing decommissioning at the Bugey NPP operated by EDF;**
- **the Superphénix reactor undergoing decommissioning and its auxiliary installations;**
- **the Ionisos irradiator in Dagneux;**
- **the international research centre of the European Organisation for Nuclear Research (CERN), situated on the French-Swiss border;**
- **small-scale nuclear activities in the medical sector:** Chapter 7 p. 204
  - 23 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 23 nuclear medicine departments,
  - 122 facilities using fluoroscopy-guided interventional procedures,
  - 164 computed tomography scanners in 109 facilities,
  - some 10,000 medical and dental radiology devices;
- **small-scale nuclear activities in the industrial, veterinary and research sectors:** Chapter 8 p. 240
  - 1 synchrotron,
  - about 490 veterinary practices (surgeries or clinics),
  - 33 industrial radiography agencies,
  - about 600 users of industrial equipment,
  - about 75 public or private research units;
- **activities associated with the transport of radioactive substances;** Chapter 9 p. 270
- **ASN-approved laboratories and organisations:**
  - 3 organisations and 8 agencies approved for radiation protection controls,
  - 11 organisations approved for taking radon activity concentration measurement.

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

Regarding conditioning of the waste, ASN authorised EDF to condition its waste in the C1PGSP package through resolution CODEP-DRC-2021-013808 of 19 July 2021. The validity of this conditioning authorisation was limited to 31 December 2023. After examining complementary studies submitted by EDF, ASN authorised the continuation of waste conditioning through resolution CODEP DRC-2023-68099 of 18 December 2023.

Further to the inspections carried out in 2023, ASN considers that the licensee's organisation and management of the waste induced by the process have improved.

INTER-REGIONAL WAREHOUSE

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

ASN conducted an inspection of the fuel reception process in 2023. The organisation of this process was considered robust, but ASN has asked for improvements in fire detection training and management.

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 performance of the Saint-Alban NPP with regard to nuclear safety, radiation protection and environmental protection is in line with the general assessment of EDF plant performance.

With regard to nuclear safety, ASN finds that the site's facilities are operated and maintained satisfactorily despite disruptions in the industrial programme in 2023. Reactor 1 was shut down for its refuelling and maintenance outage. EDF had difficulties in managing the outage activities schedule and several deviations from the safety requirements were highlighted during ASN's work site inspections. As far as reactor operation is concerned, control room monitoring and management of the operating team's skills are deemed satisfactory.

With regard to occupational radiation protection, ASN considers that the control of occupational exposure is satisfactory. However, with regard to the Significant Radiation Protection Events (ESRs) reported in 2023, ASN is still waiting for improvements in the radiation protection culture and rigour in the marking out of work sites and the management of tools and radioactive waste.

As far as environmental protection is concerned, the NPP's results are satisfactory but ASN wants to see faster responses to the technical problems impacting the environmental protection systems.

With regard to health and safety at work, ASN observes that the site is continuing the deployment of the national EDF actions, particularly regarding the electrical risks and lifting. Specific actions relating to the electrical risk have been satisfactorily implemented on the site. Although the level of accidents is broadly under control, particular vigilance must be maintained during the reactor outages.

CRUAS-MEYSSE NUCLEAR POWER PLANT

Commissioned between 1984 and 1985 and operated by EDF, the Cruas-Meysse NPP is situated in the Ardèche *département* on the municipalities of Cruas and Meysse 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-Meysse NPP with regard to nuclear safety, radiation protection and environmental protection is in line with ASN's general assessment of the EDF plant performance.

With regard to nuclear safety, ASN expects an improvement in operating rigour and activity preparation. The measures deployed in 2023 under the operating rigour improvement plan to limit maintenance non-qualities in particular (training sessions, supervision, assistance in activity preparation) must be continued. Furthermore, the occurrence of several significant events relating to inappropriate operating actions reveals difficulties in normal operational management, the preparation of activities and monitoring. ASN also observed maintenance problems during the reactor outages in 2023. ASN considers it essential for the site to improve control of the maintenance activities before starting the site's fourth ten-yearly outages, which will begin in summer 2024 on reactor 3.

Improvements in radiation protection compared with the preceding years were observed in 2023, notably with a reduction in occupational contamination events. Nevertheless, a tightened inspection on the subject revealed deviations in the upkeep of the facilities, management of the work site zone containment airlocks and management of the controlled areas.

The situation regarding environmental protection has improved compared with 2022. More specifically, the means implemented to avoid the overflow of the cooling tower ponds prevented overflows similar to those that occurred in the preceding two years. ASN notes a reduction in the number of Significant Environmental Events (ESE), but considers that the licensee must remain attentive to the control of containment of pollutions by liquids.

The site's results in occupational health and safety are satisfactory. The accident levels remain controlled, particularly during reactor outages. A handling accident occurred when carrying out work on the polar crane during the reactor 1 outage, without causing injury.

Tricastin site

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

TRICASTIN NUCLEAR POWER PLANT

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

ASN considers that the nuclear safety performance of the Tricastin NPP 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.

As regards nuclear safety, ASN considers that the plant's performance remains satisfactory, but has not improved with respect to 2022. With regard to maintenance, the second batch of modifications planned for under the fourth periodic safety review has been satisfactorily integrated on reactor 1. ASN considers that EDF satisfactorily carried out the planned activities for the three reactor outages of 2023 and complied with the corresponding safety requirements. Weaknesses in operating rigour were nevertheless observed, with several significant events linked to failure to apply the work error-reduction practices.

With regard to radiation protection, ASN considers that the performance of the NPP has deteriorated slightly. Eight ESRs were reported compared with three in 2022, and deficiencies in the control of the radiological cleanliness of the work sites were identified during the reactor outages. The tightened inspection carried out in 2023 also revealed deviations in the upkeep of the facilities and the management of controlled areas.

ASN considers that the environmental protection performance of the NPP has improved and on the whole is in line with the general assessment of the EDF plants. Although several ESEs were reported in 2023, ASN notes the efforts the site has made in this area. Furthermore, the ASN resolutions governing the site's discharges were revised in 2023, in particular to adapt the environmental monitoring programme and to reassess the methods of controlling certain substances further to changes in the operating conditions.

As far as occupational safety is concerned, ASN considers that the site's results are satisfactory and stable with respect to the preceding year. Accident levels, particularly during the reactor outages, remain under control despite a slight increase.

THE "NUCLEAR FUEL CYCLE" FACILITIES

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

The site comprises:
- the TU5 facility (BNI 155) for converting uranyl nitrate ($UO_2(NO_3)_2$) 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 (BNIs 178, 179 and 180) for storing uranium in the form of oxides or UF_6;
- the Maintenance, liquid effluent treatment and waste conditioning facilities (IARU – BNI 138);
- the Atlas process samples analysis and environmental monitoring laboratory (BNI 176);
- a Defence Basic Nuclear Installation (DBNI), which more specifically accommodates former facilities undergoing decommissioning, radioactive substance storage areas and a liquid effluent treatment unit.

Following the inspections it conducted in 2023, ASN considers that the level of safety of the Orano facilities on the Tricastin site is satisfactory. In 2023, ASN noted an improvement in the organisation for analysing conformity with the regulatory texts and implementing the necessary compliance work.

In 2023, ASN conducted a campaign of simultaneous unannounced inspections on BNIs 105, 138, 155, 168 and 176 focusing on waste management, to verify Orano's organisation in this area. In this context, the inspectors visited the waste production, sorting and collection sites. These inspections showed that the licensee has made improvements in this area.

ASN also conducted inspections in 2023 on the theme of criticality risk prevention on several of the platform's facilities and at platform level. ASN considers the results of these inspections to be broadly satisfactory, even if for the facilities undergoing decommissioning the licensee must improve knowledge of the stored legacy waste and the quantities of residual materials in certain items of equipment.

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.

In 2024, following numerous inspections and exchanges in 2023, ASN will check the progress of the decommissioning operations and the gradual emptying of areas 61 and 79 of BNI 105.

The Tricastin site has two main liquid effluent management facilities: the Chemical Effluents Treatment Station (STEC – DBNI) and the Uranium-containing Effluents Treatment Station (STEU – BNI 138). Orano is considering reorganising all the effluent movements on the Tricastin platform – DBNI included – and had to provide a Safety Options Dossier (DOS) for this project in 2023. ASN was not convinced by some of the project's preliminary orientations, obliging the licensee to modify its project which is now expected for 2024.

With regard to projects, Orano has started operating the first two buildings of the new reprocessed uranium storage facility called "FLEUR" (BNI 180), whose commissioning was authorised by ASN in January 2023.

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

Orano also started the work on building 57L of BNI 138 in mid-2023, which will enhance the safety of certain storage areas.

Lastly, to increase its enrichment capacities, Orano initiated the project to extend the Georges Besse II (GB II) North enrichment plant in 2022, which underwent a prior consultation in 2023. In June 2023, Orano submitted the application for a substantial modification to the facility authorisation decree in order to build this extension.

The ASN Chairman accompanied by two Commissioners visited the site in July 2023. On this occasion, the licensee presented the progress of the projects mentioned in 2019 during the ASN Chairman's previous visit. An interim assessment of the GB II enrichment plant extension project was carried out. Lastly, the ASN Commission reiterated that ASN expects Orano to commit the necessary resources to the new projects, as much to increase its production capacities as to improve certain support functions, such as the new container maintenance facility (AMC2), or the treatment of the backlog of radioactive substances stored on the site. The discussions also focused on the overall view of the impacts of the site, including the strategy for managing liquid effluents in the short and medium term.

ORANO'S URANIUM CHEMISTRY PLANTS TU5 AND W

The "TU5" plant can handle up to 2,000 tonnes of uranium per year, enabling it to reprocess all the uranyl nitrate ($UO_2(NO_3)_2$) produced by the Orano plant at La Hague, converting it into U_3O_8, a stable solid compound guaranteeing safer uranium storage conditions than in liquid or gaseous form. Once converted, the reprocessed uranium is placed in storage on the Tricastin site. The W plant situated within the perimeter of BNI 155 can process the depleted UF_6 from the GB II enrichment plant, to stabilise it as U_3O_8.

ASN considers that the facilities situated within the perimeter of BNI 155 are operated with a satisfactory level of safety. The drop in the number of significant or notable events, already observed in 2022, continued in 2023. ASN will nevertheless be attentive in 2024 to ensure that the licensee maintains the rigour of operation of the facilities.

ASN expects the files associated with the consequences of the project to increase the capacity of the GB II North plant on the activities of the W plant to be submitted in 2024.

ORANO URANIUM FLUORINATION PLANTS

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

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

ASN notes that the decommissioning operations on the BNI part were suspended in mid-2023 due to operational difficulties linked to waste management. Further to ASN's requests, the licensee undertook actions aiming to improve, in the short term, the safety of storage of the radioactive and hazardous substances of areas 61 and 79, which will more specifically require a transfer of these storage areas on the site. A number of new difficulties, such as prevention of the criticality risk for a portion of these materials, arose in 2023, after conducting new analyses of the stored substances. In 2024, ASN will check the progress of the decommissioning operations and the gradual emptying of areas 61 and 79.

After the technical difficulties experienced by the Philippe Coste plant in 2022, ASN considers that the licensee has stabilized its functioning and that this plant is operated satisfactorily with regard to nuclear safety. In 2024, ASN will ensure that the licensee maintains a good standard of operating rigour, and also expects the licensee to accomplish its project to design treatment units for non uranium-bearing effluents and the on-line treatment of potassium diuranate (KDU).

GEORGES BESSE I ENRICHMENT PLANT

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

After this plant stopped production in May 2012, the licensee implemented the "intensive rinsing followed by air venting" operations (Prisme operation) from 2013 to 2016. These operations allowed the extraction of virtually all the residual uranium deposited in the diffusion barriers. The main residual risk of BNI 93 is now associated with the UF_6 containers in the storage yards, which are still attached to the perimeter of the installation. At the end of the periodic safety review of the yards, ASN ordered complementary measures in its resolution CODEP-CLG-2023-012727 of 8 March 2023. These yards should in the short term be attached to the Tricastin uranium storage yards (BNI 178).

The Decree ordering Orano to proceed with the decommissioning of the Georges Besse 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. On completion of the periodic safety review of the facility, ASN sent its conclusions to the Minister of the Energy Transition on 13 July 2023, without issuing further requirements. ASN underlines that the action plan involving the management of large quantities of legacy operational waste must be strictly followed and implemented, and that attention must be paid to the facilities in service within the perimeter of the installation. ASN considers that in 2023 the monitoring operations and the progress of the decommissioning project are satisfactory, but there is room for improvement in operational rigour. ASN is expecting the detailed decommissioning scenario studies for the diffusion cascades to be completed in 2024.

GEORGES BESSE II ENRICHMENT PLANT

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

The standard of safety of the plant's facilities in 2023 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.

The examination of the concluding report of the first periodic safety review of BNI 168 is continuing. ASN conducted a dedicated inspection on this subject in June 2023 which underlined the good organisational setup put in place for the safety review and led to the formulation of demands concerning regulatory conformity and the action plan.

In 2022, Orano began the project to extend the GB II North enrichment plant in order to increase its production capacities by adding centrifuge modules. The GB II North plant extension project underwent a prior consultation from 1 February to 9 April 2023, organised by the French National Public Debates Commission (CNDP). In June 2023, Orano submitted the substantial modification application file in order to build this extension. This project will undergo a public consultation in 2024.

MAINTENANCE, EFFLUENT TREATMENT AND WASTE CONDITIONING FACILITIES

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

Concerning the periodic safety review, every six months the licensee sends a statement of the commitments made to ASN. The progress of the action plan and commitments is considered satisfactory despite some delays. ASN takes positive note of the start of work on building 57L in 2023, which will improve the safety of certain storage areas.

The results of the inspections carried out in 2023 on the themes of commitment follow-up, civil engineering monitoring, criticality safety, modification management and waste management are satisfactory. In 2023, ASN also checked the progress of the site's new linen room project, situated outside the BNI perimeters, which will improve fire risk prevention in BNI 138.

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 facilities and the platform's new emergency management premises.

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

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

Further to the three inspections at these facilities on the themes of meeting commitments, control of the criticality risk and civil engineering, ASN considers that the level of safety of the storage yards in 2023 was satisfactory. Nevertheless, with the various past and future movements of material, the way the radiological exposure induced by the yards evolves – both within and outside the site – should be monitored.

Lastly, in mid-2023 Orano started work on the AMC2 project which consists in adding a new facility for washing and rinsing containers dedicated to the transport of UF_6. This facility will replace the existing AMC which is situated in the DBNI. The creation of AMC2 was authorised by Decree 2023-1220 of 19 December 2023 following a public inquiry which ran from 10 December 2021 to 12 January 2022.

Romans-sur-Isère site

FRAMATOME NUCLEAR FUEL FABRICATION PLANTS

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

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

The Cerca plant features a "uranium zone" in which the compacted powder cores placed in aluminium frames and plates to form the fuel elements are produced, as are the irradiation targets for the production of medical radionuclides. The licensee has undertaken to replace this uranium zone by a New Uranium Zone called "NZU", in order to improve more specifically the containment of the premises, the process and the prevention of risks in the event of an extreme earthquake. The NZU construction work began in late 2017. These new buildings shall accommodate the current activities of the existing uranium zone. Due to technical problems and the impact of the Covid-19 pandemic, the NZU construction work has fallen significantly behind schedule. In 2022, Framatome applied to ASN for a partial commissioning authorisation for the NZU to enable it to transfer materials between the existing buildings and the NZU. ASN issued this authorisation in October 2022. Difficulties with the tests of certain equipment items arose in 2023, leading Framatome once again to postpone commissioning of the NZU until 2024. ASN expects increased mobilisation on the part of Framatome in order to effectively commission the NZU, and points out that the level of safety of the existing uranium zone does not permit continued long-term operation.

In 2023, Framatome conducted a fuel production campaign with Enriched Reprocessed Uranium (ERU). An application for a substantial modification to the unit fabricating nuclear fuels for PWRs, with the aim of increasing the production of fuels based on enriched reprocessed uranium, is currently being examined by ASN and will undergo a public inquiry in 2024.

The results of the inspections carried out at Romans-sur-Isère in 2023 are satisfactory, particularly regarding implementation of the new environmental monitoring plan, control of the criticality risk, restarting of production of fuels based on ERU, radiation protection and emergency management. A week-long in-depth inspection was carried out in March 2023 on the themes of operating rigour and prevention of fraud: the inspection result was broadly positive.

THE INDUSTRIAL AND RESEARCH FACILITIES

High flux reactor of the Laue-Langevin Institute

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

The RHF constitutes BNI 67 which accommodates the European Molecular Biology Laboratory (EMBL), an international research laboratory. 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.

In view of the oversight actions it conducted in 2023, ASN considers the safety of the RHF to be satisfactory. After carrying out substantial works to renovate the RHF and enhance its safety in 2022, no significant difficulties were encountered with the restarting of the reactor and its cycles in 2023.

In 2023, 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. The year also saw intensive discussions during the examination of modifications to be implemented as of mid-2024 to comply with ASN resolution 2022-DC-0738 of 28 July 2022 validating the conclusions of the periodic safety review.

In July 2022, the ILL also submitted a "public information notice" file aiming to establish new technical requirements for discharges and environmental monitoring. Elements were added to this file in 2023 and ASN is continuing to examine it.

ASN will be particularly attentive in 2024 to the preparation of the next activities with safety implications for ILL, notably the pre-clean-up operations of the former detritiation facility and the polar crane renovation. Lastly, the revision of the ASN requirements regulating discharges will be continued in 2024.

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.

ASN considers that the operational safety of the facility was satisfactory in 2023. However, ASN has also noted the simultaneous departure of the safety manager and the safety engineer, which is a source of organisational vulnerability for safety management. In view of the ongoing projects, ASN considers that the licensee must lastingly reinforce its team and its skills with regard to safety.

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 for 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 inspections by the Swiss and French authorities were held in 2023 on the themes of the management of high-activity sources and the transport of radioactive substances. These inspections found the practices to be satisfactory.

SITES UNDERGOING DECOMMISSIONING

Superphénix reactor and fuel storage facility

The Superphénix fast neutron reactor (BNI 91), a 1,200 MWe sodium-cooled industrial prototype is situated at Creys-Malville in the Isère *département*. It was definitively shut down in 1997. The reactor has been unloaded and the majority of the sodium has been neutralised 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.

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 this context, ASN inspected the end of the reactor core closure plug cutting operations. The large rotating plug was cut into three pieces stored on specific storage platforms. The reactor vessel was covered by a containment structure to seal it pending its decommissioning. This containment structure shall also be used to permit the extraction of the first internal components of the vessel in 2024.

In 2023, ASN also inspected the preparation operations for construction of the D4 tunnel facility in which the most highly activated internal parts of the reactor vessel will be cut up by remote operation.

In view of the inspections conducted in 2023, ASN considers that the safety of the Superphénix reactor decommissioning operations and of operation of the fuel storage facility is ensured satisfactorily.

Tricastin Operational Hot Unit

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

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.

Decree 2023-1049 of 16 November 2023 authorises decommissioning of the BCOT, for which the public inquiry ran from 15 February to 17 March 2022.

ASN considers that the level of safety of the BCOT is satisfactory. In 2024, ASN will be particularly attentive to compliance with the steps of the decommissioning decree and the requirements introduced by the associated new baseline requirements for carrying out the decommissioning and the structure and soil clean-up operations.

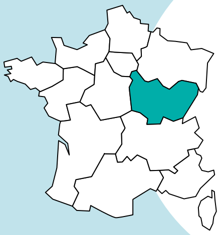
Siloette, Siloé, LAMA reactors and effluents and solid waste treatment station – *CEA Centre*

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 (BNIs 36 and 79) were the STED and the decay storage facility.

Given the final state of the site after decommissioning, ASN made their delicensing conditional upon the application of active institutional controls which enable the future use of the site to be limited to industrial purposes and the residual pollution record to be kept. ASN then declared the delicensing of the CEA Grenoble centre's last two BNIs through ASN resolution 2023-DC-0751 of 13 January 2023.



Bourgogne-Franche-Comté
REGION

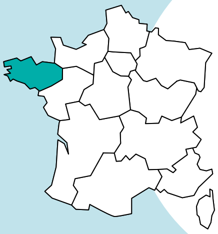
The Dijon division regulates nuclear safety, radiation protection and the transport of radioactive substances in the 8 *départements* of the Bourgogne-Franche-Comté region.

ASN conducted 51 inspections in small-scale nuclear activities in the Bourgogne-Franche-Comté region in 2023, comprising 22 inspections in the medical sector, 16 in the industrial, research and veterinary sectors, six concerning radon exposure, one to monitor approved organisations and laboratories, and six specific to the transport of radioactive substances.

ASN also devoted particular attention to the Framatome nuclear pressure equipment manufacturing plants situated in the Bourgogne-Franche-Comté region. The actions conducted by ASN in this context are described in chapter 10. ASN carried out ten inspections in these plants in 2023, of which five were in the Creusot plant and five in the Chalon Saint-Marcel plant.

The installations and activities to regulate comprise:

- **small-scale nuclear activities in the medical sector:**
Chapter 7 p. 204
  - 8 external-beam radiotherapy departments,
  - 4 brachytherapy departments,
  - 14 nuclear medicine departments, of which 3 practise internal targeted radiotherapy,
  - 36 centres performing fluoroscopy-guided interventional procedures,
  - 66 computed tomography scanners for diagnostic purposes in 48 centres,
  - about 800 medical radiology devices,
  - about 2,000 dental radiology devices;
- **small-scale nuclear activities in the industrial, veterinary and research sectors:**
Chapter 8 p. 240
  - about 180 veterinary practices, of which 4 have a computed tomography scanner and 16 practice equine radiology,
  - about 400 industrial and research centres, including 25 companies with an industrial radiography activity,
  - 1 industrial irradiator using radioactive sources,
  - 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;**
Chapter 9 p. 270
- **ASN-approved laboratories and organisations:**
  - 1 organisation 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 Nuclear Power Plant (NPP), currently undergoing decommissioning.

In 2023, ASN carried out 48 inspections, two at the Monts d'Arrée NPP currently being decommissioned, one to monitor an approved laboratory, three in the transport of radioactive substances and 39 in small-scale nuclear activities (22 in the medical sector and 17 in the industrial, veterinary and research sectors).

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 Megawatts electric – MWe), moderated with heavy water and cooled with carbon dioxide, and it was definitively shut down in 1985.

Decree 2011-886 of 27 July 2011 authorised the NPP decommissioning operations, with the exception of the reactor block. In July 2018, EDF submitted an application file for the complete decommissioning of its facilities, and this file was subject to a public inquiry from 15 November 2021 to 3 January 2022. Decree 2023-0898 of 26 September 2023, published on 28 September 2023, requires EDF to completely decommission BNI 162 and amends Decree 96-978 of 31 October 1996 authorising the creation of this facility. The Decree sets the radiological cleanliness targets, and future ASN resolutions will govern the methods of post-operational clean-up of the site, which shall be taken as far as is reasonably achievable. The end-of-commissioning date is set at 2041.

In April 2023, ASN issued the authorisation to stop the lowering of the water table underneath the effluent treatment station. During 2023, ASN also continued the revision of the resolutions governing discharges and water intakes and the examination of the general operating rules and the on-site emergency plan for the complete decommissioning.

During the same year, EDF continued its preparatory work for complete decommissioning, in particular with the removal of asbestos from the accessible places and the civil engineering work to enlarge the existing accesses and demolish bunkers. EDF also started the work to treat the water infiltrations in the facilities, which concern the "G7" gallery in particular.

Alongside this, EDF has started execution studies for certain complete decommissioning operations (such as the decommissioning of the peripheral circuits) and for upgrading the support functions that are absolutely necessary for complete decommissioning (handling cranes, ventilation in the reactor containment, etc.).

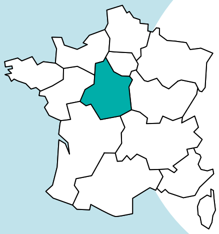
The installations and activities to regulate comprise:

- **the Basic Nuclear Installation::**
  - the Monts d'Arrée (Brennilis) NPP, undergoing decommissioning;
- **small-scale nuclear activities in the medical sector:** Chapter 7 p. 204
  - 10 external-beam radiotherapy departments,
  - 5 brachytherapy departments,
  - 10 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;
- **small-scale nuclear activities in the industrial, veterinary and research sectors:** Chapter 8 p. 240
  - 1 cyclotron,
  - 16 industrial radiography companies, including 3 performing gamma radiography,
  - 25 research units,
  - about 400 users of industrial equipment;
- **activities associated with the transport of radioactive substances;** Chapter 9 p. 270
- **ASN-approved laboratories and organisations:**
  - 8 organisations approved for measuring radon,
  - 3 head-offices of laboratories approved for taking environmental radioactivity measurements.

ASN notes that the November 2023 storm "Ciaran" had no impact on the safety of the NPP. The decommissioning operations were stopped on 2 November 2023 due to an outage of the site's main electrical power supply, and resumed on 6 November 2023.

ASN considers that the management of the NPP decommissioning project is satisfactory. ASN notes positively the management of the interfaces between the project and the site, in particular with the planned reinforcement of the project team within the NPP. Nevertheless, with regard to the monitoring of the facilities, EDF must ensure that it meets the prescribed deadlines for carrying out all the periodic checks and ensures the traceability of the characteristics of the materials with a view to their reuse or the future delicensing of the facility.

As from 2024, ASN will be particularly attentive to the application of the new baseline requirements for the complete decommissioning of the facility and to the maintenance of the equipment required for the decommissioning operations, especially the handling equipment. ASN will also maintain its vigilance regarding the radiation protection plan, particularly concerning compliance with the controlled area entry rules.



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 2023, ASN conducted 166 inspections in the Centre-Val de Loire region, of which 116 were in the nuclear installations of the EDF sites of Belleville-sur-Loire, Chinon, Dampierre-en-Burly and Saint-Laurent-des-Eaux, 39 in small-scale nuclear activities, five in the transport of radioactive substance and six concerning approved organisations or laboratories.

ASN also carried out 38 days of labour inspections in the four Nuclear Power Plants (NPPs) of the region.

In 2023, ASN was notified of 16 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale).

BELLEVILLE-SUR-LOIRE NUCLEAR POWER PLANT

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

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

From the nuclear safety aspect, ASN considers that with regard to management of the facilities, operational rigour in the control room was maintained at a satisfactory level. The site must continue its efforts in the management of system configurations (alignments, padlocking, administrative lockouts) through the action plan it has applied since early 2023. ASN notes positively the reinforcing of the action plan initiated in 2022 to address the fire sectorisation anomalies.

As far as the maintenance of the facilities is concerned, the performance of the Belleville-sur-Loire NPP is considered satisfactory. The year 2023 was marked by a particularly intensive industrial programme due to the operations to replace pipe sections linked to the stress corrosion problem. ASN considers that the overall management of these outages is satisfactory in the light of its various inspections, which revealed no major deviations.

In the area of radiation protection, ASN considers that the Belleville-sur-Loire NPP obtained satisfactory results regarding the radiological cleanliness of the premises and occupational exposure, despite large-scale works in the reactor building, which led to a significant increase in the collective dosimetry. It will nevertheless remain attentive in 2024 to the marking out of limited stay areas and to the level of contamination of the workers, a subject in which difficulties were identified during the outage of reactor 1 in 2023.

With regard to environmental protection, ASN considers that effluent management and the monitoring of discharges are satisfactory. It observes a lowering of the copper and zinc discharges in the liquid effluents, and a reduction in the number of legionella colonisation threshold overshoots compared with 2022. A tightened environmental inspection revealed several improvements concerning the control of non-radiological risks and the optimisation of effluent management. In February 2024, ASN revised the resolutions governing the site's discharges in order to take into account the installation of a legionella and amoeba treatment station in 2024.

In the area of labour inspection, ASN notes that the Belleville-sur-Loire NPP's results deteriorated significantly in 2023, particularly regarding outside contractors accident levels. Consequently, while noting that no accidents were serious or related to critical risks, ASN considers that accident prevention must be a major work focus in 2024. Alongside this, while ASN's inspections found improvements in the management of the chemical risk, ASN is still waiting for the site to take strong measures in prevention of the electrical risk, in view of the inspections it carried out on this subject in 2023.

DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT

The Dampierre-en-Burly NPP is situated on the right bank of the Loire river, in the Loiret *département*, about 10 km downstream of the town of Gien and 45 km upstream of Orléans. It comprises four 900 MWe nuclear reactors which were commissioned in 1980 and 1981. Reactors 1 and 2 constitute BNI 84, and reactors 3 and 4 BNI 85. The site accommodates one of the regional bases of the Nuclear Rapid Intervention Force (FARN), the special emergency response force created by EDF in 2011 following the Fukushima Daiichi NPP accident (Japan). Its role is to intervene in pre-accident or accident situations, on any NPP in France, by providing additional human resources and emergency equipment.

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

With regard to nuclear safety, the site implemented a plan of rigour following the significant deterioration in operational management performance observed in 2022. Several measures aiming to improve the rigour of the service responsible for operational management, particularly as regards the General Operating Rules (RGEs), were thus applied during 2023. Although management of the periodic tests, which was very poor in 2022, has improved, ASN considers that the plan of rigour is not yet fully effective given that it has not led to a significant improvement in the safety results. In effect, the number of significant events reported during the year was among the highest of the EDF reactor fleet, with causes similar to those observed in 2022 (organisational deficiencies linked to the shortcomings in the documentation and in communication between the operational management teams, inadequate knowledge of the RGEs). ASN will conduct an in-depth inspection in June 2024 in order to carry out a detailed appraisal of the site's safety performance.

With regard to maintenance of the facilities, the site's performance has improved and is now in line with the national average, in a high workload context due to the fourth ten-yearly outages of reactors 2 and 3. The site must nevertheless be particularly attentive to the maintenance of the backup diesel generator sets and the safety injection system, which are subject to regular equipment failures.

Radiation protection performance, a recurrent weakness at the Dampierre-en-Burly NPP, improved in 2023 and is now in line with the national average. Although the site has one of EDF's lowest rates of worker contamination, progress must still be made in the management of the radiological work regimes, in the performance of the radiological checks of equipment leaving controlled areas (numerous hot spots were detected in 2023 on the site's roadways) and in the management of the marking out of limited-stay areas. ASN will keep a close track on these points in 2024.

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 Fresh Fuel Warehouse (MIR);
- **small-scale nuclear activities in the medical sector:** Chapter 7 p. 204
  - 8 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 11 nuclear medicine departments,
  - 32 centres using 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:** Chapter 8 p. 240
  - 10 industrial radiography companies,
  - about 330 industrial, veterinary and research radiography devices;
- **activities associated with the transport of radioactive substances;** Chapter 9 p. 270
- **ASN-approved laboratories and organisations:**
  - 2 organisations approved for radiation protection controls,
  - 4 laboratories approved for taking environmental radioactivity measurements.

The environmental protection performance of the Dampierre-en-Burly NPP significantly improved in 2023, particularly in the management of the microbiological risk and the discharges of copper and zinc in the liquid effluents. The site must nevertheless continue its work to improve the containment of hazardous substances and undertake the necessary studies to increase the number of effluent storage tanks to take into account the effects of climate change and the problems of ageing of the existing tanks.

The year 2023 saw significant labour inspection demands in the social field due to an apparently deteriorated social dialogue between management and the personnel representative bodies, in view of the safety alerts filed by members of the NPPs social and economic committee.

ASN also notes the persistence of significant deviations in the area of electrical risks, particularly concerning the performance of the regulatory verifications and taking any measures found necessary when these verifications are carried out. Lastly, concerning the EXplosive ATmospheres (ATEX) risk, ASN considers that the correction of the identified anomalies must be improved, as the scheduling of their correction is not always effective.

Chinon site

Situated in the municipality of Avoine in the Indre-et-Loire *département*, on the left bank of the river Loire, the Chinon site accommodates various nuclear installations, some in operation, others undergoing decommissioning. On the south side of the site, the Chinon B NPP comprises four in-service reactors of 900 MWe; the first two commissioned in 1982 and 1983 constitute BNI 107, while the second two commissioned in 1986 and 1987 constitute BNI 132. To the north, the three old graphite-moderated GCRs designated Chinon A1, A2 and A3, are currently being decommissioned. The site also accommodates the Irradiated Materials Facility (AMI), currently being decommissioned, whose former expert assessment activities have been entirely transferred to a new laboratory called the "Lidec" and to Inter-Regional Fresh Fuel Warehouse (MIR).

CHINON NUCLEAR POWER PLANT

Reactors B1, B2, B3 and B4 in operation

ASN considers that the performance of the Chinon NPP stands out positively with regard to safety and is in line with the general assessment of EDF in the areas of radiation protection and the environment. The progress noted in 2022 in the area of safety was consolidated in 2023.

With regard to safety, ASN observes that operational management performance has remained satisfactory in a particularly busy industrial context, with periods of simultaneous outages of several reactors. A number of events nevertheless revealed a lack of rigour on the part of the workers or in the organisation and distribution of roles within the operational management teams. These situations rapidly led to corrective actions, the effectiveness of which must be monitored over time.

As far as maintenance of the installations is concerned, the site's performance remains satisfactory. A few areas for improvement emerge nevertheless, notably in activity preparation and worker monitoring. The year 2023 was marked by the fourth ten-yearly outage of reactor 1, during which substantial maintenance operations were carried out, including the replacement of two sections of the primary cooling system.

ASN considers that the radiation protection performance of the Chinon NPP remains in line with the average for the EDF plants. Nevertheless, the performance is variable, with a worker contamination level that is among the lowest of EDF, but persistent shortcomings in industrial radiography work. ASN considers that the areas for progress identified for 2023 concerning industrial radiography work and effective application of the chosen prevention measures with regard to radiation protection and radiological work regimes remain applicable for 2024.

The environmental protection performance of the Chinon NPP is stable. ASN considers that the NPP manages its discharges and the containment of hazardous liquid substances proficiently. However, the management of waste, and waste removal in particular, must be improved. 2024 must be used to eliminate the waste resulting from reactor maintenance which has been accumulating on the site for several years.

With regard to labour inspections and in view of the inspections conducted in 2023, ASN considers that the Chinon NPP must take better account of the electrical and ATEX risks, whether in the exhaustiveness of the checks or the correction of the anomalies detected. Furthermore, although the absence of any serious accidents is to be underlined, ASN considers that the site must make further progress in accident prevention, particularly in the activity preparation phase. Lastly, the site's responsiveness regarding its exchanges with the labour inspectors is to be underlined.

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" GCRs. 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 involves decommissioning "in air"[1] and the Chinon A2 reactor pressure vessel would be decommissioned first (see chapter 14). In this context, ASN has analysed the periodic safety review concluding reports submitted by EDF concerning the six GCRs, supplemented

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

further to the request from ASN. On completion of its analysis, ASN indicated in December 2021 that it has no objection to the continued operation of BNIs 133 (Chinon A1 reactor), 153 (Chinon A2 reactor) and 161 (Chinon A3 reactor). It will verify during the examination of the decommissioning files for these reactors, submitted by EDF at the end of 2022 and still being examined, that the decommissioning operations will be carried out under suitable conditions of safety and radiation protection, within controlled time frames.

For the Chinon A2 reactor, 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. The shells of two of the four heat exchanger premises have been removed. EDF also continued the decommissioning of the Chinon A3 heat exchangers. After completing the decommissioning work in the South heat exchangers room in 2022, the decommissioning work in the North heat exchangers room, which started in June 2022, was completed in 2023. All the cylinders have been transferred to the Cires facility (Industrial centre for collection, storage and disposal).

The storms of June and September 2023 led to the infiltration of several hundred cubic metres of water into the premises adjacent to the Chinon A1 turbine building and into various premises of Chinon A3. ASN conducted an inspection on this subject, which concluded on the importance of implementing preventive and corrective actions to remedy this situation (pumping the water, conducting surveillance rounds after storms, waterproofing work on walls and slabs, repair and/or tilting of the storm water downpipes).

ASN considers that the level of safety of the Chinon nuclear installations undergoing decommissioning (Chinon A1, A2 and A3) is satisfactory. The inspections carried out in 2023 highlighted in particular the quality of the inventory of waste with no disposal route which is currently being drawn up, the good preparation of the various decommissioning work sites and the work carried out on the identification of the causes and the immediate corrective measures further to the water infiltrations. However, the notification of four significant events relating to radiation protection must be noted, particularly concerning entries into controlled areas without wearing an active dosimeter.

The actions implemented and checked during inspections are expected to limit the recurrence of such deviations. Improvements are expected in subcontractor tracking and monitoring, whether in radiation protection or the monitoring of work sites or in the depth of the analyses of important radiation protection events.

"NUCLEAR FUEL CYCLE" FACILITIES

Inter-regional fresh fuel warehouse

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

The facility 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 2023, ASN found that the level of safety could be improved, despite the good upkeep of the premises. Indeed, ASN considers that the MIR management teams need to improve the assimilation of the documentation system and associated baseline requirements.

RESEARCH FACILITIES UNDERGOING DECOMMISSIONING

Irradiated materials facility

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

The expert assessment activities were 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 requires inerting operations[2] in order to meet the disposal criteria of the French Radioactive Waste Management Agency (Andra). As the characterisation results differed from what was expected, the necessary waiver was obtained from Andra in late 2022, thereby allowing the waste to be accepted. A work school was set up in early 2023.

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

The inerting and removal of magnesian waste should resume in 2024. ASN granted a decommissioning authorisation for the highly active liquid effluent systems in August 2023. Given that EDF reported technical and contractual difficulties as of April 2022, these operations – which were initially planned as of 2023 – have been rescheduled for 2024. The treatment of the legacy chemical products present in controlled areas continued and the transfer of this nuclear waste to facilities that can accept them has begun. Lastly, the year 2023 was marked by the resuming of "Thermip" pollution monitoring (non-radiological pollution by hydrocarbons and naphthalene), for which the management plan must be supplemented by technical elements expected in 2024.

Through the checks made during its inspections, ASN considers that the safety management applied at the AMI is satisfactory. The work sites inspected are well kept and suitably monitored. The monitoring of discharges and the environment is well managed, as is equipment qualification, examined by random checks. The alpha emitter contamination risk indicators are correctly tracked. Particular attention must nevertheless be paid to the monitoring of the buildings and the water infiltrations in the basement acting as a retention area. An improvement in the depth of analysis of important radiation protection events is also expected.

Saint-Laurent-des-Eaux site

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

SAINT-LAURENT-DES-EAUX NUCLEAR POWER PLANT

Reactors B1 and B2 in operation

ASN considers that the safety performance is in line with the general assessment of the EDF plants, and has improved compared with 2022. The radiation protection performance, however, is below the national average. The environmental performance is satisfactory and stands out favourably compared with the general assessment of the EDF plants.

ASN considers that the site's nuclear safety performance improved in 2023. There is still room for progress, however, in operational management, particularly regarding monitoring in the control room. Lastly, ASN considers that the site's fire risk management has significantly regressed, with numerous shortcomings detected during the inspections carried out in 2023, particularly in the management of fire loads, in fire sectorisation and the management of hot work permits. ASN will monitor this subject particularly closely in 2024, in order to check the progress of the action plan deployed by the site.

The maintenance performance of the Saint-Laurent-des-Eaux NPP remains at a level deemed relatively satisfactory. The year 2023 saw a significant increase in maintenance activities, notably with the fourth ten-yearly outage of reactor 2. Few significant events are caused by maintenance deficiencies, even if ASN expects improvements to be made in activity preparation and monitoring.

The radiation protection performance of the Saint-Laurent-des-Eaux NPP deteriorated in 2023. Work site preparation and the monitoring of radiological cleanliness must be improved.

The organisation of the site to meet the regulatory requirements in the area of environmental protection is considered satisfactory. ASN underlines the site's commitment in the performance and analysis of situational exercises on the theme of environmental protection, whether organised internally or carried out without prior notice at the request of ASN. Management of the storage of non-radiological hazardous substances however must be improved, and will be closely watched by ASN in 2024.

ASN notes a deterioration in occupational safety at the Saint-Laurent-des-Eaux NPP in 2023, particularly regarding outside contractor accident levels. Progress has been observed in prevention of the electrical risk. The site must nevertheless further improve its management of the ATEX risk.

Reactors A1 and A2 undergoing decommissioning

The former Saint-Laurent-des-Eaux NPP constitutes a BNI comprising two "integrated" GCRs, 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 GCRs, 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 will be carried out under suitable conditions of safety and radiation protection, within controlled time frames.

ASN has finalised the examination of the management plan for the soils polluted with hydrocarbons in the zone of the old transformers of the Saint-Laurent A2 reactor and has authorised EDF to proceed with the soil clean-up operations by a resolution of 10 February 2023.

EDF continued the decommissioning work sites in 2023, particularly the decommissioning work outside the reactor pressure vessel (Saint-Laurent A2). ASN considers that the level of safety of the Saint-Laurent-des-Eaux A reactors is satisfactory. During its inspections, ASN noted 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. Waste management, however, must be more rigorous, even if no significant deviations were discovered.

The decommissioning work was suspended in July 2023 following the discovery of lead in the dust on the worksites concerned. ASN conducted specific actions on this subject as part of its labour inspection duty. Nevertheless, even though the worksite demobilisation operations were carried out satisfactorily, ASN considers that the monitoring of outside contractors must be improved and that the traceability of decisions concerning certain modifications in the scheduling of the decommissioning operations and the associated impact studies must be reviewed.

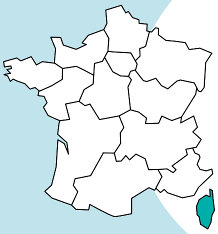
SAINT-LAURENT-DES-EAUX SILOS

The facility, authorised by the Decree of 14 June 1971, consists of two silos whose purpose is the storage of 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.



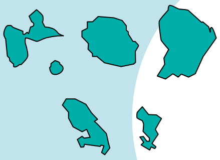
Corse (Corsica)
COLLECTIVITY

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

In 2023, ASN carried out five inspections in the Corse collectivity, four in the medical sector and one in the industrial sector.

The installations and activities to regulate comprise:

- **small-scale nuclear activities in the medical sector:** Chapter 7 p. 204
  - 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:** Chapter 8 p. 240
  - 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;** Chapter 9 p. 270
- **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 2023, 14 inspections were carried out in the small-scale nuclear activities sector in the French Overseas *départements*, regions and collectivities. Three on-site inspection campaigns were carried out by ASN.

One significant event in small-scale nuclear activities was rated level 1 on the International Nuclear and Radiological Event Scale (INES scale).

The installations and activities to regulate comprise:

- **small-scale nuclear activities in the medical sector:**
  - 4 external-beam radiotherapy departments,
  - 1 brachytherapy department,
  - 4 nuclear medicine departments,
  - 23 centres performing fluoroscopy-guided interventional procedures,
  - about 30 centres holding at least 1 computed tomography scanner,
  - more than 50 medical radiology practices;

Chapter 7 p. 204

- **small-scale nuclear activities in the industrial, veterinary and research sectors:**
  - 3 industrial radiology companies using gamma radiography devices,
  - 1 cyclotron;

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

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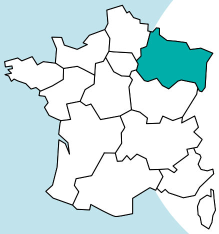


Grand Est
REGION

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 2023, ASN conducted 180 inspections in the Grand Est region, of which 63 were in the Nuclear Power Plants (NPPs) in service, 12 in radioactive waste disposal facilities and on the sites of the Fessenheim and Chooz A NPPs currently being decommissioned, 93 in small-scale nuclear activities, eight in the transport of radioactive substances and four concerning approved organisations or approved laboratories.

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

During 2023, 11 significant events reported by nuclear installation licensees in the Grand Est region were rated level 1 on the International Nuclear and Radiological Events Scale (INES scale), and one significant event was rated level 2.

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

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

CATTENOM NUCLEAR POWER PLANT

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

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

ASN considers that the performance of the Cattenom NPP with regard to nuclear safety and environmental protection is in line with ASN's general assessment of the EDF plants. The radiation protection performance of the Cattenom NPP is considered to be below the average for the fleet. The year 2023, like 2022, was a rather particular year given the long outages to address the problem of stress corrosion in the safety injection systems.

With regard to operation and reactor operational management, ASN considers that the performance remains satisfactory, as in the preceding years. The level of skills management and reactivity control is considered to be very good. However, weaknesses were noted in system configuration management and the associated padlocking operations, and in monitoring in the control room.

With regard to maintenance, 2023 was marked by relatively long and often concomitant reactor outages. ASN notes positively the monitoring of the maintenance activities, particularly in relation with the stress corrosion issue, along with the sound proper management of the unscheduled interventions carried out during the outages. Nonetheless, a few maintenance non-qualities were noted and some events call into question the adequacy of the post-maintenance tests conducted on certain items of equipment, which do not detect all the operating faults.

The area of fire risk prevention, in which weaknesses have been noted for several years, is addressed by specific measures on the site, but which are nevertheless not preventing new deviations, particularly relative to interim storage management.

The site made progress in environmental protection in 2023, with a reduction in the number of events relating to this subject. Weaknesses nevertheless persist in liquid pollution containment and in the monitoring of specific installations, particularly the oil separators, which caused a hydrocarbon spillage in 2022. Refrigerant emissions and the consumption of biocides are still high, generating large discharges. On the other hand, despite a hot and dry summer, the low water level of the Moselle river was well managed and had no impact on the site.

With regard to radiation protection, ASN considers that the site is below average, particularly in the control of contamination and industrial radiography work. Improvements were nevertheless noted in the access to limited stay areas and prohibited areas in 2023, and in radiation protection as a whole over the second half of 2023, showing that the site is well aware of its weaknesses.

Lastly, with regard to safety at work, ASN notes positively the efforts made in terms of conformity and awareness-raising, particularly regarding working time and work on Sundays, even though further progress is still expected.

CHOOZ NUCLEAR POWER PLANT

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

Reactors B1 and B2 in operation

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

ASN considers that the safety of operation of the facilities is satisfactory. Particular attention must nevertheless be paid to ensuring strict compliance with the reactor operational management documents and the checking of the activities carried out, as these two points have caused significant events.

With regard to maintenance, ASN underlines the satisfactory management of the activities, which represented a lower work load than in the preceding years, given the restarting of the reactors after the repair of the pipes displaying stress corrosion cracking.

With regard to occupational radiation protection, although the number of significant events remains low, ASN detected several weaknesses in the course of the year. They concern the monitoring of outside contractors, rigour in the implementation and monitoring of radiological protections, and the management of inspections involving industrial radiography. Furthermore, shortcomings in control of radiological cleanliness resulted in the contamination of several rooms. ASN noted the implementation of immediate corrective actions, but nevertheless urges the licensee to maintain its vigilance in view of the activities scheduled in 2024.

ASN considers that the site's environmental protection organisation is satisfactory, as in the preceding year. The licensee has in particular demonstrated a robust organisation for identifying, analysing and monitoring the few deviation situations encountered in 2023, notably in the areas of liquid pollution containment and control of discharges.

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

Reactor A undergoing decommissioning

The work undertaken in 2023 was chiefly devoted to the treatment of contamination and removal of the waste present at the bottom of the reactor building pool, and the cleaning of the walls of said pool. Renovation work on the polar crane also began at the end of 2023. These activities are prerequisites for the reactor vessel lifting operations, scheduled as of 2024, followed by the vessel cutting up operations. The decommissioning work on the effluent treatment station equipment moreover continued.

With regard to radiation protection, the inspection conducted in 2023 confirmed that the measures taken over the last few years to control the radiological cleanliness of the facilities and to protect the workers continue to improve the level of radiation protection on the site.

Lastly, in December 2022 and July 2023 EDF submitted to ASN for approval the clean-up methodology files for the facility's civil engineering structures in order to achieve the "final decommissioning state" required by the Decree of 27 September 2007. These files are currently being examined by ASN.

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 Soulaines-Dhuys in the Aube *département*;
- **the *Cigéo* geological disposal project for long-lived high- and intermediate-level radioactive waste (HL/ILW-LL);**
- **small-scale nuclear activities in the medical sector:** Chapter 7 p. 204
  - 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:** Chapter 8 p. 240
  - about 280 industrial and veterinary activities coming under the licensing system,
  - 24 companies exercising an industrial radiography activity,
  - about 50 research laboratories situated primarily in the universities of the region;
- **activities associated with the transport of radioactive substances.** Chapter 9 p. 270

FESSENHEIM NUCLEAR POWER PLANT

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

ASN considers that the site is continuing to operate the facilities and prepare for decommissioning conscientiously, particularly by adhering closely to the decommissioning preparation work schedule.

In 2023, the site underwent a profound organisational change, with its transfer within EDF from the "Nuclear Power Production" Division to the "Dismantling Wastes Projects" Division. This organisational change came with a substantial reduction in the workforce, matching the change in the activities on the site. ASN considers that the change was well managed, preparing optimally for the organisational transition.

The decommissioning preparation work also continued, in particular with the decontamination of the primary system of reactor 2, marked by a number of unforeseen events; preparation for the transportation of the lower sections of the site's old steam generators for their future decontamination and recycling by a fusion process in the Cyclife facilities in Sweden; transformation of the turbine hall into a waste management and storage zone; continuation of the treatment and removal of boron and activated operational waste. ASN considers that, apart from the unforeseen events observed during the decontamination operation, these various activities were carried out as expected.

With regard to radiation protection, the site's performance is considered to be broadly satisfactory, particularly in the context of the decontamination operation. As for safety at work, the change in the types of activities and workers must be examined in order to guarantee that the protective measures are appropriate.

NOGENT-SUR-SEINE NUCLEAR POWER PLANT

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

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

With regard to nuclear safety, ASN considers that the results are satisfactory on the whole, except in the management of equipment padlocking operations and of conformity deviations, areas in which progress must be made. The licensee must also continue its efforts to maintain an adequately sized workforce and skills in the areas of operational management and maintenance of the reactors.

The maintenance operations during the outages of the two reactors went satisfactorily on the whole.

As far as occupational radiation protection is concerned, ASN observes that the management of worksite radiological cleanliness and the number of worker internal exposures remain satisfactory. 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 inspection of radiation protection equipment, which showed some weaknesses in 2023.

With regard to protection of the environment, ASN considers that the licensee's organisation is satisfactory. Nevertheless, improvements are expected in the integration of Operating Experience Feedback (OEF) from certain maintenance operations and in the management of discharges and the containment of liquid pollutions.

Inspections by the labour inspectors confirmed the restoring of conformity of certain working equipment items, such as lighting and lifting equipment, further to the action plan initiated in 2022.

AUBE WASTE DISPOSAL FACILITY

Authorised by a Decree of 4 September 1989 and commissioned in January 1992, the Aube repository (CSA) took over from the Manche repository (CSM) which ceased its activities in July 1994, while benefiting from the OEF gained from the latter. This facility, located in Soulaines-Dhuys, has a disposal capacity of one million cubic metres (m^3) 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^3 volume, or by compacting 200-litre drums.

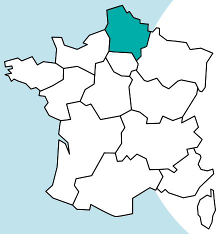
At the end of 2023, the volume of waste in the facility had reached about 378,500 m^3, or 38% of the authorised capacity. According to the estimates made by the French Radioactive Waste Management Agency (Andra), in 2016 in the concluding report on the periodic safety review of the CSA, the repository could be completely filled by 2062 rather than 2042 as initially forecast. This can be explained by having better knowledge of the future wastes and their delivery time frames, as well as by an optimisation of waste management through the compacting of certain packages.

ASN considers that the CSA is operated satisfactorily in the areas of safety, radiation protection and the environment. The inspections conducted in 2023 found that the organisation for monitoring discharges into the environment and tracking and inspecting the civil engineering operations was appropriate, and more broadly that safety management was satisfactory.

DEEP GEOLOGICAL DISPOSAL PROJECT

ASN considers that the scientific experiments and work conducted by Andra in the underground laboratory at Bure continued in 2023 with a good standard of quality, comparable with that of the preceding years.

Andra filed the Creation Authorisation Application for the *Cigéo* project with the Minister responsible for nuclear safety on 16 January 2023. ASN considered it admissible and has started the examination process (see chapter 15).



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 2023, ASN carried out 94 inspections in the Hauts-de-France region, of which 37 were in the Gravelines Nuclear Power Plant (NPP), 50 in small-scale nuclear activities and 7 in the transport of radioactive substances.

ASN also carried out 18.5 days of labour inspection in the Gravelines NPP.

During 2023, the Gravelines NPP notified ASN of four significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale).

In small-scale nuclear activities, two events were rated level 1 on the INES scale. In radiotherapy, two 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 Pressurised Water Reactors (PWRs) – each of 900 Megawatts electric (MWe) – representing a total power of 5,400 MWe. Reactors 1 and 2 constitute Basic Nuclear Installation (BNI) 96, reactors 3 and 4 BNI 97, and reactors 5 and 6 BNI 122.

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

The nuclear safety performance improved slightly in 2023, particularly as regards the NPP's operational management activities. The "plan of rigour" deployed by the licensee has renewed the emphasis on presence on the ground, refocused attention on the fundamentals and enabled the actions to be adapted according to the services. Despite the measures in place, ASN has again noted a number of inappropriate practices or behaviours, particularly failure to comply with procedures. The licensee must therefore continue its efforts to federate all the protagonists. At the end of the third quarter of 2023, ASN conducted an interim assessment of the measures implemented by the licensee through an inspection focusing on organisational and human factors and deployment of the plan of rigour. ASN's inspection found the management of the plan to be satisfactory and results to be improving on the whole.

The year 2023 saw fewer significant events notified to ASN than in 2022, but still above the average for the preceding years and the national average for the EDF reactors. The number of events rated level 1 on the INES scale dropped substantially. These drops constitute an improvement which must be maintained over time to confirm a real improvement in the site's performance.

With regard to maintenance, 2023 was again marked by the substantial extensions in the reactor outage durations, largely due to social movements which disrupted the first outage of the 2023 campaign. At least three reactors were in outage at the same time, from mid-June to early November, 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, including the fourth ten-yearly outage of reactor 2, work on the peripheral protection against external flooding and the creation of ultimate water makeups further to the lessons learned from the Fukushima Daiichi NPP accident in Japan. This situation led in particular to inadequately prepared maintenance activities. ASN thus observed maintenance non-qualities and work postponements due more specifically to the unavailability of spare parts.

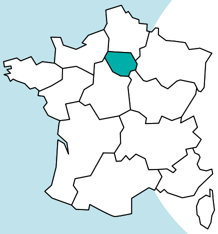
In the area of environmental protection, ASN conducted a tightened inspection of the site relating to the implications of continued operation beyond the fourth ten-yearly outages. ASN considers that the organisation and performance of the Gravelines NPP are broadly satisfactory, even if a number of deviations must be corrected, such as alerting the site personnel in the event of toxic gas emissions and the conservation of effluent samples. The efforts made over the last few years brought an improvement in the management of equipment using SF_6 (a powerful greenhouse gas) in 2023.

ASN notes some progress in occupational radiation protection. The licensee has taken into account the difficulties encountered in the previous years and the measures deployed are starting to show results that can be measured in the field. The number of significant events is slightly down compared with the preceding period and no level-1 events were reported, although the activity programme remained identical. This assessment nevertheless remains contrasted due to persistent shortcomings, notably in the application of the optimisation approach in work preparation and the coordination of radiation protection measures with outside contractors. ASN also observes an increase in deviations linked to deficiencies in the radiation protection culture or rigour of the workers, particularly regarding the conditions of access to controlled areas and taking regulatory zoning into account.

The labour inspection actions carried out in 2023 were divided between inspections on facility maintenance and modification worksites, performed jointly with the nuclear safety inspections, and theme-based inspections on lifting or the prevention of risks associated with the work carried out by outside contractors. ASN notes positively the site's prevention actions regarding safety further to the poor results of previous years, even though the number of workplace accidents remains high. Deviations were observed in the regulatory verifications of equipment used for lifting operations, some of which have been the cause of incidents. Improvements are also expected in the coordination of the prevention of risks associated with concomitant activities on the site.

The installations and activities to regulate comprise:

- **one Basic Nuclear Installation:**
  - the Gravelines NPP (6 reactors of 900 MWe) operated by EDF;
- **small-scale nuclear activities in the medical sector:** Chapter 7 p. 204
  - 19 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 30 nuclear medicine departments,
  - 90 centres performing fluoroscopy-guided interventional procedures,
  - 123 computed tomography scanners,
  - some 4,600 medical and dental radiology devices;
- **small-scale nuclear activities in the industrial, veterinary and research sectors:** Chapter 8 p. 240
  - about 600 industrial and research establishments, including 23 companies exercising an industrial radiography activity, 6 particle accelerators, including one for inspecting freight trains and 2 cyclotrons, 40 laboratories situated mainly in the universities of the region and 11 companies using gamma ray densitometers,
  - 340 veterinary surgeries or clinics practising diagnosticradiology;
- **activities associated with the transport of radioactive substances;** Chapter 9 p. 270
- **ASN-approved laboratories and organisations:**
  - 2 agencies approved for radiation protection controls.



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 244 inspections in the Île-de-France region in 2023, of which 90 were in the field of nuclear safety, 132 in small-scale nuclear activities (two of this in the area of polluted sites and soils), 12 in Radioactive Substance Transport (TSR) and ten concerning approved organisations or laboratories.

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

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

CEA Saclay site

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

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

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

THE INDUSTRIAL AND RESEARCH FACILITIES

Osiris and Isis reactors

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

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

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

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 2021.

ASN considers that the level of safety of BNI 40 is satisfactory, particularly with regard to control of the fire risk and the equipment modifications. Improvements are expected however in the management of the fire load in the premises and the implementation of the periodic inspections and tests of certain items of equipment involved in the control of fire propagation. The organisation in place for tracking the decommissioning preparation operations is appropriate. The licensee's control of the decommissioning preparation operations, the management of waste and the continuation of the studies aiming to reduce the water consumption of the facilities shall be among the themes to which ASN will be attentive in 2024.

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 were discussed following the CEA's re-prioritising of the decommissioning operations and its consequences on the updating of the decommissioning strategy of BNI 101. A new decommissioning file was submitted at the end of 2023.

Based on the facility inspections and monitoring carried out in 2023, ASN considers that the level of safety of the Orphée reactor is on the whole satisfactory. However, vigilance is required with regard to organisational and human factors and document updating, particularly on the fire theme. The significant events show that greater attention must be paid to waste monitoring and the maintenance of leak detection equipment.

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.

The installations and activities to regulate comprise:

- **Basic Nuclear Installations regulated by the Orléans division:**
  - the CEA Saclay site of the CEA Paris-Saclay centre,
  - the UPRA (Artificial Radionuclide Production Plant) operated by CIS bio international in Saclay,
  - the CEA Fontenay-aux-Roses site of the CEA Paris-Saclay centre;
- **small-scale nuclear activities in the medical sector regulated by the Paris division:** Chapter 7 p. 204
  - 26 external-beam radiotherapy departments,
  - 12 brachytherapy departments,
  - 48 *in-vivo* nuclear medicine departments and 12 *in-vitro* nuclear medicine departments (medical biology),
  - 148 centres practising fluoroscopy-guided interventional procedures,
  - more than 200 centres possessing at least 1 computed tomography scanner;
- **small-scale nuclear activities in the industrial, veterinary and research sectors under the oversight of the Paris division:** Chapter 8 p. 240
  - 8 industrial radiology companies using gamma radiography devices,
  - about 160 authorisations and 25 registrations relative to research activities;
- **activities associated with the transport of radioactive substances;** Chapter 9 p. 270
- **ASN-approved laboratories and organisations:**
  - 3 organisations approved for radiation protection controls.

Spent fuel testing laboratory

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

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

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

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

Since the end of 2022, BNI 72 no longer accepts irradiating waste from the CEA Saclay site. Consequently, the CEA has started a new project baptised "GDILE", a French acronym for "Management of irradiated waste from LECI", in order to process, package and remove the irradiating waste (existing and future) without saturating the storage capacities of LECI.

An exercise involving deployment of the Off-Site Emergency Plan (PPI) was carried out in 2023 on the site of the CEA Paris-Saclay centre (see paragraph entitled "Assessment of the CEA Paris-Saclay centre, Saclay site"). This exercise, which simulated an accident situation within the LECI facilities, served to test the deployment of the CEA's means of response and of the departmental fire and rescue service within the BNI perimeter.

The inspections conducted on LECI during 2023 were considered satisfactory, even if the manufacturers' recommendations must be better taken into account in the qualification of new equipment. Moreover, ASN still observes an increase in the times taken to reply to the inspection follow-up letters and to send in significant event reports. The CEA must take the necessary measures to remedy this situation without delay.

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 hazards (snow and wind in particular), 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 monitored. Nevertheless, particular attention must be paid to the revision of the frequencies of some of these inspections relating to radiation protection, and to the management of deviations. With regard to the management of radioactive sources, the licensee has improved the current check of sources aged more than ten years, for which an extension of the Poséidon irradiator service life has been requested, with the setting up of a system for checking sealing by immersion.

SOLID WASTE AND LIQUID EFFLUENT TREATMENT FACILITIES

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

Solid radioactive waste management zone

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

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

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.

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*. This Decree came into effect on 26 July 2023, the date on which ASN approved the revision of the general operating rules.

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.

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 with approval the removal of ten fuel cans out of the fifteen present in the pool of a building, which contributes to the gradual reduction of its dispersible inventory.

In 2023, ASN examined the organisation put in place by the facility for the management of deviations, monitoring of the ageing of the pits and the progress in the operations concerning the removal of fuel from the pool and rods of uranium oxide pellets contained in a package called "RCC". Delays are still observed in the removal of the cans contained in the RCC packaging and in the deployment of the "Removal of fuel bins" project (EPOC[2]).

The EPOC project was stopped following the breach of the project management contract. ASN notes with approval the measures taken by the CEA with the aim of taking over the management of this project. Furthermore, the opening of a pit in November 2023 to conduct non-invasive investigations was carried out satisfactorily. These operations help to consolidate the project input data. ASN nevertheless remains vigilant regarding CEA's management of the EPOC project and will monitor the recovery work on the first drum, for which the time frame remains to be consolidated by the licensee.

Alongside this, ASN's inspections find the facility to be in good overall condition. ASN nevertheless expects improvements in the tracking of the deviations observed when monitoring the condition of the waste storage pits, and in the tracking and observance of the frequency of periodic inspections and tests.

Liquid effluents management zone

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

The evaporation facility used to treat the radioactive effluents has been out of service since 2019 due to technical anomalies on an equipment item. At present the facility is no longer capable of fulfilling its functions (evaporation of effluents, encapsulation of concentrates in cement, collection of effluents from the Saclay effluent producers).

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's decision was made 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.

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. In 2023, ASN authorised a modification concerning the separator shell, enabling the evaporation campaigns to be restarted.

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 2023 revealed a satisfactory organisational set-up and tools for keeping track of the commitments made to ASN and for managing deviations. During the inspections, the inspectors found the facility and the premises to be in good overall condition and the teams to be duly responsive. Furthermore, the emptying of the pit 99 tank has been started with the tests in inactive and active mode and must be continued. Lastly, the licensee has undertaken to restore the conformity of the facility's piezometers.

Improvements are expected however, particularly regarding the finalisation of the fire-related action plan resulting from the safety review of 2017 and the management of the atmospheric effluents (iodine traps, emission measurements and flow rate). 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 underway on the Saclay site concern two BNIs (BNIs 49 and 72). Decommissioning preparation operations are carried out in two definitively shut down BNIs (BNIs 40 and 101). Operations are also being carried out on parts of the in-service BNI 35 which have ceased their activity. Two Installations Classified for Protection of the Environment (ICPEs – EL2 and EL3) previously classified as BNIs but which have not been completely decommissioned due to the lack of a disposal route for the low-level long-lived waste, are also concerned by decommissioning. Their downgrading from BNI to ICPE status in the 1980's, in compliance with the regulations of that time, could not be done today.

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

ASSESSMENT OF THE CEA SACLAY SITE

ASN considers that the CEA Saclay site BNIs are operated under suitably safe conditions on the whole, and observes that the operations to reduce the radiological inventory stored in the BNIs – which have been in progress for several years now – continued in 2023.

The decommissioning preparation operations and the decommissioning work are continuing for the BNIs concerned. Managing work progress and keeping to the associated schedules remain a major challenge for CEA Saclay. This area, which forms the subject of regular ASN inspections and meetings, must be improved, given the drifts observed over the years. ASN does however note the entry into application of the BNI 72 decommissioning decree in 2023 and the CEA's decision to internalise management of the EPOC project (project to recover drums stored in BNI 72 using equipment specially produced for the purpose) further to the defaulting of the initially selected contractor.

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. The failure to deploy the new premises, which was contrary to a requirement of ASN resolution 2016-DC-0537 or 12 January 2016, was noted during an inspection conducted in 2022. A contradictory report was therefore drawn up in early 2023 to which the CEA replied. After examining the reply and on account of the reduction in the nuclear risk of the Saclay site following the shutdown of BNIs 40 and 101, the requirement in question was repealed and a new technical requirement now regulates finalising of the construction of robust emergency situation management premises, which are expected to be commissioned by the end of 2024. An inspection was carried out in 2023 to check that the construction work had resumed.

With regard to the emergency organisation and resources, an update of the On-Site Emergency Plan (PUI) submitted by the CEA in late 2021 was discussed to clarify the chosen provisions. In May 2023, ASN authorised the modification of the PUI, retaining the provisions proposed by the CEA, with the exception of the new residual scenarios for BNIs 40 and 101, whose decommissioning files are currently being examined.

In 2023, an exercise involving activation of the large-scale PPI was carried out, simulating the accidental crash of an aircraft into the centre, causing a fire and dispersion of radionuclides into the environment. This exercise was intended to evaluate the collaboration between the security actors, their coordination in managing the victims and securing the site, and decision-making between CEA Saclay, the Prefecture's services, the CEA head office and the State authorities, including ASN. Areas for improvement in the CEA's emergency organisation and in the exchanges of information with the other emergency management actors were identified.

With regard to the environment, two ASN resolutions dating from 2009 and regulating all the discharges from the CEA's BNIs were updated. This update enabled the extremely low carbon-14 emissions induced by some of the waste stored in BNI 72 to be taken into account, and to regulate the additional discharges of carbon-14 resulting from forthcoming works necessary for the continuation of the BNI 49 decommissioning operations. These modifications do not change the total maximum value of the carbon-14 discharges set for the Saclay site as a whole, while at the same time regulating continuation of the decommissioning operations.

Lastly, ASN conducted several inspections on the Saclay site in 2023. One followed on from a significant event notified by BNI 50 and rated level 1, concerning the incorrect positioning of the emergency brakes on three lifting units. ASN thus conducted a specific inspection focusing on the maintenance of the lifting means and the monitoring of the associated outside contractors. This inspection confirmed the substantial work carried out by the CEA in bringing certain cranes into conformity following the discovery of asbestos in the linings and lagging, but it also revealed shortcomings in the application of the manufacturer's instruction manuals when performing maintenance work on the Saclay site's cranes. ASN will be attentive to the resolving of the deviations observed during this inspection. In addition, improvements were found in the monitoring of the Pressure Equipment (PE) and the electrical generator sets, even though further improvements are expected in each of the inspected BNIs on specific aspects observed during inspection. These improvements will be monitored on a case-by-case basis.

The year 2023 was also marked by the notification of one significant event for safety rated level 1 on the INES scale. This event was reclassified further to a repeat finding of bags of nuclear waste in a conventional waste production zone within BNI 101. At the same time, ASN underlines a reduction in significant event notifications in 2023 compared with the previous year.

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

High-Activity Laboratory (LHA)

The High-Activity Laboratory (LHA) comprises several laboratories intended for research work or the production of various radionuclides. It constitutes BNI 49. On completion of the decommissioning and clean-out work authorised by Decree of 18 September 2008, only two laboratories currently in operation should ultimately remain under the ICPE System. These two laboratories are the laboratory for the chemical and radiological characterisation of effluents and waste, and the packaging and storage facility for the retrieval of 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 2023 was marked primarily by the investigations and studies allowing the management of unidentified waste discovered in late 2022 in the set of structures constituting the TOTEM shielded process line after resuming the shielded process line decommissioning operations, which had been suspended since late 2018.

ASN considers that the level of safety of BNI 49 undergoing decommissioning is on the whole satisfactory. The inspections highlighted the good upkeep of the premises and the CEA's determination to move forward with finalising the decommissioning of the TOTEM shielded process line despite being behind schedule. Particular vigilance is expected in monitoring the condition of the ventilation ducts, particularly the internal sections which are inaccessible or display defective areas.

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

ARTIFICIAL RADIONUCLIDE PRODUCTION PLANT OF CIS BIO INTERNATIONAL

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

The Curium group is an important player on the French and international market for the production and development of radiopharmaceutical products. The products are mainly used for the purposes of medical diagnoses, but also for therapeutic uses. They are manufactured using a cyclotron installed on the site or using radionuclides produced by outside suppliers or other facilities of the Curium group. Until 2019, the role of BNI 29 was also to recover disused sealed sources which were used for radiotherapy and industrial irradiation. Removal of these sources, which 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 potential consequences of accident situations on the site.

After observing improvements in the safety of the facility between 2019 and 2021, the slowing of this trend observed in 2022 got worse in 2023, particularly in view of the notified significant events, be it in the number or the types of events. This observed deterioration in the general level of safety is moreover combined with substantial lateness in sending the replies to ASN follow-up letters or to significant event reports.

CIS bio international, which has been capable of mobilising its resources on new projects and large-scale actions associated with its operational services and radiopharmaceutical production, must today focus its efforts on the actions necessary to improve safety in general and the drafting of the justification documents expected by ASN. The company reorganisation initiated in late 2023 should allow the necessary means to be assigned to the departments in charge of these safety-related subjects. The inspections, including one carried out reactively following the notification of a significant event, found margins for improvement in the management of nuclear waste within the facility. Operational management of the facility's transport operations is efficient, but deviations in the documents are still observed, as they have been over several inspections now. With regard to the overshoots of the annual and monthly gaseous iodine discharge limits at the end of 2022 and beginning of 2023, which gave rise to significant event notifications, one of which was rated level 1, CIS bio international conducted an in-depth deviation analysis and established a detailed action plan which was checked by ASN during an inspection. This action plan was found to be appropriate. As a general rule and in particular further to the inspection conducted on the theme of "meeting commitments", ASN notes the difficulties CIS bio international has in meeting the deadlines associated with the action plans decided upon further to inspections or significant events.

Lastly, the inadequate responses provided after making priority corrective action requests concerning pressure equipment have led ASN to serve CIS bio international with a compliance notice on this subject. The compliance deadline has been set for 2024.

The number of significant events again shows a significant increase, with 22 notifications in 2023. As in the preceding year, human or organisational causes are predominant in these events, which concern diverse areas. Compliance with the operational management rules and the operating range, alarm management, maintenance operations and the integration of lessons learned remain the main areas for improvement. Some recurrence of nonconformities is observed in the effectiveness of the facility's ventilation system filtration levels. Certain events have led to production operations in degraded situations with the application of compensatory measures. The technical causes of these deviations must be determined and they must be prevented from recurring. Lastly, despite the considerably late submission of significant event reports, it is noted that they are always drafted to a high standard and this must be maintained.

With regard to the periodic safety review, the licensee has put in a lot of work to allow its examination. CIS bio international must continue to implement the associated action plans. Delays are nevertheless announced in the updating of the baseline requirements in order to take this examination into account. Particular efforts must be made on this file. A large number of projects, studies and works undertaken by CIS bio international were completed in 2023. In some cases, these projects help to improve the safety of the facility or to reduce the source term with the finalising of removal of disused high-activity sealed sources. Broadly speaking, the large-scale projects undertaken by CIS bio international require better scheduling so that they can be examined appropriately for the risks they represent as a whole.

To conclude, ASN observes a deterioration in CIS bio international's performance in 2023, despite the improvement process applied since 2019. Operating rigour, maintaining the safety culture and the oversight of operations remain the areas on which CIS bio international must focus its efforts. Particular attention must also be paid to the human and technical resources deployed on the themes of safety and radiation protection.

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 chapters 14 and 15).

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

PROCÉDÉ AND SUPPORT FACILITIES

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

ASN deemed that the first versions of these decommissioning decree modification application files were not admissible. In accordance with the commitments made in 2017, the CEA submitted the revised versions of these files in 2018. These files were supplemented over the 2019-2021 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. These two projects are currently being examined. The new decrees will set the future decommissioning characteristics, and notably their completion time frame.

ASSESSMENT OF THE CEA FONTENAY-AUX-ROSES SITE

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 2023, several positive points can be underlined, such as the management and monitoring of the PE present on the site, the installation of new aerosol sampling devices and the conditions of response of the local safety organisation on site in situational exercises. Nevertheless, the need to be particularly vigilant on the fire theme identified in 2022 was confirmed in 2023. Work has started on bringing the fire doors of a building in BNI 165 into conformity, on putting the fire extinguishing systems of the shielded process lines of that BNI back into service, and replacing the fire control panel. The efforts put into these projects and works must continue in 2024 to achieve the required level of safety.

An unannounced inspection confirmed that waste management still needs to be improved in both BNIs of the site. A change in the baseline requirements of these facilities is also required to allow methods of storage that are appropriate for the CEA's operating risks and constraints.

The licensee has made strong commitments regarding the implementation and scheduling of the corrective actions, including the creation of a role of scheduler. This project should allow the meeting of the CEA's commitments to be tracked more effectively.

With regard to the significant events notified in 2023, the number has increased with respect to the preceding years and they chiefly concern the fire theme, the storage of nuclear waste and the conditions of personnel access to areas presenting a radiological risk. Broadly speaking, the causes have to be analysed in greater depth and particular attention must be paid to the time frames for submitting the definitive significant event reports. Whatever the case, ASN notes that the CEA's significant event detection capability is satisfactory.

With regard to the periodic safety reviews of the facilities, the licensee has an organisational set-up that enables the associated actions to be implemented; in 2023, ASN signed the resolution setting the technical requirements stemming from the conclusions of the safety review of BNI 165. Examination of the periodic safety review of BNI 166 continued satisfactorily.

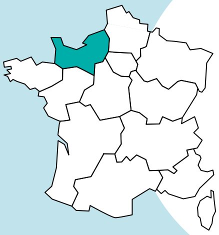
After delays identified in the preceding years in the performance of the studies, in project programming and in the decommissioning schedule of the nuclear installations of Fontenay-aux-Roses, two of the CEA's major decommissioning-related worksites were stopped for contractual and technical reasons in 2023. Resuming of these worksites will require changes in technical choices or modifications in certain aspects of the projects which could have an impact on the overall decommissioning strategy for BNI 166. The CEA must detail the expected consequences on the elements already transmitted. The CEA must 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.

The polluted sites and soils in Île-de-France

In Île-de-France, the Paris division oversees the depollution activities for polluted radiological sites, and can for example intervene to give technical opinions on site pollution management measures envisaged by the site owners (see chapter 15, part 4). In this context, it carried out two inspections in 2023 on the site of the old Fort of Vaujours and the site of a former Marie Curie laboratory in Arcueil (near Paris), and participated in the site monitoring commissions for these two sites.

By virtue of its expertise in these risks, the ASN Paris division also:

- **helped to define the measures to take to manage identified or potential cases of radiological pollution discovered in the operation of a gypsum quarry on the municipalities of Vaujours and Coubron;**
- **issued three opinions concerning the measures to manage the radiological pollution of three sites: the land of a private individual in the Essonne *département*, an industrial site in the Seine-et-Marne *département* and the Curie Institute in the 5th *arrondissement* of Paris;**
- **created and updated Soil hazard Information Sectors (SIS) concerning radiological pollutions;**
- **monitored the diagnostic studies of three polluted sites in the Seine-Saint-Denis *département* with a view to their clean-up.**



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 2023, ASN carried out 217 inspections in Normandie, comprising 68 in the Nuclear Power Plants (NPPs) of Flamanville, Paluel and Penly, 14 on the Flamanville 3 EPR reactor construction site, 69 on "fuel cycle" facilities, research facilities and facilities undergoing decommissioning, 46 in small-scale nuclear activities, 11 in the transport of radioactive substances and nine in ASN-approved organisations and laboratories.

In addition to this, 26 days of labour inspection were carried out on the NPP sites and the Flamanville 3 construction site.

In 2023, ASN was notified of 11 significant events rated level 1 on the International Nuclear and Radiological Event Scale (INES scale), of which ten occurred in Basic Nuclear Installations (BNIs) and one in small-scale nuclear activities.

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

FLAMANVILLE NUCLEAR POWER PLANT

Operated by EDF and situated in the Manche *département* in the municipality of Flamanville, 25 km south-west of Cherbourg, the Flamanville NPP comprises two Pressurised Water Reactors (PWRs), each of 1,300 Megawatts electric (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 observes that the measures taken by the site after being placed under tightened surveillance in 2019 are still being applied and form the subject of a satisfactory improvement process as regards keeping the facilities up to standard and the dissemination and application of the safety fundamentals by the EDF personnel and outside contractors.

With regard to reactor management and operation, ASN considers that the site's performance has been consolidated. The restarting of reactor 1 after replacing the Steam Generators (SGs) went well on the whole. The site coped satisfactorily with the various management operations required on the two reactors linked to equipment deficiencies. Nevertheless, the year 2023 was again marked by a large number of significant events linked to noncompliance with the baseline operating requirements. In 2024, ASN will remain vigilant regarding the improvement in the rigour of reactor operational management and the measures the site has undertaken to implement concerning system and equipment configuration management.

As a general rule, ASN considers that the licensee carried out the maintenance operations competently. ASN notes positively the durability and robustness of the site's action plan concerning the risk of equipment corrosion.

The licensee's system monitoring tools are of good quality and provide a faithful representation of the condition of the systems. ASN will be attentive to the licensee's coordination and monitoring of risky worksites in 2024, particularly during the two scheduled reactor outages.

The site's radiation protection performance improved slightly in 2023. ASN underlines that the identification and notification process for significant radiation protection events is effective. Improvements are nevertheless required in the management of waste zoning and the risk of contamination dispersion.

ASN observes a slight improvement in environmental protection. ASN underlines the observance of discharge limits and control of the conditions of storage and use of substances dangerous for the environment. However, the licensee must be particularly attentive to maintaining the mineralisation station and the oil filter in their present condition. With regard to on-site and off-site transport operations, despite the improvement in organisation observed during 2023, further progress is still to be made, particularly in the monitoring of subcontracted activities.

With regard to labour inspection, ASN considers that the licensee must be vigilant regarding the working conditions close to the new steam generators of reactor 1 and must anticipate the changes in space requirement for the future replacement of the reactor 2 steam generators. Improvements are also required in the content and depth of the analysis of workplace accidents and near-accidents to prevent their recurrence.

PALUEL NUCLEAR POWER PLANT

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

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

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

With regard to nuclear safety, ASN considers the performance of the NPP to be satisfactory. Progress is nevertheless required in system configuring in order to comply with the operating instructions and error-reduction practices. The year 2023 was marked by several situations of out-of-service equipment necessitating reactor shutdowns and reflecting a problem of reliability of these equipment items. Furthermore, following two inspections which found shortcomings in the functionality of the emergency equipment utilisation sequences, ASN wants to see significant improvements in the management of their deployment in emergency situations.

With regard to maintenance, ASN has noted that the three reactor outages for maintenance and refuelling went smoothly on the whole. ASN does however note that the site's organisation for characterising deviations when carrying out works is not sufficiently robust and must be improved. Incorrect or incorrectly applied operational documents are also the cause of inappropriate maintenance operations or maintenance quality deficiencies. The site must intensify its efforts to get the personnel to take on board the safety issues before starting work operations, and must improve work monitoring.

With regard to radiation protection, ASN notes good control of the radiological cleanliness of the facilities and of the upkeep of worksites with a dosimetric risk. ASN nevertheless considers that the site must continue the action undertaken to correct the recurrent problems of personnel failing to comply with procedures for accessing limited-stay (orange) areas and the lack of radiation protection culture.

As for environmental protection, ASN considers that the Paluel NPP has obtained satisfactory results in environmental monitoring and notes an improvement following the measures taken to reduce discharges of ozone-depleting gases. ASN has nevertheless noted shortcomings in waste management and the licensee must be particularly attentive to the management of on-site transport of hazardous materials.

The installations and activities to regulate comprise:

- **Basic Nuclear Installations:**
  - the Flamanville NPPs (2 reactors of 1,300 MWe), Paluel (4 reactors of 1,300 MWe) and Penly (2 reactors of 1,300 MWe) operated by EDF,
  - the Flamanville 3 EPR reactor construction worksite,
  - the Orano spent nuclear fuel reprocessing plant at La Hague,
  - the Manche repository (CSM) of the National Radioactive Waste Management Agency (Andra),
  - the National Large Heavy Ion Accelerator (Ganil) in Caen;
- **small-scale nuclear activities in the medical field:** Chapter 7 p. 204
  - 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:** Chapter 8 p. 240
  - 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 linked to the transport of radioactive substances;** Chapter 9 p. 270
- **ASN-approved laboratories and organisations:**
  - 9 head-offices of laboratories approved for taking environmental radioactivity measurements,
  - 1 organisation approved for radiation protection controls.

With regard to labour inspection, ASN observes that the workers know and comply with the safety requirements. The site must continue the work it has started on this subject, particularly with regard to management of the risk of falling from height and the management of pressurised gas cylinders. ASN's inspections have also revealed deviations in the application of the regulations concerning young workers.

PENLY NUCLEAR POWER PLANT

The Penly NPP operated by EDF in the Seine-Maritime *département* in the municipality of Penly, 15 km north-east of Dieppe, comprises two 1,300 MWe PWRs commissioned between 1990 and 1992. Reactor 1 constitutes BNI 136 and reactor 2 BNI 140.

ASN considers that the nuclear safety performance of the Penly NPP is broadly in line with its general assessment of the EDF plants, and that its radiation protection and environmental protection stand out positively with respect to ASN's general assessment of the EDF nuclear fleet.

With regard to nuclear safety, ASN considers that operating rigour is improving slightly, despite a few persistent weaknesses. In effect, the reactor restarting phases have been the subject of several notifications of significant safety events due to shortcomings in the alignment operations, deficiencies in the analysis of periodic tests or shortcomings in the exhaustiveness of the operating documents. ASN considers that particular attention must be paid to the quality of preparation of the activities and the associated documents, particularly the routine operation activities (periodic tests, alignments, etc.), and to taking better account of social, organisational and human factors.

In 2023, the licensee finalised the programme of checks and expert assessments and the repairs on the systems concerned following the detection of cracks linked to stress corrosion. 2023 also saw the end of the ten-yearly outage of reactor 1, with the performance of the hydrostatic test of the main primary system and the reactor building containment test, both of which went well. The maintenance operations carried out during the reactor 2 outage were well managed on the whole. ASN nevertheless found shortcomings in the traceability of maintenance operations, which had not been detected during the internal checks. Greater rigour is expected on this subject. Consequently, ASN considers that the NPP must continue its efforts to avoid maintenance non-qualities due to deficiencies in the ergonomics or completeness of the documents, or to organisational weaknesses.

In the area of radiation protection, ASN considers that progress has been made in organisational aspects, particularly with the setting up of centres of competence in radiation protection. The inspections confirmed the good upkeep of the work sites and, more generally, satisfactory management of the contamination risk. Improvements are nevertheless required in the conformity of zone transition areas and activity preparation.

As for environmental protection, ASN considers that the Penly NPP has obtained satisfactory results in waste management and notes an improvement in the measures taken to control discharges of ozone-depleting gases. Monitoring of the rod control cluster guide tube storage area must nevertheless be improved. In an unannounced exercise, ASN observed that the organisation of the NPP teams for managing a non-radiological emergency situation was satisfactory.

With regard to labour inspection, ASN observes that the workers generally know and comply with the safety requirements. However, inspections have occasionally revealed deviations in the prevention of life-endangering risks (anoxia, lifting, etc.), and the prevention of fire risks.

FLAMANVILLE 3 EPR REACTOR CONSTRUCTION WORKSITE

Following issuing of the Creation Authorisation Decree (DAC) 2007-534 of 10 April 2007 and the building permit, the Flamanville 3 EPR reactor has been under construction since September 2007. Since December 2023, the site has been working on the preparation for reactor fuel loading.

Broadly speaking, ASN notes that a substantial amount of work was carried out in 2023, be it towards the completion of the facility, the preparation and performance of the hot requalification tests, or the deployment of operating organisations and the building of personnel skills. ASN will nevertheless remain attentive to the completion of the pre-commissioning activities, particularly regarding completion of the facility, the startup tests and drafting of the operational operating procedures.

In 2023, EDF continued the analysis and correction of deviations, including finalising of repairing welds on the main secondary systems, with completion of pipe welding, performance of non-destructive tests, stress-relief heat treatments and the hydrostatic tests of these systems. In addition to the inspections of the manufacturer and the mandated organisation, ASN conducted a campaign of four inspections of EDF in 2023, focusing on these activities and their monitoring by EDF. ASN considers that the activity organisation and monitoring set up by the various parties involved is satisfactory with respect to the high standard of quality targeted for these welds, thereby making it possible to meet the break preclusion baseline requirements.

ASN observed in 2022 that work was still required in many areas to finalise the setting up of the facilities, (notably addressing deviations, performing certain start-up tests, making several equipment modifications and finishing activities). In this respect, ASN has asked EDF to submit periodic progress reports on the completion of the facilities and has initiated a verification campaign through six dedicated inspections. Furthermore, part of the in-depth inspection of May 2023 was devoted to this subject to check that EDF had taken into account the tasks still to be carried out and ensure that their completion was scheduled for before reactor commissioning. ASN noted that EDF had implemented a dedicated organisation and taken appropriate corrective actions in response to its requests. ASN thus considers that a lot of work has been carried out on the subject over the last few years, enabling a satisfactory finished state to be achieved. It will nevertheless remain attentive to the completion of the tasks that need to be completed before commissioning.

ASN continued its oversight of the start-up tests, and the equipment hot requalification phase in particular. Two inspections concerned the preparation of this phase and the identification and settling of the last prerequisites for it to be launched. ASN also conducted a three-day tightened inspection during the tests, mobilising eight inspectors and four experts from the Institute for Radiation Protection and Nuclear Safety (IRSN). ASN considers that the preparation, performance and analysis of the tests were carried out satisfactorily. ASN is examining the results of these tests, submitted at the end of 2023, within the framework of the reactor commissioning authorisation application. In 2024, ASN will continue its examination within the framework of performance of the reactor pre-commissioning tests, followed by tests of the behaviour of the reactor core and the associated instrumentation.

Alongside the completion of construction, 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. On this subject, ASN has asked EDF to submit a periodic preparation progress report, and carried out two inspections in 2023 in addition to the in-depth inspection of May 2023 on preparation for operation.

During this inspection, which lasted five days and mobilised 15 inspectors and 11 experts from IRSN, ASN noted that operational organisational set-ups were defined and in the majority of cases already deployed, and that the personnel had a sound knowledge of the facility. ASN nevertheless noted that a lot of work remained to be done, particularly on the preparation of the operational documentation for operational control and maintenance of the facility. In 2024, ASN will conduct a follow-up inspection before commissioning to ensure that the actions defined in response to ASN's requests have effectively been carried out and meet the set objectives.

Since 2020, many systems, structures and components have been mothballed during the work on the main secondary systems. After reviewing the approach defined by EDF, ASN conducted several inspections to check its implementation. The inspection conducted by ASN in 2023 confirmed that EDF's strategy proved satisfactory in view of the complementary maintenance actions implemented and the verifications carried out on the items of equipment when they are de-mothballed.

ASN also ensures the labour inspection duties on the Flamanville EPR reactor construction site. In 2023, in addition to checking that the contractors working on the site complied with the provisions concerning labour law, ASN continued examining 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), which was commissioned in 1969, was the first radioactive waste repository operated in France. 527,225 m^3 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 CSM's periodic safety review guidance file had resulted in ASN formulating specific demands at the end of 2017, concerning in particular the justification of the technical principles of deployment of the long-term cover, the CSM memory system and the updating of the impact study.

ASN is currently examining the periodic safety review report submitted by Andra in 2019. The periodic safety review inspection conducted in this context 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 of Experts for Waste (GPD) pertaining to the CSM 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. The draft resolution concerning the continued operation of the centre was made available for public consultation in December 2023.

In 2023, ASN considers that the organisation defined and implemented for operation of the CSM facilities with regard to safety, radiation protection and environmental monitoring is broadly satisfactory. More specifically, the licensee deploys an appropriate organization for monitoring the centre and its environment, and for meeting its commitments, whether concerning the inspection follow-ups or the periodic safety review process. The licensee must nevertheless consolidate the practices associated with the new framework of radiation protection competence centres.

NATIONAL LARGE HEAVY ION ACCELERATOR

The National Large Heavy Ion Accelerator (Ganil) economic interest group was authorised in 1980 to create an ion accelerator in Caen (BNI 113). This research facility produces, accelerates and distributes ion beams with various energy levels to study the structure of the atom. The high-energy beams produce strong fields of ionising radiation, activating the materials in contact, which then emit radiation even after the beams have stopped. Irradiation thus constitutes the main risk created by Ganil.

"Exotic nuclei" are nuclei which do not exist naturally on Earth. They are created artificially in Ganil for nuclear physics experiments on the origins and structure of matter. In order to produce these exotic nuclei, Ganil was authorised in 2012 to build phase 1 of the SPIRAL2 project, whose commissioning was authorised by ASN in 2019.

A new project is currently underway on the site with the "DESIR" facility, standing for Disintegration, Excitation and Storage of Radioactive Ions. The primary function of the DESIR project will be to create new experimentation areas based on beams of radioactive ions produced by the SPIRAL1 and S3 facilities (experimental area of the SPIRAL2 phase 1 facility).

This project involves modifying the BNI perimeter. Examination of this file continued in 2023 and a public inquiry was held, further to which the inquiry commissioner issued a favourable opinion. Subsequently, the building permit was issued and the works have begun.

Examination of the second periodic safety review of the facility is also in progress. In August, ASN asked the licensee to supplement the safety review concluding report, and the additional elements were provided in December 2023. An inspection of this periodic safety review on 20 December confirmed the Ganil's progress in defining requirements associated with the activities and elements important for the protection of interests, even if the incorporation of these changes into the baseline operating requirements is still to be finalised.

With regard to nuclear safety, ASN considers that the licensee's organisational set-up is satisfactory. The licensee has also been able to render its radiation protection organisation more robust.

However, greater rigour is required in filling out the documents relating to the periodic inspections and tests and increased vigilance regarding strict compliance with the regulatory frequencies.

La Hague site

The Orano site at La Hague is located on the north-west tip of the Cotentin peninsula, in the Manche *département*, 20 km west of Cherbourg and 6 km from Cap de La Hague. The site is situated about fifteen kilometres from the Channel Islands.

THE ORANO RECYCLAGE REPROCESSING PLANTS IN OPERATION AT LA HAGUE

The La Hague plants for reprocessing fuel assemblies irradiated in the nuclear reactors are operated by Orano Recyclage La Hague.

Commissioning of the various units of the Fuel reprocessing and waste packaging plants UP3-A (BNI 116) and UP2-800 (BNI 117) and the Effluent Treatment Station (STE3 – BNI 118) spanned from 1986 (reception and storage of spent fuel assemblies) until 2002 (R4 plutonium treatment unit), with the majority of the process units being commissioned in 1989-1990.

The Decrees of 10 January 2003 set the individual reprocessing capacity of each of the two plants at 1,000 tonnes per year (t/year), in terms of the quantities of uranium and plutonium contained in the fuel assemblies before burn-up (in the reactor), and limit the total capacity of the two plants to 1,700 t/year. The limits and conditions for discharges and water intake by the site are defined by ASN resolutions 2022-DC-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 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.

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 AT1 facility, prototype facility currently being decommissioned;

BNI 47 • ELAN IIB facility, research installation currently being decommissioned.

INSTALLATIONS IN OPERATION

BNI 116 • UP3-A plant:
- **T0:** Facility for dry unloading of spent fuel elements,
- **Pools D and E:** Storage pools for spent fuel elements,
- **T1:** Facility for shearing fuel elements, dissolving and clarification of the resulting solutions,
- **T2:** Facility for separating uranium, plutonium and fission products and concentrating/storing fission product solutions,
- **T3/T5:** Facilities for purification and storage of uranyl nitrate,
- **T4:** Facility for purification, conversion to oxide and packaging of plutonium,
- **T7:** Fission products vitrification facility,
- **BSI:** Plutonium oxide storage facility,
- **BC:** Plant control room, reagent distribution facility and process control laboratories,
- **ACC:** Hull and end-piece compaction facility,
- **AD2:** Technological waste packaging facility,
- **ADT:** Waste transit area,
- **EDS:** Solid waste storage area,
- **E/D EDS:** Solid waste storage/removal from storage facility,
- **ECC:** Facilities for storage and retrieval of technological waste and packaged structures,
- **E/EV South-East:** Vitrified residues storage facility,
- **E/EV/LH and E/EV/LH 2:** Vitrified residues storage facility extensions;

BNI 117 • UP2-800 plant:
- **NPH:** Facility for "under water" unloading and storage of spent fuel elements in pool,
- **Pool C:** Spent fuel element storage pool,
- **R1:** Facility for shearing and dissolving fuel elements and clarification of the resulting solutions (including the URP: Plutonium redissolution facility),
- **R2:** Facility for separating uranium, plutonium and fission products and concentrating /storing fission product solutions (including the UCD: Centralised alpha waste conditioning unit),
- **SPF (4, 5, 6):** Fission product storage facilities,
- **R4:** Facility for purification, conversion to oxide and initial packaging of plutonium oxide,
- **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.

After purification, the uranium is concentrated and stored in the form of uranyl nitrate ($UO_2(NO_3)_2$). It will then be converted into a stable solid compound (U_3O_8) in the TU5 facility on the Tricastin site. The uranium resulting from this process is called "reprocessed uranium".

After purification and concentration, the plutonium is precipitated by oxalic acid, dried, calcined into plutonium oxide, packaged in sealed containers and stored. The plutonium is then used for the fabrication of MOX (Mixed OXide) fuels in the Orano plant in Marcoule (Melox).

The effluents and waste produced by the operation of the plants

The fission products and other transuranic elements resulting from reprocessing are concentrated, vitrified and packaged in Standard vitrified waste packages (CSD-V). The pieces of metal cladding are compacted and packaged in Standard compacted waste packages (CSD-C).

Furthermore, the reprocessing operations described in the previous paragraph involve chemical and mechanical processes which produce gaseous and liquid effluents and solid waste.

The solid waste is packaged on site by either compaction or encapsulation in cement. The solid radioactive waste resulting from the reprocessing of the spent fuel assemblies from the French reactors is, depending on its composition, either sent to the Aube repository (CSA) or stored on the Orano Recyclage La Hague site until a definitive disposal solution is found (particularly the CSD-V and CSD-C packages).

In accordance with Article L. 542-2 of the Environment Code, radioactive waste from the reprocessing of spent fuels of foreign origin is shipped back to its owners. It is however impossible to physically separate the waste according to the fuel from which it originates. In order to guarantee an equitable distribution of the waste resulting from the reprocessing of the fuels of its various customers, the licensee has proposed an accounting system that tracks the entries into and exits from the La Hague plant. This system, called "EXPER", was approved by the Order of 2 October 2008 of the Minister responsible for energy.

The gaseous effluents are released mainly when the fuel assemblies are sheared and during the dissolution process. These gaseous effluents are treated by washing in a gas treatment unit. The residual radioactive gases, particularly krypton and tritium, are checked before being discharged into the atmosphere.

The liquid effluents are treated and usually recycled. Some radionuclides, such as iodine and tritium, are channelled - after being checked – to the sea discharge outfall. This outfall, like the other outfalls of the site, is subject to discharge limits. The other effluents are routed to the site's packaging units (solid glass or bitumen matrix).

FINAL SHUTDOWN AND DECOMMISSIONING OPERATIONS ON CERTAIN FACILITIES

The former Spent fuel reprocessing plant UP2-400 (BNI 33) was commissioned in 1966 and has been definitively shut down since 1 January 2004.

Final shutdown also concerns three BNIs associated with the UP2-400 plant: BNI 38 (which comprises the Effluents and solid waste treatment station No. 2 – STE2, and the Oxide nuclear fuel reprocessing facility No. 1 – AT1), BNI 47 (radioactive source fabrication unit – ELAN IIB) and BNI 80 (HAO facility).

Orano submitted two partial decommissioning authorisation requests for BNIs 33 and 38 in April 2018. The schedule push-backs requested by the licensee lead to decommissioning completion deadlines in 2046 and 2043 instead of 2035, the 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 in legacy Waste Retrieval and Conditioning (WRC). Consequently, ASN will continue to monitor the management of these projects in 2024.

LEGACY WASTE RETRIEVAL AND CONDITIONING OPERATIONS

Unlike the direct on-line packaging of the waste generated by the new UP2-800 and UP3-A plants at La Hague, most of the waste generated by the first UP2-400 plant was stored in bulk without permanent packaging. The operations to retrieve this waste are complex and necessitate the deployment of substantial means. They present major safety and radiation exposure risks, which ASN monitors with particular attention.

The retrieval of the waste contained in the old storage facilities of the La Hague site is also a prerequisite for the decommissioning and clean-out of these facilities.

NOTABLE EVENTS OF THE YEAR 2023

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 project, which is particularly complex, has required several authorisations and was addressed by 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.

ASN issued the active commissioning authorisation for the NCPF T2 project on 16 September 2022. The T2 facility was shut down at the beginning of September 2022 in order to connect the new evaporators to the existing facilities and to continue the tests prior to commissioning, which took place in mid-April 2023, not significantly behind the initial schedule. In the context of this project, ASN conducted two inspections in 2022 concerning the tests carried out by the licensee and one inspection in February 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 have been underway since October 2023, with commissioning scheduled for 2024. In the course of this project, ASN carried out one inspection relative to the tests performed by the licensee in 2023, which showed that the NCPF R2 project has effectively integrated the lessons learned from the NCPF T2 project. ASN will continue its inspection actions on the NCPF R2 project in 2024.

Retrieval and conditioning of the STE2 sludges

The STE2 station served to collect the effluents from the UP2-400 plant, to treat them and to store the precipitation sludges resulting from the treatment. The STE2 sludges are precipitates that fix the radiological activity contained in the effluents and they are stored in seven silos. A portion of the sludges has been encapsulated in bitumen and packaged in stainless steel drums in the STE3 facility. Following ASN's banning of bituminisation in 2008, Orano studied other conditioning methods for the non-packaged or stored sludges.

The scenario for the retrieval and conditioning 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);
- conditioning 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 (DAC) for STE3 was modified by the Decree of 29 January 2016 to allow the installation of the STE2 sludges treatment process.

At the end of 2017 however, Orano informed ASN that the process chosen for treating the sludges in STE3 could lead to difficulties in equipment operation and maintenance. Orano proposed an alternative scenario using centrifugation and in August 2019 it submitted a Safety Options Dossier (DOS), which is however based on as yet insufficiently substantiated hypotheses. An inspection conducted at the end of 2019 confirmed that the project was not sufficiently mature for ASN to be able to give an opinion on this DOS.

In 2022, during the technical discussions held between Orano, ASN and IRSN, Orano committed itself to a new roadmap for this project. Orano has thus abandoned the centrifugation scenario and undertaken to conduct new studies in parallel aiming firstly to look into the sludge treatment and conditioning solutions in more detail, and secondly to put in place an intermediate storage facility (new silos) under suitably safe conditions, enabling the retrieval and safe storage of these sludges to be separated from their final packaging. Orano sent ASN the DOS associated with this project to create new sludge storage silos (project called "NABUCO") in December 2023.

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". Furthermore, the civil engineering structure of silo 130 is weakened by ageing and by the fire that occurred in 1981. The water is therefore in direct contact with the waste and can contribute to corrosion of the carbon steel liner.

One of the major risks for this facility concerns the dispersion of radioactive substances into the environment (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 WRC scenario comprises four steps:
- retrieval and conditioning of the solid GCR waste;
- retrieval of the liquid effluents;
- retrieval and conditioning of the residual GCR waste and the sludges from the bottom of the silo;
- retrieval and conditioning of the soils and rubble.

Orano has built a retrieval unit above the pit containing the waste and a new building dedicated to the storing and conditioning operations.

The licensee validated industrial commissioning of the waste recovery process in 2022, further to the tests carried out in 2020 and 2021. Quantitatively speaking, 2023 saw the recovery of some fifty additional drums of waste, bringing the quantity of waste recovered since the start of the operations in 2020 to about 17% of the total.

The licensee has nevertheless had problems with recovery equipment reliability (failure lasting from August 2022 till March 2023) and the recovery rate also remains below the initial target. To increase the rate of waste recovery, the licensee took various measures in 2023, such as setting up a maintenance team dedicated to silo 130, and having the recovery teams work three 8-hour shifts per day instead of two since November 2023. ASN considers these measures to be positive, but it will keep a close track on their effectiveness and impact on the rate of waste recovery. Lastly, in December 2023, ASN issued the authorisation for the second stage of waste recovery from silo 130, corresponding to the liquid effluents.

ASSESSMENT OF THE ORANO SITE

ASN considers that the performance of the Orano Recyclage La Hague site in 2023 is satisfactory in the areas of nuclear safety, radiation protection and environmental protection.

With regard to nuclear safety, ASN found the proficiency of operational management to be satisfactory. ASN thus notes positively the tracking of the skills and staffing levels of the operational management teams in the context of the organisational changes linked to the "Convergence" project. It also noted that the teams were closely associated with the resulting changes and that the management of staff numbers was well anticipated. With regard to operational management of incidents and accidents, ASN considers that the teams concerned have a sound knowledge of the baseline requirements. Particular attention must nevertheless be paid to the training of the teams in the management of rarely encountered facility situations or configurations, which caused several significant events in 2023. Greater rigour is also expected in the tracking of periodic inspections.

The aspects relating to the control of chain nuclear reactions have been examined for several of the site's facilities, and here again ASN considers the organisational set-up to be satisfactory, even if particular attention must be paid to the filling out of the periodic inspection and test documents and compliance with the frequencies.

ASN underlines the generally good organisation of outside contractor monitoring. ASN nevertheless considers that Orano must adapt its functioning to be capable of maintaining an adequate level of monitoring during outages, when the number of work interventions is higher. Orano must also ensure that its 1st-tier contractors monitor its 2nd-tier contractors sufficiently closely. Lastly, the rigour with which the monitoring reports are filled out must be improved in some cases (reference of the monitoring actions, consistency between what is expected and the final results, etc.).

With regard to management of the fire risk, ASN considers that the work programmes to reinforce fire detection and protection are proceeding at a satisfactory pace. ASN also notes positively the responsiveness of the personnel of the facilities when unannounced exercises are initiated, and the way in which the operational management teams and local response groups duly accomplish the majority of the tasks incumbent upon them. With regard to the actions to be taken by the "material safety protection" service, ASN regrets that it was not possible to test them in 2023, as the teams withdrew from the exercise due to the concomitant operational activity. Lastly improvements are necessary in the safety analysis associated with the sectorisation losses, in the management of disabling of the fire detection system, and in the integration of new equipment deployed in the fire risk control management project.

With regard to emergency management, ASN carried out an unannounced exercise involving the activation of an on-site emergency plan and notes with approval the site's ability to deploy its emergency organisation and to feed back the facility's technical data to the ASN's Emergency Centre.

In the area of radiation protection, ASN considers the results from the setting up of radiation protection competence centres to be broadly positive, even if some documentary and operational adjustments are still to be finalised. ASN notes with approval the material and awareness-raising measures taken to reduce cases of personnel entering controlled areas without activating their active dosimeter. These measures must nevertheless be maintained and consolidated.

With regard to environmental protection in 2023, ASN notes that the organisation defined and implemented to apply the updated requirements regulating the site's discharges is satisfactory. This notably results in the operational integration of the new discharge limits which places an operational constraint on effluent management. It will however be necessary to consolidate the submitted regulatory registers and notifications, taking care in particular to ensure their consistency and exhaustiveness. Alongside this, the ongoing momentum must be maintained and materialised in anticipation of the forthcoming submittal of studies to ASN (technical-economic studies aiming to assess the possibilities of reducing discharges, study relating to the conformity of the outfalls and the conditions of dispersion of discharges in the atmosphere).

ASN also considers that as soon as possible Orano must carry out the studies and compliance work on the hydraulic structure of the Moulinets dam, with a view to restoring nominal operation of the facilities, including with respect to the routing of raw water to the site.

With regard to the storage of plutonium-bearing materials, Orano commissioned a second storage area extension within a room of the R4 facility in August 2023. Like the first storage area extension, this project was also examined and implemented in a very short time frame. An application for a third extension was filed in September 2023.

Alongside this, ASN considers that the projects relating to the installation of the new evaporators of the NCPF project ran satisfactorily, which enabled the NCPF project for the T2 facility to enter service in April 2023.

More broadly, ASN examined the organisation defined and implemented for operational application of the safety requirements relating to facility modifications. The operational implementation fits into a structured organisation that is adapted to the scale of the projects. However, this must not lead to shortcomings in the robustness of the verifications or≈in the traceability for demonstrating compliance with the specified requirements, particularly with projects involving more limited risks. This must lead, from time to time, to the reviewing of the organization and level of resources assigned to the monitoring of this type of project.

Lastly, ASN observes that the organisation for the off-site and on-site transport of radioactive substances and for the maintenance of the packagings used on the La Hague site remains satisfactory. ASN does however note an increase in significant events in off-site transport operations, and the occurrence of events on the on-site transport operations linked to deviations from the baseline requirements. Furthermore, in the context of the on-site transport system improvements, ASN – through its resolution of 6 July 2023 – has authorised a further postponement of the deadline for the improvements to the Mobile Material Evacuation Enclosure (EMEM) transport system.

The project monitoring inspections carried out at Orano and the supplier of this transport package confirmed the difficulties encountered; consequently, ASN considers that the licensee has to make a strong commitment with more robust tracking of project management in order to meet the associated regulatory deadlines.

With regard to the progress of the decommissioning and WRC projects, the work continued in 2023. Orano has also continued to implement the fundamental improvements in the organisation of the decommissioning and WRC projects, which began in 2021, aiming to achieve greater robustness.

ASN nevertheless still observes that several decommissioning and legacy WRC 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.

With regard to silo 130, which is the furthest advanced project and now in the industrial operation phase, the rate of waste retrieval remains below that planned for in the design. ASN nevertheless considers that the technical measures aiming to enhance equipment reliability and the organisational changes put in place by Orano in 2023 (working three 8-hour shifts instead of two 8-hour shifts, setting up a dedicated maintenance team, etc.) are positive and ASN will judge their impact on the project in 2024.

Concerning the project for retrieval and conditioning of the sludge from the STE2 station, ASN notes with approval Orano's commitment to build new sludge storage silos complying with current safety standards. ASN nevertheless considers that the associated implementation schedule should be optimised.

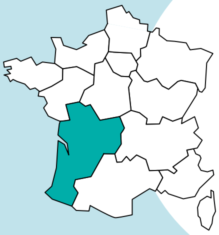
Lastly, ASN notes with approval the measures taken to control the infiltrations in certain buildings and avoid the dissemination of any radioactive materials present in the cells concerned.

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 2023, 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. Through resolution CODEP-DRC-2022-028877 of 15 July 2022, the licensee was authorised to partially commission the unit for retrieving and packaging the waste from the HAO silo and the SOC pools in ECE drums. The licensee nevertheless came across technical difficulties during the tests conducted in 2023, particularly the cementation tests with materials to simulate the waste that is to be retrieved. These difficulties led to test adjustments and repeats which caused schedule slippages.



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 2023, ASN carried out 142 inspections in the Nouvelle-Aquitaine region, comprising 58 in the Blayais and Civaux Nuclear Power Plants (NPPs), 69 in small-scale nuclear facilities, five in the area of radioactive substance transport and ten concerning ASN-approved organisations and laboratories.

ASN also carried out 18 days of labour inspection at the Blayais NPP and nine days at the Civaux NPP.

During 2023, 13 significant events rated level 1 on the International Nuclear and Radiological Events Scale (INES scale) were reported by the NPP licensees in the Nouvelle-Aquitaine region. In small-scale nuclear activities, one 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.

BLAYAIS NUCLEAR POWER PLANT

The Blayais NPP situated in the Gironde *département*, 50 km north of Bordeaux, is operated by EDF and comprises four Pressurised Water Reactors (PWRs) with a power of 900 Megawatts electric (MWe), commissioned in 1981 and 1982. Reactors 1 and 2 constitute Basic Nuclear Installation (BNI) 86 and reactors 3 and 4 BNI 110.

ASN considers that the performance of the Blayais NPP with regard to nuclear safety is below ASN's general assessment of EDF plant performance, and that the actions taken to raise this performance must be continued and increased. The radiation protection and environmental protection performance is in line with the general assessment.

With regard to nuclear safety, in 2023 the Blayais NPP did not manage to stop the deterioration in performance already observed in 2022. ASN considers that the licensee's performance in reactor operational management did not meet expectations, despite a plan of operating rigour having been put in place a plan by site senior management. Increasing staff numbers has not yet rectified this situation. ASN noted shortcomings in training and the maintaining of skills, compliance with procedures and activity preparation. Moreover, the ASN inspections focusing on operational management for incidents and accidents and on emergency situation management revealed deficiencies in the documentation and access to certain equipment items. In the area of fire risk control, ASN notes the occurrence of several notable events and still too many shortcomings in the application of the safety rules in the field. Lastly, with regard to maintenance, which was considered to have been reasonably good in 2022, ASN observed difficulties in the tracking and performance of activities in the context of an intense industrial programme on account of the ten-yearly reactor outages, which will be a focal point of vigilance in 2024.

With regard to occupational radiation protection, ASN considers that the performance has improved slightly with respect to 2022. It underlines the licensee's commitment in this area, but notes that it faces chronic difficulties in observing radiation protection fundamentals, such as wearing dosimeters, complying with alarms or the non-crossing of cordoned-off controlled areas. ASN notes with approval the good control of radiation protection during the reactor outages in 2023.

Concerning environmental protection, ASN underlines the licensee's results in improving the functioning of the wastewater treatment station, controlling legacy pollution in the soils and groundwater, and reducing its diffuse discharges of greenhouse gas refrigerants. ASN has nevertheless observed the continuation of inappropriate operating practices (handling acids outside the channels provided for this purpose) having led to non-radioactive pollutions or bypassing of the normal discharge routes. ASN considers that the licensee must improve its operating practices and the maintenance of components important for protection of the environment. ASN also adopted two resolutions in 2023 regulating the water intakes and discharges of liquid and gaseous effluents from the Blayais NPP. These new resolutions update the prescriptions of 2003 in order to integrate the changes in the regulations and the operating experience feedback from liquid and gaseous effluent discharges, leading to the lowering of certain discharge limits.

With regard to labour inspection, ASN notes that the results concerning worker safety are improving. ASN has observed risk situations for workers concerning traffic and the risk of collision between a pedestrian and a vehicle, work at height, and the occurrence of events affecting safety linked to hand-held power tools. The procedure for managing the evacuation of injured persons must be improved and taken into consideration as early as possible in worksite preparation.

ASN considers that the relevance of the risk analyses must be improved. It also underlines, despite the efforts made, another occurrence of accidental exposure of employees to asbestos fibres.

CIVAUX NUCLEAR POWER PLANT

The Civaux NPP operated by EDF in the Vienne *département*, 30 km south of Poitiers in the Nouvelle-Aquitaine region, comprises two 1,450 MWe PWRs commissioned in 1997 and 1999. Reactors 1 and 2 constitute BNIs 158 and 159 respectively. The site accommodates one of the regional bases of the Nuclear Rapid Intervention Force (FARN) created by EDF in 2011 further to the accident at the Fukushima Daiichi NPP in Japan. Its role is to intervene in pre-accident or accident situations, on any NPP in France, by providing additional human resources and emergency equipment.

ASN considers that the performance of the Civaux NPP with regard to nuclear safety and radiation protection in 2023 is in line with the general assessment of EDF plant performance. There is nevertheless a downward trend. The environmental performance stands out positively with respect to this general assessment. The two reactors of the Civaux NPP were restarted at the beginning of 2023 after outages lasting nearly 18 months, linked in particular to the repairs of the pipes presenting stress corrosion cracks.

ASN considers that the nuclear safety performance deteriorated in 2023, particularly concerning the operational management of the facilities. The restarting of the two reactors was particularly affected by errors or difficulties in maintaining the facilities in the required state. Maintenance is also considered to be down compared with the comparable previous years, with in particular a maintenance non-quality that caused the shutdown of one reactor for work, while several events occurred due to poor assimilation of the activities. Maintaining skills in the maintenance services is a point requiring particular attention. Control of the fire risk is considered to be relatively satisfactory. This being said, following the outbreak of a fire due to non-observance of a procedure, the licensee must step up its rigour of operation.

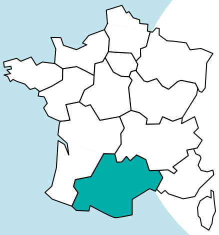
In the area of radiation protection, 2023 was marked by a contamination dispersion event in the reactor building during the outage of reactor 2: numerous malfunctions were characterised, showing a lack of radiation protection culture at the material, organisational and human levels. During the last inspection on this subject, ASN did however find greater awareness on the part of the licensee, who has implemented an action plan in response to this event.

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:** Chapter 7 p. 204
  - 19 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 24 nuclear medicine departments,
  - 90 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:** Chapter 8 p. 240
  - about 940 industrial and research centres, including 59 companies with an industrial radiography activity,
  - 1 cyclotron particle accelerator,
  - 53 laboratories situated mainly in the universities of the region,
  - some 450 veterinary surgeries or clinics practising diagnostic radiology;
- **activities linked to the transport of radioactive substances;** Chapter 9 p. 270
- **ASN-approved laboratories and organisations:**
  - 1 organisation approved for radiation protection controls,
  - 12 organisations approved for measuring radon,
  - 8 laboratories approved for taking environmental radioactivity measurements.

With regard to environmental protection, ASN notes that the creation of a retention pond for fire extinguishing water and stormwater is progressing. ASN did however find the demineralisation station facilities to be in poor condition, and this must be corrected.

The occupational safety results have remained at a satisfactory level. The labour inspector conducted an in-depth investigation further to the contamination event in reactor 2 building. ASN noted positively the setting up of an organisation to address dangerous situations. ASN has nevertheless observed delays in ensuring the regulatory compliance of equipment in explosive atmospheres. ASN also notes several events with risks of crushing or impact, as well as situations with risks of workers tripping and falling, and electrical risks.



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 2023, ASN carried out 118 inspections in the Occitanie region, comprising 53 in the Basic Nuclear Installations (BNIs), 53 in small-scale nuclear facilities, nine in the area of Radioactive Substance Transport (TSR) and three concerning ASN-approved organisations and laboratories.

ASN also carried out ten days of labour inspection at the Golfech Nuclear Power Plant (NPP).

During 2023, two significant events rated level 1 on the International Nuclear and Radiological Events Scale (INES scale) were reported by the NPP licensees of the nuclear installations in the Occitanie region. In small-scale nuclear activities, two significant radiation protection events rated level 1 on the INES scale were reported to ASN (one in the industrial sector and one in the medical sector).

ASN inspectors issued one violation report in the exercise of their oversight duties.

GOLFECH NUCLEAR POWER PLANT

The Golfech NPP operated by EDF is located in the Tarn-et-Garonne *département*, 40 km west of Montauban. It comprises two Pressurised Water Reactors (PWRs), each of 1,300 Megawatts electric (MWe), commissioned in 1990 and 1993. Reactors 1 and 2 constitute BNIs 135 and 142 respectively.

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

In the area of nuclear safety, ASN considers that the NPP's performance has improved with respect to 2022. The safety rigour plan put in place since 2019 demonstrates senior management's commitment to improving the site's nuclear safety performance. Progress has been observed in operator skills during inspections and through the satisfactory accomplishment of sensitive operating transients. ASN nevertheless observes persistent weaknesses in communication between services, in operating rigour and compliance with procedures. ASN considers that the licensee must continue its efforts in the implementation of the action plan to restore the site's performance in order to consolidate the improvements observed in 2023.

With regard to maintenance, 2023 was marked by the continuation of the ten-yearly outage of reactor 1 and the shutdown of reactor 2 for about six months. In its management of the stress corrosion phenomenon that affected certain pipes connected to the primary system, the Golfech site replaced the pipes of the safety injection system cold leg on both reactors in 2023. The work undertaken by the site to improve the quality of maintenance has stabilised its performance in this area.

ASN notes more particularly improvements in the identification and addressing of deviations and the integration 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 has improved with respect to 2022. ASN notes the strong involvement of the members of the occupational radiation protection skills centre in the training courses and the tightened radiation protection monitoring of outside contractors. The nature of the radiation protection events reported by the licensee reflects this progress. Improvements are nevertheless expected in the control of doses during reactor outages and in the observance of the procedures for accessing limited-stay (orange) areas.

In the area of environmental protection, ASN expects to see improvements in the control of containment and discharges. The year was marked by a relatively large number of events that could have an impact on the environment.

Concerning labour inspection, ASN considers that there is a slight improvement in occupational safety results. However, 2023 was marked by one severe accident. Improvements are expected in the observance of the requirements of the Labour Code, particularly regarding on-site traffic with respect to the risk of collision between a pedestrian and a vehicle. Work at height, handling and lifting are activities that always require particular and continuous attention. The ASN considers that coordination of the risks associated with the interface between different activities must be improved, as must the quality of activity preparations.

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 (Mixed OXides) fuel, the processing of radioactive waste and the irradiation of materials. The majority of the site moreover consists of the Defence Basic Nuclear Installation (DBNI) under the oversight of the Ministry 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 the Laboratory for research and fabrication of advanced nuclear fuels (Lefca), were transferred here from the CEA Cadarache centre in 2017.

ASN published resolution 2022-DC-0720 of 19 April 2022 imposing on the Alternative Energies and Atomic Energy Commission (CEA) the requirements applicable to Atalante and designed to regulate the continued operation of the BNI. ASN is attentive to the traceability of actions from their initiation through to completion. The treatment of radioactive organic liquids has been regulated by a technical requirement. The treatment must be completed before 31 December 2035.

In 2023, ASN authorised commissioning of the seismic cut-off device for the electrical power supply and the water supply, which is also a requirement for the continued operation of the BNI. The purpose of this device is to prevent an earthquake from causing a fire or a criticality accident, and to prevent the consequences of a flood.

ASN considers that the level of safety is satisfactory on the whole, particularly regarding the measure taken to monitor discharges, the emergency preparedness organisation and prevention of criticality risks.

The installations and activities to regulate comprise:

- **Basic Nuclear Installations:**
  - the Golfech NPP (2 reactors of 1,300 MWe),
  - the CEA Marcoule research centre, which includes the civil BNIs Atalante and Phénix and the Diadem waste storage facility construction site,
  - the Melox "MOX" nuclear fuel production plant,
  - the Centraco facility for processing low-level radioactive waste,
  - the Gammatec industrial irradiator,
  - the Écrin waste storage facility on the Malvési site;
- **small-scale nuclear activities in the medical field:** Chapter 7 p. 204
  - 14 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 20 nuclear medicine departments,
  - 99 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:** Chapter 8 p. 240
  - about 800 industrial and research centres, including 4 cyclotron particle accelerators, 31 companies exercising an industrial radiography activity and 60 laboratories situated mainly in the universities of the region,
  - some 600 veterinary surgeries or clinics practising diagnostic radiology;
- **activities linked to the transport of radioactive substances;** Chapter 9 p. 270
- **ASN-approved laboratories and organisations:**
  - 7 laboratories approved for taking environmental radioactivity measurements,
  - 9 organisations approved for measuring radon,
  - 2 organisations approved for radiation protection controls.

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.

ASSESSMENT OF THE CEA MARCOULE CENTRE

ASN considers that the level of nuclear safety and radiation protection of the CEA Marcoule centre remains satisfactory on the whole.

ASN has noted an improvement in the measures implemented to track the monitoring of outside contractors, whose contracts are managed at the Marcoule centre. The organisation of the CEA Marcoule site response teams dedicated to fire-fighting is also satisfactory. In view of the large number of interventions carried out, ASN has asked the CEA to take measures to maintain a balance between the operational coverage of the centre and the requirements with regard to personnel training and maintaining skills.

Transport preparation operations and maintenance of the packagings are duly carried out and monitored by the CEA.

In 2020, the CEA submitted its study on the sanitary and environmental evaluation of the liquid and gaseous chemical discharges from the Marcoule platform. Through resolution CODEP-MRS-2023-013061 of 9 March 2023, ASN has required the CEA, in association with the other licensees of the Marcoule platform installations, to have an independent organisation perform a third-party assessment concerning the evaluation of the impact on health and the environmental caused by the liquid and gaseous discharges from all the nuclear activities on the Marcoule site. A contract with a third-party expert is currently being concluded.

The technical-economic study of the measures to avoid or reduce the discharge of potentially polluted stormwater, and therefore their impact on the environment, was submitted to ASN in late 2020. The licensee finalised deployment of the measures adopted following the study in 2022. ASN expects the licensee to give it feedback on concerning effectiveness.

With regard to the conformity of the emergency management building - baptised “Centralised Surveillance of Marcoule” (SCM) – with the requirements of the hardened safety core defined further to the accident at the Fukushima Daiichi NPP (Japan) to guarantee the capability of certain items of equipment to fulfil their functions in the face of extreme hazards, a letter requesting complementary information on its accessibility and habitability was sent to the CEA in March 2023.

Removal of the irradiated fuel and equipment continued in 2023 in accordance with the ASN requirements.

Construction of the NOAH facility, which will treat the sodium from Phénix and other CEA installations, progressed in 2023 and the operating tests prior to commissioning, planned for 2028, are continuing.

In 2023, under the optimisation of the waste management routes and pursuant to article 3.1.3 of ASN resolution 2015-DC-0508 of 21 April 2015 amended, ASN authorised the disposal of the two motors taken from potential nuclear waste production zones of the Phénix installation *via* a conventional route as non-radioactive waste. ASN also authorised Phénix to modify its baseline safety requirements to integrate a methodology for the radiological characterisation of the premises with a view to their radiological delicensing.

The reference scenario which is used to set the decommissioning schedule 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.

ASN considers that the level of nuclear safety and radiation protection of Phénix is broadly satisfactory, particularly regarding the organisation in place for monitoring occupational radiation protection and the involvement of the facility’s teams to ensure that the commitments made further to inspections, significant events and the previous period safety review are met. The conditions of intervention of the local safety organisation in incident situations must nevertheless be clarified to improve the response times.

Diadem facility – *CEA centre*

The Diadem facility, currently under construction, shall be dedicated to the storage of containers of radioactive waste emitting beta and gamma radiation, or waste rich in alpha emitters, pending construction of facilities for the disposal of long-lived waste (LLW), or low- and intermediate-level short-lived waste (LL/ILW-SL) whose characteristics – especially the dose rate – mean they cannot be accepted as-is by the existing disposal facilities.

ASN considers that the CEA’s efforts to fulfil its responsibilities as nuclear licensee are effective and satisfactory, particularly through it taking over project management. Changes are currently being made in the project organisation and should be effective in early 2024.

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. These files are currently being examined. The CEA also informed ASN in 2023 that it wishes to file a request to push back the facility commissioning deadline.

The CEA must maintain the efforts it is devoting to management of the worksite and the works still to be carried out.

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 areas of nuclear chain reaction control and static and dynamic containment, and broadly satisfactory in the areas of waste management, monitoring of outside contractors, TSR and the monitoring of discharges and the environment.

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.

For several years now the licensee has had difficulties in producing the planned quantities of fuel conforming to the safety specifications of the nuclear reactors. This situation has led to the production of a large quantity of manufacturing rejects, which are sent to the La Hague site for interim storage. This creates a risk of reaching the maximum storage capacity for plutonium-containing materials at the La Hague site in the short term.

In 2022, the licensee qualified a new uranium oxide powder which enabled fuel production to be increased and reduced the quantity of rejects in 2023. This improvement must now be continued over the long term.

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 ("PPRM" project) continued in 2023.

The numerous maintenance operations have consequences in terms of radiation protection, with a growing reliance on outside contractors and a high collective dosimetry. They have moreover led to a significant increase in waste production, resulting in a risk of local storage capacities reaching their limit. The licensee has defined an action plan to prevent storage limits being reached. Among the focuses of this action plan is the creation of a new nuclear waste storage area which was authorised by ASN in 2023.

Construction of the emergency centre was completed in 2023. The licensee notified ASN of the commissioning of this building in June 2023, in accordance with the ASN requirement.

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 its process is then routed to the Aube repository (CSA) of the National radioactive waste management agency (Andra). The facility comprises:

- **a melting unit, melting a maximum of 3,500 tonnes (t) of metallic waste per year;**
- **an incineration unit, in which the incinerable waste is burned, with a maximum of 3,000 t of solid waste and 2,000 t of liquid waste per year;**
- **and storage areas.**

ASN considers that the safety of the facility in 2023 is relatively satisfactory on the whole. The findings of the inspections on management of the fire risks and external hazards were below expectations. One waste management inspection was considered relatively satisfactory. Further to these inspections, the licensee had to put in place measures aiming in particular to guarantee fire sectorisation and proper management of the facility's fire loads. The procedures and the operational means that were lacking, called out in the facility's baseline requirements for external hazard events, have also been defined.

Implementation of these actions was checked by an unannounced inspection on this subject held at the end of the year, with a positive conclusion.

ASN also conducted inspections on the pressure equipment and the monitoring of discharges and the environment, with broadly positive results.

The periodic safety review concluding report was submitted on 18 February 2021 in accordance with ASN resolution 2014-DC-0446 of 17 July 2014. This dossier is currently being examined. Monitoring and control of ageing of the facility, particularly as regards the equipment protecting against the fire risk, constitute one of the themes examined for the periodic safety review.

In September 2022, the licensee submitted an application to modify the on-site emergency plan, in order to move its emergency management premises into the perimeter of the BNI, in accordance with section 3.1.3 of ASN Guide No. 9. This modification was authorised in 2023.

Furthermore, ASN is currently revising the resolutions regulating the facility's discharges, in particular to take into account the Industrial Emissions Directive (IED), in order to achieve a high standard of environmental protection.

GAMMATEC IRRADIATOR

The Gammatec irradiator (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.

ASN conducted one unannounced inspection in 2023 focusing on the management of deviations, further to which improvements are required. Nevertheless, the level of safety in 2023 remains broadly satisfactory.

ÉCRIN FACILITY

The Écrin facility, BNI 175, is situated in the municipality of Narbonne in the Aude *département*, within the Malvési site operated by Orano, which represents the first step of the "fuel cycle" (excluding extraction of the ores). The transformation process produces liquid effluents containing nitrated sludge loaded with natural uranium. The Écrin BNI consist of two storage basins (B1 and B2) containing the legacy sludge from the plant. These two basins have BNI classification due to the presence of traces of artificial radioisotopes. The entire plant is subject to the system governing Seveso high-threshold Installations Classified for Protection of the Environment (ICPEs).

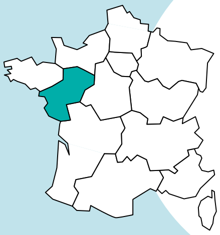
The Écrin facility was commissioned by ASN resolution 2018-DC-0645 of 12 October 2018. The works defined in the Decree of 20 July 2015, which began in 2019, were completed in 2023 with the finalising of installation of the bituminous cover over the zone of the PERLE cell (PERLE is a French acronym standing for "Project for Reversible Lagoon Storage in the Écrin BNI"), excavated to the south of storage basin B2.

The final containment provisions for the storage of waste within the BNI are now in place.

An unannounced inspection was held in July 2023 and served in particular to verify the PERLE cell filling results, the monitoring of the cell remodelling work and the preparation for installation of the bituminous cover.

Alongside this, ASN continued its examination of the report submitted on 12 February 2021 in application of Article 7 of the Decree of 20 July 2015, describing the state of progress of the studies and investigations to assess the feasibility of the disposal options for the waste currently stored in Écrin.

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 2023, ASN carried out 45 inspections, comprising three in the facilities of the company Ionisos (in the municipalities of Pouzauges and Sablé-sur-Sarthe), one concerning approved organisations, two in the area of radioactive substance transport and 39 in small-scale nuclear activities (14 in the medical sector, 22 in the industrial, research or veterinary sectors, and three in the area of natural radioactivity – radon).

Two significant events in 2023 were rated level 1 on the International Nuclear and Radiological Events Scale (INES scale), one in the industrial sector and one at the Ionisos facility in Pouzauges, and one event in radiotherapy was rated level 1+ on the ASN-SFRO scale.

IONISOS IRRADIATOR

The company Ionisos operates two industrial ionisation installations on the sites of Pouzauges (Vendée *département*) and Sablé-sur-Sarthe (Sarthe *département*) respectively, which use high-activity cobalt-60 sealed radioactive sources. These installations constitute Basic Nuclear Installations (BNIs) 146 and 154 respectively.

The gamma radiation emitted is used for sterilisation purposes or to reinforce (by cross-linking) the technical properties of certain polymers, by exposing the products to be ionised (single-use medical equipment, packaging, raw materials and finished products for the pharmaceutical and cosmetic industries, packing films) for a pre-determined length of time.

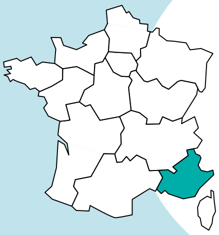
Each installation comprises a pool for underwater storage of the radioactive sources, surmounted by a bunker in which the ionisation operations are performed, premises for storing the products before and after treatment, and offices and technical rooms.

ASN considers that the safety of operation of the Pouzauges and Sablé-sur-Sarthe irradiators has regressed slightly compared with the preceding years. ASN thus expects Ionisos to reinforce its safety management and skills management, and to show greater rigour in the inspections and verifications of activities and safety-important equipment. ASN noted the simultaneous departure of the safety manager and the group safety engineer, and the departure of the Pouzauges site manager, which constitutes a situation requiring vigilance in terms of organisation.

Two modifications concerning the reference “waste” zoning were authorized in May 2023 on each of the Pouzauges and Sablé-sur-Sarthe facilities. An exercise on implementation of the “Organisation of the Civil Security Response relative to the Transport of Radioactive Materials” (Orsec-TMR) of the Vendée *département* was held on the Ionisos Pouzauges site on 12 October 2023.

The installations and activities to regulate comprise:

- **Basic Nuclear Installations:**
  - the Ionisos irradiator in Pouzauges,
  - the Ionisos irradiator in Sablé-sur-Sarthe;
- **small-scale nuclear activities in the medical sector:** Chapter 7 p. 204
  - 7 external-beam radiotherapy departments,
  - 2 brachytherapy units,
  - 11 nuclear medicine departments,
  - 39 centres performing fluoroscopy-guided interventional procedures,
  - 56 computed tomography scanners,
  - some 2,500 medical and dental radiology devices;
- **small-scale nuclear activities in the industrial, veterinary and research sectors:** Chapter 8 p. 240
  - 1 cyclotron,
  - 29 industrial radiography companies, including 7 performing gamma radiography,
  - 19 research units,
  - about 400 users of industrial equipment;
- **activities associated with the transport of radioactive substances;** Chapter 9 p. 270
- **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 2023, ASN carried out 128 inspections in the Provence-Alpes-Côte d'Azur region, comprising 65 in the Basic Nuclear Installations (BNIs), 57 in small-scale nuclear facilities, four in the area of radioactive substance transport and two concerning ASN-approved organisations and laboratories.

During 2023, two significant events rated level 1 on the International Nuclear and Radiological Events Scale (INES scale) were notified by the nuclear installation licensees.

In small-scale nuclear activities, three significant events in the industrial sector rated level 1 on the INES scale were notified to ASN, and two significant events in the medical sector rated level 2 on the ASN-SFRO scale were notified to ASN.

Cadarache site

CEA CADARACHE CENTRE

Created in 1959, the CEA Cadarache centre is situated in the municipality of Saint-Paul-lez-Durance in the Bouches-du-Rhône *département* and covers a surface area of 1,600 hectares. This site focuses its activity primarily on nuclear energy and, as concerns its civil installations in operation, on research and development to support and optimise the existing reactors and the design of new-generation systems. A large part of the centre's facilities are moreover involved in conducting the strategy for decommissioning and management of radioactive materials and waste of the Alternative Energies and Atomic Energy Commission (CEA).

The following BNIs are located on the site:
- the Pégase-Cascad installation (BNI 22);
- the Cabri research reactor (BNI 24);
- the Rapsodie research reactor (BNI 25);
- the Plutonium technology facility (ATPu – BNI 32);
- the Solid Waste Treatment Station (STD – BNI 37-A);
- the Active Effluent Treatment Station (STE – BNI 37-B);
- the Masurca research reactor (BNI 39);
- the Éole / Minerve research reactor (BNI 42-U);
- the enriched Uranium Processing Facilities (ATUe – BNI 52);
- the Central Fissile Material Warehouse (MCMF – BNI 53);
- the Chemical Purification Laboratory (LPC – BNI 54);
- the High-Activity Laboratory LECA-STAR (BNI 55);
- the solid radioactive waste storage area (BNI 56);
- the Phébus research reactor (BNI 92);
- the Laboratory for research and experimental fabrication of advanced nuclear fuels (Lefca – BNI 123);
- the Chicade laboratory (BNI 156);
- the Cedra storage facility (BNI 164);
- the Magenta storage warehouse (BNI 169);
- the Effluent advanced management and processing facility (Agate – BNI 171);
- the Jules Horowitz Reactor (JHR – BNI 172), under construction.

The CEA Cadarache centre operates numerous installations which vary in their nature and their safety implications. At the Cadarache centre, ten installations are in final shutdown status, nine are in operation and one is under construction. ASN has started or is continuing the examination of the periodic safety review guidance files or the concluding reports for 13 of the 20 installations: Cascad, Cabri, STE, ATPu, Éole / Minerve, MCMF, LPC, LECA-STAR, Phébus, Lefca, Cedra, Magenta and Agate, and has issued its conclusions on the periodic safety review of 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.

The update of the CEA's decommissioning file was submitted to ASN at the end of 2023, after completion of the assessment of the initial file.

In July 2022, as part of the "DECAP" project for removing the araldite-encapsulated fuels from Pégase, the CEA submitted to ASN a request for authorisation to receive fuel cans stored in the perimeter of the Defence Basic Nuclear Installation (DBNI) of Cadarache, originating historically from the Pégase facility pool. In view of the justifications presented by the CEA concerning the impact on the Pégase facility decommissioning schedule, resolution CODEP-CLG-2017-006524 on the Pégase facility fuel removal operations was modified to allow the reception of these fuels, which took place in 2023.

ASN considers the organisation of nuclear safety and radiation protection at the Pégase-Cascad facility to be satisfactory on the whole. ASN's oversight actions have highlighted that the Pégase shielded cell commissioning tests were correctly carried out and the deviations during this phase were duly remedied. ASN has nevertheless noted shortcomings in the process for reporting deviations by the outside contractors who participate in the manufacture of new Protection Important Components (PICs), particularly for deviations that occurred when performing services outside the BNI.

In 2024, ASN will be particularly attentive to compliance with the commissioning schedule for the DECAP project and to the treatment of the first cans by this process. The implementation of the modifications in the methods of accepting fuels at Cascad, authorised by ASN, will also be examined.

Cabri research reactor – *CEA centre*

The Cabri reactor (BNI 24), created on 27 May 1964, is intended for conducting experimental programmes aiming to achieve a better understanding of the behaviour of nuclear fuel in the event of a reactivity accident. The reactor has been equipped with a pressurised water loop since 2006 in order to study the behaviour of the fuel at high combustion rates in accident situations of increasing reactivity in a Pressurised Water Reactor (PWR). Since January 2018, 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.

The programmes of CIP tests and the electronic component irradiation tests continued in 2023. Alongside these tests, ASN examined the request for underwater repair of the hodoscope, which will finish the complete restoration of the reactor further to the discovery of defects in 2020. This repair will have to be carried out as soon as the ongoing test programme is completed, around the end of 2025.

ASN's examination of the periodic safety review continued in 2023. When compiling its safety review file, the licensee analysed the reactor components identified as requiring specific monitoring with regard to ageing of the facility. In 2024, ASN will be attentive to its operational application. Particular attention shall also be devoted to the long-term retention of the skills of the engineer teams in charge of operation and of the reactor operators.

ASN considers that the level of nuclear safety and radiation protection of the Cabri facility is on the whole satisfactory.

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 irradiator;
- **small-scale nuclear activities in the medical sector:** Chapter 7 p. 204
  - 13 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 16 nuclear medicine departments,
  - 100 centres practising 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:** Chapter 8 p. 240
  - 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;** Chapter 9 p. 270
- **ASN-approved laboratories and organisations:**
  - 3 laboratories approved for taking environmental radioactivity measurements,
  - 4 organisations approved for measuring radon,
  - 1 organisation approved for radiation protection controls.

Furthermore, ASN is waiting for information from the CEA on the outlook for the reactor's activity beyond the ongoing test programme.

Rapsodie research reactor – *CEA centre*

The Rapsodie reactor (BNI 25) is the first sodium-cooled Fast-Neutron Reactor (FNR) built in France. It operated from 1967 to 1978. A sealing defect in the reactor pressure vessel led to its final shutdown in 1983. Decommissioning operations were subsequently undertaken, but have been partially stopped further to a fatal accident in 1994 during the washing of a sodium tank.

The fuel has been unloaded from the core and evacuated from the facility. Furthermore, a large part of the radioactive fluids and components have been removed, and the reactor vessel is contained. The reactor pool has been emptied, partially cleaned out and decommissioned and the waste containing sodium has been removed.

The Rapsodie Decommissioning Decree was signed on 9 April 2021. This Decree sets the perimeter of the facility and regulates, until 2030, the operations for treating the sodium from the reactor through to introducing air into the vessel containing it. An authorisation application file will be submitted to ASN for the reactor vessel washing operation. The 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 continued during 2023 and consisted in characterising, repackaging and removing waste packages. The preparation for the treatment of the sodium still held in the facility, called "Recure Na", requires renovation of the reactor building's polar crane. To this end, the old trolleys have been removed to install a new trolley, and the crane has been requalified for a new maximum working load. Operation "Pétole", which consists in placing in final shutdown status and removing the equipment involved in the dynamic containment of the cleaned-out hot cells, has started.

The licensee submitted its periodic safety review guidance file at the end of December 2022. This file is currently being examined by ASN. The periodic safety review file is to be submitted in 2025.

ASN considers that the level of nuclear safety and radiation protection of this facility in 2023 is broadly satisfactory, particularly with regard to the management of waste and effluents and the decommissioning work.

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 radioactive waste (ILW-LL) 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 work on this project (called "Pagode") continued in 2023 with the commissioning of the Moderately Irradiating Package Transport Packagings ("ETCMI" in French) and the first civil engineering work.

ASN considers that the level of safety of the facility is satisfactory on the whole, and more specifically as regards management of the emergency resources, the design-construction, and the monitoring of the condition of the systems, equipment and buildings, themes covered by three inspections in 2023. With regard to the follow-up of commitments, a theme that was also inspected in 2023, even if it will not be possible to meet the deadlines for some of the commitments, the schedule slippages seem to be under control and the reasons for them are relevant. ASN is also continuing the examination of the periodic safety review report submitted in 2022.

Active Effluents Treatment Station – *CEA centre*

The Active Effluents Treatment Station (STE – BNI 37-B) has been shut down since 1 January 2014. The CEA submitted the decommissioning file for this facility in December 2021.

As part of the Decommissioning Preparation Operations (DECPROs), the licensee is continuing the video examinations of the tanks in order to characterise the substances still present and to determine the works required to ensure accessibility to the tanks in building 322. The characterisation work is a prerequisite for the deployment of processes, which do not yet exist, for treating these effluents. The state of safety of the storage tanks of building 322 and room 22A within building 321 must be improved pending their complete emptying. This action, resulting from the periodic safety review file, should also improve knowledge of the state of the facility, and will be put to good account in the decommissioning preparation operations. The licensee's work has also enabled the study of the fire stability of building 321 to be refined.

The discovery of contaminated stormwater, leading to the presence of artificial radionuclides outside the legacy contaminated zones already identified, continues to form the subject of significant event notifications to ASN, as it has since 2021. This situation persists despite the implementation of a stormwater management action plan, for which ASN is still waiting to receive formal assessment of the effectiveness from the licensee. In view of the successive contaminations, this action plan will continue and will be supplemented in 2024.

In 2023, ASN carried out two inspections on the theme of waste and meeting commitments. Broadly speaking, the follow-up of the action plan resulting from the periodic safety review is satisfactory, as is waste management.

ASN considers that the level of safety of BNI 37-B in 2023 remains broadly satisfactory.

Plutonium Technology Facility and Chemical Purification Laboratory

– CEA centre

The Plutonium Technology Facility (ATPu – BNI 32) produced plutonium-based fuel elements intended for FNRs or experimental reactors as from 1967, then, from 1987 until 1997, for PWRs using MOX (Mixed OXides) fuel. The activities of the Chemical Purification Laboratory (LPC – BNI 54) were associated with those of the ATPu: physical-chemical verifications and metallurgical examinations, treatment of effluents and contaminated waste. The two facilities were shut down in 2003 and are currently undergoing decommissioning.

The examination of the periodic safety review files of the two facilities continued in 2023. The operations associated with monitoring, upkeep and operation (SENEX operation), management and monitoring of solid waste and liquid effluents (characterisation, grouping, removal) also continued and enabled the dispersible inventory of the two facilities to be reduced. The cryogenic treatment process removal work also continued.

The inspections conducted by ASN in 2023 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 2023, 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, linked to 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 access to areas regulated for radiation protection purposes at the CEA shall be examined in particular.

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 FNRs, 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. This decommissioning file is currently being examined and organisation of the public inquiry is in progress. A file concerning the removal of equipment containing sodium was submitted in late 2023.

ASN made a position statement on the safety review guidance file in July 2023. The periodic safety review file is expected in 2025.

ASN considers that the level of nuclear safety, particularly regarding the monitoring of outside contractors and radiation protection – themes that were inspected in 2023 – is satisfactory on the whole.

Éole and Minerve research reactors

– CEA centre

The experimental reactors Éole and Minerve are very-low-power (less than one kilowatt) critical mock-ups that were used for neutron studies, in particular to evaluate the absorption of gamma rays or neutrons by materials.

The Éole reactor (BNI 42), whose construction was authorised by a Decree of 23 June 1965, was intended primarily for neutron studies of moderated arrays, in particular those of PWRs and Boiling Water Reactors (BWRs). The Minerve reactor (BNI 95), whose transfer from the Fontenay-aux-Roses studies centre to the Cadarache studies centre was authorised by a Decree of 21 September 1977, is situated in the same hall as the Éole reactor. Teaching and research activities were carried out on these mock-ups until their final shutdown on 31 December 2017. Decree 2023-1176 of 12 December 2023 brought together the two BNIs 42 and 95 in a single BNI (BNI 42-U) called "Éole / Minerve", and prescribed the decommissioning operations for this facility.

The examination of the decommissioning file for the two facilities ended in 2023. After its referral to the Nuclear Safety and Radiation Protection Mission (MSNR), ASN issued a favourable opinion on the draft decree bringing together BNIs 42 and 95 in a single BNI (BNI 42-U), and requiring the CEA to decommission this facility.

ASN considers that the level of safety of BNI 42-U is satisfactory on the whole, particularly regarding the progress of the latest DECPROs, the organisation of the characterisation and repackaging operations, the radioactive material removal operations and the monitoring of outside contractors. The licensee must however make progress in the monitoring of waste with no immediate disposal route and move forward with the design of containers for removing the start-up sources.

The Enriched Uranium Processing Facilities *– CEA centre*

From 1963 to 1995, the Enriched Uranium Processing Facilities (ATUe – BNI 52) converted uranium hexafluoride (UF_6) from the Cadarache enrichment plants into sinterable oxide, and ensured the chemical reprocessing of waste from the manufacture of fuel elements. Decommissioning of this facility was authorised by Decrees in February 2006 and 2021, accompanied by ASN requirements describing the conditions of performance of the future decommissioning operations dated 14 October 2021.

The activities in the facility in 2023 were essentially maintenance and periodic and regulatory inspection operations. The decommissioning operations are currently resuming following the examination of the new baseline requirements submitted in 2022.

ASN considers that the level of safety of BNI 52 (ATUe) in 2023 is satisfactory on the whole.

Most of the actions stemming from the periodic safety review of 2017 have been completed, with the exception of the roof sealing work, the completion of which is pushed back to the end of 2025.

Central Fissile Material Warehouse

– CEA centre

Created in 1968, the Central Fissile Material Warehouse (MCMF – BNI 53) was a warehouse for storing enriched uranium and plutonium until its final shutdown and removal of all its nuclear materials on 31 December 2017. The licensee submitted its decommissioning file in November 2018.

The examination of the decommissioning file ended in 2023. The MSNR submitted the facility's draft decommissioning decree to ASN and consulted the licensee, with the aim of publishing this decree in 2024.

The licensee must also submit its next periodic safety review report to ASN before the end of December 2024.

ASN considers that the DECPROs continued satisfactorily in 2023. The main operations carried out by the licensee were complementary radiological characterisations and removals of equipment and waste.

High-Activity Laboratory LECA-STAR

– CEA centre

BNI 55 combines the Active Fuel Examination Laboratory (LECA) and its extension, the Treatment, Clean-out and Reconditioning Station (STAR). These two units constitute the CEA's expert assessment tools for analysing irradiated fuels. Commissioned in 1964, the LECA laboratory enables the CEA to carry out destructive and non-destructive examinations of spent fuel from the nuclear power, research and naval propulsion sectors. As the facility is old, it was partially reinforced in the early 2010's to improve its earthquake resistance.

The guidance file (DOR) for the next periodic safety review of LECA was submitted by the CEA in January 2022. The examination of this file led ASN to request additional information concerning the conformity check and the re-assessment of the control of risks and drawbacks.

In the context of continued operation of LECA and in compliance with the technical requirements set by the resolution of 10 July 2020 on the completion of the LECA reinforcement works to guarantee that the shielded cells would not be damaged by the main building in the event of an earthquake, the CEA submitted modification requests to ASN and these are currently being examined.

Commissioned in 1999, the STAR facility is an extension of the LECA laboratory, designed for the stabilisation and reconditioning of spent fuel.

ASN is currently finalising its examination of the STAR periodic safety review report submitted in 2018.

In 2023, the CEA reported one significant event involving a load falling onto a fire door situated in the fire sector containing the STAR shielded cells. The damage to the door called into question its two-hour fire-resistance qualification. This event was examined as part of an inspection and was rated level 1 on the INES scale, essentially because of a safety culture deficiency in the way the deviation was addressed.

ASN considers that the level of nuclear safety of the LECA-STAR facility in 2023 is broadly satisfactory, particularly with regard to the prevention of criticality risk and meeting the commitments made in the context of the LECA and STAR periodic safety reviews.

Solid radioactive waste storage area

– CEA centre

BNI 56, declared in January 1968 for the disposal of waste, is used for storing legacy solid radioactive waste from the Cadarache centre. It comprises three pools, six pits, five trenches and hangars, which contain in particular ILW-LL waste from the operation or decommissioning of CEA facilities. BNI 56 is one of the priorities identified by the CEA in its new decommissioning and waste management strategy.

Examination of the facility decommissioning file, which was submitted in 2018, continued in 2023. A meeting of the Advisory Committee of Experts for Decommissioning (GPDEM) to discuss this file is scheduled in April 2024.

The CEA continued its Waste Retrieval and Conditioning (WRC) operations in the BNI in accordance with the schedule presented at the start of the year. The video inspections of pit 1 began. Clean-out work has also been carried out on the extraction cell of trench T2.

ASN considers that the nuclear safety of the facility in 2023 is broadly satisfactory with regard to static and dynamic containment, as is the condition of the systems, themes checked during inspections. ASN has more specifically observed improvements in the tracking and traceability of the modification work procedures. ASN will nevertheless be extremely 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 stormwater.

Phébus research reactor *– CEA centre*

The Phébus reactor (BNI 92) is an experimental pool-type reactor with a power rating of 38 Megawatts thermal (MWth) which functioned from 1978 to 2007. Phébus was designed for the study of serious accidents affecting light water reactors and for defining operating procedures to prevent core melt-down or to mitigate its consequences.

In 2023, ASN finalised the examination of the decommissioning and periodic safety review files, submitted in 2018 and 2017 respectively.

All the fuel and all the radioactive sources used during operation of the facility the facility have been removed since December 2021, in accordance with the priority objectives of the DECPROs. The start-up neutron source is stored in the reactor building pool pending the identification of a disposal route.

ASN considers that the nuclear safety of the facility in 2023 is broadly satisfactory with regard to management of the fire risk, a theme which was inspected.

Laboratory for research and experimental fabrication of advanced nuclear fuels – *CEA centre*

Commissioned in 1983, the Laboratory for research and experimental fabrication of advanced nuclear fuels (Lefca – BNI 123) was a laboratory tasked with conducting studies on plutonium, uranium, actinides and their compounds with the aim of understanding the behaviour of these materials in the reactor and in the various stages of the "fuel cycle". In 2018, Lefca finalised the transfer of part of its research and development equipment to the Atalante laboratories (BNI 148) at Marcoule.

In April 2023, ASN transmitted its opinion on the facility's DOR, submitted by the CEA in March 2022. The licensee submitted its periodic safety review concluding report in December 2023, which presents the case for continued operation of the facility. The planned new activities will have to be authorised by decree.

ASN considers that the nuclear safety of the facility in 2023 is broadly satisfactory with regard to control of chain nuclear reactions and the condition of the systems, themes which were inspected. It would nevertheless be advisable to improve the formalisation of many Protection-Important Activities (AIPs), particularly those contributing to the control of chain reactions in order to guarantee that safety is adequately maintained despite the potential personnel movements.

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.**

In 2023, the licensee started the facility for packaging disused sealed sources in the "870L Vrac Source" package authorised by an ASN resolution. The CEA produced the first package on 5 May 2023.

With regard to environmental protection, in May 2023 the CEA submitted a request to modify the facility's Creation Authorisation Decree (DAC), more specifically to take gaseous discharges of tritium into account. A request for a minor modification of the perimeter has also been submitted. These files are currently being examined by ASN.

ASN considers that the level of safety and radiation protection is satisfactory on the whole, particularly with regard to the management of deviations and the measures taken for management of the waste produced by the facility.

Cedra storage facility – *CEA centre*

Since 2006, the Cedra facility (BNI 164) is used to store ILW-LL waste pending the creation of appropriate disposal routes. The CEA forecasts that this facility will be filled to capacity by 2030. The studies concerning a project to double the storage capacity began in 2020.

The studies concerning the project to double the facility's storage capacity continued in 2023.

ASN considers that the organisation put in place for the periodic safety review of 2022 is satisfactory. ASN has nevertheless asked for additional information concerning the content of this report.

ASN considers that the level of nuclear safety and radiation protection in the facility is satisfactory on the whole. Improvements are nevertheless required in the monitoring of work carried out in the facility by outside contractors. ASN also remains vigilant regarding the maintaining of operating skills and know-how, in a context of a high turnover of the operational personnel.

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 concluding report in February 2021. In 2023, the licensee supplemented this file at the request of ASN, and an inspection dedicated to the application of the action plan was carried out.

Densification of the storage of certain types of package in the facility was authorised in 2023 in order to optimise the occupied surface area so that new materials can be accommodated.

ASN considers that the nuclear safety of the facility in 2023 is satisfactory, particularly regarding the control of chain reactions. An inspection dedicated to the periodic safety review concluded that the action plan was followed and implemented satisfactorily.

ASSESSMENT OF THE CEA CADARACHE CENTRE

ASN considers that the level of nuclear safety of the CEA Cadarache centre in 2023 remains satisfactory on the whole.

The follow-up of commitments and the responses to ASN further to inspection operations are broadly satisfactory. ASN has however observed that deadlines are not always met, particularly regarding the action plans resulting from the periodic safety reviews of the facilities and certain decommissioning operations.

With regard to the management of deviations relating to nuclear safety, the CEA's quality organisation enables the corrective actions to be carried out. Improvements are required however in the analysis of the causes of certain deviations.

Furthermore, in 2023 ASN focused particular attention on the theme of control of sub-criticality in the centre's facilities. It was noted that the centre has an organisation relating to the control of chain reactions that complies with ASN resolution 2014-DC-0462 of 7 October 2014.

Moreover, in the context of revival of the nuclear sector, ASN will be attentive to the maintaining of skills, as much with the CEA's personnel as≈with the outside contractors performing PIAs.

With regard to the accomplishment of new work projects, ASN notes large disparities depending on the worksites concerned. The JHR construction work is carried out with rigour and diligence, in both its organisation and worksite monitoring, but major shortcomings were noted at the beginning of the year in the general organisation, conducting and monitoring of the construction work of the Cadarache emergency centre, baptised "CIRCE", a French acronym standing for "Response centre withstanding extreme conditions". Progress was nevertheless noted on these themes as of mid-year, although efforts are still≈required in the organisation and quality of performance of the activities on the worksite and the management of deviation processing. ASN will remain particularly attentive to the Cadarache emergency centre construction work, and to the constructions necessary for the decommissioning of the facilities.

With regard to the theme of on-site transport of radioactive substances, improvements are expected in the application of the requirements of the Technical Operating Rules (RTEs) concerning packaging maintenance operations and the checks of packaging-content compatibility.

With regard to emergency situation management, the situational exercise performed during an inspection showed the good coordination between the BNI personnel and the Local Safety Organisation (FLS) of the CEA Cadarache centre. During the 2023 inspection of the FLS, the inspectors noted the quality of its organisation. Improvements are nevertheless required in the traceability of skills currency training.

ASN considers that the radiation protection situation of the CEA Cadarache centre remains at the same level as in the preceding years. The Cadarache centre has set up its radiation protection skills centres under Articles R. 593-112 of the Environment Code and R. 4451-113 of the Labour Code further to the authorisation issued by ASN on 23 December 2022.

Concerning waste management in the BNIs, the management of deviations and the traceability of waste monitoring are adequately ensured. Progress is nevertheless expected in the categorisation of certain wastes currently identified as having no available disposal route, with the aim of reducing the volume of waste stored in the facilities. Particular attention shall be paid to the tracking of the filling dates of drums containing this waste in order to reduce their storage time in the BNIs. ASN will also remain vigilant to the legacy waste characterisation and repackaging operations, and to the prospects of disposal routes for sources surplus to requirements.

ASN observes that the level of environmental protection is relatively satisfactory. Improvements have been made in the analyses carried out in the Environmental Chemistry Laboratory (LCE) of the centre. Areas for progress are still identified in the checks of the industrial effluents network, the compliance work on the installed base of piezometers, and the management of the centre's stormwater.
The management approach for polluted sites and soils is still a subject of discussion at the CEA. ASN is still waiting to receive the update of the centre's impact study, taking into account the summed discharges from the Cadarache platform facilities. ASN is finishing the examination of a first modification to the centre's discharge authorisations to take into account the changes to the BNIs since 2016.

Effluent advanced management and processing facility (Agate) – *CEA centre*

The Effluent advanced management and processing facility (Agate – BNI 171), commissioned in 2014 to replace BNI 37-B which is now shut down, uses an evaporation process to concentrate radioactive liquid effluents containing mainly beta- and gamma-emitting radionuclides.

In 2023, the CEA filed a request to modify the facility creation decree to enable it to process new types of radioactive effluents. The CEA must submit the concluding report for its first periodic safety review to ASN no later than 29 April 2024.

ASN considers that the standard of safety, radiation protection and operation of the facility are satisfactory and consistent with an objective of continuous safety improvement.

ASN underlines that this facility plays a central role in the management of the CEA effluents and as such constitutes a sensitive facility in the CEA's decommissioning and material and waste management strategy.

Jules Horowitz Reactor project – *CEA centre*

The Jules Horowitz Reactor (JHR – BNI 172), under construction since 2009, is a pressurised-water research reactor designed to study the behaviour of materials under irradiation and of power reactor fuels. It will also allow the production of artificial radionuclides for nuclear medicine. Its power is limited to 100 MWth.

The equipment construction and manufacturing activities continued in 2023, particularly in the reactor building and the nuclear auxiliary building. The defects observed on the primary/secondary heat exchanges are undergoing expert assessments. The corrective action plan is to be submitted in early 2024.

ASN conducted four inspections in 2023. They focused in particular on the primary cooling system of the reactor for the aspects relating to correction of the deviations detected on the heat exchangers and taking into account the risk of migrating bodies, on the water-proofing of the floors and walls, and correcting the deviation concerning the severing of several reinforcing bars of a slab in the leak collection zone. The assembly of the reactor equipment and of the fluid circuits, the lining of the pools, the treatment of the corrosion at the bottom of the reactor pool and the fire protection of the nuclear buildings also underwent verifications.

Following the submittal in late 2021 of a revision of the facility's safety analysis report taking into account the changes and modifications introduced since the start of construction, ASN – assisted by the Institute of Radiation Protection and Nuclear Safety (IRSN) – continued the technical examination of various themes in 2023 in preparation for the future commissioning.

ASN notes the rigour of the organisation put in place the construction of the JHR and underlines the effective and satisfactory handling of the main deviations detected on the worksite.

A project completion road map has been produced by the CEA, with a new reference schedule for the construction and commissioning of the facility. The Nuclear Policy Council meeting of 19 July 2023 endorsed the continuation of the investments by the State and the nuclear sector to finalise construction of the JHR, with commissioning expected around 2032-2034. In September 2023, the CEA submitted a new request to modify DAC 2009-1219 of 12 October 2009, to set the commissioning date to 14 October 2037 at the latest, taking into account margins for the project.

ITER

The International Thermonuclear Experimental Reactor (ITER – BNI 174), under construction on the Cadarache site since 2010 and adjacent to the CEA facilities, will be a fusion experimental reactor used for the scientific and technical demonstration of the control of thermonuclear fusion energy obtained by magnetic confinement of a deuterium-tritium plasma during long-duration experiments with a significant power level (500 MW developed for 400 seconds). This international project enjoys financial support from China, South Korea, the United States, India, Japan, Russia and the European Union, who make in-kind contributions by providing equipment for the project.

The large quantities of tritium that will be brought into play in this installation, the intense neutron flow and the resulting activation of materials have serious implications regarding radiation protection and will represent true challenges for the safe management of waste during the operation and decommissioning of the installation.

In 2022, ITER Organization (IO) announced its intention to develop a new "baseline " for the project, and in 2023 it detailed the main directions the baseline would take. These directions take into account in particular the difficulty for the licensee to provide a completed safety case for the project as a whole with its different phases, given that, due to the experimental nature of the facility and its unprecedented scientific ambition, the technical and scientific knowledge expected from its first experimental phases is necessary to prepare the subsequent phases. More specifically, the new baseline would reportedly include a modified scheduling of the "plasma phases", comprising a first phase – without fusion – with an increased technical scope, while a specific hold point would be planned after the first experimental fusion phase at reduced power, before starting the last phase with the power levels planned for in the project objectives. Several technical choices should also be modified, such as the planned replacement of beryllium by tungsten as the lining material for the first wall of the vacuum chamber. The approach proposed by the licensee to establish the safety case for its facility should be revised accordingly, with in particular a "step-by-step" method corresponding to the successive phases of commissioning and operation.

ASN is not opposed to the planned method involving a safety case comprising several steps. ASN does however underline that this approach presents a significant industrial risk, should the technical choices made and the knowledge acquired at a given stage finally not enable the licensee to demonstrate control of the safety and radiation protection risks for the subsequent steps.

Once the IO has finished redefining its experimentation programme and the changes to its facilities, ASN will be able to redefine the examination programme and scheduling accordingly and analyse the impact of the planned modifications.

The works on the site and the manufacture of the equipment continued in 2023, except for the work on the tokamak, stopped on account of construction deviations in the first sectors of the vacuum chamber which necessitate repairs before they are installed and assembled, and the problem of stress corrosion in the thermal shield cooling systems, which also makes it necessary to repair or replace some of the equipment items concerned. Corrective actions for these various problems are currently being defined. The first sector installed in the tokamak pit in May 2022 was removed in 2023 to go back onto one of the Sector Sub-Assembly Tools (SSAT) in the assembly hall. This will allow the necessary repair operations to be carried out. As the vacuum chamber constitutes a Nuclear Pressure Equipment (NPE) item and a PIC, particularly due to the containment of radioactive substances, the sector repair procedures and the qualification of these processes will be carefully verified by ASN.

The revised schedule, including an assessment of the impact of the Covid-19 pandemic and the repair times for the sectors and thermal shields, should be submitted in 2024.

In 2023, IO sent ASN a new authorisation application for water intakes and discharges of non–radioactive effluents for the facility construction phase, and it is currently being examined. A first file on this subject was judged inadmissible in 2022.

Five inspections were carried out on the site in 2023, focusing in particular on the design and construction and the monitoring of outside contractors. These inspections served to verify, for example, the design and installation of components of the Vacuum Vessel Pressure Suppression System (VVPSS), the follow-up of a significant event concerning the use of an X-ray fluorescence device outside the regulatory framework for using this type of device, the construction of a bridge linking the tokamak building to the cryogenic plant, consideration of the hazards in the dimensioning of the building or equipment, the manufacture of the vacuum chamber, the addressing of dimensional nonconformities, and the installation of the fuel systems in the tokamak building, to mention but these.

In the light of the inspections, ASN considers that improvements have been made, but further efforts are needed in the formalising and traceability of the activities and the handling of deviations, or in taking into account the safety issues and the application of the defined requirements.

GAMMASTER IRRADIATOR

Since 2008, the company Steris has been operating an industrial irradiator called "Gammaster", situated on the land of the municipality of Marseille. Gammaster treats products by ionisation (emission of gamma radiation) with the aim of sanitising, sterilising or improving the performance of materials. The facility is made up of an industrial bunker and houses high-activity cobalt-60 sealed sources which provide the radiation necessary for the facility' operations.

In 2023, ASN carried out two inspections on the organisation of the emergency resources, on radiation protection and the follow-up of commitments. Although some commitments fall behind schedule, the progress of the actions is well tracked and comes with deadlines.

ASN considers that the level of safety and radiation protection in 2023 is broadly satisfactory.

CONTENTS

01

Nuclear activities: ionising radiation and health and environmental risks

01

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 (beta radiation) or a helium nucleus (alpha radiation), or of photons (X-rays or gamma rays), ionising radiation can interact with the molecules making up the cells of living matter and alters them chemically. Of the resulting damage, the most significant concerns the DNA of the cells and this damage is not fundamentally different from that caused by certain toxic chemical substances, whether exogenous (external to the organism) or endogenous (resulting from cellular metabolism).

When not repaired by the cells themselves, this damage can lead either to cell death or to the appearance of harmful biological effects if tissues are no longer able to carry out their functions.

These effects, called "deterministic effects", have been known for a long time, as the first effects were observed with the discovery of X rays by W. Roentgen (in the early 1900's). They depend on the nature of the exposed tissue and are certain to appear as soon as the quantity of radiation absorbed exceeds a certain dose level. These effects include, for example, erythema, radiodermatitis, radionecrosis and cataract formation. The higher the radiation dose received by the tissue, the more serious the effects.

Cells can also repair the damage thus caused, although imperfectly or incorrectly. Of the damage that persists, that to DNA is of a particular nature because residual anomalies in the chromosomes can be transmitted by successive cellular divisions to new cells. A single genetic mutation is far from being sufficient to cause the transformation into a cancerous cell, but this damage due to ionising radiation may be a first step towards cancerisation which appears after a variable lapse of time, up to several years after exposure.

The suspicion of a causal link between exposure to ionising radiation and the appearance of a cancer dates back to 1902 (observation of skin cancer in a case of radiodermatitis). In this case we talk of "radiation-induced cancer".

Subsequently, several types of cancers were observed in occupational situations, including certain types of leukaemia, broncho-pulmonary cancers (owing to radon inhalation) and jawbone sarcomas. Outside the professional area, the monitoring for more than sixty years of a cohort[1] of about 85,000 people irradiated during the nuclear bombings of Hiroshima and Nagasaki (Japan) has provided data on the morbidity and mortality due to cancer following exposure to ionising radiation, enabling 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 Nuclear Power Plant (NPP) accident (Ukraine) which, as a result of the radioactive iodine released, caused in the areas near the accident an excess in the incidence of thyroid cancers in young people exposed during their childhood.

The health consequences of the Fukushima Daiichi NPP in Japan for the neighbouring populations have also formed the subject of work and analyses, some of which are still in progress, in order to learn the epidemiological lessons.

The risk of radiation-induced cancer is not linked to the exceeding of a threshold. It is materialised by an increase in the probability of developing cancer according to the 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* or more; others are "specialised registers", focusing on a particular type of cancer. Their geographical perimeter can vary (town, *département*, region, or even nationwide). Of the three national registers, one concerns pleural mesothelioma, primarily in the context of exposure to asbestos fibres, while the other two cover all the cancerous pathologies in the child and adolescent up to 18 years of age (source: INCa).

The aim of the register for a given area is to highlight differences in spatial distribution, to reveal changes over time in terms of increased or reduced rate of incidence in the different cancer locations, or to identify clusters of cases.

Some registers, depending on the quality of their population database and their age, are used in numerous studies exploring cancer risk factors (including environmental risks).

Epidemiological investigation is complementary to monitoring. Its purpose is to highlight an association between a risk factor and the occurrence of a disease, between a possible cause and an effect, or at least to enable such a causal relation to be asserted with a very high degree of probability. The intrinsic difficulty in conducting these surveys or in reaching a convincing conclusion when the illness is slow to appear or when the expected number of cases is low, which is the case with low exposure levels of a few tens of millisieverts (mSv) for example, must be borne in mind.

Cohorts such as those of Hiroshima and Nagasaki have clearly shown an excess of cancers for an average exposure of about 200 mSv. Due to insufficient data on the impact of low doses on the occurrence of a cancer, estimates are provided by making linear no-threshold extrapolations of the observed effects described for high doses. These models give estimations of the risks run during exposure to low doses of ionising radiation, which nevertheless remain scientifically controversial. Studies are currently being conducted on very large populations to better characterise these risks. Recent epidemiological studies on nuclear industry workers[(2)] and on children and adolescents exposed to ionising radiation during computed tomography examinations[(3)] find an increase in the risk of cancer that is proportional to the dose received which remains significant, including when the studied interval is limited to low cumulative doses of less than 100 milligrays (mGy), thereby underpinning what until then was simply a hypothesis.

These results consolidate knowledge on the impact of ionising radiation at low doses and confirm the importance of the principles of optimisation and justification for the radiological protection of exposed populations, whatever the cause of exposure (natural radiation, medical exposure, nuclear industry, etc.).

On the basis of the scientific syntheses of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP) has published the risk coefficients for death by cancer due to ionising radiation, *i.e.* 4.1% excess risk per sievert (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[(4)] is based on a large number of epidemiological studies conducted directly in the home, in France and internationally. These studies have shown a linear relationship, even at low exposure levels (200 becquerels per cubic metre – Bq/m^3) over a period of twenty to thirty years. In 2009, the World Health Organisation (WHO) recommended a reference level of 100 Bq/m^3, and whatever the case to remain below 300 Bq/m^3. ICRP publication 115 compared the risks of lung cancer observed through studies on uranium miners with those observed in the overall population and concluded that there was a very good correlation between the risks observed in these two conditions of exposure to radon. The ICRP recommendations consolidate those issued by the WHO which considers that radon constitutes the second-highest risk factor in lung cancer, coming far behind tobacco. Furthermore, for given levels of exposure to radon, the risk of lung cancer is much higher in smokers: three quarters of the deaths by lung cancer that can be attributed to radon reportedly occur in smokers.

In metropolitan France, about 12 million people spread over some 7,000 municipalities are potentially exposed to high radon concentrations. According to the French Public Health Agency (2018), an estimated 4,000 new cases of lung cancer are caused by radon in metropolitan France each year, far behind the number due to tobacco (the estimated number of new cases of lung cancer in Metropolitan France in 2018 was 46,000). A Radon National Action Plan has been implemented since 2004 on the initiative of ASN. It is updated periodically. The 4th 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.

2. Source: Inworks study – IRSN, Information notice of 3 October 2023, irsn.fr.
3. Source: EPI CT study – IRSN, irsn.fr.
4. Radon is a natural radioactive gas, a progeny product of uranium and thorium, an emitter of alpha particles and has been classified as a known human pulmonary carcinogen by the International Agency for Research on Cancer (IARC) since 1987.

1.3.1 The individual response to ionising radiation

The effects of ionising radiation on personal health vary from one individual to the next. As early as 1906, Bergonié and Tribondeau stated for the first time that a given dose does not have the same effect when received by a growing child or by an adult.

The variability in individual radiosensitivity is observed at high doses of ionising radiation, notably in terms of tissue responses. It has been well documented by radiation oncologists and radiobiologists. High levels of radiosensitivity have been observed in subjects suffering from genetic diseases affecting the repair of DNA and cellular signalling. Such abnormal responses are also observed in people suffering from neurodegenerative diseases.

This variability in radiosensitivity at low and moderate doses, particularly at cellular level, is increasingly documented, as is the fact that radiosensitivity at a given dose level does not necessarily imply radiosensitivity at other dose levels. Thanks to the lowering of detection thresholds, some recent methods of immunofluorescence of molecular targets for signalling and repairing DNA damage enable the effects of ionising radiation at low doses to be better documented. The results of the research work conducted using these new investigation methods must still be confirmed in the clinical environment before being integrated into medical practices.

The work of the European research group on low doses (Multidisciplinary European Low Dose Initiative – MELODI) and in the medical field (European platform for research activities in medical radiation protection – Euramed) is continuing on this subject. The ICRP task group (TG111) dedicated to this subject has published a review of the state of knowledge on individual radiosensitivity and the possibilities of predicting it with a view to developing international radiation protection recommendations. At this stage however, no valid biomarker allowing such a prediction has been identified. The individual response to ionising radiation remains an important subject of research and application in radiobiology and radiation protection (Euratom 2021-2022).

1.3.2 Effects of low doses

The linear no-threshold relationship

The linear no-threshold relationship is a model used in radiation protection to estimate the probability of risk associated with an exposure to ionising radiation taking into account the principle of precaution. According to this relationship, there would be a risk from the first exposure, proportionate to the radiation dose received. There are nevertheless many uncertainties. This is why some feel that the effects of low doses could be higher, while others believe that these doses could have no effect below a certain threshold, and some others even assert that low doses have a beneficial effect. Research in molecular and cellular biology is progressing, as are epidemiological surveys of large cohorts. The ICRP considers that the hypothesis of this relationship, used to model the effect of low doses on health (see point 1.2), constitutes a cautious basis for managing the risks due to exposure to ionising radiation. It is the obvious option for decision-makers given the uncertainties that subsist faced with the complexity of the phenomena of DNA repair and mutation and the methodological limits of epidemiology, despite the progress of research in molecular and cellular biology.

Dose, dose rate and duration of exposure

The epidemiological studies performed on individuals exposed to the Hiroshima and Nagasaki bombings have given a clearer picture of the effects of radiation on health, concerning exposures due to external irradiation (external exposure) received in a few fractions of a second at high dose and high dose rate[5] of ionising radiation. The studies carried out in the countries most affected by the Chernobyl accident (Belorussia, Ukraine and Russia) were also able to improve our understanding of the effects of radiation on health caused by exposure through internal contamination (internal exposure), more specifically through radioactive iodine. Studies on nuclear industry workers have given a clearer picture of the risk associated with chronic exposures at low doses established over many years, whether as a result of external exposure or internal contamination.

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).

The Order of 16 November 2023 defining the methods of calculating the effective doses and equivalent doses resulting from the exposure of persons to ionising radiation updated the dose coefficients for radon as of 1 January 2024. This update changes the calculation of the average effective dose received by the population in France, which thus increases from 3.5 to 6.5 millisieverts per year (mSv/year)[*], with exposure to radon now representing 54% of the overall exposure (compared with 33% previously).

* Exposure of the French population to ionising radiation – *Results for 2014-2019, IRSN, 2021.*

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.

01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 AP

Hereditary and teratogenic effects

The occurrence of possible hereditary effects from ionising radiation has not been demonstrated in humans. Such effects have not been observed among the survivors of the Hiroshima and Nagasaki bombings. But hereditary effects have been documented in experimental work on animals; more specifically, the mutations induced by ionising radiation in germ cells (cells that develop into reproductive cells: spermatozoa or ovules) can be transmitted to the progeny. An ICRP Task Group, TG121, is currently working on the heritable effects and their modes of transmission to future generations.

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).

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 76% of the total annual exposure[6].

2.1.1 Cosmic radiation

Cosmic radiation is made up essentially of ions. They have a directly ionising component and an indirectly ionising component due to the presence of neutrons (the "neutron component"), which vary according to altitude and longitude.

Considering the altitude of each municipality, the average time spent inside the home and a housing protection factor of 0.8 (housing attenuates the ionic component of cosmic radiation), the French Institute for Radiation Protection and Nuclear Safety (IRSN) evaluates the average individual effective dose per person in France at 0.31 mSv with a variation of 0.3 to 1.1 mSv/year depending on the municipalities.

Passengers and flight crew are exposed during air travel, depending on the flight altitude and the journey, to exposure varying from a few microsieverts (µSv) for short-haul domestic flight within France to nearly 80 µSv for a flight from Paris to Ottawa (Canada). The average annual effective dose received by the population in France is 14 µSv.

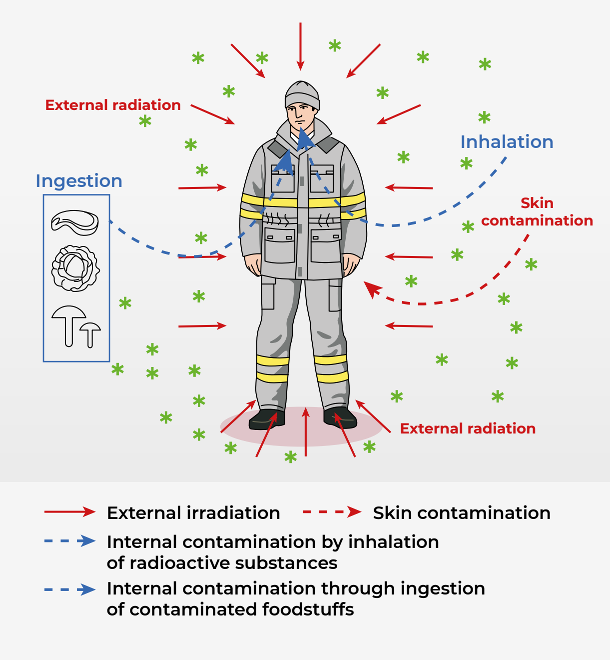
On account of the increased exposure to cosmic radiation due to extensive periods spent at high altitude, flight personnel must be subject to dosimetric monitoring (see point 3.1.3).

2.1.2 Natural terrestrial radiation (excluding radon)

Natural radionuclides of terrestrial origin are present at various levels in all the compartments of our environment, including inside the human body. They lead to external exposure of the population owing to gamma rays emitted by the uranium-238 and thorium-232 daughter products and by the potassium-40 present in the soil.

6. *Exposure of the French population to ionising radiation – Results for 2014-2019, IRSN, 2021.*

Sources and routes of exposure to ionising radiation



External exposure to gamma rays of terrestrial origin

Based on the results of a) ambient gamma dose rate measurements taken in France inside buildings, b) the mapping of the uranium potential of geological formations, c) a correlation between the gamma dose rate of terrestrial origin outside the home and inside the home, and d) assumptions on the time spent by the population inside and outside the home (92% and 8% respectively), the IRSN estimates that the average annual effective dose due to external exposure to gamma radiation of terrestrial origin in France is about 0.63 mSv per person per year. It varies from 0.30 mSv/year to 2.0 mSv/year depending on the municipality.

Exposure linked to the incorporation of radionuclides of natural origin

The average internal exposure due to the incorporation of radionuclides of natural origin is estimated at 0.55 mSv/year. The two main components of this exposure are the incorporation through foodstuffs and drinking water of potassium-40 (0.18 mSv) and descendants of the uranium and thorium chains (0.32 mSv).

Depending on the individual consumption habits, in particular the consumption of fish, seafood and tobacco, this exposure can vary greatly: from 0.4 mSv/year up to more than 3.1 mSv/year, respectively, for people who do not consume these products and those who consume them in large quantities.

Waters intended for human consumption, in particular groundwater and mineral waters, become charged in natural radionuclides due to the nature of the geological strata in which they lie. The concentration of uranium and thorium daughters and of potassium-40 varies according to the resource exploited, given the geological nature of the ground. The average effective dose linked to the decay products of the U-Th chains in drinking water is estimated by IRSN at 0.01 mSv/year. A high value of 0.30 mSv/year is retained to illustrate the variability of this exposure.

2.1.3 Radon

Some geological areas have a high radon exhalation potential due to the geological characteristics of the ground (granitic bedrock, for example). The concentration measured inside homes also depends on the tightness of the building (foundations), the ventilation of the rooms and the life style of the occupants.

National measuring campaigns have enabled the French *départements* to be classified according to the radon exhalation potential of the ground. In 2011, IRSN published a map of France considering the radon exhalation potential of the ground, based on data from the French Geological and Mining Research Office (BRGM).

Based on this, a more fine-grained classification, by municipality, was published through the Interministerial Order of 27 June 2018 (see search engine by municipality and mapping accessible on *asn.fr* and *irsn.fr*).

Working from the available measurement results and the mapping of the geogenic radon potential of the territory, the average time spent inside the home and assumptions on the type of housing concerned (collective or individual), IRSN has estimated the average radon concentration for each municipality: the average concentration of radon-222 inside housing in metropolitan France, weighted for the population and type of housing, is 60.8 Bq/m^3. With the dose factor in effect since 1 January 2024, the average effective dose per inhabitant is estimated at 3.5 mSv/year. This effective dose varies from 0.75 mSv/year to 47 mSv/year depending on the municipality (see box page 102).

The new obligation for radon detector analysis laboratories to send IRSN the measurement results and the expected results of action 7 of the 4th French action plan for management of the radon risk (see point 3.2), relative to the defining of organisation methods for collecting the radon measurement data should improve knowledge of radon exposures in France.

2.2 IONISING RADIATION ARISING FROM HUMAN ACTIVITIES

The human activities involving a risk of exposure to ionising radiation, called nuclear activities, can be grouped into the following categories:
- operation of BNIs;
- small-scale nuclear activities;
- removal of radioactive waste;
- management of contaminated sites;
- transport of radioactive substances;
- activities enhancing natural ionising radiation.

2.2.1 Basic Nuclear Installations

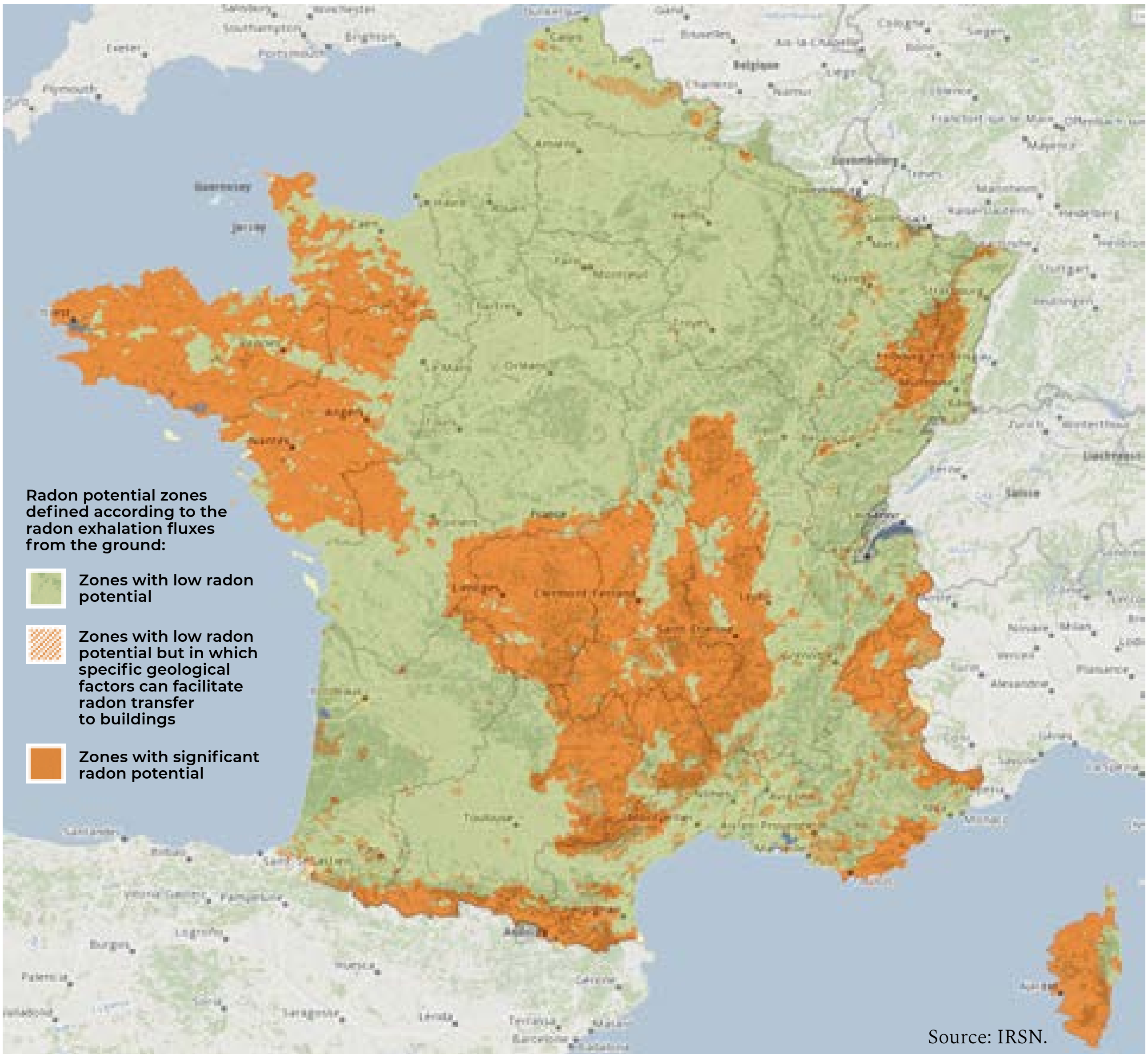
Nuclear activities are highly diverse, covering any activity relating to the preparation or utilisation of radioactive substances or ionising radiation. These activities are subject to the general provisions of the Public Health Code and, depending on their nature and the risks that they involve, to a specific legal system. BNIs are defined in Article L. 593-2 of the Environment Code:

1. Nuclear reactors;

2. Facilities, corresponding to characteristics defined by Decree of the Council of State, for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels, or for the treatment, storage or disposal of radioactive waste;

01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 AP

Radon potential zones in metropolitan France defined by the Order of 27 June 2018



3. Facilities containing radioactive or fissile substances and meeting characteristics defined by Decree of the Council of State;

4. Particle accelerators meeting characteristics defined by Decree of the Council of State;

5. Deep geological repositories for radioactive waste mentioned in Article L. 542-10-1 of the Environment Code.

The installations and facilities are subject to the BNI System, governed by Chapters III and VI of Title IX of Book V of the Environment Code and their implementing texts.

The list of BNIs as at 31 December 2023 figures in an appendix to this report.

Prevention of accidental risks and nuclear safety

The fundamental internationally adopted principle underpinning the specific organisational system and regulations applicable to nuclear safety is that of the responsibility of the licensee (see chapter 2). The public authorities ensure that this responsibility is fully assumed, in compliance with the regulatory requirements. As regards the prevention of risks for workers, BNI licensees are required to implement all necessary means to protect workers against the hazards of ionising radiation. They must more particularly ensure compliance with the general rules applicable to all workers exposed to ionising radiation (work organisation, accident prevention, medical monitoring of workers, including those of outside contractors, etc.).

As regards protection of the population and the environment, the BNI licensee must also take all necessary steps to achieve and maintain an optimum level of protection. More particularly, discharges 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 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 6.5 mSv per person per year, but this exposure is subject to wide individual variability (factor of 1 to 20), particularly depending on the place of residence (radon potential of the municipality, level of terrestrial radiation), the number of radiological examinations the person undergoes, consumption (smoking, foodstuffs) and living habits (air travel). Diagram 1 shows an estimate of the respective contributions to the average total dose of the different sources of exposure to ionising radiation for the French population, considering firstly the radon dose coefficient stipulated by the current regulations, and secondly with the dose coefficient that was in effect until 31 December 2023.

3.1 DOSES RECEIVED BY WORKERS

3.1.1 Monitoring occupational exposure to ionising radiation

The system for monitoring the external exposure of persons liable to be exposed to ionising radiation, working in BNIs or in small-scale nuclear facilities for example, has been in place for several decades.

This system is based primarily on the mandatory wearing of passive dosimeters for workers liable to be exposed and enables compliance with the regulatory limits applicable to workers to be checked. These limits concern the total exposure (since 2003, the annual limit expressed in terms of effective dose has been 20 mSv for 12 consecutive months), obtained by adding the dose due to external exposure to that resulting from any internal contamination; other limits, called "equivalent dose limits", are defined for the external exposure of certain parts of the body such as the hands and the lens of the eye (see "References" heading on *asn.fr*).

The recorded data allow the identification of the cumulative exposure dose for a given period which cannot exceed three months, for each worker, including those from outside contractors. They are grouped together in 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 2022 assessment entitled *La radioprotection des travailleurs – exposition professionnelle aux rayonnements ionisants en France* (Worker radiation protection – occupational exposure to ionising radiation in France). From the methodological aspect, as in the five preceding years, the IRSN 2022 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 2022 are not directly comparable with those established since 2017. Nevertheless, in order to establish trends, the results for the years 2015 and 2016 have been reassessed applying the new methodological approach (see Table 3).

Tables 1 and 2 present, per area of activity and for the year 2022, the breakdown of the populations monitored, the collective dose (the collective dose is the sum of the individual doses received by a given group of persons), and the number of times the annual limit of 20 mSv was exceeded. They show a large disparity in the breakdown of doses depending on the sector.

For example, the medical (including dental) and veterinary activities sector, which comprises a significant share of the population monitored (59.5%), accounts for only 11.4% of the collective dose; on the other hand, the nuclear industry, which represents just 20.7% of the headcount, accounts for 48.7% of the collective dose. Moreover, the sector concerned by exposure to natural radioactivity (excluding military aircrew), which represents just 5.7% of the total headcount, accounts for 33.2% of the collective dose. The non-nuclear industry and the research sectors represent 4.1% and 2.7% of the headcount respectively and account for 3.2% and 0.4% of the collective dose respectively.

Table 3 shows that for external exposure, the total number of workers[7] monitored in 2022 was 386,080, a 1.5% decrease compared with 2021. The collective dose is 88.4 man-Sv, a figure that is 7% higher than that for 2021, which in turn was 14% up on that of 2020, but nevertheless without reaching the value of 2019 (112.3 man-Sv). This increase concerns all areas of activity but can be explained chiefly by the recovery of air traffic with the improved health situation following the Covid-19 pandemic.

With regard to the dosimetry of the extremities (fingers and wrists), 27,598 workers were monitored in 2022, down by 2.6% compared with 2021 (*i.e.* 7.1% of the total number of persons monitored).

With regard to dosimetric monitoring of the lens of the eye, it had been increasing since 2015, and has been stabilising since 2021. It concerned 5,906 workers in 2022.

In 2022, six cases of exceeding the regulatory limit of 20 mSv for the effective whole body dose were registered, of which two were confirmed by the occupational physician. Four of the cases were registered in the medical sector (three in diagnostic radiology and one in radiotherapy), of which one – confirmed by the occupational physician – corresponds to the accumulation of several doses in 2022 (external exposure of 20 mSv over twelve sliding months); the other three cases were retained by default, as there was no feedback from the occupational physician on the conclusions of the investigation. The fifth case was registered in the research sector for accumulations of several doses in 2022 and was confirmed by the occupational physician. The sixth case however, which was registered in the non-nuclear industry sector, was not confirmed by the occupational physician.

Alongside this, two cases of exceeding the regulatory limit for the equivalent dose to the skin of 500 mSv were registered, the first in the medical sector, in nuclear medicine, with a dose estimated at 2.1 Sv and the second in the research sector (cumulative dose of 500 mSv).

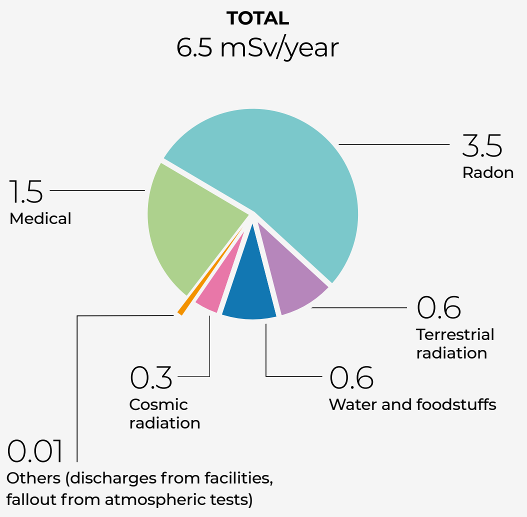
Lastly, one exceedance of the regulatory limit for the equivalent dose to the extremities, confirmed by the occupational physician, was registered in the medical sector (FGIPs) with the cumulative doses attaining 502.9 mSv.

To conclude, as in the preceding years, the assessment of monitoring of workers exposed to ionising radiation in France in 2022 published by IRSN in June 2023, shows the overall effectiveness of the prevention system introduced in facilities where sources of ionising radiation are used, because for nearly 92.7% of the population monitored, the annual dose remained below 1 mSv (effective annual dose limit for the public due to nuclear activities). The regular reduction in the number of the most heavily exposed workers over the last ten years should also be noted. Exceedances of the regulatory limit values remain exceptional.

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 interventional radiology.

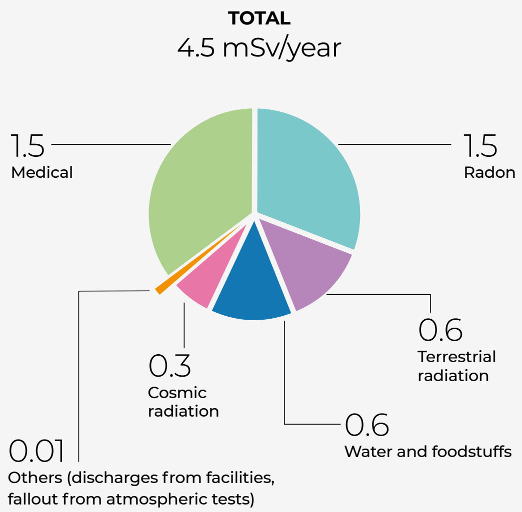
7. The total number of workers monitored comprises all the workers, including those working in military and defence activities.

DIAGRAM 1A **Average exposure using the dose coefficient currently in effect**



Source: IRSN, 2021.

DIAGRAM 1B **Average exposure using the dose coefficient in effect prior to 1 January 2024**



Source: IRSN, 2021.

3.1.2 Case of worker exposure to natural radioactivity

Exposure to radioactive substances of natural origin and to radon of geological origin
Worker exposure to radioactive substances of natural origin results either from the ingestion of dust from materials containing large amounts of radionuclides (phosphates, metal ores), or from the inhalation of radon formed by uranium decay (poorly ventilated warehouses, thermal baths) or from external exposure due to industrial process deposits (scale forming in piping for example).

In 2022, 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) concerned 667 workers monitored for external exposure (including 39 workers exposed to more than 1 mSv) and 311 workers monitored for internal exposure (of whom 18 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.

As at 31 December 2022, SievertPN had transmitted to Siseri all the flight crew doses for 14 airlines having subscribed to the system, giving a total of 21,162 flight crew members monitored by this system. In 2022, nearly 33% of the individual annual doses were below 1 mSv and 66% of the individual annual doses were between 1 mSv and 5 mSv. The maximum individual annual dose was 3.68 mSv.

In 2022, the collective dose was 29.5% higher than in 2021. This increase can be explained by the recovery of air traffic in 2022 after the improvement in the health situation following the Covid-19 pandemic.

3.2 DOSES RECEIVED BY THE POPULATION

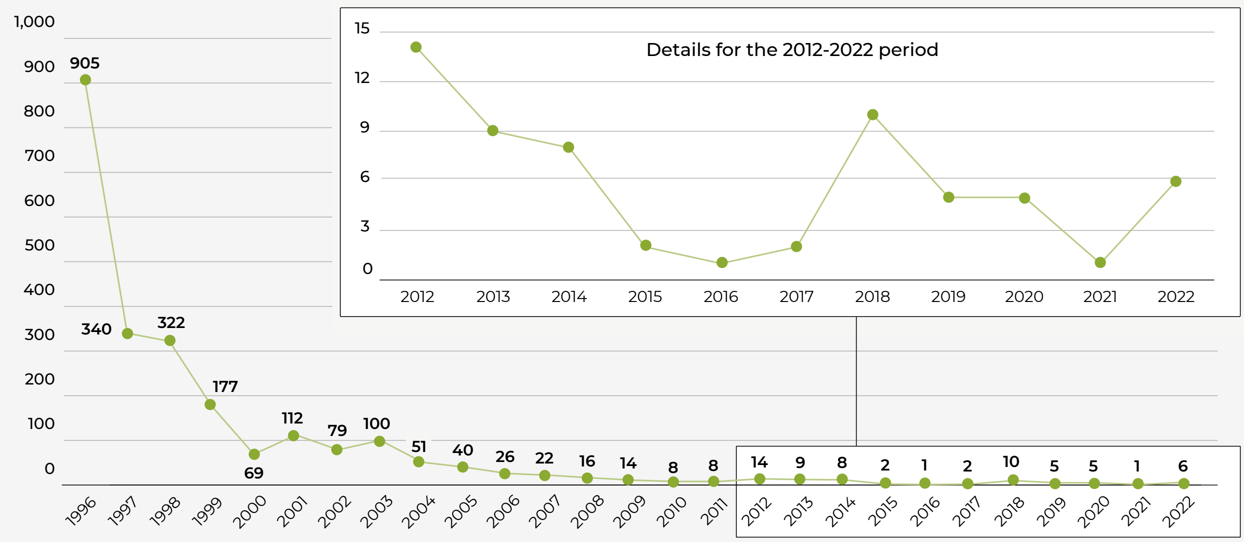
3.2.1 Exposure of the population as a result of nuclear activities

The automated monitoring networks managed nationwide by IRSN (*Téléray*, *Hydrotéléray* and *Téléhydro* networks) offer real-time monitoring of environmental radioactivity and can highlight any abnormal variation. In the case of an accident or incident leading to the release of radioactive substances, these measurement networks would play an essential role by providing data to inform the decisions to be taken by the authorities and to inform the population. In normal situations, they contribute to the evaluation of the impact of BNIs (see chapter 3).

On the other hand, there is no overall monitoring system able to provide an exhaustive picture of the doses received by the population as a result of nuclear activities. Consequently, compliance with the population exposure limit (effective dose set at 1 mSv/year) cannot be controlled directly. However, for BNIs, there is detailed accounting of radioactive effluent discharges and radiological monitoring of the environment is implemented around the installations. On the basis of the data collected, the dosimetric impact of these discharges on the populations in the immediate vicinity of the installations is then calculated using models simulating transfers to the environment. The dosimetric impacts vary, according to the type of installation and the lifestyles of the chosen representative persons, from a few microsieverts to several tens of microsieverts per year (µSv/year). An estimation of the doses from BNIs is presented in Table 4 which shows, for each site and per year, the estimated effective doses received by the most exposed representative persons.

There are no known estimates for nuclear activities other than BNIs owing to the methodological difficulties involved in identifying the impact of these facilities and in particular the impact of discharges containing small quantities of artificial radionuclides resulting from the use of unsealed radioactive sources in research or biology laboratories, or in nuclear medicine units. To give an example, the impact of hospital discharges could lead to doses of a several tens of microsieverts per year for the most exposed persons, particularly for certain jobs in sewage networks and wastewater treatment plants (IRSN studies 2005 and 2015).

DIAGRAM 2 **Evolution of number of workers monitored, with an annual effective dose in excess of 20 mSv from 1996 to 2022**



Source: IRSN.

RESULTS OF DOSIMETRY MONITORING OF WORKER EXTERNAL EXPOSURE TO IONISING RADIATION (EXPOSURE TO NATURAL RADIOACTIVITY INCLUDED) IN 2022

(Source: *Worker radiation protection: occupational exposure to ionising radiation in France, IRSN 2022 report, June 2023*)

- Total population monitored: **386,080 workers**
- Monitored population for whom the annual effective dose remained below the detection threshold: **287,517 workers, *i.e.* 74.5%**
- Monitored population for whom the annual effective dose remained between the detection threshold and 1 mSv: **70,293 workers, *i.e.* about 18.2%**
- Monitored population for whom the annual effective dose remained between 1 mSv and 20 mSv: **28,264 workers, *i.e.* more than 7.3% of the total population monitored**
- Monitored population for whom the annual effective dose exceeded 20 mSv: **6 workers**(*)
- Monitored population for whom the equivalent dose to the extremities exceeded 500 mSv: **1 worker**
- Monitored population for whom the equivalent dose to the extremities exceeded 500 mSv: **2 workers**
- Monitored population for whom the equivalent dose to the lens of the eye exceeded 100 mSv over 5 years: **none** (1 exceedance was reported, but the dose that led to the exceedance was annulled by the occupational physician)
- Collective dose (sum of the individual effective annual doses): **88,43 man-Sv**
- Average annual individual effective dose in the population which recorded a dose higher than the detection threshold: **0.9 mSv**

Results of internal exposure monitoring in 2022 (natural radioactivity excluded)

- Number of routine examinations carried out: **231,030** (of which 0.5% were considered positive)
- Population for which a dose estimation was made: **522 workers**
- Number of special monitoring examinations: **9,649** (of which 18% are higher than the detection threshold)
- Population having recorded a committed effective dose exceeding 1 mSv: **4 workers**

Results of monitoring of internal exposure to natural radionuclides from the uranium and thorium decay chains in 2022

- Internal exposure:
  - collective dose for 311 workers: **73.89 man-mSv**
  - Average annual individual effective dose in the population which recorded a dose higher than the detection threshold: **0.42 mSv**

** Four of these cases were retained by default, as the occupational physician gave no feedback on the conclusions of the investigation.*

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 µSv/year in metropolitan France (1.3 µSv/year for strontium-90 and 1 µSv/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 µSv/year for people living in areas of high persistence of this fall-out and 9.3 µSv/year for people over the rest of the country, that is to say an average dose per inhabitant of 12 µSv/year for the country as a whole (IRSN 2021).

With regard to the fall-out in France from the Fukushima Daiichi accident (Japan), the results published for France by IRSN in 2011 show the presence of radioactive iodine at very low levels, resulting in estimated effective doses for the populations of less than 2 µSv/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

TABLE 1 **Monitoring of external exposure of workers in the civil nuclear field (year 2022)**

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv (*))	INDIVIDUAL DOSE > 20 mSv
Reactors and energy production (EDF)	24,387	6.59	0
"Fuel cycle"; decommissioning	12,640	4.01	0
Transport	583	0.062	0
Logistics and maintenance (contractors)	33,577	30.84	0
Effluents, waste	738	0.11	0
Others	7,995	1.44	0
Total civil nuclear	79,920	43.055	0

*Man-Sv: unit of quantity of collective dose. For information, the collective dose is the sum of the individual doses received by a given group of persons.
(Source: *Worker radiation protection: occupational exposure to ionising radiation in France – IRSN report 2022)*

TABLE 2 **Monitoring of external exposure of workers in small-scale nuclear activities (year 2022)**

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv (*))	INDIVIDUAL DOSE > 20 mSv
Medicine	159,799	8.18	4 (1)
Dental	44,815	1.42	0
Veterinary	24,946	0.49	0
Industry	15,887	2.84	1 (2)
Research and education	10,261	0.38	1
Natural (**)	21,829	29.32	0
Total small-scale nuclear activities	277,537	42.63	6

(1) Three of these cases were retained by default, as the occupational physician gave no feedback on the conclusions of the investigation.
(2) This case was retained by default, as the occupational physician gave no feedback.
* Man-Sv: unit of quantity of collective dose.
** "Natural" covers flight crew and workers exposed to natural radionuclides of the uranium and thorium decay chains.
(Source: *Worker radiation protection: occupational exposure to ionising radiation in France – IRSN report 2022*)

TABLE 3 **Development of number of persons monitored and average collective and individual doses in the exposed population from 2015 to 2022 (*) in all areas combined (A) and in the "natural" area (B)**

YEAR	NUMBER OF PERSONS MONITORED		COLLECTIVE DOSE (man-Sv (*))		AVERAGE INDIVIDUAL DOSE (mSv)	
	(A)	(B)	(A)	(B)	(A)	(B)
2015 (*)	372,881	352,641	104.41	65.61	0.98	0.76
2016 (*)	378,304	357,527	107.53	66.71	0.96	0.73
2017	384,198	360,694	100.58	53.52	1.03	0.72
2018	390,363	365,980	104.14	55.24	1.12	0.80
2019	395,040	369,712	112.31	58.73	1.20	0.85
2020	387,452	364,614	72.43	49.97	0.78	0.71
2021	392,180	370,756	82.71	60.09	0.85	0.78
2022	386,080	363,595	88.43	59.01	0.90	0.77

* 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 2022 report, June 2023)*

TABLE 4 Radiological impact of the BNIs since 2017 calculated by the licensees from the actual discharges from the facilities and for a "person representative" of the most exposed persons within the population (data provided by the nuclear licensees)

LICENSEES/SITE	REPRESENTATIVE PERSONS IN 2022	DISTANCE TO SITE in km	ESTIMATION OF RECEIVED DOSES, in mSv [a] (the values calculated by the licensee are rounded up to the next higher unit)					
			2017	2018	2019	2020	2021	2022
Andra / CSA	Multi-activity group Ville-aux-Bois	1.7	2.10^{-6}	3.10^{-7}	3.10^{-7}	4.10^{-7}	3.10^{-7}	2.10^{-7}
Andra's Manche repository	Hameau de La Fosse	2.5	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	1.10^{-4}	1.10^{-4}
CEA / Cadarache [b]	Saint-Paul-lez-Durance	5	$<2.10^{-3}$	$<3.10^{-3}$	$<2.10^{-3}$	$<6.10^{-4}$	$<5.10^{-4}$	$<6.10^{-4}$
CEA / Fontenay-aux-Roses [b]	Achères	30	$<2.10^{-4}$	$<2.10^{-4}$	$<2.10^{-4}$	$<2.10^{-4}$	$<2.10^{-4}$	$<2.10^{-4}$
CEA / Grenoble [c]	–	–	[c]	[c]	[c]	[c]	[c]	[c]
CEA / Marcoule [b] (Atalante, Centraco, Phénix, Melox, CIS bio)	Codolet	2	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-4}$	$<2.10^{-3}$
CEA / Saclay [b]	Le Christ de Saclay	1	$<2.10^{-3}$	$<2.10^{-3}$	$<4.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<8.10^{-4}$
EDF / Belleville-sur-Loire	Beaulieu-sur-Loire	1.8	3.10^{-4}	4.10^{-4}	4.10^{-4}	3.10^{-4}	4.10^{-4}	3.10^{-4}
EDF / Blayais	Braud et Saint-Louis	2.5	4.10^{-4}	5.10^{-4}	4.10^{-4}	5.10^{-4}	2.10^{-4}	5.10^{-4}
EDF / Bugey	Vernas	1.8	2.10^{-4}	2.10^{-4}	2.10^{-4}	9.10^{-5}	2.10^{-4}	1.10^{-4}
EDF / Cattenom	Kœnigsmacker	4.8	8.10^{-3}	9.10^{-3}	1.10^{-2}	7.10^{-3}	7.10^{-3}	5.10^{-3}
EDF / Chinon	La Chapelle-sur-Loire	1.6	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Chooz	Chooz	1.5	4.10^{-4}	5.10^{-4}	5.10^{-4}	3.10^{-4}	4.10^{-4}	1.10^{-4}
EDF / Civaux	Valdivienne	1.9	8.10^{-4}	8.10^{-4}	2.10^{-3}	1.10^{-3}	1.10^{-3}	1.10^{-4}
EDF / Creys-Malville	Creys-Mépieu	0.95	1.10^{-4}	2.10^{-5}	2.10^{-5}	8.10^{-6}	2.10^{-5}	4.10^{-6}
EDF / Cruas-Meysse	Savasse	2.4	4.10^{-4}	3.10^{-3}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Dampierre-en-Burly	Lion-en-Sulias	1.6	5.10^{-4}	5.10^{-4}	5.10^{-4}	3.10^{-4}	5.10^{-4}	4.10^{-4}
EDF / Fessenheim	Fessenheim	1.3	2.10^{-5}	5.10^{-5}	4.10^{-5}	3.10^{-5}	7.10^{-6}	5.10^{-6}
EDF / Flamanville	Flamanville	0.8	2.10^{-4}	2.10^{-4}	7.10^{-5}	2.10^{-5}	6.10^{-5}	2.10^{-4}
EDF / Golfech	Valence	3.4	2.10^{-4}	2.10^{-4}	2.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}
EDF / Gravelines	Grand-Fort-Philippe	2.5	5.10^{-4}	8.10^{-4}	1.10^{-3}	8.10^{-4}	7.10^{-4}	1.10^{-3}
EDF / Nogent-sur-Seine	Saint-Nicolas-la-Chapelle	2.3	5.10^{-4}	5.10^{-4}	4.10^{-4}	4.10^{-4}	5.10^{-4}	6.10^{-4}
EDF / Paluel	Paluel	1.1	3.10^{-4}	4.10^{-4}	3.10^{-4}	3.10^{-4}	2.10^{-4}	9.10^{-4}
EDF / Penly	Berneval-le-Grand	3.1	5.10^{-4}	5.10^{-4}	4.10^{-4}	3.10^{-4}	3.10^{-4}	9.10^{-4}
EDF / Saint-Alban / Saint-Maurice	Saint-Maurice-l'Exil	1.7	2.10^{-4}	2.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
EDF / Saint-Laurent-des-Eaux	Lestiou	1.7	1.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}	9.10^{-5}	1.10^{-4}
EDF / Tricastin	Bollène	1.3	2.10^{-4}	2.10^{-4}	2.10^{-4}	1.10^{-4}	1.10^{-4}	2.10^{-4}
Framatome Romans	Ferme Riffard	0.2	2.10^{-5}	2.10^{-5}	3.10^{-5}	1.10^{-5}	1.10^{-5}	1.10^{-5}
Ganil / Caen	IUT	0.6	8.10^{-3}	8.10^{-3}	7.10^{-3}	7.10^{-3}	7.10^{-3}	7.10^{-3}
ILL / Grenoble	Fontaine (gaseous discharges) and Saint-Égrève (liquid discharges)	1 and 1.4	5.10^{-5}	2.10^{-5}	3.10^{-5}	5.10^{-5}	2.10^{-4}	3.10^{-5}
Orano Cycle / La Hague	Digulleville	2.8	2.10^{-2}	2.10^{-2}	2.10^{-2}	1.10^{-2}	1.10^{-2}	1.10^{-2}
Orano / Tricastin (Comurhex, Eurodif, Socatri, SET)	Les Girardes	1.2	2.10^{-4}	9.10^{-5}	8.10^{-5}	4.10^{-5}	6.10^{-5}	1.10^{-4}

(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 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.

receives tap water whose quality complies at all times with the total indicative dose of 0.1 mSv/year set by the regulations. This generally satisfactory assessment also applies to the radiological quality of bottled water produced in France (DGS/ASN/IRSN report published in 2013).

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 (PABs), were extended to certain workplaces in 2008. In 2016, radon was introduced into the indoor air quality policy.

Transposition of Council Directive 2013/59/Euratom of 5 December 2013 laying down Basic Safety Standards for protection against the dangers arising from exposure to ionising radiation led to the amending of the provisions applicable to radon since 1 July 2018. A reference level of 300 Bq/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 (zone 3).
- In workplaces, the regulations have been extended to cover professional activities exercised on ground floor levels (only activities carried out in basements were concerned until now) and in certain specific workplaces. Whatever the radon potential zone in which the workplace is situated, radon must be considered in the risk assessment. If necessary, a measurement can be taken in this context, if there is a risk of reaching or exceeding the reference level of 300 Bq/m^3. If the reference level is exceeded, the employer must take action to reduce the radon activity concentration. If the action turns out to be ineffective, the employer must identify potential "radon zones" from the moment the dose received by the workers exceeds 6 mSv/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 PABs, 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[8]. The type of action to be taken if the reference level of 300 Bq/m^3 is exceeded is graded according to the measurement results: simple corrective actions for radon concentrations between 300 and 1,000 Bq/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 reach or exceed 1,000 Bq/m^3.

ASN issues the approvals to the organisations that measure radon in certain PABs. In 2023, 42 approvals were issued, of which 34 were level 1 and 8 level 2, bringing their total number to 77, with 15 level-2 approvals as at 13 October 2023. The list is available in the ASN *Official Bulletin* at *asn.fr.* The level-1 organisations take the measurements to evaluate the average annual concentration in the buildings. If the reference level is exceeded, additional measurements – corresponding to the level-2 approvals – can be taken. They are used to determine the radon sources and the entry and transfer pathways in the buildings. They provide additional data to support the expert assessment, particularly for buildings with a large surface area and complex substructures. Over the last four years, between 40 and 100 additional measurements have been taken each year.

The data transmitted to ASN each year by these organisations in their annual report concern the measurements taken in the PABs that are subject to monitoring of exposure of the public, defined in Article D. 1333-32 of the Public Health Code (level 1 approval). The analysis of the data over the last seven measurement campaigns shows a trend towards an improvement in the situation, with a gradual reduction in the number of buildings exceeding the reference level of 300 Bq/m^3 and the 1,000 Bq/m^3 level in the context of the initial and ten-yearly measurements (see Diagram 3). During the last campaign of 2022-2023, the radon activity concentration was below the reference level of 300 Bq/m^3 in 77% of the educational establishments measured, 86% of day-care facilities for children under 6 years of age, 86% of the healthcare, social and medico-social facilities and in 60% of spa facilities (no measurements were taken in prisons).

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 seven years shows an improvement trend in the situation, with a gradual increase in the number of facilities managing to get below the reference level of 300 Bq/m^3. This improvement may be attributed to greater effectiveness in the works carried out, to the drop in the initial radon concentration levels, or a combination of both these factors (see Diagram 4).

For the last seven measuring campaigns, the categories of establishments having undergone initial or ten-yearly measurements are broken down as follows: 60% educational institutions (from nursery school to secondary high school), 11% day-care facilities for children under 6 years of age, 28% healthcare, social and medico-social institutions, and less than 1% spas and prisons (see Diagram 5).

More generally, the management strategy for the radon risk is set out in a national action plan. Implementation of this plan will improve the way the general public and the stakeholders concerned are informed and will enhance knowledge of radon exposure in the home and how it evolves.

The 4th French national plan for the 2020-2024 period was published in early 2021. It fits into the framework of the 4th National Health and Environment Plan which now coordinates all the sector-based plans concerning health or the environment, which is itself driven by the National Public Health Strategy 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.)"*.

8. 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.

This plan follows on from the preceding plans (the assessment of the 3rd plan is available on *asn.fr*). It can be broken down into 13 actions focusing on three lines:

Line 1 aims to implement an information and awareness-raising strategy. The health issue that radon represents requires continuation of the awareness-raising and information measures directed towards all the players (regional authorities, employers, building professionals, health professionals, teachers, etc.) and the general public, both nationally and locally, with the promotion and accompanying of regional measures for the integrated management of the radon risk in the home.

A specific communication campaign shall target smokers, because they constitute the population the most at risk of developing lung cancer linked to cumulative exposure to radon and tobacco. The operational implementation of the information system incorporating all the radon monitoring results, as well as the consolidation and centralising of the existing measures, would appear moreover to be essential for informing the public.

Line 2 aims to continue to improve knowledge. The publication in 2018 of a new map on the municipal scale, based on three radon-potential zones, enabled a graded approach to radon risk management to be implemented. This map must nevertheless be improved so as to better integrate certain geological factors that could facilitate radon transfer to buildings (karst zones in particular). Furthermore, the 4th Radon Plan provides for the updating of knowledge of exposure of the French population by organising the collection of measurement data obtained in particular during the local awareness-raising operations organised by the ARS and the regional authorities to cover the areas for which insufficient data are available. These operations consist in proposing screening kits to the inhabitants of a given region to raise their awareness of the radon risk.

Lastly, **line 3** aims to take better account of the management of the radon risk in buildings. In order to help members of building trade organisations improve their skills, these organisations have recently developed training courses dealing with methods to prevent and reduce concentration levels and various media to address the needs. The various French-language aids have been listed. To supplement the offering, a guide intended for professionals and private individuals alike was published in 2023. It provides recommendations concerning prevention in new constructions and remediation in existing buildings (see box next page). 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.

DIAGRAM 3 **Trend in the distribution of initial and ten-yearly measurements per results bracket since 2016**

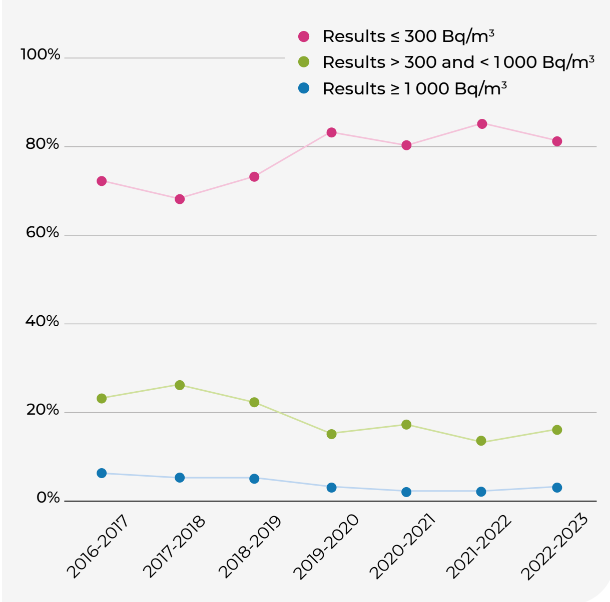
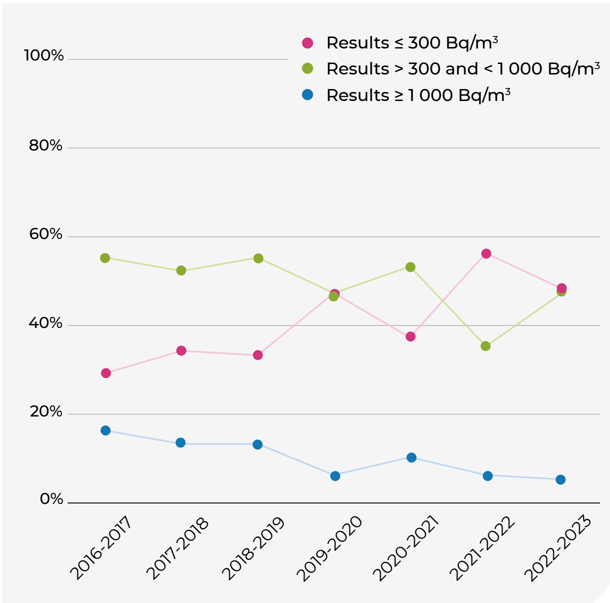
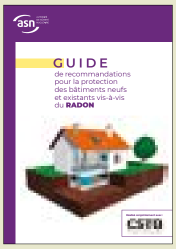


DIAGRAM 4 **Trend in the distribution of measurements after corrective actions and works per results bracket since 2016**



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.

PROTECTION OF BUILDINGS AGAINST RADON: A GUIDE FOR EVERYONE



In order to enhance the awareness of the building trade professionals (project owners, project managers, architects, companies, distributors, etc.), ASN offers them a guide presenting an overview of the means of protecting buildings against radon. This guide is also intended for private individuals wishing to find out about the work to be carried out. The technical part of this document has been prepared by the Scientific and Technical Centre for Building (CSTB). The guide is divided into two parts, concerning existing buildings and new construction projects respectively:

- **For existing buildings**, the implementation of effective corrective actions usually consists in an adaptation and a judicious combination of three types of generic solutions: airtightness of the substructure and the networks, ventilation of the building and treatment of the substructure by ventilation or placing under negative pressure. A flow chart is provided to help choose the appropriate corrective actions according to the indoor air radon concentration measured in the premises.
- **For future building constructions**, particularly in zones with significant radon potential, it is judicious to use prevention means. It is important to integrate these means at the building design stage to ensure effective results for a marginal cost. The construction project can thus sometimes be improved by avoiding certain designs that foster the entry of radon (for example, avoid underground storeys and intercommunication between basements and occupied volumes). Possible additional preventive actions consist for example in ventilating the crawl space or the basement, or even installing a soil depressurisation system. Whatever the case, the substructures must be meticulously sealed.

On completion of the works, whether reduction work in an existing building or the construction of a new building, the effectiveness of the actions taken must be verified by measuring the radon concentration in the premises, using a detector which must remain in place for at least two months, preferably between 15 September and 30 April.

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:

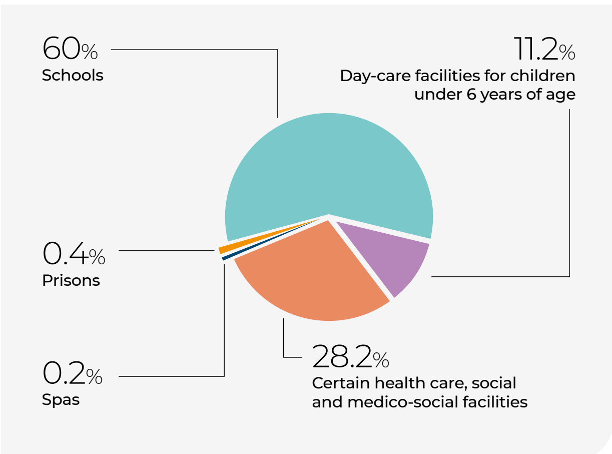
- A national headcount estimated at more than 30,000 patients was exposed to a cumulative effective dose of more than 100 mSv in 2017 due to multiple computed tomography examinations. This figure reaches 500,000 if a cumulative period of six years is considered. This highly exposed population seems to 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 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.

DIAGRAM 5 **Distribution of the initial and ten-yearly measurement by PAB category from 2016-2017 to 2022-2023**



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 of Experts for Radiation Protection of Worker and the Public (GPRP, formerly GPRADE) issued an opinion in September 2015. Following the recommendations of this opinion, at the end of 2017 ASN set up a pluralistic and multi-disciplinary working group coordinated by the IRSN to produce a methodological guide for assessing the impact of ionising radiation on the flora and fauna, based on a graded approach. The draft of the *Methodological guide for assessing the radiological risk for the wild flora and fauna – Concepts, fundamentals and implementation within the impact study* was submitted to ASN at the end of 2020 and presented to the GPRADE in June 2021. The final version of the guide was published in January 2022 on the ASN website taking into account the recommendations of the GPRADE's opinion on the operational nature of the methodology.

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.

ASN ACTIONS **TO PREVENT THE RADON RISK** IN THE REGIONS

The ASN regional divisions the most concerned by the radon risk (regions with a large number of municipalities situated in significant radon potential areas), continued to conduct radon-related risk awareness-raising actions in 2023 for elected officials, building trade professionals, employers, PAB managers and the general public, assisted by other administrations concerned (Regional Directorate for the Environment, Planning and Housing – Dreal, ARS, Regional Directorate of the Economy, Employment, Labour and Solidarity – Dreets) and partner organisations (Cerema, professional associations, local authorities, etc.).

Alongside this, the screening actions targeting specific workplaces and the managers of PAB fleets, which have been underway for several years now, continued.

* *Lille Division (Hauts-de-France): with the exception of a few municipalities of the Nord and Pas-de-Calais* départements, *the region is in a zone of low radon potential.*
** *Paris Division (Île-de-France): the entire region is in a zone of low radon potential.*
*** *Orléans Division (Centre-Val de Loire): with the exception of a few municipalities in the south of the Cher and Indre* départements, *the region is in a zone of low radon potential.*

AWARENESS-RAISING ACTIONS

AUVERGNE-RHÔNE-ALPES

LYON DIVISION

- Participation in an awareness-raising initiative organised by the Prevention and Occupational Health Services (SPST) under the Regional Occupational Health Plan (PRST) 4.

BOURGOGNE-FRANCHE-COMTÉ

DIJON DIVISION

- Participation in the scaling up of the regional health / environment network baptised *"Éclaireurs QAI-radon"* (Interior Air Quality Pathfinders – Radon) (drawing up and launching a roadmap). Created in 2022, this network aims to organise and energise the actions taken in Bourgogne-Franche-Comté to promote the improvement of interior air quality (radon included).

BRETAGNE / PAYS DE LA LOIRE

NANTES DIVISION

- Cofinancing of several initiatives in Pays de la Loire to assist private individuals in conducting voluntary campaigns to measure radon in the home and participation in the public kick-off meetings.
- Contribution to the working groups of the Regional Health Environment Plans (PRSEs) and the PRSTs of the two regions.

In this context, in Pays de la Loire, holding of an interview for a film-review of PRSE3, participation in the production of an animated film on radon in the working environment and the drafting of Frequently Asked Questions (FAQ) for the employers in the region.

- Cofinancing and participation in an information morning on radon for the owners and/or managers of PABs and employers in Pontivy (Morbihan *département*) during the European Radon Day on 7 November.
- Joint visit with the ARS in July to a household in the Maine et Loire *département* where a very high radon level was registered during the winter campaign of 2022-2023.

GRAND EST

STRASBOURG AND CHÂLONS-EN-CHAMPAGNE DIVISIONS

- Participation in the radon-related initiatives of the region PRST.

NOUVELLE-AQUITAINE / OCCITANIE

BORDEAUX DIVISION

- Participation in an information session for the preventers of the Nouvelle-Aquitaine region during a webinar on the regulations relative to radon exposure organised as part of PRST4.
- Participation in the Nouvelle-Aquitaine and Occitanie PRSE4 preparation meetings.
- Presentation of the regulations relative to occupational exposure to radon during the scientific days of the "South-West Network of Radiation Protection Experts & Radiation Protection actors".

NORMANDIE

CAEN DIVISION

- Participation with the Dreets, ARS and the occupational health services of West Normandie in the creation of a training course for the occupational health services on taking the radon risk into account in companies, which will be launched in 2024.
- Involvement in the work to launch PRSE4 Normandie.

PROVENCE-ALPES-CÔTE D'AZUR / OCCITANIE

MARSEILLE DIVISION

- Participation in the preparation of the PRSE4 Occitanie jointly with the Bordeaux division.
- Participation in the updating of the Departmental File on Major Risks in the Pyrénées-Orientales (DDRM 66 – 2023 Issue).

OVERSIGHT ACTIONS

AUVERGNE-RHÔNE-ALPES

LYON DIVISION

- Two inspections of local authorities (towns of Saint-Étienne and Aurillac) responsible for educational institutions. The follow-up of radon risk management in the nursery schools and public schools concerned is broadly satisfactory, but one PAB in Saint-Étienne has persistently exceeded the reference level for more than ten years now, despite having taken corrective measures. Further measures are already scheduled to remedy this. For the town of Aurillac, slippages were noted in the screening schedule for two PABs, leading the division to issue a reminder of the regulatory obligations regarding management of the radon risk in PABs.
- Vicat quarry in Saint-Laurent-du-Pont: the risk of worker exposure to radon is taken into account; however, the recent developments on the site make a new measurement campaign necessary.
- Orbagnoux mines in Corbonod and Samin quarries in Châtillon-en-Michaille: the radon exposure risk is taken into account and the latest measurement results available show the effectiveness of the prevention measures; an update of the risk assessment must nevertheless be carried out to take into account the changes in activity (Orbagnoux mines) and above-ground buildings (Samin quarries).
- EDF Mont-Cenis dam: the radon risk prevention approach has been very well assimilated.

BOURGOGNE-FRANCHE-COMTÉ

DIJON DIVISION

- Four inspections of municipal federations *("Mille Étangs", "Morvan Sommets et Grands Lacs", "Avallon Vézelay Morvan" and "Arroux, Loire et Somme")*. With the exception of *"Avallon Vézelay Morvan"* which manages the radon risk in a highly satisfactory manner, these local authorities have not started applying the regulatory obligations under both the Public Health Code (initial measurements of the radon activity concentration in PABs) and the Labour Code (risk assessment). This finding led ASN to demand that the regulatory screening measurements be carried out, jointly with the occupational exposure risk assessment.
- One inspection of a spa (Bourbon Lancy Spa) which had taken radon measurements as required under the Public Health Code and the Labour Code revealing several exceedances of the reference level, but without taking the necessary corrective actions. The division required the facility implement an action plan to reduce the risk (see box on spas page 119).
- One specific workplace inspection at the Vouglans hydroelectric dam, operated by EDF Hydro Alpes. The organisation and the measures to ensure the radiation protection of the workers against the risk of radon exposure are highly satisfactory and duly formalised on this site.

...

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BRETAGNE / PAYS DE LA LOIRE

NANTES DIVISION

- Three inspections of PAB managers (municipal councils of Saint-Herblain and Saint-Malo, and the Group VYV3 Pays de la Loire, which manages nursery schools in the Loire-Atlantique and Maine-et-Loire *départements*). The inspections found that the radon risk is duly taken into account, even if some improvements are required in the regulatory posting of the results, in the assessment of the radon risk for workers, and lastly in taking into account the radon risk in buildings when works are carried out.

- Two specific workplace inspections: Keolis Rennes (metro) and Effia Stationnement. These inspections revealed that the assessment of the radon risk for workers had been carried out either recently or not at all by these organisations.

GRAND EST

STRASBOURG AND CHÂLONS-EN-CHAMPAGNE DIVISIONS

- Three inspections of PAB managers (Regional Council, European Collectivity of Alsace, and ADAPEI *Papillons Blancs*, an association providing facilities for disabled persons). These managers have taken due account of the radon risk, even if the PABs concerned are not always fully identified. Furthermore, a number of deviations were noted regarding the measurement frequency and the implementation of corrective actions, expert assessments and works when the reference level is exceeded. Lastly, two points requiring particular attention were noted: the first concerns the conservation of the history of past actions and the second the methods of assessing the radon risk for workers, which differ from those for the public.

- One specific workplace inspection at the Tellure mining tourist park, within which management of the radon exposure risk has just started.

- Two inspections of spas: Vittel and Contrexéville (see box on spas next page).

NOUVELLE-AQUITAINE / OCCITANIE

BORDEAUX DIVISION

- In Occitanie, inspections of the Departmental Councils of the Ariège and Hautes-Pyrénées *départements* with the participation of the ARS of Occitanie. ASN notes that the regulations are duly taken into account in the Ariège *département*, whereas there are some shortcomings in the Hautes-Pyrénées *département*, where expert assessments of buildings must be undertaken.

- In Nouvelle-Aquitaine, inspections of three Departmental Councils: Deux-Sèvres, Creuse and Haute-Vienne. The radon risk is clearly identified and taken into account (measurement campaigns, remedial actions undertaken, etc.); additional actions are nevertheless required in the cases where reference level is still exceeded (Deux-Sèvres, Haute-Vienne) or to check the effectiveness of the corrective actions (Creuse).

- One inspection of a spa facility in Jonzac. This facility has carried out studies revealing concentrations below the reference level in the rooms measured, and relatively low radon concentrations in the spa water. A campaign of workplace measurements is scheduled for 2024; the assessment of the radon exposure risk for the workers will have to be formalised accordingly.

NORMANDIE

CAEN DIVISION

- Inspections of PAB managers (the Normandie Region and the Departmental Council of Orne) with highly positive results as the radon risk is addressed with great diligence in the PABs concerned.

- One specific workplace inspection carried out in the last quarter (the Rabodanges dam operated by EDF, where the plant features a well and an underground gallery): the risk assessment procedure has been started but measurement campaigns have not yet been carried out.

PROVENCE-ALPES-CÔTE D'AZUR / OCCITANIE

MARSEILLE DIVISION

- One specific workplace inspection at ESCOTA, a subsidiary of Vinci Autoroutes, manager of motorway tunnels. The radon risk assessment procedure has not yet been implemented in this company, which did not know the regulations applicable in this domain. The division asked for a risk reduction action plan to be put in place within three months, with a progress assessment in early 2025.

- One inspection of the Cannes municipal council as PAB manager, with the competent ARS. The municipal council has taken due account of the regulations (training of an in-house resource person, measurements in virtually all the educational institutions with posting of the results).

In 2023, 12 organisations approved for measuring radon were inspected with the assistance of the regional divisions. The scope of ASN's oversight concerned the verification of compliance with the applicable requirements of the Public Health Code, and its Articles L. 1333-29 to 31 and R. 1333-166 in particular, the Order of 26 February 2019 on the methods of managing radon in certain PABs, and three ASN resolutions, two of which entered into application on 1 January 2023: resolutions 2015-DC-0506 of 9 April 2015, 2022-DC-0743 and 2022-DC-0745 of 13 October 2022.

The results are broadly satisfactory. Most of the requirements of the new ASN resolution 2022-DC-0743 of 13 October 2022 regarding the content of the intervention reports have been effectively taken into account in the report templates examined, even if a few omissions sometimes subsist. These inspections moreover revealed several positive points, including the putting in place of procedures and an organisation for supervising the work, the use of detectors complying with regulatory requirements in all cases, storage conditions guaranteeing that detector performance is maintained, and compliance with the measurement frequencies and durations.

Efforts must nevertheless be made within some organisations to improve the monitoring of regulations and standards and to guarantee the quality of the measurement services.

Improvements are also required in the following: knowledge of the scope of the regulations (particularly in the case of PABs situated in zones 1 and 2); the methodology for determining and selecting homogeneous zones (failure to take into account the temperature level and poor knowledge of the rules of progression in the levels); the methodology for calculating the activity concentration values to be attributed to a homogeneous zone if a result is below the detection limit; the safeguarding and reliability of the report drafting aids; the processing of deviations and their consequences on the conclusions; the follow-ups given when several buildings are persistently above the reference level; compliance with the deadlines for sending the detectors to the laboratories and the reports to the ordering parties; lastly, the completeness of the measurement data transmitted *via* the platform *démarches-simplifiées.fr*.

RESULTS OF THE INSPECTIONS OF SPA FACILITIES

IN SPA FACILITIES THERE ARE TWO TYPES OF IONISING RADIATION TO WHICH THE SPA CUSTOMERS AND THE WORKERS ARE EXPOSED:

- radon, which is the main source of exposure. Apart from the usual sources found in buildings, namely the subjacent ground and the construction materials, the radon can also be present in the spa water which has become charged with radon during its underground routing and is released when the water is used during the treatments;

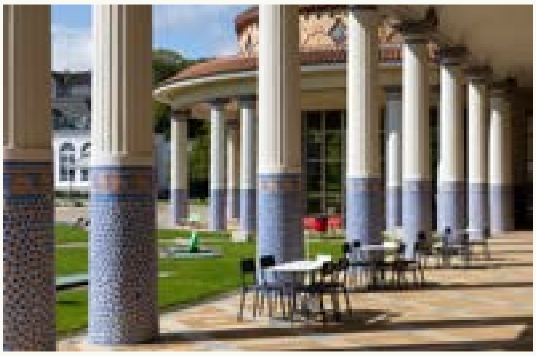
- ambient radiation generated by the other radionuclides present in the spa water (above all uranium-238, radium-226, radium-228, lead-210 and polonium-210). Deposits of material contaminated by these radionuclides can form and create "hot spots", particularly in the pool sand filters and the water treatment system. Analyses of the poultices applied to the skin of patients have revealed no radioactivity to date.

In June 2022, 111 spa facilities accredited by the French health insurance organisation were present in 90 towns(*). Since 2018, ASN has carried out 14 inspections on 13 sites.
These facilities have the particularity of being subject to three regulations relating to ionising radiation: the Public Health Code as a PAB, the Labour Code as a specific workplace where workers may be exposed to radon and, possibly, as an activity using radioactive substances of natural origin.

THE INSPECTION FINDINGS REVEAL THAT:

- only one of the facilities took radon risk into account in the occupational risks analysis, showing that the facilities have not identified the new requirements of the Labour Code regulations, which have been applicable since 2018;

- all the facilities have carried out at least one campaign to measure the radon concentration in the interior air of the premises frequented by the spa customers and the workers. The procedure provided for in the Public Health Code has therefore been initiated. The results show that the measured concentrations are broadly higher than those measured in PABs as a whole. This can be explained by the use of spa water which can constitute an additional source of radon.



The radon concentration in the premises is moreover strongly influenced by two factors: the intermediate storage of the spa water which allows degassing of the radon, and the ventilation of the premises;

- the exposure of the spa customers is very limited in time (typically three weeks for a health cure reimbursed by the healthcare system). The workers are more exposed than the customers because they go into places where the concentration is higher and their exposure time is longer;

- in the facilities where the reference level of 300 Bq/m^3 is exceeded (5 facilities where places frequented by customers exceed this level and 6 facilities were places frequented by the workers exceed this level, out of the 13 sites inspected), the works to reduce the radon concentration, which are provided for in the regulations, have only been carried≈out in half the cases (2 facilities out of 5 for the places frequented by the customers and 3 facilities out of 6 for the places frequented by the workers). Few facilities had checked the effectiveness of the works. As in PABs in general, they do not always manage to achieve a radon concentration below the reference level of 300 Bq/m^3. This is a known difficulty and it is sometimes necessary to proceed iteratively. The simplest actions implemented first can prove insufficient and need to be supplemented by more consequential work later on;

- as regards the radiation produced by the other radionuclides of natural origin, no characterised substance displayed a level of radioactivity that makes radiation protection measures necessary.

Based on these findings, ASN will continue its oversight in this sector, particularly through re-inspections, and in 2024 it will conduct an awareness-raising campaign with all the spa facilities. In this context, an overview of the inspections and the points requiring attention in the application of the regulations shall be issued along with information on the new radon dose coefficients, which will become applicable in 2024 and will have a significant impact on management of the radon risk in premises where the workers' activity is mainly non-sedentary.

* *Information from the website ameli.fr.*

CONTENTS

02

The principles of nuclear safety and radiation protection and the regulation and oversight stakeholders

02

Nuclear security is defined in the Environment Code as comprising *"nuclear safety, radiation protection, prevention and combating of malicious acts and civil protection actions in the event of an accident"*. Nuclear safety is *"the set of technical provisions and organisational measures – related to the design, construction, operation, shutdown and decommissioning of Basic Nuclear Installations (BNIs), as well as the transport of radioactive substances – which are adopted with a view to preventing accidents or limiting their effects"*. Radiation protection is defined as *"protection against ionising radiation, that is the set of rules, procedures and means of prevention and surveillance aimed at preventing or mitigating the direct or indirect harmful effects of ionising radiation on individuals, including in situations of environmental contamination"*.

Nuclear safety and radiation protection obey principles and approaches that have been put in place progressively and continually enhanced by a process of Operating Experience Feedback (OEF). The basic guiding principles are advocated internationally by the International Atomic Energy Agency (IAEA). In France, they are included in the Constitution or enacted in law, as well as now figuring in European Directives.

In France, the regulation and oversight of the nuclear safety and radiation protection of civil nuclear activities is the responsibility of the French Nuclear Safety Authority (ASN), an independent administrative Authority, together with Parliament and the other State players, within the Government and the offices of the Prefects. This regulation, which covers related areas such as chronic pollution of all types emitted by certain nuclear activities, is based on expert technical analysis and assessment, 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 124 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"*.

Responsibility of licensees and responsibility of ASN

Application of this principle results, for example, in the adoption of a linear, no-threshold dose-effect relationship where the biological effects of exposure to low doses of ionising radiation are concerned. This point is clarified in chapter 1 of this report.

1.1.4 The public participation principle

This principle allows public participation in the decision-making process by the public authorities. Following on from the Aarhus Convention, Article 7 of the Environment Charter defines it in these terms: *"Within the conditions and limits defined by law, all individuals are entitled to access environmental information in the possession of the public authorities and to participate in the taking of public decisions affecting the environment"*.

In the nuclear field, this principle notably leads to the organisation of national public debates, which are mandatory prior to the construction of a Nuclear Power Plant (NPP) for example, or now before certain plans and programmes subject to strategic environmental assessments, such as the National Radioactive Material and Waste Management Plan (PNGMDR). One should also mention the public inquiries, notably during examination of the files concerning the creation or decommissioning of nuclear installations, consultation of the public on draft resolutions with an impact on the environment, or the submission by a BNI licensee of its file concerning a modification to its installation liable to lead to a significant increase in water intake or discharges into the environment of the installation.

1.1.5 The justification principle

The justification principle, defined in Article L. 1333-2 of the Public Health Code, states that: *"A nuclear activity may only be undertaken or carried out if its individual or collective benefits, more specifically its health, social, economic or scientific benefits so justify, given the risks inherent in the human exposure to ionising radiation that it is likely to entail"*.

Assessment of the expected benefit of a nuclear activity and the corresponding drawbacks may lead to prohibition of an activity for which the benefit would not seem to outweigh the health risk. For existing activities, justification may be reassessed if the state of know-how and technology so warrants.

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[1] principle, leads for example to reducing the quantities of radionuclides present in the radioactive effluents from nuclear installations allowed in the discharge licenses, to requiring monitoring of exposure in the workplaces in order to reduce it to the strict minimum and to ensuring that medical exposure as a result of diagnostic procedures remains close to the pre-determined reference levels.

1.1.7 The limitation principle

The limitation principle, defined in Article L. 1333-2 of the Public Health Code states that *"[...] exposure of a person to ionising radiation [...] may not increase the sum of the doses received beyond the limits set by regulations, except when the individual is exposed for medical purposes or for the purposes of research as mentioned in 1° of Article L. 1121-1"*.

The exposure of the general public or of workers as a result of nuclear activities is subject to strict limits. These limits include significant safety margins to prevent deterministic effects from appearing, as well as aiming to reduce the appearance of probabilistic effects in the long term to the lowest level possible.

Exceeding these limits leads to an abnormal situation and one which may give rise to administrative or criminal sanctions.

In the case of medical exposure of patients, no dose limit is set, provided that this voluntary exposure is justified by the expected health benefits for the person exposed.

1.1.8 The prevention principle

To anticipate any environmental damage, the prevention principle, defined in Article 3 of the Environment Charter, stipulates the implementation of rules and measures which must take account of *"the best available technology at an economically acceptable cost"*.

In the nuclear field, this principle underpins the concept of "Defence in Depth", presented below.

1. The ALARA (As Low As Reasonably Achievable) principle appeared for the first time in Publication 26 from the International Commission on Radiological Protection (ICRP) in 1977. It was the result of a process of reflection on the principle of optimising radiological protection. Over the past thirty years, the acceptance and implementation of the ALARA principle has developed significantly in Europe, with strong backing from the European Commission, leading in 1991 to the creation of a European ALARA network.

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.

1.2 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.

A research project on safety culture within ASN began in September 2023. This study, conducted in partnership with the Nantes-Atlantique Economy and Management Laboratory of Nantes University, will last one year. It will cover the three components of ASN regulation and oversight (examination, inspection and enforcement), through three levels of analysis: strategic (political and managerial communications with the staff), organisational system (structure, formal framework for inspection practices) and operational (actual reality of practices, their effects on the ASN and licensee staff).

1.2.2 The "Defence in Depth" concept

The concept of "Defence in Depth" consists in implementing a series of levels of defence based on the intrinsic characteristics of the installation, material, organisational and human measures and procedures designed to prevent accidents and then, if this fails, to mitigate their consequences. "Defence in Depth" is a concept which applies to all stages in the lifetime of a facility, from design to decommissioning.

These levels of defence are consecutive and independent in order to prevent an accident from developing.

An important element for the independence of the levels of defence is the use of different technologies ("diversified" systems).

The design of nuclear installations is based on a "Defence in Depth" approach. For example, the following five levels are defined for nuclear reactors:

Level 1: Prevention of abnormal operation and system failures
This is a question firstly of designing and building the facility in a robust and conservative manner, integrating safety margins and planning for resistance with respect to its own failures or to hazards. It implies conducting the most exhaustive study possible of normal operating conditions to determine the severest stresses to which the systems will be subjected. It is then possible to produce an initial design basis for the facility, incorporating safety margins. The facility must then be maintained in a state at least equivalent to that planned for in its design through appropriate maintenance. The facility must be operated in an informed and careful manner.

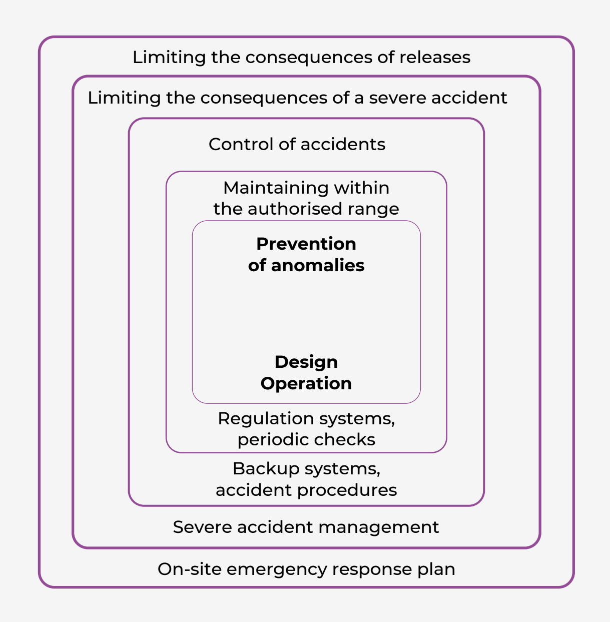
Level 2: Keeping the installation within authorised limits
Regulation and governing systems must be designed, installed and operated such that the installation is kept within an operating range that is far below the safety limits. For example, if the temperature in a system increases, a cooling system starts up before the temperature reaches the authorised limit. Condition monitoring and correct operation of systems form part of this level of defence.

Level 3: Control of accidents without core melt
The aim here is to postulate that certain accidents, chosen for their "envelope" characteristics (the most penalising in a given family), can happen and to design and size backup systems to withstand those conditions.

Such accidents are generally studied with pessimistic hypotheses, that is to say the various parameters governing this accident are assumed to be as unfavourable as possible. In addition, the single failure criterion is applied, in other words we postulate that in the accident situation and in addition to the accident, there will be the most prejudicial failure of one of the components used to manage this situation. As a result of this, the systems brought into play in the event of an accident ("safeguard" systems ensuring emergency shutdown, injection of cooling water into the reactor, etc.) comprise at least two redundant and independent channels.

Level 4: Control of accidents with core melt
These accidents were studied following the Three Mile Island accident in the United States (1979) and are now taken into account in the design of new reactors such as the European Pressurised Water Reactor (Evolutionary Power Reactor – EPR). The aim is to preclude such accidents or to design systems that can withstand them.

The 5 levels of "Defence in Depth"



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 NPPs, the level 1 PSAs consist in establishing event trees for each "initiating event" leading to the activation of a safeguard system (level 3 of "Defence in Depth"), defined by the 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.

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, organisational and human factors

The importance of Social, Organisational and Human Factors (SOHF) 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 SOHF as being all the aspects of working situations and the organisation which will have an influence on the work done by the operators. The elements considered concern the individual (training received, fatigue or stress, etc.) and the organisation within which they work (functional and hierarchical links, joint contractor work, etc.), the technical arrangements (tools, software, etc.) and, more broadly, the working environment with which the individual interacts.

The working environment for instance concerns the heat, sound or light environment of the workstation, as well as the accessibility of the premises.

The variability in worker characteristics (vigilance varies with the time of day, the level of expertise varies according to the seniority in the position) and in the situations encountered (unexpected failure, social tension) explains that these workers constantly need to adapt how they work in order to optimise effectiveness and efficiency. This goal must be achieved at an acceptable cost to the persons concerned (in terms of fatigue or stress) and provide a benefit to them (the feeling of a job well done, recognition by both peers and the hierarchy, development of new skills). Thus, an operating situation or a task achieved at very high cost to the operators is a potential source of risks: a small variation in the working context, human environment or working organisation can prevent the persons concerned from performing their tasks as expected.

Integration of SOHF

ASN considers that SOHF 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 SOHF 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. That concerning the radiation protection of patients is the responsibility of the Minister for Health. These roles are currently held by the Minister for Labour, Health and Solidarity.

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.

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.

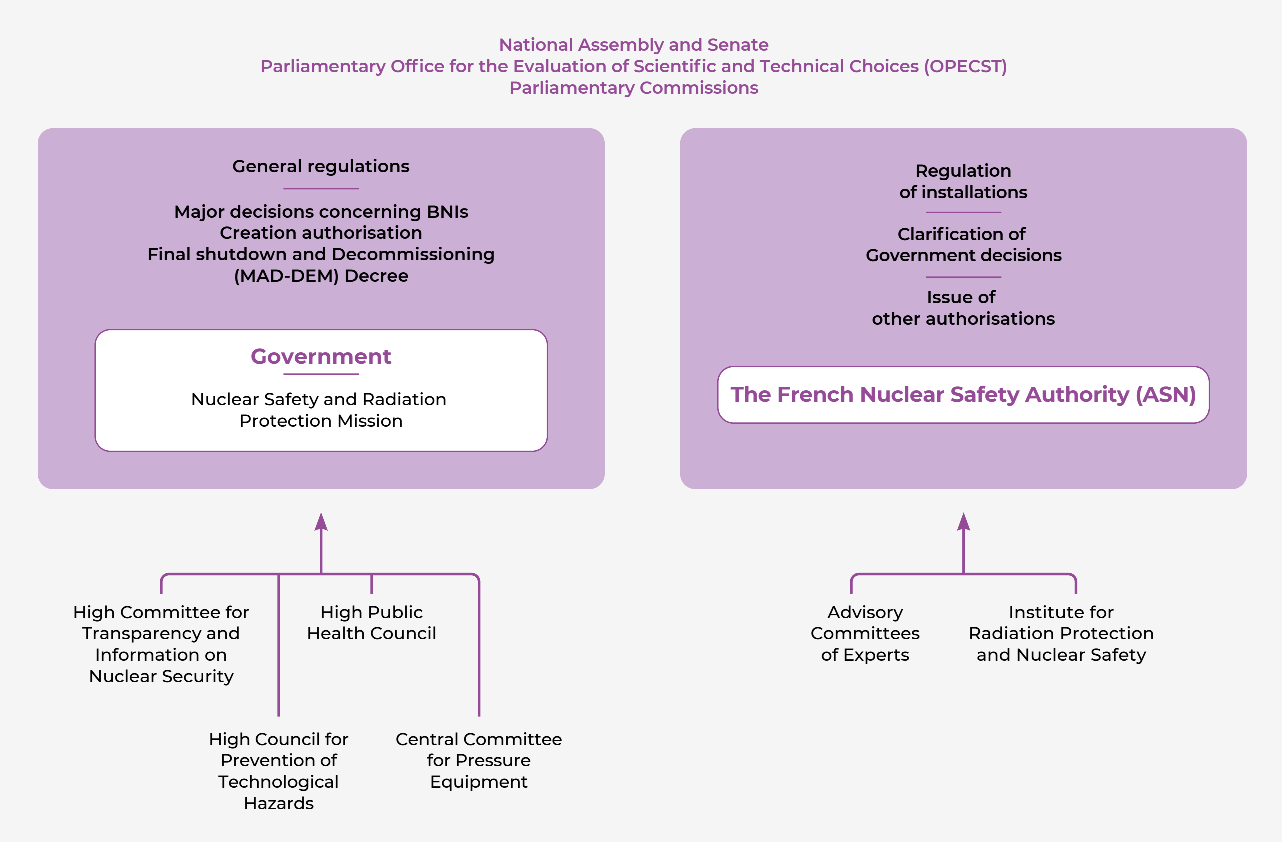
ASN maintains close relations with the Regional Directorates for the Environment, Planning and Housing (Dreal), the Regional and Interdepartmental Directorate for Public Works, Development and Transport of Île-de-France (Drieat), the Regional Directorates for the Economy, Employment, Labour and Solidarity (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.

Regulation of nuclear safety and radiation protection in France



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*.

Regulation and oversight
ASN verifies compliance with the general rules and specific requirements for nuclear safety and radiation protection applicable to BNIs, to the PE designed specifically for these facilities and to the transport of radioactive substances. It also regulates the activities mentioned in Article L. 1333‑1 of the Public Health Code and the ionising radiation exposure situations defined in Article L. 1333‑3 of the same Code. ASN organises a permanent radiation protection watch throughout the national territory.

From among its staff, it appoints nuclear safety inspectors, radiation protection inspectors and inspectors carrying out labour inspectorate duties.

ASN issues the required approvals and certifications to the organisations participating in the verifications and in nuclear

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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 which take part 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 managing radiological emergency situations. It provides technical assistance to the competent Authorities for the drafting of emergency response plans, taking account of the risks resulting from nuclear activities.

When such an emergency situation occurs, ASN verifies the steps taken by the licensee to make the facility safe. It assists the Government with all matters within its field of competence and submits its recommendations on the medical or health measures or civil protection steps to be taken. It informs the general public of the situation, of any releases into the environment and their consequences. It acts as the Competent Authority within the framework of international conventions, by notifying international organisations and foreign countries of the accident.

Chapter 4 of this report describes ASN actions in this field.

In the event of an incident or accident concerning a nuclear activity and, pursuant to Articles L. 592-35 and R. 592-23 *et seq.* of the Environment Code relative to technical inquiries into accidents or incidents concerning a nuclear activity, ASN may carry out a technical inquiry.

Information
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), since 2012, ASN has regularly issued opinions on the need for research on subjects with major nuclear safety and radiation protection implications. In 2023, ASN notably published an opinion on research subjects requiring greater investigation in the field of the ageing of non-metallic materials for the continued operation of the nuclear power reactors beyond the initial operating lifetime included in the design of some of their equipment. Its opinions and those of its Scientific Committee are published on *asn.fr* and are transmitted to the public and private research programmers. ASN is continuing to reinforce its relations with the research organisations and the institutions in charge of programming and funding research at both national and European levels.

ASN takes part in the steering committee for the "Nuclear Safety and Radiation Protection Research" (RSNR) Call for Projects, launched in 2013 by the National Research Agency, under the Investments in the Future programme, for which funding was completed in 2023. The evaluation made of this action in 2023 will return its conclusions during the course of 2024.

2.3.2 Organisation

ASN Commission
The ASN Commission comprises five full-time Commissioners. Their mandate is for a period of six years and is not renewable. The Commissioners perform their duties in complete impartiality and receive no instructions from either the Government or any other person or institution. The President of the Republic may terminate the duties of any member of the Commission in the event of a serious breach of his or her obligations.

The Commission defines ASN's strategy. More specifically, it is involved in developing overall policy, *i.e.* the doctrines and principles that underpin ASN's main missions of regulation, inspection, transparency, management of emergency situations and international relations.

Pursuant to the Environment Code, the Commission submits ASN's opinions to the Government and issues the main ASN regulations and decisions. It decides on the public position to be adopted on the main issues within ASN's sphere of competence. The Commission adopts the ASN internal rules of procedure which set out its organisation and working rules, as well as its ethical guidelines (see page 134). The Commission's decisions and opinions are published in the ASN *Official Bulletin*.

In 2023, the ASN Commission met 49 times. It issued 22 opinions and 26 decisions.

Administrative Enforcement Committee
"Nuclear" Ordinance 2016-128 of 10 February 2016 created the ASN Administrative Enforcement Committee (Articles L. 592-41 to L. 592-44 of the Environment Code). It was set up on 19 October 2021. The creation of this Committee supplements the arsenal of enforcement measures available to ASN. When referred to by the ASN Commission, it 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 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 *Cour de Cassation*. It also comprises alternate members. The duration of the members' mandate is six years.

At their first meeting, on 19 October 2021, the regular members elected Mr. Maurice 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.

An annual information exchange meeting between the members of the Administrative Enforcement Committee, the ASN Commission and the ASN general management concerning the year 2023, was held on 8 January 2024.

The members of the executive committee

***From left to right:* J. Collet, P. Bois, O. Gupta, D. Delalande, V. Cloître and C. Quintin (*not on photo:* S. Cadet-Mercier)**

As set out by law, the Committee will meet exclusively when convened by the ASN Commission. This latter may decide to open a procedure leading to issue of a fine after clearly determining that the person responsible for nuclear activities has not complied with a formal notice, in other words has not taken the measures required by this formal notice.

The fines will be proportional to the seriousness of the observed breaches and in particular take into account the extent of the impact on the environment. The maximum amount of the fines is set by law at 10 million euros, in the event of a breach of the provisions applicable to BNIs, one million euros for a breach of the provisions applicable to NPE, €30,000 in the field of transport of radioactive substances, and €15,000 for small-scale nuclear activities.

The administrative fine issue procedure includes compliance with the adversarial principle. No penalty can be imposed without the party concerned or their representative having been heard or summoned. The Committee's decision may be made public. The decisions pronounced by the Administrative Enforcement Committee may be referred to the administrative jurisdiction (Council of State) by the person concerned, by the ASN Chairman or by the third parties.

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, a delegation in charge of innovative reactors, and nine departments covering specific themes.

Under the authority of the ASN Director General, the Executive Committee organises and manages the departments on a day-to-day basis. It ensures that the orientations determined by the Commission are followed and that ASN's actions are effective. It oversees and coordinates the various entities.

The role of the departments is to manage national affairs concerning the activities under their responsibility. They take part in defining the general regulations and coordinate and oversee the actions of the ASN regional divisions:

- The Nuclear Power 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 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 underground research laboratory (Meuse/Haute-Marne) 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

The members of the management committee

From left to right: **F. Simon, A. Clos, F. Feron, R. Catteau, O. Rivière, J. Husse, C. Messier, C. Picart and A. Contesso (*not on photo:* L. Chanial, P. Dupuy, J.-P. Goudalle et C. Rousse)**

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 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.

The Regional Division Heads

From left to right: **R. Zmyslony, A. Baltzer, M. Rasson, M. Champion, G. Lafforgue-Marmet, E. Jambu, C. Périer and P. de Guibert (*not on photo:* A. Fontaine, N. Khater et M. Riquart)**

- The Innovative Reactors Delegation (MRI) is responsible for checking industrial or experimental prototype for new Small Modular Reactor (SMR) projects which use a technology other than that of the PWRs. Oversight concerns the technical but also the organisational and human aspects of nuclear safety, radiation protection, environmental protection, safety-security interfaces and the management of emergency situations.

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 Drieat 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 2023, the ASN total headcount stood at 521 staff, divided among the head office departments (303 staff) and the regional divisions (218 staff).

This workforce can be further broken down as follows:
- 466 tenured or contract staff members;
- 55 staff members seconded by public establishments (National Radioactive Waste Management Agency – Andra, Alternative Energies and Atomic Energy Commission – CEA, IRSN, Departmental Fire and Emergency Response Service - SDIS).

ASN utilises a diversified hiring policy with the aim of ensuring that there are sufficient numbers of the qualified and complementary human resources needed to perform its duties.

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 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 NPPs, 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 2023, ASN employed 317 nuclear safety or radiation protection inspectors holding at least one qualification, or nearly 61% of the 521 ASN staff.

The Regional Representatives (as at 31 December 2023)

***From left to right:* S. Forest, J.-P. Deneuvy, A. Beauval, H. Brûlé, E. Gay, J. Labit and H. Vanlaer (*not on photo:* O. David, V. Jechoux et O. Morzelle)**

Training re-engineering work to adapt the modules following the Covid-19 pandemic, led to optimisation of the training time. Thus in 2023, 2,445 days of training were provided for the ASN staff over a wide variety of topics, representing 111 training actions either face to face or by video-conference. These figures are supplemented by a large number of hours devoted to self-training by each trainee.

The training committee ensures that the training system matches the needs and strategic objectives set out in the Multi-Year Strategic Plan (PSP).

Social dialogue

As a State administration, ASN has three social dialogue bodies:
- the Local Social Administration Committee (CSAP) which replaced the Social Dialogue Committee as of 1 January 2023;
- the Joint Consultative Commission (CCP);
- the Organisation specialising in health safety and working conditions (FSSSCT) set up within the CSAP, as of 1 January 2023, and which takes over most of the duties of the former committee (Committee for Health, Safety and Working Conditions – CHSCT).

The CSAP and its specialist organisation are two bodies which allow extensive and regular discussions on all subjects affecting collective work issues.

The CSAP deals with questions regarding the organisation and working of the departments, the strategic orientations for human resource policy and the organisation of work.

The specialist organisation is competent for topics regarding the protection of physical and mental health, hygiene, staff safety, the use of digital tools and improvements to working conditions.

The CCP is a body that is competent to examine and be consulted on certain decisions regarding the individual situation of contractual staff.

During the course of 2023, the ASN CSAP met six times to deal with various subjects (organisation and working of the departments, additional social protection, the HR policy implemented to reinforce the attractiveness of ASN, renewal of the IT equipment and the deployment of Rainbow (instant messaging and video-conference software), inclusion of SOHF in dealing with the merger between ASN and IRSN, etc.).

It issued opinions on the texts presented by the administration (the internal rules of procedure of the bodies, the creation of an MRI delegation, the internal procedure for collecting and processing whistle-blower alerts, an assessment of tele-working, the single social report, the travel charter, etc.).

The CSAP was specifically asked for its opinion on the bill concerning the organisation of nuclear safety and radiation protection governance, in order to address the challenge of the nuclear industry's revival.

For its part, the FSSSCT met twice in 2023. It placed great emphasis on taking account of occupational health and safety aspects, the prevention of occupational risks, improvement of working conditions in ASN's organisation and operations modification projects and in the performance of its duties.

As part of its role of preventing occupational risks, the FSSSCT was informed of the intended procedure for Psychosocial Risks Management (RPS), as well as the system for sending staff to the site in the event of an emergency.

The FSSSCT also issued opinions on the assessment of radiation protection in 2023 and the plans to redevelop the head office premises.

The CCP, which has competence for the contractual staff, met once in 2023. The debates primarily concerned the working methods of the CCP, for which the mandates were renewed during the professional elections of December 2022.

Finally, the social dialogue process involved regular meetings between the personnel representatives throughout the year.

For the purposes of the merger between IRSN and ASN, planned to take place on 1 January 2025, the trades union organisations at ASN and IRSN signed an agreement in December 2023 creating a Consultative Committee for the Merger Project (called the "CCPF") which supplements the personnel representative bodies of each entity, in order to promote consultation between the general management and personnel representatives of both ASN and IRSN.

"Nuclear safety" inspector training programme, Pressurised Water Reactor (PWR), Laboratories, Plants, Decommissioning and Waste (LUDD) and cross-disciplinary qualification

Mandatory qualification

"ASN core activities" basic training
- Inspection at ASN
- Sanctions
- General knowledge of ASN personnel
- Regulation radiation protection training for ASN staff likely to intervene in a regulated area
- Introduction to general communication

Joint "nuclear safety" "qualifying" technical training
- Nuclear licensees routine operation approach – Immersion
- BNI technical regulations

Specific PWR training
- PWR
- Fire
- External hazards
- Ventilation
- Nuclear Pressure Equipment
- Monitoring of PWR safety

Specific LUDD training
- Introduction to atomic engineering
- Fire
- External hazards
- Ventilation

Specific cross-disciplinary training
- PWR
- Fire
- External hazards
- Ventilation

Qualifying professional experience

Joint nuclear safety inspector qualifying experience
- Has followed two inspections as an observer
- Has played a hands-on role in three inspections

PWR inspectors qualifying experience (excludining Pressure Equipment – PE), LUDD
- Has taken part in three Article 26 notification examinations
- Has taken part in three significant event investigations (ASN regional divisions)

PWR inspector qualifying experience with intervention limited to PE field
- Has taken part in investigating five PE-related files
- Has taken part in three technical meetings on PE-related topics
- A tutor's report produced following the training period

Professional ethics

The ethical rules concerning the ASN Commissioners, staff and experts, as set out in several legislative and regulatory texts since 2011, are compiled in the two appendices to the ASN internal rules of procedure adopted in 2018: the first contains provisions regarding the professional ethics of the Commissioners and staff, while the second contains provisions concerning external analysis and assessment performed at the request of ASN, for example by the GPEs (see below).

With the aim of preventing conflicts of interest, the rules in force at ASN more specifically include the following declaration obligations:

- Public Declaration of Interests (DPI) stipulated in Article L. 1451-1 (derived from Act 2011-2012 of 29 December 2011 on strengthening the safety of drugs and health products) and Articles R. 1451-1 *et seq.* of the Public Health Code: the 4 July 2012 resolution CODEP-CLG-2012-033820 by the ASN Chairman applies the DPI requirements to the members of the Commission, the management committee and the Advisory Committee for Radiation Protection for Medical and Forensic Applications of Ionising Radiation (GPMED), now incorporated into the Advisory Committee for Radiation Protection (GPRP) and the regional delegates and regional division heads. Until mid-July 2017, the DPI were posted on *asn.fr*. The DPI are henceforth declared on the single on-line declaration site. About 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 members of the administrative enforcement commission, the Director General, the Deputy Director Generals, and the General Secretary since 15 February 2017 following modification of the Act of 13 October 2013;
- "Civil Service" Declaration of Interests, set out in Article L. 122-2 of the General Civil Service Code governed by Decree 2016-1967 of 28 December 2016: the professional ethics coordinator and the ASN staff carrying out labour inspectorate duties in the NPPs are subject to this obligation;
- management by the ASN Director General of his financial instruments in conditions which preclude all right of review on his part, pursuant to Article L. 122-19 of the General Civil Service Code and Decree 2017-547 of 13 April 2017: the ASN Director General submitted justification data to the HATVP before 2 November 2017.

In a decision dated 28 January 2020, the ASN Chairman appointed Mr. Alain Dorison as professional ethics officer.

He was also appointed as secularity coordinator for internal alerts in this same decision.

He was reappointed for a further three-year term by a resolution dated 30 January 2023.

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.

Over and above implementing the obligations recalled above, ASN defined an internal inspection procedure for staff wishing to work in the private sector or to apply to combine activities in order to create or take over a business, in accordance with the Civil Service Transformation Act 2019-828 of 6 August 2019 and Decree 2020-69 of 30 January 2020. Actions were also taken to raise personnel awareness of the internal professional ethics culture and prevent conflicts of interest. These were for example posting practical documents on-line on the intranet (such as prevention of conflicts of interest and the role of professional ethics oversight of departures to the private sector), the insertion of a module concerning professional ethics rules applicable to ASN staff during training sessions organised for newcomers and a video interview in which the professional ethics coordinator uses a number of examples to describe professional ethics and which actions in a person's professional life demand particular vigilance.

Over the course of 2023, the professional ethics officer was contacted for 23 individual cases, broken down as follows:
- 3 opinions on a hiring;
- 10 opinions on continuation of a career;
- 8 opinions on related activities;
- 2 opinions on professional behaviour.

Mr. Alain Dorison was also contacted regarding a case in his capacity as secularity coordinator.

Financial resources
ASN's financial resources are presented in point 3.

In its opinion 2023-AV-0422 of 22 June 2023 relative to the nuclear safety and radiation protection inspection budget in France for the years 2023-2027, ASN asked for its workforce to be increased over the period 2024-2027 by 29 Full-Time Equivalent (FTE), including 12 as of 2024. ASN repeated its request for modification of the scope of its budget and the creation of a single budget programme for nuclear safety and radiation protection under the responsibility of the ASN Chairman.

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.* 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 PSP 2023-2027 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.

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 for ensuring safety in this field. These missions take account of regulatory, technical and strategic aspects, make comparisons with IAEA Safety Standards and, as applicable, take account of best 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.

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.

In 2006, ASN welcomed the first IRRS review mission concerning all the activities of a safety regulator. A follow-up mission took place in 2009 and then ASN welcomed a further IRRS mission in 2014, expanded to take in management of the safety/security interfaces. This mission then led to a follow-up mission in 2017. The reports from these various missions can be consulted on *asn.fr*.

A new IRRS mission had been scheduled for March 2024, but given the ongoing reforms to nuclear safety and radiation protection regulation and oversight, the decision was taken to postpone this mission to a time when the new organisation is in place.

In addition, several ASN staff members also take part as experts in IRRS missions abroad.

The HCTISN can issue an opinion on any question in these fields, as well as on controls and the relevant information. It may also examine all questions concerning the accessibility of information on nuclear safety and propose all measures such as to guarantee or improve nuclear transparency. It can be called on by the Government, Parliament, the CLIs or the licensees of nuclear facilities, with regard to all questions relating to information about nuclear safety and its regulation and oversight.

The HCTISN's activities are described in chapter 5.

2.4.2 The High Council for Public Health

The High Council for Public Health (HCSP), created by Act 2004-806 of 9 August 2004 concerning public health policy, is a scientific and technical consultative body reporting to the Minister 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 BNI Local Information Committees (CLIs) are tasked with a general duty of monitoring, information and consultation on the subject of nuclear safety, radiation protection and the impact of nuclear activities on humans and the environment, with respect to the facilities on the site or sites which concern them. They may request expert assessments or have measurements taken on the installation's discharges into the environment.

The CLIs, whose creation is incumbent upon the President of the General Council of the *département*, comprise various categories of members: representatives of *département* General Councils, of the municipal councils or representative bodies of the groups of 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 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 2023, the IRSN total workforce stood at 1,783 staff; IRSN's technical support for ASN mobilised 430 FTE personnel in 2023.

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 resolutions, 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 Advisory Committees every four years. In 2023, they were broken down according to their areas of expertise:
- the Advisory Committee of Experts for Decommissioning (GPDEM);
- the Advisory Committee of Experts for Nuclear Reactors (GPR);
- the Advisory Committee of Experts for Laboratories and Plants (GPU);
- the Advisory Committee of Experts for Waste (GPD);
- the Advisory Committee of Experts for Transport (GPT);
- the Advisory Committee of Experts for Nuclear Pressure Equipment (GPESPN);
- the Advisory Committee of Experts for 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)
The GPDEM comprises experts appointed for their competence in the field of BNI decommissioning. It comprises 32 members and is chaired by Chantal Mommaert.

Advisory Committee for Waste (GPD)
The GPD is chaired by Marie-Pierre Comets and comprises experts appointed for their competence in the nuclear, geological and mining fields. It comprises 35 members.

Advisory Committee for Nuclear Pressure Equipment (GPESPN)
The GPESPN has been chaired by Matthieu Schuler since 6 October 2018, and comprises experts appointed for their competence in the field of NPE. It has 33 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.

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.

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. 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. 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. It comprises 30 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 eight current members of the Scientific Committee, on the basis of their expertise notably in the fields of research. Under the Chairmanship of Michel Schwarz, the Committee in 2023 consisted of 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 2023. It continued its meetings with research organisations, notably in the fields of ageing of the metal materials of nuclear power reactors, metrology on nuclear sites undergoing post-operational clean-out, and the combined effects of mixtures of chemical and radiological toxic substances.

The Scientific Committee issued its opinion on metrology in a site post-operational clean-out situation (contaminated facilities and soils). It is published on *asn.fr*.

2.5.4 ASN's other technical support organisations

To diversify its expertise and benefit from other particular skills, ASN committed credits of about €175,000 in 2023.

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 contract to provide it with external expertise on organisational and human factors, as well as on the non-radiological risks from nuclear facilities. Finally, it financed the setting up of a patient monitoring register for adaptive radiotherapy treatment.

2.6 THE PLURALISTIC WORKING GROUPS

ASN has set up several pluralistic working groups; they enable the stakeholders to take part in developing doctrines, defining action plans or monitoring their implementation.

2.6.1 The working group on the National Radioactive Material and Waste Management Plan

Article L. 542-1-2 of the Environment Code requires the drafting of a National Radioactive Material and Waste Management Plan (PNGMDR), which is revised every five years and serves to review the existing management procedures for radioactive materials and waste, to identify the foreseeable needs for storage and disposal facilities, specify the necessary capacity of these facilities and the storage durations and, for radioactive waste for which there is as yet no final management solution, determine the objectives to be met.

The Working Group (WG) tasked with 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).

TABLE 1 **Advisory Committee of Experts meetings in 2023**

GPE	DATE	MAIN TOPIC
GPESPN	24 January 2023	• GPESPN opinion on the baseline safety requirements for components, the situation and the workloads for the EPR 2 – with participation by members of the GPR
GPR	31 January 2023	• Participation by the GPR and GPESPN in the preparatory meeting of the ACRS (Advisory Committee on Reactor Safeguard – consultative group on reactor safeguards)
GPR	17 February 2023	• Kick-off meeting
GPU	8 March 2023	• Visit to BNI 29 – CIS bio international, in Saclay
GPR	14 and 15 March 2023	• During the ACRS, participation of the GPR and GPESPN in the discussions about PWR safety, between equivalent entities in Washington (guest countries: Canada, France, Great Britain, Japan, South Korea, United States)
GPU	16 March 2023	• Kick-off meeting • GPU opinion on the Periodic safety review of BNI 29 – CIS bio international
GPDEM	20 March 2023	• Visit to BNIs 165 and 166 – Fontenay-aux-Roses
GPDEM	21 March 2023	• Visit to BNI 56 – Le Parc, in Cadarache
GPDEM	23 March 2023	• Kick-off meeting • Information meeting with EDF – Gas-Cooled Reactor (GCR) decommissioning strategy
GPD	28 March 2023	• GPD kick-off meeting • Information meeting with Andra – *Cigéo* Creation Authorisation Decree (DAC)
GPDEM	4 April 2023	• GPDEM opinion on the decommissioning decree modification request, the installation's periodic safety review, Measuring and Conditioning Equipment (EMC) and safety options files of the STD (BNI 166) in the CEA Centre in Fontenay-aux-Roses
GTRPP	6 April 2023	• Presentation of IRSN referral – Bibliographical study of new radionuclides and prospects for clinical uses in France & Radiation protection of patients and their entourage • Presentation of the opinion of the Committee for Analysis of New Techniques and Practices using Ionising Radiation (Canpri) on the ZAP-X radiosurgery gyroscopic platform – Artificial intelligence in the medical world: what are the challenges?
GPRP	11 April 2023	• Draft opinion on the demarcation of zones applicable to pulsed field working equipment (application of Article R. 4451- 23 I 2° of the Labour Code – GPRP approval) • Presentation of the Canpri opinion and IRSN expert assessment on the ZAP-X radiosurgery gyroscopic platform
GPDEM	14 April 2023	• GPDEM opinion on the decommissioning file for the CEA storage facility (BNI 56) in Cadarache
GPESPN	25 and 26 May 2023	• Kick-off meeting • GPESPN opinion on maintaining as-is the indications detected during the search for stress corrosion cracks, over more than one cycle
GPESPN	1 June 2023	• GPESPN opinion on maintaining in-service austenitic-ferritic stainless steel elbow castings on the main primary system of the 900 MWe reactors and the nozzles of the Safety Injection Systems (SIS) of Paluel NPP reactors 1 and 2
GPU	2 June 2023	• GPU visit to the UP3-A plant (BNI 116) at La Hague
GTRPP	6 June 2023	• Presentation of the working group report on the Diagnostic Reference Levels (DRLs) in mammography • Presentation of the results of the survey carried out by the Centre for Studies on Evaluating Protection in the Nuclear field (CEPN) at the request of ASN, regarding patient radiation protection training • Presentation of the "entourage recommendations" referral – creation of the working group
GPU	8 June 2023	• GPU opinion on the periodic safety review of the T0 units, pools D and E in the UP3-A plant (BNI 116) at La Hague
GPR	13 June 2023	• GPR opinion on the guidelines for the fourth periodic safety review of the 1,450 MWe reactors
GPESPN	20 and 21 June 2023	• Information meeting – 2nd closing GP on the NPE, EPR reactor subjects
GPDEM	22 June 2023	• GPDEM opinion on the decommissioning file for the Fessenheim NPP (BNI 75)
GPR	29 June 2023	• GPR opinion on OEF from the year 2021
GPRP	6 July 2023	• International news – Presentation of the draft report from the International Commission on Radiological Protection (ICRP) on dose coefficients after internal exposure of members of the public (Part 1 – TG95) and dose coefficients for workers (comparisons between the new and the old coefficients) • GTRPP opinion on the referral concerning "RDL in mammography" (GPRP approval)
GPD	27 and 28 September 2023	• Visit to Andra's Meuse/Haute-Marne centre (*Cigéo* DAC)
GPRP	3 October 2023	• News – Changes to the organisation of regulation and research in radiation protection and nuclear safety • Low doses – Inworks 2023 study on the link between low dose ionising radiation and cancer-related deaths – IRSN viewpoint on the Linear No Threshold (LNT) model • Presentation of the IRSN report concerning occupational exposure to ionising radiation in France – 2022 results • Draft GPRP opinion on RDL in mammography (GPRP approval)
GPESPN	17 October 2023	• GPESPN opinion on maintaining in-service the channel heads of the steam generators manufactured by JCFC and FLC
GPR	20 October 2023	• Fifth periodic safety review of the 900 MWe reactors – Preliminary discussion on guidelines
GTRPP	28 November 2023	• Presentation of the IRSN report on the use of Cone beam computed tomography (CBCT) in the dental field, and the draft referral by ASN (creation of the working group) • Presentation of the progress of the report from the "notice to promoters" working group
GPRP	5 December 2023	• Presentation of the IRSN report on the use of CBCT in the dental field, and the draft referral by ASN (creation of the working group) • Presentation of the progress of the report from the "notice to promoters" working group: identification of the rapporteurs • ASN referral on existing exposure situations
GPDEM	7 December 2023	• Information meeting – Presentation of the decommissioning guide

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 from learned societies, appointed by ASN, along with representatives of the French health institutions (National Authority for Health – HAS, National Cancer Institute – INCa, Ministry responsible for health, IRSN). 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. Barring exceptions, it meets twice a year. In 2023, its work led it to issuing an opinion on the conditions surrounding the installation in France of the ZAP-X gyroscopic radiosurgery platform. For more details on the other subjects with which it dealt, refer to point 1.3.2 of chapter 7.

2.6.4 The other pluralistic working groups

Considering that it was necessary to move forward with regard to the deliberations and the work being done on the contribution of humans and organisations to the safety of nuclear facilities, ASN decided in 2012 to set up the Steering Committee for Social, Organisational and Human Factors (Cofsoh). The purpose of the Cofsoh is on the one hand to allow exchanges between stakeholders on such a difficult subject as SOHF 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 shortage of data or lack of 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*. 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*. 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.

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 €559.62 million in 2023. The proceeds go to the central State budget.

For certain BNIs, said Act also creates three additional taxes, known as "research", "support" and "disposal", respectively. The revenue from these taxes amounted to €124.51 M in 2023 and is paid to the *Objectif Meuse et Haute-Marne* public interest groupings ("support"), the municipalities and public inter-municipal cooperation bodies ("disposal") and Andra ("research"), in addition to the revenue from the special contribution.

In addition, since 2014, ASN has been tasked with assessing and ordering payment of the special contribution on behalf of Andra created by Article 58 of the 2013 Budget Amendment Act 2013-1279 of 29 December 2013, which will be payable up until the date of the deep geological disposal facility's creation authorisation.

In the same way as the additional taxes, this contribution is due by BNI licensees, as of the creation of their facility and up until the delicensing decision. The revenue from this contribution represents €79.33 M in 2023.

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 €61.14 million in 2023..

TABLE 2 Status and activities of the main civil nuclear safety regulators(*)

COUNTRY/ REGULATORY AUTHORITY	STATUS			ACTIVITIES							
	ADMINIS-TRATION	GOVERNMENT AGENCY	INDEPENDENT AGENCY	SAFETY OF CIVIL FACILITIES	RADIATION PROTECTION			SECURITY (PROTECTION AGAINST MALICIOUS ACTS)		TRANSPORT SAFETY
					LARGE NUCLEAR INSTALLATIONS	OUTSIDE BNIs	PATIENTS	SOURCES	NUCLEAR MATERIALS	
Europe										
Germany/*Bmub + Länder*	■			■	■	■	■	■	■	■
Belgium/AFCN		■		■	■	■	■	■	■	■
Spain/CSN			■	■	■	■	■	■	■	■
Finland/STUK		■		■	■	■	■	■	■	■
France/ASN			■	■	■	■	■	■(**)		■
United Kingdom/ ONR		■		■	■			■	■	■
Sweden/SSM		■		■	■	■	■	■	■	■
Switzerland/ENSI			■	■	■				■	■
Other countries										
Canada/CCSN			■	■	■	■	■	■	■	■
China/NNSA	■			■	■	■		■	■	■
Korea/NSSC		■		■	■	■		■	■	■
United States/ NRC			■	■	■	■	■	■	■	■(***)
India/AERB		■		■	■	■	■	■	■	■
Japan/NRA		■	■	■	■	■	■	■	■	
Russia/ *Rostekhnadzor*	■	■		■	■			■	■	■
Ukraine/SNRIU	■	■		■	■	■		■	■	■

* Schematic, simplified representation of the main areas of competence of the entities (administrations, 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.

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 2023 Budget Act, the ASN budget (action 9 of programme 181 "Risk prevention") amounted to €71.62 million in payment credits. It included €53.79 million for personnel expenses and €17.83 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 regional 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".

TABLE 3 **Breakdown of licensee contributions**

LICENSEE	AMOUNT FOR 2023 (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	5.62
CEA	4.36	16.68	12.33	6.94
Andra	5.41	3.30	–	0.40
Others	1.25	1.67	–	0.71
Total	559.62	124.51	79.33	61.14

The total IRSN budget for 2023 amounted to €298 million, of which €85.1 million were devoted to the provision of technical support for ASN. IRSN credits for providing ASN with technical support come in part (€43.7 million) from programme 190 (see below). The rest (€41.4 million) comes from a contribution from the nuclear licensees. This contribution was set up under the amended Budget Act of 29 December 2010. Moreover, in the light of a rise in spending linked to inflation effects (mainly concerning salary levels, and operations) affecting all of IRSN's activities, including technical support for ASN, additional funding was obtained by drawing on the establishment's working capital.

In total, in 2023, the State's budget for transparency and the regulation and oversight of nuclear safety and radiation protection in France amounted to €311.87 million.

By way of comparison, the amount of taxes collected by ASN in 2023 amounted to €763.46 million:
- €559.62 million from BNI taxes (paid into the State's general budget);
- €124.51 million from additional "support", "disposal" and "research" taxes (allocated to various establishments, including Andra, municipalities and Public Interest Groupings – GIP);
- €79.33 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 2024 will be marked by the ASN and IRSN merger project. This project entails legislative and regulatory modifications that will be examined by Parliament during the first half of the year. At the same time, and in order to be ready on 1 January 2025, working groups set up jointly by ASN and IRSN will work to produce an organisational template. This template should enable full advantage to be taken from the resources and synergies of the two structures. All the personnel will be involved to varying degrees in the construction of this future Authority. Social dialogue will take place both through the existing social bodies and through a CCPF specially created for this purpose.

The MRI, created in 2023, will continue to ramp up in order to oversee the new industrial or experimental prototype SMR projects.

With regard to skills, and in line with implementation of the PSP, ASN will continue to 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.

With regard to the budget and funding, work will continue in conjunction with the other State departments on defining a budget programme to underpin the merger project.

With regard to expert assessment, the work to involve the various GPEs will continue given the growth in the volume of the important examinations, such as the Nuward project, the 4th periodic safety review of the 1,300 MWe reactors, the EPR 2 or the *Cigéo* project.

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 2022 AE (€M)	INITIAL BUDGET ACT 2022 CP (€M)	INITIAL BUDGET ACT 2023 AE (€M)	INITIAL BUDGET ACT 2023 CP (€M)	BNI TAX 2023 (€M)
Ministerial mission **Ecology, sustainable development and spatial planning**	**Programme 181:** Risk prevention	**Action 9:** Regulation of nuclear safety and radiation protection	Staff costs (including seconded employees)	50.67	50.67	53.79	53.79	559.62
			Operating and intervention expenditure	12.93	17.63	13.13	17.83	
			Total	63.60	68.30	66.92	71.62	
		Action 1: Prevention of technological risks and pollution	Operation (evaluation) of High Committee for Transparency and Information on Nuclear Safety	0.15	0.15	0.15	0.15	
			Sub-total	63.75	68.45	67.07	71.77	
Ministerial mission **Oversight of Government actions**	**Programme 217:** Management and coordination of policies for ecology, sustainable development and mobility **Programme 354:** State's regional administration	–	Part of the shared operation of ASN's 11 regional divisions (real estate, etc.)	The credits allocated to ASN for these various programmes cannot be identified owing to the overall, shared nature of these programmes				
Interministerial mission **Management of public finances and human resources**	**Programme 218:** Implementation and coordination of economic and financial policies	–	Part of the shared operation of the ASN central services					
Interministerial mission **Research and higher education**	**Programme 190:** Research in the fields of energy and sustainable development and spatial planning	**Sub-action 11-2 (area 3):** French Institute for Radiation Protection and Nuclear Safety	IRSN technical support activities for ASN	41.80	41.80	43.70	43.70	
		Sub-action 11-2 (3 other areas): French Institute for Radiation Protection and Nuclear Safety	–	129.00	129.00	135.70	135.70	
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)			–	19.36	19.36	19.27	19.27	
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			–	41.73	41.73	41.43	41.43	
			Sub-total	**231.89**	**231.89**	**240.10**	**240.10**	**559.62**
Grand Total (excluding IRSN and programmes 217, 218 and 354)				**147.28**	**151.98**	**152.20**	**156.90**	**559.62**
Grand Total ASN and IRSN (excluding programmes 217, 218 and 354)				**295.64**	**300.34**	**307.17**	**311.87**	

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.

CONTENTS

03

Regulation of nuclear activities and exposure to ionising radiation

03

In France, the party Responsible for a Nuclear Activity (RNA) must ensure that this activity is safe and may not delegate this responsibility. They must ensure permanent monitoring of both this activity and the equipment used. Given the risks linked to ionising radiation for humans and the environment, the State regulates nuclear activities, a task it has entrusted to the French Nuclear Safety Authority (ASN). With the aim of ensuring greater administrative efficiency, ASN has also been entrusted with the oversight of regulations concerning the environment and Pressure Equipment (PE) in Basic Nuclear Installations (BNIs).

Control and regulation of nuclear activities is a fundamental responsibility of ASN.

Its primary goal is to ensure that a party RNA effectively assumes its obligations. ASN has a vision of control and regulation encompassing material, organisational and human aspects. Following safety and radiation protection assessments in each activity sector, ASN implements its oversight action by issuing resolutions, 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 means deployed by those responsible for the activities to control them and their behaviour. In the priority areas, ASN must reinforce its oversight. Conversely, for lower-risk areas, ASN must be able to explicitly 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 a graded approach when determining its actions, so that the scope, conditions and extent of its regulatory action are commensurate with the human and environmental protection implications involved.

When applicable, this oversight can call on the support of the French Institute for Radiation Protection and Nuclear Safety (IRSN).

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 Substance Transport (TSR);
- the persons responsible for activities entailing a risk of exposure of persons and workers to ionising radiation, including medical applications of ionising radiation;
- those in charge of implementing ionising radiation exposure monitoring measures, such as the approved organisations and laboratories;
- the nuclear licensees, their suppliers, contractors or subcontractors 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 2023 concerning the inspection of the Nuclear Power Plants (NPPs) procurement chain.

In this chapter, these persons or entities are called the "licensees".

In addition, within the BNIs, the ASN inspectors have rights and prerogatives given to the environmental inspectors to verify the provisions regarding protection of the environment.

ASN also oversees the organisations and laboratories that it approves in order to take part in the inspections and oversight of nuclear safety and radiation protection.

Finally, ASN carries out labour inspectorate duties in the NPPs (see chapter 10).

2 Ensuring that regulation uses a graded approach to the implications

ASN aims to organise its regulatory work in a way that uses a graded approach 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 organisations and laboratories taking part in radioactivity measurements and radiation protection inspections, as well as qualification of PE monitoring organisations;
- presence in the field, also frequently outside actual inspections;
- consultation with the professional organisations (trades unions, professional orders, 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 PE, which include NPE.

The Environment Code states that ASN is the administrative Authority with competence for issuing individual resolutions and checking the in-service monitoring of the PE installed within the perimeter of a BNI.

PE operation is regulated. This regulation in particular applies to the in-service monitoring programmes, non-destructive testing, maintenance work, disposition of nonconformities affecting these systems and periodic requalification.

ASN also assesses the compliance of the most important new NPE with the requirements of the regulations. It approves and monitors the organisations responsible for assessing the conformity of the other NPE.

Regulation and monitoring of the transport of radioactive substances

Transport comprises all operations and conditions associated with movements of radioactive substances, such as packaging design, manufacture, maintenance and repair, as well as the preparation, shipment, loading, carriage, including storage in transit, unloading and receipt at the final destination of the radioactive substance consignments and packages.

Regulation and monitoring of activities comprising a risk of exposure to ionising radiation

In France, ASN is in charge of drafting and 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 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 eight Full-Time Equivalent – FTE – two of whom are for the labour inspectorate mission) has been reinforced in the field since 2009, particularly during reactor outages, with inspection visits, advisory roles at the meetings of the Committee for Health, Safety and Working Conditions (CHSCT) and the Inter-company Committees on Safety and Working Conditions, as well as regular discussions with the social partners.

2.2 INTERNAL CHECKS PERFORMED BY THE LICENSEES

2.2.1 Internal monitoring of the licensees of Basic Nuclear Installations

In 2017, ASN issued a resolution (2017-DC-0616 of 30 November 2017) which specifies the criteria for distinguishing the 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*.

ASN thus approves organisations so that they can perform the technical inspections or verifications required by the regulations in the fields within its scope of competence:
- radiation protection verifications;
- measurement of radon activity concentration in Public Access Buildings (PABs);
- assessment of NPE conformity and inspection of PE in service.

TABLE 1 **Methods of ASN regulation of the various radiation protection stakeholders**

	EXAMINATION/AUTHORISATION	INSPECTION	COOPERATION
Users of sources of ionising radiation	• Examination of the files required by the Public Health Code (Articles R. 1333-1 *et seq.*) • Pre-commissioning inspection, mainly in the medical field • Receipt of notification, registration or issue of authorisation (Article R. 1333-8)	• Radiation protection inspection (Article L. 1333-29 of the Public Health Code)	• Jointly with the professional organisations, drafting of guides of good practices for users of ionising radiation
Organisations approved for radiation protection checks	• Examination of approval application files for performance of inspections required by Article R. 1333-172 of the Public Health Code • Organisation audit • Delivery of approval	• Second level inspection: – in-depth inspections at head office and in the branches of the organisations – unannounced field supervision inspections	• Jointly with the professional organisations, drafting of rules of good practices for performance of radiation protection checks

In order to approve the applicant organisations, ASN ensures that they perform the inspections in accordance with their technical, organisational and ethical obligations and in compliance with the rules of professional good practice. Compliance with these provisions should enable the required level of quality to be obtained and maintained.

ASN ensures that benefit is gained from the approval, in particular through regular exchanges with the organisations it has approved and the mandatory submission of an annual report. Examination of these reports on the one hand makes it possible to check that the mandatory verifications have actually been carried out and, on the other, enables the licensees to be questioned about the steps taken to remedy any nonconformities.

In 2022, the Approved Organisations for Radiation Protection (AORPs) verifications carried out 28,439 verifications, with the breakdown per type of source and per field being given in Table 2. The main reason for the drop in the number of verifications is specified subsequently.

The reports of the verifications performed in each facility by the AORP verifications are at the disposal of and examined by ASN personnel on the occasion of:
- licence renewals or modifications requiring ASN authorisation;
- inspections.

ASN also approves laboratories to conduct analyses requiring a high level of measurement quality if the results are to be usable. It thus approves laboratories to monitor radioactivity in the environment (see point 4.3).

In addition, on the advice of the standing sub-committee in charge of the transport of hazardous goods within the High Council for the Prevention of Technological Risks (CSPRT), ASN approved:
- the training organisations for drivers of vehicles carrying radioactive materials; two organisations have been approved;
- the organisations responsible for certifying the conformity of packagings designed to contain 0.1 kilogramme (kg) or more of uranium hexafluoride (UF_6);
- 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_6 packagings.

As at 31 December 2023, the following are approved or accredited by ASN:
- ten organisations responsible for radiation protection verifications. No initial approval or approval renewal was issued during the course of 2023;
- 77 organisations responsible for measuring radon activity concentration in buildings (level 1), 15 of which are also approved to identify sources and entry routes and transfer of radon in buildings (level 2). In 2023, 42 new approvals or approval renewals were issued, 34 of which were level 1 and eight of level 2;
- four organisations qualified for NPE inspections as part of the new NPE conformity assessment;
- two organisations qualified for NPE inspections as part of in-service monitoring;
- three organisations qualified for PE and simple pressure vessels within the perimeter of BNIs (in-service monitoring);
- 18 inspection departments qualified for in-service monitoring of NPE and simple pressure vessels within the perimeter of NPPs;
- 67 laboratories for environmental radioactivity measurements covering 966 approvals currently valid as at 1 January 2024, of which 149 are approvals or approval renewals delivered or maintained during the course of 2023.

Since 2020, the regulations have gradually restricted the scope of intervention of the AORP by delegating the verification duties set out in the Labour Code to verification organisations accredited by the French Accreditation Committee (Cofrac). All of these verifications (Labour and Public Health Codes) were carried out under the previous regulations solely by the AORPs. In addition, the Public Health Code verifications no longer concern the BNIs. The number of AORP has significantly fallen as a result of these changes to the regulations.

In 2023, the regulations concerning the verifications and services performed by the AORPs changed.

Since 1 January 2023, the Order of 24 October 2022 relative to the procedures and frequencies of the checks on the rules put into place by the person RNA repealed ASN resolution 2010-DC-0175 of 4 February 2010 defining the procedures for verification of the AORPs. This text modifies the scope of the AORP verifications. The Order applies to medical and industrial nuclear activities subject to the systems set out in Article L. 1333-8 of the Public Health Code when these activities generate effluents or waste contaminated by radionuclides, or liable to be so contaminated, including by activation. It does not apply to nuclear activities from which the only waste generated is inseparable activated parts of a particle accelerator, as defined in Appendix 13-7 to the Public Health Code. ASN resolution 2022-DC-747, which entered into force on 5 February 2023, supplements this Order.

TABLE 2 Radiation protection verifications performed in 2022 by organisations approved for radiation protection verifications

	MEDICAL	VETERINARY	RESEARCH/ TEACHING	INDUSTRY EXCLUDING BNIs	BNIs	TOTAL
Sealed sources	128	0	353	13,072	724	14,277
Unsealed sources	133	0	223	12,471	83	12,910
Mobile electrical generators of ionising radiation	228	0	1	60	0	289
Fixed electrical generators of ionising radiation	249	4	204	497	7	961
Particle accelerators	0	0	0	2	0	2
Total	738	4	781	26,102	814	28,439

This resolution defines the rules specified in the Order of 24 October 2022, that the party in charge of a nuclear activity is required to have verified by an AORP. This resolution is based on rules defined in ASN resolution 2008-DC-0095 of 29 January 2008, specifying the technical rules to be met by the elimination of effluents and waste contaminated by radionuclides, or liable to be so contaminated as a result of a nuclear activity, as well as resolution 2014-DC-0463 of 23 October 2014 relative to the minimum technical rules for the design, operation and maintenance of *in vivo* nuclear medicine facilities.

Finally, ASN resolution 2010-DC-0191 of 22 July 2010 was replaced by resolution 2022-DC-0748 which entered into force on 5 February 2023. This resolution sets the conditions and procedures for approval of organisations responsible for the verifications mentioned in Article R. 1333-172 of the Public Health Code.

3 Performing efficient regulation and oversight

3.1 INSPECTION

3.1.1 Inspection objectives and principles

The inspection carried out by ASN is based on the following principles:
- The inspection aims to verify compliance with the provisions that are mandatory under the regulations. It also aims to assess the situation with regard to the nuclear safety and radiation protection implications; it seeks to identify best practices, practices that could be improved and assess possible developments of the situation.
- The scope and depth of the inspection is 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 of other nuclear activities decided on the basis of topical events (OEF, whistle-blower reports, context showing difficulties, etc.);
- inspections of approved organisations and laboratories.

The inspections may be unannounced or notified to the licensee a few weeks beforehand. They take place mainly on the site or during the course of the activities (work, transport operation, etc.). They may also concern the head office departments or design and engineering departments at the major nuclear licensees, the workshops or engineering offices of the subcontractors, the construction sites, plants or workshops manufacturing the various safety-related components.

ASN uses various types of inspections:
- routine inspections, usually two inspectors for one day;
- reinforced inspections, which consist in conducting an in-depth examination of a targeted topic by a larger team of inspectors than for a routine inspection;
- 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[1], which more particularly involve:
- checking application of the Labour Code by EDF and outside contractors in the NPPs (verification operations that include inspections);
- participation in meetings of the Health, Safety and Working Conditions Commissions (CSSCT), 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.

Remote inspections can be performed by the inspectors, in conjunction with on-site inspections. This tool is suitable for certain inspection topics. On-site inspection however remains the preferred method of verification. Only a few percent of the inspections are performed remotely each year.

The implementation of remote inspection measures in 2020 required that ASN modify the inspection indicators. For this type of inspection, the critical review of documents transmitted by a party RNA, 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.

1. The intervention is the unit representative of activity traditionally used by the labour inspectorate.

In addition, Table 5 (see next page) presents the total number of inspector.days devoted to inspections, whether performed on-site, remotely, or using a combination of the two.

ASN sends the licensee an inspection follow-up letter, published on *asn.fr*, which officially documents:
- deviations between the situation observed during the inspection and the regulations or documents produced by the licensee pursuant to the regulations;
- anomalies or aspects warranting additional justifications;
- best practices or practices to which improvements could be made, even if not directly constituting requirements.

The requests contained in the follow-up letters may concern requests for corrective actions or additional information, in the light of the deviations found during the inspections.

The follow-up letter prioritises the actions requested by ASN, so that the licensees can also implement a graded approach to processing the deviations found and optimise coordination of the means at their disposal.

The actual performance of the actions requested by ASN is followed up in a manner proportional to the issues at stake. Thus the priority action requests undergo exhaustive checks when their deadlines expire. The other requests are monitored by sampling, using appropriate methods (documentary check, follow-up inspection, etc.).

Any non-compliance found during the inspection can lead to administrative or criminal penalties (see point 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;
- by welcoming inspectors trained in other inspection practices. ASN encourages the integration into its departments of inspectors from other regulatory authorities, such as the Regional Directorate for the Environment, Planning and Housing (Dreal), ANSM, Regional Health Agencies (ARS), etc. It also proposes organising joint inspections with these authorities on activities falling within their common areas of competence;
- by organising the participation of its staff in inspections on subjects in different regions and fields, notably to promote the uniformity of its practices. Each ASN inspector in a particular region takes part every year in at least one inspection performed in a different region.

Table 3 presents the headcount of inspectors, which stood at 307 on 31 December 2023. Some inspectors operate in several inspection fields, and all the operational entity heads and their deputies fulfil both managerial and inspection functions.

Most of the inspections are carried out by inspectors assigned to the regional divisions, who represent 51% of the ASN inspectors. The 150 inspectors assigned to the departments take part in ASN inspections within their field of competence; they represent 49% of the inspector headcount and carried out 20% of inspections in 2023, 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.

TABLE 3 **Breakdown of inspectors per inspection field as at 31 December 2023**

INSPECTOR CATEGORIES	DEPARTMENTS	DIVISIONS	TOTAL
Nuclear safety inspectors	130	111	241
including nuclear safety inspectors for transport	*17*	*39*	*56*
Radiation protection inspectors	37	98	135
Labour inspectors	3	19	22
Inspectors for all fields	150	157	307

TABLE 4 **Number of inspections per field in 2023**

BASIC NUCLEAR INSTALLATION (EXCEPT PRESSURE EQUIPMENT)	PRESSURE EQUIPMENT	TRANSPORT OF RADIOACTIVE SUBSTANCES	SMALL-SCALE NUCLEAR ACTIVITIES	APPROVED ORGANISATIONS AND LABORATORIES	TOTAL
718	147	88	771	66	1,790

In 2023, the ASN inspectors carried out a total of 1,790 inspections, representing 4,136 inspection man.days in the field. About 1% of the inspections were carried out remotely. The breakdown per area of activity is shown in Table 4.

ASN inspections programme

To guarantee a distribution of the inspection resources with a graded approach to the safety and radiation protection implications of the various facilities and activities, ASN drafts a forecast inspections schedule every year, taking account of the inspection implications (see point 3.1). The results of the year's priority actions are presented in the specific chapters for nuclear installations and activities. For example, an inspection campaign on management of the correct configuration of fluids and electrical systems of the nuclear reactors was carried out in 2023. Its conclusions are detailed in chapter 10.

This inspection programme is not communicated to the licensees or to those in charge of nuclear activities.

ASN monitors the performance of the programme and the follow-up given to the inspections, through periodic reviews. This follow-up enables the inspected activities to be assessed and contributes to the continuous improvement of the inspection process.

Information relative to the inspections

ASN informs the public of the steps taken following the inspections by posting the inspection follow-up letters on-line, on *asn.fr*.

Moreover, after each in-depth inspection, ASN publishes an information notice on *asn.fr*.

3.1.3 Inspection of Basic Nuclear Installations and Pressure Equipment

In 2023, 2,458 inspector.days were devoted to the on-site field inspection of BNIs and NPE, corresponding to 856 inspections. Of these, 21% were unannounced. Furthermore, nine inspections were conducted remotely.

Inspection work in the field can be broken down into 1,257 inspector.days in the NPPs (401 on-site inspections), 841 inspector.days in the other BNIs (313 on-site inspections), that is mainly the "fuel cycle" facilities, research facilities and installations undergoing decommissioning, and 360 for NPE (142 on-site inspections).

The remote inspections can be broken down as follows: three inspections for the NPPs, one inspection for the other BNIs and five inspections for NPE.

Three in-depth inspections were conducted in 2023 on the Nogent-sur-Seine NPP and the Flamanville EPR, as well as on the Romans-sur-Isère site operated by Framatome, corresponding to 144 inspector.days on-site.

In addition, the ASN labour inspectors also carried out 477 interventions during the 149 inspection days in the NPPs.

3.1.4 Inspection of radioactive substance transport

In 2023, 148 inspector.days were devoted by ASN to on-site inspection of transport activities, corresponding to 87 on-site inspections. Of these, 14% were unannounced. One remote-inspection was also carried out.

3.1.5 Inspection of small-scale nuclear activities

ASN organises its inspection activity so that it is with a graded approach to the radiological issues involved in the use of ionising radiation and consistent with the actions of the other inspection services.

In 2023, 1,429 inspector.days were devoted to on-site inspections of small-scale nuclear activities, corresponding to 768 inspections, 6% of which were unannounced, plus three remote inspections. This inspection work was notably distributed among the medical, industrial, veterinary, research or naturally occurring radioactivity fields.

3.1.6 Inspection of ASN approved organisations and laboratories

ASN carries out a second level of inspection on approved organisations and laboratories. In addition to reviewing the application file and issuing the approval, this comprises surveillance actions such as:
- approval audits (initial or renewal audit);
- checks to ensure that the organisation and operation of the entity concerned comply with the applicable requirements;
- supervisory checks, which are usually unannounced, to ensure that the organisation's staff work in satisfactory conditions.

In 2023, 100 inspector.days were devoted to checking approved organisations and laboratories, corresponding to 57 inspections, 21% of which were unannounced, plus nine remote inspections.

TABLE 5 **Breakdown of on-site inspection days by topic in 2023**

PER FIELD	NUMBER OF INSPECTOR DAYS	NUMBER OF ON-SITE INSPECTIONS PERFORMED
Basic Nuclear Installation /Pressurised water reactor	1,257	401
Basic Nuclear Installation/Laboratories plants waste and decommissioning	841	313
Basic Nuclear Installation/Pressure Equipment	360	142
Small-scale nuclear activities/Industry	467	255
Small-scale nuclear activities/Medical	794	400
Small-scale nuclear activities/Natural radioactivity	39	32
Small-scale nuclear activities/Polluted sites and ground	5	4
Small-scale nuclear activities/Research	91	54
Small-scale nuclear activities/Veterinary	25	19
Small-scale nuclear activities/Other	6	4
Transport of radioactive substances	148	87
Approved organisations/Approved laboratories	100	57
Total (*)	4,136	1,768

* The fact that the various numbers are rounded off gives a total slightly different from the sum of each line.

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3.1.7 Checks on exposure to Radon and Naturally Occurring Radioactive Materials

ASN also checks radiation protection in premises where the exposure of persons to naturally occurring radiation may be reinforced owing to the underlying geological context (radon in PABs and in the workplace).

Monitoring exposure to radon

Article R. 1333-33 of the Public Health Code states that the activity concentration of radon in PABs is measured either by IRSN, or by organisations approved by ASN. These measurements are to be taken between 15 September of a given year and 30 April of the following year.

Article R. 4451-44 of the Labour Code stipulates that, whenever required, the initial checks on the radon activity concentration in areas identified owing to the radon risk must be carried out by accredited organisations.

Monitoring natural radioactivity in water intended for human consumption

Monitoring the natural radioactivity in water intended for human consumption is the role of the ARS. The 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 Analysing the files transmitted by BNI licensees

Reviewing the supporting documents produced by the licensees and the technical meetings organised with them are one of the forms of control carried out by ASN.

Whenever it considers it necessary, ASN requests an opinion from its technical support organisations, the most important of which is IRSN. The safety review implies cooperation by numerous specialists, as well as efficient coordination, in order to identify the essential points relating to safety and radiation protection.

The IRSN assessment is based on in-depth technical discussions with the licensee teams responsible for designing and operating the installations. It is also based on studies and 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 a GPE, are described in chapter 2.

At the design and construction stage, ASN – aided by its technical support organisation – assesses the safety analysis reports describing and justifying the design principles, equipment and system design calculations, utilisation rules and test procedures, and quality organisation provisions implemented by the prime contractor and its suppliers. It also analyses the facility's environmental impact assessment. ASN regulates and oversees the construction and manufacture of structures and equipment, in particular those of the main primary system and the main secondary systems of Pressurised Water Reactors (PWRs). In accordance with the same principles, it checks the packages intended for 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 concern specific topics such as fire protection, fuel management in PWRs, relations with the outside contractors, etc.

The licensee therefore also periodically provides activity reports as well as summaries of water intake, liquid and gaseous discharges and waste produced.

3.2.2 Review of the applications required by the Public Health Code

ASN is responsible for reviewing applications to possess and use ionising radiation sources in the medical and industrial sectors. ASN also deals with the specified procedures for the acquisition, distribution, import, export, transfer, recovery and disposal of radioactive sources. It in particular relies on the inspection reports from the approved organisations and the reports on the steps taken to remedy nonconformities detected during these inspections.

In addition to the verifications carried out under the responsibility of the facilities and the periodic checks required by the regulations, ASN carries out its own checks when examining the applications.

3.3 LESSONS LEARNED FROM SIGNIFICANT EVENTS

3.3.1 Anomaly detection and analysis

Background

The international Conventions ratified by France (section VI of Article 19 of the Convention on Nuclear Safety of 20 September 1994; section V of Article 9 of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management of 5 September 1997) require that BNI licensees implement a reliable system for early detection and notification of any anomalies that may occur, such as equipment failures or errors in the application of operating rules. Ten years previously, the "Quality Order" of 10 August 1984 already required such a system in France.

ASN thus drafted three guides defining the principles and reiterating the obligations binding on the licensees with regard to notification of incidents and accidents:
- the Guide of 21 October 2005 contains the provisions applicable to BNI licensees. It concerns Significant events relating to nuclear safety (ESS), radiation protection (ESRs) and environmental protection (ESEs), applicable to BNIs;
- Guide No. 11 of 7 October 2009, updated in July 2015, contains provisions applicable to those in charge of nuclear activities as defined in Article L. 1333-1 of the Public Health Code and to the heads of the facilities in which ionising radiation is used (medical, industrial and research activities using ionising radiation);
- Guide No. 31 describes the procedures for notification of 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, EDF detects and analyses several hundred anomalies every year for each reactor.

Prioritising the anomalies should enable the most important ones to be addressed first. The regulations have defined a category of anomalies called "significant events". These are events which are sufficiently important in terms of safety, the environment or radiation protection to justify that ASN be rapidly informed of their occurrence and subsequently receive a fuller analysis. Significant events must be 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 OEF about the event.

The purpose of this system is not to identify or penalise any individual person or party.

Moreover, the number and the rating on the International Nuclear and Radiological Event Scale (INES scale) of the significant events which have occurred in a nuclear facility are not on their own indicators of the facility's level of safety.

On the one hand, a given rating level is an over-simplification and is unable to reflect the complexity of an event and, on the other, the number of events listed depends on the level of notification compliance. The trend in the number of events does not therefore reflect any real trend in safety levels.

3.3.2 Implementation of the approach

Event notification

The licensee of a BNI or the person responsible for 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 RNA must report any event which could lead to accidental or unintentional exposure of persons to ionising radiation and liable to significantly prejudice the protected interests.

According to the provisions of the Labour Code, employers are obliged to report significant events affecting their workers. When the head of a company carrying out a nuclear activity calls in an external contractor or non-salaried worker, the significant events concerning the workers are reported in accordance with the prevention plans and the agreements concluded pursuant to the provisions of Article R. 4451-35 of the Labour Code.

The reporting party assesses the urgency of notification in the light of the confirmed or potential seriousness of the event and the speed of reaction needed to avoid an aggravation of the situation or to mitigate the consequences of the event. The notification time of two working days (four days for significant TSR events), mentioned in the ASN notification guides, does not apply when the consequences of the event require intervention by the public authorities.

When a given event potentially concerns several facilities, it is referred to as "generic". The most common example is a fault in an equipment item installed on several nuclear reactors (see chapter 10). In this case, ASN analyses the event as a single event, with the response being essentially common to all the facilities affected. This process follows the IAEA recommendations, which specify that a single notification may be appropriate in the case of an event affecting "Defence in Depth" and concerning several similar facilities.

ASN analysis of the notification

ASN analyses the initial notification to check the implementation of immediate corrective measures, to decide whether to conduct an on-site inspection to analyse the event in depth, and to prepare for informing the public if necessary.

Within two months of the notification, it is followed by a report indicating the conclusions the licensee has drawn from analysis of the events and the steps it intends to take to improve safety or radiation protection and prevent the event from happening again. This information is taken into account by ASN and its technical support organisation, IRSN, in the drafting of the inspection programme and when performing the BNI periodic safety reviews.

ASN ensures that the licensee has analysed the event pertinently, has taken appropriate steps to remedy the situation and prevent it from 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 to a safe condition, and the pertinence of the submitted analysis.

ASN and IRSN also carry out a more wide-ranging examination of the operating experience feedback from the events. The significant event reports and the periodic reviews sent by the licensees, as well as their 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 2023, 2,018 significant events were reported to ASN:
- 1,164 significant events concerning nuclear safety, radiation protection, the environment and the on-site transport of hazardous materials within BNIs, 1,098 of which are rated on the INES scale (86 level 1 events and two level 2 events). Of these events, 16 significant events were rated as "generic events", in other words concerning several reactors, including one at level 2 on the INES scale;
- 86 significant events concerning the TSR on the public highway (two events rated level 1 on the INES scale);
- 768 ESRs for small-scale nuclear activities, including 201 rated on the INES scale (25 level 1 events).

Graphs 1 to 6 (see next pages) describe in detail the significant events reported to ASN in 2023, differentiating between them according to the various notification criteria for each field of activity.

In 2023, two events were rated level 2 on the INES scale:

The first concerns the presence of a deep crack on the safety injection circuit of Penly NPP reactor 1 detected as part of the action plan defined following the discovery of stress corrosion cracks at the end of 2021. It falls within the scope of the generic event concerning this phenomenon and which has been covered by numerous ASN publications. The event is presented in a box in chapter 10 (see page 297).

The second concerns the external contamination of a worker in the Cattenom NPP, leading to exceeding of the annual statutory dose limit for the equivalent dose to the skin. This event is also described in more detail in chapter 10 (see page 313).

An event reported in 2022, concerning contamination of an employee of a nuclear medicine department, was also re-rated level 2 on the INES scale in 2023, following analyses which demonstrated that the regulation skin exposure limit had been exceeded in a single event.

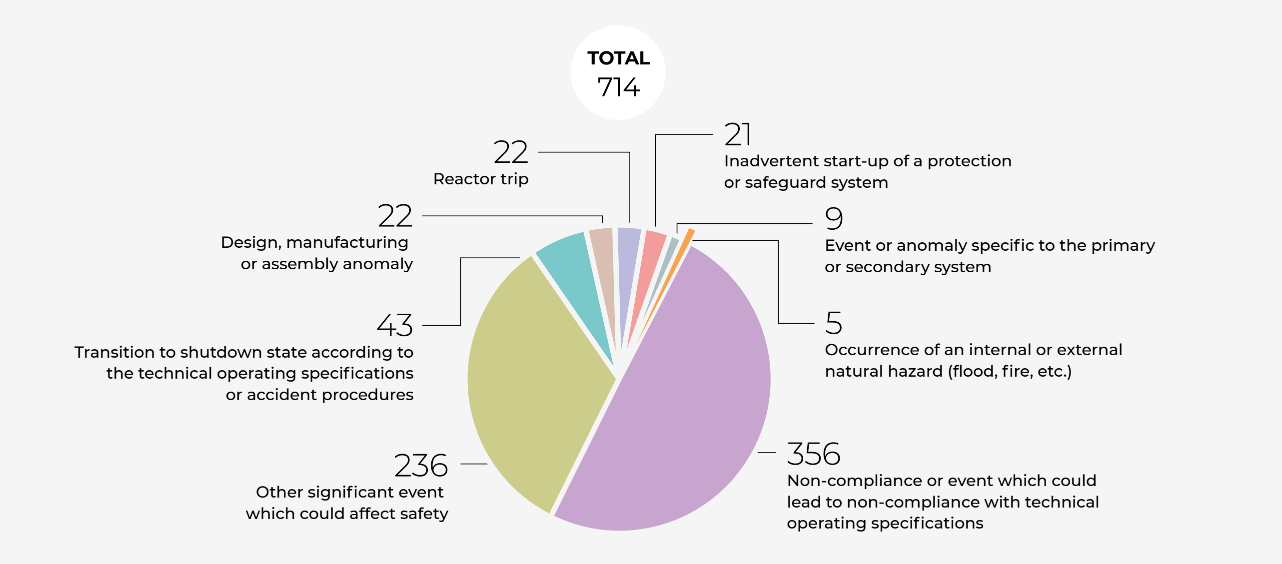
As indicated earlier, these data must be used with caution: they do not in themselves constitute a safety indicator. ASN encourages the licensees to report incidents, which contributes to transparency and the sharing of experience.

TABLE 6 **Number of significant events rated on the INES scale between 2018 and 2023**

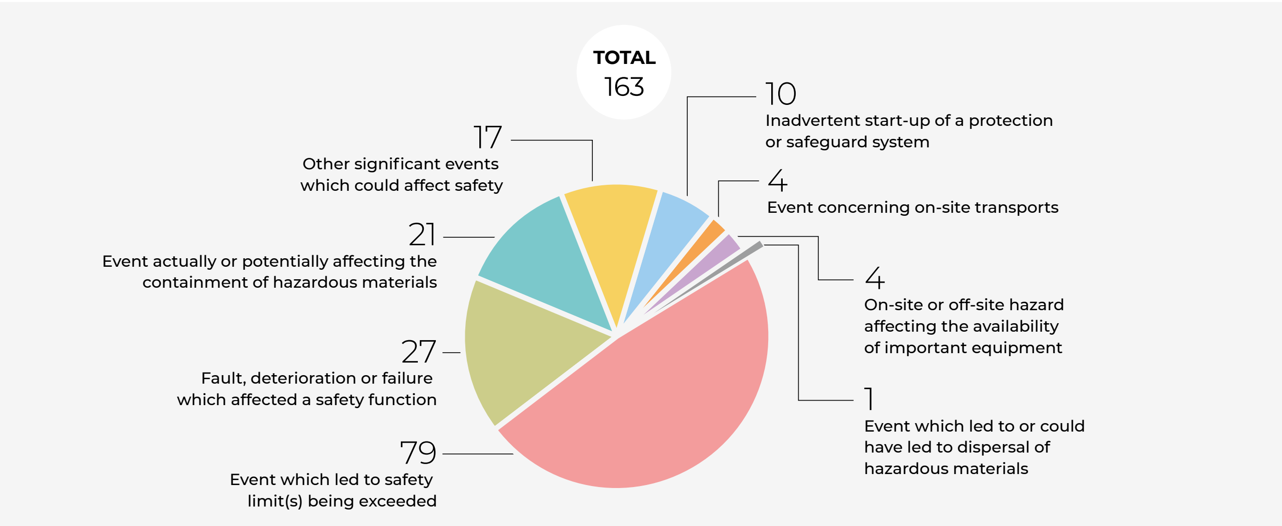
		2018	2019	2020	2021	2022	2023
Basic Nuclear Installations	Level 0	989	1,057	1,033	1,068	985	1,010
	Level 1	103	112	107	103	97	86
	Level 2	0	3	2	1	0	2
	Level 3 and +	0	0	0	0	0	0
	Total	**1,092**	**1,172**	**1,142**	**1,172**	**1,082**	**1,098**
Small-scale nuclear activities (medical and industry)	Level 0	143	142	135	177	163 (*)	176
	Level 1	22	35	24	33	37 (*)	25
	Level 2	0	2	1	0	2 (*)	0
	Level 3 and +	0	0	0	0	0	0
	Total	**165**	**179**	**160**	**210**	**202**	**201**
Transport of radioactive substances	Level 0	88	85	71	80	76	84
	Level 1	3	4	4	4	12	2
	Level 2	0	0	0	0	0	0
	Level 3 and +	0	0	0	0	0	0
	Total	**91**	**89**	**75**	**84**	**88**	**86**
	Grand Total	**1,348**	**1,440**	**1,377**	**1,466**	**1,372**	**1,385**

* 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).

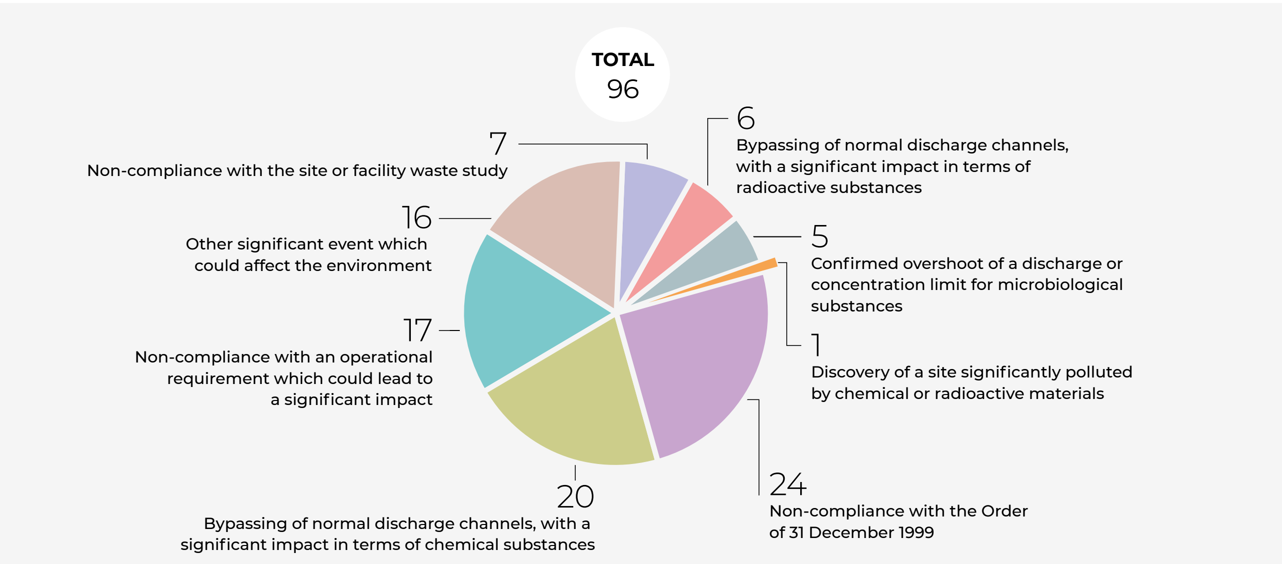
GRAPH 1 **Events involving safety in the NPPs notified in 2023**



GRAPH 2 **Events involving safety in BNIs other than the NPPs notified in 2023**



GRAPH 3 **Significant environment-related events in BNIs notified in 2023**



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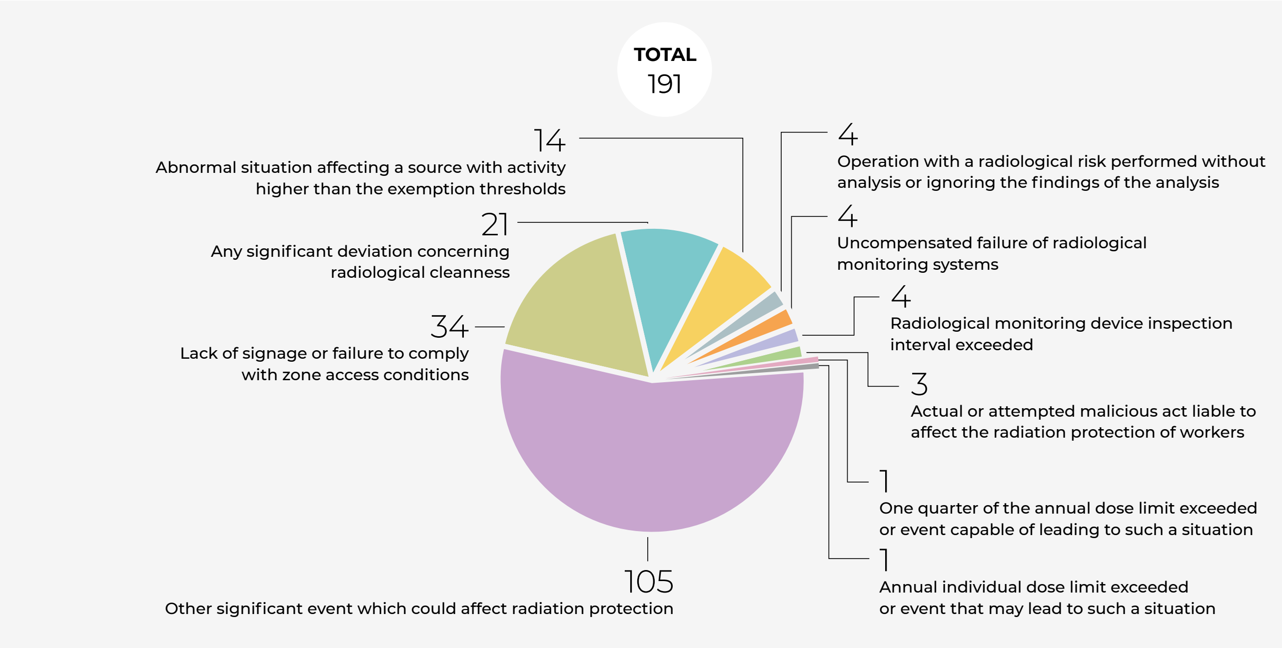
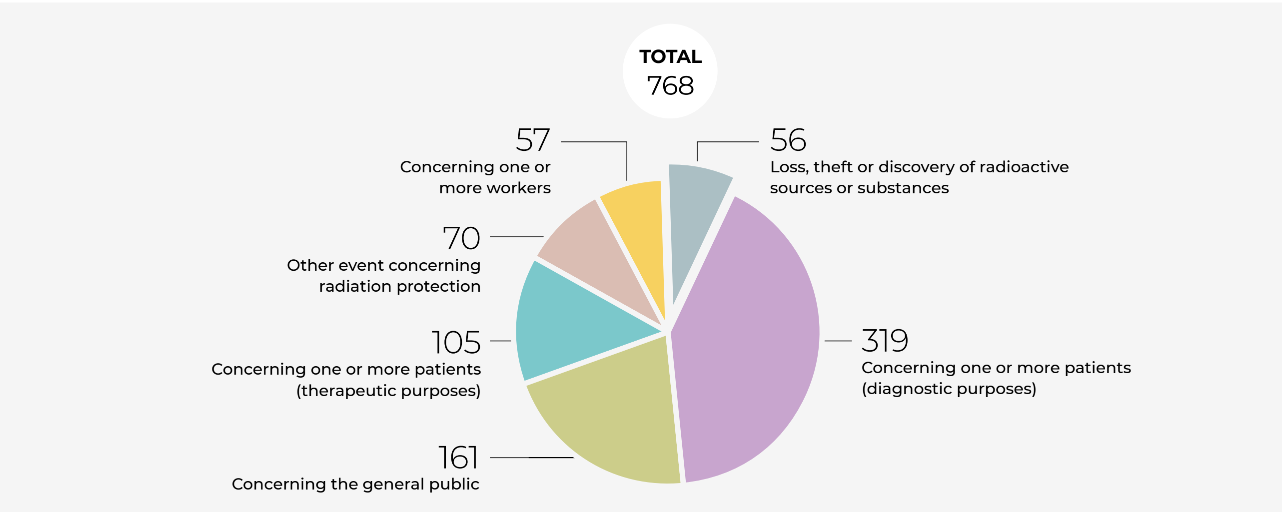
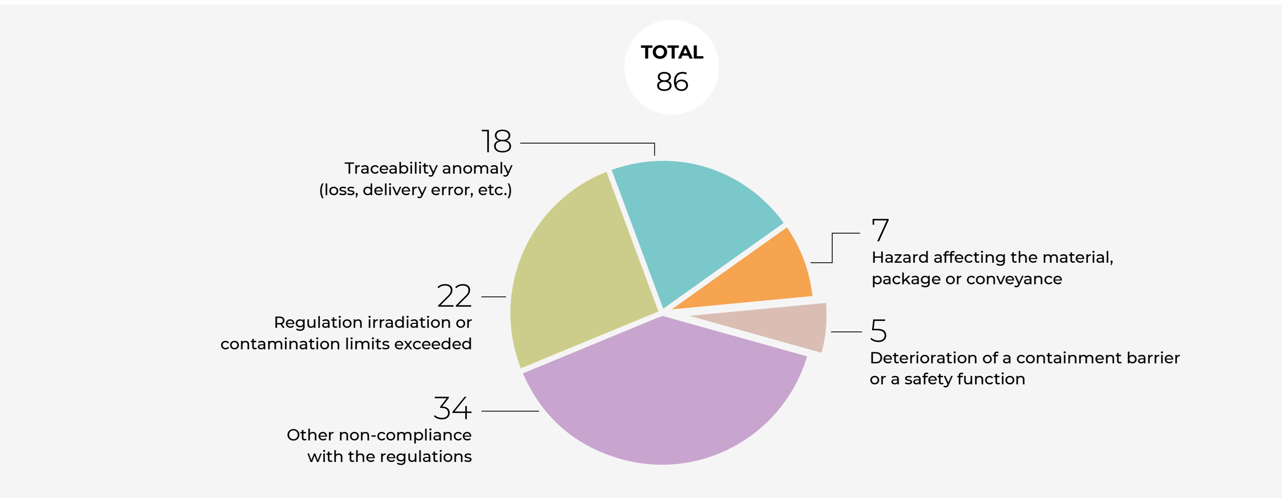
GRAPH 4 **Events involving radiation protection in BNIs notified 2023**



GRAPH 5 **Events involving radiation protection (other than BNIs and TSR) notified in 2023**



GRAPH 6 **Events involving the transport of radioactive substances notified in 2023**



The breakdown of significant events rated on the INES scale is given in Table 6 (see page 155). As the INES scale does not apply to significant events concerning patients, the rating of significant events affecting one or more patients in radiotherapy on the ASN-SFRO scale[2] is specified in chapter 7.

Similarly, significant events concerning the environment but involving non-radiological substances are not covered by the INES scale. They are classified as "out of INES scale" events.

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;
- 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.

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 upon them with regard to the management of discharges and the environmental and health impact of their facilities. Every year, it carries out about 90 inspections of this type, split among the following three topics:
- prevention of pollution and management of detrimental effects and non-radiological hazards;
- water intake and effluent discharge, monitoring of discharges and the environment;
- waste management.

Each of these topics covers both radiological and non-radiological aspects.

Every year, ASN carries out 10 to 20 inspections with sampling and measurement. They are generally unannounced and are run with the support of specialist, independent laboratories appointed by ASN. Effluent and environmental samples are taken for radiological and chemical analyses. Finally, every year, ASN carries out several reinforced inspections which aim to check the organisation put into place by the licensee to protect the environment;

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.*

01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 AP

the scope of the inspection is then broadened to cover all of the above-mentioned topics. Within this context, situational exercises can be carried out to test the organisation implemented for pollution management (see chapter 10).

Accounting of BNI discharges

The rules for accounting of discharges, both radioactive and chemical, are set in the general regulations by amended ASN resolution 2013-DC-0360 of 16 July 2013 relative to control of the detrimental effects and the impact of BNIs on health and the environment. These rules were set so as to guarantee that the discharge values declared by the licensees, notably those considered in the impact calculations, will in no case be under-estimated.

For discharges of radioactive substances, accounting is not based on overall measurements, but on an analysis per radionuclide, introducing the notion of a "reference spectrum", listing the radionuclides specific to the type of discharge in question.

The principles underlying the accounting rules are as follows:
- radionuclides for which the measured activity exceeds the decision threshold for the measurement technique are all counted;
- the radionuclides of the "reference spectrum" for which the measured activity is below the decision threshold (see box opposite) are considered to be 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.

Per- and Polyfluoroalkyl Substances

Per- et Polyfluoroalkyl Substances (PFAS) are substances which degrade very slowly and are highly persistent in the environment, which poses many questions regarding their toxicity, both for human health and for the environment.

Following the action plan initiated by the Government in January 2023 to reduce PFAS-related hazards and improve the awareness of the population regarding exposure to these substances, ASN asked the BNI licensees whose activities are liable to be the cause of PFAS emissions to draw up a list of the PFAS used, produced, processed or discharged by their facility and then to carry out a campaign to search for and quantify their presence in the aqueous discharges from their facility.

The results of these measurement campaigns are expected for the end of 2024 and could, if PFAS are confirmed as being present in BNI discharges, lead ASN to issue binding requirements to regulate these discharges by setting emission limits and appropriate monitoring procedures.

Monitoring of discharges in the field of small-scale nuclear activities

Pursuant to ASN resolution 2008-DC-0095 of 29 January 2008, radioactivity measurements are taken on the effluents coming from the places that produce them.

In hospitals that have a nuclear medicine department, these measurements chiefly concern iodine-131 and technetium-99m (see chapter 7).

In the small-scale industrial nuclear sector, few facilities discharge radioactive effluents apart from cyclotrons (see chapter 8). The discharge permits stipulate requirements for the discharges and their monitoring, which are subject to particular scrutiny during inspections.

For nuclear medicine units and research laboratories, IRSN proposes a graded approach to monitoring of radioactive discharges into the public sewer system. This approach could consist of sampling and measurement protocols, as well as guideline levels to be compared with the results of these measurements in order to decide whether any corrective measures are needed.

4.1.2 Evaluating the radiological impact of nuclear activities

The radiological impact of effluents produced by medical activities and small-scale nuclear activities

The impact of radioactive discharges on sanitation workers (sewerage workers and wastewater treatment plant workers) and on workers responsible for removing and spreading wastewater treatment sludge can, since 2019, be evaluated using the CIDRRE tool (Calculation of impact of radioactive discharges into the networks), developed by IRSN.

The final result is a prudent over-estimation, which gives an approximate idea of the doses liable to be received per category of sanitation workers, according to the facility which carries out the discharge, the collection system receiving it and the plant which treats the wastewater. CIDRRE is a means of ensuring that the annual dose received by the sanitation workers remains below 1 millisievert (mSv).

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 ≈ 2 x SD.

For the measurement results on chemical substances, the Quantification Limit is equivalent to the Detection Limit used to measure radioactivity.

Reference spectra

For the NPPs, the reference spectra of discharges comprise the following radionuclides:
- **Liquid discharges:** tritium, carbon-14, iodine-131, other fission and activation products (manganese-54, cobalt-58, cobalt-60, nickel-63, silver-110m, tellurium-123m, antimony-124, antimony-125, caesium-134, caesium-137);
- **Gaseous discharges:** tritium, carbon-14, iodine (iodine-131, iodine-133), other fission and activation products (cobalt-58, cobalt-60, caesium-134, caesium-137), noble gases: xenon-133 (permanent discharges from ventilation networks, when draining "RS" effluent storage tanks and at decompression of reactor buildings), xenon-135 (permanent discharges from ventilation networks and at decompression of reactor buildings), xenon-131m (when draining "RS" tanks), krypton-85 (when draining "RS" tanks), argon-41 (at decompression of reactor buildings).

For the population, the estimated radiological impact linked to radioactive discharges from nuclear medicine units and research laboratories into the sewerage systems would appear to be below 300 microsieverts per year (µSv/year) in all the studies, even in worst-case scenarios considering all the radionuclides detected in the sanitation systems. This impact is estimated to be lower than 1 µSv/year when the radionuclides used in nuclear medicine are not taken into account, with realistic hypotheses (IRSN data).

The radiological impact of BNIs

In accordance with the optimisation principle, the licensee must reduce the radiological impact of its facility to values that are as low as possible under economically acceptable conditions.

The licensee is required to assess the dosimetric impact of its activity. As applicable, this obligation is the result of Article L. 1333-8 of the Public Health Code, or the regulations concerning BNI discharges (article 5.3.2 of 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.

In accordance with the provision of Articles R. 1333-23 and R. 1333-24 of the Public Health Code, the estimation is calculated for a "person representative" of the persons most exposed within the population, except for those with extreme or rare habits and according to scenarios that are as realistic as possible. These scenarios take account of parameters specific to each site: distance from the site, meteorological data, etc. The differences observed from one site to another and from one year to another can to a large extent be explained by the use of these specific parameters.

The Table entitled "Radiological impact of BNIs since 2017" in chapter 1 presents an assessment of the doses due to BNIs calculated by the licensees.

For each of the nuclear sites presented, the radiological impact remains far below, or at most represents about 1% of the limit for the public, this limit being 1 mSv/year. Therefore in France, the discharges produced by the nuclear industry have an extremely small radiological impact.

4.1.3 Monitoring within the European framework

Article 35 of the EURATOM Treaty requires that the Member States establish the facilities needed to carry out continuous monitoring of the level of radioactivity in the air, water and soil and to ensure compliance with the basic standards of health protection for the general public and workers against the hazards of ionising radiation.

All Member States, whether or not they have nuclear facilities, are therefore required to implement environmental monitoring arrangements throughout their territory.

Article 35 also states that the European Commission (EC) may access the monitoring facilities to verify their operation and their effectiveness. During its verifications, it gives an opinion on the means implemented by the member states to monitor radioactive discharges into the environment and the levels of radioactivity in the environment around nuclear sites and over the national territory. It notably gives its assessment of the monitoring equipment and methodologies used and of the organisational setup.

Since 1994, the EC has carried out about ten verification visits to different types of nuclear facilities in France (NPPs, "fuel cycle" plants, research centres, former uranium mines).

4.2 ENVIRONMENTAL MONITORING

4.2.1 The French National Network for Environmental Radioactivity Monitoring

In France, many parties are involved in environmental radioactivity monitoring:
- the nuclear facility licensees, who perform monitoring around their sites;
- ASN, IRSN (whose duties as defined by Decree 2016-283 of 10 March 2016 include participation in radiological monitoring of the environment), the Ministries (General Directorate for Health, General Directorate for Food, General Directorate for Competition Policy, Consumer Affairs and Fraud control, etc.), the services of the State and other public players carrying out monitoring duties across the national territory or in particular sectors (foodstuffs controlled by the General Directorate for Competition Policy, Consumer Affairs and Fraud control, for example);
- the approved air quality monitoring associations (local authorities), environmental protection associations and Local Information Committees (CLIs).

The French National Network of Environmental Radioactivity 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.fr*). The quality of these measurements is guaranteed by a laboratories approval procedure (see point 4.3).

The guidelines of the RNM (for examine, the new types of measurements to be integrated into the RNM) are decided by a network steering committee made up of representatives from all the stakeholders in the network: ministerial departments, ARS, representatives of nuclear licensee or association laboratories, members of the CLIs, IRSN, ASN, etc.

After the RNM website was launched in 2009 and overhauled for the first time in 2016, ASN and IRSN undertook work to modernise the tool in 2022 so that it was more in line with the needs of web users, whether the general public or more informed visitors.

A pluralistic working group consisting of the main nuclear licensees, representatives of civil society, ministers, IRSN and ASN, therefore met between 2022 and 2023 in order to identify areas for improvement and propose a number of changes to the site. Some have already been made, such as improving the function for performing searches around the sites. Modernisation of the website will continue in 2024 and 2025.

At the same time, thought is being given to how to reinvigorate the working of the network steering committee and ensure closer involvement by the stakeholders. The ASN Chairman's resolution CODEP-DEU-2023-053424 of 29 November 2023 enacted the broadening of the composition of the RNM steering committee, notably appointing representatives of the CLIs, of the National Association of Local Information Committees and Commissions (Anccli), of environmental protection associations and of the Dreal, as members of the committee.

4.2.2 The purpose of environmental monitoring

The licensees are responsible for monitoring the environment around their facilities. The content of the monitoring programmes to be implemented in this respect (measurements to be taken and frequency) is defined in amended ASN resolution 2013-DC-0360 of 16 July 2013, and in the individual requirements applicable to each installation (Creation Authorisation Decrees or ASN resolutions regulating water intake and discharges), independently of the additional measures that can be taken by the licensees for the purposes of their own monitoring.

This environmental monitoring:
- contributes to understanding the radiological and radioecological state of the facility's environment through measurements of parameters and substances regulated in the requirements, in the various environmental compartments (air, water, soil) as well as in the biotopes and food-chain (milk, plants, etc.): a datum is determined before the facility is created and monitoring the environment throughout the lifetime of the facility enables any changes in this datum to be followed;
- helps verify that the impact of the facility on health and the environment is in conformity with the impact assessment;
- detects any abnormal increase in radioactivity as early as possible;
- ensures that the licensees comply with the regulations and that there are no facility malfunctions, notably by analysing the ground water;
- contributes to transparency and information of the public through the transmission of monitoring data to the RNM.

4.2.3 Content of monitoring

All the nuclear sites in France that produce discharges are subject to systematic environmental monitoring. This monitoring uses a graded approach to the environmental risks or detrimental effects of the facility, as presented in the authorisation file, particularly the impact assessment.

The regulation monitoring of the environment of BNIs is tailored to each type of facility, depending on whether it is a nuclear power reactor, a plant, a research facility, a waste disposal centre, and so on. The minimum contents of this monitoring are defined by the amended Order of 7 February 2012 setting the general rules for BNIs and by the above-mentioned modified resolution of 16 July 2013. This resolution obliges BNI licensees to have approved laboratories take the environmental radioactivity measurements required by the regulations.

Depending on specific local features, monitoring may vary from one site to another. Table 7 (see next page) gives examples of the monitoring performed by the licensee of an NPP and of a "fuel cycle" plant.

When several facilities (whether or not BNIs) are present on the same site, joint monitoring of all these installations is possible, as has been the case, for example, on the Cadarache and Tricastin sites since 2006.

These monitoring principles are supplemented in the individual requirements applicable to the facilities by monitoring measures specific to the risks inherent in the industrial processes they use.

Each year, in addition to sending ASN the monitoring results required by the regulations, the licensees transmit nearly 120,000 measurements to the RNM.

4.2.4 Environmental monitoring nationwide by IRSN

IRSN's nationwide environmental monitoring is carried out by means of measurement and sampling networks dedicated to:
- air monitoring (aerosols, rainwater, ambient gamma activity);
- monitoring of surface water (watercourses) and groundwater (aquifers);
- monitoring of the human food chain (milk, cereals, fish, etc.);
- terrestrial continental monitoring (reference stations located far from all industrial facilities).

This monitoring is based on:
- continuous on-site monitoring using independent systems (remote-monitoring networks) providing real-time transmission of results. This includes:
  - the *Téléray* network (ambient gamma radioactivity in the air) which uses a system of continuous measurement monitors around the whole country. The density of this network is being increased around nuclear sites within a radius of 10 to 30 km 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.

TABLE 7 **Example of radiological monitoring of the environment around BNIs**

ENVIRONMENT MONITORED OR TYPE OF CONTROL	CATTENOM NPP (ASN RESOLUTION 2014-DC-0415 OF 16 JANUARY 2014)	ORANO PLANT AT LA HAGUE (AMENDED ASN RESOLUTION 2015-DC-0535 OF 22 DECEMBER 2015)
Air at ground level	• 4 stations continuously sampling atmospheric dust on a fixed filter with daily measurements of total β activity (βG): – γ spectrometry if βG > 2 mBq/m³ – Monthly γ spectrometry on groups of filters per station • 1 continuous sampling station downwind of the prevailing winds, with weekly measurement of atmospheric ^{3}H	• 5 stations continuously sampling atmospheric dust on a fixed filter, with daily measurements of the total α activity (αG) and total β activity (βG): – γ spectrometry if αG or βG > 1 mBq/m³ – Monthly α (Pu) spectrometry on grouped filters per station • 5 continuous sampling stations for halogens on specific adsorbent with weekly γ spectrometry to measure different kinds of iodine • 5 continuous sampling stations with weekly measurement of atmospheric ^{3}H • 5 continuous sampling stations with bi-monthly measurement of atmospheric ^{14}C • 5 continuous measurement stations for ^{85}Kr activity in the air
Ambient γ radiation	• Continuous measurement with recording: – 4 detectors at 1 km – 10 detectors on the site boundary – 4 detectors at 5 km	• 5 detectors with continuous measurement and recording • 11 detectors with continuous measurement at the site fencing
Rain	• 1 continuous sampling station under the prevailing winds with bi-monthly measurement of βG and ^{3}H	• 2 continuous sampling stations including one under the prevailing winds with weekly measurement of αG, βG and ^{3}H – γ spectrometry if significant αG or βG
Receiving environment for liquid discharge	• Sampling from the river upstream of the discharge point and in the good mixing area for each discharge – Measurement of βG, potassium (K)* and ^{3}H • Continuous sampling in the river at the good mixing point – ^{3}H measurement (average daily mixture) • Annual sampling in aquatic sediments, fauna and flora upstream and downstream of the discharge point with γ spectrometry, free ^{3}H measurement and, on fish, organically bound ^{14}C and ^{3}H • Periodic sampling from a stream and in the dam adjoining the site with measurements of βG, K, ^{3}H	• Daily seawater samples from 2 points on the coast, with daily measurements (γ spectrometry, ^{3}H) at one of these points and for each of the 2 points, α and γ spectrometry and βG, K, ^{3}H and ^{90}Sr measurements • Quarterly seawater samples at 3 points offshore with γ spectrometry and βG, K, ^{3}H measurements • Quarterly samples of beach sand, seaweed and limpets at 13 points with γ spectrometry + ^{14}C measurements and α spectrometry for the seaweed and limpets at 6 points • Sampling of fish, crustaceans, shellfish and molluscs in 3 coastal zones of the Cotentin with α and γ spectrometry and ^{14}C measurement • Quarterly sampling of offshore marine sediments at 8 points with α and γ spectrometry and ^{90}Sr measurement • Weekly to six-monthly samples of water from 19 streams around the site, with αG, βG, K and ^{3}H measurements • Quarterly sampling of sediments from the 4 main streams adjacent to the site, with γ and α spectrometry • Quarterly samples of aquatic plants in 3 streams in the vicinity of the site with γ spectrometry and ^{3}H measurement
Groundwaters	• Monthly sampling at 4 points, bi-monthly at 1 point and quarterly at 4 points with βg, K and ^{3}H measurement	• 5 sampling points (monthly check) with αG, βG, K and ^{3}H measurement
Water for consumption	• Annual sampling of water intended for human consumption, with βG, K and ^{3}H measurements	• Periodic sampling of water intended for human consumption at 15 points, with αG, βG, K and ^{3}H measurements
Soil	• 1 annual sample of the topsoil with γ spectrometry	• Quarterly samples at 7 points with γ spectrometry and ^{14}C measurement
Vegetation	• 2 grass sampling points, including one under the prevailing winds, monthly γ spectrometry and quarterly ^{14}C and C measurements • Annual campaign for the main agricultural crops, with γ spectrometry, ^{3}H and ^{14}C measurements	• Monthly grass sampling at 5 points and quarterly at 5 other points with γ spectrometry and ^{3}H and ^{14}C measurements, – Annual α spectrometry at each point • Annual campaign for the main agricultural crops, with α and γ spectrometry, ^{3}H, ^{14}C and ^{90}Sr measurements
Milk	• 2 sampling points situated at 0 to 10 km from the installation, including one under the prevailing winds, with monthly γ spectrometry, quarterly ^{14}C measurement and annual ^{90}Sr and ^{3}H measurement	• 5 sampling points (monthly check) with γ spectrometry, K, ^{3}H, ^{14}C and ^{90}Sr measurement

αG = α total; βG = β total
* Measurements of total concentration of potassium by spectrometry for ^{40}K.

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.

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 a RNM and a procedure to have the radioactivity measurement laboratories approved by ASN. The RNM working methods are defined by the above-mentioned amended ASN resolution 2008-DC-0099 of 29 April 2008.

This network is being deployed for two main reasons:
- to pursue the implementation of a quality assurance policy for environmental radioactivity measurements by setting up a system of laboratory approvals granted by ASN resolution;
- to ensure transparency by making the results of this environmental monitoring and information about the radiological impact of nuclear activities in France available to the public on the RNM website (see point 4.2.1).

The approvals cover all environmental matrices for which regulatory oversight is imposed on the licensees: water, soil or sediment, biological matrices (fauna, flora, milk), aerosols and atmospheric gases. The measurements concern the main artificial or natural gamma, beta or alpha emitting radionuclides, as well as the ambient gamma dosimetry. The list of the types of measurements covered by an approval is defined by the above-mentioned ASN resolution 2008-DC-0099 of 29 April 2008, amended.

In total, the approvals cover about fifty measurements, for which there are as many Inter-laboratory Comparison Tests (ILTs). These tests are organised by IRSN in a 5-year cycle, which corresponds to the maximum approval validity period.

4.3.1 Laboratory approval procedure

The above-mentioned amended ASN resolution 2008-DC-0099 of 29 April 2008 specifies the organisation of the national network and sets the approval arrangements for the environmental radioactivity 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 an ASN resolution published in its *Official Bulletin*. The list of approved laboratories is updated every six months and published on *asn.fr*.

4.3.2 The approval commission

The approval commission is tasked with ensuring that the measurement laboratories have the organisational and technical competence to provide the RNM with high-quality measurement results.

The commission is authorised to propose approval, rejection, revocation or suspension of approval to ASN. It issues a decision on the basis of an application file submitted by the candidate laboratory and its results in the ILTs organised by IRSN. It meets every six months.

The commission, chaired by ASN, comprises qualified persons and representatives of the State services, laboratories, standardising authorities and IRSN.

In 2023, ASN renewed the composition of the approval commission in ASN Chairman's resolution CODEP-DEU-2023-052098 of 13 October 2023, concerning nominations to the approvals commission for environmental radioactivity measurement laboratories.

4.3.3 Approval conditions

Laboratories seeking approval must set up an organisation meeting the requirements of standard NF EN ISO/IEC 17025 concerning the general requirements for the competence of calibration and test laboratories.

In order to demonstrate their technical competence, they must take part in ILTs organised by IRSN. The five-year programme for these tests is updated annually. It is reviewed by the approval commission and published on the RNM's website. Up to 70 laboratories sign up for a type of test, including a number of laboratories from other countries.

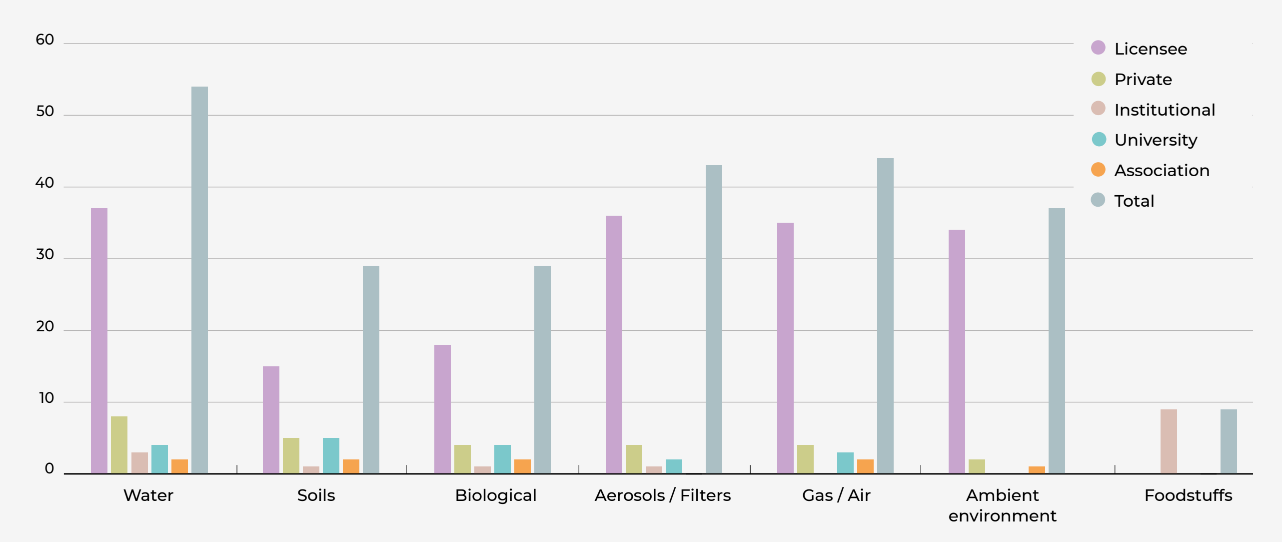
The approval commission defines the evaluation criteria used for analysis of the ILTs. When the result obtained in an ILT by a laboratory is not conclusive enough, ASN may, on the advice of the approval commission, issue an approval for a trial period of one to two years for example, or make issue of the approval contingent upon the provision of additional data, or even the participation in a further corroborating test.

In 2023, IRSN organised seven ILTs and three cross-check tests. Since 2003, 110 ILTs have been carried out, covering 60 types of approval. The most numerous approved laboratories (54) are in the field of monitoring of radioactivity in water. Between 29 and 44 laboratories are approved for measurement of biological matrices (fauna, flora, milk), atmospheric dust, air, or ambient gamma dosimetry. There are 29 approved laboratories for soils and sediments. Although most laboratories are competent to measure gamma emitters in all environmental matrices, between 10 and 20 of them are approved to measure carbon-14, transuranic elements or radionuclides of the natural chains of uranium and thorium in water, soil and sediments and the biological matrices (grass, plant crops or livestock, milk, aquatic fauna and flora, etc.).

In 2023, ASN issued 149 approvals or approval renewals. As at 31 December 2023, the total number of approved laboratories stood at 67, which represents 966 approvals of all types currently valid on 1 January 2024.

The detailed list of approved laboratories and their scope of technical competence is available on *asn.fr*.

GRAPH 7 **Approved laboratories per type of matrix as at 1 January 2024**



5 Inspections concerning counterfeit, falsifications and suspected fraud, and processing of reported cases

5.1 INSPECTIONS CONCERNING COUNTERFEIT, FALSIFICATIONS AND SUSPECTED FRAUD

Since 2015, several cases of irregularities that could be considered to be falsifications have been brought to light at known manufacturers, suppliers or organisations who have been working for many years on behalf of the French nuclear industry. Confirmed cases of counterfeit or falsification have also been encountered in a number of other countries in recent years. The term of irregularity was initially employed by ASN to cover any intentional modification, alteration or omission of certain information or data. ASN will gradually adopt the term of "Counterfeit, Falsification or Suspected fraud" (CFS), which is better suited to the issue as it is more in line with the term usually employed internationally: Counterfeit, Fraudulent and Suspect Items (CFSI). A CFS detected by ASN can be dealt with by a judge in a case of criminal fraud.

The number of confirmed or suspected cases remain few in number but they do exist, despite the high level of quality demanded in the nuclear industry and the robustness of the monitoring and inspection chain, the key links of which are the manufacturers, suppliers and licensees. The licensees have improved their monitoring and therefore the detection of CFS. They must however maintain their efforts to adapt more adequately to the prevention, detection, analysis and processing of cases of CFS.

In 2016, ASN began to look at adapting BNI inspection methods in an irregularity context. In so doing, it questioned other regulation and oversight administrations, its foreign counterparts and the licensees with regard to their practices, in order to learn the pertinent lessons. This particular risk gave rise to changes to ASN's oversight methods (specific check list, dedicated governance bodies, development of awareness of licensees and suppliers, etc.). The existing framework is used for processing.

ASN also reminded the BNI licensees and the main manufacturers of nuclear equipment in 2018 that a CFS is a deviation as defined by the BNI Order. The requirements of the Order therefore apply to the prevention, detection and processing of cases of CFS. More generally, the regulatory requirements concerning the safety and protection of persons against the risks related to ionising radiation also apply. For example, applying a signature to certify that an activity has been correctly carried out, whereas in reality it has not, could – depending on the circumstances – be a breach of the rules of organisation, technical inspection of activities, skills management, etc.

In 2023, the search for CFS continued during the inspections. For a number of years now this search has become one of the usual inspection practices and specific internal tools have been made available to the inspectors.

Incorporating CFS into inspections corresponds to three contexts:
- inspections further to known subjects, resulting from CFS discovered in other facilities, or to monitor the processing of a case previously detected;
- inspections including an in-depth search for proof in the performance of activities, for example with verification of the actual presence of a person who certified that they had carried out an activity on a given date, or the examination of inspection registration source data;
- inspections with the purpose of raising awareness concerning the risks of CFS, notably during supplier inspections, where the risk of CFS in the subcontracting chain is dealt with.

About fifty inspections were thus carried out in 2023. They mainly took place on the nuclear sites and at the manufacturers of equipment intended for use there. Inspections devoted to this topic were also carried out in the head office departments of the main nuclear licensees. The inspections of suppliers of safety-important nuclear equipment are detailed in chapter 10.

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.

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In 2023, ASN issued three of these notifications. When the Public Prosecutor initiates investigations, ASN provides support for the investigators appointed by the legal authorities for technical analysis of documents and to facilitate dealings with the nuclear licensees.

In addition, the question of data integrity, that is ensuring that data have not been modified or destroyed without authorisation, linked to the risk of CFS, given that shortcomings in traceability can facilitate irregularities, continued to be frequently addressed in 2023 and formed the subject of requirements in several inspection follow-up letters.

New CFS are still being detected, both by the licensees, within the context of their monitoring and internal checks, and by the ASN inspectors. Several cases were reported to ASN in 2023 and are being followed-up and processed in close collaboration with the licensees and manufacturers.

ASN's actions to prevent, detect and process CFS are not limited just to the inspections. For example, ASN informs the main licensees and manufacturers of the cases detected and analyses their responses. It holds 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 for anyone, potentially a whistle-blower, wishing to report irregularities potentially affecting the protection of persons and the environment.

Act 2022-401 of 21 March 2022 aiming to improve whistle-blower protection, which modifies the system created by the "Sapin 2" Act of 9 December 2016, entered into force on 1 September 2022. It is supplemented by Constitutional Act 2022-400 of the same date, which aims to reinforce the role of the Defender of whistle-blower rights. These two Acts reinforce the whistle-blower protection system. They transpose Directive (EU) 2019/1937 of 23 October 2019 defining a common framework for this protection and take it even further.

A broader definition of whistle-blower, simplification of the alert procedures, reinforcement of the whistle-blower protections, a new status for the entourage of the whistle-blower and an expansion of the roles of the Defender of Rights with regard to whistleblowing are the main contributions of these Acts. Furthermore, Decree 2022-1284 of 3 October 2022 relative to the procedures for collecting and processing alerts submitted by whistle-blowers and setting out the list of external authorities instituted by the above-mentioned Act 2022-401 supplements these provisions by detailing the whistle-blowing report processing mechanisms. This Decree designated ASN as having competence to process whistle-blower alerts regarding radiation protection and nuclear safety. The system set up by ASN, which was originally voluntary, has been added to and meets these obligations.

By means of a system of pseudonyms for the reports received, ASN guarantees the confidentiality of anyone sending it a report. Only a request from a judicial authority could override this confidentiality, something which has never yet happened.

It is however preferable for the person sending in the notification to leave their contact details so that ASN can:
- acknowledge receipt of the notification;
- contact them if clarification is required (this is frequently the case);
- inform them if action has been taken following their alert.

In 2023, 46 reports were sent to ASN: three-quarters (33) *via* the whistle-blower portal, the others by alternative means of transmission, mainly (nine 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.

Several whistle-blower reports processed in 2023 concern the on-line sale of radioactive sources. In this type of case, ASN systematically reminds the platform concerned of the regulatory requirements in force regarding the possession, distribution or transfer of radioactive sources. In addition to cancelling the advertisement, the platform is also asked to contact the advertiser so that it can, if necessary, collect and retrieve the sources in its possession or that it has distributed.

A significant proportion of the valid whistle-blower reports received in 2023 concern non-compliance with radiation protection rules in the medical field (organisational malfunctions, missing or inappropriate equipment, etc.). For most of them, the inspections carried out by the ASN inspectors enable the professionals to be reminded of the regulatory requirements binding upon them with respect to radiation protection of workers and patients. The findings are included in the evaluations expressed in chapter 7.

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 party RNA, 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.

Ten reports were verified during the course of inspections. The follow-up to these inspections is dealt with in the same way as routine inspections.

Few reports received in 2023 were anonymous (nine), which make it easier to process them.

6 Identifying and correcting deviations

ASN implements enforcement measures, making it possible to oblige a licensee or party RNA to restore compliance with the regulations, along with penalties.

In certain situations in which the actions of the licensee or party RNA fail to comply with the regulations in force, or when it is important that appropriate action be taken by it to remedy the most serious risks without delay, ASN may resort to enforcement measures and impose the penalties provided for by law. The principles of ASN actions in this respect are:
- actions that are impartial, justified and appropriate to the level of risk presented by the situation concerned. Their scale is with a graded approach 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 RNA or a licensee, more particularly:
- the inspector's observations;
- the official letter from the ASN departments (inspection follow-up letter);
- formal notice from ASN to regularise the administrative situation or to comply with the regulations in force, within a time-frame determined by itself;
- enforcement measures or administrative sanctions, applied after non-compliance with the formal notice served.

These measures, as set out in law, are as follows:
- deposit in the hands of a public accountant of a sum covering the total cost of the work to be performed;
- have the work carried out without consulting the licensee or the party RNA 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 8 January 2024. The Act also provides for interim 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;
- at all times require 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 RNA, after having informed the party concerned that it is entitled to submit observations within a given time, in order to comply with the exchange of views procedure.

In 2023, ASN sent out formal notice on three occasions: two for BNIs and one for small-scale nuclear activities.

ASN also decided to modify the technical prescriptions for a BNI following inspections.

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 violations observed are written up in reports by the nuclear safety and radiation protection inspectors and transmitted to the Public Prosecutor's Office, which decides on whether or not to prosecute.

The Environment Code makes provision for criminal penalties, a fine or even a term of imprisonment (up to €150,000 and three years in prison), depending on the nature of the violation. For legal persons found to be criminally liable, the amount of the fine can reach €10M, depending on the infringement in question and the actual prejudice to the interests mentioned in Article L. 593-1.

The Public Health Code also makes provision for criminal penalties, consisting of a fine of from €3,750 to €15,000 and a term of imprisonment of six months to one year.

TABLE 8 **Number of reports transmitted by the ASN inspectors between 2018 and 2023**

	2018	2019	2020	2021	2022	2023
Report excluding labour inspection in the NPPs	14	8	4	2	3	4
Labour inspection report in the NPPs	2	4	8	0	2	2

Depending on the gravity of the offence, additional sentences may be applied to legal persons.

Class five penalties (fines) are stipulated in the field of nuclear safety for infringements mentioned in Article R. 596-16 of the Environment Code, as well as in the field of radiation protection for infringements mentioned in Articles R. 1337-14-2 to 5 of the Public Health Code, for example with regard to non-compliance with the requirements for notification of a significant event, to the administrative system (transmission of the title application file, compliance with general requirements, information concerning changes to the RPA).

With regard to pressure equipment, the provisions of Chapter VII of Title V of Book V of the Environment Code, which apply to products and equipment representing a risk, which covers pressure equipment, including that installed in BNIs, notably order the payment of a fine, plus a daily penalty payment as applicable, until compliance with the formal notice served on the licensees. This Chapter also includes provisions applicable to the manufacturers, importers and distributors of such equipment, aiming to ban the marketing, commissioning or continued operation of an equipment item and to serve the licensee with formal notice to take all steps necessary to ensure conformity with the legislative and regulatory provisions applicable to its activity.

In the performance of their duties in NPPs, the ASN labour inspectors have at their disposal all the inspection, decision-making and enforcement resources of ordinary law inspectors (pursuant to Article R. 8111-11 of the Labour Code). Observation, formal notice, administrative sanction, report, injunction (to obtain immediate cessation of the risks) or even stoppage of the works, offer the ASN labour inspectors a broad range of incentive and constraining measures.

Finally, the inspector may record offences which do not fall within their scope of competence, such as an irregularity comparable to fraud (see point 5.1). In this case – and in the event of a misdemeanour this is mandatory – a report is sent to the Public Prosecutor's Office.

In 2023, six violation reports were drawn up by the ASN inspectors. Table 8 shows the number of Violation Reports drawn up by the ASN inspectors between 2018 and 2023.

CONTENTS

04

Radiological emergency and post-accident situations

04

Nuclear activities are carried out within a framework which aims to prevent accidents but also to mitigate their consequences. Despite all the precautions taken, an accident can never be completely ruled out and the necessary provisions for managing a radiological emergency situation must be planned for and regularly tested and revised.

Radiological emergency situations, resulting from an incident or accident liable to lead to an emission of radioactive substances or to a level of radioactivity potentially jeopardising public health, include:
- emergency situations arising on Basic Nuclear Installations (BNIs);
- accidents involving the transport of radioactive substances;
- emergency situations occurring in the field of small-scale nuclear activities.

Emergency situations affecting nuclear activities can also comprise non-radiological risks, such as fire, explosion or the release of toxic substances.

These emergency situations are covered by specific material and organisational arrangements, which include the contingency plans and involve both the licensee or party responsible for the activity and the public authorities.

The French Nuclear Safety Authority (ASN) is involved in managing these situations, with regard to questions concerning the regulation of nuclear safety and radiation protection and, backed more particularly by the expertise of its technical support organisation, the Institute for Radiation Protection and Nuclear Safety (IRSN), it has the following four key duties:
- check the steps taken by the licensee and ensure that they are pertinent;
- advise the authorities on population protection measures;
- take part in the dissemination of information to the population and media;
- act as Competent Authority within the framework of the international Conventions on Early Notification and Assistance.

In 2005, at the request of the Prime Minister, ASN also set up a Steering Committee for the Management of the Post-Accident Phase (Codirpa) so that, following on from the management of a radiological emergency, preparations can be made for the post-accident phase.

This pluralistic Committee notably comprises experts, representatives of the State's services, local elected officials, Local Information Committees (CLIs), associations, etc.

In 2022, this Committee published its latest recommendations to the Government. These aim notably to include the lessons learned from the accident at the Fukushima Daiichi Nuclear Power Plant (NPP – Japan) and the national emergency exercises 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 site emergency and contingency plans

The emergency and contingency plans relative to accidents occurring at a BNI define the measures necessary to protect the site personnel, the general public and the environment, and to control the accident.

a) Major Nuclear or Radiological Accident National Response Plan

ASN took part in drafting the Major Nuclear or Radiological Accident National Response Plan (PNRANRM), which was published by the Government in February 2014. The Plan incorporates the lessons learned from the Fukushima Daiichi NPP accident and the post-accident doctrine drawn up by the Codirpa in 2012. It specifies the national response to a nuclear accident, the strategy to be applied and 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 Plans
In the vicinity of the facility, the Off-site Emergency Plan (PPI) is established by the Prefect of the *département* concerned pursuant to Articles L. 741-6, R. 741-18 *et seq.* of the Domestic Security Code, *"to protect the populations, property and the environment, and to cope with the specific risks associated with the existence of structures and facilities whose perimeter is localised and fixed. The PPI implements the orientations of civil protection policy in terms of mobilisation of resources, information, alert, exercises and training"*. These Articles also stipulate the characteristics of the facilities or structures for which the Prefect is required to define a PPI.

The PPI specifies the initial actions to be taken to protect the general public, the roles of the various services concerned, the systems for giving the alert, and the human and material resources likely to be engaged in order to protect the general public.

The PPI falls within the framework of the Disaster and Emergency Response Organisation (Orsec) which describes the protective measures decided on by the public authorities in large-scale emergencies. Therefore, beyond the application perimeter of the PPI, the *département* or zone Orsec plan is activated. ASN assists the Prefect, who is responsible for the drafting and approval of the PPI, by analysing the various aspects with its technical support organisation, IRSN, including those concerning the nature and scale of the radiological consequences of an accident.

The PPIs currently make it possible to plan the public authorities' response in the first hours of the accident in order to protect the population living within a 20 km radius around the affected installation. The PPIs 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 PPIs 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 PPIs provide for the preventive distribution of stable iodine tablets for certain installations (reactors in particular), the adoption of measures to restrict consumption in the event of an accident, plus reinforced information of the populations regarding the risks from the installation and the appropriate behaviour to be followed.

The additional measures to be taken beyond the zone covered by the PPI are specified, as applicable, through a joint approach which can be based on the Orsec arrangements, taking account of the characteristics of the accident and the weather conditions.

c) On-site Emergency Plan
As part of the BNI commissioning authorisation procedures, ASN examines and approves the On-site Emergency Plans (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 PUI, known as the "emergency" resolution, approved by the Order of 28 August 2017.

1.1.2 Response plans for radioactive substance transport accidents

The transport of radioactive substances represents nearly a million packages carried in France every year. The dimensions, weight, radiological activity and corresponding safety implications can vary widely from one package to another.

ASN examines and approves the management plans for events linked to the transport of radioactive substances drawn up by the stakeholders for the transport of such substances pursuant to the international regulations for the carriage of dangerous goods. These plans describe the steps to be taken, depending on the nature and scale of the foreseeable hazards, in order to avoid damage or, as necessary, mitigate the effects. The content of these plans is defined in ASN Guide No. 17.

To deal with the possibility of a radioactive substances transport accident, each *département* Prefect must include in their implementation of the PNRANRM a part devoted to this type of accident, the Orsec-TMR (Transport of Radioactive Materials) plan. Faced with the diversity of possible types of transport operations, this part of the plan defines the criteria and simple measures enabling the first respondents (Departmental Fire and Emergency Service – SDIS – and law enforcement services in particular) to initiate the first reflex response measures to protect the general public and sound the alert, based on their findings on the site of the accident.

1.1.3 The response to other radiological emergency situations

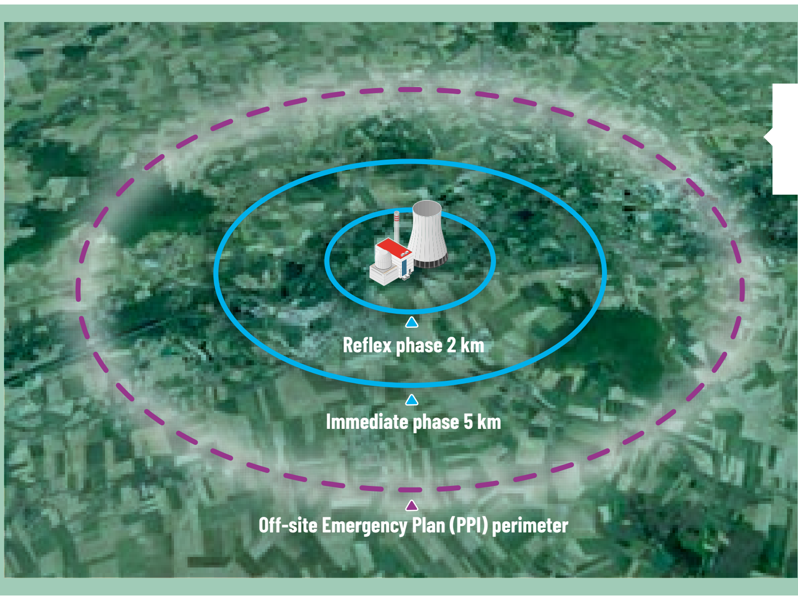
Apart from the incidents or accidents which could affect nuclear installations or radioactive substances transport operations, radiological emergency situations can also occur:
- during performance of a nuclear activity for medical, research or industrial purposes;
- in the event of intentional or inadvertent dispersal of radioactive substances into the environment;
- if radioactive sources are discovered in places where they are not supposed to be.

In such cases, intervention is necessary to limit the risk of human exposure to ionising radiation. Together with the Ministries and the parties concerned, ASN therefore drafted Circular DGSNR/DHOS/DDSC No. 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**



Nationwide:
Application of the Major Nuclear or Radiological Accident National Response Plan

Situation 1 of the Plan: Immediate and short-duration release	**Reflex phase**	Shelter and await instructions over 2 km Consumption restrictions
Situation 2 of the Plan: Immediate and long-duration release	**Immediate phase**	Shelter and await instructions over 2 km, then evacuation over 5 km Consumption restrictions
Other situation	**Joint response**	Protection measures for the population based on dose forecasts and taking account of the local context

1.1.4 Controlling urban development around nuclear sites

The aim of controlling urban development is to limit the consequences of an accident for the population and property. An approach of this type has been in place since 1987 around non-nuclear industrial facilities and was reinforced following the AZF plant accident in Toulouse in 2001. Act 2006-686 of 13 June 2006 concerning transparency and security on nuclear matters (TSN Act, now codified in Books I and V of the Environment Code), enables the public authorities to control urban development around BNIs, by implementing institutional controls limiting or prohibiting new constructions in the vicinity of these facilities.

The actions to control urban development entail a division of responsibilities between the licensee, the mayors and the State:
- The licensee is responsible for its activities and the related risks.
- The Mayor is responsible for producing the town planning documents and issuing building permits.
- The Prefect informs the mayors of the existing risks, verifies the legality of the steps taken by the local authorities and may impose institutional controls as necessary.

ASN supplies technical data in order to characterise the risk, and offers the Prefect its assistance in the urban development control process.

The current approach to controlling activities around nuclear facilities exclusively concerns those subject to a PPI and primarily aims to preserve the operational nature of the contingency plans, in particular for sheltering and evacuation, while limiting the population numbers concerned as far as possible. It focuses on the PPI "reflex" zone, determined by the Circular of 10 March 2000 revising the PPIs for BNIs, the pertinence of which was confirmed by the instruction of 3 October 2016.

In this "reflex" zone, immediate steps to protect the population are taken in the event of a rapidly developing accident (see point 1.1.1 b).

A 17 February 2010 Circular from the Ministry responsible for the environment concerning the control of activities in the vicinity of BNIs liable to present dangers off the site asked the Prefects to exercise increased vigilance with regard to urban development in the vicinity of nuclear facilities. This Circular states that the greatest possible attention must be paid to projects that are sensitive owing to their size, their purpose, or the difficulties they could entail in terms of protection of the general public in the "reflex" zone.

ASN is consulted on construction or urban development projects situated within this zone. The opinions issued are based on the principles explained in ASN Guide No. 15 on the control of activities around BNIs published in 2016. This guide, drawn up by a pluralistic working group jointly overseen by ASN and the General Directorate for Risk Prevention (DGPR), comprising elected officials and the National Association of Local Information Committees and Commissions (Anccli), has the following basic objectives:
- preserve the operational nature of the contingency plans;
- give priority to regional development outside the "reflex" zone;
- allow controlled development that meets the needs of the resident population.

1.2 THE EMERGENCY SITUATION STAKEHOLDERS

The response by the public authorities to a major nuclear or radiological accident is determined by a number of texts concerning nuclear safety, radiation protection, public order and civil protection, as well as by the emergency plans.

Act 2004-811 of 13 August 2004 on the Modernisation of Civil Protection, makes provision for an updated inventory of risks, an overhaul of operational planning, performance of exercises involving the general public, information and training of the general public, an operational watching brief and alert procedures. Several Decrees implementing this Act, codified in Articles L. 741-1 to L. 741-32 of the Domestic Security Code, more specifically concerning the Orsec plans and PPIs, clarified it in 2005.

How radiological emergency situations are dealt with is specified in the Interministerial Directive of 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation (see Diagram 1).

Thus, at the national level, ASN is an active participant in interministerial work on nuclear emergency management.

The Fukushima Daiichi NPP accident showed that it was necessary to improve preparation for the occurrence of a 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 advise the prefect regarding population protection measures.
- The Prefect of the defence and security zone is responsible for coordinating reinforcements and the support needed by the Prefect of the *département*, for ensuring that the steps taken between *départements* are consistent, and for coordinating regional and national communications.
- Owing to his or her role in the local community, the Mayor has an important part to play in anticipating and supporting the measures to protect the population. To this end, the Mayor of a municipality included within the scope of application of a PPI must draw up and implement a local safeguard plan to provide for, organise and structure the measures to accompany the Prefect's decisions. The Mayor also plays a role in relaying the information and heightening population awareness, more particularly during iodine tablet distribution campaigns.

1.2.2 National response organisation

In a radiological emergency situation, each Ministry – together with the decentralised State services – is responsible for preparing and executing national level measures within their field of competence.

In the event of a major crisis requiring the coordination of numerous players, a governmental crisis organisation is set up, under the supervision of the Prime Minister, with activation of the Interministerial Crisis Committee (CIC). The purpose of this Committee is to centralise and analyse information in order to prepare the strategic decisions and coordinate their implementation at interministerial level. It comprises:
- all the Ministries concerned;
- the competent safety Authority and its technical support organisation (IRSN);
- representatives of the licensee;
- administrations or public institutions providing assistance, such as *Météo-France* (national weather service).

1.3 PROTECTING THE POPULATION

The steps to protect the populations during the emergency phase, as well as the initial actions as part of the post-accident phase, aim to protect the population from exposure to ionising radiation and to any chemical and toxic substances that may be present in the releases. These measures are mentioned in the PPIs.

1.3.1 General protection measures

In the event of a major nuclear or radiological accident, a number of measures can be envisaged by the Prefect in order to protect the population:
- Sheltering and awaiting instructions: the individuals concerned, alerted by a siren, 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.

A first information and iodine tables distribution campaign within a radius of 0 to 10 km around the NPPs was carried out in 2016-2017, supplemented in 2019-2021 by a campaign in the 10-20 km zone following extension of the PPI.

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 have drawn up plans to distribute stable iodine tablets in a radiological emergency situation, which can be included in 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 first version of which was published in 2018, and the drafting of which was coordinated by ASN, 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 protocols and methods for treating contamination, was published in June 2023.

1.4 UNDERSTANDING THE LONG-TERM CONSEQUENCES

The post-accident phase concerns the handling over a period of time of the consequences of long-term contamination of the environment by radioactive substances following a nuclear accident.

It covers the handling of consequences that are varied (economic, health, environmental and social), by their nature complex and that need to be dealt with in the short, medium or even long term, with a view to returning to a situation considered to be acceptable.

The procedure followed by the Codirpa, set up by ASN in 2005 at the request of the Prime Minister, led to the development of constituents of a first national doctrine for the post-accident management of a moderate scale nuclear accident leading to short-duration releases (less than 24 hours), published in 2012.

Following the work done by Codirpa to take better account of the lessons learned from the accident at the Fukushima Daiichi NPP, Operating Experience Feedback (OEF) from emergency exercises, changes to the regulations and to the international recommendations, a new version of the recommendations for post-accident management of a nuclear accident was published in 2022.

This document today constitutes the basis for post-accident management of a nuclear accident in France. It is intended for the local and national stakeholders concerned. 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 strategies to reduce the contamination of an area affected by a radiological or nuclear accident related to management of the associated waste, while taking account of the implications for the various types of environments affected (urban, agricultural, forest, etc.). In addition and in accordance with the mandate from the Prime Minister dated 18 June 2020, the examination of the pertinence of the post-accident management doctrine in the event of releases of radioactive substances into aquatic environments, whether the sea, lakes or rivers, was started at the beginning of 2023.

ASN continued with its approach to include the population in the drafting of Codirpa's recommendations and organised two meetings with the pupils of middle and high schools situated within the perimeter of the PPI of the Nogent-sur-Seine NPP. Finally, in the same way as for the meetings held in 2021 and 2022, ASN will be organising discussion sessions in 2024 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.

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.

Checking the steps taken by the licensee

In the same way as in a normal situation, ASN acts as the regulatory authority in an accident situation. In this particular context, ASN ensures that the licensee exercises in full its responsibility for keeping the accident under control, mitigating the consequences, and rapidly and regularly informing the public authorities. It draws on IRSN's expertise and assessments and can at any time ask the licensee to perform appraisals and take the necessary actions, without however taking the place of the licensee in the technical operations.

Advising the *département* and zone Prefects and the Government

The decision by the Prefect concerning the general public protection measures to be taken in radiological emergency and post-accident situations depends on the actual or foreseeable consequences of the accident around the site. The law states that it is up to ASN to make recommendations to the Prefect and the Government, incorporating the analysis carried out by IRSN. This analysis covers both a diagnosis of the situation (understanding of the situation of the installation affected, analysis of the consequences for humans and the environment) and a prognosis (assessment of possible developments, notably radioactive releases). These recommendations more specifically concern the steps to be taken to protect the population in the emergency and post-accident phases.

Circulation of information

ASN is involved in informing:
- the media and the public: publication of press releases and organisation of press conferences; it is important that this action be coordinated with the other entities required to communicate (Prefects, licensees at both local and national levels, etc.);
- institutional and associative stakeholders: local authorities, ministries, Prefectures, political authorities, general directorates of administrations, CLIs, etc.;
- foreign nuclear safety regulators.

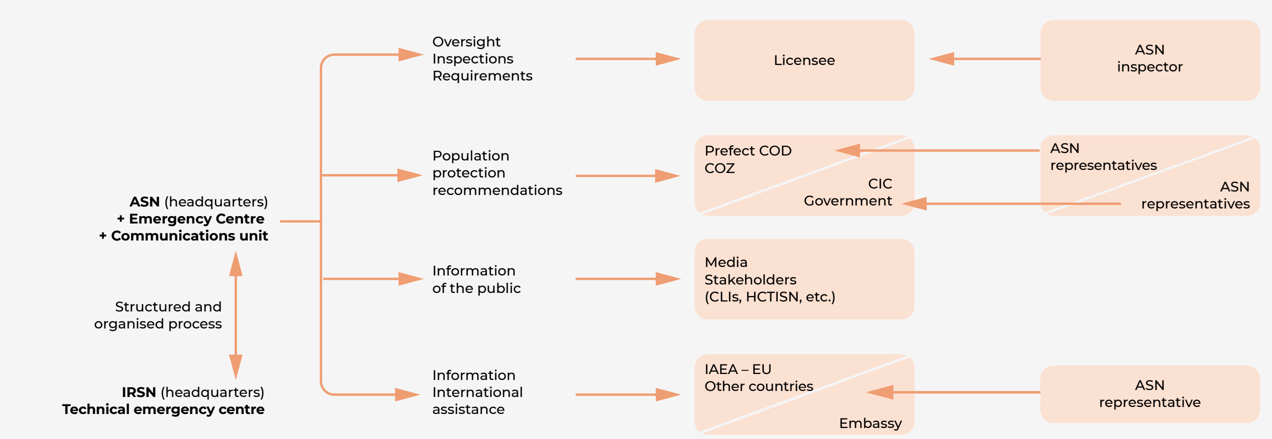
Function of Competent Authority as defined by international conventions

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.

DIAGRAM 2 **The role of ASN in a nuclear emergency situation**



COD: Departmental Operations Centre – **COZ:** Zone operations Centre – **CIC:** Interministerial Crisis Committee – **CICNR:** Interministerial Committee for Nuclear or Radiological Emergencies – **CLI:** Local Information Committee – **HCTISN:** High Committee for Transparency and Information on Nuclear Security

INSPECTION OF THE EMERGENCY ORGANISATION AND RESOURCES AT THE BLAYAIS NPP

In December 2023, ASN carried out an inspection in the Blayais NPP on the topic of emergency organisation and resources, focusing more specifically on the services of the Nuclear Rapid Response Force (FARN(*)). This inspection was part of a wide-ranging exercise involving a FARN intervention on the NPP site, during which numerous mobile resources were deployed (helicopter, emergency generating sets, independent telecommunication resources, etc.). The inspection continued with interviews with the various FARN parties involved in the exercise, in order to compare the observations made in the field by the inspectors, with feedback from the various players. This inspection enabled the ASN inspectors, in direct contact with the FARN teams, to observe the operational nature of the FARN's resources and how it works.

** The FARN is a national emergency system set up by EDF, involving specialised crews and equipment for intervening on a site affected by an accident within less than 24 hours.*

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 2023, the ASN Emergency Centre was activated 15 times for 11 national exercises, 2 international exercises and 2 real situations.

The ASN emergency organisation was called on several times in 2023, following triggering of the PUI on nuclear installations.

On 3 March 2023 at 21h11, the Cattenom NPP in the Moselle *département* (57) activated its PUI following an outbreak of fire on a fan in the controlled zone. The discussions between ASN and EDF led to the alert rapidly being lifted as the fire had been extinguished by the fire brigade on the site.

On 30 July 2023 at 16h52, the Bugey NPP in the Ain *département* (01) activated its PUI following an outbreak of fire in the reactor 4 turbine hall, outside the controlled zone. The on-call team was activated in order to monitor the development of the situation and prepare to activate the Emergency Centre if necessary. The fire was rapidly extinguished, with no consequences for the safety of the installation and ASN authorised lifting of the PUI a few hours after it was activated.

On 17 October 2023 at 12h27, the Blayais NPP in the Gironde *département* (33) activated its PUI following the inflammation of an acetylene cylinder stored on a welding worksite in the reactor 1 turbine hall, outside the nuclear zone. ASN activated its Emergency Centre in order to monitor the situation. After the gas bottle was sprayed by the EDF response teams and then by the outside emergency services, it was removed from the turbine hall at about 15h30, immersed in a container of water to stop combustion and placed under surveillance. ASN then authorised lifting of the PUI.

On 19 October 2023 at 8h59, the Institut Laue Langevin in the Isère *département* (38) activated its PUI following a bomb threat. ASN activated its Emergency Centre in order to monitor the situation and anticipate any consequences for the safety of the facility. After a detailed inspection of the facility, no explosive device was found.

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.

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) *Météo-France*	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

Since 2018, an on-call duty system reinforces the robustness and the mobilisation and intervention reactivity of the ASN staff.

Diagram 2 (see page 175) summarises the role of ASN in a nuclear emergency situation. This functional diagram illustrates the importance of the ASN representative to the Prefect, who relays and explains the recommendations coming from the ASN Emergency Centre.

Table 1 shows the positions of the public authorities (Government, ASN and technical experts) and the licensees in a radiological emergency situation. These players each operate in their respective fields of competence with regard to assessment, decision-making, intervention and communication, for which regular audio-conferences are held. The exchanges between the players lead to decisions and orientations concerning the safety of the facility and the protection of the general public. Similarly, relations between the communication units and the spokespersons of the emergency centres ensure that the public and media are given coherent information.

3 Learning from experience

3.1 CARRYING OUT EXERCISES

The main aim of these nuclear and radiological emergency exercises is to test the planned response in the event of a radiological emergency, in order:
- to measure the level of preparedness of all the entities involved (safety Authorities, technical experts, licensees);
- to ensure that the plans are kept up to date, that they are well-known to those in charge and to the participants at all levels and that the alert and coordination procedures they contain are effective;
- to train those who would be involved in such a situation;
- to implement the various aspects of the organisation and the procedures set out in the Interministerial Directives: the emergency plans, the contingency plans, the local safeguard plans and the various conventions;
- to contribute to informing the media and to develop a general public information approach so that everyone can, through their own individual behaviour, contribute to civil protection;
- to build on emergency situation management knowledge and experience.

These exercises, which are scheduled by an annual interministerial instruction, involve the licensee, the Ministries, the offices of the Prefects and services of the *départements*, ASN, the Defence Nuclear Safety Authority (ASND), IRSN and *Météo-France*, which can represent up to 300 people when resources are deployed in the field. They aim to test the effectiveness of the provisions made for assessing the situation, the ability to bring the installation or the package to a safe condition, to take appropriate measures to protect the general public and to ensure satisfactory communication with the media and the populations concerned.

3.1.1 National nuclear and radiological emergency exercises

In the same way as in previous years, and together with the SGDSN, the DGSCGC and the ASND, ASN prepared a programme of national nuclear and radiological emergency exercises for 2023, concerning BNIs and the transport of radioactive substances.

This programme was announced to the Prefects in the interministerial instruction of 17 January 2023.

TABLE 2 **National nuclear and radiological emergency exercises conducted in 2023**

NUCLEAR SITE	DATES OF EXERCISE	MAIN CHARACTERISTICS
FBFC, Framatome (Romans-sur-Isère – 26)	1 and 2 March	• Addressing chemical and radiological hazards • Decision-making process, dispatch of ASN inspectors to the affected site • Consideration of OEF from the 2022 incident
Orano TN (11)	13 April	• Coordination with transport stakeholders • Feedback of transmission from the field
Istres naval base (13)	10 and 11 May	• Interfacing with ASND and simulated media pressure • Recommendations for post-accident management
EDF Saint-Laurent-des-Eaux NPP (41)	23 and 24 May	• Decision-making process and simulated media pressure • ASN inspectors dispatched to the affected site
EDF Golfech NPP (82)	7 and 8 June	• Decision-making process and simulated media pressure • ASN inspectors dispatched to the affected site
CEA Saclay centre (91)	22 and 23 June	• ASN inspectors dispatched to the affected site
EDF Chooz NPP (08)	12 and 13 September	• Exchange of information with neighbouring country • ASN inspectors dispatched to the affected site
Institut Laue Langevin research reactor (38)	9 November	• Transmission of data from the facility • Decision-making process and simulated media pressure
Toulon naval base (13)	22 and 23 November	• Decision-making process and simulated media pressure
EDF Nogent-sur-Seine NPP (10)	23 and 24 November	• Decision-making process and simulated media pressure • ASN inspectors dispatched to the affected site
Orano Melox site (30)	6 and 7 December	• Consideration of alpha particle releases • Decision-making process and simulated media pressure

PARTICIPATION BY SCHOOLS AND RAISING AWARENESS AMONG THE YOUNG DURING THE EMERGENCY EXERCISE ON THE NOGENT-SUR-SEINE NPP

During the emergency exercise held on the Nogent-sur-Seine NPP (Aube *département* – 10) on 23 and 24 November 2023, several schools carried out their Emergency Operations Plan (EOP) activation exercises. This exercise was also an opportunity to organise two meetings with 4th and 6th year high-school students. The purpose was to discuss their vision of the nuclear accident, the correct reflexes in the event of an alert and what are the best means of communication to actually raise awareness among this young audience.

Following a presentation of the nuclear hazard and the protective measures to be taken, the students made suggestions for targeted awareness actions that could be used during national emergency exercises carried out by the public authorities. Unsurprisingly, the emphasis was on social media, with the inclusion of links to awareness-raising sites, the creation of original content, involvement of influencers. Other proposals, such as the creation of video games, escape games, or the use of virtual reality also emerged.

These meetings also used the ASN-IRSN exhibition as a teaching tool. The results of these meetings will be included in the Codirpa work on the safety and radiation protection culture, and incorporated into the final report to the Government, scheduled for 2024.

Generally speaking, these exercises enable the highest-level decision-making circles to be tested, along with the ability of the leading players to communicate, sometimes with simulated media pressure on them.

Table 2 describes the key characteristics of the national exercises conducted in 2023.

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 2023, 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 2022.

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 international bodies (IAEA, European Commission, Nuclear Energy Agency – NEA);
- the Ministries for Health, the Interior, etc.

The experience acquired during these exercises should enable the ASN personnel to respond more effectively in real emergency situations.

CODIRPA RECOMMENDATIONS FOR MANAGING 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 (Japan) and from national emergency exercises, involving all the stakeholders (experts, State's services, CLIs, associations, licensees, etc.). The new *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.

3.2 ASSESSING WITH A VIEW TO IMPROVEMENT

Assessment meetings are organised immediately after each exercise in each emergency centre and at ASN a few weeks after the exercise. ASN, along with the other players, endeavours to identify best practices and the areas for improvement brought to light during these exercises.

These assessment meetings enable the players to share their experience through a participative approach. They more specifically revealed:
- the importance of having scenarios that 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

Following on from the efforts made in 2023, particular attention will be paid during the exercises to emergency information and communication. Regular work will also continue on transboundary coordination with neighbouring countries in order to provide a coherent and harmonised response to any transboundary accident.

The dispatch of ASN inspectors to a site that has experienced an accident, which has been regularly tested since 2021, will also be continued during the exercises.

With regard to inspections, ASN will continue its efforts to test the operational nature of emergency management at the licensee by means of simulations.

2024 is the last year of the Codirpa's current mandate. The inclusion of new panels of citizens incorporating the general public into the pluralistic group for drafting of proposals to the Government, will enable the work on the following to be finalised: the consideration of accidents other than those in NPPs, waste management, and the management of aquatic environments in the post-accident phase. The INEX 6 exercise, proposed by the NEA in 2024, will be an opportunity to compare French post-accident doctrine with that of other countries, and to consolidate it if necessary.

Finally, ASN and IRSN will in 2024 carry out the preparatory work needed for the merging of their emergency organisations around a single emergency centre. The aim is to reinforce the effectiveness and visibility of the support provided to the State's services in an emergency situation.

CONTENTS

05

Informing the public

05

The Act of 13 June 2006 on Transparency and Security in the Nuclear Field defined not only the public's right to be informed but also the nuclear players' duty of transparency. To fulfil its duty to inform, the French Nuclear Safety Authority (ASN), focuses its efforts in two directions:

- 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 stakeholders (NGOs, professionals, local authorities, etc.) to obtain documents or to find out 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, but also for people living close to nuclear installations). To this end, ASN develops relations with its stakeholders and uses diverse vectors: printed or digital publications, website, social networks, events communication, etc.

Since 2022, ASN has participated in National resilience day (13 October) which aims to raise citizen awareness to natural and industrial risks. This national day brings together several nuclear sector actors (the National Association of Local Information Committees and Commissions – Anccli, EDF and the Institute for Radiation Protection and Nuclear Safety – IRSN) in order to raise public awareness of the nuclear risks and what to do in the event of a nuclear alert. To do this, the partners conducted a coordinated drive on the social networks during the month of October.

In its youth-focused work, ASN renewed its support for the "International High School Radiation Protection Meetings", where French and foreign high school pupils can share the research work they have s carried out during the academic year. On 23 and 24 May 2023, about a hundred high school pupils and their teachers from France, Japan and Moldova gave a presentation on the Marcoule site (Gard *département*) of their work on the prevention of risks associated with radioactivity.

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.

International High School Radiation Protection Meetings – May 2023

The *Cahiers de l'ASN* are distributed to nearly 6,000 subscribers and are available at *asn.fr*. Four *Cahiers* have been published since 2018 (Cahier #01 – *Nuclear power plants going beyond 40 years: the issues of the fourth periodic safety review of the French 900 MWe nuclear power reactors*; Cahier #02 – *Nuclear power plants going beyond 40 years: what are the conditions for the continued operation of EDF's 900 MWe reactors?*; Cahier #03 – *10 years after Fukushima: what safety improvements for nuclear facilities in France?*; Cahier #04 – *The decommissioning challenges: ensuring the correct performance of this final phase in the life of a nuclear facility).* A *Cahier de l'ASN* focusing on the issues of the fourth periodic safety review of the 1,300 Megawatts electric (MWe) reactors and another on the management of radioactive waste will be published in early 2024.

Furthermore, ASN launched a new magazine series in 2023: The *Cahiers Histoire de l'ASN* magazine, the first issue of which is devoted to nuclear accidents and developments in safety and radiation protection.

ASN sends its two-monthly *Lettre de l'Autorité de sûreté nucléaire* (ASN) 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 73,000 visits per month on average, the *asn.fr* website is at the heart of ASN's information organisation. It posts the draft opinions and resolutions that represent the most important issues for consultation.

The website is also a reference source of information for the more informed audiences: citizen experts, professionals, members of environmental associations. In all, nearly 3.5 million pages of the website were viewed in 2023.

The aim of the website is to facilitate access to its 25,000-odd pages devoted to the oversight of nuclear safety and radiation protection, the regulations, and ASN's actions in the areas of health, industry and nuclear research. Content and functionalities are available under the same 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.

A high-performance search engine and a map of the facilities (nuclear power, industrial and medical) provide for fast precise browsing.

The website endeavours to facilitate access to the desired information according to the audiences:
- workers in the sectors subject to ASN oversight and regulation (for the on-line services and forms in particular), technical experts, lawyers, people living near nuclear facilities, patients and medical practitioners, elected officials and journalists can access the news of the sites or the inspection documents that interest them: inspection follow-up letters, significant event notices, etc.;
- citizens interested in the safety issues and wishing to be involved in the decision-making process. Educational content (videos, computer graphics, topical files) is available and the "public consultation" module has been improved.

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 2023, 33 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 X, 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's social media accounts would also be used to inform the public in an emergency situation.

ASN news is followed and passed on by more than 17,200 subscribers on X, 47,600 on LinkedIn and 4,900 on Facebook.

1.1.3 The ASN/IRSN exhibition

As part of their duty to inform the public, ASN and IRSN have created educational content intended for high school pupils, students, employees, hospital personnel, patients, etc., and to the citizens in general. Comprising more than 80 display boards covering eleven themes, the exhibition, entitled *"Radioactivité – découvrir et comprendre"* (Learning about and understanding radioactivity) is designed to provide information on radioactivity – whether natural or artificial – its uses, its implications and its effects on human health and the environment.

The exhibition was hosted in 35 places in 2023: high schools, CLIs, healthcare facilities, regional authorities, etc.

This exhibition is made available on request, free of charge. It can be integrated into numerous events and meet the needs of varied situations (see next page).

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 2023, the on-line information centre responded to more than 656 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 nuclear safety and radiation protection. Over the last few years it has thus undertaken a major overhaul of the technical and general regulations applicable to Basic Nuclear Installations (BNIs), while always being attentive to the clarity and completeness of the information delivered to the professionals concerning these regulations. The same goes for radiation protection of workers and patients in the medical and industry sectors: ASN makes guides, practical sheets and reference manuals available to everyone.

"RADIOACTIVITÉ
DÉCOUVRIR & COMPRENDRE"

AN EXHIBITION TO RAISE PUBLIC AWARENESS

The ASN-IRSN exhibition *"Discovering and understanding radioactivity"* intends to disseminate clear and objective information, without taboos or biases, on radioactivity, its uses, its risks, and its effects on health and the environment.

Each display board features computer graphics along with precise explanations, a "debate" section setting out the diversity of opinions and a popularised presentation of the subject for the younger audiences.

Organise the exhibition to meet your specific need

You can set up the exhibition that will best meet the needs of your audience. It can be consulted on-line to choose the appropriate display boards.

Easy to set up

The exhibition takes the form of lightweight roll-up display boards that are easy to set up and take down. It can be adapted to the surface area and the layout of the hosting site.

It can be set up by a single 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.

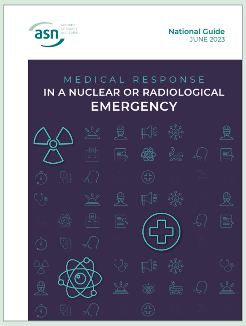
To borrow the exhibition, go to:
asn.fr/l-asn-informe/exposition-asn-irsn

11 SEQUENCES

85 DISPLAY BOARDS

- Radioactivity, what is it?
- The 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 with radioactive waste?
- The nuclear stakeholders

NATIONAL GUIDE – MEDICAL RESPONSE IN A NUCLEAR OR RADIOLOGICAL EMERGENCY



Coordinated by ASN through the Advisory Committee of Experts for Radiation Protection (GPRP), the national guide *Medical response in a nuclear or radiological emergency* was completely recast by a group of experts comprising physicians and medical personnel, including teams from the Emergency Medical Assistance Service (SAMU) and the Emergency Medical and Resuscitation Service (SMUR), the fire brigade and experts in radiation protection, internal dosimetry and bioassays.

Intended for the healthcare and civil security actors, this reference work covers the initial management and care of victims of nuclear or radiological emergencies, ranging from accidental exposure in the professional environment to a radiological emergency situation or terrorist action.

The 2023 issue incorporates the organisational changes that have come about since 2008 and the new contamination treatment protocols and means. Fully updated and supplemented, its layout has also been revisited further to a study of usages to adapt it to the needs of the professionals in the field.

This *Medical response to nuclear or radiological emergencies* guide is presented as operational sheets enabling the necessary information to be found whatever the situation: treatment in the event of irradiation, action to take in the event of contamination, procedure for removing clothing, means of protection, etc.). It also includes the possible treatments and dosage for each radionuclide.

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.

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. In 2023, ASN published revised versions of two ASN guides on transport: Guide No. 44 – *Quality management system applicable to the transport of radioactive substances* and Guide No. 29 – *Radiation protection in radioactive substance transport activities.*

The guide *New regulatory radiation protection provisions applicable in medical and dental radiology* of October 2021 was updated in October 2023.

ASN met the radiology professionals at the French Radiology Days (JFR) in Paris in October, and the radiation protection professionals at the congress of the French Society for Radiation Protection (SFRP) in Dijon in June. During these events, ASN presented the changes in the regulations, particularly the new registration system and the verifications of equipment and workplaces, in the form of a quiz and practical sheets.

A radiotherapy seminar to build ASN's oversight of tomorrow
On 15 March 2023, ASN brought together the radiotherapy professionals to assess the results of the fifteen years of quality initiatives in radiotherapy. Some 250 participants asked about how the quality initiatives contribute to the performance of the care system, in a context of greater complexity, fewer resources and major innovations.

The quality-safety culture has significantly improved since 2008 and the main safety fundamentals are in place in the radiotherapy departments. The seminar nevertheless brought to light a risk of "routinisation" and loss of momentum in the continuous improvement initiatives. It established the need to reflect collectively upon the simplification of these initiatives and the choosing of indicators that are result-oriented rather than process-oriented.

ASN will continue its reflections in collaboration with all the radiotherapy actors in order to adapt its oversight.

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 15 new registration application forms available to nuclear activity supervisors in the industrial, medical, veterinary and research sectors. ASN thus introduced a dematerialised procedure as soon as the new regulations came into effect.

1.2.3 Media for sharing good practices

The *Patient safety – Paving the way for progress* bulletin was created in March 2011 to disseminate the lessons learned from significant radiation protection events to medical professionals.

Since July 2019 it alternates between subjects devoted to radiotherapy, diagnostic medical imaging (conventional, computed tomography scanning and nuclear medicine) and Fluoroscopy-Guided Interventional Practices (FGIPs). Produced by multidisciplinary working groups coordinated by ASN, the newsletter offers a thematic presentation, good practices and recommendations developed by the learned societies of the discipline concerned and the health and radiation protection institutions.

Two bulletins were published in 2023. The May issue on the control of medical devices in FGIP, intended for the medical imaging professionals, and the October issue on the prospective risk analysis, for radiotherapy professionals.

In the industrial sector, a sheet entitled *Éviter l'accident – Appareils électriques émetteurs de rayons X : sécurités et signalisations en installation* (Avoiding accidents – Electrical devices emitting X-rays: safety systems and signalling in the installation facility) was published in May 2023. It aims to remind users of the importance of complying with the safety devices and the indications informing of the risk, to protect people against accidental exposure when conducting non-destructive inspections using industrial radiography.

These publications are available on *asn.fr*.

THE SUBJECTS THAT FOCUS MEDIA ATTENTION

A number of subjects received particular attention from the media and the public opinion in 2023: the stress corrosion cracks discovered on certain reactors, the Flamanville EPR reactor construction site and the problems with welds, the fourth periodic safety review of the 900 MWe reactors, the revival of nuclear energy and the development of Small Modular Reactors (SMRs), the nuclear sector's need for skills, the management of radioactive waste and taking climate change into account in the nuclear installations.

The incidents that occurred on certain nuclear sites (Bugey, Blayais) also interested the local media.

With regard to current events in the medical sector, the press focused on the events that occurred in certain radiotherapy departments, on dose optimisation, especially in the area of nuclear medicine, and exposure to radon.

1.3 THE MEDIA

ASN maintains regular relations with the regional, national and foreign media throughout the year. Each year, the ASN spokespersons respond to more than 500 press requests and give some twenty local and national press conferences.

The news in 2023 was largely taken up by the debates concerning the energy policy in France, with the Government announcing the construction of several Evolutionary Power Reactors (EPRs). The media also focused attention on the state of safety of the nuclear fleet and the continued operation of the reactors beyond 50 years.

The regional conferences provided local information for the media on the latest news of the oversight of the facilities, the risk culture and how it is integrated by the population. ASN also maintains relations with the medical press on the subjects of patient and medical personnel radiation protection.

Each year at the time of the publication of its annual *Report on the situation of nuclear safety and radiation protection in France*, ASN meets regional press journalists. Nine regional conferences held between late May and July 2023 brought together 70 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[1]. In order to prepare for this, ASN staff receive specific training and take part in exercises. Emergency exercises are held each year, with simulated media pressure from journalists designed to test ASN's responsiveness to the media, as well as the consistency and quality of the messages put across by the various players, both nationally and locally (see chapter 4). The social networks have been integrated in these simulations since 2011.

1.4 ELECTED OFFICIALS AND INSTITUTIONAL BODIES

Each year, ASN presents its annual *Report on the 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.

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.

1.5 INTERNATIONAL COOPERATION

ASN invests itself on the international scene to promote the sharing of best practices in informing the public. It 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 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 the information held by the licensees

The nuclear sector has a system that fosters public access to information. In application of Article L. 125-10 of the Environment Code, licensees must communicate to any person who so requests, the information they hold on the risks their activity presents for public health and the environment and on the measures taken to prevent or reduce these risks. This right to information on the risks also concerns those responsible for the transport of radioactive substances when the quantities involved exceed the thresholds set by law.

1. *According to Article L. 592-32 of the Environment Code.*

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).

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 licensee's expense.

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 development of public decisions having an impact on the environment. French law accordingly provides for a number of public participation instruments (public inquiries or on-line consultations).

On this account, a large number of draft texts (ASN regulations or individual resolutions) subject to ASN opinion or produced by ASN, are subject to public participation. ASN has developed a policy that is highly favourable to public participation and it also consults the public on certain draft opinions or guides.

2.3.1 Consultation of the public on draft ASN 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 subject to public participation. The same approach is applied for the ASN regulations relative to the transport of radioactive substances.

ASN's regulations relating to radiation protection are also submitted to public participation if they concern activities involving significant discharges into the environment, producing a significant quantity of waste, causing significant nuisance for the neighbourhood or representing a risk for the people living nearby and the surrounding environments in the event of an accident.

Lastly, ASN applies the same procedure to certain draft guides and draft opinions, even though they do not constitute ASN regulations within the meaning of Article L. 123-19-1. Ten consultations held in 2023 concerned draft ASN regulations.

The consultation for ASN regulations concerning 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.

2.3.2 Consultation of the public on draft individual resolutions

The individual resolutions[2] concerning nuclear safety and radiation protection can form the subject of several public consultation procedures which are presented below.

The public inquiry
In application of the Environment Code, the BNI creation authorisation and decommissioning applications are subject to a public inquiry[3]. The file that undergoes the public inquiry contains the impact analysis and the risk control analysis, among other things. The impact analysis and the risk control analysis provide a clearly understandable inventory of the risks that the projected installation represents and an analysis of the measures taken to prevent these risks. This analysis also includes a non-technical summary intended to facilitate the general public's understanding of the information it contains.

Since 2017, the public inquiry file can be consulted on line throughout the duration of the inquiry, and is provided in printed format in one or more predetermined places as soon as the public inquiry opens. The preliminary safety report (a more technical document) is not included in the public inquiry file but can be consulted throughout the inquiry period under the conditions set by the order governing the inquiry.

Article L. 593-19 of the Environment Code requires the review report submitted by the licensee following the periodic safety reviews beyond the 35th year of operation of a nuclear power reactor to be subject to public inquiry. This provision is particular in that the public inquiry in this case does not concern a project that is subject to authorisation by the administration, but a safety review report drawn up by the licensee. Articles R. 593-62-2 to R. 593-62-9 of the Environment Code set the conditions necessary for holding this public inquiry, notably to foster the effectiveness of public participation by enabling the public to assess the safety improvements already implemented and planned by the licensee in the context of the continued operation of its installation. ASN must take the results of this public inquiry into account in the resolution it may then have to issue to set additional requirements.

CONSULTATIONS, WHAT THEY INVOLVE

The public participation procedure consists, in the case of ASN regulations, in posting the draft regulation on the ASN website for at least 21 days in order to give people time to make their comments.

A synthesis of the remarks received, indicating how they were taken into account and a document setting out the reasons for the regulation are published on *asn.fr* at the latest on the date of publication of the regulation.

An indicative list of the scheduled consultations on draft ASN regulations and guides having an impact on the environment is updated every three months on *asn.fr*.

For the individual resolutions:
- it is the application file that is made available to the public if the resolution concerns an application,
- documents are available for consultation for fifteen days at least.

2. Resolutions that apply to a licensee for a given installation.
3. In application of the provisions of Article L. 593-8 or L. 593-28 of the Environment Code.

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 2023, 67 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 CLI (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 INFORMATION ACTORS

2.4.1 High Committee for Transparency and Information on Nuclear Safety

The High Committee for Transparency and Information on Nuclear Safety (HCTISN), created by the TSN Act, is a Committee that informs, discusses and debates on nuclear activities, their safety and their impact on human health and the environment.

It can also deal with any issue concerning the accessibility of nuclear security information and propose any measures such as to guarantee or improve transparency.

The HCTISN develops opinions and makes them public. It organises four plenary meetings per year, at which major topical subjects are presented and discussed: all the presentations are available at *hctisn.fr.* The ASN Chairman is a member of the High Committee; ASN sits on the board of the HCTISN in an advisory capacity, takes part in its various working groups and regularly provides information on the subjects on plenary session agendas.

In 2023, the two HCTISN groups, one devoted to the consultation on the fourth periodic safety review of the 900 MWe and 1,300 MWe nuclear power reactors, the other to the consultation for the *Cigéo* project, continued their work.

2.4.2 Institute for Radiation Protection and Nuclear Safety

The Institute for Radiation Protection and Nuclear Safety (IRSN) implements a policy of information and communication that is consistent with the objectives agreement signed with the State.

The Energy Transition for Green Growth Act, (called the "TECV Act") has obliged IRSN to render public the opinions it issues to the authorities who refer matters to it. Thus, since March 2016, IRSN publishes twice monthly on its website all the opinions it issues at the request of ASN. These opinions are the synthesis of the expert assessment carried out by IRSN in response to ASN's request.

On subjects that prompt questions on the part of the public or the public actors, ASN and IRSN ensure that their statements are properly coordinated in order to guarantee coherent, clear and consistent information.

2.4.3 Local Information or Monitoring Committees

The Local Information or Monitoring Committees (CLIs) have a general mandate of monitoring, informing and consultation with regard to nuclear safety and radiation protection. They analyse the impacts of nuclear activities on people and the environment within their scope[4].

ASN considers that the smooth functioning of the CLIs contributes to safety and it maintains a meaningful dialogue with them. It is attentive to ensuring that the CLIs are as fully informed as possible, including by attending their public meetings. In partnership with Anccli (see point 2.4.4), ASN fosters the networking of the CLI special advisors and gives the CLIs the necessary tools and assistance for them to provide reliable information to "layman" audiences. ASN assisted the CLIs at their request: on technical issues through its inspectors, and on questions of dissemination of information through its communication supervisors. The ASN-IRSN exhibition is regularly made available to the CLIs.

The ASN inspectors can also give the CLI representatives the opportunity to take part in inspections[5]. They motivate the BNI licensees to facilitate CLI access to files of the procedures in which their opinion will be required, and encourage involving the CLIs in the preparation of emergency exercises.

ASN considers that the development of a diversified range of expertise in the nuclear field is essential to enable the CLIs to base their opinions on expert assessments other than those carried out for the licensee or ASN itself. Anccli assists and supports the CLIs through its group of scientific experts. On 30 May 2023, it organised a technical discussion on the fourth periodic safety review of the 1,300 MWe reactors to which ASN contributed. Some CLIs call upon external service providers to advise them concerning technical files on which they wish to take a stance.

4. The operating framework for the CLIs is defined by Articles L. 125-17 to L. 125-33 of the Environment Code and by Decree 2008-251 of 12 March 2008 relative to the CLIs for the BNIs, and by Decree 2019-190 of 14 March 2019 codifying the provisions applicable to BNIs, to the transport of radioactive substances and to transparency in the nuclear field.

5. In the current situation, only the ASN inspectors and the experts accompanying them have an enforceable right of access to the licensee's facilities. This means that the consent of the licensee is necessary for observers from CLIs to participate in inspections.

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 35th CLI conference

The 35th CLI conference, organised on the initiative of ASN in partnership with the National Association of Local Information Committees and Commissions (Anccli), was held in Paris on 28 November 2023 and attended by more than 180 participants.

The morning session reviewed the prospects for the nuclear sector: the consultation on the fourth periodic safety reviews of the 1,300 MWe nuclear reactors, climate change and SMRs.

The afternoon session, which began with a presentation of the sociology of risk, was devoted to two round tables on the risk culture.

The first panel of foreign participants provided new perspectives on the nuclear, health and natural risk, with contributions from the French Nuclear Protection Evaluation Centre (CEPN), the World Health Organisation (WHO) and the Civil Security of Terrebonne in Quebec.

The second round table started with the lessons learned from the ASN barometer produced by Verian (formerly Kantar Public) on emergency management preparedness. It then highlighted the inspiring cross-border initiative of the Cattenom CLI with regard to post-accident preparedness and the mobile application *"Face aux Risques"* (Responding to Risks) developed by the Artois region's Permanent Secretariat for Prevention of Pollution and Industrial Risks.

The conference was illustrated by a graphic facilitator to foster its sharing within the CLIs.

2.4.4 National Association of Local Information Committees and Commissions

Article L. 125-32 of the Environment Code provides for the setting up of an association of CLIs (see point 2.4.3), and the Decree of 12 March 2008 details the mandate of this federation.

The National Association of Local Information Committees and Commissions (Anccli) brings together the 35 French CLIs and the 34 Committees put in place for the defence-related installations. Anccli has a scientific committee and has set up five thematic advisory groups ("Radioactive materials and waste", "Post-accident – territories", "Safety", "Decommissioning" and "Health"). It is also heavily involved in the discussion and interchange bodies set up by its partners (HCTISN, ASN, IRSN, etc.).

Partnership with ASN

Anccli takes part in various Advisory Committees of Experts or *ad hoc* working groups set up by ASN on topics such as environmental monitoring, waste, post-accident situations, and social, organisational and human factors. Thanks to the presence of Anccli, the viewpoint of civil society can be heard.

Anccli maintains a technical dialogue with ASN and IRSN on the high-stake issues and takes part in the public consultations on nuclear questions. In this context, ASN organised two technical webinars for CLI members in 2023: "heatwave and drought" (7 June) and "stress corrosion" (4 July).

Each year, ASN organises the national conference of CLIs in cooperation with Anccli.

The ASN Commissioners meet annually with the members of the Anccli Board of Directors, and ASN is invited to take part in the Anccli general meeting. Over time, these various interchanges have led to a relationship of trust and partnership between Anccli and ASN, over and beyond the multi-year agreement that binds the two institutions.

The activity of Anccli

Anccli runs the network of CLIs that it represents. By ensuring regular monitoring and issuing clarifications and information that can be readily understood by the general public, Anccli helps give the CLIs the means to fulfil their public information duties. Attentive to the concerns of the CLIs and in relation with diverse sources of expertise, Anccli conducts national reflections on nuclear safety issues and widely passes on the results of this work (Anccli positions) to the national and European bodies and to local elected officials and CLI audiences.

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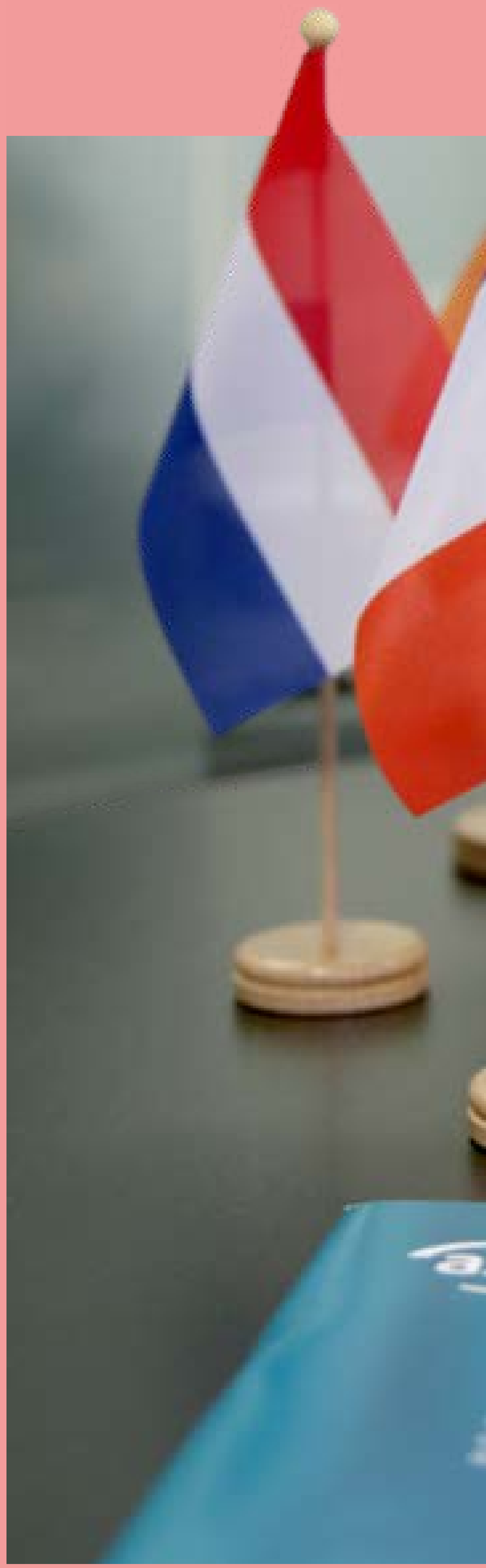


06

International relations

06

Through a range of bilateral, European and multilateral cooperation frameworks, in which it participates, the French Nuclear Safety Authority (ASN) aims to promote the establishment of ambitious international baseline requirements. Within these frameworks, ASN also ensures that the French positions and doctrines are made known and that international best practices are adopted to achieve progress in nuclear safety and radiation protection in France and worldwide.

ASN also submits proposals to the Government regarding France's positions in international negotiations within its field of competence, and represents France in the relevant international and community bodies.

1 ASN's objectives regarding international relations

The international arena is a strategic challenge to which ASN devotes particular attention and resources. ASN's actions in this field aim for continuous improvement in safety, based on changing knowledge and sharing of practices, in particular in terms of regulation and oversight. This action also aims to ensure ambitious harmonisation of international requirements regarding nuclear safety and radiation protection.

At a time of major changes in the international situation and of new challenges in the nuclear field, ASN's strategic goals are on the one hand to influence the establishment of international standards and practices and, on the other, to make the most of international feedback and collaborations. ASN's objectives are thus organised around four main points:

- to promote the creation of ambitious international baseline requirements;
- to make the French and European positions and regulations known to its counterparts;
- to encourage international work on the priority technical issues identified by ASN;
- to benefit from the best international practices to achieve progress in nuclear safety and radiation protection in France.

To achieve these goals, ASN maintains close bilateral relations with numerous countries. It also takes part in numerous multilateral exchanges within bodies and organisations with different statuses, whether at European level with the European Nuclear Safety Regulators Group (ENSREG), the Western European Nuclear Regulators Association (WENRA) and the Heads of the European Radiological Protection Competent Authorities (HERCA) or at the international level, more particularly with the International Atomic Energy Agency (IAEA) or the Nuclear Energy Agency (NEA) of the Organisation for Economic Cooperation and Development (OECD).

Through its bilateral relations, ASN has direct and fruitful exchanges with its counterparts on topical subjects or on particular points regarding regulations or oversight.

These exchanges are an opportunity for ASN to share its experience and compare its positions and practices. They also cast an outside light on position statements, technical questions or societal acceptability, thereby enriching the national debates and consolidating decisions and resolutions. They also enable ASN to be directly informed of the nuclear safety and radiation protection situation in other countries. In this respect, ASN's relations with its counterparts in neighbouring countries are of particular interest. These exchanges are also essential in the management of emergency situations.

Europe is one of the priority areas for ASN's international actions. ASN's goal is to contribute to the sharing, harmonisation and improvement of nuclear safety and radiation protection. ASN shares its vision of the priority issues, compares its analyses and discusses the nuclear safety and radiation protection practices of its counterparts. It ambition is to help establish a high level of stringency in this field at the European level, that can rely on harmonised baseline requirements and doctrines drawn up in a collaborative manner.

ASN is also working to develop the sharing of France's good practices and regulations in nuclear safety and radiation protection outside Europe. On this point, it aims to ensure that European doctrine, which promotes the highest levels of stringency, constitutes a benchmark worldwide, notably for countries adopting new reactor models and countries gaining access to nuclear energy for the first time. These international exchanges, which take place in a variety of circles, also enable ASN to benefit from international best practices and experience, thus helping to advance nuclear safety and radiation protection in France.

ASN is therefore active at three levels of international cooperation. It aims to ensure that a constant and balanced presence is maintained within each one, considering that each one is specific and that the complementarity between them contributes to the target of harmonisation and continuous improvement of nuclear safety and radiation protection.

2 The European framework for ASN's international relations

European harmonisation of nuclear safety and radiation protection principles and standards has always been a priority for ASN. In this context, ASN participates actively in exchanges between the national nuclear safety and radiation protection authorities of the Member States.

2.1 THE EURATOM TREATY AND ITS WORKING GROUPS

The Treaty instituting the European Atomic Energy Community (EURATOM) was signed on 25 March 1957 and constitutes the primary source of law in the field. It allowed the harmonised development of provisions allowing a strict regime of oversight for nuclear safety and security and radiation protection. In 2002, in its jurisprudence C-29/99, the Court of Justice of the European Union (EU) recognised that the Euratom Community shared competences with the Member States in the field of nuclear safety, going beyond simply the fields of radiation protection and information about emergency situations.

ASN experts participate in the work of the EURATOM Treaty committees and working groups in the following areas:

- Radiation Protection Basic Standards (Article 31);
- verification and monitoring of environmental radioactivity (Article 35);
- information concerning the monitoring of radioactivity in the environment (Article 36);
- notifications relative to radioactive effluent discharges (Article 37).

The Article 31 group of experts met twice in June and November 2023. It was informed of and consulted on the work of the European Commission notably with regard to:

- the SAMIRA strategy (Strategic Agenda for Medical Ionising Radiation Applications) and in particular various projects: QuADRANT, with the publication of RP 198 (EC Radiation Protection Guide No. 198), EU-JUST-CT (clinical peer audit in the field of the medical justification of computed tomography procedures) and SIMPLERAD (study on the implementation of the Euratom and the EU legal bases with regard to the therapeutic uses of radiopharmaceuticals);
- the evaluation of national radon plans, with publication of EC Guide RP 199 "Review and evaluation of national radon action plans in EU Member States according to the requirements of Council Directive 2013/59/Euratom";
- repeal of regulation 2021/1533 on product controls setting particular conditions for the import of foodstuffs and animal feedstuffs originating in or shipped from Japan, following the accident that struck the Fukushima Daiichi Nuclear Power Plant (NPP – Japan).

This group also issued an opinion on taking account of the dose coefficients published by the International Commission on Radiological Protection (ICRP) for estimations of effective doses and dose equivalents.

In addition, a scientific seminar was organised in November 2023 to review radiation protection issues concerning new external radiotherapy techniques. The proceedings of the 2022 "Safety and radiological protection considerations of nuclear fusion reactors" seminar were published.

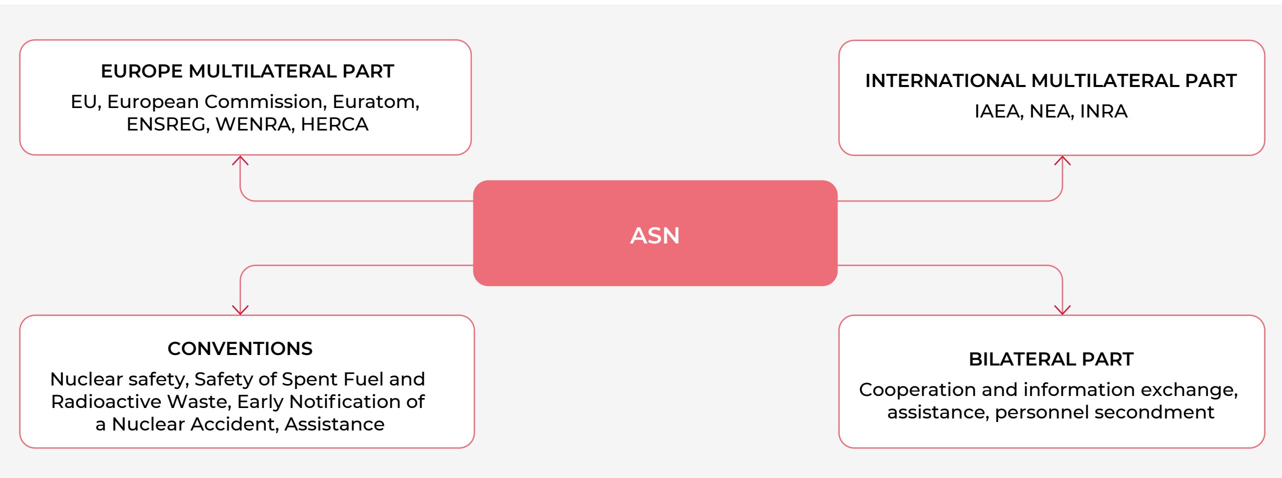
The group of experts of Article 37 of the EURATOM Treaty met in July 2023 to examine the radioactive waste geological repository project in Olkiluoto (Finland). In its opinion issued in December 2023, the European Commission considered that the operation of this repository would not be such as to lead to significant radioactive contamination of the waters, soil or air of another EU Member State. This was the first case of this type assessed by the European Commission, which will also be required to rule in the coming years on the impact of the *Cigéo* deep geological repository project.

2.2 THE EUROPEAN EURATOM DIRECTIVE ON THE SAFETY OF NUCLEAR FACILITIES

The Council 2009/71/Euratom Directive of 25 June 2009, revised in 2014 following the accident at the Fukushima Daiichi NPP, establishes a Community framework to ensure nuclear safety within the European Atomic Energy Community and to encourage the Member States to guarantee a high level of nuclear safety (see "Regulation" section on *asn.fr*).

It notably makes provision for greater powers and independence for the national safety regulators, reinforces requirements regarding transparency, sets an ambitious safety objective for all Member States (derived from the baseline safety requirements produced by WENRA), establishes a European peer review system for safety topics and requires periodic safety reviews every 10 years. It also reinforces provisions concerning education and training.

ASN action on the international stage



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 nuclear safety within the EU, by making the Member States more accountable for the management of their spent fuels and their radioactive waste.

This Directive is legally binding and covers all the aspects of spent fuel and radioactive waste management, from production through to long-term disposal.

It reiterates the prime responsibility of the producers and the ultimate responsibility of each Member State to ensure the management of the waste produced on its territory, making sure that the necessary measures are taken to guarantee a high level of safety and to protect workers and the general public against the dangers of ionising radiation.

It clearly defines the obligations regarding the safe management of spent fuel and radioactive waste and requires that each Member State adopt a legal framework for safety issues, making provision for the creation of:
- a competent regulatory authority with a status that guarantees its independence from the waste producers;
- authorisation procedures involving authorisation applications examined on the basis of the safety cases required from the licensees.

The Directive regulates the drafting of national spent fuel and radioactive waste management policies to be implemented by each Member State. More specifically, it requires each Member State to establish a legislative and regulatory framework designed to set up national programmes for the management of spent fuel and radioactive waste.

The Directive also contains provisions concerning transparency and participation of the public, the financial resources for management of spent fuel and radioactive waste, training, as well as obligations for self-assessment and regular peer reviews of the national framework and the competent regulatory authority. These aspects constitute major advances in reinforcing the safety and accountability of spent fuel and radioactive waste management in the EU. The Energy Transition for Green Growth Act of 2015 and the Ordinance of 10 February 2016 ensured that the provisions of the Directive were transposed into French law.

2.4 THE EUROPEAN EURATOM DIRECTIVE ON RADIATION PROTECTION “BASIC STANDARDS”

Directive 2013/59/Euratom of 5 December 2013 on Radiation Protection Basic Standards applies to the justification, optimisation and limitation of doses, regulatory control, preparedness for emergency situations, training and other related fields (for example the radon risk, Naturally Occurring Radioactive Substances and Construction Materials – 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 – the European Nuclear Safety Regulators Group – was created in 2008 and brings together experts delegated by the Member States of the European Union, 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, which began in 2017, concerned the management of nuclear reactor ageing and, with regard to France, ended with the publication of the closing report in 2021.

Work on the second thematic peer review concerning the protection of nuclear facilities against fire risks continued in 2023, with submission by the Member States of their national self-assessment reports. The France report, covering 11 installations representative of all the French installations, is available on *asn.fr*, in both French and English. It will be analysed by international experts in 2024, in the same way as the national reports by other Member States will be analysed by French experts.

2.6 THE EUROPEAN COMMUNITY URGENT RADIOLOGICAL INFORMATION EXCHANGE SYSTEM (ECURIE)

ECURIE, the European Community Urgent Radiological Information Exchange system, is one of the rapid action systems set up by the 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.

This system was put into place by a Decision of the EU Council of 14 December 1987, notably in the wake of the Chernobyl NPP accident (Ukraine) in 1986. This Decision was ratified by all the EU Member States and a certain number of third-party countries, such as Switzerland and Turkey. Within this context, ASN takes part in the “ECUREX” exercises organised by the European Commission. In 2023, ASN took part in two exercises of this type.

2.7 THE WESTERN EUROPEAN NUCLEAR REGULATORS’ ASSOCIATION (WENRA)

The Western European Nuclear Regulators’ Association (WENRA) was created in 1999 at the initiative of ASN and its current members are the 19 heads of the safety regulators of the European countries with experience in electricity generating reactors. It is open to 13 other countries with associate member or observer status.

WENRA was chaired from 2019 to November 2023 by the ASN Director General, Olivier Gupta.

WENRA plenary meeting in Montrouge – November 2023

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 members, aiming for the highest level of safety that is reasonably achievable. To achieve this, WENRA developed "safety reference levels" for each technical topic, based on the most recent IAEA Safety Standards. Subject to peer review, the WENRA members then examine whether these reference levels are indeed included in the regulations of their country, and modify them if not. Work has also been started to compare the procedures for actually implementing these reference levels in the nuclear installations.

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 2023 led to a number of significant advances, in particular:
- approval of the association's new strategy, taking account of the new international context and its nuclear challenges. WENRA thus decided to give priority to (i) establishing common safety requirements to be applied by each member on high-stakes subjects, (ii) establishing and adopting best practices in terms of regulatory cooperation for the evaluation of new technologies and (iii) drafting common positions on high-stakes subjects;
- confirmation of the need to revise the safety objectives currently applicable to the new reactors, in order to take account of the case of Small Modular Reactors (SMRs);
- publication of recommendations for the surveillance, detection and processing of the stress corrosion phenomenon that can affect welds on the stainless steel lines of pressurised water reactor primary systems;

CHANGE IN PRESIDENCY AT THE HEAD OF WENRA

Handover of the presidency of WENRA from Olivier Gupta (ASN) to Mark Foy (ONR)

During the plenary meeting in November 2023, WENRA approved the appointment of Mark Foy, Executive Director and Senior nuclear inspector of the United Kingdom's Office for Nuclear Regulation (ONR), and current Vice-President of WENRA, as the new President of the association. He thus replaces Olivier Gupta, ASN Director General, who occupied this position since 2019 and who becomes one of the two Vice-presidents, with the second one still being Petteri Tiippana, Director General of the Finnish nuclear safety regulator (*Säteilyturvakeskus* – STUK).

This change in presidency was an opportunity for the members of the association to highlight a number of achievements over the period 2019-2023, in particular regarding the work to update the Safety Reference Levels (SRLs) and harmonise the regulatory frameworks of WENRA's members, the publication of several joint positions on high-stakes subjects, the clarification of criteria for the expansion of WENRA, WENRA's actions to support Ukraine, the increase in WENRA's visibility both within and outside Europe, as well as the adoption of a new strategy taking account of the new international nuclear context.

- adoption of a joint declaration on the challenges linked to SMR development, underlining the benefits for the members of implementing joint evaluation processes for reactors with a sufficiently mature design, informing industry of their requirements, so that such joint evaluations can be satisfactorily implemented.

With respect to the war in Ukraine, WENRA maintained its exchanges with the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU) so that it could provide it with any support necessary. In 2023, the group of experts specifically appointed by WENRA in 2022 to carry out activities related to the war in Ukraine published its safety assessment of the Zaporizhzhia NPP following the failure of the Kakhovka dam.

In 2023, the WENRA Chairman also took part in various conferences organised by the WENRA stakeholders, such as IAEA or NEA, during which he shared his vision of the challenges faced by safety regulators, governments and industry in the new nuclear context.

For 2024, one of WENRA's priorities will be the implementation of its new strategy.

2.8 THE ASSOCIATION OF THE HEADS OF EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES (HERCA)

In the field of radiation protection, HERCA, founded in 2007, also at the instigation of ASN, is an association of the Heads of the European Radiological Protection Competent Authorities. Its aim is to reinforce European cooperation in radiation protection and to harmonise national practices.

HERCA now comprises 56 authorities from 32 European countries, comprising the 27 members of the EU, Iceland, Norway, the United Kingdom, Serbia and Switzerland. For the first semester of 2023, its technical secretariat was entrusted to the Swedish nuclear safety regulator (*Strålsäkerhetsmyndigheten* – SSM) which also chaired the association before this role was transferred to ASN. Since June 2023, Jean-Luc Lachaume, an ASN Commissioner, has chaired HERCA with the support of two vice-chairs, one from the Luxembourg health ministry and the other a Commissioner of the Spanish nuclear safety regulator (*Consejo de Seguridad Nuclear* – CSN).

Six expert groups are currently working on the following themes:
- practices and sources in the industrial and research fields;
- medical applications of ionising radiation;
- preparedness for and management of emergency situations;
- veterinary applications;
- natural radiation sources;
- education and training.

HERCA also hosts a network of experts which collaborate at several levels: collection, registration and reporting of occupational doses.

In June 2023, the association met in Stockholm, and then again remotely in November.

The undertakings made by the new Chair concern the concrete implementation of HERCA's strategy, with ASN making a significant contribution to its definition. The main areas for focus in 2023 are the following:
- reinforcing HERCA communications and visibility in order to improve the accessibility of its technical documentation and its positions by its stakeholders and the public;
- its continued active participation in the project to overhaul the recommendations of the ICRP;
- preparation of a seminar dedicated to implementation of Council Directive 2013/59/Euratom of 5 December 2013 (see point 2.4), by its member countries and with the participation of the European Commission in May 2024.

In June 2023, HERCA also organised a seminar devoted to radiotherapy inspection and took part in a number of international events, including those organised by the ICRP and North Atlantic Treaty Organisation (NATO) in September 2023, dedicated to management of emergency situations. Finally, HERCA published the "country data sheets" of its members regarding the designation of radiation protection experts and officers required by Directive 2013/59/Euratom.

2.9 THE EUROPEAN COMMISSION'S ASSISTANCE PROGRAMMES

At the European level, through the Instrument for Cooperation on Nuclear Safety (ICNS) it created in 2007, the European Commission enables nuclear safety regulators in emerging countries to benefit from assistance missions to help them set up or reinforce their regulatory framework and practices in the field of nuclear safety and radiation protection.

In 2021, the European Parliament approved a new instrument equivalent to the ICNS, the European instrument for assistance and cooperation in nuclear safety (EINS), endowed with a budget of 300 million euros for the period 2021-2027. This budget allows funding of activities carried out by the nuclear safety regulators of the Member States, their technical support organisations and other organisations, as applicable, on behalf of the beneficiary countries.

It was thus in 2023 that ASN contributed to structuring a project to support the Forum of Nuclear Regulatory Bodies in Africa (FNRBA). The European Commission has allocated a budget of 4.8 million euros to this project, the aim of which is to support the development of a nuclear safety culture in several African countries and help them implement a regulatory framework based on the strictest nuclear safety and radiation protection standards.

If this project, which is to start in 2024, is confirmed, it would be implemented with the participation of several European States *via* their nuclear safety regulator or their technical support organisation within a consortium for which ASN would assume technical leadership and Expertise France administrative management.

The EINS instrument is supplemented by other international technical assistance programmes in response to resolutions taken by the G8 or by IAEA to improve nuclear safety in third-party countries and which are financed by contributions from donor States and from the EU.

3 The multilateral framework for ASN's international relations

At the multilateral level, cooperation takes place notably within the framework of the IAEA, a United Nations agency founded in 1957, and the NEA, created in 1958. These two agencies are the two most important intergovernmental organisations in the field of nuclear safety and radiation protection.

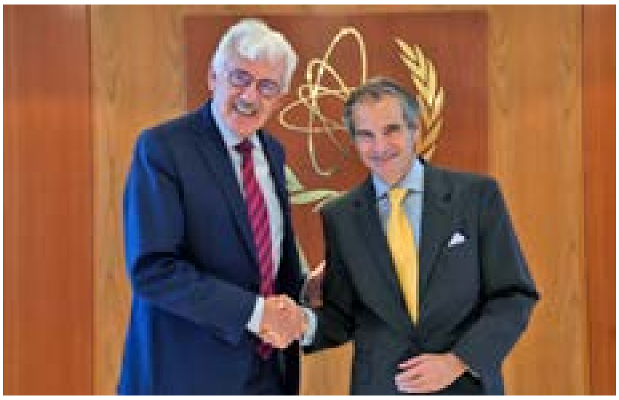
3.1 THE INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA)

The IAEA is a United Nations organisation based in Vienna and comprises 177 Member States. IAEA's activities are focused on two main areas: one of them concerns the control of nuclear materials and non-proliferation and the other concerns all activities related to the peaceful uses of nuclear energy. In this latter field, two IAEA departments are tasked with developing and promoting nuclear energy on the one hand and the safety and security of nuclear facilities and activities, on the other.

Following on from the action plan approved by the IAEA Board of Governors in September 2011 and with the aim of reinforcing safety worldwide by learning the lessons from the Fukushima Daiichi NPP accident, the IAEA is in particular focusing its work on the following fields: Safety Standards and peer review missions.

Safety Standards

The IAEA Safety Standards describe the safety principles and practices that the vast majority of Member States use as the basis for their national regulations. This activity is supervised by the IAEA's Commission on Safety Standards (CSS), set up in 1996. The CSS comprises 24 highest level representatives from the national safety regulators, appointed for a term of four years. One ASN Commissioner sits on this Commission. It coordinates the work of five committees tasked with drafting documents in their respective fields: NUSSC (Nuclear Safety Standards Committee) for the safety of reactors, RASSC (Radiation Safety Standards Committee) for radiation protection, TRANSSC (Transport Safety Standards Committee) for the safety of radioactive substances transport, WASSC (Waste Safety Standards Committee) for the safe management of radioactive waste and EPReSC (Emergency Preparedness and Response Standards Committee) for preparedness and coordination in a radiological emergency situation. France, represented by ASN, is present on each of these committees, which meet twice every year. Representatives of the various French organisations concerned also take part in the technical groups which draft these documents.



27 September 2023 meeting in Vienna between Bernard Doroszczuk, ASN Chairman, and Rafael Grossi, IAEA Director General

The year 2023 was notably marked by the publication of a large number of safety guides. A working group, of which ASN is a member, was also set up with the aim of drawing up a new long-term plan for the safety standards. The previous long-term plan dates from 2008 and its objectives have to a large extent been met. The new plan will identify the priorities for drafting new safety standards and will set guidelines for the committees and the secretariat. It should cover a period of 15 to 20 years and it should be approved in 2026.

Peer review missions

IAEA proposes several types of review missions for those Member States which so request. These missions are carried out by teams of experts on particular topics in the countries which so request. Each team of auditors consists of experts from Member States and from the IAEA. The audits are produced on the basis of the IAEA's baseline Safety Standards. Several types of audit are proposed, notably the IRRS (Integrated Regulatory Review Service) missions devoted to the national regulatory framework for nuclear safety and the working of the safety regulator, the OSART (Operational Safety Review Team) missions, devoted to the safety of NPPs in operation, or the ARTEMIS (Integrated Review Service for Radioactive waste and Spent Fuel Management, Decommissioning and Remediation) missions, devoted to national radioactive waste and spent fuel management programmes. The audit results are written up in a report transmitted to the requesting country and may comprise various levels of recommendations while also recognising good practices. It is up to the requesting country to take account of the recommendations issued by the experts. A follow-up mission, the purpose of which is to verify the progress made in taking account of the recommendations, is held between 18 months and 4 years after the initial mission, depending on the type of audit. ASN's situation regarding these missions is presented below.

IRRS Missions

The IRRS missions are devoted to analysing all aspects of the framework governing nuclear safety and the activity of a safety regulator. ASN is in favour of holding these peer reviews on a regular basis, and incorporates their results into its continuous improvement approach. It should be noted that, pursuant to the provisions of the 2009/71/Euratom Directive amended in 2014, the Member States of the EU are already subject to periodic and mandatory peer reviews of their general nuclear safety and radiation protection oversight organisation. The IRRS missions are a means of meeting this obligation.

In 2023, several ASN staff members took part in IRRS missions in the Czech Republic, Belgium, Romania and Morocco.

Given the ongoing reform of nuclear safety regulation and oversight in France, the decision was taken to postpone the IRRS mission in France, initially planned for 2024, to a later date.

OSART Missions

In France, it is ASN that asks the IAEA to organise OSART missions devoted to the safety of NPP operation, in coordination with EDF, the licensee of the NPPs.

Three OSART missions were held in France in 2023, in the Belleville-sur-Loire and Paluel NPPs (follows-up mission) as well as at Penly.

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 2023, in addition to preparing assistance for the nuclear safety regulators of Ghana and Poland, the RCF continued to reinforce its cooperation with the EU (EINS) and with regional safety regulator forums.

Management of nuclear and radiological emergency situations
ASN takes part in the IAEA's work to improve notification and information exchanges in radiological emergency situations.

On this subject, ASN takes part in the exercises organised by the IAEA to test the operational provisions of the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency, called "convention exercises" or "ConvEx exercises". These exercises, which are more specifically designed to enable the participants to acquire practical experience and understand the procedures involved in preparing and running these interventions, are of three types:
- the ConvEx-1 exercises, more specifically designed to test the emergency lines of communication established with the points of contact in the Member States;
- the ConvEx-2 exercises, designed to test particular aspects of the international framework for the preparation and performance of emergency interventions and the assessment and prognosis provisions and tools for emergency situations;
- the ConvEx-3 exercises, aimed at assessing the emergency intervention provisions and the resources in place to deal with a severe emergency for several days.

In 2023, ASN took part in two "ConvEx" exercises (see chapter 4).

ASN also takes part in defining international assistance strategy, requirements and means and in developing the Response Assistance Network (RANET) within the IAEA. This network was mobilised in 2022 to address the needs for individual protection and radiation protection resources expressed by Ukraine.

3.2 THE NUCLEAR ENERGY AGENCY (NEA) OF THE OECD

Created in 1958, the NEA today comprises 38 member countries from among the most industrially developed states. Its main goal is to help the member countries maintain and expand the scientific, technological and legal bases essential to the safe, environmentally-friendly and economical use of nuclear energy. Owing to the war in Ukraine, Russia's membership of the NEA was suspended on 2 April 2022.

Within the NEA, ASN is more particularly involved in the work of the Committee on Nuclear Regulatory Activities (CNRA). It also takes part in the Committee on Radiological Protection and Public Health, the Radioactive Waste Management Committee, the Committee on Decommissioning of Nuclear installations and Legacy Management, as well as several working groups of the Committee on the Safety of Nuclear Installations, including the Working Group on Human and Organisational Factors (WGHOF).

The various NEA committees coordinate working groups of experts from the member countries. 2023 was the first year of work by the groups created following the reorganisation of the CNRA. Five working groups, two expert groups and an information exchange forum have thus begun their activities. ASN is involved in each of them and in particular chairs the working group on the nuclear procurement chain and the working group on reactor surveillance, and is vice-chair of the expert group on sharing operational experience feedback.

3.3 THE INTERNATIONAL NUCLEAR REGULATORS' ASSOCIATION (INRA)

The International Nuclear Regulators Association (INRA) comprises the heads of the regulators of Canada, France, Germany, Japan, South Korea, Spain, Sweden, the United Kingdom and the United States. This association is a forum for regular and informal discussions concerning topical matters in these various countries and the positions adopted on common international issues. It meets twice a year in the country holding the Presidency, with each country acting as president for one year in turn.

Two meetings were held in 2023. The first, held in Canada, discussed the situation of the nuclear installations in Ukraine, more particularly the Zaporizhzhia NPP, national news and issues from the members of the association, and SMR development projects. In this respect, in a joint public declaration, the INRA members recalled their desire to develop collaboration to allow joint evaluations of SMR models at a sufficiently advanced stage in their design, while recalling the need to preserve national sovereignty with regard to the issuing of authorisations. During the second meeting, held in the margins of the AIEA General Conference, the head of SNRIU presented the state of safety in the country's nuclear installations, which led to a discussion on the impact of armed conflicts on the safety and security of nuclear installations. The members of INRA also tackled the issues related to maintaining safety culture and competence for NPP decommissioning programmes.

4 International conventions

ASN is the national point of contact and the Competent Authority for the two nuclear safety conventions which deal with NPPs (Convention on Nuclear Safety) and spent fuel and radioactive waste (Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management) respectively. ASN is also the Competent Authority for the two Conventions dedicated to the transboundary management of the possible consequences of accidents (the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency).

4.1 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 on Nuclear Safety was signed by France in 1994 and entered into force on 24 October 1996. At the end of 2023, it had 94 contracting parties.

The objectives of the Convention are to attain and maintain a high level of nuclear safety worldwide, to establish and maintain effective defences in nuclear facilities against potential radiological risks and to prevent accidents which could have radiological consequences and mitigate their consequences should they occur. The areas covered by the Convention have long been part of the French approach to nuclear safety.

In 2015, the contracting parties to the convention, taking account of the lessons learned from the Fukushima-Daiichi NPP accident, adopted the Vienna Declaration on nuclear safety. This Declaration, which extensively incorporates the principles of the European Directive on the safety of nuclear facilities, sets ambitious nuclear safety objectives aiming to prevent nuclear accidents worldwide and to mitigate the radiological consequences if one were to occur.

The Convention makes provision for review meetings by the contracting parties every three years, to develop cooperation and the exchange of experience.

As Competent Authority, ASN coordinates French participation in this three-yearly peer review exercise, in close collaboration with the institutional and industrial partners concerned. This coordination work concerns the drafting of the national report, analysis of the reports from the other contracting parties and participation in the review meetings.

Owing to the Covid-19 pandemic, the review meeting could not be held in 2020. A review meeting common to the 8th and 9th cycles was finally held in March 2023. ASN was present and active throughout this meeting, to ensure a presence and participation in the discussions in all the country groups.

During this review meeting, ASN presented France's report, which led to the identification of two good practices to involve the public in the 4th periodic safety review of the 900 Megawatts electric (MWe) reactors, and for collaboration with the Czech and Finnish authorities on the review of the Nuward reactor.

ASN is also actively participating in the meetings aiming to improve the effectiveness and efficiency of the Convention on Nuclear Safety, in preparation for the 10th review cycle, for which the reports are expected in 2025.

4.2 THE JOINT CONVENTION ON THE SAFETY OF SPENT FUEL MANAGEMENT AND ON THE SAFETY OF RADIOACTIVE WASTE MANAGEMENT

The Joint Convention is the counterpart to the Convention on Nuclear Safety for the management of spent fuel and radioactive waste from civil nuclear activities. France signed it on 29 September 1997, and it entered into force on 18 June 2001. At the end of 2023, this Convention had 89 contracting parties. In the same way as the Convention on Nuclear Safety, it is founded on a peer review mechanism, with each contracting party submitting a 3-yearly national report to the other parties for review, along with a review meeting.

The next meeting will be held in March 2025. The French report, for which the drafting is coordinated by ASN, will be submitted to IAEA in August 2024. In 2023, ASN began preparatory work on the drafting of this report, notably taking account of the lessons learned from its analysis of the previous report.

4.3 THE CONVENTION ON EARLY NOTIFICATION OF A NUCLEAR ACCIDENT

The Convention on Early Notification of a Nuclear Accident entered into force on 27 October 1986, six months after the Chernobyl accident and had 133 contracting parties at the end of 2023.

The contracting parties undertake to inform the international community as rapidly as possible of any accident leading to the uncontrolled release of radioactive substances into the environment and liable to affect a neighbouring State. For this purpose, the IAEA proposes a tool to the Member States for notification and assistance in the event of a radiological emergency.

ASN made an active contribution to the production of this tool, the USIE (Unified System for Information Exchange in Incidents and Emergencies), which is in use in ASN's Emergency Centre and is tested on the occasion of each exercise.

The Interministerial Directive of 30 May 2005 specifies the conditions of application of this text in France and mandates ASN as the Competent National Authority. It is therefore up to ASN to report the events to the international institutions without delay, to rapidly provide pertinent information about the situation, in particular to border countries, so that they can take the necessary population protection measures and, finally, to provide the ministers concerned with a copy of the notifications and the information transmitted or received.

4.4 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 123 contracting parties at the end of 2023.

Its aim is to facilitate cooperation between countries should one of them be affected by an accident having radiological consequences. This Convention has already been activated on several occasions as a result of irradiation accidents caused by abandoned radioactive sources. More specifically, France's specialised medical services regularly provide treatment for the victims of such accidents.

5 The bilateral framework for ASN's international relations

ASN collaborates with about twenty foreign safety regulators under bilateral agreements. 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

In March 2023, for the purpose of technical exchanges between ASN and the South African National Nuclear Regulator (NNR), two inspectors from ASN's Lyon regional division were welcomed at the NNR's Cape Town regional division, located near the Koeberg NPP. The mission concerned the fourth ten-yearly outages, continued operation of the reactors, inspection and oversight practices for reactor outages, and steam generator replacement operations. A remote bilateral meeting was also held between the ASN and NNR managements and confirmed the principle of an equivalent mission at ASN's Lyon regional division for NNR inspectors during the course of 2024.

GERMANY

The Franco-German Commission was created as an intergovernmental 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 2023, the Commission met on **14 and 15 June** and covered a number of topical subjects, including the situation of the NPPs located near the Franco-German border and updating of post-accident doctrine in France.

On the occasion of the 57th meeting of the working group on NPP safety, an ASN delegation went to Germany in September and was able to visit the waste treatment and storage facilities at the Karlsruhe Technology Institute.

In November, ASN also received German representatives as part of a working group focusing on preparedness for emergency situations, as well as a German inspector during a cross-inspection at the Cattenom NPP.

BELGIUM

The exchanges between ASN and its Belgian counterpart, the Federal Agency for Nuclear Regulation (*Agence fédérale de contrôle nucléaire* – AFCN), lead to national and local level cooperation actions, in particular with the border regional divisions of Lille and Châlons-en-Champagne. They are coordinated by the Franco-Belgian steering committee, which met at the ASN headquarters in Montrouge on **16 October 2023**. The two delegations, consisting of representatives of the authorities and their respective technical support organisations, the Institute for Radiation Protection and Nuclear Safety (IRSN) and Bel V, notably discussed energy policy changes in both countries and their consequences on NPP operations. The stress corrosion phenomenon observed on the French reactors in 2022 was also discussed. ASN also presented the progress made by the inspections and repairs on the Chooz and Gravelines reactors, which are those closest to the Franco-Belgian border. Finally, the topic of the continued operation of the NPPs was extensively discussed.

CANADA

On 5 December 2023, an ASN delegation headed by ASN Commissioner Sylvie Cadet-Mercier, met a delegation from the Canadian Nuclear Safety Commission (*Commission canadienne de sûreté nucléaire* – CCSN) headed by Ramzi Jammal, its interim Chairman, at the CCSN headquarters in Ottawa.

This meeting covered the issues associated with France's new energy policy, the extension of the operating life of the existing NPP fleet, the examination and assessment process implemented at the CCSN, safety culture and preparation of the CCSN's

Signing of cooperation agreements between ASN and its counterparts. ***From left to right:*** **NRA (Japan), ONR (United Kingdom) and NNSA (China)**

Meeting between Commissioners from ASN and the NRC (United States) – January 2023

inspection programme. The meeting was followed by a visit to GE Hitachi, concerning the BWRX-300 reactor project, and a visit to the Darlington NPP in Ontario. ASN and the CCSN restated their commitment to continue their cooperation and their information exchanges.

CHINA

The bilateral meeting between ASN and its Chinese counterpart, the National Nuclear Safety Administration (NNSA) was held on **14 November 2023**, in Beijing. The discussions notably concerned the stress corrosion affecting some of the French nuclear power reactors, radioactive waste management, recycling of very low level metallic waste and the SMR licensing process.

In addition, a number of technical meetings were held on Operating Experience Feedback (OEF) of the Taishan NPP, which houses the world's first two EPR type reactors to have been commissioned. These exchanges primarily aimed to examine to what extent Chinese OEF could be used in the current examination of the commissioning application for the Flamanville EPR.

SOUTH KOREA

A technical visit was organised around indoor presentations and site visits from **3 to 5 April 2023** by ASN's Bordeaux regional division for a delegation from the South Korean Nuclear Safety and Security Commission (NSSC).

The goal was to share ASN's inspection methods for industrial small scale nuclear facilities utilising ionising radiation. These technical exchanges will continue during a forthcoming ASN visit to South Korea.

UNITED ARAB EMIRATES

On 14 September 2023, ASN and its counterpart in the Emirates, the Federal Authority for Nuclear Regulation (FANR) signed an extension of their cooperation agreement for a period of five years.

SPAIN

The bilateral meeting between ASN and its Spanish counterpart (*Consejo de Seguridad Nuclear* – CSN) was held on **18 October 2023** in Madrid. The discussions notably covered national and regulatory topical subjects in both countries, decommissioning of installations, remediation of soils contaminated by radioactive substances, analysis of seismic risks in NPPs and the radon risk. ASN and the CSN also decided during this meeting to set up a system of short-term personnel secondments.

UNITED STATES

The ASN Commission and the American Nuclear Regulatory Commission (NRC) met **in January 2023** at the NRC headquarters to discuss SMRs, the continued operation of NPPs, involvement of the public and stakeholders in decision-making and safety and radiation protection culture among the general public.

This meeting was followed by a visit to the Vogtle site which is home to two AP1000 reactors and a visit to the Electric Power Research Institute (EPRI) in Washington on research subjects related to the continued operation of reactors and accident-resistant fuel.

In July 2023, ASN took part in an international seminar organised by the NRC on prolonging the lifetime of reactors.

In September 2023, an NRC Commissioner visited ASN and, along with the ASN Caen regional division, went to the Orano facilities at La Hague.

In December 2023, the 13th bilateral meeting between ASN and the NRC, held at the ASN headquarters, covered SMRs and continued operation of the reactors. Finally, in September, ASN and the NRC renewed their cooperation and information exchange agreement.

ISRAEL

In September 2023, in the margins of the IAEA general conference, a meeting was held between ASN and its Israeli counterpart (Israel Atomic Energy Commission – IAEC). This was an opportunity to renew the cooperation and information exchange agreement between the two regulators.

JAPAN

A bilateral meeting was held on **17 April 2023** in Tokyo. It enabled ASN to hold discussions with its Japanese counterpart (Nuclear Regulation Authority – NRA) on subjects such as continued operation of the NPPs, SMRs and inspection programmes. Participation by the Japanese Ministry of Health, the authority responsible for regulation and radiation protection of patients, also allowed discussions on this subject. A visit to the Fukushima Daiichi site followed the meeting.

In addition, a number of meetings and visits took place in France, including that by the Chairman of the NRA, with a visit organised to the Flamanville site, as well as technical meetings about the Fukushima Daiichi accident and inspection programmes. The visit by a delegation of NRA lawyers led to an unprecedented exchange on the litigious subjects being addressed by the safety regulators. This was followed by a visit to the Blayais site, focusing on natural external hazards. Technical exchanges on stress corrosion were also carried out remotely.

LUXEMBOURG

The Franco-Luxembourg joint Commission on nuclear safety held its 21st meeting on **12 June 2023** at the ASN headquarters in Montrouge. On this occasion, the Commission discussed recent developments in both countries in the fields of nuclear safety and radiation protection, including the 2022 results from the Cattenom NPP, stress corrosion phenomena, the fourth periodic safety review of the 1,300 MWe reactors, the new organisation for the transboundary alert system and preparedness for emergency situations.

Visit to the Orano facilities at La Hague by an American delegation – September 2023

NORWAY

On 19 September 2023, an ASN delegation met the Norwegian nuclear safety regulator (*Direktoratet for strålevern og atomsikkerhet* – DSA) in Oslo. During this meeting, the two delegations covered several technical subjects such as installations decommissioning, radioactive waste management, the radiation protection issues linked to the new techniques used in the medical sector, or preparedness for and response to emergency situations. This meeting was accompanied by a visit to the Kjeller research reactor currently being decommissioned.

NETHERLANDS

The first bilateral meeting between the Dutch nuclear safety regulator (*Autoriteit Nucleaire Veiligheid en Stralingsbescherming* – ANVS) and ASN was held in Montrouge on **10 November 2023**. The meeting was an opportunity to discuss topical subjects in both countries, changes to French and Dutch policies and programmes, new reactor construction projects in France and the Netherlands and OEF from ASN's Caen regional division regarding oversight of the Flamanville EPR reactor.

The desire for cooperation between the two regulators led to the signing of an agreement on **26 September 2023**, in the margins of the IAEA general conference in Vienna. A visit to the ASN Emergency Centre was also organised on **9 November 2023**.

CZECH REPUBLIC

In the margins of the 67th general conference of the IAEA, the ASN Chairman Bernard Doroszczuk met his Czech counterpart Dana Drábová from the Czech nuclear safety regulator (*Státní úřad pro jadernou bezpečnost* – SUJB). During this interview they discussed topical matters in both countries and the international issues regarding nuclear safety and radiation protection, in particular at a time of renewal of the nuclear sector and growing interest for SMRs. On this occasion, ASN and the SUJB welcomed the tripartite assessment carried out with the Finnish nuclear safety regulator (*Säteilyturvakeskus* – STUK) of the Nuward SMR project safety options. The collaboration agreement between ASN and the SUJB was renewed for a period of five years, thus confirming their desire to reinforce their bilateral relations.

UNITED KINGDOM

The bilateral relations with the British Office for Nuclear Regulation (ONR) took on a new dynamic in 2023 with a bilateral meeting in London from **8 to 10 February.** Against the backdrop of renewed interest in the nuclear sector in both countries, numerous subjects were covered, in particular new reactor projects, including SMRs and advanced reactors, and the consequences of global warming. This meeting also led to a visit to the EPR reactors construction site at Hinckley Point. Inspection practices during the construction phase of a nuclear installation were then discussed. The stress corrosion phenomenon was also a point of common interest, which subsequently led to the sharing of information between the specialist departments, as had been the case during the Sizewell reactor outage in March 2023.

The cooperation agreement between ASN and the ONR was renewed in 2023 for a period of five years.

SWEDEN

A bilateral meeting with ASN's Swedish counterpart (*Strålsäkerhetsmyndigheten* – SSM) was held in Stockholm from **31 May to 1 June 2023**. Several subjects of common interest were covered, such as the reuse of very low level metallic radioactive waste, international SMR initiatives, OEF from oversight of decommissioning of nuclear installations and management of the risks related to exposure to radon.

Visit by a Swedish delegation to the Chinon NPP – November 2023

The ASN delegation went to the Oskarshamn site for discussions on high level and intermediate level, long-lived waste management, as well as on the future spent fuels encapsulation plant.

A cycle of cross-inspections with the Swedish regulator was also restarted in 2023. In November, SSM inspectors accompanied ASN's Orléans regional division for an inspection on the Chinon NPP on the subject of fire.

The collaboration agreement between ASN and the SSM was renewed in 2023 for a period of five years, during the 67th general conference of the IAEA.

SWITZERLAND

The Franco-Swiss Commission (CFS) was created as an intergovernmental body and involves several national authorities competent at both national and local levels. This Commission met on **26 and 27 April 2023** at Cadarache in France. This meeting was an opportunity for the two delegations to visit the ITER fusion reactor construction site.

With regard to ASN, the CFS involves both the head office departments and the ASN Lyon and Strasbourg regional divisions.

5.2 ASN ASSISTANCE ACTIONS IN A BILATERAL FRAMEWORK

ASN may be required to respond to assistance requests *via* bilateral actions with the safety regulator of the country concerned, in addition to the instruments, both European (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.

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6 Outlook

ASN's dynamic international relations observed in 2022 were confirmed in 2023, with close relations with numerous foreign safety regulators and a strong presence by ASN in the international bodies.

The international nuclear environment is in a period of flux, with the emergence of new challenges. Following on from the actions already initiated in 2023, ASN will help to identify the priority and strategic subjects to be regularly tackled with its counterparts, notably those related to regulatory practices to authorise and oversee new nuclear reactor projects, such as SMRs, or the continued operation of the reactors in service.

At a time of renewed interest in nuclear energy in a certain number of countries, in particular in Europe (Sweden, Netherlands, etc.), ASN will in 2024 continue with the exchanges started in 2023 in order to meet the needs of its counterparts regarding the authorisation and oversight of new installations. Relations could also be intensified with the authorities of certain countries (Poland, Czech Republic, etc.) according to the political choices they will be making with regard to nuclear development.

At a European level, ASN will continue its actions within WENRA and HERCA, aiming to consolidate the role of the two associations on the international stage and reinforce the ability of their members to deal with the new challenges.

The year 2024 will also see a large number of international events, with the publication in the summer of the national report in preparation for the 8th review meeting of the Joint convention on the safety of spent fuel management and the safety of radioactive waste management, scheduled for March 2025. In addition, within the context of the 2nd thematic peer review under the European nuclear safety Directive, the year will also be devoted to work following on from the October 2023 publication of the national self-assessment report regarding the handling of the fire risk in nuclear installations.

ASN will also be maintaining its commitment to the NEA and the IAEA by promoting its position, in particular for the IAEA's Nuclear Harmonization and Standardization Initiative (NHSI) regarding SMRs.

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 bring out further progress with regard to safety.

CONTENTS

07

Medical uses of ionising radiation

07

For more than a century now, medicine has made use of ionising radiation produced either by electric generators or by radionuclides in sealed or unsealed sources for both diagnostic and therapeutic purposes. These techniques represent the second source of exposure of the population to ionising radiation (behind exposure to natural ionising radiation) and the leading source of artificial exposure (see chapter 1).

The exposure of patients to ionising radiation for diagnostic or therapeutic purposes is distinguished from the exposure of workers, the public and the environment, for which there is no direct benefit. The principle of dose limitation does not apply to patients due to the need to adapt the delivered dose to the diagnostic or therapeutic end-purpose. The principles of justification and optimisation are fundamental, even if the radiation protection risks differ according to the medical uses.

In radiotherapy (external-beam or brachytherapy) as in Internal Targeted Radiotherapy (ITR) which is developing strongly at present, the major risk is linked to the administered dose and, if applicable, the high dose rates used. There are specific risks linked to the use of sealed radionuclide sources (in brachytherapy, with high-activity sources) and unsealed sources (in nuclear medicine), associated in the latter case with the doses delivered to the patient's carers and comforters, as well as the management of waste and effluents. The ever-continuing expansion of Fluoroscopy-Guided Interventional Procedures (FGIPs) carried out using increasingly sophisticated devices can lead to significant exposure of the patient for whom the procedure brings health benefits, but also for the personnel in the immediate vicinity. Lastly, Computed Tomography (CT) examinations, although they do not present a major risk in terms of delivered dose or dose rate for an individual, contribute very significantly to population exposure resulting from medical diagnostic procedures due to their frequency of use, underlining the importance of justification for each procedure using ionising radiation.

1 Radiation protection and medical uses of ionising radiation

1.1 THE DIFFERENT ACTIVITY CATEGORIES

Medical nuclear activities can be divided into 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, radiosurgery, brachytherapy and ITR[1].

These different activities and the techniques used are presented in sections 2.1 to 2.6.

1.2 EXPOSURE SITUATIONS IN THE MEDICAL SECTOR

1.2.1 Exposure of health professionals

Medical professionals are subject in particular to the risk of external exposure created by the Medical Devices (MDs – devices containing radioactive sources, X-ray generators or particle accelerators) or by sealed or unsealed sources. When using unsealed sources, the risk of contamination must also be taken into consideration in the risk assessment (in nuclear medicine and in the biology laboratory).

According to the data collected in 2022 by Institute for Radiation Protection and Nuclear Safety (IRSN), the medical and veterinary sectors account for the majority of the people monitored: 52.5%, *i.e.* 204,614 people were subject to dosimetric monitoring of their exposure. These figures have decreased overall by nearly 3% compared with 2021. The average individual annual dose received is 0.33 millisievert (mSv) in the medical sector and 0.20 mSv in the dental sector. This figure remained relatively stable between 2015-2022, with the exception of 2020, when it dropped by 17% due to the Covid-19 pandemic. The average individual dose in the medical sector nevertheless increased by 7% in 2022 compared with 2021 (0.31 mSv).

Among the health personnel liable to be exposed and therefore subject to dosimetry monitoring, those working in radiology (71% of the medical personnel monitored, in diagnostic radiology and intervention radiology alike) receive an average individual annual dose of 0.20 mSv. The nuclear medicine personnel, who represent 5% of the monitored health personnel, are exposed to an average individual annual whole body dose that is four time greater, estimated at 0.83 mSv.

The medical activities sector accounts for the majority of exposures of worker extremities. Consequently, 16,645 people were subject to dosimetric monitoring of the extremities by ring or wrist dosimeter. This represents 60% of the workers monitored in this way and contributes to 68% of the total dose to the

1. Internal Targeted Radiotherapy (ITR) aims to administer a RadioPharmaceutical Drug (RPD) or implant a radioactive medical device so that the ionising radiation delivers a high dose as close as possible to the organ that needs to be treated (also called the "target organ") for curative or palliative purposes. The majority of these treatments are dispensed within nuclear medicine departments.

extremities. The radiology sector has the largest number of monitored workers, with about 68% of the total headcount of medical personnel monitored by dosimetry at the extremities (47% for interventional radiology and 21% for diagnostic radiology), and represents 29% of the total exposure dose to the extremities in the medical field. The nuclear medicine sector represents 19% of the monitored personnel and accounts for 68% of the total dose in this area. One hundred and thirty-eight workers in the dental sector are subject to dosimetry monitoring at the extremities and represent less than 0.1% of the total dose to the extremities.

The contribution of interventional activities to the total dose is probably underestimated, particularly due to insufficient use of extremity dosimeters by staff in the operating theatre.

Lastly, nearly 87% of the personnel monitored for exposure to the lens of the eye work in medical activities, representing 5,906 workers accounting for 60% of the total dose to the lens of the eye. The average individual dose for medical activities in 2022 was 1.59 mSv. Nearly two-thirds of the personnel monitored for lens of the eye dosimetry work in the FGIP sector which accounts for 60% of the total dose in the medical sector. Under the noteworthy events of 2022, a nuclear medicine worker received a dose to the lens of the eye of between 20 mSv and 50 mSv, with a cumulative five-year dose exceeding 100 mSv which, for the transient 2018-2023 period provided for by the regulations, exceeds the regulatory limit.

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. For therapeutic applications, the dose delivered must be much higher than in diagnostic applications in order to destroy the targeted cells while preserving the surrounding healthy tissue as best possible. As the principle of limitation does not apply to patients, the principles of justification and optimisation (see point 1.3) must be applied all the more rigorously.

In medical imaging, the principles of optimisation and justification (avoiding unnecessary examinations, or those whose result can be obtained using non-irradiating techniques that give an equivalent diagnostic level when available) are at the centre of the action plans for controlling doses delivered to patients. These action plans were developed by the French Nuclear Safety Authority (ASN) in 2011 and 2018 in collaboration with the services of the Ministry of Solidarity and Health and the health professionals. The action plan of 2018 will be updated after finalising the situation assessment carried out in 2024 with all the stakeholders.

The optimisation principle, defined by Article L. 1333-2 of the Public Health Code (see chapter 2), known as the ALARA[2] principle, has led to the introduction, in the area of medical imaging using ionising radiation, of the concept of "Diagnostic Reference Levels" (DRLs).

These DRLs, which must not be considered to be "dose limits" or "optimum doses", are established for standard examinations and typical patients. The DRLs are thus dosimetric indicators of the quality of practices.

The comparison of a DRL value with a dose received during an individual examination is not relevant for a given individual, because in certain situations the conditions of the examination can explain a higher value (to take into account the patient's morphology for example, or other factors that do not call into question the benefit/risk of the procedure). The optimisation principle should lead the persons/entities Responsible for a Nuclear Activity (RNA) that uses imaging by ionising radiation to compile their own Local Dose Reference Levels (LDRLs) to continue optimising their practices if this is compatible with obtaining a diagnostic quality image. ASN encourages such practices and wants the medical professionals to generalise them in the interest of the patients. ASN resolution 2019-DC-0667 of 18 April 2019 sets the DRL values and requires heads of radiology and nuclear medicine departments to carry out (or have others carry out) periodic dosimetric evaluations and to send the results to IRSN. The data collected by IRSN are analysed with a view to updating the DRLs. In 2023, ASN asked IRSN and then the Advisory Committee of Experts for Radiation Protection (GPRP – see chapter 2) to produce new DRL values for Digital Radiography (DR) mammography and tomosynthesis (3D) mammography. ASN will update the above-mentioned resolution in 2024 on the basis of these new values.

The last "ExPRI" study, which analyses exposure of the French population to ionising radiation due to medical imaging examinations, was published by IRSN in late 2020. It presents the data for 2017, which are compared with those of 2012 to show how they have evolved. These analyses are carried out using diagnostic imaging procedures drawn from a representative sample of beneficiaries of the French health insurance system, by method of imaging (conventional, interventional and dental radiology, CT scans and nuclear medicine), by explored anatomical region, by age and by sex. The analyses reveal stability of exposure on average (see chapter 1, point 3.3).

1.2.3 Exposure of the public

The impact of medical applications of ionising radiation is likely to concern:
- members of the public who live near facilities that emit ionising radiation and the persons working in these facilities who are not workers classified in application of the Labour Code with regard to the radiological risk;
- embryos or foetuses exposed *in utero* during a radiological or nuclear medicine examination of pregnant women;
- the personnel of the sewage networks and wastewater treatment plants who could be exposed to effluents produced by nuclear medicine departments, and in the event of non-compliance with waste management procedures, the personnel working in waste treatment facilities who could be exposed to waste produced by nuclear medicine departments or by patients at home having received therapeutic nuclear medicine treatment;
- persons supporting and comforting patients having received therapeutic nuclear medicine treatment and healthy volunteers participating in biomedical research involving exposure to ionising radiation; as these exposures enter into the scope of the regulatory obligations applicable to medical exposures, they are not subject to the public dose limits but they must comply with the dose constraints (see point 1.2.3).

The estimated doses for the public (people external to the health facility) resulting from discharges from nuclear medicine departments are a few tens of microsieverts (µSv) per year for the most exposed people, primarily the personnel working in sewage networks and wastewater treatment plants (IRSN studies, 2005

2. The "As Low As Reasonably Achievable" (ALARA) principle appeared for the first time in Publication 26 of the International Commission on Radiological Protection (ICRP) in 1977. It was the result of a process of reflection on the principle of optimising radiological protection. Over the past thirty years, the acceptance and implementation of the ALARA principle has developed significantly in Europe, with strong backing from the European Commission, leading in 1991 to the creation of a European ALARA network.

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. Situations of exposure of waste treatment personnel associated with the handing of radioactive waste from nuclear medicine healthcare services or produced by patients at home are exceptional and of very limited scale, even if radiation portal monitors do get activated from time to time at the entrance to waste treatment facilities (see point 2.3.3.4).

With regard to the *in utero* exposure of the embryo or foetus, less than a quarter of the Significant Radiation Protection Events (ESRs) notified to ASN each year concern the exposure of women unaware of their pregnancy (see point 2.7). The doses delivered to the uterus by imaging examinations are usually less than 100 milligrays (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%)[3].

In nuclear medicine, a source of radionuclides is administered to the patient. This source of ionising radiation can lead to exposure of the patients' carers and conforters. 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 undergone a nuclear medicine procedure. In clinical practice, nuclear medicine departments make the discharging of patients having received a high activity (therapeutic application) conditional on an equivalent dose rate of about 20 microsieverts per hour (µSv/h) at a distance of 1 m (recommendations of the GPRP in Medical Applications – October 2017). It is usually necessary to hospitalise the patient in a radiation-proof room while waiting for the activity to decay. The introduction of new RPDs will lead to the updating of the instructions for the carers and family circle. The GPRP is currently working on this (see chapter 2).

1.2.4 The environmental impact

In nuclear medicine, the radioactive sources administered to the patients will undergo physical decay (period of time stemming from 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 *via* the urinary tract. Nuclear medicine departments are designed and organised for the collection, storage and disposal of the radioactive waste and effluents produced in the facility, particularly the radionuclides contained in patients' urine (see point 2.3.2), and are required to draw up an Effluents and Waste Management Plan (EWMP) detailing the collection, management and disposal arrangements. In addition, a discharge monitoring system must be put in place.

The environmental impact of using ionising radiation for medical purposes is measured by the environmental radiological monitoring ensured by IRSN (see chapter 3). The measurement results are approximately equivalent to the background radiation. Radioactivity measurements in major rivers or wastewater treatment plants of large towns occasionally reveal the presence of artificial radionuclides used in nuclear medicine (iodine-131, for example; assessment of the radiological condition of the French environment from 2018 to 2020). However, no trace of these radionuclides has been detected in water intended for human consumption (see chapter 1). Furthermore, the bibliographic study conducted by IRSN[3] in 2021 reveals a low radiological impact on the public of the radioactive discharges from nuclear medicine departments into the sewage systems (from its analysis of two French studies, IRSN estimates that the exposure of people living near wastewater treatment plants is less than 1 microsievert per year – µSv/year).

1.3 REGULATIONS

1.3.1 General regulations

Protection of the personnel working in facilities that use ionising radiation for medical purposes is governed by the provisions of the Labour Code (Articles R. 4451-1 to R. 4451-135).

In order to protect the public and the workers, the facilities that use MDs emitting ionising radiation must also satisfy the technical rules defined in the ASN resolutions (see technical rules described in points 2.1.2, 2.2.2, 2.3.2, 2.4.2, 2.5.2 and 2.6.2 of this chapter).

The monitoring of sources (radioactive sources including RPDs, devices emitting ionising radiation, particle accelerators) is subject to specific rules figuring in the Public Health Code (Articles R. 1333-152 to R. 1333-164). These rules concern the acquisition, distribution, import, export, sale, transfer, recovery and disposal of the sources. If the sources are not exempted, they must be notified, registered or licensed, depending on their nature. The sources are inventoried, then taken back when expired, and they can be subject to financial guarantees to ensure their recovery by the supplier.

1.3.2 Radiopharmaceutical drugs and medical devices

The radionuclides used in nuclear medicine can be classified in two categories:
- the RPDs, subject to obtaining a Marketing Authorisation (MA), issued by either the French Health Products Safety Agency (ANSM) or the European Medicines Agency (EMA);
- the MDs that require the manufacturer to place a "CE" marking on them in order to be put on the market in European Union (EU) member countries or parties to the agreement with the European Economic Community (*e.g.* implantable MD, such as the 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.

The MDs emitting ionising radiation (electrical X-ray generators and particle accelerators) used in nuclear-based medical activities must meet the essential requirements defined in the Public Health Code (Articles R. 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

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.

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TABLE 1 **Classification of nuclear-based medical activities according to the radiation exposure risks**

ACTIVITIES	PATIENTS	PROFESSIONALS	PUBLIC AND ENVIRONMENT
External-beam radiotherapy	3	1	1
Brachytherapy	2	2	2
Internal targeted radiotherapy	3	2	3
Fluoroscopy-guided interventional practices	2 to 3 depending on the procedures	2 to 3 depending on the procedures	1
Diagnostic nuclear medicine	1 to 2 depending on the procedures	2 to 3 depending on the procedures	2
Computed tomography	2	1	1
Fluoroscopy-guided procedures on remote 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

to MDs has been modified to reinforce the provisions concerning the display of the dose during imaging procedures.

Moreover, the new European regulation EU 2017/745 entered into application on 26 May 2021 and its gradual implementation will mean that its requirements become applicable in full as of 27 May 2027 (after this date it will no longer be possible to put on the market or put into service MDs which do not comply with Council Directives 90/385/EEC and 93/42/EEC). This new European regulation reinforces patient safety on the one hand through a better clinical assessment of the MDs, and transparency on the other, thanks to the European Database on Medical Devices (EUDAMED). This database is accessible to the manufacturers and competent authorities alike, and partly accessible to the general public. The aim of giving access to the information in this database is:
- to help to improve the collaboration between:
  - the manufacturers or their representative and the competent authority of the country in which the MDs are manufactured/sold/installed,
  - the European competent authorities;
- to ensure greater public transparency, in particular by making available to the public the summary of the safety and clinical performance characteristic of each MD.

To facilitate early access of patients to innovative and useful technologies which do not yet have the "CE" marking, the French National Authority for Health (HAS) has instituted an "innovation pass". This innovation pass is a derogation and temporary mechanism put in place to facilitate early access of patients to innovative technologies (MDs) which are in the early phase of clinical development. The clinical study is conducted with the aim of confirming the human health benefit of the new technology.

The clinical assessments conducted in order to put on the market MDs, RPDs, or for derogation processes allowing patients to receive an innovative treatment, are determining factors in the application of the justification principle (see point 1.3.4).

To anticipate the radiation protection issues associated with the introduction of new techniques and emerging practices, the Committee for the Analysis of New Techniques and Practices using Ionising Radiation (Canpri – see chapter 2) is working on the ZAP-X® gyroscopic stereotactic intracranial radiosurgery and radiotherapy platform, on the new radionuclides for nuclear medicine and on flash radiotherapy. It focused on two subjects in particular in 2023:
- the ZAP-X® gyroscopic platform manufactured by ZAP Surgical;
- flash radiotherapy.

With regard to the ZAP-X® platform, in 2023 Canpri issued its opinion on the radiation protection of patients, workers, the fitting out of the rooms and the management of waste after use. Its opinion includes recommendations related to the preceding subjects intended for future users, manufacturers and institutions (Ministry of Health, HAS, ANSM, ASN, learned societies, etc.). ASN will issue a position statement on this basis in 2024.

Canpri's opinion on flash radiotherapy is expected in 2024.

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 abovementioned 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 workers, the public, patients and the environment. Licensing serves to regulate the activities presenting the greatest risks, for which ASN checks, when examining the application file, that these risks have effectively been identified by the applicant and that the barriers intended to mitigate their effects are appropriate. This system is applicable to radiotherapy (including radiosurgery), brachytherapy and nuclear medicine for diagnostic and therapeutic purposes. Registration also involves the submission of documents for examination, but fewer in number.

Thus, since 1 July 2021, the ASN on-line services portal allows RNAs to register their activities. The list of medical activities subject to registration has been defined on the basis of the radiation protection risks (see Table 1 above) 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 French healthcare licensing system came into effect in 2023. Healthcare facilities, physicians and legal entities involved in the area of health and wishing to develop a new healthcare activity or acquire or replace major medical equipment are now required to file a licence application with the Regional Health Agencies (ARS) in accordance with a calendar defined by the regional health schemes, which should extend over the next two years. The healthcare activities licence is a constituent of the application for a licence to possess and use a radioactive source or a device emitting ionising radiation. Among the changes stemming from the reform is the introduction of new healthcare activities, including interventional radiology and nuclear medicine and the reinforcing of the quality and safety approach with extension of the enforceability of the technical operating conditions of radiotherapy to neurosurgery departments. The healthcare activities and the major medical equipment items will have to comply with the Installation Conditions (ICs – they detail the levels of the procedures in particular) and the Technical Operating Conditions (TOCs – they include for example requirements concerning the composition of the teams, qualification of the personnel, fitting out of the rooms, patient follow-up methods, recourse to certain treatment methods, etc.). The entry into effect of this reform will change the existing organisational arrangements by encouraging, among other things, cooperation between the care structures, possibly making it necessary to change the nuclear activity licences issued by ASN (change of RNA, creation or modification of agreements, etc.). For example, in nuclear medicine certain devices may be shared between healthcare facilities and the radiosurgery activity may be attached to a neurosurgery department. ASN will be attentive to the impact of this reform on the nuclear activity licences and on radiation protection conditions because of these organisational changes.

1.3.4 The particularities of radiation protection of patients

Justification and optimisation – The protection of patients undergoing medical imaging examinations or therapeutic procedures using ionising radiation is regulated by specific provisions of the Public Health Code (Articles R. 1333-45 to R. 1333-80). The principles of justification of the procedures and optimisation of the delivered doses constitute the cornerstone of this regulation. The principle of dose limitation does not apply to patients due to the need to adapt the delivered dose to the diagnostic or therapeutic end-purpose for each patient. ASN ensures that this regulatory framework is updated through specific provisions with regard to optimisation, quality assurance, training and qualification as described below.

The required qualifications – The use of ionising radiation on the human body is restricted to physicians and dental surgeons having the necessary skills to perform these procedures (Article R. 1333-68 of the Public Health Code). 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 ASN resolution 2011-DC-0238 of 23 August 2011 and updates the required qualifications for physicians and dental surgeons who perform procedures using ionising radiation for medical or research purposes involving humans. It also sets the requirements for designating physicians coordinating a medical nuclear activity and to apply for a license or registration as a natural person.

The quality assurance obligations – To control the doses delivered to patients and thereby contribute to improved treatment safety, the obligations of the RNAs with regard to quality assurance for all medical activities involving ionising radiation are now governed by two ASN resolutions:

- resolution 2019-DC-0660 of 15 January 2019 in medical imaging, that is to say in nuclear medicine for diagnostic purposes, in dental and conventional radiography, in computed tomography and for FGIPs;
- resolution 2021-DC-0708 of 6 April 2021 for therapeutic procedures, that is to say external-beam radiotherapy, including contact therapy and intraoperative radiotherapy, brachytherapy, nuclear medicine for therapeutic purposes (ITR) and radiosurgery.

These resolutions oblige the RNA, with requirements proportionate to the radiation protection risks, to formalise the work instructions associated with the operational implementation of the two general principles of radiation protection, namely justification for the procedures and dose optimisation, and those concerning Learning From Experience (LFE), the training and authorisation of professionals and, for therapeutic procedures, the prospective risk analysis. The above-mentioned 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 work processes are outsourced.

A clinical peer review figures among the quality assurance obligations.

The principle of the clinical peer review has been written into Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. Transposed into French law in Article R. 1333-70 of the Public Health Code, the clinical peer review, which is included in the quality assurance system provided for in Article L. 1333-19, is the "*assessment method which, in view of the criteria determined by the quality assurance baseline, gives the patient guarantees regarding the competence of the medical and healthcare team, the quality of care and the safety of the procedures, which includes patient radiation protection*".

The clinical peer reviews were gradually put in place in 2023, on the initiative of the General Directorate for Health (DGS) in the areas of imaging and radiotherapy initially, with the backing of the learned societies and national councils concerned. ASN participates in the steering committees set up by the DGS to monitor implementation of these clinical peer reviews. The review grids are finalised and a pilot phase has been organised for the two areas to test the review process as a whole (organisation, documentation, etc.), and the appropriateness of the grids. After a period of recruiting and training the reviewers (physicians, medical physicists and radiographers) and finding centres willing to test the process, the first clinical reviews were carried out at the end of 2023. These pilot phases will continue during the first half of 2024.

On completion of these pilot phases, the results shall be analysed in order to extend these clinical reviews to the whole of France. ASN encourages the deployment of these reviews in the sectors with high radiation protection risks which are not covered at present, namely radiosurgery and therapeutic nuclear medicine.

Training in patient radiation protection – The obligations for continuous training in patient radiation protection are set in Articles L. 1333-19, R. 1333-68 and R. 1333-69 of the Public Health Code. The system as a whole was revised in ASN resolution 2019-DC-0669 of 11 June 2019 amending resolution 2017-DC-0585 of 8 January 2015, further to discussions with all the National Professional Councils (CNPs) concerned. This resolution aims to clarify and enhance the teaching objectives concerning justification, to integrate new actors and to foster interfacing with the other continuous training systems. Pursuant to this resolution, 18 professional guides have been produced by the learned societies, validated by ASN and put on line on *asn.fr*[4].

4. *https://www.asn.fr/espace-professionnels/activites-medicales/guides-professionnels-de-formation-continue-a-la-radioprotection*

TABLE 2 **Inspection frequency by nuclear-based medical activity**

NUCLEAR-BASED MEDICAL ACTIVITY	ROUTINE FREQUENCY
External-beam radiotherapy	Every 4 years
Brachytherapy	Every 4 years
Diagnostic nuclear medicine	Every 5 years
Therapeutic nuclear medicine on out-patient basis (*e.g.* iodine < 800 megabecquerels (MBq), synoviortheses, etc.)	Every 4 years
Therapeutic nuclear medicine with complex therapies using iodine > 800 MBq, lutetium-177, yttrium-90 and hospitalisation	Every 3 years
Fluoroscopy-guided interventional practices	Every 5 years
Computed tomography (emergencies or paediatrics with radiation protection risks)	Sampling: about twenty facilities per year

To monitor the practical implementation of this new regulatory framework, a qualitative and quantitative assessment involving all the professions was carried out in 2022. An inventory of the training offerings has been drawn up to identify the main players (health facilities, 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 was presented to the committee that monitors the national plan for controlling imaging doses and to the GPRP (see chapter 2) and will continue in 2024 with, in particular, a presentation of the results to the organisations providing training in patient radiation protection.

1.4 THE RISKS AND OVERSIGHT PRIORITIES

In order to establish its oversight priorities, ASN has classified the nuclear-based medical activities according to the risks for the patients, the personnel, the public and the environment. This classification takes particular account of the doses delivered or administered to the patients, individually or collectively, the fitting out of the premises and the conditions of use of sources of ionising radiation by the medical professionals, the production of waste and effluents contaminated by radionuclides, the source security risks (high-activity sealed sources), lessons learned from significant events 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 inspection priorities must focus in priority on external-beam radiotherapy – including radiosurgery, brachytherapy, nuclear medicine and FGIPs. The inspection frequencies, based on an approach graded according to the radiation protection risks (see Table 2), enable all the safety-significant activities to be inspected over a period of three to five years, depending on the sectors. These frequencies are increased when vulnerabilities that could have an impact on radiation protection are identified (difficulties linked to human resources, technical or organisational changes, quality management or insufficient control of risks – lateness in formalising practises, absence of risk assessments, lack of risk culture, particular risks associated with certain techniques, etc.). This can lead ASN to place certain centres under tightened surveillance, when significant persistent malfunctions have been found, and to inspect them at least annually (see chapter 3). The inspection frequency for FGIPs can be reduced by ASN depending on the knowledge of the radiation protection situation of the facilities, on the basis in particular of the inspections carried out when issuing a registration.

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 2023 were:
- in radiotherapy – including radiosurgery, 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 quality assurance approach, the management of adverse events and the process of specific work tasks training and authorisation;
- in FGIPs: implementation of the optimisation approach.

Although the RNAs are given advance notice of the majority of routine inspections (see chapter 3), unannounced inspections may be carried out. Two unannounced inspections were carried out in radiotherapy in 2023 (see point 2.1.3). Furthermore, inspections may be carried out in the commissioning context when installing new MDs or for new facilities, and when investigating ESRs.

1.5 SIGNIFICANT RADIATION PROTECTION EVENTS

It is mandatory for ASN to be notified of ESRs pursuant to the Public Health code (Articles L. 1333-13, R. 1333-21 and 22) and the Labour Code (Article R. 4451-74 – see chapter 3, point 3.3). In the medical field, ESRs have been 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.

An on-line services portal has been provided at *teleservices.asn.fr* to enable all the medical professionals to file their reports on line. This portal is integrated in the adverse public health events reporting portal managed by the Ministry of Solidarity and Health. Depending on the type of event reported, the notification is sent automatically to ASN (regional division and Department of ionising Radiation and Health – DIS), to the ARS for all events concerning the patient and to the ANSM for events relating to medical devices vigilance or drug safety monitoring.

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 ASN Guide No. 11 for the medical sectors, which details the event reporting procedures. The resolution and guide should be published in the course of 2024. The ASN-SFRO scale for rating events concerning patients undergoing radiotherapy or brachytherapy treatment remains unchanged. The aim of this scale, developed in collaboration with the French Society for Radiation Oncology (SFRO), is to inform the public about radiation protection events affecting patients in the course of a radiotherapy or brachytherapy treatment, taking into account, in addition to the confirmed consequences, the potential effects of the event and the number of patients exposed (see chapter 3).

In addition to this, the incident notices are published on *asn.fr*.

To encourage sharing of the lessons learned from the feedback from medical professionals, ASN publishes the newsletter "Patient safety - Paving the way for progress", first issued in March 2011, "LFE" sheets further to ESRs, and circular letters addressed to the RNAs. Produced by multidisciplinary working groups coordinated by ASN, the "Patient safety" 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. The aim of the "LFE" sheet is to alert the health professionals to a particular ESR incident reported to ASN to prevent it from occurring in another healthcare facility.

2 Nuclear-based medical activities

2.1 EXTERNAL-BEAM RADIOTHERAPY

Radiotherapy, along with surgery and chemotherapy, is one of the key techniques employed to treat cancerous tumours. Radiotherapy uses ionising radiation to destroy malignant cells and also dysfunctional non-malignant cells. 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, either via the natural cavities or by catheters (see point 2.2).

The radiation sessions are always preceded by the preparation of a treatment plan which serves to set the conditions for achieving a high dose in the target volume while preserving the surrounding healthy tissues. The treatment plan defines the dose to deliver, the target volume(s) to treat, the 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 have occurred or 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* (Recorad), updated in February 2022. This technique uses three-dimensional images of the target volumes and neighbouring organs obtained with a CT scanner, sometimes in conjunction with other imaging examinations (Positon 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 and is the reference technique for prostate and head and neck cancers. This technique consists in irradiating a target volume by continuous modulated irradiation rotating around the target volume and therefore around the patient.

Helical radiotherapy, or tomotherapy, enables radiation treatment to be delivered by combining the continuous rotation of an 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 (whether cancerous or not) 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 and uses specific identification techniques in order to localise the lesions with millimetric accuracy.

This therapeutic technique essentially 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.

A new mono-energy radiotherapy accelerator, a self-shielded gyroscopic platform called "ZAP-X®" (ZAP Surgical, 3 MV, FFF mode) was authorised in March 2023 for use in France for stereotactic intracranial radiotherapy and radiosurgery (see Canpri opinion in point 1.3.2 and box opposite).

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 after surgical removal of the tumour. It is primarily a technique for treating small cancers of the breast, certain colorectal cancers and certain cancers of the abdominal stage (pancreas, liver). In April 2016, the HAS published the results of the assessment of this practice for breast cancers 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 extent possible.

Hadron therapy is a treatment technique based on the use of beams of charged particles (hadrons comprising protons and carbon ions), which can deliver the dose in a highly localised manner during treatments, thereby drastically reducing the volume of healthy tissue irradiated. 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.

Adaptive radiotherapy is a radiotherapy technique that takes into account the movements and deformations of the organs and the tumour during the treatment. The treatment planning system recalculates the dose distribution before the each delivery of the treatment fraction of the day, this new dose distribution is either accepted or not by the radiation oncologist. It is also possible to associate real-time monitoring (gating) of the target volume during delivery of the treatment. If the target volume goes out of the temporal gate, the treatment stops and resumes as soon as the target volume returns to within the tolerated movement limits (often set at ≤ 1 mm). This technique is still relatively recent and only used by a few centres that are already equipped for it, even if the trend is moving upwards. Given this context, ASN wanted to encourage an initiative to assess this new technique. To this end, in late 2023 it initiated a study with the SFRO and the National Council of Radiation Oncologists (CNPO) to collect the data necessary for a large-scale assessment before the technique becomes widely adopted in France. A steering committee in which participate the HAS, the DGS, the General Directorate of the Healthcare Offering (DGOS), the National Cancer Institute (INCa), IRSN, the SFRO and the CNPO, has been set up by ASN to conduct and follow-up this study in compliance with the rules of good assessment practice.

ZAP-X® GYROSCOPIC STEREOTACTIC INTRACRANIAL RADIOTHERAPY AND RADIOSURGERY PLATFORM

A first application for a license to possess and use this device (*) was filed in France in April 2022 with the Paris division of ASN by the Porte de Saint-Cloud Cancerology Centre (Boulogne-Billancourt, Hauts-de-Seine *département*). After examining the application documents and with the assistance of IRSN for occupational radiation protection, ASN issued the licence on 27 March 2023. Particular requirements have been set in the licence issued by ASN in order to better characterise the worker exposure levels, given the limited data provided by the manufacturer. The first patient was treated in April 2023 and more than 115 treatment sessions have now been carried out. The first results concerning occupational exposure are expected in the 1st quarter 2024.

** Manufacturer: ZAP Surgical, USA, "CE" marked obtained in February 2021.*

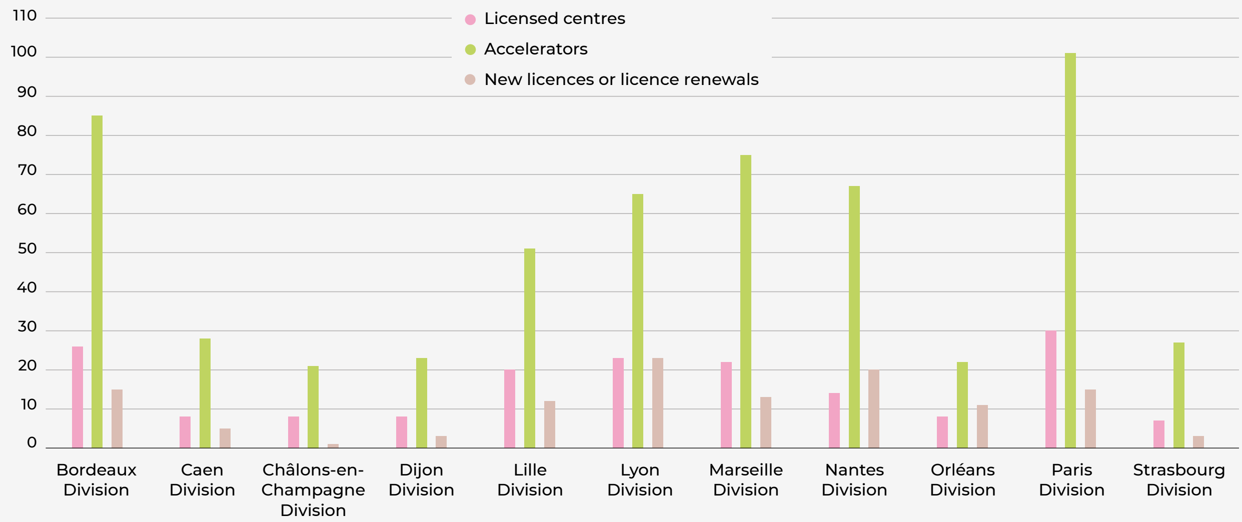
2.1.2 Technical rules applicable to external-beam radiotherapy facilities

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 (RPA). This study defines the thicknesses and nature of the various protections required, which are determined according to the conditions of use of the device, the characteristics of the radiation beam and the use of the adjacent rooms, including those vertically above or below the treatment room. This study must be included in the file submitted to ASN to support the application for a license to use a radiotherapy installation.

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 2023**



ASN CARRIED OUT TWO UNANNOUNCED INSPECTIONS IN TWO RADIOTHERAPY CENTRES OF THE RAMSAY SANTÉ GROUP IN MARSEILLE

ASN carried out two unannounced inspections concomitantly on 3 July 2023 in two radiotherapy centres of the Ramsay Santé group, the Iridis Clairval and the Beauregard centres in Marseille. The main purpose of these inspections was to check that the human resources present on the sites matched the required criteria for ensuring the treatments, particularly radiotherapists, medical physicists and radiographers at the console of each accelerator in each centre. Furthermore, given the particularity of the centres established on two geographically close sites enabling the medical professionals to move from one centre to the other, the work tasks qualification required by article 7 of ASN resolution 2021-DC-0708 was checked, as was the knowledge of the work environment.

Further to these inspections, ASN made demands concerning in particular:
- the measures taken to recruit radiographers and a health executive, and well as the mode of functioning of the department according to the number of radiotherapists and radiographers;
- the training and qualification of the medical professionals in order to include the different irradiation techniques;
- knowledge of the work environment and identification of the organisational particularities;
- the methods of assessing newly recruited staff;
- the analysis of certain recurrent malfunctions noted internally, and the methods of selecting adverse events that must undergo a systemic analysis.

These unannounced inspections, which are part of ASN's inspection arsenal, are a useful complement to the announced inspections for verifying compliance with certain regulatory requirements such as the presence of qualified medical professionals in sufficient numbers. The type of inspection also allows work situations to be observed over a limited period of time without entailing preparatory work for the licensee.

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. Furthermore, with the arrival of self-shielded MDs such as the ZAP-X®, the centres can envisage installation and operating conditions other than those existing in the radiotherapy and radiosurgery departments, subject to compliance with the same regulatory requirements in the two types of facility (see point 2.1.1).

2.1.3 Radiation protection situation in external-beam radiotherapy

The installed base of external-beam radiotherapy facilities in 2023 comprises 565 particle accelerators installed in 174 radiotherapy centres subject to ASN licensing (see Graph 1 above).

More than 214,000 patients[(5)] are treated each year, which represents 4.3 million radiation sessions (in 2021). The French Radiotherapy Observatory (INCa), lists 901 radiotherapists (headcount in 2021). In 2023, ASN notes a upward trend in the number of radiotherapy department relocations in order to enlarge them and purchase new accelerators. ASN issued 121 licenses in 2023, which represents a 5% increase on 2022. These applications are either for new facilities (about 21%) 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 further increase in the coming years.

5. In 2021, 214,000 cancer patients were treated by radiotherapy by 4.3 million treatment sessions (source: INCa Observatory).

01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 AP

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. It also takes up more medical and medical physics time and requires work organisation adaptations. Furthermore, the reform of care licensing (see point 1.3.3) is likely to lead to changes in the porting of nuclear activity licences (for radiosurgery for example), and organisational changes. ASN will be extremely attentive to the impact of these changes on radiation protection, and in particular to the adequacy of the planned resources for implementing treatments of this type.

The safety of radiotherapy treatments has been a priority area of ASN oversight since 2007 on account of the high doses delivered to the patient. Since 2019, the four-yearly inspection programmes have placed the emphasis on the ability of the centres to deploy a risk management approach. Skills management, the implementation of new techniques or practices and the mastery of the equipment are also examined in depth, depending on the centres.

ASN has continued its graded inspection approach:
- by reducing, in the light of the progress made in the control of treatment safety, the average frequency of inspections, which since 2020 has been reduced to once every four years (instead of the previous three-yearly frequency), enabling all the centres to be inspected every four years;
- by maintaining a higher frequency for the centres presenting vulnerabilities or risks, particularly for some centres having necessitated tightened inspections.

ASN conducted 68 inspections in 2023, representing 39% of the French centres. Out of the 68 inspections, ten were conducted in combined mode, that is to say both on site and remotely. Two inspections were unannounced (see box previous page). 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. In addition to the routine inspections, commissioning inspections carried out following the introduction of new services, change of site further to a relocation and the acquisition of new machines, and inspections carried out following an ESR are counted in these 68 inspections.

ASN observes that in addition to the existing difficulty in recruiting radiographers and medical physicists, it is now difficult to recruit radiotherapists, whatever the region. This lack of personnel has impacts on the activity, the organisational set-ups and the medical staff (reduction in treatment slots, overstretched personnel, tensions in the teams, etc.). Holding interviews with the medical and paramedical teams and medical physicists during the inspections can bring to light situations of tension and malfunctioning, which are sources of risks for the patients despite a formalised reference framework. Holding interviews with senior management enables these conflictual situations to be discussed with a view to helping the department identify technical, human and organisational lines for improvement.

These inspections focusing on Human and Organisational Factors (HOFs) are conducted regularly by ASN in the area of radiotherapy and are extending increasingly to other medical fields (see box below); they sometimes detect situations representing a risk for patient safety that would not be found during a conventional inspection.

2.1.3.1 Radiation protection of external-beam radiotherapy professionals

When the radiotherapy facilities are designed in accordance with the rules in force, the radiation protection risks for the medical staff are limited due to the protection provided by the facility.

The results of the inspections conducted in 2023 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.

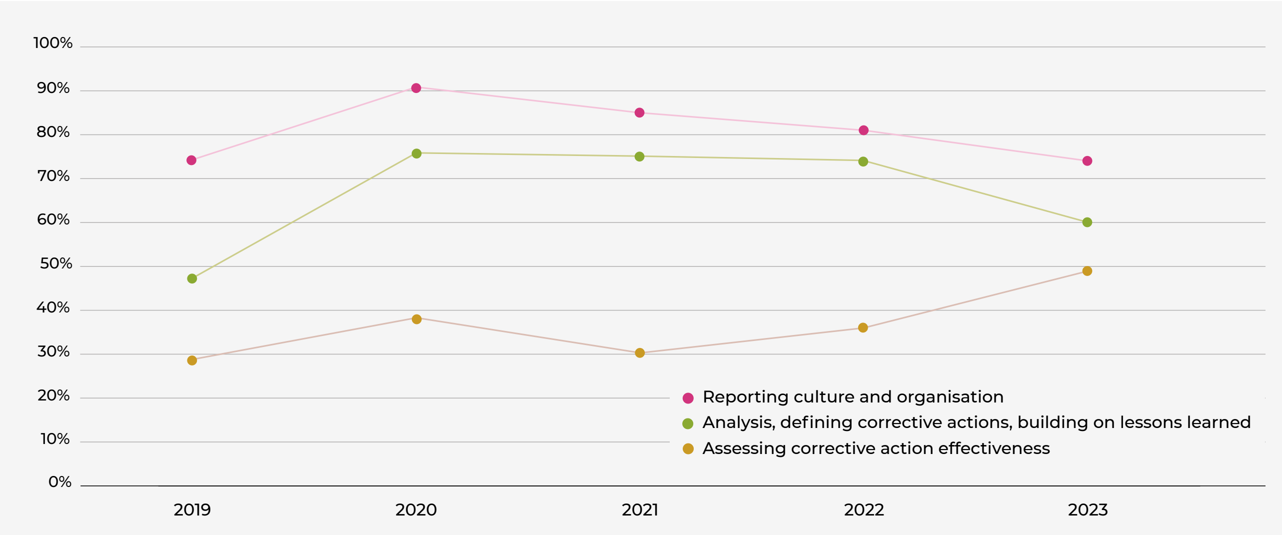
ASN ADAPTS ITS OVERSIGHT TO TAKE BETTER ACCOUNT OF THE HUMAN AND ORGANISATIONAL FACTORS IN ITS INSPECTIONS

The inspections that include an HOF approach are increasing in the medical sector in order firstly to better consider the context of the healthcare facilities and their actual organisational set-ups that could create difficulties for application of the regulations, and secondly to question adaptive safety. This is because the radiation protection of workers and patients is not based solely on the defining of regulatory requirements, or on them being broken down into standards, baseline requirements, protocols and organisation memos (normative safety). It is also ensured by a set of regulations applied on a daily basis by the healthcare personnel (adaptive safety) because the work conditions and actual organisational set-ups are usually different to those defined and envisaged by management. The risks do not arise only from deviations from the regulations; they are also linked to the actual work conditions.

"*Invoking human error to hastily in the event of a malfunction or even an accident, is often a shortcut that does not foster prevention. The question is rather to ask what were the organisational conditions that led to the malfunction or accident. Considered as one of the three pillars of safety, the human and organisational factors approach consists in identifying the conditions that foster safe behaviour at all levels of the organisation*" (Institute for an Industrial Safety Culture – ICSI).

HOFs are being taken into account in inspections progressively. They are currently taken into account in inspections further to an ESR or when events are repeated in a given department, or when situations of internal conflict that could affect patient safety have been reported to ASN. But this type of inspection can also be implemented in the case of a significant technical and/or organisational change.

GRAPH 2 **Percentage conformity of external-beam radiotherapy facilities in the management of events in 2023**



ASN notes that the requirements concerning the medical physics organisation and the presence of a medical physicist during the treatments are satisfied in all the centres, even if there may be personnel shortages from time to time.

The ASN inspectors observe that the authorisation process is being deployed, but with disparities between the medical and paramedical personnel, given that it is applied mostly for the paramedical staff.

Furthermore, the analysis of compliance with regulatory requirements concerning the management of events over the 2019-2023 period shows that a constant proportion of departments complied with the regulations over the last three years, with significant disparities depending on the requirements concerned (see Graph 2 above):

- The detection of adverse events, their reporting (internally or to ASN) and their recording are deemed satisfactory on the whole, with rates varying between 74% and 85% over the period in question but dropping from 2021 to 2023.
- The analysis of these adverse events, the defining of corrective actions and building on the lessons learned, after an initial phase of progress followed by stabilisation in 2021 and 2022 at around 75%, is now dropping with 60% of the inspected centres carrying out these steps satisfactorily in 2023.
- The improvement in practices resulting from Incident Learning Systems (ILS) and assessing the effectiveness of the corrective actions still represent the weak spot of these events analysis procedures, with the situation being deemed satisfactory in only 29% to 36% of the centres inspected. The results for the 2019-2023 period is stable, but with a degree of progress on this point in 2023 with 49% satisfaction (see Graph 2 above). These approaches must bring together representatives of all the professionals involved in the delivery of treatments. ASN observes greater participation of the radiotherapists in these approaches in the centres inspected in 2023. 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 (see box page 218), 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 2023. These investigations reveal that:

- The requirements for quality and safety management in radiotherapy departments are satisfied in the majority of cases. Disparities still persist between centres. Thus, the prospective risk analysis is only complete or updated in less than half the inspected centres (44%), mainly due to lack of training or resources, or to a change in the operational quality manager. This incompleteness concerns, for example, the failure to take into account LFE (that of other centres for example, disseminated *via* the ASN publications – "Patient safety" newsletter and "LFE" sheets) or new practices or the organisation of the centre if there is a change in the technical platform.
- The risk management approach is coordinated satisfactorily in 66% of the centres inspected. These are the centres in which management is involved in the approach and has defined a policy with shared, assessable and assessed operational objectives, has allocated the necessary resources, in particular to the operational quality manager and communicated on the results of this policy. Conversely, these procedures stand still or regress when senior management does not sustainably grant sufficient means to the operational quality manager or when s/he does not have sufficient authority to deploy them.

The implementation of management reviews and internal audits is also observed but remains highly dependent on an internal dynamic and relies to a large extent on the availability of the persons in charge of quality (operational quality managers and health executives).

ASN still 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

SEMINAR OF THE RADIOTHERAPY STAKEHOLDERS: ASN REVIEWS THE SITUATION OF THE QUALITY-SAFETY APPROACH IN RADIOTHERAPY TO ADAPT ITS OVERSIGHT OF TOMORROW

The regulatory provisions laying down the quality assurance obligations for the radiotherapy centres were published in 2008. They are part of a set of measures taken by the French authorities further to radiotherapy accidents that occurred in Epinal and Toulouse at the end of the years 2000.

On 15 March 2023, ASN brought together the radiotherapy professionals to assess the results of the 15 years of quality initiatives in radiotherapy. Some 250 participants – radiotherapy professionals, representatives of the public health institutions and ASN radiation protection inspectors – asked about how the quality initiatives contribute to the performance of the care system, in a context of greater complexity, fewer resources and major innovations.

Invited as a star witness, René Amalberti, director of the Foundation for in Industrial Safety Culture, brought up the current crisis of the healthcare system and questioned the risk of "over-quality" in his opening contribution. The floor was then given to the representatives of the radiotherapy centres to discuss the implementation of the quality assurance systems, the prospective risk analysis, the LFE procedures following adverse events and change management. The seminar also provided the opportunity, in the presence of the Minister responsible for health and the HAS, to discuss the contribution of the clinical peer reviews, the experimentation of which began in 2023, and the methods of evaluating innovative techniques and practices, particularly through the innovation pass.

The seminar also confirmed that the main safety fundamentals are in place in the radiotherapy departments and that the quality-safety culture has improved very significantly since 2008. It highlighted the need for the radiotherapy departments to assimilate these procedures and find their own methods of implementation, adapting them to ensure their sustainability. The seminar also brought to light a risk of routinisation and loss of momentum in the continuous improvement initiatives. Several centres have taken measures to give renewed meaning and maintain the interest of the medical professionals in the quality-safety initiatives. Their testimonial showed the importance of leadership, teamwork and communication, as well as the support of qualiticians and consideration of the actual work situations. The contribution of ASN oversight was also underlined. It enables the centres to re-examine their quality-safety approaches and to find new ways of working that help to maintain the collective dynamic.

Lastly, the discussions brought to light the limits of the quality procedures, particularly the tendency to have more and more documents and indicators that are too process-oriented rather than results-oriented. These findings, which are not specific to France, necessitate collective reflection on how to simplify these procedures and on the choice of indicators. ASN will continue its reflections on the quality assurance and risk management procedures, in collaboration with all the radiotherapy stakeholders, in order to develop its future oversight activities.

change management process is being increasingly deployed but not always completely in the centres concerned by recent or ongoing changes. The lessons from the inspections in 2023 effectively show that when a new technique is put in place, the change management procedure is considered satisfactory in only half of the centres (50%), a proportion that remains constant for the 2019-2023 period. Management of the changes in project mode (appointing a coordinator, project planning, training of teams, organisation of the continuity of routine work during project execution, updating documents) is being deployed in the centres to varying extents, and depending on whether the centres have projects planned for the near future or not. To help them to better adopt material and/or technical changes, IRSN has published, in partnership with the radiotherapy professionals and at the request of ASN, a *Guide to the adoption of a material or physical change in radiotherapy*.

In a context of medical staff shortages, organisational changes due to the reform of the healthcare licences or healthcare facility buy-out operations, ASN urges the decision makers, RNAs and medical professionals to be vigilant regarding the need to assess the impact of these large-scale changes in the work activity of the medical staff, insofar as these projects demand significant investment on the part of the personnel, adding to their existing workload.

ASN organised a seminar for radiotherapy stakeholders on 15 March 2023 in Montrouge, which reviewed the quality-safety approaches in radiotherapy since 2008, change management, and the contribution of the LFE initiatives and their improvement (see box above). The lessons from the seminar will be used as inputs to ASN's reflections for its next radiotherapy inspection programme starting in 2025.

2.1.3.3 Significant events in external-beam radiotherapy

In 2023, 88 ESRs were reported in radiotherapy under criterion 2.1 (exposure of patients for therapeutic purposes). Among these events, 37 were rated level 1 on the ASN-SFRO scale, *i.e.* 42% of the total, and seven were rated level 2. The latter concerned:

- four laterality errors (see box next page), of which two involved delivery of the entire or virtually entire treatment to the wrong side (25 sessions out of 28). The other two laterality errors occurred in breast cancer treatments during six sessions out of 15 and 19 out of 33 respectively; the analysis of this type of event can reveal that the safety barriers put in place, such as those for checking that the treatment is delivered to the correct side, have been ineffective, which should lead to the revising of the prospective risks analysis and team reflection to find more robust countermeasures;
- a positioning error that resulted in the entire treatment being delivered to the wrong vertebra;
- an error linked to an overlap zone not taken into account during the contouring, which resulted in an excess dose being delivered to the organs situated in this zone in a re-irradiation context;
- a dose error in treating a breast by Volumetric Modulated Arc Therapy (VMAT), with five treatment sessions more than the prescribed number, resulting in the volume as a whole receiving a total dose that was 20% higher than intended.

Two ESRs rated level 1 on the ASN-SFRO scale concerned cohorts of patients as a result of:

- an error when calibrating the patient positioning control system used for external-beam radiotherapy sessions, which caused an offset in the positioning of six patients;
- a positioning error that concerned seven patients further to an offset of the treatment isocentre of a repositioning imaging device.

SIGNIFICANT EVENTS RESULTING FROM LATERALITY ERRORS

Four of the seven ESRs reported in 2023 and rated level 2 on the ASN-SFRO were laterality errors (right-left reversal).

In a first case, the laterality error occurred during the preparation for treatment of a breast cancer by external-beam radiotherapy, resulting in the left breast being contoured as the zone to treat instead of the right breast. A treatment plan was thus defined with a total of 28 sessions and a planned dose of 2.25 grays (Gy) at each session. One of the factors that contributed to this laterality error is the presence of conflicting information in the initial medical consultation report. The subsequent steps, including the contouring and the various validations, failed to identify this error, which was not detected until the end of the 25th treatment session.

In the second case, which also concerned a breast cancer treatment, six external-beam radiotherapy sessions (out of the 15 scheduled) were delivered to the wrong breast. The analysis of the causes revealed a failure to perform the laterality check (by all the medical staff): during the contouring and validation of the dosimetry by the physician, when entering the prescription and during the double check of the file by the physicist and during preparation of the file and delivery of the treatment sessions by the radiographers. A history of radiotherapy treatment on both breasts which figured in the patient's medical file could have fostered the confusion.

In the third case, the laterality error resulted in delivery of the entire stereotactic radiotherapy treatment to a nodular lesion on the left lung instead of the lesion on the right lung as was planned. The event was due to a prescription error, which led to the treating of an existing nodular lesion but contralateral to the intended lesion, whereas the diagnostic information and the conclusions of the multidisciplinary consultation meeting prior to the treatment indicated the correct localisation. The event was detected during an imaging examination to prepare for the patient's post-treatment follow-up consultation in the radiotherapy department.

In the fourth case, the laterality error occurred during the treatment of an oropharyngeal cancer and was detected after 19 treatment sessions out of the 33 scheduled. The 19 sessions were carried out on the healthy pharyngeal side instead of the affected side. The in-depth analysis of the causes revealed the absence of laterality verification rules and the need for better communication between the various persons involved.

ASN draws the attention of the radiotherapy professionals to the need to evaluate the robustness of the safety barriers put in place to guard against laterality errors, which form the subject of several ESR notifications each year. ASN points out that the "*Patient safety – Paving the way for progress – Laterality errors*" bulletin of May 2014 enables the centres to ponder on the risk situations and effective prevention and detection measures. This bulletin proposes keys for avoiding these laterality errors, recommendations from two centres that have conducted an in-depth analysis further to such an event, and the testimony of the ARS of Bretagne on its prevention action implemented jointly with the Eugène Marquis Centre (Rennes).

Most of the events reported in 2023 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 keeping of the patients' medical files, which provide an overall picture and give access to the required information at the right time; the earlier the error is committed in the treatment process (*e.g.* wrong side), particularly in the initial consultation and prescription elaboration phase, the less the laterality information is called into question in the subsequent stages of the patient care pathway; it is therefore essential to test the barriers in place at these stages of the process;
- validation steps in which the parameters to verify are not sufficiently explicit (What check? At what stage of the process? By which operator?);
- the management of the patients' medical file movements which, if it is not optimised, creates constraints on the work activity of the medical staff, fostering the overlooking of certain verification steps.

As a general rule, variations in practices within a given centre, frequent task interruptions, a high and uncontrolled workload with, among other things, an impact on the length of working hours, the deployment of a new technique or practice that is not fully mastered, constitute situations that disrupt work activities and weaken the safety measures defined in the Quality Management System (QMS). It is therefore essential to assess these measures regularly and to draw lessons from the malfunctions that occur.

In 2023, ASN published a "Patient Safety" bulletin devoted to the prospective risk analysis procedure. The aim of this bulletin is to bring out a common vision of the patient care and treatment process, anticipate the potential risks and define and improve the safety measures needed to control them. For example, treatment interruptions further to a machine failure, a technical fault or maintenance work, disrupt the team's organisation and are sources of potential risks for the patient, without necessarily resulting in an ESR. This bulletin examines not only the risk factors for the patient during a treatment interruption, but also the safeguarding factors. The multidisciplinary group behind the "Patient Safety" bulletin has tested the EPECT method, recently developed by IRSN, on a scenario combining different cases of treatment interruption.

ASN notes a significant drop in ESR notifications in radiotherapy since 2015 (see point 2.7, Graph 14 page 237), and of about 35% since 2019. 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, contour 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.

Nevertheless, the ASN inspectors also observe, as in 2022, a decrease in the number of adverse events recorded internally and analysed (fewer meetings of Experience Feedback Committees – CREX) and superficial analyses of the events with little exploration of their root causes. The inspectors also note a lack of integration of the lessons learned from the events reported at national level.

Although no radiation protection events linked to cyberattacks were reported to ASN in 2023, unlike 2022 and 2021 (three radiotherapy centres, one in 2021 and two in 2022, and one nuclear medicine centre in 2022), the risk of such attacks, leading to paralysis of the computing systems and serious disruptions in the organisation of treatments, is very real. Cybersecurity does not lie within ASN's scope of competence, but it is nevertheless informed of cyberattack situations which form the subject of a notification if they lead to an ESR. As these cyberattacks call into question the current practices of "all electronic" patient medical records, ASN had encouraged the medical professionals to conduct a reflection on this subject.

The SFRO set up a working group in 2023, in which ASN participated, and in December 2023 it published recommendations for anticipating and limiting the risks associated with cyberattacks in a context of increasing digitising of data. This article underlines the importance of retaining a minimum amount of "hard copy" data so that treatment can be continued if the electronic (computerised) data are not available: patient's contact details, summary of the medical record, dose-volume histograms, number of sessions carried out, description of the treatment plan, etc.

SUMMARY

In radiotherapy, the inspections carried out by ASN in 40% of the radiotherapy units in 2023, considered alongside those carried out over the period 2019-2022, 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. ASN also underlines the progress in clinical peer reviews, with performance of the first such reviews in radiotherapy at the end of 2023 and encourages their rapid extension to radiosurgery.

However, the analysis of the 2019-2023 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. Furthermore, the learning from experience approaches are losing momentum, with fewer CREX meetings and less thorough ESR analyses. The number of ESRs reported to ASN has dropped significantly since 2015. Although this drop can be partly attributed to improved treatment safety, the risk of routinisation and the need to give renewed meaning to these procedures in order to maintain the interest of the medical professionals and the collective dynamic were underlined at the national seminar of radiotherapy actors organised by ASN on 15 March 2023. In addition, the prospective risk analyses are still insufficiently updated prior to organisational or technical changes or after analysing the lessons learned from events.

The occurrence of events such as laterality and positioning errors, delineation of organs at risk and/or target organs and calibration errors, still reveals organisational weaknesses and the need to regularly assess practices.

The assessment of new techniques and practices is still an important subject, to allow, among other things, an assessment of long-term radiation induced effects (hypofractionation, flash therapy, etc.) and the demonstration of their benefits compared with the existing techniques. It is in this context that ASN initiated a study in 2023 to define and collect the data necessary for the assessment of adaptive radiotherapy. In 2024, it will continue the analysis of the radiation protection risks associated with flash therapy, included in the Canpri studies.

Lastly, in 2024, in a context of increasing complexity, fewer resources, extensive innovation and organisational changes, ASN will define the directions of its next four-yearly inspection programme in collaboration with the stakeholders and drawing the lessons from the inspection practices of its counterparts and other authorities in charge of activities involving risks. In this context, ASN once again urges the decision makers, RNAs and medical professionals to be vigilant regarding the need to assess the impact of the changes on the safety of treatments.

2.2 BRACHYTHERAPY

Brachytherapy can be used to treat certain pathologies and cancerous tumours in particular either specifically or as a complement to another treatment technique.

This technique consists in placing radionuclide sources, in the form of sealed sources, either in contact with or inside the solid tumours to be treated. The main radionuclides used in brachytherapy are iridium-192 and iodine-125.

Brachytherapy uses three techniques (detailed below), which differ more specifically in the dose rate applied according to the indications.

As with radiotherapy, the radiation protection issues are linked to the intensity of the dose delivered to the patient and, if applicable, the high dose rates and the mastery of the equipment. Furthermore, as high-activity sources are involved, the management of emergency situations in the event of source jamming, as illustrated by the feedback from events 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).

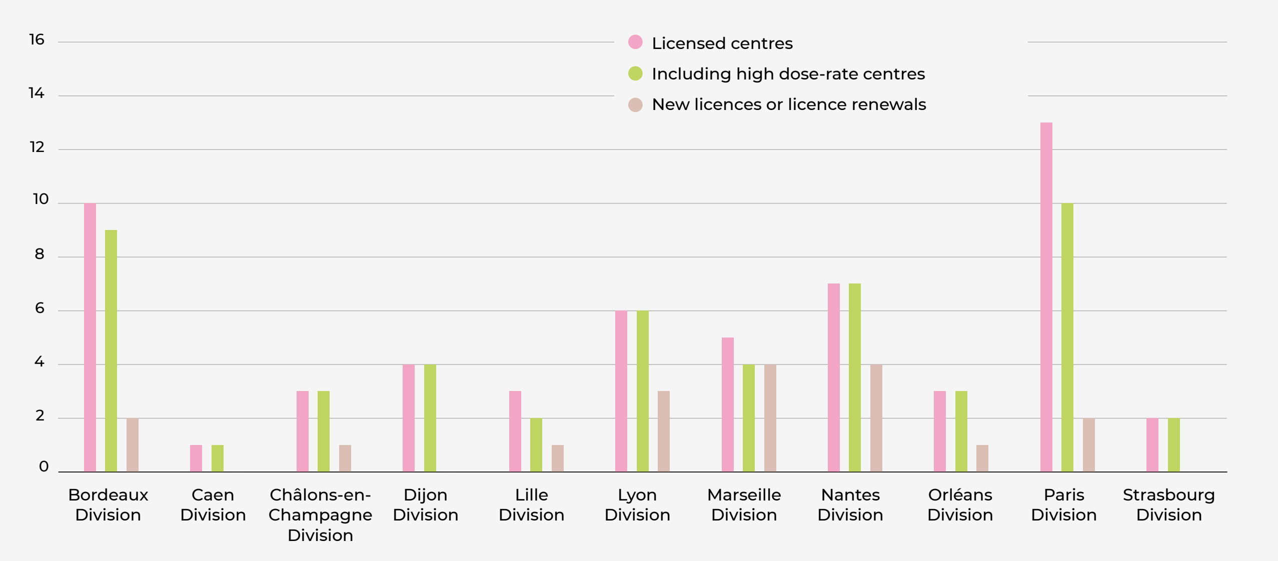
The use where necessary of source afterloaders means that the medical personnel do not have to handle the sources and allows the patient to be treated without irradiating the personnel. On the other hand, it is necessary to make provisions for accident situations associated with malfunctioning of the source afterloader and the high dose-rate delivered by the sources used.

Low Dose-Rate (LDR) brachytherapy is carried out at present using sealed sources of iodine-125 in the form of permanently implanted seeds, or caesium-137 applied temporarily. The dose rates are between 0.4 and 2 grays per hour (Gy/h).

A new medical technique called "DaRT" (Diffusing alpha emitters Radiation Therapy) is currently being tested in a clinical investigation into the treatment of skin cancers. This technique consists in implanting sealed radium-224 sources which emit alpha particles in the tumour using an afterloader; the sources are left in the tumour for 15 to 20 days.

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.

GRAPH 3 **Breakdown, by ASN regional division, of the number of brachytherapy centres, of high dose-rate brachytherapy centres and the number of new licenses or license renewals in 2023**



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. Positioning is done using an afterloader containing the source. The treatments are delivered on an out-patient basis, in one or more sessions of a few minutes, spread over several days if necessary.

2.2.2 Technical rules applicable to brachytherapy facilities

The rules for radioactive source management in brachytherapy are comparable to those defined for all sealed sources, regardless of their use (see point 1.3.3).

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 rate used.

The Order of 29 November 2019 sets the obligations concerning the protection of ionising radiation sources and batches of radioactive sources of categories A, B, C and D against malicious acts. The requirements concerning the protection barriers and their resistance time for category A, B and C sources are enforceable since 1 July 2022 (see chapter 8, point 2.3.2).

As some centres could not enlarge their premises or build new bunkers, ASN licensed two centres with "mixed-purpose" bunkers for joint external-beam radiotherapy and HDR brachytherapy practices on the basis of an expert assessment by IRSN concerning the design rules for premises housing both medical linear electron accelerators and HDR source projectors. The regulatory provisions to protect high-activity sources against malicious acts have been taken into account.

ASN was particularly attentive to the analysis of the licensee's provisions regarding the following main points:
- organisation of the alternations between the different treatments and the quality control time slots (number of patients treated, organisation of the schedules, time slots for MD quality controls, time slots for treatments, etc.);
- patient positioning that facilitates their evacuation in case of emergency;
- specific safety systems preventing the simultaneous operation of two devices;
- separate and clearly identified indicator lights and emergency stop controls for the two systems;
- double zoning plan displayed at the entrance;
- procedure if personnel get shut inside, for both devices.

2.2.3 Radiation protection situation in brachytherapy

ASN has licensed 57 brachytherapy centres, 51 of which use the HDR technique. Eighteen licenses were updated in 2023 (see Graph 3 above). The brachytherapy activity is stable, with HDR brachytherapy still representing the majority of treatments. ASN observes that some brachytherapy centres have difficulties in maintaining certain activities due to a lack of medical staff trained in brachytherapy techniques, even if they wish to maintain these activities in order to offer the patients the most appropriate treatments for their pathology.

The INCa Observatory records 600 to 700 LDR treatments, 750 to 800 PDR treatments for gynaecological cancers and between 4,550 and 5,000 HDR treatments.

01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 AP

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 2023, 13 inspections were carried out on the theme of radiation protection, representing about a quarter of the licensed departments.

2.2.3.1 Management of sources

The management of brachytherapy sources is deemed satisfactory. Thus, all the centres inspected in 2023 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 set-ups enable the category of each source or batch of sources to be identified in virtually all the centres inspected. Although 71% of the centres inspected have put in place appropriate measures to prevent unauthorised access to these sources, in 2023 only half of them have issued their personnel with the authorisations necessary for access to high-activity sealed sources, which is less than the proportion observed in 2022 (75%).

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 configuration of the premises or the places in which the category C sources are stored pending recovery or loading, and the cost of the ensuing compliance work.

2.2.3.2 Emergency situations and management of malfunctions

The malfunctions of brachytherapy devices which can result in jams or incorrect positioning of the source can lead to overexposure of staff or patients, sometimes with serious consequences (radiation necrosis). Consequently, this type of event underlines the need to comply with the technical requirements concerning the use of these devices, and the obligations to provide training in emergency situation management and to conduct exercises.

2.2.3.3 Radiation protection of medical professionals

The occupational radiation protection measures deployed in 2023 by the brachytherapy departments were considered satisfactory in only half the departments. Of the 13 centres possessing high-activity sources inspected in 2023, only 46% 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 measures must be taken to enhance the radiation protection training of the medical professionals when high-activity sources are possessed, and to take source jamming situations into account in the individual assessments of exposure of medical professionals to ionising radiation.

2.2.3.4 Radiation protection of patients

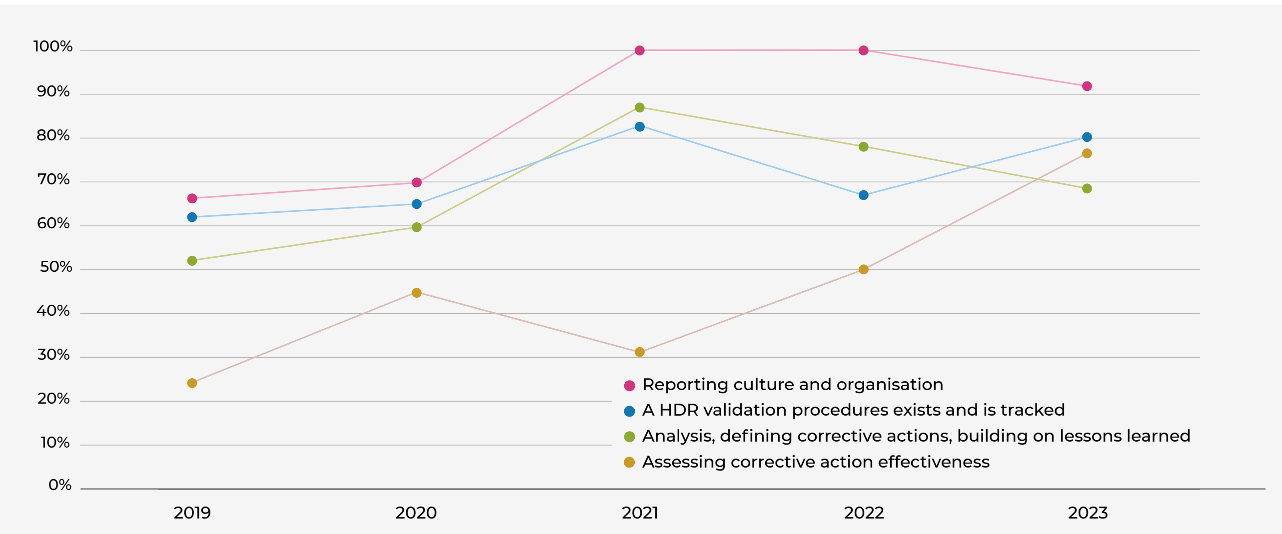
As with external-beam radiotherapy, the radiation protection of brachytherapy patients is assessed from the inspections concerning the implementation of the treatment quality and safety management system and the medical physics organisation.

ASN notes that the requirements concerning the medical physics organisation and the presence of a medical physicist during the treatments are satisfied in all the inspected centres.

2.2.3.5 The treatment quality and safety management system

The qualitative result of the inspections carried out in 2023 has shown that the majority of brachytherapy departments inspected have deployed a QMS, with the support of the external-beam radiotherapy departments (see Graph 4 below).

GRAPH 4 **Percentage conformity of brachytherapy facilities in the management of events in 2023**



A review of the inspections carried out over the 2019-2023 period and covering all the departments reveals the following trends:

- The notification culture and the organisation for managing the reports are considered satisfactory for all the departments inspected in recent years, with ratings of 100% in 2021 and 2022, and 92% in 2023.
- The analysis, the defining of corrective actions and capitalising on them are considered satisfactory in two thirds of the departments, with a situation that is less satisfactory in 2023 (the rate has diminished over the last three years, from 87% in 2021 to 78% in 2022 and 69% in 2023).
- The assessment of corrective action effectiveness has been progressing since 2019. While only a quarter of the departments assessed the effectiveness of corrective actions in 2019, more than three quarters of the inspected centres did so in 2023.
- Most of the departments inspected over the period from 2019 to 2023 have a validation procedure for HDR treatments (ranging from two thirds to over three quarters of the centres).
- The authorisation process is being deployed, but there are still disparities between the medical and paramedical personnel, given that it is applied mostly for the paramedical staff.

Maintenance and quality controls – The majority of the centres have an inventory of the MDs and a register for recording maintenance operations and quality controls. In the absence of regulatory baseline requirements for the quality controls of brachytherapy devices, the quality controls implemented are based on the recommendations of the manufacturers or learned societies. Guide of the European Society Radiation Oncology (ESTRO) Booklet No. 81 and Guide No. 36 of the French Society of Medical Physics (SFPM).

Maintenance of the afterloaders (for HDR and PDR applications) – This is ensured by the manufacturers, particularly when replacing sources. The brachytherapy departments rely on these verifications to guarantee correct operation of the devices. The source activity is verified at each delivery, and verifications are also carried out on source removal.

ASN notes that the verifications performed by the departments can sometimes prove insufficient when a new device is received, and draws attention to the need to clearly define these verifications taking into account the manufacturer's requirements, particularly for HDR brachytherapy. As the doses delivered at each brachytherapy session are about 4 to 10 Gy, errors in treatment delivery can have serious consequences for the health of the patient.

2.2.3.6 Significant events in brachytherapy

Eight ESRs concerning brachytherapy were reported in 2023 under criterion 2.1 (exposure of patients undergoing therapeutic treatment), all rated level 1 on the ASN-SFRO scale.

One ESR in brachytherapy rated level 1 on the ASN-SFRO scale concerned a cohort of patients (about one hundred) in three different healthcare facilities. The event was reported after the manufacturer gave notification of a roundoff error in the software leading to an imprecision in the space between the computed tomography slices imported for the dosimetric planning of the treatments. This event also led to a medical devices vigilance notification to the ANSM. This imprecision could have resulted in a dose error of about 5 to 10% on each brachytherapy treatment fraction in certain conditions of use. The manufacturer proposed corrective measures involving the software parameter settings.

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.

Furthermore, one event concerns the potential exposure of workers linked to the contamination of tongs and a soaking tank by radium-224 during a brachytherapy procedure involving the temporary implantation of Alpha DaRT™ sources. The tongs used to implant the sources came into contact with the sources during their insertion into the tumour. On arrival in the hospitalisation sector at the end of the procedure, the tongs were placed in the disinfection tray instead of the decontamination tray. When the tray was checked, it was found to be contaminated. This event occurred in a context of incomplete risk mapping and an incomplete protocol, leading the personnel to underestimate the contamination risk, and poor management of discarded and reusable instruments.

SUMMARY

In brachytherapy, the inspections carried out in 2023 in nearly a quarter of the brachytherapy units, considered alongside those carried out over the 2019-2022 period, enabling all the departments to be covered, confirm that the radiation protection rules are properly applied. ASN does however find that the management of high-activity sealed sources is less satisfactory in 2023, with less than half the centres having put in place enhanced training in emergency situations and organised situation simulation exercises, particularly for the management of jammed source situations. 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. Furthermore, ASN underlines 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. Lastly, ASN underlines the challenges concerning resources and skills that must be met in the coming years in order to maintain the brachytherapy activity.

TABLE 3 **Main radionuclides used in diverse *in vivo* nuclear medicine explorations**

TYPE OF EXAMINATION	RADIONUCLIDES USED
Thyroid metabolism	Iodine-123, technetium-99m
Myocardial perfusion	Rubidium-82, technetium-99m, thallium-201
Lung perfusion	Technetium-99m
Lung ventilation	Krypton-81m, technetium-99m
Osteoarticular process	Fluorine-18, technetium-99m
Renal exploration	Technetium-99m
Oncology – search for metastases	Fluorine-18, gallium-68, technetium-99m
Neurology	Fluorine-18, technetium-99m

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.

Furthermore, the reform of healthcare licences (see point 1.3.3) has introduced two licensing "levels" for nuclear medicine (levels A and B) in application of Decree 2021-1930 concerning the conditions of installation of nuclear medicine departments. Level A concerns the diagnostic or therapeutic activities other than the treatment of cancerous pathologies, carried out by administering RPDs that are ready to use or are prepared using an aseptic process in a closed system. Level B is attributed when the activity includes, in addition to the procedures covered by level 1, the following procedures:
- procedures with the administration of an RPD prepared using an aseptic process in an open environment;
- diagnostic procedures carried out for explorations of cellular marking of the formed elements of the blood by one or more radionuclides;
- therapeutic procedures carried by the administration of active implantable MDs;
- therapeutic procedures for cancerous pathologies performed by administering RPDs.

The healthcare activity licence for nuclear medicine shall henceforth be granted by geographical site on condition that the provisions concerning the number of Single Photon Emission Computed Tomography (SPECT) and PET devices are observed (see point 2.3.1). The facilities will have to regularise their situation and submit applications to install new devices in already authorised sites or for the creation of new sites with the ARS. The licenses to possess and use a radioactive source or a device emitting ionising radiation issued by ASN shall be updated according to the nature of these changes (change of holder, site, device, sharing of devices, etc.).

Nuclear medicine 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. Depending on the type of radionuclide used, the term SPECT, still called "gamma-camera", is used for radionuclides emitting gamma radiation and PET for radionuclides emitting positons.

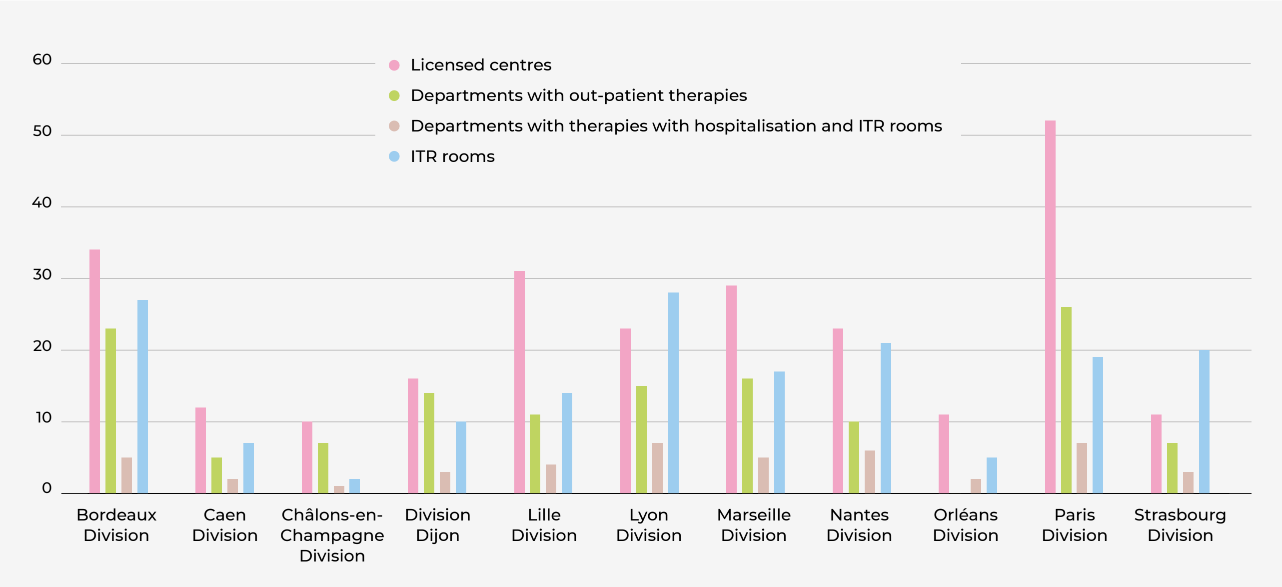
In order to make it easier to merge functional and morphological images, hybrid appliances have been developed. They combine PET cameras or gamma cameras with a CT scanner (PET-CT or SPECT-CT). A PET camera can also be coupled with an MRI scanner, but this is rarer.

***In vitro* diagnostic nuclear medicine** is a medical biology technique used to assay certain compounds contained in the biological fluids sampled beforehand from the patient (*e.g.* hormones, tumoral markers, etc.); it is used frequently because it has the highest detection sensitivity of the techniques using ionising radiation. This technique uses assaying methods based on immunological reactions (reactions between antigens and antibodies 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 RPDs to deliver a high dose of ionising radiation to a target organ for curative or palliative purposes. Two areas of therapeutic application of nuclear medicine can be identified: oncology and non-oncological diseases.

Human Subject Research (HSR) in nuclear medicine has been particularly dynamic in recent years, primarily in the field of oncology therapy with the emergence of new vectors and radionuclides.

GRAPH 5 **Overview of the national nuclear medicine base in 2023**



ITR treatments can be administered either by mouth (*e.g.* capsule of iodine-131) or by systemic route (intravenous injection or *via* a catheter).

Some treatments – depending on the administered activity or the nature of the radionuclide used – require patients to be hospitalised for several days in specially fitted-out rooms in the nuclear medicine department to ensure the radiation protection of the personnel, of people visiting the patients and of the environment. The radiological protection of these rooms is adapted to the nature of the radiation emitted by the radionuclides, and the contaminated urine of the patients is collected in tanks.

Forty-five nuclear medicine departments have a combined total of 170 ITR rooms for therapeutic purposes (see Graph 5 above).

Until recently, ITR was a minority technique among the therapeutic strategies in cancerology, but today it is undergoing an increasing number of clinical tests, particularly in oncology. It raises many questions regarding radiation protection of the patients, their family circle and the medical staff, as well as the fitting out of nuclear medicine departments and the management of waste and effluents. The use of these new treatments therefore necessitates deeper knowledge of the specific radiation protection issues, as from the clinical research phase. For this reason, in 2023 ASN referred the matter to the GPRP, initiated discussions with the nuclear medicine actors and became involved in the European SimpleRad project (Study on the implementation of Euratom and EU legal bases with respect to the therapeutic uses of radiopharmaceuticals) which aims to improve the understanding of the links and interdependencies between the European pharmaceutical legislation and the Euratom requirements with regard to radiation protection.

Medical dispensaries

On account of the ongoing reform of healthcare licences (see point 2.3), the authorisation for level A holders requires that a radiopharmacist be attached to the medical dispensary if the nuclear medicine department is located in a site that has a dispensary. For the holders of level B, the radiopharmacist duties are ensured and organised within the medical dispensary of the site and the RPD preparation room within the nuclear medicine department, called the "nuclear pharmacy", forms part of the medical dispensary. In 2020, there were 105 nuclear pharmacies in the nuclear medicine departments in public healthcare institutions and non-profit private healthcare institutions, such as the cancer centres. The radiopharmacist is primarily responsible for managing the RPD circuit (procurement, possession, preparation, control, dispensing and traceability) and the quality of preparation. The ANSM published a guide to *Good preparation practices* on 20 September 2023, which came 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 devices are also used in the preparation and injection of RPDs marked with fluorine-18 and gallium-68.

2.3.2 Technical rules applicable to nuclear medicine facilities

The radiation protection constraints specific to nuclear medicine are linked to the use of radionuclides in unsealed sources. The departments are designed and organised for the reception, storage and handling of these unsealed radioactive sources with a view to their administration to patients or in the laboratory (in the case of radioimmunology). Provision is also made for the collection, storage and disposal of radioactive wastes and effluents produced in the facility, particularly the radionuclides contained in patients' urine.

Compliance with the technical design, operating and maintenance rules of nuclear medicine departments

Nuclear medicine departments must satisfy the rules prescribed by ASN resolution 2014-DC-0463 of 23 October 2014 relative to the minimum technical rules of design, operation and maintenance to be satisfied by *in vivo* nuclear medicine facilities.

This resolution details in particular the rules for the ventilation of nuclear medicine department premises and the rooms accommodating patients receiving, for example, treatment for thyroid cancer with iodine-131. Guide No. 32 detailing certain aspects of this resolution was published by ASN in May 2017 and was updated in February 2020.

In addition, facilities equipped with a CT scanner coupled with a gamma-camera or a PET camera must comply with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017 laying down the minimum technical design rules to be satisfied by premises in which electrical devices emitting X-rays are used.

Management of waste and effluents from nuclear medicine departments

The management of waste and effluents potentially contaminated by radionuclides must be described in a management plan which includes, more specifically, the conditions of monitoring of discharged effluents in accordance with Article R. 1333-16 of the Public Health Code and ASN resolution 2008-DC-0095 of 29 January 2008. Premises must be dedicated to these activities, as must specific equipment for monitoring the conditions of effluent discharges (tank filling levels, leakage alarm systems, etc.). The compliance of the facilities for collecting the effluents and wastes produced by nuclear medicine departments must be verified regularly. Revision of this resolution began at the end of 2020 and will also lead to an update of ASN Technical Guide No. 18 of 26 January 2012.

One of the 15 recommendations of the Working Group report "*Discharging of effluents containing radionuclides from nuclear medicine units and research laboratories into the sewage network*" published in June 2019 on *asn.fr* introduces the notion of setting "contractual" or "management" 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[6] 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 submitted its reports[7] to ASN in 2023; the IRSN recommendations shall be analysed as part of the revision of ASN resolution 2008-DC-0095 of 29 January 2008.

2.3.3 Radiation protection situation in nuclear medicine

The nuclear medicine facilities installed base in 2023 comprises 252 licensed nuclear medicine departments, of which 45 practice high-activity ITR requiring hospitalisation in a radiation-proof room and 134 practice moderate-activity ITR on an out-patient basis.

One hundred forty-three nuclear medicine licences were issued during 2023, including: equipment changes or commissioning (PET scanners in particular), increases in the activity of radioisotopes already used, license extensions to allow the use of new radionuclides, and licences to perform clinical studies with new RPDs (such as actinium-225 and holmium-166).

ASN inspections in nuclear medicine are scheduled applying a graded approach that takes into account the breakdown of the types of procedures performed in the departments, with risks that differ depending on whether they concern diagnostic or therapeutic procedures. In this context, the inspection frequency is five-yearly for departments that only perform diagnostic examinations, four-yearly for departments performing diagnostic examinations and out-patient therapeutic procedures (delivery of iodine with activities below 800 MBq, synoviortheses, etc.) and three-yearly for the departments performing complex therapies using iodine with delivered activities exceeding 800 MBq, lutetium-177, yttrium-90 (with hospitalisation in a room that may or may not be radiation-proof). This means that about a quarter of the national installed base is inspected each year.

With regard to the radiation protection risks, the ASN inspections focus on radiation protection of workers (organisation of radiation protection, delimiting restricted areas, ambient dosimetry, staff dosimetry) and patients (analysis of DRLs, quality control of medical devices, control of dispensing of RPDs,) and source management (circuit followed by unsealed sources, from delivery to disposal, such as the delivery reception premises, storage tanks and effluent discharges).

In 2023, 61 nuclear medicine departments were inspected, representing 24% of the facilities. During these inspections the centres mentioned staffing problems, particularly with radiographers (recruitment difficulties, high turnover), and difficulties in recruiting practitioners in certain regions, leading them to have recourse to telemedicine. ASN endeavours to question the centres about the adequacy of their resources, particularly when new projects are underway and in a context of increasing activity.

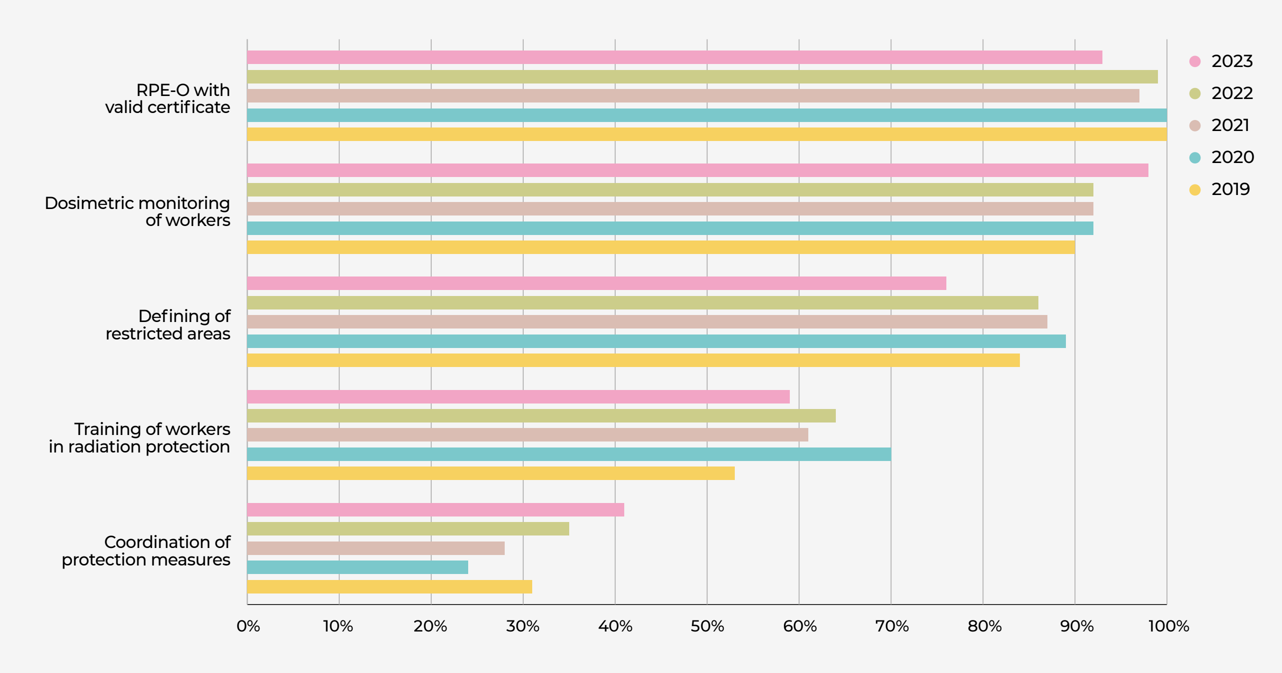
2.3.3.1 Radiation protection of nuclear medicine professionals

From the radiological viewpoint, the personnel are subjected to a risk of external exposure – in particular on the fingers – due to the handling of certain radionuclides (case with fluorine-18, iodine-131, gallium-68 or yttrium-90) when preparing and injecting RPDs, and a risk of internal exposure through accidental intake of radioactive substances.

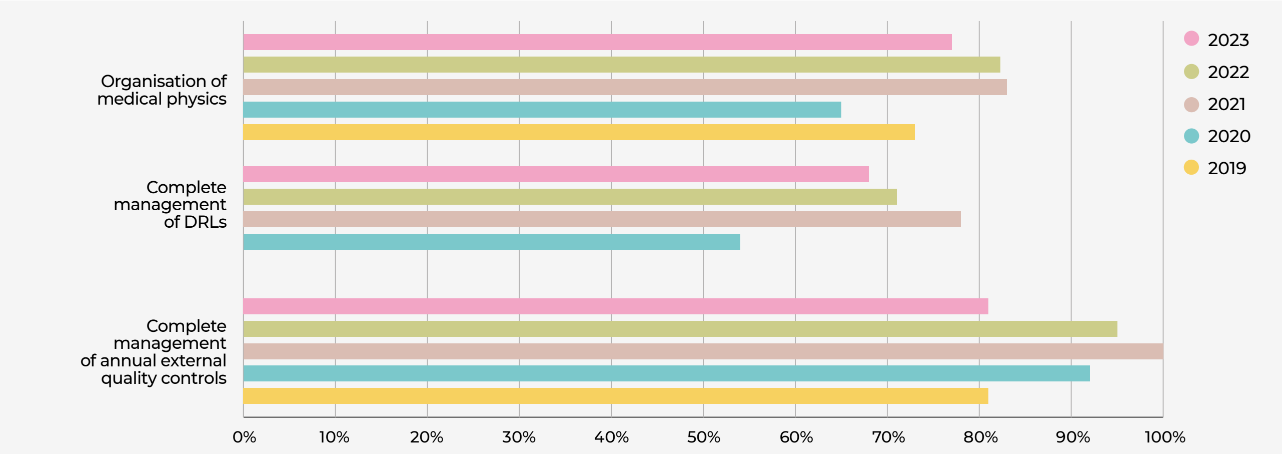
The inspections in 2023 find that occupational radiation protection requirements are taken into account less well than in the preceding years (see Graph 6 next page). The observed deviations concern the appointing of a Radiation Protection Expert (RPE-O) dedicated to this activity (valid certificate issued by the employer in all the inspected departments), failures to verify the risk of atmospheric contamination or non-contamination of areas adjacent to rooms in which radionuclides are handled, application of the provisions concerning the delimiting of restricted areas consistently with the verifications of the work environments and the radiation protection technical controls. The latter verifications were carried at the required regulatory frequency for all the sources and devices in 62% of the departments inspected in 2023, a percentage that is significantly lower than in the preceding years. Furthermore, only 45% of the departments inspected had carried out compliance work further to the nonconformities found at the last verifications. However, nearly all of the departments inspected in 2023 monitor and analyse the dosimetric results of their staff.

6. Referral CODEP-DIS-2020-013834 – Request for expert assessment concerning the definition of a measurement protocol and a method of utilising the results in order to establish local guide levels for environmental discharges containing radionuclides coming from nuclear medicine departments and research laboratories.
7. IRSN Report No. 2023-00061 – Guide levels for the discharge of radionuclides concerning the defining of a measurement protocol and a method of utilising results in order to establish local guide levels for environmental discharges containing radionuclides coming from nuclear medicine departments: situation analysis and proposals.
IRSN Report No. 2023-00241 – Guide levels for the discharge of radionuclides concerning the defining of a measurement protocol and a method of utilising results in order to establish local guide levels for environmental discharges containing radionuclides coming from research laboratories: situation analysis and proposals.

GRAPH 6 **Development of nuclear medicine department compliance with occupational radiation protection regulations (2019-2023)**



GRAPH 7 **Development of nuclear medicine department compliance with patient radiation protection regulations (2019-2023)**



NB: no DRL regulations in 2019.

In 2023, there are still two areas for improvement, as in the preceding years. The first concerns the updating of personnel training in occupational radiation protection (in 59% of the departments inspected in 2023, all the staff concerned received their training less than three years ago), a requirement for which ASN notes a slight regression over the last three years. The second recurrent area for improvement is in the coordination of the prevention measures with outside contractors, even if a small improvement is noted in 2023, with slightly more than a third of the nuclear medicine departments having drawn up a prevention plan with all the outside contractors.

2.3.3.2 Radiation protection of nuclear medicine patients

Since ASN resolution 2019-DC-0667 of 18 April 2019 on DRLs[8] came into effect, ASN has been assessing the new requirements concerning the quality of collection of doses, their analysis and the optimisation put in place where necessary. The ASN inspectors note that the percentage of departments deploying a complete optimisation approach (see Graph 7 above) is relatively stable at 68%, with improvements required in the evaluation and analysis of the delivered doses and administered activities.

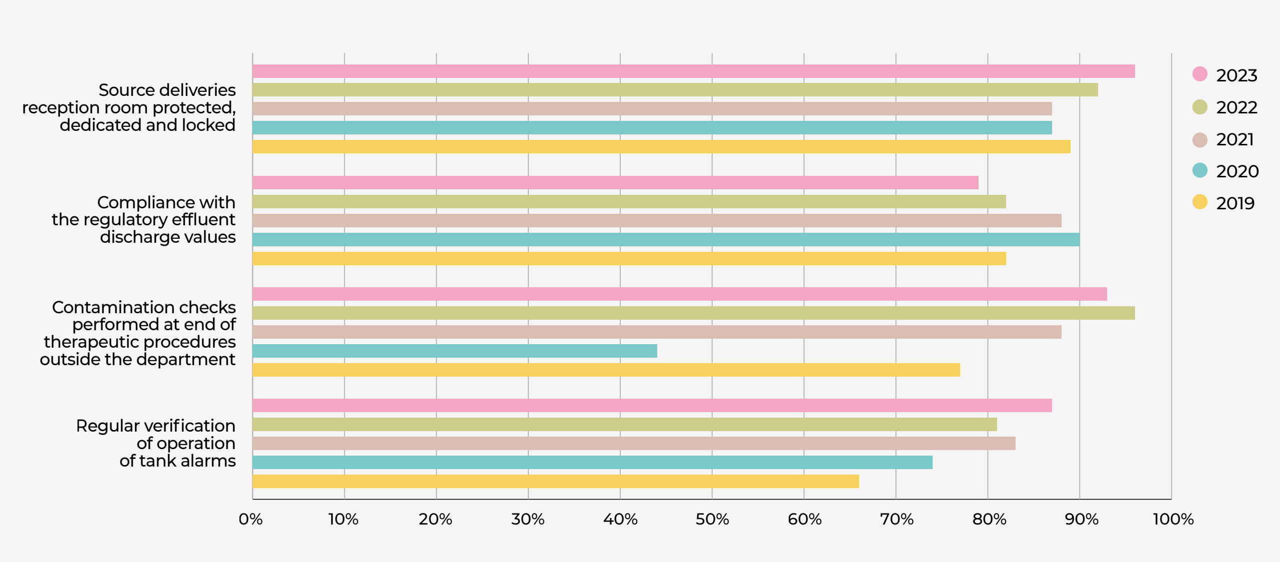
Management of the third-party quality controls of the MDs remains satisfactory but ASN notes a regression in 2023, with 81% of the inspected departments having carried out the quality controls on all their MDs at the required regulatory frequency, compared with more than 95% in the preceding years (see Graph 7 above).

The organisational measures in place to allow the involvement of a medical physicist, the identification of their duties and the recording of the time they are present on the site are slightly less

8. 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.

01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 AP

GRAPH 8 **Development of nuclear medicine department compliance with protection of the public and the environment (2019-2023)**



effective than in the preceding two years, with 77% of the departments presenting a good medical physics organisation in 2023 compared with 83% in 2021 and 2022 (see Graph 7 previous page). However, for some services inspected in 2023, the Medical Physics Organisation Plan (POPM) was incomplete and the medical physics organisation described in the POPM was considered inadequate.

Lastly, following the publication of two ASN resolutions 2019-DC-0660 and 2021-DC-0708, laying down the quality assurance obligations in medical imaging and for therapeutic procedures respectively, ASN notes a strong commitment and significant investment on the part of the medical departments in the deployment of the QMS. ASN observes that the authorisation process is being deployed, but there are still disparities between the medical and paramedical personnel, given that it is applied mostly for the paramedical staff. Although the events notification culture is present in a large proportion of the inspected departments, it must be improved or be reinforced, as ASN observed that some centres had not reported ESRs.

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 inspected over the 2019-2023 period (96% in 2023) have a dedicated and protected deliveries area (see Graph 8 above), that complies with the requirements of ASN resolution 2014-DC-0463 of 23 October 2014. About 20% the departments inspected each year (21% in 2023) 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 8 above). Improvements have been observed these last three 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 (87% in 2023). The inspections have also revealed that the EWMPs do not always contain all the required elements, such as the discharge agreement signed with the manager of the public wastewater drainage network, and the setting of a maximum permissible value at the outlet of the centre.

Alongside this, over the last three years ASN has observed an improvement in performance of the non-contamination checks at the end of therapeutic procedures when the procedures are performed outside the nuclear medicine departments, which are performed satisfactorily by more than 90% of the inspected departments (93% in 2023).

ASN notes that the RNAs have difficulties in implementing the new regulations concerning the verifications to be carried out under the Public Health Code which are applicable since 1 January 2023. The main difficulty is linked to the definition of the requirements (scope of the verification action) of the Order, for the approved organisations and healthcare centres alike.

2.3.3.4 Significant events in nuclear medicine

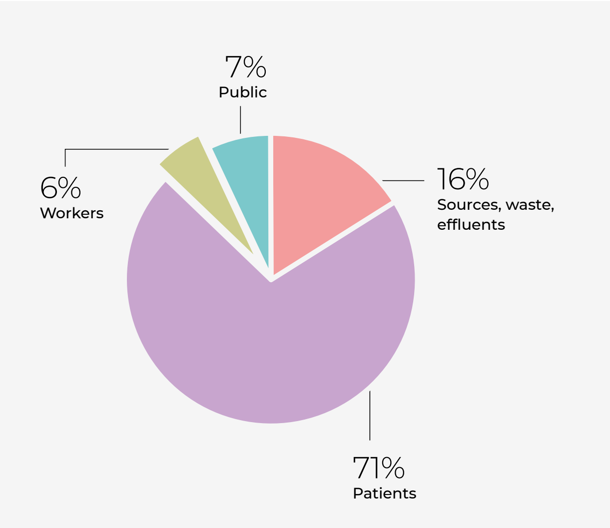
Out of the 61 departments inspected, most of them have a system for recording adverse events. For the majority of events reported to ASN, the proposed action plan is appropriate but shortcomings are sometimes observed in the analysis of their root causes. On the other hand, several inspected departments had not reported certain ESRs to ASN, primarily due to the personnel's lack of awareness of events reporting.

Altogether, 201 ESRs were reported in 2023, a figure that is slightly higher than in 2022 and which has been increasing on the whole over the last few years (40% since 2019 – see point 2.7).

As in the preceding years, the majority of the reported events (71%) concern patients (see Graph 10). Most of the reported events have no expected clinical consequences, in view of the activities injected.

ASN notes that deployment of the nuclear medicine activity, particular when new medical devices are purchased, changes the organisational arrangements and the work activity and can be a source of ESRs if it is not managed properly. This was ASN's finding during an inspection in 2023 after a centre reported two events that occurred in its PET sector in a period of ten days. It was found that the significant increase in the department's activity with the acquisition of a fourth PET scanner, without recruiting additional personnel, combined with the introduction of a barcode system to make the RPD preparation and injection process safer but requiring accustomisation, with personnel who could be assigned to several different sectors, were factors contributing to these events.

GRAPH 9 **Breakdown (in %) of ESRs in nuclear medicine in 2023**



Significant events concerning patients (142 ESRs, *i.e.* 71% 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 or wrong activity injected in more than 50% of the ESRs) or identity monitoring errors in 30% of the cases (RPD administered to the wrong patient), and result from organisational and human malfunctions, usually in high workload situations. Five events of this type in 2023 concerned children. Nine reported events involved RPD extravasation[9].

In 2023, ten events that occurred during therapeutic procedures were reported, four linked to complications associated with the use of yttrium-90 microspheres). The other ESRs concern errors in the handling or injection of RPDs (four ESRs with lutetium-177 and one with iodine-131).

Significant events concerning medical professionals (13 ESRs, *i.e.* 6% of the reported ESRs)

Thirteen events concerning nuclear medicine professionals were reported in 2023. They result from contaminations that led to internal or external exposures (surface contaminations as a result of handling errors or reception of a broken vial). None of these ESRs resulted in the regulatory dose limit for the workers concerned being exceeded.

Significant events concerning the public (14 ESRs, *i.e.* <7% of the reported ESRs)

Thirteen events concerning the public result from exposure of the foetus in women unaware of their pregnancy. The doses received had no consequences for the unborn child. A “Patient safety” newsletter published in 2021 was devoted to this type of event. The 14th event involving the public concerns a high dose rate (hot spot) discovered in a corridor of a day hospital care department.

Significant events concerning radioactive sources, waste and effluents (32 ESRs, *i.e.* 16% of the reported ESRs)

These ESRs are mostly related to source losses/discoveries, the dispersion of radionuclides (resulting from overflows of radioactive effluent tanks or leaks in the effluent evacuation circuit), deliveries that do not comply with the licenses and unauthorised discharges of effluents into the environment (emptying of tanks, etc.).

Difficulties have recently emerged in the management of the solid waste produced in the ITR treatments of certain prostate cancers with RPDs using lutetium-177. The patient is given instructions on leaving the nuclear medicine department regarding the management of the waste produced at home (sanitary protections, for example) in the days following treatment, including storage of their waste in the home for several weeks. At present these instructions are not harmonised nationally. Storage of this type of waste in the home can be difficult (lack of space or a suitable area). Consequently, it can happen that waste arrives at the waste treatment facilities before the time indicated in the patient’s discharge instructions has lapsed, triggering the radiation portal monitors. Solutions have been proposed by domestic waste treatment centres, such as providing patients with larger-volume collectors and having them picked up by a door-to-door service, while at the same time enhancing patient awareness.

However, as these one-off solutions are costly and this is a promising type of treatment which is bound to develop, ASN draws the medical profession’s attention to the need to find long-term solutions which can be applied across the country.

SUMMARY

The inspections carried out in 2023 in nearly a quarter of the nuclear medicine departments, considered alongside those carried out over the 2019-2022 period, enabling all the departments to be covered, confirm that the radiation protection rules are properly applied in the majority of the departments. The observations made in 2023 nevertheless confirm that effluent management must be improved, even if some progress has been observed in checking the operation of tank alarms, in formalising the coordination of the prevention measures with outside contractors (for maintenance and cleaning services, services of private practitioners, etc.) and in personnel training. ASN notes that further progress is needed in the deployment of the QMS’s and in the quality of the ESR analyses. Among the reported ESRs, those concerning drug administration errors show that the drug administration process must be regularly assessed to ensure it is controlled (see the bulletin “*Safeguarding the medication circuit in nuclear medicine*”). Although a medical physics organisation is in place in most centres, particular attention must be devoted to it given the strong development of the therapy with the introduction of new RPDs. More generally, the increasing emergence of clinical tests involving new vectors and new radionuclides (lutetium-177, actinium-225, lead-212, holmium-166, etc.) makes it necessary to acquire deeper knowledge of the associated radiation protection risks, not only for the patients and their carers and comforters, but also for the medical professionals, the public and the environment. The work undertaken nationally by the GPRP at the request of ASN, and at European level through the SimpleRad project, should lead to recommendations to respond to new risks.

9. Extravasation is an inappropriate accidental and unintentional injection or leakage of drugs into the perivascular or subcutaneous spaces rather than into the targe vascular compartment.

2.4 FLUOROSCOPY-GUIDED INTERVENTIONAL PRACTICES

Fluoroscopy-Guided Interventional Practices (FGIPs) group all the imaging techniques using ionising radiation for the purpose of imaging, guidance or verification, for performing invasive medical or surgical procedures for diagnostic, preventive and/or therapeutic purposes.

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.

On account of the exposure levels involved, as much for the patients as for the professionals who can be obliged to work close to the radiation sources, FGIPs and operating theatres in particular, due to a less well-developed radiation protection culture, are part of ASN's national inspection priorities.

2.4.1 Description of the techniques

The healthcare centres

According to the codes of the common classification of medical procedures and the activity data reported by the healthcare centres to the Agency for Information on Hospital Care (AIHC), about 900 centres perform FGIPs involving risks (with regard to radiation protection) in one or more disciplines. The risk-prone FGIPs include cardiology (implanting a defibrillator, angioplasty, etc.), interventional neurology (embolization of arterioveinous malformation), vascular radiology (embolization of the coeliac artery), or uterine embolization. Graph 10 (see below) shows the breakdown of the number of centres by FGIP category for the centres having declared the FGIPs they practice[10]. Based on available information, the most widely practised procedures in the centres are those performed on the digestive and visceral system, in urology, and on the musculoskeletal system (some 450 centres concerned).

The equipment

The equipment items used in FGIPs are either fixed C-arm devices installed in the interventional imaging departments in which vascular specialities (neuroradiology, cardiology, etc.) are carried out, or mobile C-arm radiology devices used chiefly in operating theatres in several surgical specialities such as vascular surgery, gastroenterology, orthopaedics and urology.

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 "photofluorography", or "cineradiography") intended to produce images with high spatial and temporal resolution. Practitioners can also use the subtraction method to obtain images, after injecting a contrast agent.

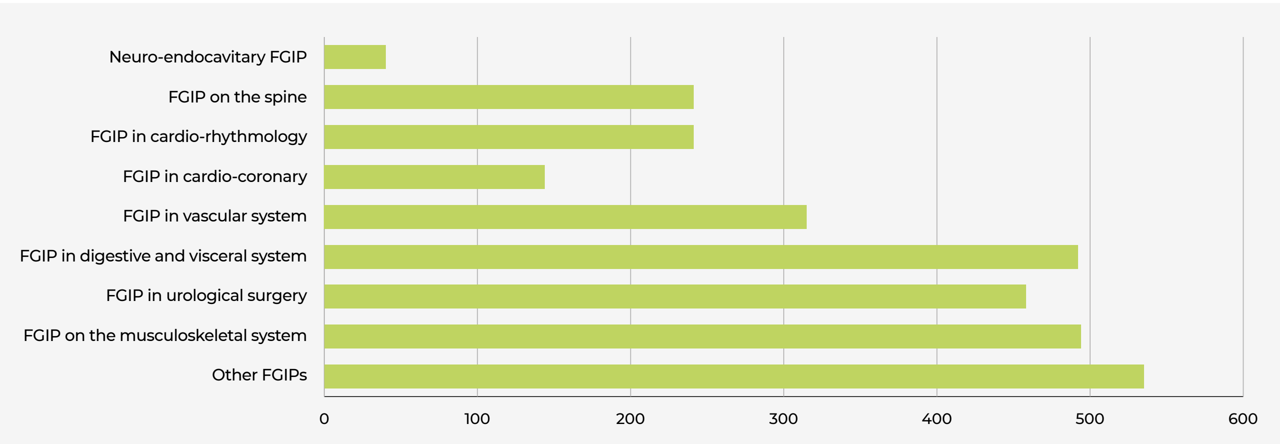
The centres practising FGIPs are equipped with ever-more efficient and sophisticated medical devices. "Hybrid" operating room facilities, which combine the characteristics of a conventional operating theatre with those of an interventional imaging room, are continuing to develop. These operating rooms contain fixed or mobile C-arm units and fixed or mobile scanners. This combination enables the surgeon to perform "mini-invasive" surgery with 2D and 3D imaging. Give that the delivered dose levels are higher than in other interventional procedures, practices must be optimised in order to reduce the exposure doses for both the patients and the operators, who often work in the immediate proximity of the patient.

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

GRAPH 10 **Breakdown of the number of centres by category of fluoroscopy-guided interventional practices in 2023**



10. Form that the centres had to fill out with the information requested in paragraph I 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 theatre. Simple and practicable instructions must be favoured in a context of multiple risks and a complex environment. The signalling systems moreover count among the most effective prevention measures, as does the wearing of appropriate Personal Protective Equipment (PPE) and dosimeters by each operator, from the moment a restricted area is delimited due to the risk of exposure to ionising radiation.

Some centres are equipped with operating halls that constitute technical platforms allowing procedures to be performed simultaneously with the sharing of certain members of staff. Compliance with the regulatory requirements, particularly those concerning signalling, can be more complicated in these halls.

2.4.3 Radiation protection situation in fluoroscopy-guided interventional practices

For some years now ASN has been receiving regular reports on ESRs in the area of FGIPs, but their number remains low for the number of procedures performed. In the course of its inspections, ASN still finds that the medical professionals lack knowledge of the criteria for reporting significant events, even though the doses administered in some centres are high and sometimes exceed the dose 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 optimises 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 PPE. Concerning patients, particular attention is paid to the optimisation of doses delivered to the patient (putting in place DRLs and dose analysis), personnel training in patient radiation protection and the use of the MDs. Application of ASN resolution 2019-DC-0660 of 15 January 2019 laying down the quality assurance obligations in medical imaging using ionising radiation helps the centres manage the risks arising from ionising radiation.

As FGIPs are numerous, varied, and performed in many different departments (neuroradiology, interventional cardiology, interventional radiology and operating theatres) within a given centre, the inspection programme is established so that all the departments performing radiation-risk procedures are inspected every five years. Nevertheless, the progress made in certain centres, the checks carried out when examining the FGIP registration applications, and the need to focus inspections more on the departments that are falling seriously behind in fulfilling the regulatory radiation protection obligations have led ASN to adjust the inspection frequency.

Inspection prioritisation is based on the number of procedures performed within a centre, the nature of the procedures which determine the radiation protection risks for the patients and medical staff, the condition of the facilities, (compliance with facility fitting out rules and persistence of nonconformities), the radiation protection culture of the teams and the situational factors (ESRs, vulnerabilities identified in previously inspected centres). This is why, since 2018, ASN prioritises its inspections in operating theatres, where the radiation protection culture is less firmly anchored than in interventional imaging departments.

COMPLIANCE NOTICES SERVED BY ASN ON A CENTRE IN THE AREAS OF FGIPS IN 2023

ASN exercised its powers of sanction in 2023 in the areas of FGIPs by issuing formal notice to the Bordeaux University Hospital to carry out the continuous training in patient radiation protection of the medical professionals concerned in order to comply with the provisions of Article R. 1333-68 of the Public Health Code and those of ASN resolution 2017-DC-0585 of 14 March 2017 amended. This centre was also given formal notice to comply with the fitting out rules for interventional procedure rooms defined in ASN resolution 2017-DC-0591 of 13 June 2017.

In 2023, 210 medical departments were inspected in 139 centres. As in 2022, the operating theatre complexes of the university hospital centres and the largest hospital centres, represent 65% of the inspections, and the departments licensed by the ARS (licensed for treatments in cardiac rhythmology, interventional cardiology and neuroradiology) were prioritised.

During these inspections, ASN finds differences between the procedures for which the structure is registered with ASN and those effectively practised. In effect, the FGIP offering in the inspected centres changes frequently because it depends on the specialists the centres are able to recruit (mobility, lack of personnel in certain specialities).

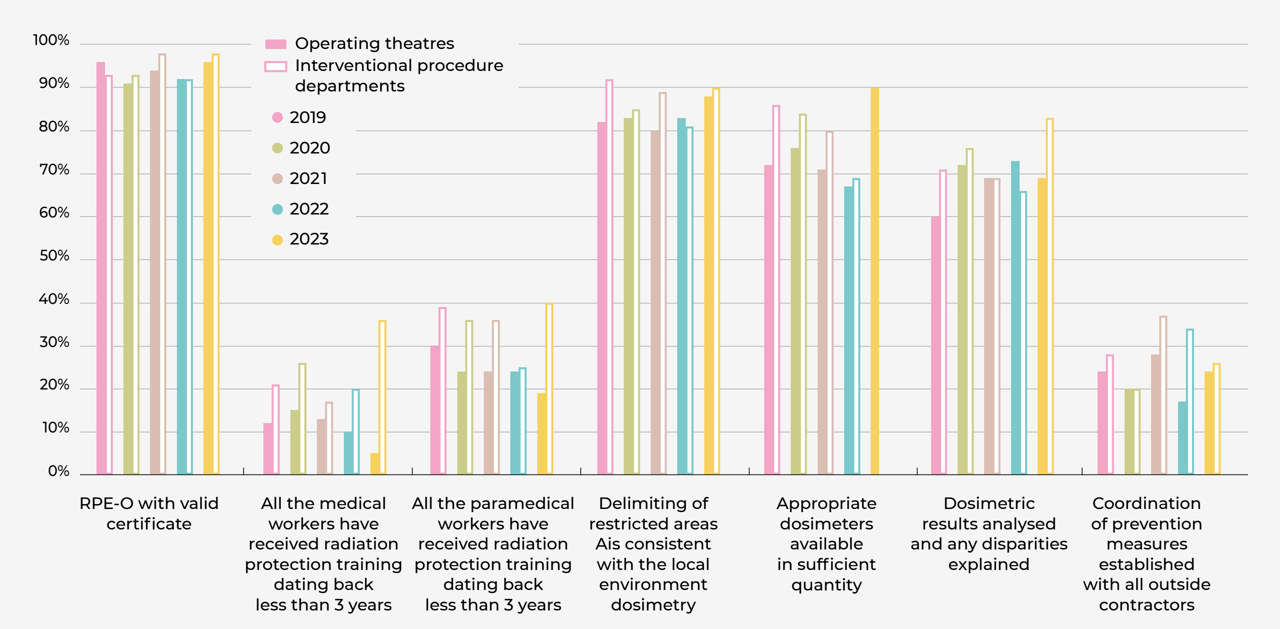
At present, 65% of the interventional imaging departments and 40% the operating theatres have rooms conforming to the requirements of ASN resolution 2017-DC-0591 of 13 June 2017 setting the technical fitting out rules and have drawn up a conformity report. These percentages have varied little over the last five years. The centres still mention financial difficulties and technical difficulties in particular in meeting the signalling requirements in the restricted areas, particularly with the emergence of new technologies that make electrical network modifications necessary. After several years without improvement despite the compliance commitments made by the centres, ASN deployed an enforcement approach in 2023 (see box above).

2.4.3.1 Radiation protection of medical professionals

The radiation protection of the medical professionals is considered satisfactory with regard firstly to the implementation of radiological zoning of the facilities (91% of the inspected departments), with a better assimilation of the notions of zoning in the operating theatres over the last five years, and secondly the appointing of an RPE-O (98% of the inspected departments).

Nevertheless the lack of training of medical professionals in occupational radiation protection has been a recurrent finding in inspections over the last five years. The situation in interventional imaging departments is better in 2023, but it has further deteriorated in the operating theatres. Only 5% of the operating theatres have trained all their medical personal and 19% have trained all their paramedical personnel; for interventional imaging departments these figures are 36% and 40% respectively. ASN thus notes a drop in the number of operating theatres that have trained all their personnel in the space of five years, and the proportion is very small. Yet this training is essential to understand of the radiation protection risks and identify the risk situations, and to be capable of implementing the prevention measures to ensure the safety of the personnel. The centres explain this situation by a lack of availability of the medical staff and/or a lack of mobilisation due to a certain amount of repetitiveness in the content delivered in

GRAPH 11 **Percentage of conformity of the FGI facilities inspected on the theme of medical staff radiation protection in 2023 (operating theatres and interventional departments)**



these training sessions. To overcome this problem, several centres are trying to deploy new training methods, such as e-learning, flash training in the operating theatre or even training through immersive 3D headsets, with positive feedback from the trainees.

In 2023, ASN observes significant use of RPOs, either as a specialised contributor to assist a RPE-O, or as an RPA. The use of RPOs can partly explain the difficulties in training the personnel due to the lower organisational flexibility of outsourced training sessions. Furthermore, calling upon an RPOs necessitates supervision of this service with strong internal mobilisation and an interlocutor who is capable of following through with the radiation protection questions, because the on-site presence of the RPOs personnel is often very limited. Without close involvement of the centres, the RPO's will use standard documents that ignore the departments' particularities. They are moreover often poorly known or unknown to the teams, who have difficulties in assimilating them. ASN observes that compliance with and assimilation of the requirements relating to occupational radiation protection is dependent on strong involvement of the persons responsible for radiological zoning, the radiation protection controls and the occupational radiation protection training courses.

Coordinating prevention measures with outside contractors, including private practitioners, is also an area for progress in interventional imaging departments and operating theatres alike. The percentage of inspected departments having formalised prevention measures with all their service providers through a prevention plan varies between 17 and 28% for the 2019-2023 period. In 2023, only 24% of the inspected centres had formalised these measures. Yet knowledge of the risks linked to ionising radiation and of the appropriate prevention measures for the situations encountered, particularly by private practitioners, is a prerequisite for ensuring their radiation protection and that of other professionals.

In 90% of the operating theatres inspected in 2023, the medical personnel have dosimetric monitoring devices available in sufficient quantity and appropriate for their types of exposure, a great improvement on the preceding four years, where the average was about 70%.

ASN also observes that the analysis of the dosimetric results by the RPE-Os has slightly improved over the last five years, enabling the bad practices to be identified and corrected; the situation is better in the interventional imaging departments than in operating theatres, with 83% of the departments having analysed the dosimetric results in 2023 compared with 71% in 2019, while the figures for the operating theatres stand at 70% in 2023 and 60% in 2019.

Radiation protection technical verifications

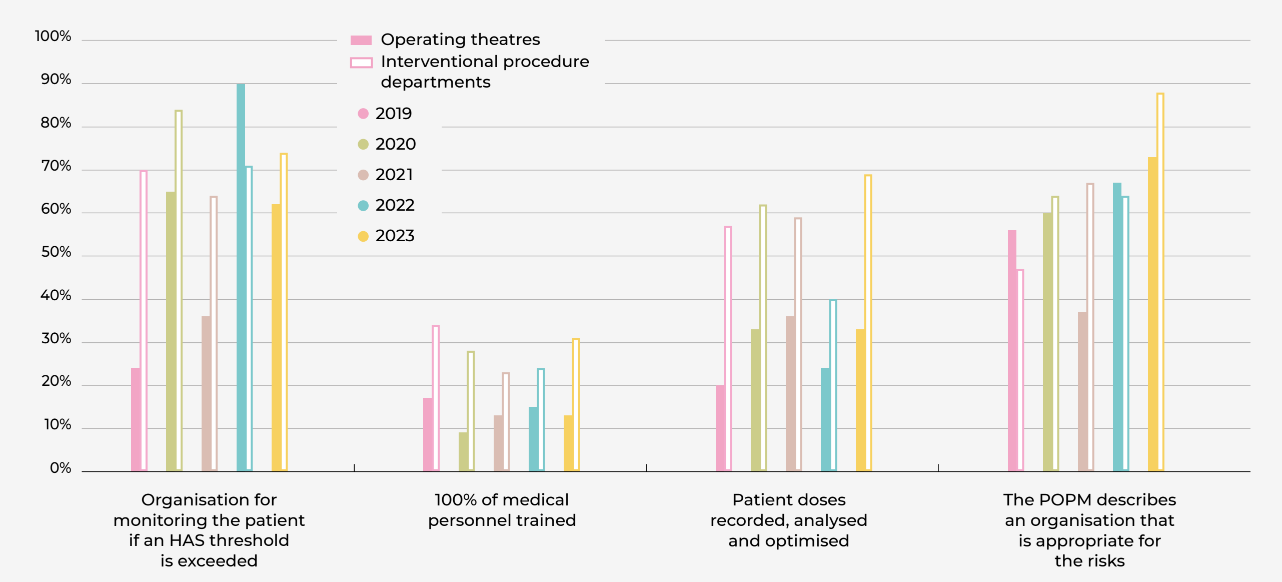
ASN notes that the verification programme for work equipment and radiation protection instrumentation is drawn up and implemented in 58% of the interventional imaging departments and 54% of the operating theatres. When nonconformities had been identified, they had been corrected or were in the course of being corrected on the date of inspection in 90% of the cases.

2.4.3.2 Radiation protection of patients

Of the departments performing FGIPs inspected in 2023, 77% call upon a medical physicist and have a POPM describing the organisation for involving a medical physicist, whose duties and times of presence on site are defined according to the centre's activities. This figure has remained relatively stable over the 2019-2023 period. Recourse to outside contractors for medical physics services continues to expand in private sector centres and public hospitals alike. The outsourcing of medical physics duties is largely delegated to special advisors who intervene on site as and when required. ASN points out that close collaboration between operators and the medical physicist and regular presence of the physicist in the departments lead to optimised use of the equipment, with the setting up of protocols adapted to the procedures, recording of delivered doses and evaluation with regard to the locally-defined dosimetric reference levels. ASN notes that the external medical physicists working under a service contract are rarely present on the sites, including when the presence of a medical physicist is required by the regulations, for example during medical device acceptance tests and the setting up of optimised protocols under article 10 of ASN resolution 2021-DC-0704.

The training of physicians in patient radiation protection is a recurring weak spot: about 13% of the operating theatres have trained all the physicians. This finding, recurrent for some centres, has led ASN to issue a compliance notice to one centre for

GRAPH 12 **Percentage of conformity of the FGI facilities inspected on the theme of radiation protection of patients in 2023 (operating theatres and interventional departments)**



failing to meet these requirements (see box page 230). The medical personnel in the interventional imaging departments medical are trained to a greater extent, with 31% of the departments having trained all their medical personnel, an improvement compared with 2022 (24%).

Over the last five years, 58% of the interventional imaging departments on average have collected, analysed and optimised the doses. ASN notes a better situation in 2023, where 69% of the interventional imaging departments have met these obligations compared with 40% of those inspected in 2022. On the other hand, only 30% of the operating theatres on average have satisfied these optimisation requirements over the last five years. ASN finds the same weakness in the application of the optimisation principle in setting machine parameters and optimising the protocols used. The training time for the medical staff is insufficient and the recurrent shortage of paramedical personnel does not facilitate the scheduling and following of training courses. Nevertheless, reference levels for the most common examinations are being developed locally more and more often. This approach makes it possible, among other things, to set alert levels for triggering appropriate medical monitoring of the patient according to the dose levels delivered to the patient. Patient dose archiving and analysis systems are also deployed and facilitate the development of these reference levels and the programming (or adaptation) of local alert levels per machine and by type of procedure. These systems are an asset for tracking the doses previously received by the patient and for patient monitoring, and they contribute to the optimisation of the dose delivered.

ASN is regularly alerted by situations of noncompliance with the required qualifications in the operating theatre. The shortage of radiographers in operating theatres means that nurses are required to operate devices emitting ionising radiation under the responsibility of the physicians. ASN is also questioned about the scopes of intervention and the patient radiation protection training obligations of State-Registered Operating Theatre Nurses (SROTNs) and State-Registered Nurses (SRN). ASN reiterates that devices emitting ionising radiation may only be operated by radiographers whose training in patient radiation protection is current and under the responsibility of a physician. With regard to SROTNs, they now have new prerogatives and can, under the responsibility of a surgeon, assist in certain interventional procedures (performed under mobile C-arm unit in the operating theatre, not requiring a protocol adjustment and delivering a dose of less than 10 grays per square centimetre (Gy/cm^2) (Dose Area Product – DAP – at end of procedure) without being authorised to operate or set the parameters of the medical device. They must also have a specific work tasks qualification and be current in their patient radiation protection training (ASN resolution approving the patient radiation protection continuous training guide for SROTNs). With regard to SRNs, they can only operate devices emitting ionising radiation under the responsibility of a physician in the context of a cooperation protocol approved by the ARS in accordance with the Article of Act 2019-774 of 24 July 2019 on the organisation and transformation of the health system.

Patient monitoring if the skin exposure threshold defined by the HAS[11] is exceeded is formalised to a greater extent in the interventional imaging departments (81%) inspected in 2023 than in the operating theatres (62%); interventional imaging departments are more frequently concerned by procedures leading to such exposure levels than the operating theatres.

The external quality controls 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 relating to fluoroscopy-guided interventional practices

An events recording system is in place in more than 75% of the inspected sites performing FGIPs. In 2023, 26 significant events were reported concerning:
- overexposures of patients (8 ESRs);
- exposures of medical staff (11 ESRs);
- exposure of foetuses in women unaware of their pregnancy at the time of the procedure (5 ESRs).

Among these ESRs, two are linked to an MD malfunction (stopping of the device or computing malfunction).

11. *Improving patient monitoring in interventional radiology and fluoroscopy-guided procedures – reducing the risk of deterministic effects of 21 May 2014.*

One of the events identified during a dosimetric analysis by the centre revealed an increase in the doses delivered during 2022. After seeking the causes, the centre identified that the increase came further to a maintenance operation in September 2022 during which the parameters displayed by default did not correspond to the initially set and optimised parameters. This event shows the importance of having good communication between the centre and the maintenance workers and the merits of defining the expected work scope of the maintenance contract. The analysis of this event also shows that all the people involved have a role to play. ASN has published a "Patient safety" bulletin on the role of the team in the management of MDs in FGIP.

The majority of patient overexposures are due to long and complex procedures (in interventional neuroradiology, urology, digestive tract surgery, fitting Implantable Venous Access Devices – IVAD, also called "implanted ports").

Analysis of the events reveals various causes, such as a lack of protocol optimisation, inappropriate utilisation of the devices by the operators revealing deficiencies in operator training and the importance of implementing a specific work task qualification procedure. These weak points constitute areas for improvement.

The FGIP sector involves significant occupational radiation protection risks. One ESR in 2023 led to exceeding of the equivalent dose to the extremities (500 mSv) for a surgeon after a temporary relocation in a room less suitable for the types of procedures performed. A second ESR concerns the exceeding, on the quarterly passive dosimeter, of the annual limit of 20 mSv for a State-Registered Nurse Anaesthetist (SRNA), even though the dose liable to be received in this type of job is very much lower than this value; the investigations could not identify another cause on exposure in the work environment.

ASN reiterates the importance of the radiation protection culture and compliance with its rules, in particular the providing of all the tools allowing the optimisation of practices, the use of personal and collective protective equipment, and compliance with the rules concerning the wearing of passive and active dosimeters, including their stowage on the panels provided for this purpose, for exposure monitoring and reactive alert in the event of abnormal exposure.

Lastly, events were 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.

SUMMARY

The inspections conducted in 2023 in the area of FGIPs, considered with those performed over the period 2019-2022, 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 remains better in the interventional imaging departments than in the operating theatres. In most facilities, the premises are slowly being brought into conformity to comply with the technical design rules, even though these modifications are essential in order to prevent the occupational risks. Even if the appointment of RPE-Os, the delimiting of restricted areas, the performance of technical verifications and quality controls of 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. Having observed persistent weaknesses in this area for several years now, ASN has decided to adopt an enforcement policy, giving one centre formal notice in 2023 to comply with the regulatory requirements concerning the radiation protection training of the medical staff and the fitting out of the operating theatre rooms.

ASN observes moreover that the centres are turning increasingly to RPOs, either as specialised contributors to assist an RPE-O, or as an RPA and that this outsourcing, if it is not adequately managed, leads to a dilution of the responsibilities of the RNAs and poorer assimilation of, or even a deterioration in, radiation protection. Although the use of medical physicists and formalising of the POPMs is gaining ground, further progress must be made in the implementation of the optimisation procedure, particularly in the operating theatres where doses are still insufficiently analysed and 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. Furthermore, it is in this area that the events concerning occupational radiation protection are the most significant, with notifications of dose limit exceedances in 2023, underlining the importance of complying with the radiation protection rules, especially the use of personal and collective protective equipment. 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. The French Society of Radiology and Medical Imaging issues a Guide for Radiology and Medical Imaging Examination Referrals (ADERIM) to enhance the relevance of the examinations requested by referring physicians.

If the dose delivered does not in itself represent a radiation protection health risk, it is the large number of examinations carried out among the population that contributes significantly to the collective dose of medical origin.

2.5.1.1 Medical radiodiagnosis

Conventional radiology
Conventional radiology (producing radiographic images, or radiographs), if considered by the number of procedures, represents the large majority of radiological examinations performed.

The examinations mainly concern the bones, the thorax and the abdomen. Conventional radiology can be carried out in fixed facilities reserved for diagnostic radiology or, in certain cases, using portable devices if justified by the clinical situation of the patient.

Angiography
This technique, used for exploring blood vessels, involves injecting a radio-opaque contrast agent into the vessels which enables the arterial (arteriography) or venous (venography) tree to be visualised. Angiography techniques benefit from computerised image processing (such as digital subtraction angiography).

Mammography
Given the composition of the mammary gland and the fineness of detail required, screening for breast cancer necessitates the use of mammography units, specific radiology devices providing high-definition and high-contrast images. Two complementary imaging techniques are currently available, planar imaging (2D) and tomosynthesis imaging (3D). 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 participated in a working group coordinated by the HAS, which has assessed the position of tomosynthesis mammography in the breast cancer screening strategy. In 2019, the HAS published a first report on the technical performance of tomosynthesis mammography in breast cancer screening of average-risk women. A second report on the evaluation of the performance and the position of tomosynthesis mammography in the French organised breast cancer screening programme was published by the HAS in April 2023. It recommends integrating tomosynthesis mammography (3D) in the organised screening programme, on condition that it is always 2D synthetic image reconstruction (2Ds) in order to improve the screening performance without increasing the dose of ionising radiation.

The use of these devices is subject to quality controls defined by the ANSM. The 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 external quality controls for the tomosynthesis devices.

ASN has asked the GPRP to update the collection methods and the DRLs for 2D-DR mammography and to establish them for tomosynthesis mammography. The opinion given by the GPRP in June 2023 will allow the updating of ASN resolution 2019-DC-0667 of 18 April 2019 on the methods of evaluating ionising radiation doses delivered to patients during radiology, FGIP or nuclear medicine procedures and the updating of the associated DRLs.

Computed tomography
Computed Tomography (CT) scanners use a beam of X-rays emitted by a tube that rotates around the patient's body as the bed moves linearly, describing a helical scan. These scanners produce a three-dimensional reconstruction of the organs with very much better image quality than that of conventional radiology devices. An examination can comprise multiphase image acquisitions on the same given anatomical location or on different anatomical regions.

This technique can, like MRI, be associated with functional imaging provided by nuclear medicine in order to obtain fusion images combining functional information with structural information.

The technologies developed over the last few years (such as multi-energy photon-counting CT scanners) have made examinations easier and faster to perform, and have led to an increase in exploration possibilities (example of dynamic volume acquisitions) and in the indications[12]. The placing of mobile CT systems on the market for intraoperative use is to be underlined, as is the increase in fluoroscopy-guided interventional CT procedures.

On the other hand, these technological developments have led to an increase in the number of examinations, resulting in an increase in the doses delivered to patients and thus reinforcing the need for strict application of the principles of justification and optimisation (see point 1.3.4). Technical progress has nevertheless brought a new mode of image reconstruction in the form of iterative reconstruction. CT can thus provide consistent image quality at reduced doses. The devices can also be equipped with dose-reduction tools. Strict application of the principles of justification of the procedures and optimisation of the protocols remains as topical as ever.

Teleradiology
Teleradiology is a remote medical practice of radiological medicine that essentially concerns conventional radiology and computed tomography and provides the possibility of performing and remotely interpreting radiological examinations. Essentially two methods are used:
- Telediagnosis allows the performance of a synchronous imaging procedure. The question asked and the reply, if the patient is not present, do not necessarily take place simultaneously or synchronously. The radiographer takes charge of the patient to perform the radiological or CT examination after receiving the instructions from the teleradiologist. At the end of the examination, the images are sent to the teleradiologist in order to formalise a results report in a manner comparable with what an on-site radiologist would have done.
- Tele-expertise enables a medical professional to request from a distance, by e-mail or any other secure communication tool, the opinion of one or more medical professionals in a given medical situation.

Teleradiology is a medical procedure defined in the Public Health Code that is more than just a remote interpretation of images. Its development is becoming more widespread to allow continuity of out-of-hours service and to reduce the waiting times before receiving medical care. The organisation of the practice, the way it interfaces with the personnel on site and the many responsibilities are specified by contract between the healthcare facility and the teleradiology service provider.

In May 2019 the HAS published a Guide to good practices concerning the quality and safety of tele-imaging procedures. Details are provided, with organisational, technical and operational recommendations. The French Professional Council of Radiology and Medical Imaging (G4) and the French Council of the Order of Physicians jointly published a teleradiology charter in February 2020, containing nine general recommendations. Lastly, the G4 also drafted baseline requirements for the profession and the skills of the radiologist in January 2023. It reinforces the

12. The term "indication" means a clinical sign, an illness or a situation affecting a patient which justifies the value of a medical treatment or a medical examination.

position of teleradiology in the regional healthcare organisation and the availability, preferably in person, of the radiologist.

ASN is currently conducting a study with the CEPN to assess the situation of teleradiology practices in France by conducting a survey with the teleradiology users and the teleradiologists. The conclusions of this study are expected in late 2024.

2.5.1.2 Dental radiodiagnosis

Intra-oral radiography
Intra-oral radiography generators, which are usually mounted on an articulated arm, are used to take localised planar images of the teeth (the radiological detector is placed in the patient's mouth). They operate with low voltage and current and a very short exposure time, of a few hundredths of a second. This technique is usually associated with a digital system for processing and filing the radiographic image.

Panoramic dental radiography
Panoramic radiography (orthopantomography) gives a single picture showing both jaws in full, by rotating the radiation generating tube around the patient's head for a few seconds.

Cone-beam computed tomography
3D Cone-Beam Computed Tomography (CBCT) is developing very rapidly in all areas of dental radiology, due to the exceptional quality of the images produced (spatial resolution of about 100 microns – µm). The trade-off for this better diagnostic performance is that these devices deliver significantly higher doses than in conventional dental radiology. They must be used in accordance with the recommendations given by the HAS in 2009, the conclusions of which indicate that it should only be proposed in certain duly selected clinical indications and reiterate that whatever the case, the fundamental principles of justification and optimisation must be applied.

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 RNA.

Portable electrical X-ray generating devices
ASN and the Dental Radiation Protection Commission published an information notice in May 2016 reiterating the rules associated with the possession and utilisation of portable X-ray generating devices: *"The performance of radiological examinations outside a room fitted out for that purpose must remain the exception and be justified by vital medical needs, limited to intraoperative examinations or for patients who cannot be moved. Routine radiology practice in a dental surgery equipped with a compliant facility shall not be carried out using mobile or portable devices".*

This position is consolidated by that adopted by the 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).

ASN notes the emergence of a mobile radiology offering to meet specific healthcare needs (treatment of Cerebrovascular Accidents – CVAs [strokes], ageing population, etc.) or the needs of regions confronted with medical deserts, without at present having any visibility on how this trend will evolve. Consequently, trucks providing dental care circulate in rural areas to relieve congested emergency services (trucks in the Alsace region equipped with MDs capable of responding to emergencies) or to provide care to patients who cannot travel (acquisition of new portable dentistry devices for people in retirement homes, autistic patients, etc.). Experimentation is in progress as part of the ASPHALT project involving the Paris SAMU (Emergency Medical Assistance Service) and nine Paris hospitals, with CT scanners carried in ambulances to treat stroke victims.

2.5.3 Radiation protection situation: focus on the computed tomography scanner

In France, medical applications represent the primary source of artificial exposure of the public to ionising radiation, chiefly due to CT examinations (see chapter 1). Imaging examinations have proven their benefits for both diagnosis and treatment.

The issue at stake however is to avoid examinations that are not really necessary or that offer no real benefit for the patients, or the results of which could be obtained by other available, non-irradiating techniques. In order to control the increase in doses observed over these last few years, two successive dose control plans (see chapter 1) have been developed in recent years. Issued in this context, ASN resolution 2019-DC-660 of 15 January 2019 relative to quality assurance in medical imaging contributes to the control of doses by requiring operational implementation of the justification and optimisation principles. Each year, ASN conducts about twenty inspections in computed tomography, adopting a graded approach by targeting the Accident & Emergency (A&E) departments (most often shared with the radiology department) and the paediatric CT scanners because of the vulnerability of children. Numerous ESRs occur in CT examinations in the A&E departments and are caused by poor communication or organisation between the A&E staff and radiology. The inspections conducted by ASN focus in particular on the verification of proper application of the requirements defined by the above-mentioned ASN resolution 2019-DC-0660 of 15 January 2019, especially the justification of the examinations and optimisation of the procedures.

ASN carried out 35 inspections in departments equipped with CT scanners in 2023. These inspections reveal the difficulties the departments have in assimilating the quality assurance system and the associated tools (risk mapping, lessons learned from adverse events, action plan development) and a lack of involvement of the decision makers in the management of the approach.

Furthermore, work on describing the various steps of examination justification must continue, from reception of the request, analysis of its justification and its validation, through to the decision to perform the procedure or not, or to use an alternative procedure. This finding also applies to the remote management of a teleradiology examination (validation of the examination indication according to the clinical picture, medical history search, quality of the report, discussion with the radiographers on the optimisation of the examination, etc.). The informed consent of the patient is not always found or recorded. The specific work tasks qualification procedures, often carried out for the paramedics, are still incompletely applied for the medical staff.

The ASN inspectors observe that the departments are turning increasingly to teleradiology, creating a high level of activity during the teleradiology time slots, which sometimes creates operational problems (inter-software communication, task delegation, heavy workload for radiographers). The recourse to teleradiology is no longer limited to maintaining an out-of-hours service, but aims to allow shifts to be scheduled during working hours due to the shortage of radiologists. The inspections of the centres using teleradiology have detected inconsistencies in the agreements (several service providers for the same duty time slots and scheduled shifts), failure to present radiation protection training certifications for the service providers, incomplete POPMs that do not always take into account the teleradiology activity and the associated dose optimisation measures. Furthermore, the specific work task qualification procedures are to be continued, or in some cases started, for the contract personnel.

ASN notes moreover that 25 ESRs out of the 237 ESRs reported in computed tomography (about 10.5%) occur in a teleradiology context and are linked to communication problems between the on-site and the remote medical professionals.

2.5.4 Significant events reported in medical and dental radiodiagnosis

In 2023, 322 ESRs were reported in medical and dental radiodiagnosis (+12% compared with 2022):
- 81 in conventional radiology, of which 35 concerned women unaware of their pregnancy;
- 237 in computed tomography, off which 93 concerned women unaware of their pregnancy;
- four in dental radiology.

The ESRs mainly concern women who were unaware of their pregnancy (128 notifications). A specific Patient safety bulletin was produced and published in September 2021 to improve the organisational measures to reduce the number of events of this type. The analysis of the reported ESRs shows that checking for pregnancy when registering the appointment, checking-in and installing the patient can be further improved. The β-HCG level is not always assayed, or is sometimes incorrectly interpreted or not consulted. Urinary self-tests are little used. The other causes of ESRs are linked to shortcomings in the patient management process (errors in identity monitoring, in the anatomical region exploration protocol, in examination scheduling).

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 and optimisation principle. The departments still have to assimilate the quality assurance procedures and the associated tools (risk mapping, action plan, lessons learned from adverse events, etc.). Furthermore, efforts must be maintained in the application of the justification principle with a description of the various steps from reception of the request, analysis of its justification and its validation, through to the decision to perform the procedure or not, or to use an alternative procedure.

ASN notes that teleradiology is progressing constantly with technical and organisational constraints that are frequently underestimated by the centres (software interfaces, communication problems) which are liable to foster the occurrence of ESRs if the service is not managed properly.

Lastly, ASN notes the emergence of a mobile radiology offering to meet particular healthcare needs (treating strokes, ageing population, medical deserts in certain regions, etc.) with no visibility at present of how this trend will evolve. It will keep a watchful eye on these developments in order to assess the impacts with regard to radiation protection.

2.6 HUMAN BODY PRODUCT IRRADIATORS

2.6.1 Description

The irradiation of products from the human body is used in particular to prevent post-transfusion reactions in blood-transfusion patients. The blood bag is irradiated with a dose of about 20 to 25 grays.

Since 2009, source irradiators have been gradually replaced by X-ray generators, which have been subject to notification to ASN since 2015. In 2023, the inventory stood at 135 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.

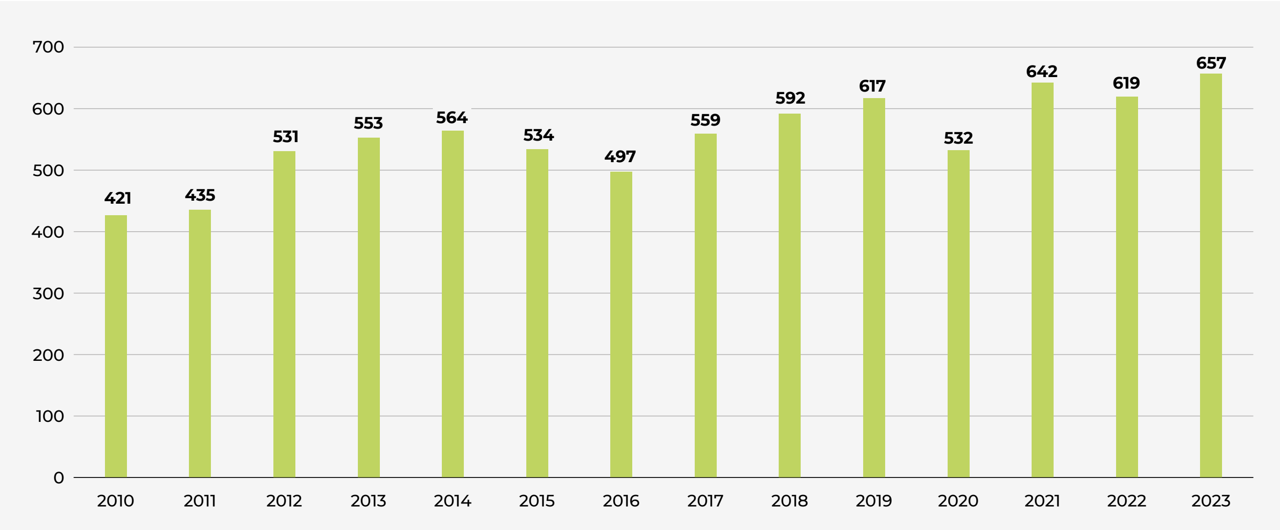
2.7 SIGNIFICANT RADIATION PROTECTION EVENTS

The number of ESRs reported to ASN (657) in 2023 is slightly higher than in 2022 (619), but has remained relatively stable over the last five years, with the exception of 2020 due to the Covid-19 pandemic (see Graph 13 next page). ASN underlines the importance of reporting ESRs in order to share ILS's and improve radiation protection.

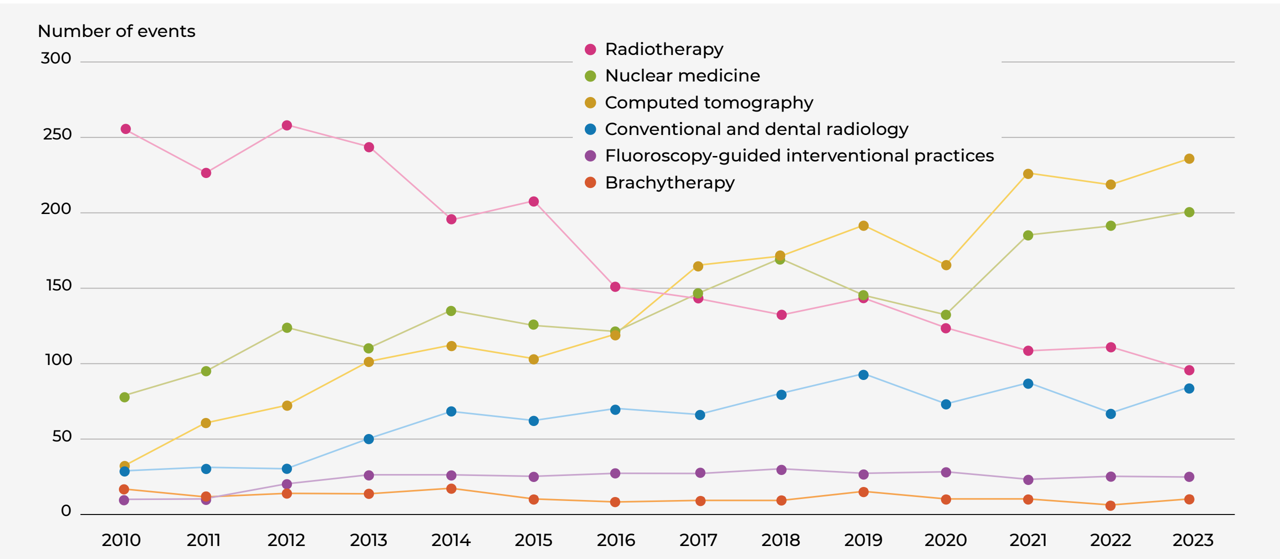
Graphs 13 and 14 (see next page) illustrate how the number of ESRs has evolved by activity category since 2010. Graphs 15 and 16 (see next page) illustrate the breakdown of the number of ESRs in 2023 by area of exposure (environmental impact, exposure of the general public, exposure of patients, exposure of professionals) and by category of activity. Although the number of ESRs in radiotherapy and been dropping steadily since 2012, it has been increasing in CT and nuclear medicine since 2010. CT is thus the activity for which the number of ESRs reported is the highest (237), whereas until 2016 radiotherapy held this position.

In the light of the events reported to ASN in 2023, 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. With regard to occupational radiation protection, it is in the area of FGIPs that the risks are greatest, with cases of exceeding regulatory dose limits (see point 2.4.3.3).

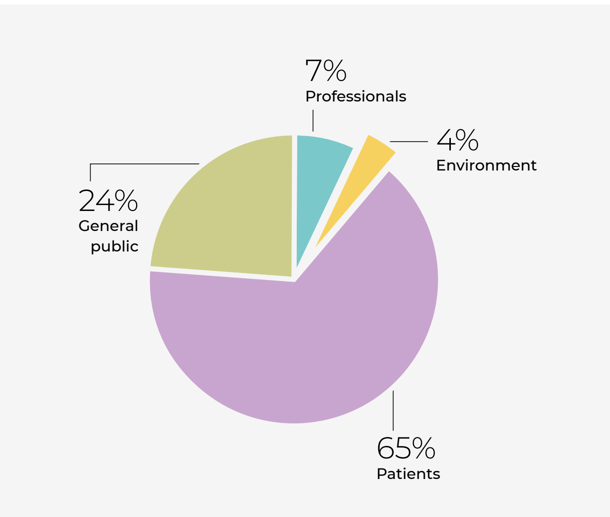
GRAPH 13 **Development of the number of annual ESR reports from 2010 to 2023**



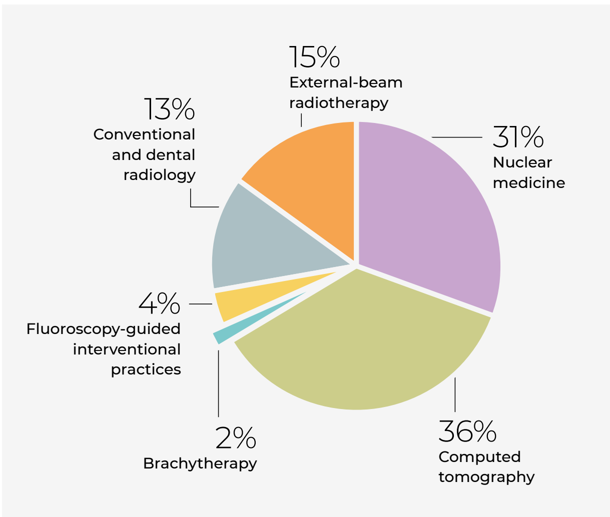
GRAPH 14 **Number of ESRs by activity category during the period 2010-2023**



GRAPH 15 **Breakdown (in %) of ESRs by exposure category in 2023**



GRAPH 16 **Breakdown (in %) of ESRs by activity category concerned in 2023**



3 Synthesis and prospects

On the basis of the inspections carried out in 2023 and an analysis of the period 2019-2023 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 which led it to adopt an enforcement approach in the area of FGIPs in 2023.

It underlines the progress in the area of clinical audits, with the first experiments started in 2023 in radiotherapy and radiology, but encourages their extension to the most risk-prone activities, giving priority to radiosurgery and therapeutic nuclear medicine.

ASN nevertheless detects several signals that could lead to a deterioration in the current situation:

- a widespread finding of diminished resources with strained staffing levels for radiographers, medical practitioners and medical physicists, with the development temporary work and tasks being performed by personnel without the required qualifications;
- the recourse, in imaging, to services insufficiently mastered to assist the centres' RPE-Os and medical physicists, liable to lead to a loss of radiation protection skills and a lack of flexibility for the implementation of the regulatory radiation protection requirements (training, verifications, etc.);
- the emergence of mobile radiology and the constant growth of teleradiology, with centres underestimating the technical and organisational constraints associated with this method of working (communication problems, software interfacing);
- the complexification of organisational structures, with resource sharing and the risk of diluting responsibilities, in a context of reforms in the healthcare licences and the buying out of centres;
- conflictual situations in a context of overstretched human resource or organisational changes brought to ASN's knowledge during inspections or *via* the system for collecting alerts from whistle-blowers.

In this context, ASN draws the attention of decision makers to the need to assess the impact of these changes on the organisational set-ups and the work of those involved and to precisely define their roles and responsibilities so that the radiation protection requirements are satisfied.

In radiotherapy, although the safety fundamentals are in place, the LFE procedures are losing momentum with less detailed ESR analyses and less frequent CREX meetings, underlining the need to give renewed meaning to these procedures in order to maintain both the interest of the medical professionals and the collective dynamic. The repetition of target errors (laterality and positioning errors in particular) reported in 2023, once again emphasises the need to regularly assess the barriers put in place by taking greater advantages of the LFE at national level. ASN insists on the importance of the prospective risk analysis when making technical and organisational changes. ASN communicated a methodology for performing the prospective risk analysis in its "Patient safety" bulletin of September 2023.

The inspections in brachytherapy confirm that the radiation protection rules are duly taken into account, but the drive to reinforce training in emergency situations involving source jamming must be maintained over time. ASN underlines the challenges to maintaining the resources and skills necessary for this activity in the years to come.

The inspections in nuclear medicine find that radiation protection is duly taken into account, while at the same time underlining the need to continue deploying the quality assurance procedures to ensure the safety of the drug administration process, particularly for therapeutic procedures, and for procedures involving children in view of the reported ESRs. Alongside this, the formalisation of the coordination of prevention measures with the outside contractors (for maintenance, cleaning services, private physicians, etc.), personnel training and analysis of the DRLs are still areas for improvement.

In the area of FGIPs, and more particularly in the operating theatre, regulatory nonconformities persist over the years regarding the technical rules for fitting out facilities, the occupational and patient radiation protection training requirements and the coordination of prevention measures during concomitant activities, particularly when private physicians are involved. These deviations have led ASN to give one centre formal notice to comply with the rules concerning radiation protection of the staff and the fitting out of the rooms used for interventional procedures. ASN observes moreover that the centres are turning increasingly to RPOs, either as specialised contributors to assist a RPE-O, or as an RPA and that this outsourcing, if it is not adequately managed, leads to a dilution of the responsibilities of the RNAs and poorer assimilation of, or even a deterioration in radiation protection.

In 2024, ASN will continue its inspections in the priority sectors, namely radiotherapy, radiosurgery, nuclear medicine, FGIPs and computed tomography, in line with the inspections performed in 2023. Particular attention will be devoted to the signals mentioned previously and the weak points identified in 2023 (training, analysing events and learning lessons from the reported ESRs, coordination of prevention measures during concomitant activities, bringing the facilities into compliance with the fitting out rules, maintenance), and the implementation of the quality assurance obligations and change management. Unannounced inspections shall be carried out if necessary. In radiotherapy and nuclear medicine, on the basis of the lessons learned from the ESRs reported over the last few years, specific inspections on the mastering of the accelerator calibration process and the verification of non-contamination shall be carried out in 2024, with the assistance of IRSN. With regard to FGIPs, ASN will conduct targeted inspections of private practitioners who, although they are not RNAs and do not own the equipment they use, have radiation protection obligations for themselves and as employers of personnel classified on account of exposure to ionising radiation.

On the regulatory front, ASN will revise ASN resolution 2019-DC-0667 of 18 April 2019 setting the DRL values, to update the values for mammography procedures and will continue the preparatory work for the revision of ASN resolution 2008-DC-0095 of 29 January 2008 laying down the technical rules applicable to the disposal of effluents and waste contaminated by radionuclides.

Lastly, the deployment of new techniques and practices in therapy (radiotherapy, ITR) remains a subject of vigilance for ASN, which will endeavour to promote any measures aiming to better assess the radiation protection risks and allow a better demonstration of their advantages compared with the existing techniques. To this end, ASN will continue its work in cooperation with the various institutional actors in the health sector, the professional organisations and assisted by its groups of experts, particularly the Canpri, particularly with regard to flash radiotherapy and adaptive radiotherapy. In nuclear medicine, which is witnessing the emergence of new vectors and radionuclides for therapeutic purposes, forecasts of growth in the number of patients eligible for these new treatments with methods of treatment on an out-patient basis and limited infrastructure, ASN underlines the importance of anticipating the radiation protection risks for the patients and carers and comforters, for the workers, and with regard to fitting out the facilities and the management of effluents and waste. It has referred this matter to the GPRP, and keeps track of the European work carried out for the SimpleRad project and maintains a dialogue with the nuclear medicine actors to reiterate the regulatory framework and check that it remains in keeping with the developments.

CONTENTS

08

Sources of ionising radiation and their industrial, veterinary and research applications

08

The industrial and research sectors have been using sources of ionising radiation in a wide range of applications and locations for many years now. The purpose of the radiation protection regulations is to check that the safety of workers, the public and the environment is properly ensured. This protection involves more specifically ensuring proper management of the sources, which are often portable and used on worksites, and monitoring the conditions of possession, use and disposal, from fabrication through to end of life. It also involves monitoring the main stakeholders, that is to say the source manufacturers and suppliers, and enhancing their accountability.

The radiation sources used are either radionuclides – essentially artificial – in sealed or unsealed sources, or electrical devices generating ionising radiation. The applications presented in this chapter concern the manufacture and distribution of all sources, the industrial, research and veterinary uses (medical activities are presented in chapter 7) and activities not regulated under the Basic Nuclear Installations (BNIs) System (these are presented in chapters 10, 11 and 12).

The 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”.

As of 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

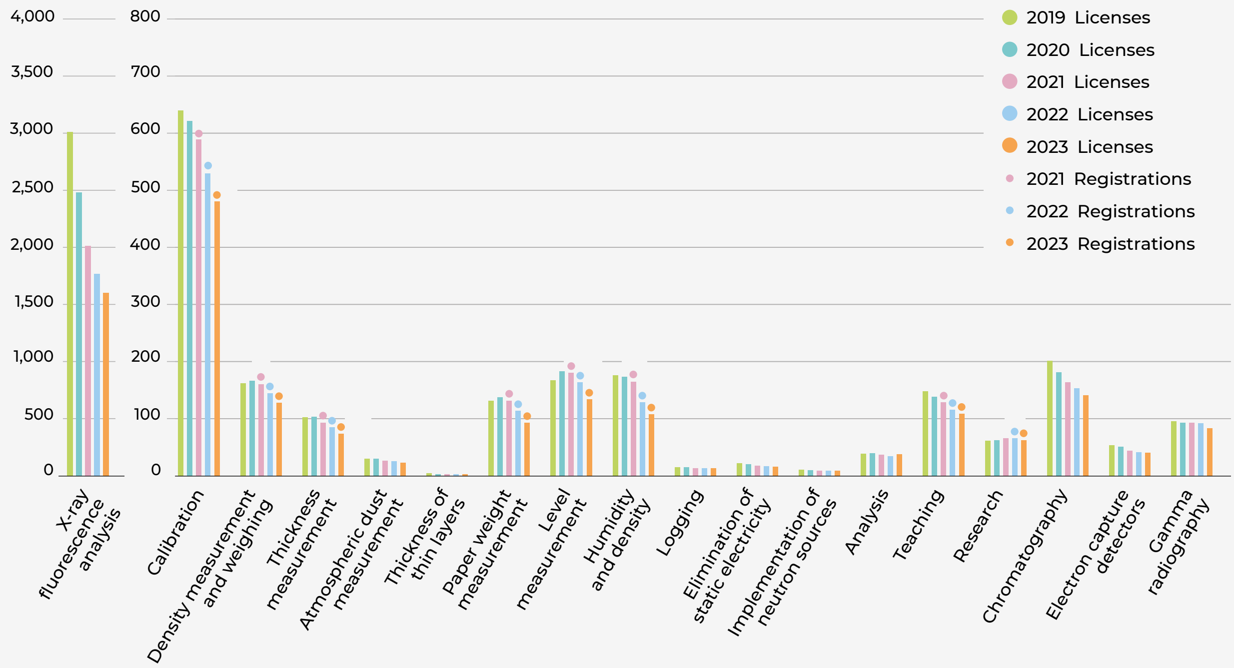
The operating principle of these physical parameter verification devices is the attenuation of the signal emitted: the difference between the emitted signal and the received signal can be used to assess the desired information.

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).

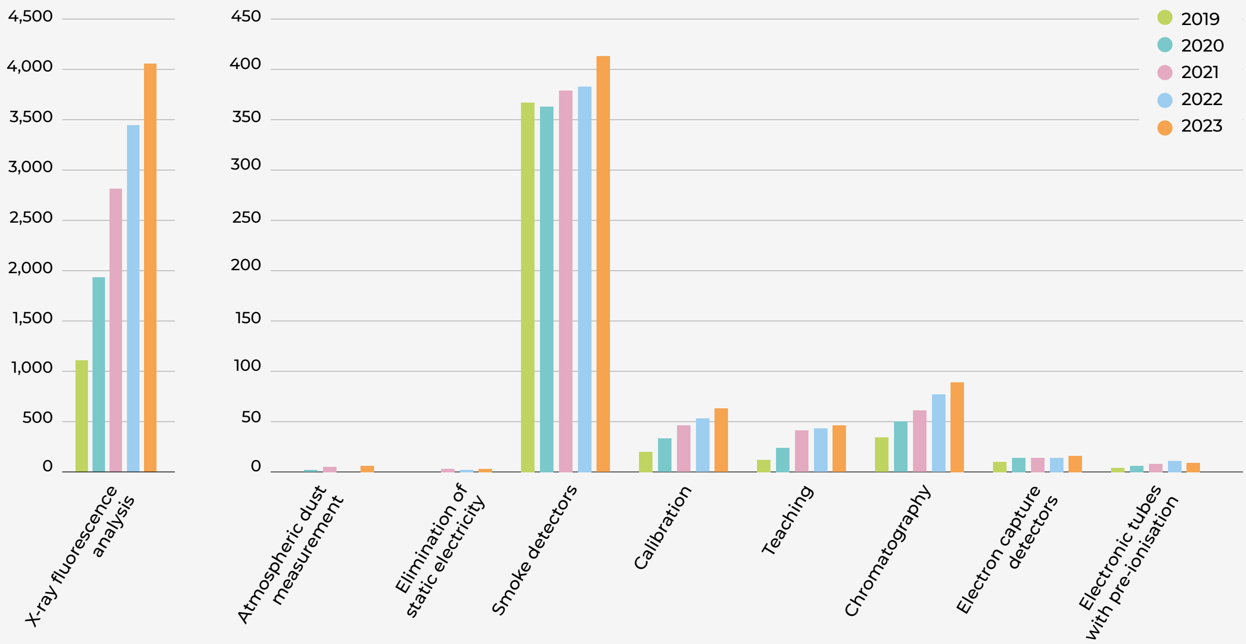
The sources are used for the purpose of:
- Atmospheric dust measurement: the air is permanently filtered through a tape placed between the source and detector and running at a controlled speed. The intensity of radiation received by the detector depends on the amount of dust on the filter, which enables 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 industrial plants.
- Paper weight measurement: a beam of beta radiation passes through the paper and hits a detector situated opposite. The signal attenuation on this detector indicates the density of the paper, and therefore its weight per unit area. The sources used are generally krypton-85 or promethium-147, with activities of 3 GBq at the most.
- Liquid level measurement: a gamma radiation beam passes through the container holding the liquid. It hits a detector situated opposite. The signal attenuation measured on this detector indicates the filling level of the container and automatically triggers certain operations (stop/continue filling, alarm, etc.). The radionuclides used depend on the characteristics of the container and the content. 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 licences 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:
- gamma radiography which is a non-destructive inspection method (see point 3.3);
- industrial irradiation, used for sterilisation in particular (see point 3.2);
- eliminating static electricity;
- calibrating radioactivity measurement devices (radiation metrology);
- practical teaching work concerning radioactivity phenomena;
- detection by electron capture. This technique uses sources of nickel-63 in gaseous phase chromatographs and can be used to detect and dose various chemical elements;
- ion mobility spectrometry used in devices that are often portable and used to detect explosives, drugs or toxic products;
- detection by X-ray fluorescence. This technique is used in particular for detecting lead in paint. The portable devices used today contain sources of cadmium-109 (half-life of 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, were to extend through to 31 December 2023 and are now going to extend through to 1 July 2026 (see point 2.4.2) for those subject to registration since 1 July 2021.

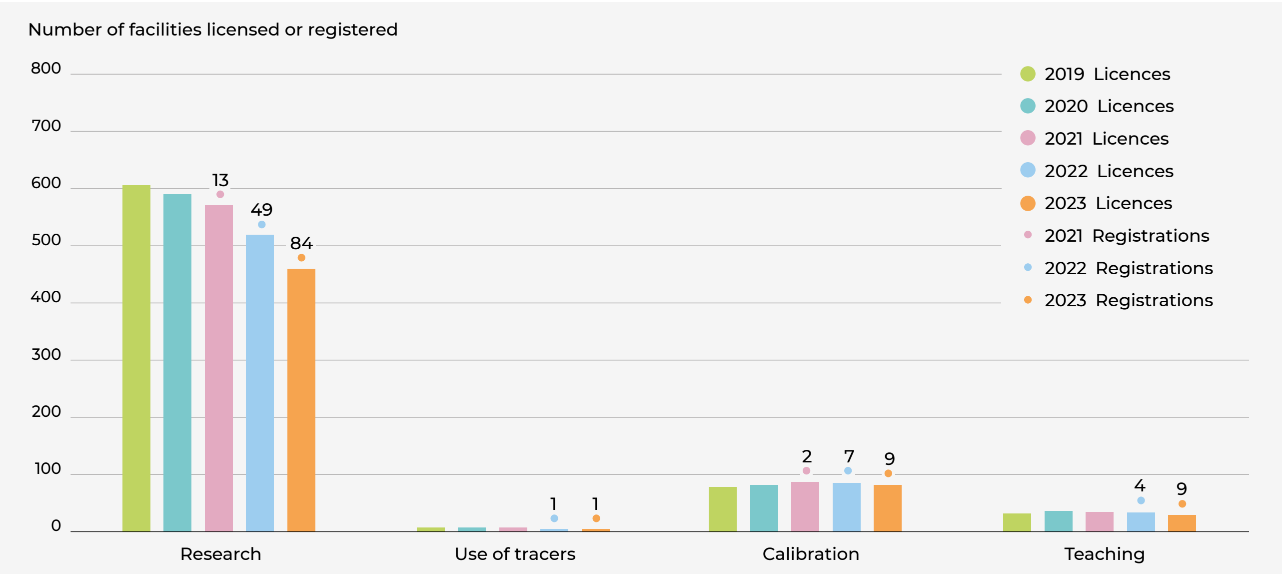
1.2 USES OF UNSEALED RADIOACTIVE SOURCES

The main radionuclides used in the form of unsealed sources in non-medical applications are phosphorus-32 or 33, carbon-14, sulphur-35, chromium-51, iodine-125 and tritium. They are used in particular in research and in the pharmaceutical sector. They constitute a powerful investigative tool in cellular and molecular biology. Using radioactive tracers incorporated into molecules is common practice in biological research. There are also a number of industrial uses, for example as tracers or for calibration or teaching purposes. Unsealed sources are used as tracers for measuring wear, detecting leaks or friction spots, building hydrodynamic models and in hydrology.

As at 31 December 2023, 576 facilities were authorised to use unsealed radioactive sources (to which can be added 103 registered facilities).

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.

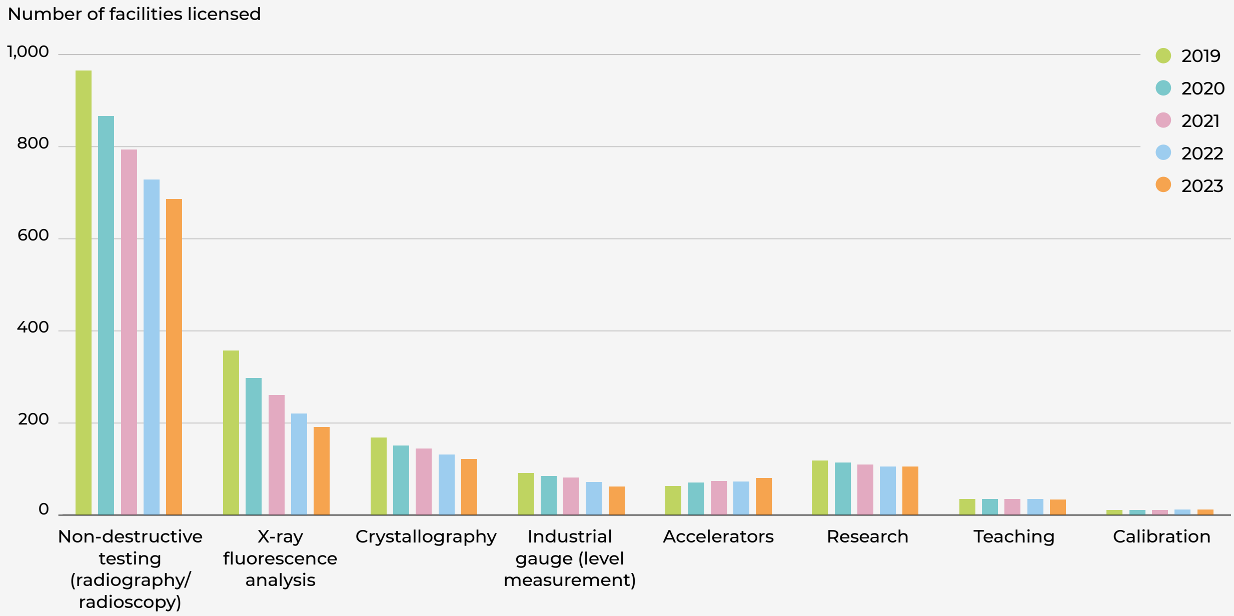
GRAPH 2 **Use of unsealed radioactive sources by end-purpose**



01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 AP

USE OF ELECTRICAL DEVICES EMITTING IONISING RADIATION BY END-PURPOSE (VETERINARY SECTOR EXCLUDED)

GRAPH 3A Breakdown of licences for electrical devices emitting ionising radiation



GRAPH 3B Breakdown of notifications or registrations of electrical devices emitting ionising radiation

1.3 THE USES OF ELECTRICAL DEVICES EMITTING IONISING RADIATION

1.3.1 Main industrial applications

In industry, electrical devices emitting ionising radiation are used mainly in non-destructive testing, where they replace devices containing radioactive sources.

Graphs 3A and 3B (see previous page) show the number of facilities using electrical devices generating ionising radiation in the listed applications under the licensing, registration or notification systems respectively. They illustrate the diversity of these applications and their development over the last five years. This development is closely related to the regulatory changes which have gradually created a new system of licensing or notification, and more recently registration (see point 2.4.2), concerning the use of these devices. At present, measures to bring the professionals concerned into compliance are very widely engaged in many activity sectors.

The electrical devices emitting ionising radiation are chiefly X-ray generators. They are used in industry for non-destructive structural analyses (analysis techniques such as tomography, diffractometry, also called X-ray crystallography, etc.), checking the quality of weld beads or inspecting materials for fatigue (in aeronautics in particular).

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 and also the detection of foreign bodies in foodstuffs.

The increase in the number of types of device available on the market can be explained more particularly by the fact that when possible, they replace devices containing radioactive sources. The advantages of this technology with regard to radiation protection are linked in particular to the total absence of ionising radiation when the equipment is not in use. Their utilisation does nevertheless lead to worker exposure levels that are comparable with those resulting from the use of devices containing radioactive sources.

Baggage inspection

Ionising radiation is used constantly in security screening checks, whether for the systematic verification of baggage or to determine the content of suspect packages. The smallest and most widely used devices are installed at the inspection and screening checkpoints in airports, in museums, at the entrance to certain buildings, etc.

The devices with the largest inspection tunnel areas are used for screening large baggage items and hold baggage in airports, as well as for air freight inspections. These devices are supplemented by tomographs, which give a series of series of cross-sectional images of the object being examined.

The irradiation zone inside these appliances is sometime delimited by doors, but most often simply by one or more lead curtains.

X-ray body scanners

This application is mentioned for information only, since the X-ray scanners are not currently used for security checks on people in France (in application of Article L. 1333-18 of the Public Health Code). Some experiments have been carried out in France using non-ionising imaging technologies (millimetre waves).

Inspection of consumer goods

The use of devices for detecting foreign bodies in certain consumer products has developed over the last few years, such as for detecting unwanted items in food products or cosmetics.

X-ray diffraction analysis

Research laboratories are making increasing use of small devices of this type, which are self-shielded. Experimental devices used for X-ray diffraction analysis can however be made up from parts obtained from various suppliers (goniometer, sample holder, tube, detector, high-voltage generator, control console, etc.) and assembled by the experimenters themselves.

X-ray fluorescence analysis

Portable X-ray fluorescence devices are used for the analysis of metals and alloys.

Measuring parameters

These devices, which operate on the principle of X-ray attenuation, are used as industrial gauges for measuring fluid levels in cylinders or drums, for detecting leaks, for measuring thicknesses or density, etc.

Irradiation treatment

More generally used for performing irradiations, the self-shielded devices exist in several models that sometimes differ only in the size of the self-shielded chamber, while the characteristics of the X-ray generator remain the same.

Radiography for checking the quality of weld beads or for the fatigue inspection of materials is detailed in point 3.1.1.

1.3.2 Veterinary diagnostic radiology

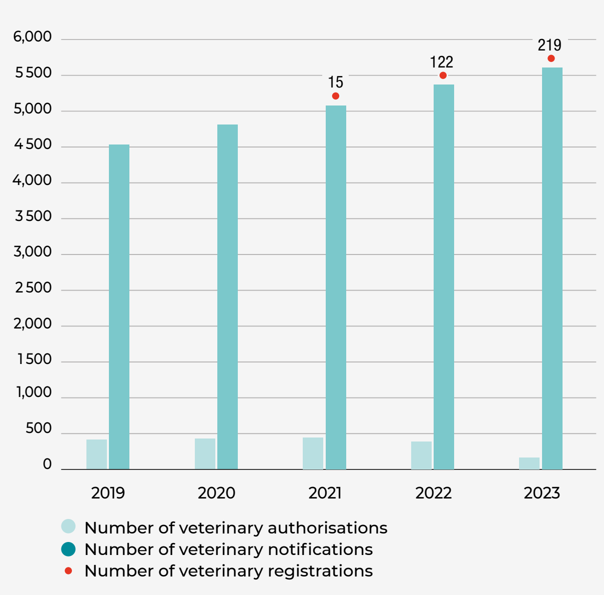
In 2023, the profession counted 20,844 veterinary surgeons, about 20,000 non-veterinarian employees and 6,625 veterinary facilities. These facilities increasingly belong to large groups, sometimes set up as a network grouping several hundred veterinary practices, thereby allowing the sharing of resources between facilities. This trend goes hand in hand with the tendency for veterinary surgeons to no longer necessarily want to own their own practice. 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 next page).

To continue grading the regulatory requirements to the radiation exposure risks, all activities using electrical devices emitting X-rays used for veterinary diagnostic radiology come under the registration system (see point 2.4.2), with the exception of pet-care activities which remain eligible for the notification system. Consequently, only a few high-risk activities (brachytherapy, external-beam radiotherapy and interventional radiology) stemming from the medical sector are still subject to licensing.

GRAPH 4 **Use of electrical devices generating ionising radiation for veterinary activities**



The devices used in the veterinary sector are sometimes derived from the medical sector. However, the profession is increasingly adopting new devices specially developed to meet its own specific needs.

With regard to veterinary facilities, the administrative situation has been continuously improving for a number of years now. At the end of 2023, ASN counted nearly 6,000 notifications, registrations or licenses, that is to say virtually all of the veterinary facilities identified as using ionising radiation in France.

Among the veterinary activities, those performed on large animals (mainly horses) outside specialised veterinary practices (under "field" conditions), are considered to be those with the most significant radiation exposure risks, more specifically for persons external to the veterinary practice taking part in these procedures (horse owners and stable lads).

During its various oversight actions (carried out as and when required or during thematic campaigns) covering all veterinary activities involving ionising radiation, ASN has seen the results of the efforts the veterinary bodies have made in the last few years to comply with the regulations and has noted good field practices in the inspected veterinary facilities, including in particular:

- the presence of in-house Radiation Protection Experts (RPEs) 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 The legislative and regulatory framework for industrial, research and veterinary activities

2.1 THE AUTHORITIES REGULATING THE SOURCES OF IONISING RADIATION

ASN is the authority that grants the licenses, issues the registration decisions and receives the notifications, depending on 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 and must therefore be licensed, registered or have 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^3) for either of the activities are subject to the system governing ICPEs (excluding the medical sector and particle accelerators). Any sealed radioactive sources also possessed or used by these establishments are regulated by ASN under the Public Health Code.

Nuclear materials are subject to specific regulations provided for in Article L. 1333-1 *et seq.* of the Defence Code. Application of these regulations is overseen by the Minister of Defence for nuclear materials intended for defence needs, and by the Minister in charge of energy for nuclear materials intended for any other use.

2.2 UNJUSTIFIED OR PROHIBITED ACTIVITIES

2.2.1 Application of the ban on the intentional addition of radionuclides in consumer goods and construction products

The Public Health Code states "*that any addition of radionuclides [...] to consumer goods and construction products is prohibited*" (Article R. 1333-2). Thus, the trading of accessories containing sources of tritium such as watches, key-rings, hunting equipment (sighting devices), navigation equipment (bearing compasses) or river fishing equipment (strike detectors) is specifically prohibited. Article R. 1333-4 of this same Code provides that waivers to these prohibitions can, if they are justified by the advantages they bring, be granted by Order of the Minister responsible for health and, depending on the case, by the Minister responsible for consumer goods or the Minister responsible for construction, after obtaining the opinion of ASN and of the High Council for Public Health (HCSP). ASN considers that granting waivers to the regulations must remain very limited.

This waiver to the regulations was implemented for the first time in 2011 for a waiver request concerning the use of a neutron analysis device in several cement works of the Lafarge-Holcim group, a waiver that has since been renewed. In 2022, a waiver on neutron analysis was also granted for one of the cement works of the Ciments Calcia group. This neutron analysis device is based on a different technology to that used in the Lafarge-Holcim group cement works, namely an accelerator rather than a sealed radioactive source. In 2023, ASN was asked to give its opinion on the waiver requests concerning another cement works of the Ciments Calcia group and three cement works of the Eqiom group. These requests are based on the use of an accelerator and are currently being examined.

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 (ICSDs) from approximately 300,000 sites over ten years;
- supervising the maintenance or removal operations, which necessitate certain precautions with regard to worker radiation protection;
- preventing any uncontrolled removals and organising the collection operations in order to avoid detectors being directed to an inappropriate disposal route, or even simply being abandoned;
- monitoring the pool of detectors.

In this context, as at 31 December 2023, ASN had issued 413 acknowledgements of notification and 8 national licenses (issued to industrial groups with a total of 90 agencies) for ICSD removal activities. Among these companies, three are authorised to perform ICSD decommissioning operations, thereby guaranteeing a disposal route for the existing detectors.

In order to keep track of the pool of ICSDs, the French Institute for Radiation Protection and Nuclear Safety (IRSN) set up in 2015, in collaboration with ASN, a computerised system enabling the professionals working in this sector (maintenance technicians, installers and removal companies) to file annual activity reports on line. The transmitted information is nevertheless not exhaustive enough to establish a reliable assessment.

Although the removal operations have progressed over the last few years, not all the ICSDs have been removed by the deadline set in the Order of 18 November 2011, that is to say 5 December 2021. It is estimated that nearly one million ICSDs are still installed. Faced with this situation, ASN has been discussing with the professionals on continuing regulating the possession of such detectors and their removal and dismantling operations in order to complete the transition of all the fire detection devices to the optical technology, while at the same time allowing for safe disposal of the removed ICSDs and the radioactive sources they contain. ASN has also continued discussions with other actors concerned by the removal of these devices, notably the Ministry of Energy Transition (MTE), in order to study the various possible regulatory options. These reflections have not resulted in new regulatory provisions, but this does not call into question the removal and dismantling operations governed by the notifications, registrations or licenses issued by ASN, which enables the removal of the ionic detectors to continue, which remains the desired aim. The deadline of 5 December 2021 indicated in the abovementioned Order led to an increase in removal operations at the end of 2021. Since then, the removal operations have been continuing and are gradually decreasing.

ASN continues to maintain close relations with Qualdion, an association created in 2011 which labels the companies that comply with the regulations relative to radiation protection and fire safety. The list of Qualdion-labelled companies is available on the Internet. ASN participates with the association in communication campaigns targeting the holders of ionic detectors and the professionals (Expoprotection trade fair, Mayors' trade fair, etc.).

Surge suppressors

Surge suppressors (sometimes called lightning arresters), not to be confused with lightning conductors, are small objects with a very low level of radioactivity used to protect telephone lines against voltage surges in the event of lightning strike. These are sealed devices, often made of glass or ceramic, enclosing a small volume of air containing radionuclides to pre-ionise the air and facilitate electrical sparkover. The use of surge suppressors has been gradually abandoned since the end of the 1970s, but the number remaining to be removed, collected and disposed of is still very high (several million units). When installed, these devices represent no risk of exposure for individuals. However, there can be a risk of exposure and/or contamination, albeit very low, if these objects are handled without precautions or if they are damaged. ASN issued a reminder to the company Orange (formerly *France Télécom*), which has begun an experimental process to identify, remove, sort and dispose of surge suppressors in the Auvergne-Rhône-Alpes region and has proposed a national removal and disposal plan. This plan was presented to ASN, and led in September 2015 to the issuing of a license governing the removal of all surge suppressors containing radionuclides present on the Orange network in France and their interim storage on identified sites. This license was renewed in 2021. The search for a disposal route is in progress in collaboration with Andra, the French National Agency for Radioactive Waste Management. 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.

Additional characterisations are going to begin, with the aim more specifically of determining whether or not occluded gases are present in the surge arresters (gases which could be present from the manufacturing stage in certain models) in order to subsequently determine the appropriate methods of dealing with these devices.

Lightning conductors

Radioactive lightning conductors were manufactured and installed in France between 1932 and 1986. The ban on the sale of radioactive lightning conductors was declared in 1987. This Order did not make the removal of installed radioactive lightning conductors compulsory. Consequently, there is no obligation at present to remove the radioactive lightning conductors installed in France, except in certain ICPEs (Order of 15 January 2008 which set the removal deadline at 1 January 2012) and in certain installations under Ministry of Defence responsibility (Order of 1 October 2007 which set a removal deadline at 1 January 2014).

ASN nevertheless considers it necessary for all existing radioactive lightning conductors to be removed and transferred to Andra, given the risks they can represent, depending in particular on their physical condition. For several years now ASN has been working to raise professional awareness of the radiation risks for workers and the public. ASN has stepped up its action in this respect by reminding the professionals of their obligations, particularly that of being licensed or registered by ASN for the removal and storing of lightning conductors pursuant to Articles L. 1333-1 and 2, L. 1333-8, and R. 1333-104 of the Public Health Code. ASN conducts field oversight operations targeting the companies involved in recovering these objects, combined with unannounced inspections on the removal sites.

The number of lightning conductors installed in France 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 250 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 replaced ASN resolution 2013-DC-0349 of 4 June 2013 without creating additional requirements for already compliant facilities. It concerns facilities in the industrial and scientific (research) sectors, such as industrial X-ray radiography in bunkers and veterinary radiology. It takes account of experience feedback and sets the radiation protection goals by adopting a graded approach to the risks.

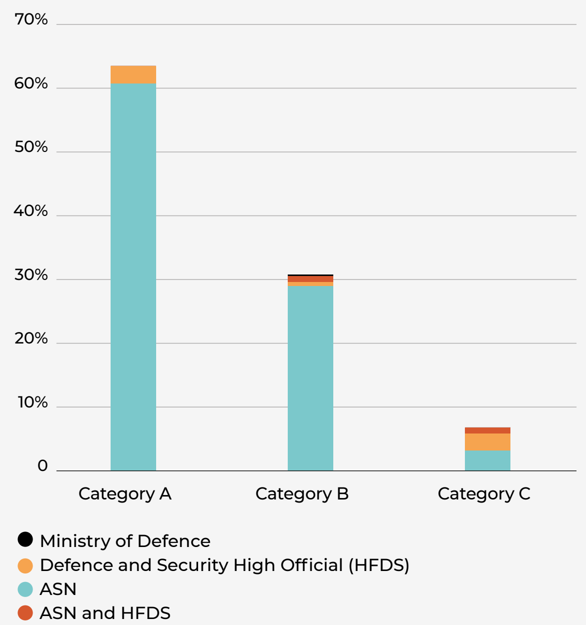
ASN considers that these provisions, which are directed exclusively at the use these devices, must be supplemented by provisions concerning their actual design.

CATEGORISATION OF RADIOACTIVE SOURCES

Radioactive sources have been classified by the International Atomic Energy Agency (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**



The sources in category A of the Public Health Code correspond to the IAEA category 1 sources.

The Public Health Code category B sources correspond to:
- the IAEA category 2 sources,
- the IAEA category 3 sources contained in a mobile or portable device.

The Public Health Code category C sources correspond to the IAEA category 3 sources not contained in a mobile or portable device.

This is because, for electrical devices used for non-medical purposes, there is no equivalent of the "CE" marking that is mandatory for medical devices, certifying conformity with several European standards that cover various aspects, including radiation protection. Furthermore, experience feedback shows that a large number of devices do not have a certificate of conformity to the standards applicable in France. These standards have been mandatory for many years now, but some of their requirements have become partly obsolete or inapplicable due to the lack of recent revisions.

On the basis of the work done in collaboration with the Electrical Certification and Testing Entity (LCIE), the Alternative Energies and Atomic Energy Commission (CEA) and IRSN, draft texts have been produced with the aim of defining minimum radiation protection requirements for the design of these devices and an informal technical consultation of the stakeholders (suppliers, French and foreign manufacturers and the principal users) was conducted in 2015. The various contributions are currently being analysed with the assistance of IRSN and the reference players (CEA and LCIE). The conclusions of this work will be taken into account to adapt the regulatory framework and subject the supply of electrical devices emitting ionising radiation to licensing, in the same way as for radioactive sources. Since 2021, ASN has thus been conducting work to characterise the advantages, drawbacks and the feasibility of various regulatory provisions for regulating, on the basis of appropriate technical baselines (work conducted with IRSN in particular), the design of industrial radiography devices. The discussions with the General Directorate for Labour (DGT) on the various options are continuing and highlight the need to strengthen their link with the existing European framework.

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 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 the persons/entities Responsible for Nuclear Activities (RNAs) and by the regulatory bodies when reviewing the licensing applications.

The sources and installations concerned

Oversight of source protection against malicious acts concerns all sources of ionising radiation, that is to say all the devices that could cause exposure to radiation. The majority of the regulatory measures are however taken to increase the security of the sources presenting the greatest radiological risks: this concerns radioactive sources of categories A, B and C as defined in the Public Health Code, which stems directly from that of the IAEA. The protection requirements are proportionate to the intrinsic dangerousness of the sources. The graded approach therefore implies stricter obligations for the sources (or batches of sources) in category A than 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 240 facilities in the civil sector in France hold slightly less than 6,000 radioactive sources presenting such security risks. These sources are used essentially for industrial purposes (irradiation, radiography, measurements, etc.) or medical purposes (such as telegammatherapy and brachytherapy. Due to their frequent movements when on worksites, industrial radiography sources present particular security risks.

If sources of different categories are stored together, the lower category sources may be subject to the stricter security measures applicable to the higher category sources.

Regulations

The Decree modifying the regulatory part of the Public Health Code taken in application of Ordinance 2016-128 of 10 February 2016 (Decree 2018-434 introducing various provisions with regard to nuclear activities) was published on 4 June 2018. It contains several provisions concerning the protection of sources against malicious acts, and more specifically:

- the classification of ionising radiation sources and aggregation (batching) of radioactive sources into category A, B, C or D according to the intrinsic level of risks presented by these sources or batches of sources. The category A sources are the most dangerous and the category D sources the least dangerous (Article R. 1333-14 of the Public Health Code);
- the obligation to promptly notify the various administrative authorities, particularly the regionally competent law enforcement agencies, of any actual or attempted malicious act or loss concerning a source of ionising radiation or a batch of radioactive sources of category A, B or C (R. 1333-22);
- the sending of sensitive information, that is to say elements that could facilitate malicious acts by separate, specially identified mail (R. 1333-130);
- the issuing of a nominative and written authorisation to the persons having access to ionising radiation sources or batches of radioactive sources in category A, B or C, transporting them, or having access to information concerning their protection against malicious acts (R. 1333-148).

INTERNATIONAL FOCUS GROUP ON ALTERNATIVE TECHNOLOGIES

Radioactive sources present radiation exposure and safety risks for their users, the general public and the environment, which must be taken into consideration in the reflection phase preceding the deployment of a nuclear activity. Consequently, in France, when technologies presenting lower risks than a nuclear activity are available under technically and economically acceptable conditions, they must be implemented instead of the nuclear activity initially envisaged: this is the principle of justification.

On this basis, as of 2014 and subsequently at the Nuclear Security Summit in Washington in April 2016, France was the initiator of an international initiative now supported by 31 countries and by Interpol. The aim is to support research into and the development of technologies that do not use high-activity sealed radioactive sources and to promote the use of these technologies.

In this context, in April 2015, ASN and the National Nuclear Security Administration (NNSA) of the United States of America jointly created an informal focus group, comprising several countries, to explore the replacement of high-activity radioactive sources by alternative technologies. The aim of this group, which meets once a year, is to foster greater awareness of the benefits of such alternatives and to share experience feedback from each country in this respect.

In December 2018, during the International Conference on Nuclear Security organised by the IAEA, the subject of alternative technologies was addressed by several presentations and two panel sessions, and the relevance of this think tank was underlined.

The group's meeting of 2023, like that of 2022, was an virtual on-line meeting attended by 200 participants. It provided the opportunity to carry out a first assessment of the experience acquired by several facilities after using X-ray irradiators or accelerators instead of radioactive source irradiators for a few years. Several contributors underlined the need to plan ahead with regard to device maintenance. More generally, access to the theoretical and practical training courses, for both the device operators and support teams, such as maintenance, is still problematic in certain countries. Lastly, the NNSA underlined the publication in spring 2023 by the US Government of the *National Security Memorandum* 19 which includes guidelines on the transition towards these alternative technologies.

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.

Subsequently, the Ministerial Order setting the organisational and technical requirements to protect sources of ionising radiation (or batches of radioactive sources) against malicious acts was signed on 29 November 2019 and published in the *Official Journal of the French Republic* on 11 December 2019. Its provisions were brought progressively into effect over a period extending to the end of 2022. Today they are all applicable.

The Order of 29 November 2019 amended also applies to the transport of category A, B and C sources, whether individually or in batches.

The main requirements of this Order aim, by adopting a graded approach based on categories A, B, C (and D for two items), to have the licensee put in place physical barriers and equipment, along with a policy and an internal organisation to protect sources against malicious acts. These technical and organisational provisions are intended to:

- prevent or delay the theft of radioactive sources through access control measures, reinforcement of physical barriers and their openings (doors, windows, etc.), alarms and crossing-detection;
- protect sensitive information (access limited to duly authorised personnel, promotion of good information technology security practices);
- detect an actual or attempted malicious act (theft in particular) as early as possible;
- take action or alert the local law enforcement agencies after preparing their on-site actions;
- raise awareness, inform, and regularly train the personnel in the issue;
- periodically check the effectiveness of the equipment and organise exercises.

For obvious reasons of restricting access to sensitive information, some of the provisions of this Order, detailed in its appendices, were not published in the *Official Journal*. ASN therefore, within its area of competence, sent the relevant appendices by personalised letter to each of the nuclear activity licensees concerned.

ASN also accompanied the publishing of the Order by actions in the regions at professional events between 2020 and 2022 and by holding *ad hoc* meetings with professionals concerned.

To help with the understanding of this Order, which introduced a new regulatory field that is little known to the RNAs, two important documents have also been produced:

- a guide produced jointly by ASN/SHFDS (Service of the Defence and Security High Official of the Ministry for Energy Transition) so that professionals and inspectors alike have a common understanding of the requirements of the Order;
- a guide on assessing the break-in resistance of opening elements: doors, shutters, windows, etc. Nowadays, professional reference systems and standards addressing protection against malicious acts enable this aspect to be covered satisfactorily from the technical viewpoint. However, the majority of the facilities concerned were built at a time when little consideration was given to the question of malicious acts. Based on the work of IRSN, which has an office specialised in the physical protection of facilities, a guide assigning a number of points to the leaves, locks and hinges of an opening element enables it to be given an overall rating and decide whether it complies with the requirements of the appendices of the Order.

The forms used to apply for authorisation to exercise a nuclear activity have moreover been adapted, and two dedicated forms have been created for the category A, B or C sources or batches of sources.

INTERNATIONAL TRANSFERS OF RADIOACTIVE SOURCES: THE PRIOR CONSENT PROCEDURE

Guaranteeing the control of sealed radioactive sources and protecting them against malicious acts during their import or export is crucial. The IAEA has published a document entitled *Guidance on the Import and Export of Radioactive Sources*, which aims to offer its members a consistent international framework. This framework is not mandatory, but it is intended to be taken into account by the IAEA member countries in their regulations. Its aims to ensure regulatory oversight that is as harmonised as possible throughout the transfer of these sources between the origin and destination countries.

The guidance is complementary to that of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources. To date, 135 countries, including France, have undertaken to take up these principles in their regulations.

The guidance on the import and export of radioactive sources was published in 2005, two years after the Code of Conduct was adopted. The current version, updated in 2012, focuses primarily on the category 1 and 2 radioactive sources (the most dangerous), which are widely used in the medical and industrial sectors. Maintaining control of these sources during their import or export is of crucial importance given their high level of radioactivity, which represents a risk in the event of unintentional exposure or illegal or unauthorised use.

These recommendations include in particular obtaining the consent of the importing country before the export of category 1 sources is permitted, and for the exporting company to send notification to the importing country seven days before the planned date of dispatch (for sources in category 1 or 2).

The aim is to know when batches of sources of categories 1 or 2 arrive in or leave the national territory in order to respond rapidly in the event of an attempted malicious act or an emergency situation (accident, climatic event, etc.).

ASN resolution 2015-DC-0521 of 8 September 2015 (see box page 254) has enshrined these principles in French law. Forms have been drawn up and "contact points" have been designated, as recommended in the IAEA guidelines, in order to streamline the international exchanges of information.

The consent requests concerning France come essentially from three countries: the United States, Canada and the United Kingdom. There are slightly fewer than ten import consents per year, and about half as many export consents.

In 2023, ASN took part in a seminar organised by the IAEA in Vienna attended by 103 "contact points" designated by 76 countries to discuss the regulatory measures adopted in each of the countries on the basis of the IAEA recommendations. ASN gave a presentation demonstrating the importance of not overlooking any details.

The discussions confirmed the persistent difficulties encountered in these operations. For example, what do you do if the exporting country does not acknowledge the IAEA guidelines or if the importing country is slow in providing the required information? Questions of this type were the focal point of the discussions, showing the joint desire to find solutions to streamline exchanges and guarantee safe international transfers of sources.

Lastly, to supplement the information for professionals, a brochure intended for RNAs who only possess category D sources (for which the number of regulatory obligations is limited) is also available on *asn.fr*.

2.4 LICENSING, REGISTRATION AND NOTIFICATION OF IONISING RADIATION SOURCES USED FOR INDUSTRIAL, RESEARCH OR VETERINARY PURPOSES

2.4.1 Integration of the principles of radiation protection in the regulation of non-medical activities

With regard to radiation protection, ASN verifies application of the three major principles governing radiation protection which are written into the Public Health Code (Article L. 1333-2), namely: justification, optimisation of exposure and dose limitation.

Assessment of the expected benefit of a nuclear activity and the corresponding health drawbacks may lead to prohibition of an activity for which the benefit does not seem to outweigh the risk. Either generic prohibition is declared, or the license required for radiation protection purposes is not issued or is not extended. For the existing activities, the elements supporting implementation of the justification principle are recorded in writing by the person RNA, and are updated every five years and whenever there is a significant change in available knowledge or techniques.

Optimisation is a notion that must be considered in the technical and economic context, and it requires a high level of involvement of the professionals. ASN considers in particular that the suppliers of devices are at the core of the optimisation approach (see point 4). They are effectively responsible for putting the devices on the market and must therefore design them such that the exposure of the future users is minimised. ASN also checks application of the principle of optimisation when examining the license applications, when conducting its inspections, and when analysing reported significant events.

2.4.2 The licensing, registration and notification systems

Applications relating to the possession and utilisation of ionising radiation are examined by the ASN regional divisions, while those concerning the manufacture and supply of sources or devices containing sources are examined at the ASN head office by the Department of Transport and Sources (DTS). The entry into effect on 1 July 2018 of Decree 2018-434 of 4 June 2018, introducing various provisions in the nuclear field, has introduced a third administrative system lying between the notification system and the licensing system: it is a simplified authorisation system called the “registration system”.

ASN has prepared a classification system to allocate the various categories of nuclear activities to one of these three systems, whose implementation began on 1 January 2019 with the entry into effect of the ASN resolution extending the notification system to additional nuclear activities which until then were subject to licensing, and continued on 1 July 2021 with the entry into effect of the resolution concerning the registration system.

The licensing system

Small-scale nuclear activities in the industrial sector stand out by their considerable diversity and the large number of licensees involved. The licensing system is designed to regulate the nuclear activities involving the greatest radiation protection implications, for which ASN checks, when examining the license application, that the applicant has identified the risks and that the measures intended to limit their effects have been studied and planned for. To support this process, licensing application forms adapted to each activity are available on *asn.fr*.

These forms are designed for the licensing applications to be formulated by the representative of a legal person, although it is possible for a physical person to apply for a license. These forms list the documents that must be enclosed with the application. All the 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 five years) license is issued for the exercise of the nuclear activity.

To further the implementing of a graded approach in the oversight of the nuclear activities coming under the Public Health Code, ASN continued revising the above-mentioned resolution, which started in 2022. 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 RNA in the industrial, research or veterinary sectors, that comes under the notification system, can carry out the notification procedure *via* the ASN “on-line services” portal.

Through ASN resolution 2018-DC-0649 of 18 October 2018 amended, approved on 21 November 2018, ASN has extended the list of activities subject to notification. The notification system extension has to date concerned about 7,000 files which were previously subject to the licensing system.

The new registration system (simplified authorisation)

The new registration system came into effect on 1 July 2021, after approval on 4 March 2021 of ASN resolution 2021-DC-0703 of 4 February 2021. This resolution governs nuclear activities in industry, research and veterinary applications, as nuclear activities for medical purposes that come under this system are governed by another resolution (see chapter 7). This system applies to certain sources of ionising radiation, whether in the form of sealed or unsealed radioactive sources, and X-ray generators, where the risks and drawbacks of possessing or using them can be prevented by complying with the specific general requirements set by the resolution. The resolution therefore defines, apart from the nuclear activities concerned, the content of the simplified authorisation application and the conditions for exercising (specific general requirements) the nuclear activity with which the licensees must comply.

Its entry into effect marks the second stage – following that of extension of the notification system – of effective implementation of the reform of small-scale nuclear activity regulation, aiming to better materialise a graded approach to the risks. The resolution effectively implies significant alleviations in the administrative procedures compared with those for nuclear activities subject to licensing, such as: a simplified application (both in the information and the substantiation documents to provide), ten year registration validity by default (and even unlimited

ADMINISTRATIVE TRACKING OF RADIOACTIVE SOURCES

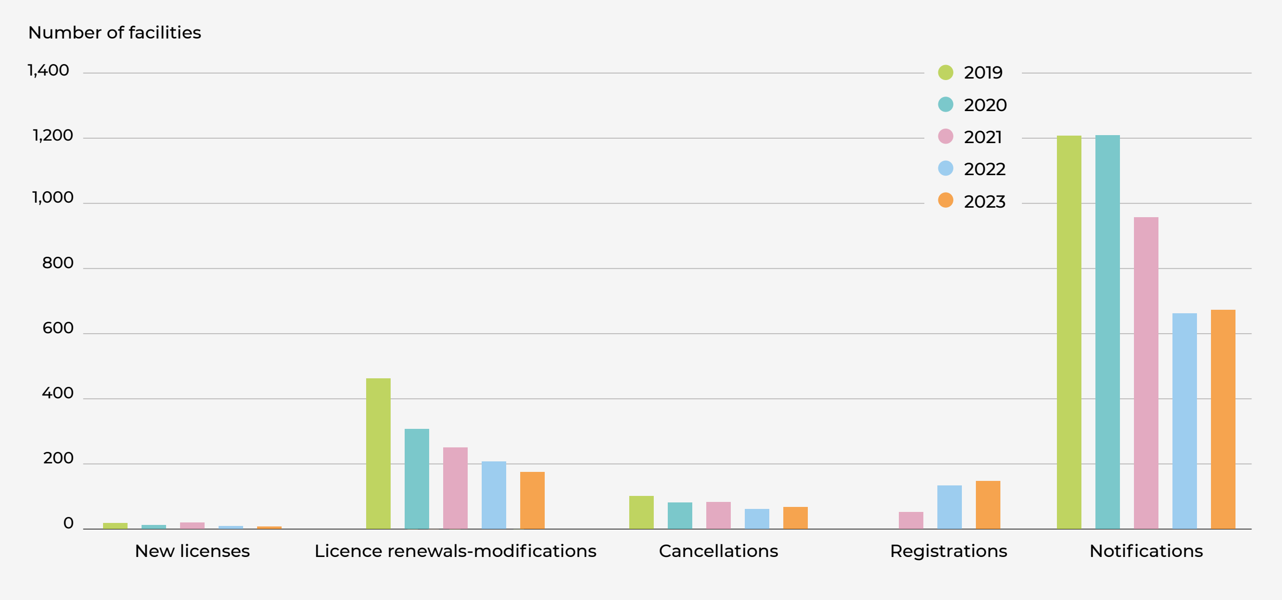
Articles R. 1333-154, 156 and 157 of the Public Health Code provide for the prior registration by IRSN of transfers of radioactive sources and Article R. 1333-158 for administrative tracking of these sources.

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.

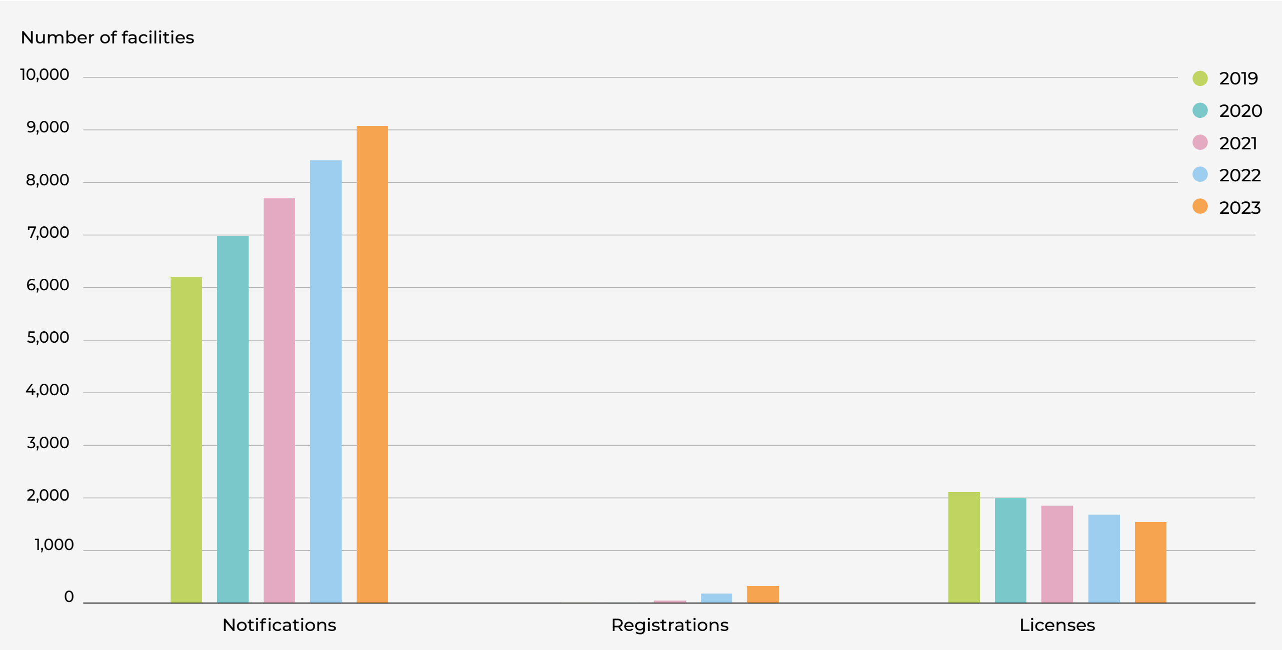
This resolution, applicable as of 1 January 2016, takes into account the existing mode of functioning and supplements it as follows by:

- 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.

GRAPH 6 "User" licences, registrations and notifications for radioactive sources issued each year



GRAPH 7 "User" licences, registrations and notifications for electrical generators of ionising radiation in effect over the last five years



validity by default for certain nuclear activities), the possibility of applying for registration *via* the on-line registration service which is available on *asn.fr*, review and assessment by ASN within six months, with silence after six months being considered as acceptance of registration of the applicant nuclear activity.

Entry into effect of the registration system should ultimately concern between 1,200 and 2,000 licensees in industry, research and veterinary applications, hitherto subject to the licensing system. However, the number will not be able to be accurately quantified until a five-year period has expired (1 July 2026). This is because, in accordance with the principle of grandfathering, the licenses issued before 1 January 2021 will act as registration until the license reaches term, on condition that in the interim there is no change in the nuclear activity.

2.4.3 Statistics for the year 2023

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 2023, 89 radioactive source supply license applications or license renewal applications were examined by ASN, and 43 inspections were carried out (all ionising radiation sources combined).

Users

The case of radioactive sources

In 2023, ASN examined and issued seven new licences, 174 license renewals or updates, 67 license cancellations, and 147 registration decisions. ASN also issued 672 notification acknowledgements for sealed radioactive sources in 2023. Graph 6 (see previous page) shows the regulatory acts issued by ASN for radioactive sources in 2023 and, where applicable, their development over the last five years. The entry into effect of ASN resolution 2018-DC-0649 of 18 October 2018 amended (see point 2.4.2) is the main reason for the very large drop in the number of licenses issued in favour of the issuance of notification acknowledgements, 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 2.4.2.) 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 previous page).

The case of electrical generators of ionising radiation

ASN has been responsible for the oversight of these devices since 2023, devices for which numerous administrative compliance actions are still required.

In 2023 it granted 23 new licenses, 130 license renewals or updates and issued 140 registration decisions for the use of electrical devices emitting X-rays. ASN also delivered 649 notification acknowledgements for electrical generators of ionising radiation. As with radioactive sources, the large reduction in the number of licenses issued and, conversely, the significant increase in notification acknowledgements and issuing of the first registration decisions, are the direct consequence of the entry into effect of the abovementioned ASN resolutions 2018-DC-0649 of 18 October 2018 and 2021-DC-0703 of 4 February 2021.

Altogether, 1,537 licences, 318 registrations and 9,069 notification acknowledgements for electrical devices emitting ionising radiation are in effect at the end of 2023. Graph 7 (see previous page) illustrates the development over the last few years.

3 Assessment of the radiation protection situation in applications involving radiation risks in the industrial, research and veterinary sectors

3.1 INDUSTRIAL RADIOGRAPHY

Industrial radiography is a non-destructive inspection method that consists in obtaining an image of the material density of an object through which electromagnetic radiation is passed in the form of X-rays or gamma rays (gamma radiography). The image is obtained *via* a detector which can be a photographic silver film, a photostimulable screen with reusable memory or a set of digital detectors.

Industrial radiography can be used in particular to assess defects in material uniformity, such as weld beads, or to check for fatigue. It is widely used in fabrication and maintenance operations in diverse industrial sectors such as boilermaking, petrochemicals, nuclear power plants, public works, aeronautics and armament.

Radiography can be carried out in an indoor facility (in which case physical protection of the operators is ensured by the facility's radiation protection features and safety devices) or in worksite conditions (in which case the work area must be marked out).

3.1.1 The different methods used

Gamma radiography

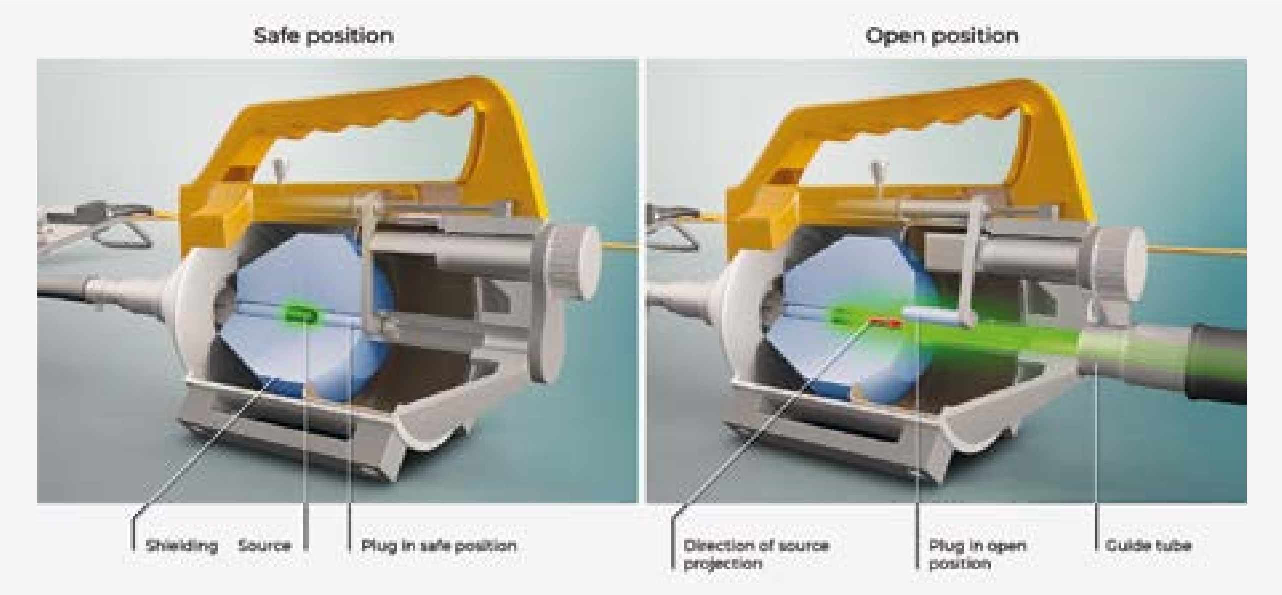
Gamma radiography devices usually contain high-activity sealed sources, mainly iridium-192, cobalt-60 or selenium-75, whose activity can reach about twenty terabecquerels. A gamma radiography device is usually a mobile device which can be moved from one worksite to another.

It consists primarily of:
- a source projector, which acts as a storage container and ensures radiological protection when the source is not in use;
- a guide tube which guides the movement of the source up to the object to be examined;
- and a remote control cable allowing remote manipulation by the operator.

When the source is ejected out of the projector, the dose rates can reach several grays per hour at one metre from the source, depending on the radionuclide and its activity level.

As a result of the activity of the sources and the movement of the sources outside the storage container when the device is being used, gamma radiography can entail significant risks for the operators in the event of incorrect use, failure to comply with radiation protection rules, or operating incidents. Furthermore, it is often carried out on work sites under difficult conditions (working at night, or in places that are exposed to the elements, or in cramped spaces). On this account, it is an activity with serious radiation protection implications that figures among ASN's inspection priorities.

Schematic diagram of the functioning of a gamma ray projector



Industrial X-ray radiography

Industrial X-ray radiography devices are very varied, ranging from fixed devices (integrated in a facility of very variable size) to mobile devices which can be used equally well in worksite conditions as in a facility. In application of the principle of optimisation, they must be used instead of gamma radiography devices when the conditions so permit because they do not make use of a radioactive source.

Apart from non-destructive inspection, these devices can also be used for more specific and therefore rarer purposes, such as radiography for the restoration of musical instruments or paintings, archaeological study of mummies or the analysis of fossils.

3.1.2 Evaluation of the radiation protection situation

Industrial radiography activities are high-risk activities which have been an inspection priority for ASN for several years now.

In 2023, ASN conducted 124 inspections in this area, slightly fewer than in the preceding years. Among these inspections, 43 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 (RPA), worker dose monitoring and radiological zoning of their facilities (less than 10% non-compliance 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 one case of non-compliance observed, concerning use in a facility).

SELENIUM-75 GAMMA RADIOGRAPHY

The use of selenium-75 in gamma radiography has been authorised in France since 2006. Implemented in the same devices as those functioning with iridium-192, selenium-75 offers significant radiation protection advantages. This is because the equivalent dose rates are about 55 millisieverts per hour and per terabecquerel (mSv/h/TBq) one metre from the selenium-75 source, as opposed to 130 mSv/h/TBq for iridium-192. Yet it can be used in place of iridium-192 in numerous industrial fields, especially the petrochemical or boilermaking industry, and it enables the cordoned-off safety area to be significantly reduced and facilitates intervention in the event of an incident. In France, about 15% of the devices are equipped with selenium-75 sources. The use of selenium-75 has stagnated over the last few years and even decreased in 2023 (20% in 2022). More specifically, the current geopolitical context (sanctions against Russia because of the war in Ukraine) is resulting in a restructuring of the global supply chain for gamma radiography sources, accompanied in particular by delays in delivery. Nevertheless, 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.

Note that as from 1 January 2025, pursuant to the new Articles R. 4451-62 and R. 4451-63 of the Labour Code, the utilisation of an industrial radiology device containing one or more high-activity sealed sources in a work zone will require at least two of the owner company's employees to hold the CAMARI certificate (see point 5).

The inspectors also noted that the efforts made by the companies to train newly-arrived classified workers had been maintained. Consequently, this information was duly dispensed to the new staff in 94% of the inspected facilities concerned in 2023.

Furthermore, although the inspections found no 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 (deviation level of 8% observed)

Lastly, the companies must devote considerable efforts not only to defining an exhaustive programme of verifications as required by the Labour Code and implementing it correctly, but also to correcting the nonconformities found during these verifications and ensuring the traceability of the corrections made (deviations noted in more than one inspection out of three).

Despite a slight improvement in 2023, ASN still considers that the deviations observed in cordoning off the work zones on worksites (found in virtually one inspection in four) give cause for concern. ASN underlines that the lack of preparation and cooperation between the ordering customers and the radiography contractors before starting worksites is one of the causes of

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 2023 in Germany, a radiologist was exposed to a dose of 71.5 millisieverts (mSv) after entering a facility when the electrical device emitting ionising radiation used in that facility was still in operation. The causes of the event are still being investigated.
- In 2023 in the United States, a trainee radiographer was exposed several times to a source of iridium-192 on a worksite when carrying out various operations (replacement of the film, movement of the guide tube) while the source was still positioned in the irradiation endpiece due to the detachment of the source holder. In the course of this incident, several radiation protection barriers were not observed, notably by the lack of supervision of the trainee radiographer (particularly during the source holder connection phase), failure to wear a dosimeter or use a radiation meter and verify that the source had returned properly into the projector (check of the indicator light, measurements, etc.). The trainee radiographer only noticed the problem when the guide tube became disconnected from the source projector. The dosimetric reconstruction (as no dosimeter was worn) gave an effective received dose estimate of 75 mSv and 258 mSv at the extremities.
- In 2022 in the United States, a team of three operators of a non-destructive testing company was performing gamma radiography work. One of the operators was close to the cobalt-60 source when it was ejected by his colleague who did not have direct visual contact with him. Given the very noisy environment of the worksite, the operator did not hear the alarm of his monitoring devices and was exposed to a dose of 55 mSv for about one minute.
- In 2022 in Belgium, a radiographer was exposed (14 mSv whole body, extremity dose not specified) to a selenium-75 source for a short period (60 to 90 seconds) when he tried to disconnect the device collimator while the source was still present in it. The alarm of his active dosimeter did not function because its battery was discharged; furthermore, the operator was not wearing his radiation meter. It was the triggering of his assistant's active dosimeter alarm when he approached the source that signalled the incident.
- In 2022 in Hungary, an operator was exposed to about 134 mSv when handling the collimator and the guide tube, as the selenium-75 source was not retracted into the safe position in the projector.
- In 2021 in the USA, an employee of a non-destructive testing company was exposed to a dose of 70 mSv (whole body) while carrying out gamma radiography exposures within a dedicated facility. The procedures in force at the time of this accident authorised the operator to be present inside the facility even when the source was in the irradiation position. An employee of another non-destructive testing company was exposed to a dose of 93 mSv (whole body) when manipulating a defective gamma radiography projector whose source was not in the safe position. These two events were rated level 2 on the International Nuclear and Radiological Event Scale (INES).
- In 2021 in Serbia, an iridium-192 source became detached from the remote control cable during an outdoor non-destructive test. The two operators did not check that the source had returned to the safe position at the end of the inspection and did not notice its absence until they got back to their company base. The source was found the next day after the intervention of a specialised laboratory. The two operators were exposed to doses of 451 mSv and 960 mSv.
- In 2021 in Spain, an employee of a non-destructive testing company was exposed after entering a gamma radiography bunker when the iridium-192 source was not in the safe position (source jammed). The passive dosimeter of the first employee indicated a dose of about 70 mSv, and that of the second about 3 sieverts (Sv). The event was rated level 2 on the INES scale.
- 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.

The data for earlier incidents can be consulted in the previous issues of this annual report, which are available on *asn.fr*, under the headings "ASN informs", "Publications", "ASN Reports".

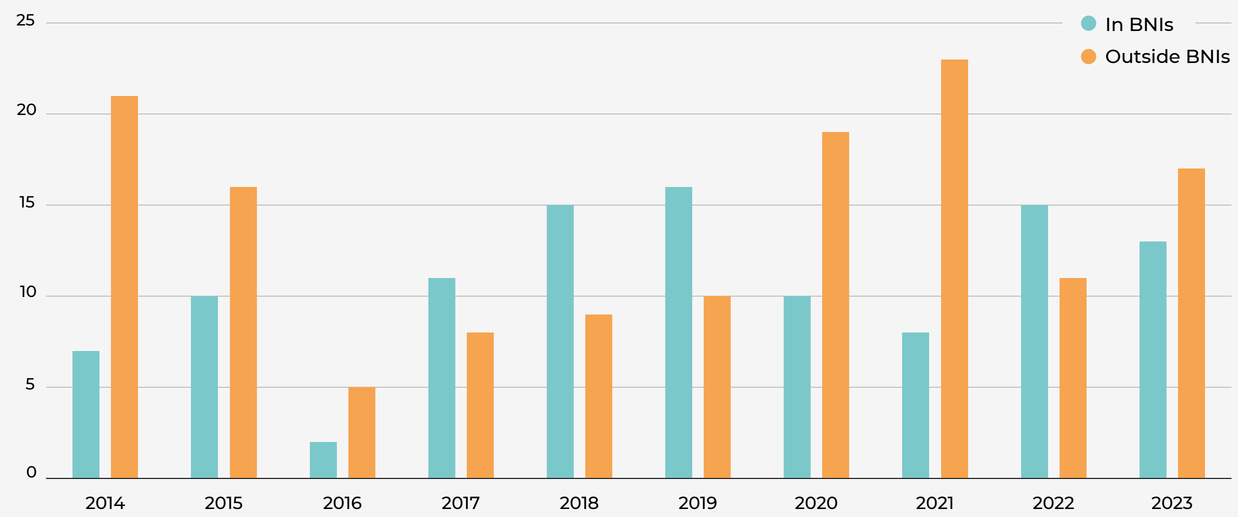
LOSS OF CONTROL OF THE SOURCE IN GAMMA RADIOGRAPHY

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.

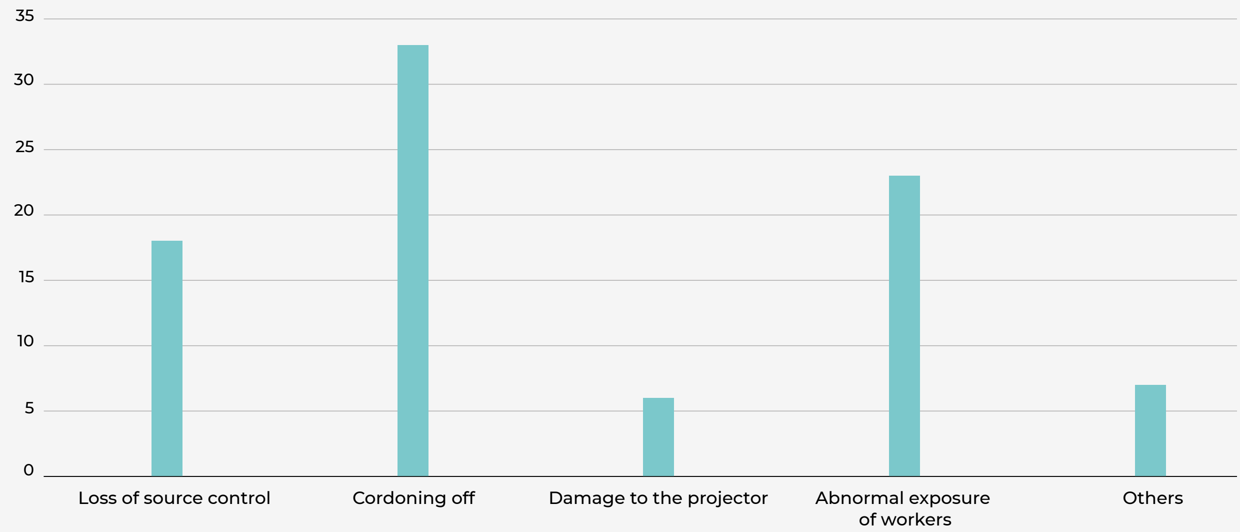
In France, gamma radiography projectors comply with technical specifications that are stricter than the international ISO standards. However, equipment failures can never be ruled out, especially in the event of poor upkeep of the equipment. In the last few years, incorrect manipulations have also been observed further to "source jamming" incidents.

GRAPH 8 **Trend in the number of industrial radiography events reported to ASN**



Note: the 24 events of 2018 and the 26 events of 2019 led to 25 and 27 notifications to ASN. respectively. In both cases, one event was reported twice by both the ordering customer and the industrial radiography contractor.

GRAPH 9 **Main factors leading to the reporting of significant industrial radiography events to ASN over the 2021-2023 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. National administrative tracking indicators have been put in place.

This administrative tracking has been adapted to take account of the gradual entry into effect of the requirements of the Order of 29 November 2019 amended. On 1 January 2021, the number of indicators increased from the initial four to six, all relative to organisation. On 1 January 2022, two indicators were abandoned and replaced by five new indicators concerning the installed technical protection devices.

Altogether, the number of inspection items – which depends on the activity – is 10 at the most: the technical devices are more numerous for category A or B sources or batches than for category C; moreover, certain inspection items address transport vehicles which the majority of RNAs 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 only the first two indicators aggregate five years of results. The others have only been tracked for two or three years.*

Classification of radioactive sources or batches of sources

The findings of 2023 are compared with the aggregated results for the years 2019-2022 for this indicator and the following one.

In 2023, nearly 90% of the inspections performed in industrial facilities raised no comment on this point. None of the remaining facilities had taken any action. This good result for 2023 is an improvement of 33% on the findings made over the 2019-2022 period.

Likewise, 90% of the medical centres inspected in 2023 have classified their sources. The increase in compliant situations in 2023 compared with the previous four years is more than 20%.

The number of sites that have not yet classified their sources is therefore low. The situation 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 2023, 60% duly issued the necessary authorisations. This result is identical to last year, but represents an improvement of 40% with respect to what had been examined between 2019 and 2022. The percentage of situations without any authorisation observed in 2023 is marginal (about 5%). The situation can nevertheless be further improved in a third of the cases for 2023.

The situation in the medical sector in 2023 is comparable with that of the preceding year, with one case out of two found compliant. In medical facilities however, far more people can have access to radioactive sources than on industrial sites, and the increase in compliant situations observed last year compared with the preceding years is continuing.

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. Such a statement signed by senior management is not enough in itself, but it must allow the initiation of an acculturation process that makes all the personnel aware of the question of malicious acts.

The industrial sector has such a policy, and prompted no observations in half the cases in 2023; the absence of a policy was noted in just 15% of the situations. There is a slight increase in the number of facilities that raised no comments compared with the two preceding years.

In the medical sector, about a quarter of the sites inspected in 2023 have a statement from management that raised no observations, a figure that is considered all the poorer given that nearly half the sites did not have a general policy to present. This was already the finding last year. It could partly explain the fact that the majority of the other indicators are poorer in the medical sector than in the industrial sector.

Identification and control of sensitive information

In 2023, 40% of the industrial facilities inspected had a procedure on this theme that was correctly applied. This figure is lower than it was last year and stable if compared with the aggregated findings over the preceding years (2021 and 2022). In a third of the situations in 2023 there was no documented procedure.

In the medical sector, 50% of the facilities had no document addressing this question. This percentage is identical to those of the preceding years.

Principle of barriers

This inspection item concerns the provisions with regard to break-in resistance, which is now based on precise criteria. This indicator and the following one, whose obligations came into force in 2022, can therefore only be compared with the latter.

Two thirds of the industrial sites inspected are considered to have "clearly identified "barriers". This is a great improvement on last year, where this indicator showed about 40% of compliant situations. This percentage is improving in the medical sector, rising from 50% of the inspected facilities in 2022 to more than 70% in 2023.

Therefore, although there is still room for improvement, it is to be noted that none of the sites inspected in 2023 had taken no protection measures.

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 in a third of the inspected companies, exactly the same level as in 2022. In half the 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.

The situation in the medical sector is better. Slightly over half the inspected sites have a maintenance plan, but in 25% of the cases the question has not been addressed at all. The remaining 20% or so of the facilities inspected in 2023 have a plan that is inappropriate or poorly applied.

While maintenance is an everyday function in industry and for the devices used in brachytherapy, these low levels indicate that the protection devices are monitored less rigorously than the "work tool".

these deviations. Thus, more than 40% of the inspections found deviations concerning the prevention plan (for example: no plan, operators unaware of the plan, plan not available on the worksite, or shortcomings in the content).

ASN points out that the work area must be cordoned off before the work begins and, in all events, before the radiography 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 one or more measurements and to record the results. Cordoning off the work zone effectively constitutes 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 nonconformities.

ASN considers that the risks of incidents and the workers' occupational exposure are generally well controlled by the companies when radiography is performed in a bunker complying with the applicable regulations.

France has a good network of permanent industrial radiography facilities. The figures in 2023 stand at:
- 95 licensed gamma radiography facilities (35 gamma radiography facilities and 60 combined facilities, that is to say which can accommodate either gamma ray projectors or electrical devices emitting X-rays);
- 465 licensed X-ray radiography facilities (398 facilities using electrical devices, 60 combined facilities and 7 facilities using accelerators).

This network thus enables 82% of the professionals to propose industrial radiography services within facilities (55% for gamma radiography).

Despite the availability of such facilities, ASN still observes too often that parts that undergo radiography on worksites could have been easily moved to a facility. Apart from optimising doses for the workers, it would also eliminate the risk of having to temporarily shut down the worksite (which could last several days) due to the setting up of an exclusion area, in the event of an incident preventing the radioactive source of a gamma ray projector from returning to the safe position.

ASN considers that the ordering customers have a key role to play to improve radiation protection in industrial radiography, by favouring industrial radiography services in a facility, or even turning to alternative technologies. Indeed, with regard to application of the principles of justification and optimisation, the long-term reflections undertaken by the non-destructive testing professionals have resulted in guidelines which aim to promote the use of alternative methods to industrial radiography. The work is continuing within the professional bodies, in particular with the updating of the construction and maintenance codes for industrial equipment, in order to promote the use of non-ionising inspection methods.

Enhancing the awareness of all the players is therefore a priority. The regional initiatives to establish charters of good practices in industrial radiography implemented for several years now at the instigation of ASN and the labour inspectorate, particularly in areas corresponding to the (former) regions of Provence-Alpes-Côte d'Azur, Normandie, Auvergne-Rhône-Alpes, Nord-Pas-de-Calais, Bretagne and Pays de la Loire, allow regular exchanges between 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 2023 as in the last few years, no cases of overexposure of industrial radiography operators were reported to ASN, even if several significant events linked to loss of source control (source "jamming") did occur during the use of gamma ray projectors. Unlike the last three years, the operators have undertaken no inappropriate or prohibited actions or manipulations, thereby avoiding causing unnecessary exposure or complicating the subsequent work that would be necessary to restore a normal situation.

ASN points out the obligation for all gamma ray projector users to obey the instructions applicable in the event of a situation of "source jamming" outside the projector, which consists during the emergency phase in immediately stopping any handling of the projector or its accessories, rapidly cordoning off the area to avoid any further exposure to ionising radiation and contacting the device supplier for assistance.

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 13). In many sectors, X-ray generators are gradually replacing high-activity sealed sources for the irradiation of products (see point 1.3.1).

3.2.2 Evaluation of the radiation protection situation

BNIs excluded, ASN carried out 18 inspections from 2019 to 2023 (two of which were in 2023) in this sector, out of the 25 facilities currently licensed. These inspections show that the radiation protection organisation (in particular the appointing of an RPA), the radiological zoning put in place on the inspected licensees'premises, the informing of new employees and the performance 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).

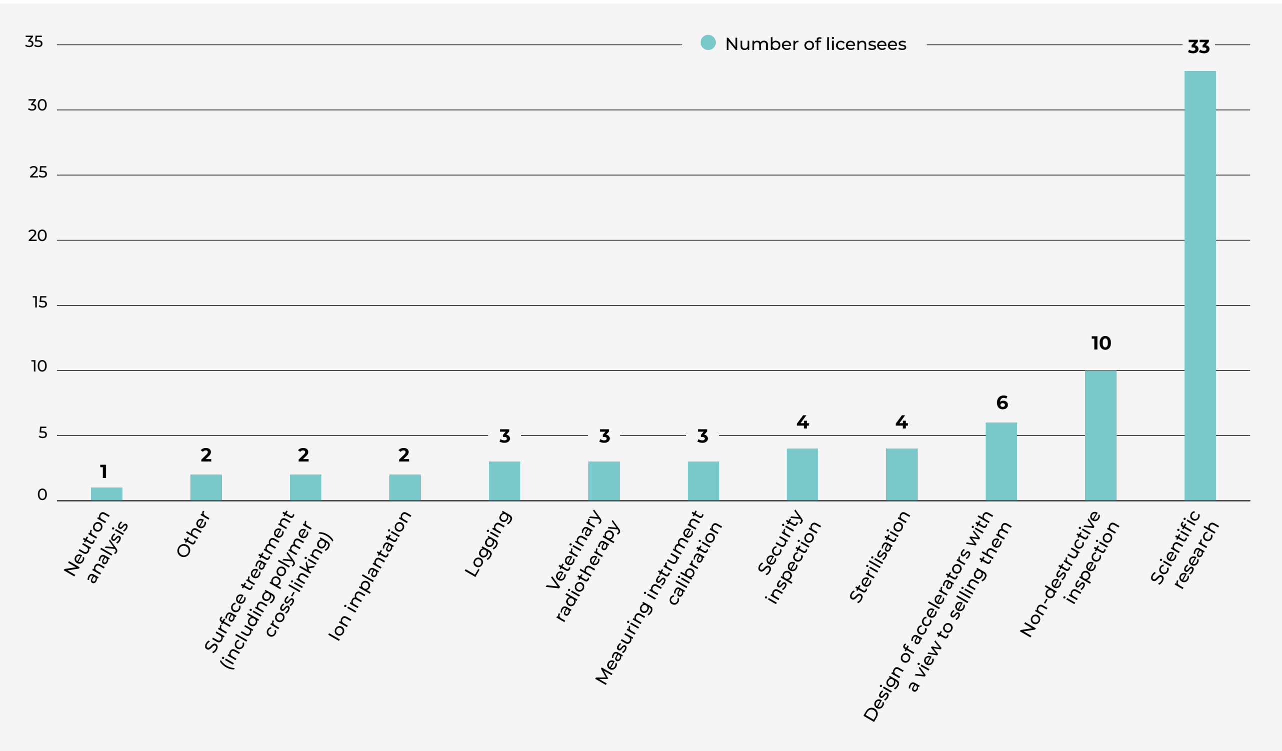
When they meet the characteristics specified in Article R. 593-3 of the Environment code concerning the BNI nomenclature, these facilities are listed as BNIs.

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 73 licensed facilities[1] (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.

GRAPH 10 **Breakdown of particle accelerators by end-purpose in 2023**



1. To which can be added seven licenses to use an accelerator, either exclusively under worksite conditions, or for the shared use of a device of which possession is regulated by the other party's license.

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.

Today one sees more and more particle accelerators used for research purposes and functioning on the principle of laser-plasma interactions: these devices can generate beams of highly energetic particles (up to a few hundreds of MeV in some facilities) and over very short times, down to the femto second (10^{-15} second).

Particle accelerators have been used for several years now in France to fight fraud and large-scale international trafficking. This technology, which the operators consider effective, must however be used under certain specific conditions in order to comply with the radiation protection rules applicable to workers and the public, in particular:

- a ban on activation of construction products, consumer goods and foodstuffs as specified by Article R. 1333-2 of the Public Health Code, by ensuring that the maximum energy of the particles emitted by the accelerators used excludes any risk of activation of the materials being verified;
- a general ban on the use of ionising radiation on the human body for purposes other than medical;
- the setting up of procedures to ensure that the checks conducted on the goods or transport vehicles do not lead to accidental exposure of workers or other individuals. The use of ionising technologies to seek out illegal immigrants in transport vehicles is prohibited in France. During customs inspections of trucks using tomographic techniques, for example, the drivers must be kept away from the vehicle and other checks must be performed prior to irradiation to detect the presence of any illegal immigrants, in order to avoid unjustified exposure of people during the inspection.

3.3.2 Evaluation of the radiation protection situation

The use of particle accelerators presents significant radiation exposure risks for the workers; ASN is particularly attentive to these facilities and therefore inspects them regularly.

Between 2019 and 2023, 66 facilities equipped with these devices were inspected by ASN, 14 of them in 2023.

ASN considers the radiation protection situation in the facilities using these devices to be satisfactory on the whole. In effect, the key requirements for conducting this activity with a satisfactory level of radiation protection (organisation of radiation protection, informing and training, technical verifications, radiological zoning and design of the premises in which these devices are used) are appropriately implemented by the large majority of the licensees concerned.

Nevertheless, the inspections have also highlighted areas for improvement on which ASN will remain vigilant:

- compliance with the regulations concerning the frequency of technical verifications of radiation devices and associated equipment and the formalised processing of any nonconformities detected during these checks;
- 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;
- the control of the technical means (password, dedicated key, etc.) allowing the security systems to be bypassed for highly specific maintenance and servicing procedures. These means must be kept under constant surveillance to prevent their use other than for these special procedures.

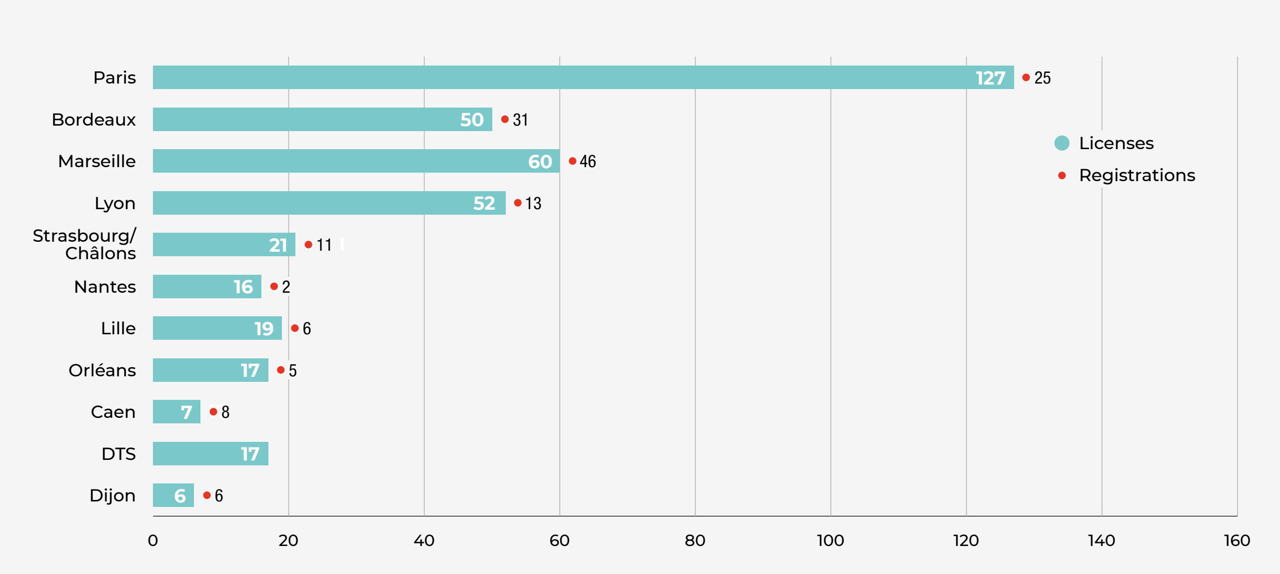
Lastly, with regard to experience feedback, no Significant Radiation Protection Event (ESR) was reported to ASN in 2023, apart from the recurrent events associated with the use of particle accelerators in shipment security checks. When conducting these checks, the customs services take precautions (such as broadcasting information messages in several languages) to avoid 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

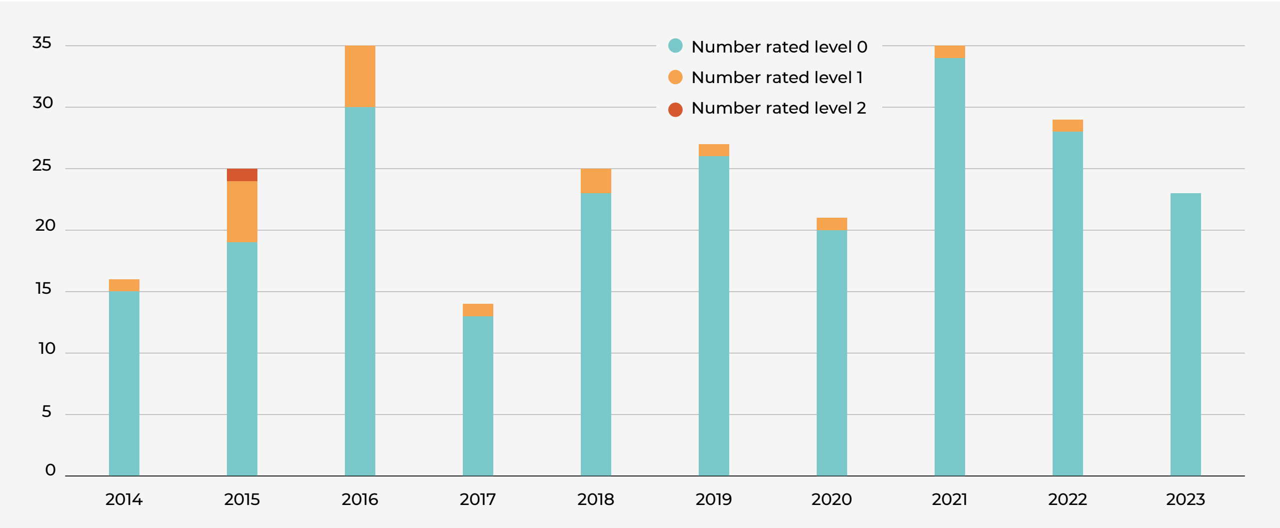
3.4.1 The devices used

In the research sector, as at 31 December 2023, ASN counted 392 licenses and 153 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 2.4.2). This new system addresses in particular the possession/use of unsealed source which until then were governed solely by the licensing system.

GRAPH 11 **Breakdown over the French territory, according to the competent ASN entity, of licensed or registered facilities using sources of ionising radiation in the research sector in 2023**



GRAPH 12 **Trends in the number of events reported to ASN in the research sector from 2014 to 2023**



The complete transitions of research laboratories from the licensing system to the registration system will continue over the coming years, particularly for the laboratories that reduce the quantities of radionuclides handled. These facilities and laboratories use mainly unsealed sources for medical and biomedical research, molecular biology, the agrifood business, the sciences of matter and materials, etc. They can also be suppliers of unsealed sources. They also use sealed sources for performing gas-phase chromatography, liquid scintillation counting or in irradiators. Electrical devices emitting ionising radiation are also used for X-ray fluorescence or X-ray diffraction spectrum analysis, while particle accelerators are used for research into matter or for the production of radionuclides.

3.4.2 Evaluation of the radiation protection situation

In 2023, ASN carried out 56 inspections in this sector[(2)] (compared with 55 inspections per year on average over the 2019-2023 period).

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.

As in 2022, the level of radiation protection in the research laboratories remains satisfactory on the whole and the trend towards improved practices is continuing. This nevertheless remains dependent on the involvement of the RPAs and the means at their disposal. The radiation risks in many research laboratories are fairly low or are tending to decrease, resulting in their nuclear activity changing from the licensing system to the registration. Furthermore, the cessation of nuclear activities in the research sector continues as techniques using ionising radiation are abandoned in favour of alternatives that do not.

ASN has nevertheless identified areas for improvement on which particular attention will be focused in the next inspections,

2. Among these inspections, 17 focused exclusively on the use of sealed radioactive sources or electrical devices emitting ionising radiation.

particularly regarding the management and storage of sources and waste/effluents, with shortcomings in the performance and recording of checks prior to their disposal.

The research facilities also still have difficulties in assimilating the new regulations concerning radiation protection verifications, which can prove complicated to apply in the "*Unités Mixtes de Recherche*" – UMRs (Joint Research Units).

ASN therefore considers that the conditions of storage and removal of sealed radioactive sources at end of life and of radioactive waste and effluents are still the main difficulties encountered by the research units. This situation is particularly pronounced in universities, where the limited financial resources of public laboratories can be an obstacle hindering more specifically the recovery of waste and expired/disused sources.

ASN thus remains attentive to the situation in certain universities, with tightened monitoring or even enforcement measures, particularly regarding the management of the substantial "legacy" in certain laboratories which have not removed their waste or expired/disused sources.

The technical, economic and regulatory difficulties concerning the disposal of old sealed sources also persist.

With regard to occupational radiation protection, the inspections in 2023 brought to light persistent shortcomings in the organisation and performance of the radiation protection verifications of equipment, workplaces and radiation protection instrumentation due to the difficulties the research units have in assimilating the regulations in force. This chiefly concerns the full application of the periodic verifications programme (verifications incomplete or not carried out) or the performance of the verifications. The performance concerning this indicator tends to be down with respect to the situation in 2022.

The same goes for the verifications provided for under the Public Health Code by the Order of 24 October 2022 and the Order of 18 January 2023 approving ASN resolution 2022-DC-0747, for which the situation can be improved. In effect, only 47% of the inspected research units perform these verifications correctly.

In 2023, 61% of the inspected sites have systems for recording and analysing adverse events and ESRs, compared with 76% in 2022. In 2023, ASN registered 23 ESRs concerning research activities (see Graph 12), all rated level 0 on the INES scale.

The majority of the ESR notifications concern the discovery of sources (39%), then in order of frequency of occurrence, the exposure of workers, without exceeding the regulatory limit values (17%), the storage of sources in unauthorised places, (13%) and the loss of integrity of sealed sources (13%). The other four notified events were of diverse origins: unauthorised environmental discharges (two ESRs), loss of sealed radioactive sources (one ESR) and failure to protect information relative to sources (one ESR for which a file containing the identities and serial numbers of a laboratory's personnel access badges was freely accessible on the Internet).

The discoveries of sources can be explained in particular by poor general traceability, often resulting from failure to take action to dispose of them when the laboratories cease their activity, or irregular and incomplete keeping of the source inventories.

With regard to worker exposure, diverse causes are identified, such as the contamination of a worker's shoes on leaving a work zone, the contamination of a worker when transferring a waste container, or the intervention of an outside contractor in a regulated work area despite being forbidden to do so by the ordering customer.

ASN reactivated its collaboration with the General Inspectorate for Education, Sport and Research (IGESR) in 2023. The IGESR is the competent body for labour inspection in the public research sector. The agreement signed in 2014, which provides for mutual information sharing to improve the effectiveness and complementarity of the inspections, is currently being updated. Annual meetings are also organised between ASN and the IGESR.

4 Manufacturers and distributors of radioactive sources and their oversight by ASN

4.1 THE ISSUES AND CHALLENGES

The aim of ASN oversight of the suppliers of radioactive sources or devices containing them is to ensure the radiation protection of the future users. It is based on the technical examination of the devices and sources with respect to operating safety and radiation protection conditions during future utilisation and maintenance. It also allows the tracking of source transfers and the recovery and disposal of disused or end-of-life sources. Source suppliers also play a teaching role with respect to users.

At present, only the suppliers of sealed radioactive sources (or devices containing them) and of unsealed radioactive sources are regulated in France (see point 2.3.1). ASN lists around 110 suppliers with safety-significant business, including 36 low and medium-energy cyclotrons which are currently licensed under the Public Health Code in France. Of these 36 cyclotrons, 31 are active and produce radionuclides.

Cyclotrons are used to produce positron-emitting radionuclides in unsealed sources (primarily fluorine-18). These radionuclides are used either for medical applications, especially *in vivo* diagnosis, or in clinical trial protocols (human subject research), or for research activities.

4.2 CYCLOTRONS

Operation

As at 31 December 2023, four cyclotrons were on standby, one shut down and 31 in service. Among the 31 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 one produces radionuclides exclusively for non-medical research.

After undergoing tests in the second half of 2023, the cyclotron of the university hospital of the Martinique will enter service in early 2024 to produce fluorine-18 initially, and subsequently carbon-11, oxygen-15, zirconium-89 and copper-64, with a view to conducting *in vivo* diagnostics and participate in clinical tests.

Another two cyclotrons will be licensed by ASN in the near future for tests before starting nominal operation in the course of 2024.

Evaluation of the radiation protection situation 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

CYCLOTRONS

A cyclotron is a device 1.5 to 4 metres in diameter, belonging to the circular particle accelerator family. The accelerated particles are mainly protons, with energy levels of up to 70 MeV.

A cyclotron consists of two circular electromagnets producing a magnetic field and between which there is an electrical field, allowing the rotation and acceleration of the particles at each revolution. The accelerated particles strike a target containing a liquid, gaseous or solid product which, once irradiated, will produce the desired radionuclide.

Low and medium energy cyclotrons are primarily used in research and in the pharmaceutical industry to produce positron emitting isotopes, such as fluorine-18 or carbon-11. The radionuclides are then combined with molecules of varying complexity to form radiopharmaceuticals used in medical imaging. The best known of them is ^{18}F-FDG (fluorodeoxyglucose marked by fluorine-18), which is an industrially manufactured injectable drug, commonly used for early diagnosis of certain cancers.

Other radiopharmaceutical drugs manufactured from fluorine-18 have also been developed in recent years, such as ^{18}F-Choline, ^{18}F-Na, ^{18}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. Some facilities are also starting to produce copper-64 or zirconium-89, which are still used today in research and clinical tests.

The approximate levels of activities involved for the fluorine-18 usually found in pharmaceutical facilities vary from 30 to 500 GBq per production batch.

The positron emitting radionuclides produced for research purposes involve activities that are usually limited to a few tens of gigabecquerels.

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.

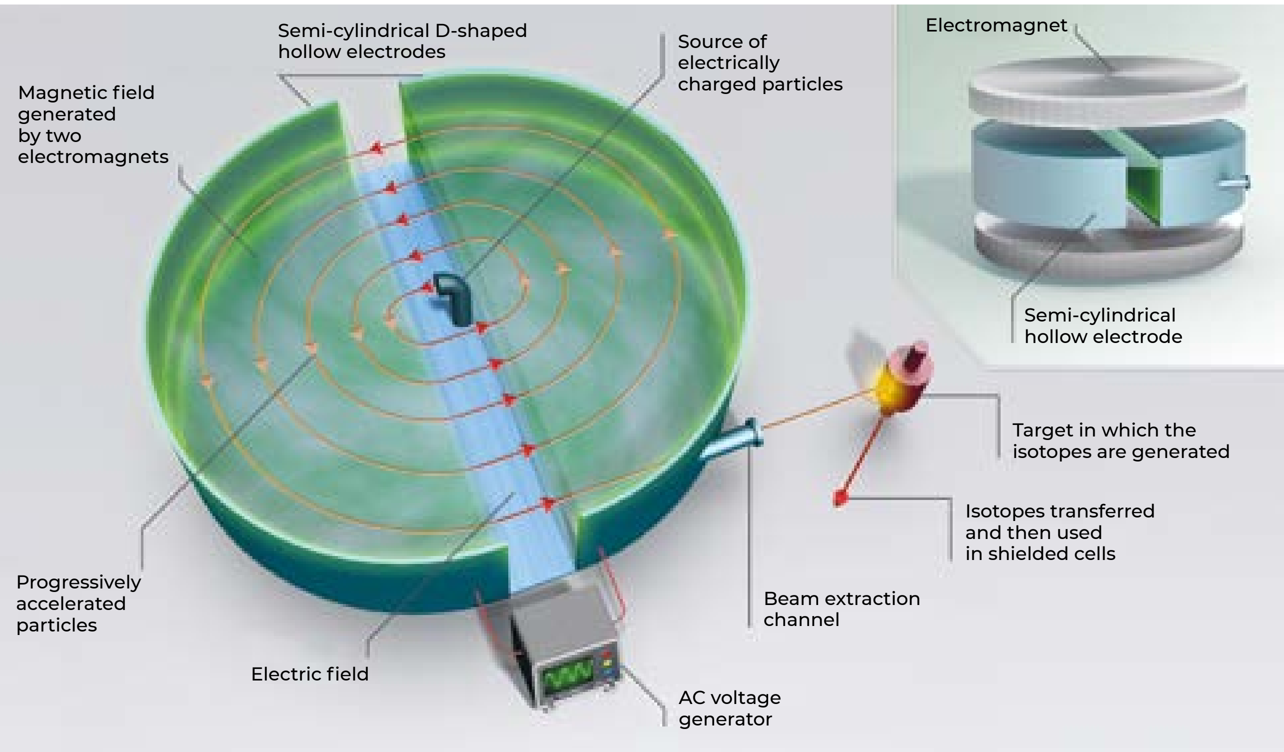
Facilities that have a cyclotron used to produce radionuclides and products containing radionuclides are subject to gaseous effluent discharge limits specified in their license. The discharge levels depend on the frequency and types of production involved.

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. An increasing number of licensees are also installing – as close as possible to the shielded enclosures – systems for collecting and storing the gases to let them decay before being discharged, bringing a substantial reduction in the activities discharged into the environment. These radioactive gas compression systems are then emptied after a decay time that is appropriate for the type of radionuclide.

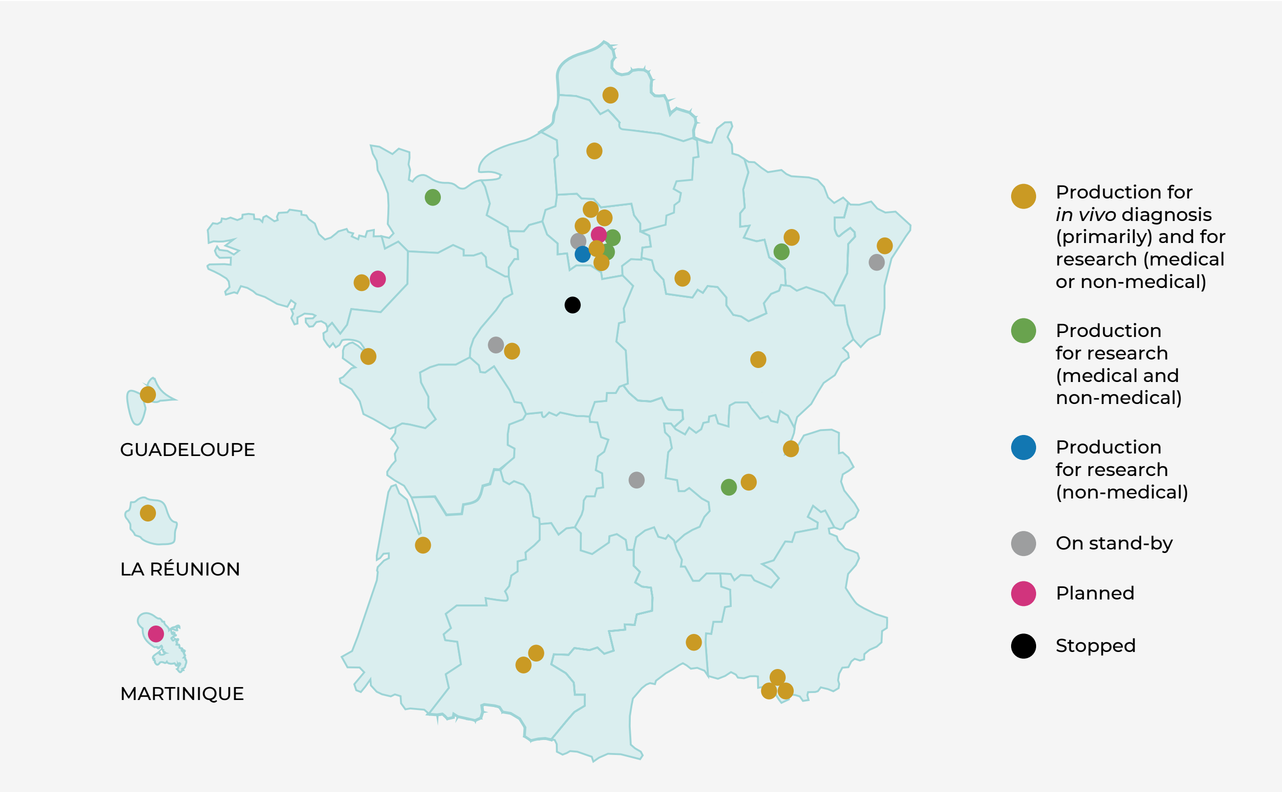
Consequently, the discharged activity levels and the short half-life of the radionuclides discharged in gaseous effluents mean there is no significant impact on the public or the environment.

The work 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.

Simplified diagram of the operation of a cyclotron



Location of cyclotrons in France



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.

ASN and IRSN worked jointly, with the participation of the cyclotron licensees, to clarify in particular the way atmospheric discharge limits are worded in the licences. At present, only the maximum dischargeable activity is usually indicated. The conclusions of this work will be an input for developing the future draft regulation relative to cyclotrons (see next page).

ASN performs about ten inspections at facilities of this type each year. Nine inspections were carried out in 2023, one a reactive inspection following an ESR notification (accidental release of carbon-11 – see below – causing the facility's authorised discharge limit to be exceeded).

Apart from the distribution of unsealed radioactive sources, the aspects relating to radiation protection, safety of use and the correct operation of cyclotrons and production platforms receive particular attention during the inspections. The scope of the inspections performed includes – apart from 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.

The distribution of radiopharmaceuticals and radiochemicals is duly taken into account by the licensees.

The organisation of radiation protection on the nine sites inspected is satisfactory. All the sites have designated at least one RPA, and in just one case the RPA did not have a certificate in the appropriate sector. Eight of the inspected sites have at least one person who holds the CAMARI certificate, and for the ninth site a person was undergoing CAMARI training at the time of the inspection.

The exposed workers are trained and are all subject to appropriate dose monitoring.

All the companies have a work equipment and radiation protection instrumentation verification programme that is established or currently being updated under the company's annual action plan. Likewise, the inspections and verifications of the presence and correct functioning of the cyclotron safety and alarm devices, of the shielded enclosures and of the recipients containing radionuclides are carried out on all the sites.

Concerning the management of radioactive sources, the maximum activity of the radionuclides held complies with the stipulations of the authorisation and appropriate measures are taken to prevent unauthorised access to the sources.

The checks prior to final disposal of the waste and contaminated effluents are carried out and traced in seven of the eight sites inspected on this subject. Waste management remains a point requiring particular attention regarding the regular removal of the waste that is to be recovered by Andra. The atmospheric discharges are generally well monitored. It is this monitoring that enabled the abovementioned accidental discharge to be detected rapidly.

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 ESRs were reported by the cyclotron licensees in 2023. None of these events led to significant exposure of workers or the public.

Two events concerning the accidental release of carbon-11 during a production operation were reported because of leaks on a target in the first case and at a transfer valve seal in the second case. Given the very short half-life and the one-off release of the carbon-11, the impact on the workers, the public or the environment close to each of the sites is negligible. In the second case, because the leak caused the authorised limit for radioactive atmospheric discharges to be exceeded, the event was rated level 1 on the INES scale and published on *asn.fr* as an incident notice.

The other four ESRs concerned exceeding of the dose constraint (set by the company) to the hands of workers on several occasions, the removal of a drum of liquid waste containing fluorine-18 by a waste removal contractor before the required decay time had elapsed, the loss of the atmospheric discharge monitoring data covering a short period of time and the crushing of a 10 kBq sealed source of caesium-137 de when conducting quality controls using a new chromatography device.

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 2024 in order to create a single regulatory baseline for the whole sector concerned. The main conclusions of this regulatory work are already being used when examining license applications for these facilities in order to include appropriate requirements in the individual licenses. The conclusions resulting from the considerations on the wording of the atmospheric discharge limit values will also be included.

4.3 THE OTHER SUPPLIERS OF SOURCES

Evaluation of the radiation protection situation

Suppliers of radioactive sources, cyclotrons excluded, propose technical solutions for the industrial, medical and research sectors. Suppliers may be manufacturers of "bare" sources or of devices containing sealed radioactive sources, manufacturers of unsealed sources, or distributors who import sources from other countries. Whatever the case, ASN examines the license application files for the sources these suppliers wish to distribute in France.

In 2023, cyclotrons excluded, 35 inspections were carried out at the manufacturers/distributors of radioactive sources or sources emitting ionising radiation, an increase on the preceding year. These inspections were carried out at manufacturers/distributors of sealed and unsealed radioactive sources, companies removing lightning conductors or removing and dismantling ICSDs, and companies manufacturing, installing, or maintaining electrical generators of ionising radiation or particle accelerators (although they are not yet subject to a distribution authorisation, these devices are subject to utilisation regulations, including in particular the commissioning or maintenance operations carried out by the companies that sell them). Several of the inspections concerned priority themes other than those mentioned above; more specifically, five inspections focused on the protection of radioactive sources against malicious acts and two concerned the possession and national use of radioactive sources by the armed forces. Lastly, one inspection concerned a foreign company that distributes radioactive sources in France.

These inspections 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). Furthermore, there is a distinct improvement in the verifications suppliers must carry out before delivering any sources compared with 2022.

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 sources 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. Compliance with the obligation of unconditional recovery of distributed sealed radioactive sources that have expired (ten years counting from the date of the first registration figuring on the supply form) or surplus to requirements, has also improved compared with 2022.

These inspections also provided the opportunity to inform the suppliers about the latest regulatory developments, particularly those relative to the new modalities of the radiation protection verifications required under the Public Health Code and those induced by the Defence Code modification which lowers some thresholds of nuclear material quantities, thereby making some suppliers subject to the licensing system under this Code, in addition to their obligations under the Public Health Code.

The inspections carried out during 2023 nevertheless also revealed certain points requiring particular attention, particularly as regards tracking of the distribution of particle accelerators and electrical devices emitting ionising radiation. In effect, the tracking tools used by the distributors were judged insufficient on half the inspected sites and inexistent on one site.

ESR notifications are significantly lower than in 2022, and no significant event rated level 1 or higher on the INES scale was recorded in 2023. The ESRs notified in 2023 mainly concerned poor management of dosimeters (dosimeter left in the radiography room and in luggage during X-ray security checks in an airport zone) resulting in incorrect dose recordings, and the discovery of radioactive substances (sources, effluent canisters, traces of contamination in places not provided for in the licenses of the sites concerned. On one licensee's premises, an irradiator containing high-activity sealed sources suffered serious damage, necessitating the shutting down one of the irradiation lines pending repair. None of the supplier ESRs notified for 2023 had any significant consequences on the environment or the workers.

5 Conclusion and outlook

Implementation of the new regulatory framework applicable to nuclear activities

In 2021, reinforcing of the graded approach to oversight, based on a classification of the different categories of nuclear activities involving sources of ionising radiation continued, with the entry into effect of resolutions relative to the registration system and the development of the associated remote registration system for on-line submission of application files.

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 electrical devices emitting X-rays. This work continued in 2023 and should result in 2024 in a first modification of the content of the information required for nuclear activities subject to licensing.

ASN is continuing, 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.

In 2023, ASN also participated in the updating of the part of the Labour Code relative to the protection of workers against the risks arising from ionising radiation (Decree 2023-489 of 21 June 2023).

More specifically, as from 1 January 2025, the utilisation in work zones of industrial radiology devices whose manipulation presents a high risk of exposure to ionising radiation and which contain one or more high-activity sealed sources, will necessitate at least two CAMARI-certificated employees of the company possessing the device.

In this context, the provisions of the current ASN resolution 2007-DC-0074 of 29 November 2007 amended, (which establishes the list of devices or device categories whose operation requires the CAMARI certificate) and those of the Order of 21 December 2007 amended (which defines the conditions of CAMARI training and certification), will be updated by a new order in 2024. ASN will participate in the drafting of this new Order, which will also set the conditions of deployment and utilisation of mobile industrial radiology devices in a work zone.

Oversight of the protection of radioactive sources against malicious acts

ASN has been designated as the authority to oversee the provisions to protect radioactive sources against malicious acts in the majority of facilities. This essentially concerns activities associated with gamma radiography and brachytherapy. Publication of the Decree of 4 June 2018 enabled the first provisions on the subject to enter into effect: RNAs must more specifically give individual authorisations for access to the most hazardous sources, including for their transport, and for access to sensitive information.

These initial provisions have been reinforced with the entry into effect on 1 January 2021 of part of the amended Order of 29 November 2019 which requires company functioning and organization to be adapted to these specific risks.

Although these are new regulatory provisions, it is above all an additional risk to be managed and integrated in the corporate culture particularly through measures to raise awareness and inform the personnel, which must be renewed periodically.

On this account, the quality management system must include measures to combat malicious acts, and senior management of the companies concerned must henceforth define and formalise a policy of protection against malicious acts implemented by the person RNA. This person must be assigned the necessary resources and have the requisite skills (assisted if necessary by a person trained in this area) and sufficient authority.

The measures adopted must also take account of the “cyber” aspect in order to fight against the compromising of sensitive information, a matter provided for explicitly by the Order of 29 November amended. All the company staff and external partners must be made aware of this subject. In order to have appropriate rules, the company’s sensitive information must be clearly identified and framed.

On 1 July 2022 the Order entered fully into effect and the technical provisions for the physical protection of sources should have been put in place, both within facilities and at worksites (utilisation, possession) and for road transport operations. Although the situation is not yet fully compliant, the six-monthly review of the indicators nevertheless shows an improvement trend.

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 reached “cruising speed” as of 2023 with more than 60 inspections. This level of inspection will be maintained in 2024 and 2025.

When examining the nuclear activity licensing applications, ASN also ensures that the necessary organisation and material provisions have been put in place. The content of the files to be provided takes this question into account.

ASN has moreover continued the training of its personnel and made in-house aids available to them (inspection guide, license application examination matrices, question-and-answer sheets, networks of regional correspondents).

To conclude, some effects of the Order of 29 November 2019 amended have been clearly visible for slightly more than a year: reduction in the stock of sealed radioactive sources of certain licensees, grouping of industrial radiography agencies and equipping of vehicles.

The year 2024 should witness the continuation of two works in progress:

- **the modification of the Order of 29 November 2019 amended**. Based on what has been learned from past inspections, it is more a question of clarifying or even relaxing certain provisions than adding requirements. Proposals have already been made to the MTE, the text signatory, and the discussions will continue in 2024;
- **the reflection concerning the protection of unsealed sources**. IRSN has been mandated by the MTE to conduct field investigations to assess the general level of protection of unsealed sources. These sources, which are used mainly in the medical or research sectors, very often have a radiological half-life of a few days at the most. However, some activities use products which no longer really have such reassuring characteristics. The MTE should adopt a position late 2024 on the principle of regulating such sources or not. ASN will participate in each stage of the reflection.

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09

Transport of radioactive substances

09

The transport of radioactive substances is a specific sector of dangerous goods transport characterised by the risks associated with radioactivity. The radioactive substance transports being regulated cover a wide range of activities in the industrial, medical and research sectors. This is based on strict international regulations.

1 Radioactive 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 materials, etc.). Class 7 covers radioactive substances.

The transport of radioactive substances stands out owing to its considerable diversity. Packages of radioactive substances can weigh from a few hundred grams up to more than a hundred tons and the radiological activity of their content can range from a few thousand becquerels to billions of billions of becquerels for the packages of spent nuclear fuel. The safety implications are also extremely varied. The vast majority of packages have limited individual safety implications, but for a small percentage of them, the potential safety consequences are very high.

About 770,000 consignments of radioactive substances are transported each year in France. This represents about 980,000 packages of radioactive substances, or just a few percent of the total number of dangerous goods packages transported each year in France. The vast majority of shipments are made by road, but some also take place by rail, by sea and by air (see Table 1). These shipments concern three activity sectors: the non-nuclear industry, medical sector and nuclear industry (see Graph 1).

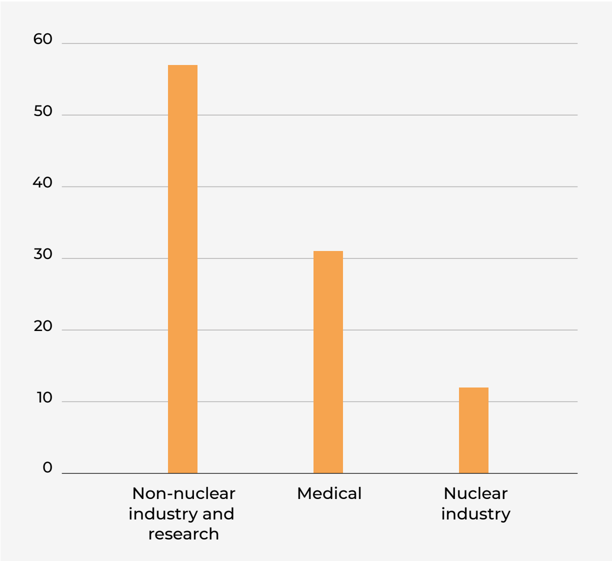
Most of the packages transported are intended for the non-nuclear industry, or for research: this mainly involves devices containing radioactive sources which are not used in a single location and which therefore need to be transported with considerable frequency. For example, these could be devices for detecting lead in paint, used for real estate sale diagnostics, or gamma radiography devices used to detect defects in materials. Travel to and from the various worksites explains the very large number of shipments for the non-nuclear industry. The safety issues vary considerably: the radioactive source contained in lead detectors has very low radiological activity, while that contained in gamma radiography devices has a far higher activity.

About one third of the packages transported are used in the medical sector: this involves providing health care centres with radioactive sources, for example sealed sources used in radiotherapy, or radiopharmaceutical products, and removing the corresponding radioactive waste. The activity of radiopharmaceutical products decays rapidly (for example, the radioactive half-life of fluorine-18 is close to two hours). Consequently, these products have to be regularly transported to the nuclear medicine units, creating a large number of shipments, which have to be carried out correctly to ensure the continuity of the health care given. Most of these products have low activity levels, although a small proportion of them, such as the sources used in radiotherapy or the irradiated sources used to produce technetium (used in medical imaging) have significant safety implications.

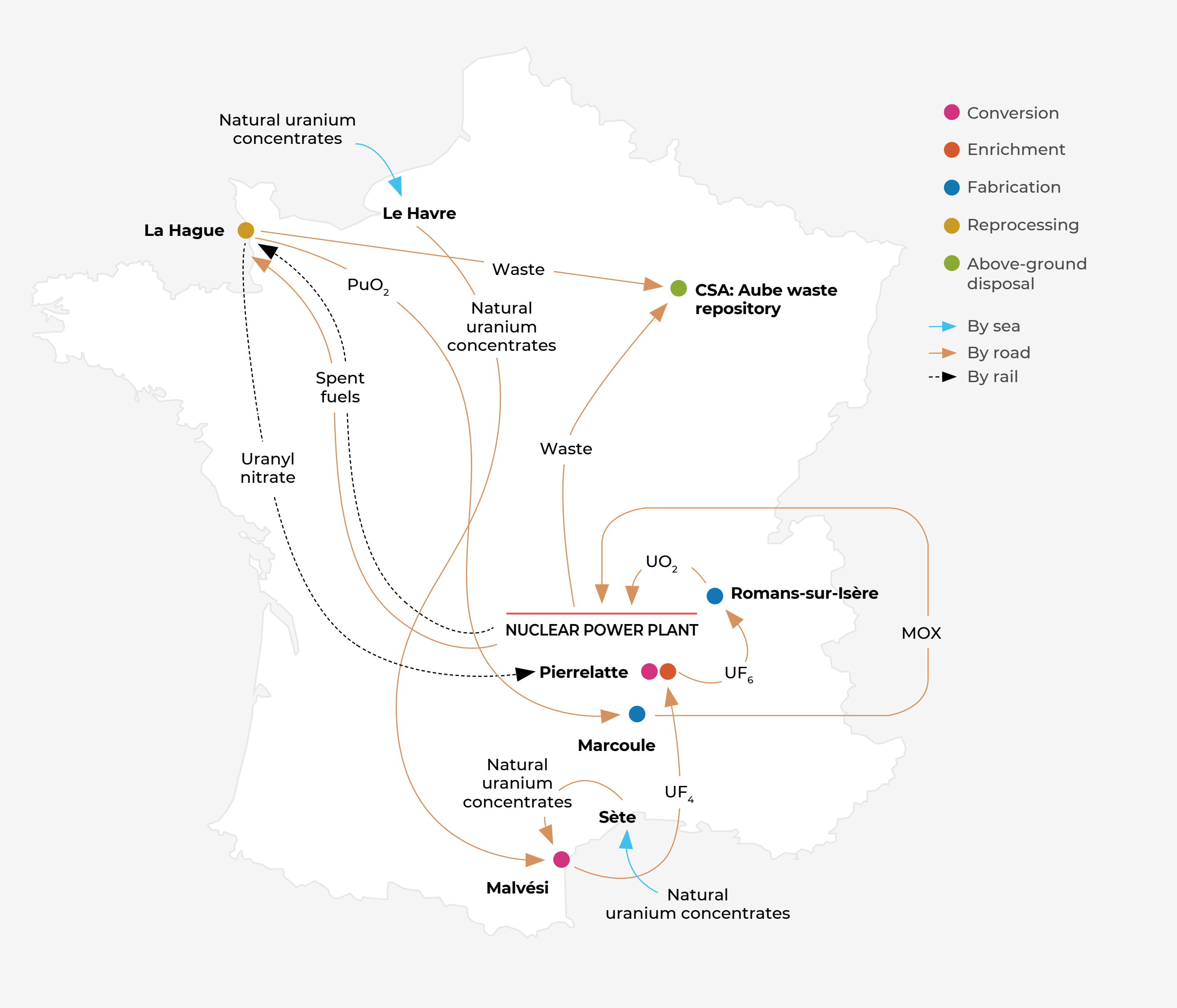
Finally, 12% of the packages transported in France are for the nuclear industry. This represents about 19,000 shipments annually, involving 114,000 packages. These shipments are required to ensure the working of the "fuel cycle", owing to the distribution of the various facilities and Nuclear Power Plants (NPPs) around the country (see map 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_6) whether or not enriched (dangerous more specifically owing to the toxic and corrosive properties of the hydrogen fluoride formed by UF_6 in contact with water), the spent fuel shipments to the La Hague reprocessing plant and the transport of certain nuclear wastes. The annual transports linked to the nuclear industry can be broken down approximately as follows:

- 200 shipments transporting spent fuel from the NPPs operated by EDF to the Orano reprocessing plant at La Hague;
- about 100 shipments of plutonium in oxide form between the La Hague reprocessing plant and the Melox fuel production plant in the Gard *département*;
- 250 shipments of UF_6 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;

GRAPH 1 **Proportion of packages transported per field of activity in %**



Transport operations relating to the "fuel cycle" in France



- 2,000 shipments from or to foreign countries or transiting *via* France, representing about 58,000 packages shipped (industrial, A and B type packages).

The statistical data presented in this chapter come from a study conducted by ASN in 2012. They are based on information collected from all the consignors of radioactive substances (Basic Nuclear Installations – BNIs, laboratories, hospitals, source suppliers and users, etc.), as well as on reports from the transport safety advisers. A summary is available on *asn.fr* (heading *"L'ASN informe/Dossiers pédagogiques/Transport des substances radioactives en France"*). The information available to ASN shows that these statistical data are still currently valid.

TABLE 1 **Breakdown per mode of transport (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_6, 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_6 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_6	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 radionuclides 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 limited, provided that appropriate accident management measures are taken. The regulations do not therefore require that this type of package be able to withstand a severe accident.

Due to the limited safety implications, type A and industrial packages are not subject to ASN approval: the design of the packages and the performance of the tests are the responsibility of the manufacturer. These packages and their safety case files are subject to spot checks during the ASN inspections.

2.3.3 Type B packages and packages containing fissile substances

Type B packages are those used to transport the most radioactive substances, such as spent fuels or high-level vitrified nuclear waste. The packages containing fissile substances are industrial, A or B type packages, which are also designed to carry materials containing uranium-235 or plutonium and which can thus lead to the start of an uncontrolled nuclear chain reaction. These packages are essentially used by the nuclear industry. Gamma radiography devices also fall into the type B package category.

Given the high level of risk presented by these packages, the regulations require that they must be designed so that, including in the case of a severe transport accident, they maintain their ability to confine the radioactive substances and ensure radiological protection (for type B packages) as well as sub-criticality (for packages containing fissile materials). The accident conditions are simulated by the following tests:
- A 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 9m 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 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_6 is used in the "fuel cycle". This is the form in which the uranium is enriched. UF_6 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_6 also presents a significant chemical risk. The regulations thus set out particular prescriptions for packages of UF_6. 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 bars.

Packages containing enriched, and therefore fissile UF_6, are also subject to the prescriptions previously presented (see point 2.3.3).

The UF_6 is transported in type 48Y or 30B metal cylinders. In the case of enriched UF_6, 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_6 must also be approved by ASN or a competent foreign authority, before they can be allowed to travel.

2.3.5 Type C packages

Type C packages are designed for the transport of highly radioactive substances by air. In France there are no approved type C packages for civil uses.

2.4 THE REQUIREMENTS GUARANTEEING THE RELIABILITY OF THE TRANSPORT OPERATIONS

2.4.1 Radiation protection of workers and the public

The radiation protection of workers and the public during shipments of radioactive substances must be a constant concern. The public and non-specialist workers must not be exposed to a dose greater than 1 millisievert per year (mSv/year). However, this limit is not intended to be an authorisation to expose the public to up to 1 millisievert (mSv). Moreover, the justification and optimisation principles applicable to all nuclear activities also apply to the transport of radioactive substances (see chapter 2).

Radiation protection is the subject of specific requirements in the regulations applicable to the transport of radioactive substances. Thus, for transport by road, the regulations stipulate that the dose rate at the surface of the package must not exceed 2 millisieverts per hour (mSv/h). This limit may be raised to 10 mSv/h in "exclusive use"[1] conditions, because the consignor or consignee can then issue instructions to restrict activities in the vicinity of the package. In any case, the dose rate must not exceed 2 mSv/h in contact with the vehicle and must be less than 0.1 mSv/h at a distance of 2 metres from the vehicle. Assuming that radiation at the surface of a transport vehicle reaches the limit of 0.1 mSv/h at 2 metres, a person would have to spend 10 consecutive hours at a distance of 2 metres from the vehicle for the dose received to reach the annual public exposure limit.

These limits are supplemented by requirements relative to the organisation of radiation protection within companies. The companies working in transport operations are required to implement a radiological protection programme, comprising the steps taken to protect the workers and the public from the risks arising from ionising radiation. This programme is more specifically based on a forecast evaluation of the doses to which the workers and the public are exposed. According to the results of this evaluation, optimisation measures must be taken to ensure that these doses are As Low As Reasonably Achievable (ALARA[2] principle): for example, lead-lined trolleys could be made available to handling staff to reduce their exposure. This evaluation also makes it possible to decide on whether to implement dosimetry to measure the dose received by the workers, if it is anticipated that it could exceed 1 mSv/year.

Finally, all the transport players must be trained in the risks linked to radiation, so that they are conscious of the nature of the risks, as well as how to protect themselves and how to protect others.

The workers involved in the transport of radioactive substances are also subject to the provisions of the Labour Code concerning protection against ionising radiation.

ASN has updated Guide No. 29 to help carriers meet their regulatory obligations relative to the radiation protection of workers and the general public. This update aims to take account of the new provisions introduced by Directive 2013/59/Euratom, known as the "BSS Directive", notably the periodic check that vehicles used to carry radioactive substances are contamination free.

2.4.2 Package and vehicle marking

So that the workers can be informed of the level of risk arising from each package and so that they can protect themselves effectively, the regulations require that the packages be labelled. There are three types of labels, corresponding to different dose rate levels in contact and at 1 metre from the package. The workers operating close to the package thus have a visual means of knowing which packages entail the highest dose rates, and can thus limit the time they spend close to them and can put them as far away as possible (for example by loading them towards the rear of the vehicle).

The packages containing fissile materials must also display a special label. This is to ensure that these packages are kept apart to prevent the triggering of a nuclear chain reaction. The special label enables compliance with this prescription to be easily verified.

Finally, the markings on packages must comprise their type, the address of the consignor or consignee and an identification number. This enables delivery errors to be avoided and allows packages to be identified if lost.

The vehicles carrying packages of radioactive substances must also have specific markings. Like all vehicles carrying dangerous goods, they carry an orange-coloured plate at the front and back. They must also carry a placard with the radiation trefoil and the word "Radioactive". The purpose of these vehicle markings is to provide the emergency services with the necessary information in the event of an accident.

2.4.3 Responsibilities of the various transport players

The regulations define the responsibilities of the various parties involved during the lifetime of a package, from its design up to the actual shipment. These responsibilities entail special requirements. Therefore:
- The package model designer shall have designed and sized the packaging in accordance with the intended conditions of use and the regulations. It must obtain an ASN certificate (or in certain cases a certificate from a foreign authority) for type B or fissile packages containing UF_6.
- 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,

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.

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.

On 6 July 2023, ASN updated its Guide No. 44 intended for professionals involved in radioactive substances transport operations and which specifies ASN's requirements regarding the contents of a quality management system. In particular, this update addresses the graded approach, with the level of requirements for the management system being proportionate to the safety implications of the activity of these professionals and the size of the company concerned.

The regulations also require that all operators involved in transport receive training appropriate to their functions and responsibilities. This training must in particular cover the steps to be taken in the event of an accident.

Contractors which carry, load, unload or handle (after loading and before unloading) packages of radioactive substances on French soil shall declare these transport activities to the ASN on-line services portal before carrying them out. This on-line service is also available in English.

The transport of certain radioactive substances (notably fissile substances) must first be notified by the consignor to ASN and to the Ministry of the Interior, seven days prior to departure. This notification stipulates the materials carried, the packagings used, the transport conditions and the details of the consignor, the carrier and the consignee. It is a means of ensuring that the public authorities have rapid access to useful information in the event of an accident.

In 2023, 1,427 notifications were sent to ASN.

2.5 PREPAREDNESS FOR MANAGEMENT OF EMERGENCIES

The management of emergency situations is the final level of "Defence in Depth". In the event of an accident involving transport, it should be able to mitigate the consequences for persons and the environment.

As a transport accident can happen anywhere in the country, it is probable that the emergency services arriving on the scene would have no specific training in radiological risks and that the population in the vicinity would be unaware of this particular risk. It is therefore particularly important that the national emergency response organisation be robust enough to take account of these points.

In this respect, the regulations set obligations on the various stakeholders in the field of transport. All those involved must therefore immediately alert the emergency services in the event of an accident. This is more particularly true for the carrier, who would in principle be the first party to be informed. It must also transmit the alert to the consignor. Furthermore, the vehicle crew must have written instructions available in the cab, stipulating the first steps to be taken in the event of an accident (for example: trip the circuit-breaker, if the vehicle is so equipped, to prevent any outbreak of fire). Once the alert has been given, the parties involved must cooperate with the public authorities to assist with the response operations, including by providing all pertinent information in their possession. This in particular concerns the carrier and the consignor who have information about the package and its contents that is of great value for determining the appropriate measures to be taken. To meet these regulatory obligations, ASN recommends that the parties involved implement emergency response plans allowing the organisation and tools to be defined in advance, enabling them to react efficiently in the event of an actual emergency.

ASN Guide No. 17 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 plates bearing the trefoil signal on the vehicles, indicating the presence of radioactive substances, also signal the presence of dangerous goods: the emergency services are then instructed to automatically evacuate an area around the vehicle, usually with a radius of 100 metres, and to notify the radioactive nature of the load to the office of the Prefect, which will then alert ASN.

Management of the accident is coordinated by the Prefect, who oversees the response operations. Until such time as the national experts are in a position to provide him or her with advice, the Prefect relies on the emergency plan adopted to deal with these situations.

ASN is able to offer the Prefect assistance by providing technical advice on the more specific measures to be taken. The Institute for Radiation Protection and Nuclear Safety (IRSN) assists ASN in this role, by assessing the condition of the damaged package and anticipating how the situation could develop. Furthermore, the ASN regional division dispatches a staff member to the Prefect to facilitate liaison with the national Emergency Centre (see chapter 4 devoted to radiological and post-accident emergency situations).

At the same time, human and material resources would be sent out to the scene of the accident as rapidly as possible (radioactivity measuring instruments, medical means, package recovery means, etc.). The fire service teams specialising in the radioactive risk (the Mobile Radiological Intervention Units – CMIR) would be called on, along with IRSN's mobile units, or even those of 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 2024 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 within the perimeter of BNIs.

This is why the on-site transport of dangerous goods is subject to the requirements of the Order of 7 February 2012 setting out the general rules applicable to BNIs. This Order requires that on-site transport operations be incorporated into the baseline safety requirements for BNIs.

The Environment Code, supplemented by ASN resolution 2017-DC-0616 of 30 November 2017, defines the on-site transport operations for which authorisation must be requested from ASN. In addition, ASN published Guide No. 34 providing the licensees with recommendations for implementing the regulatory requirements concerning on-site transport operations.

3 Roles and responsibilities in regulating the transport of radioactive substances

3.1 REGULATION OF NUCLEAR SAFETY AND RADIATION PROTECTION

In France, ASN has been responsible for regulating the nuclear safety and the radiation protection of transports of radioactive 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, represents the Regulatory Authority responsible for preventing malicious acts targeting nuclear materials.

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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	General Directorate for Infrastructures, Transports and the Sea (DGITM) at the Ministry for the Environment. In particular, the DGITM is responsible for regulating compliance with the prescriptions applicable to ships and contained in the International Code for the Safe Carriage of irradiated nuclear fuel, plutonium and high-level radioactive wastes on board ships ("Irradiated Nuclear Fuel" Code).	The DGITM has competence for regulation of dangerous goods packages in general and is in close collaboration with ASN for radioactive substances packages.
By road, rail and inland waterways	General Directorate for Energy and Climate (DGEC) of the Ministry for the Environment.	The General Directorate for the Prevention of Risks (DGPR) is responsible for regulation of packages of dangerous goods in general and, in close collaboration with ASN, of packages of radioactive substances.
By air	General Directorate for Civil Aviation (DGAC) at the Ministry for the Environment	The DGAC has competence for regulation of dangerous goods packages in general and is in close collaboration with ASN for radioactive substances packages.

In the field of transport security, the IRSN Transport Operations Section (EOT) is responsible for managing and processing applications for approval of nuclear material shipments, for supervising these shipments and for notifying the authorities of any alerts concerning them. This security mission is defined by the Order of 28 February 2023 relative to the security of transport of nuclear materials, implementing Articles R. 1333-4 and R. 1333-17 to R. 1333-19 of the Defence Code. Thus, prior to any transport operation, the Defence Code obliges the carriers to obtain a transport authorisation. The EOT reviews the corresponding application. This review consists in checking the conformity of the intended provisions with the requirements defined by the Defence Code and the above-mentioned Order of 28 August 2023.

ASN has initiated the process to update its resolution 2015-DC-0503 of 12 March 2015 relative to the notification system for companies transporting radioactive substances on French 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 structure is tasked with measures relative to the safe transport of dangerous goods other than class 7 (radioactive) by road, rail and inland waterways. It has a consultative body (standing sub-committee in charge of dangerous goods transport, within the High Council for the Prevention of Technological Risks – CSPRT), that is consulted for its opinion on any draft regulations relative to the transport of dangerous goods by rail, road or inland waterway. Inspections are carried out by land transport inspectors attached to the Regional Directorates for the Environment, Planning and Housing.

For the regulation of dangerous goods to be as consistent as possible, ASN collaborates regularly with the administrations concerned.

The breakdown of the various inspection duties is summarized in Table 3.

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 kilogram of UF_6 must be have an ASN approval certificate in order to be used for transportation. The designers of the package models who request approval from ASN must support their application with a safety case demonstrating the compliance of their package with all the regulatory requirements. Before deciding whether or not to issue an approval certificate, ASN reviews this safety case, drawing when necessary on the expertise of IRSN, in order to ensure that the safety cases are pertinent and conclusive. If necessary, the approval certificate is issued with requests in order to improve the safety case.

In some cases the IRSN appraisal is supplemented by a meeting of the Advisory Committee of Experts for the Transport of radioactive substances (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).

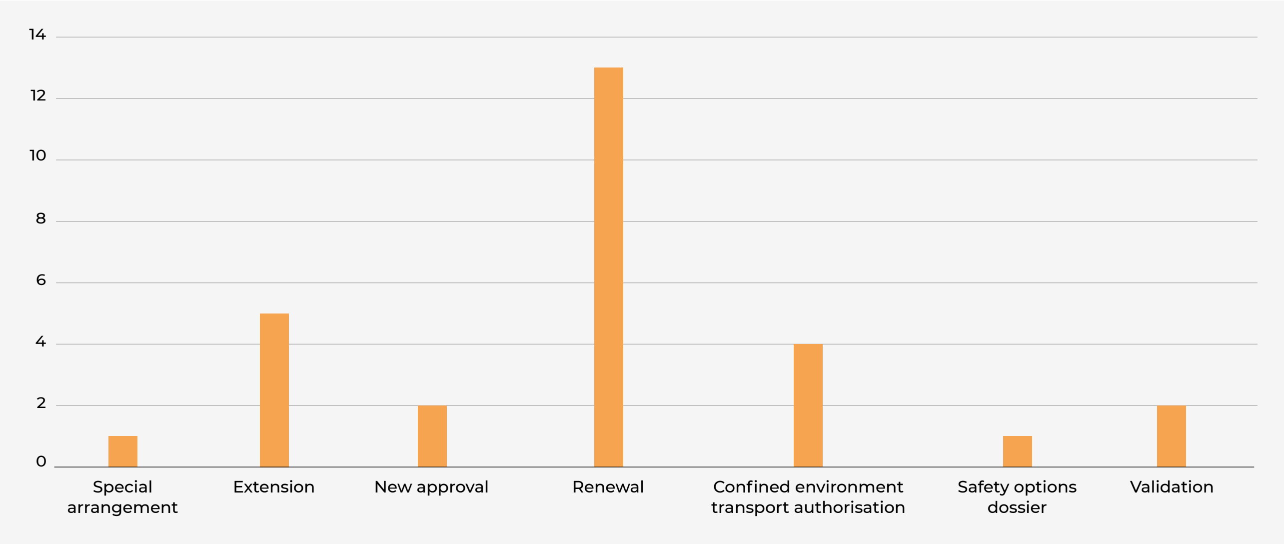
FIRST FRENCH APPROVAL CERTIFICATE FOR SCO-III SHIPMENT

EDF intends to send the lower parts of the used steam generators from the Fessenheim NPP to Sweden, for reuse of the metal. To this end, it submitted an authorisation application to ASN in July 2022 for multimodal transport of surface contaminated objects, known as "SCO III". The 2018 edition of the IAEA's international transport regulations, SSR-6, created this additional category of surface contaminated objects in order to meet the need for the transport of very large sized contaminated objects, resulting from installations decommissioning or the replacement of heavy components, such as steam generators. Owing to their dimensions, it is thus impossible to load these objects into a dedicated transport packaging. After completing the review of the application, ASN issued the first approval certificate for SCO-III shipment in July 2023.

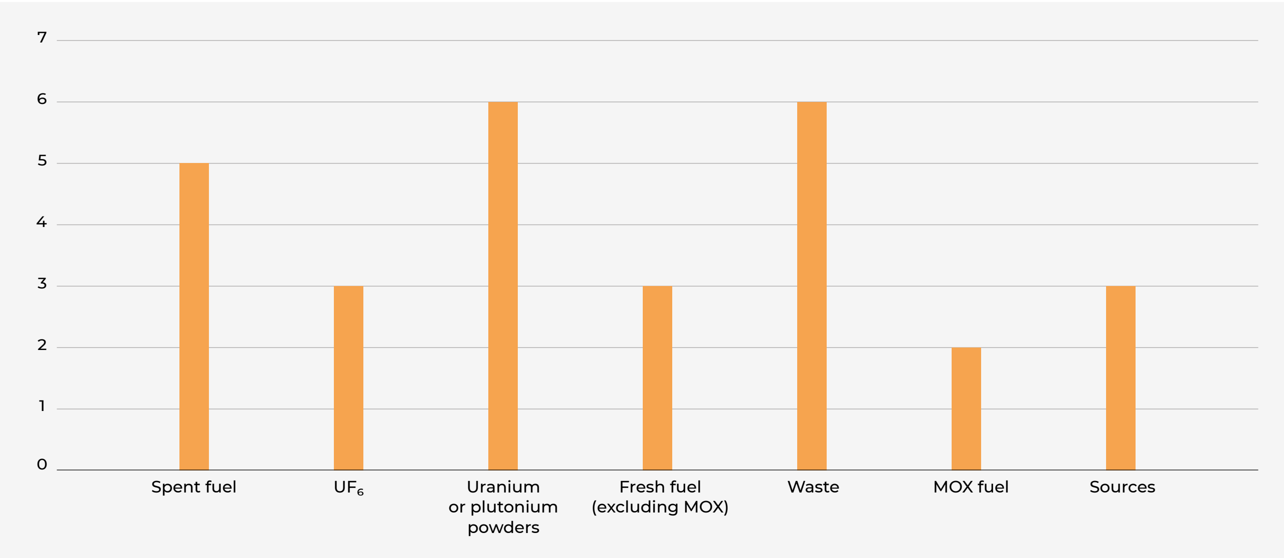
These approval certificates are usually issued for a period of five years. If a package is unable to meet all the regulatory requirements, the regulations nonetheless allow for its transport by means of a shipment under special arrangement. The consignor must then define compensatory measures to ensure 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 therefore of a violent shock on the package, is thus considerably reduced. A shipment under special arrangement is only possible with the approval of the competent authority, which then issues approval for shipment under special arrangement, stipulating the compensatory measures to be applied.

In the case of certificates issued abroad, the international regulations provide for their recognition by ASN. In certain cases, this recognition is automatic and the foreign certificate is directly valid in France. In other cases, the foreign certificate is only valid if endorsed by ASN, which then issues a new certificate.

GRAPH 2 **Breakdown of number of approvals according to type, issued in 2023**



GRAPH 3 **Breakdown of number of approvals according to content carried, issued in 2023**



In 2023, 20 approval applications were submitted to ASN.

ASN issued 28 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 2023, ASN carried out 100 inspections in the field of radioactive substances transport (all sectors considered). The follow-up letters to these inspections are available on *asn.fr*.

Since 2023 and twice a year, ASN publishes the applicable list of package model approval certificates that it has issued, on its website.

4.2.1 Regulation of package manufacturing

The manufacture of transport packaging is subject to the regulations applicable to the transport of radioactive substances. The manufacturer is responsible for producing packagings in accordance with the specifications of the safety case, demonstrating regulatory compliance of the corresponding package model. To do this, it must implement a quality management system covering all the operations from procurement of parts and raw materials up to final inspections. Furthermore, the manufacturer must be able to prove to ASN that it complies with the regulatory provisions and, in particular, that the as-built packagings are compliant with the specifications of the safety case.

The inspections carried out by ASN in this field aim to ensure that the manufacturer satisfactorily fulfils its responsibilities.

In 2023, ASN carried out ten 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.

INSPECTION ORGANISATIONS FOR TANKS AND UF_6 PACKAGINGS

In January 2023, ASN renewed the approvals for the organisations responsible for checking conformity, issuing approvals for tanks designed to transport radioactive substances, and checking the conformity of packagings containing UF_6. These approvals were issued further to a favourable opinion from the CSPRT. Only *Bureau Veritas Exploitation* and *Apave Exploitation France* hold five-year approval to carry out these operations.

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 2024, ASN intends to continue 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 is still finding shortcomings in the demonstration by some of the players (designers, manufacturers, distributors, owners, consignors, companies performing the regulatory drop tests, package maintenance, etc.) of package conformity with the regulations. The areas for improvement concern the following points in particular:
- the description of the authorised contents per type of packaging;
- the demonstration that there is no loss or dispersion of the radioactive content under normal conditions of transport;
- compliance with the regulatory requirements regarding radiation protection, more specifically the demonstration, as of the design stage, that it would be impossible to exceed the dose rate limits with the maximum authorised content.

4.2.4 Monitoring the shipment and transportation of packages

The scope of ASN inspections includes all regulatory requirements binding on each of the transport players, that is compliance with the requirements of the approval certificate or declaration of conformity, training of the personnel involved, implementation of a radiological protection programme, satisfactory stowage of packages, dose rate and contamination measurements, documentary conformity, implementation of a quality assurance programme, etc.

More particularly with respect to transports concerning small-scale nuclear activities, the ASN inspections confirm significant disparities from one carrier to another. The differences most frequently identified concern the quality assurance programme, actual compliance with the procedures put into place and radiation protection of the workers.

Knowledge of the regulations applicable to the transport of radioactive substances seems to be sub-standard in the medical sector in particular, where the procedures adopted by some hospitals or nuclear medicine units for package shipment and reception need to be tightened. Their quality management system has not yet been formally set out and deployed, more specifically with regard to the responsibilities of each member of staff involved in receiving and dispatching packages.

UNSCHEDULED EVENING INSPECTION OF A GAMMA INDUSTRIAL RADIOGRAPHY WORKSITE

On 7 September 2023, ASN inspectors went to a worksite where a non-destructive testing company was to check the weld on a district heating network pipeline using gamma radiography, in the 14th arrondissement of Paris. They observed the arrival of the vehicle containing the gamma ray projector. They noted the absence of external signage and placarding on the vehicle and, after the van was opened, the lack of correct stowage of the gamma ray projector. The orange plates and the regulation "7D" label-holders, along with the chains and padlocks intended for package stowage were however on-board the vehicle. As these numerous breaches constituted a class 5 violation, the gamma radiography company was cited in a report which was sent to the Public Prosecutor's Office.

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.

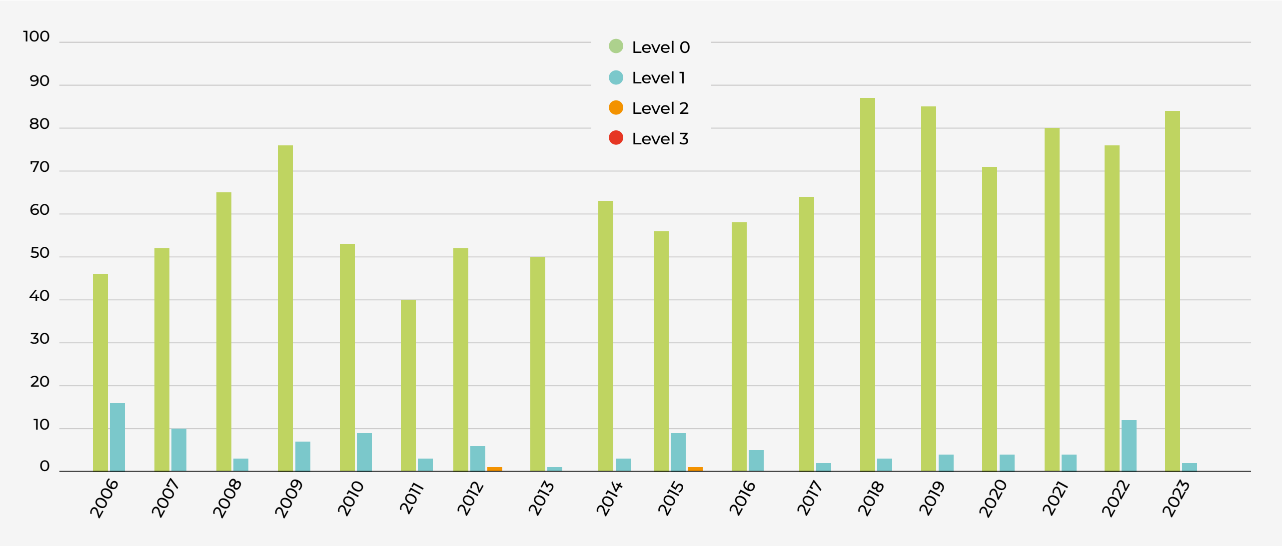
4.2.5 Analysis of transport events

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.

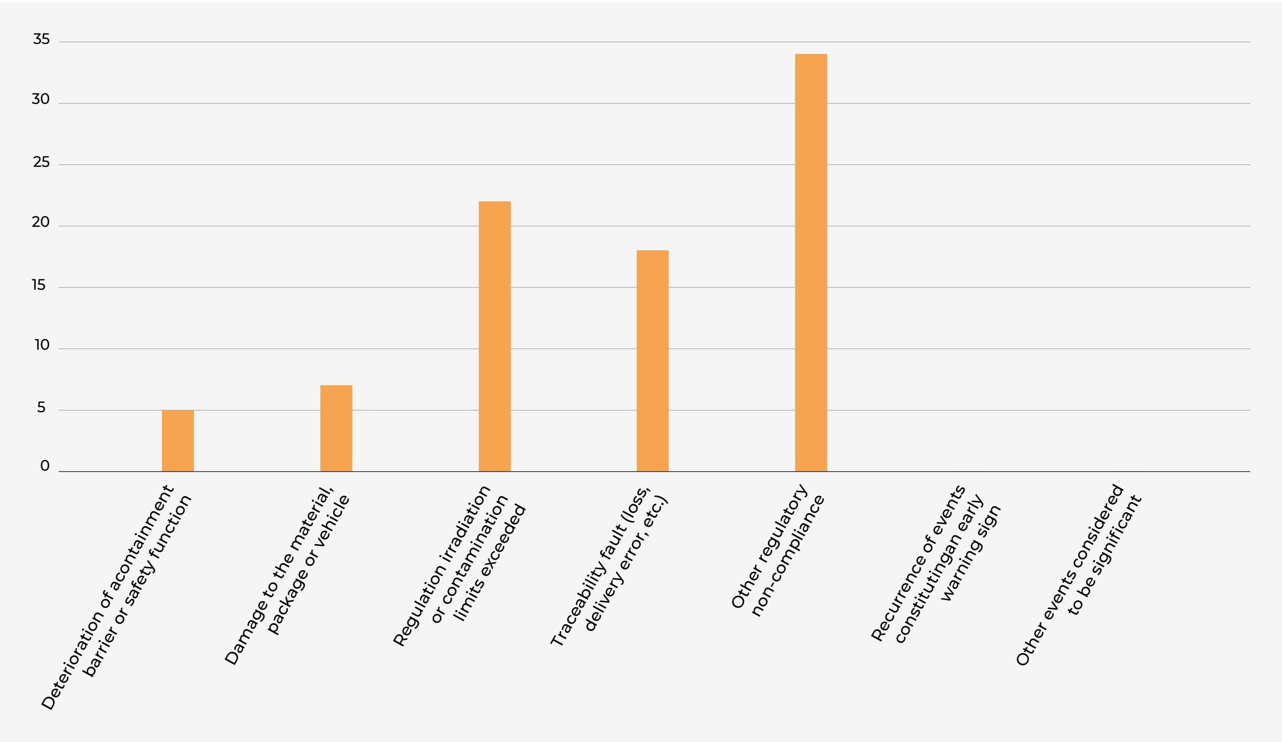
The regulations also require on-line notification to ASN of the most significant events so that they can ensure that the detection system, the analysis approach and the integration of Operating Experience Feedback (OEF) are effective. This also provides ASN with an overview of events so that the sharing 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.

GRAPH 4 **Trend in the number of significant events affecting the transport of radioactive substances notified between 2006 and 2023**



GRAPH 5 **Breakdown of significant events notified in 2023 by notification criterion**

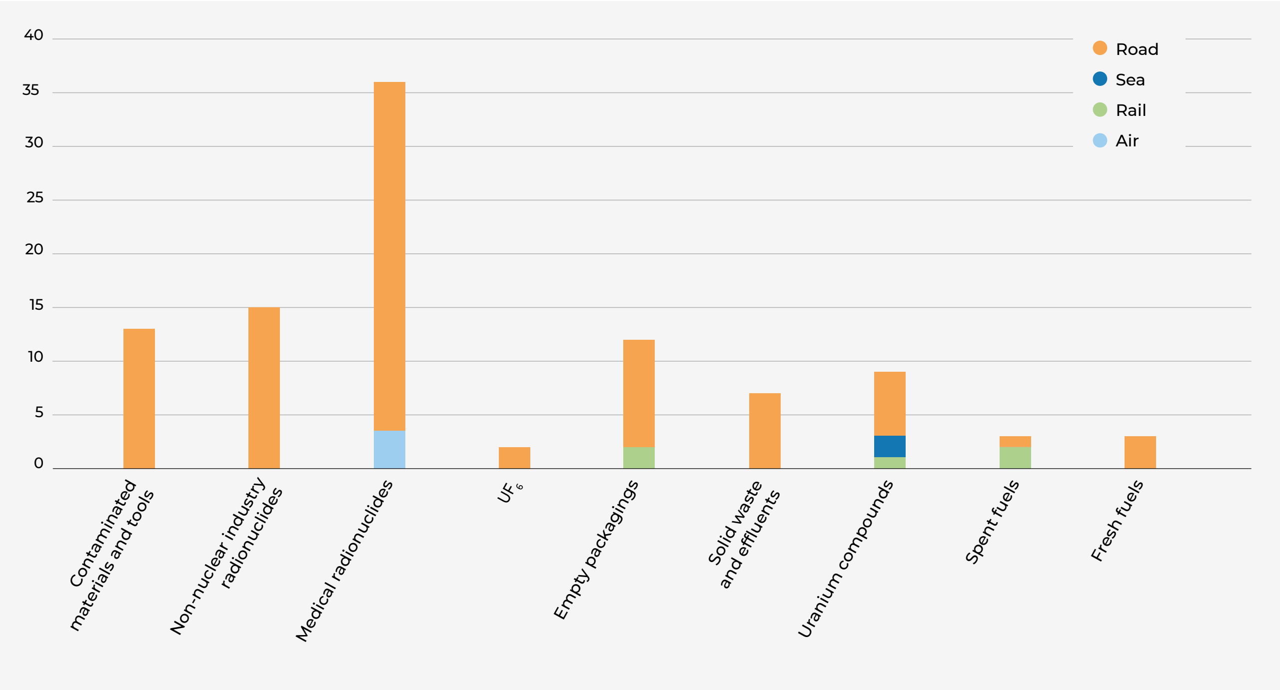


Events reported in 2023

In 2023, in the field of the transport of radioactive substances, ASN was notified of 84 events rated level 0 on the International Nuclear and Radiological Event Scale (INES scale) and 2 events rated level 1. A slight rise in the number of level 0 events is observed by comparison with 2022, whereas the number of level 1 events has significantly fallen. Graph 4 shows the variations in the number of significant events notified since 2006.

ASN was also notified of 61 Events of Interest for the safety of Transports (EITs), a figure which is slightly up on 2022. Because they have no actual or potential consequences, these events are not rated on the INES scale. There is thus no obligation to notify ASN, but the latter does encourage periodic information so that it has an overview of the EITs and can potentially detect any recurrence or trends which could be indicative of a problem.

GRAPH 6 **Breakdown of notified transport events by content and mode of transport in 2023**



Finally, with regard to on-site transports at nuclear sites, three events rated level 0 on the INES scale, and one level 1 event were notified in 2023. The number of events rated level 0 is stable by comparison with 2022. For the event rated level 1, this is the first one regarding on-site transports since ASN's on-line notification system was set up.

Sectors concerned by these events

As in 2022, most of the significant events notified concern the nuclear industry. Only 15% of the events are related to non-nuclear industry transports. In addition, by comparison with 2022, the number of transport events involving pharmaceutical products fell slightly: they account for 31% of significant events (as opposed to 38% in 2022).

The events rated level 1 on the INES scale in 2023 are:

- the theft of a low-level sealed radioactive source during transport was rated INES level 1, on the grounds of a lack of radiation protection culture;
- the second public highway transport event rated INES level 1 concerns failure to engage the five ball-lock pins participating in the closure system of the UX-30 overpacks containing a 30B cylinder loaded with UF_6. The grounds were non-compliance with the package model safety case;
- and finally, the last event rated level 1 on the INES scale concerns non-compliance with a regulatory limit for controlling the criticality risk during on-site transports.

None of these three 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 2023 include the following:

- nonconformities affecting the package: they primarily concern labelling faults (error or omission) or signalling faults and anomalies regarding the stipulations of the package model safety files. These events had no actual consequences for safety or radiation protection;
- the presence of surface contamination spots slightly exceeding the regulatory limits, detected on conveyances which have been used to transport spent fuel packages, gamma ray projectors or contaminated tooling, or on the outer surface of packagings. These events had very little impact on radiation protection of the workers but also of the public, who cannot have access to the contaminated areas;
- cases where the regulatory dose rate limit of the packages was slightly exceeded. These events had no actual consequences for the radiation protection of workers, the public or the environment;
- radiopharmaceutical products delivery errors, with no real consequences, as the products delivered are appreciably the same. Most of them could therefore be used with no impact on patient treatment or on the environment.

The EITs reported to ASN are primarily deviations relating to incorrect labelling (detachment or error) of packages and the detection of foreign objects in empty packagings.

As for the on-site transport significant events, these concern the absence of an internal lid on a container during transport, the recurrence of events concerning the 45g threshold of fissile material per package being exceeded, and a labelling error on a bottle transporting UF_6.

Participants in the IAEA TRANSSC Committee No. 47 – 6 to 10 November 2023

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 CSPRT, which is called on to issue an opinion on any draft regulation for the transport of dangerous goods by rail, road and inland waterway. ASN is also consulted by the Ministry responsible for transport when a modification of the three Orders mentioned above can have an impact on the transport of radioactive substances.

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_6, in order to provide mechanical and thermal protection during the regulatory 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_6 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 of the UX-30 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 extended 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 6kg powder or CO_2 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.

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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 (RNA). Article L. 125-10 of the Environment Code sets the thresholds beyond which the person responsible for transport must communicate the information requested by a citizen. The thresholds are defined as being those *"above which, in application of the international conventions and regulations governing the transport of dangerous goods, of the Code of Transport and of their implementing texts, the transport of radioactive substances is subject to the issuance – by ASN or by a foreign Authority competent in the field of radioactive substance transport – of an approval of the transport package design or a shipment approval, including under special arrangement"*. Any citizen may therefore ask the persons in charge of transport for information on the risks presented by the transport operations referred to in the Environment Code.

On *asn.fr*, ASN has also published an information file presenting the transport of radioactive substances.

4.5 PARTICIPATION IN INTERNATIONAL RELATIONS IN THE TRANSPORT SECTOR

International regulations are drafted and implemented as a result of fruitful exchanges between countries. ASN incorporates these exchanges into a process of continuous improvement in the level of safety of radioactive substance transports, and encourages exchanges with its counterparts in other States.

4.5.1 Work of the European Association of Competent Authorities on Transport

An 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.

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.

ASN PARTICIPATION IN THE PATRAM SYMPOSIUM IN 2023

The PATRAM (Packaging and Transportation of Radioactive Materials) symposium is the only international event specifically devoted to packagings and the transport of radioactive materials. Every four years, it attracts an average of 800 participants to plenary conferences, technical sessions or poster sessions. The purpose of this event is to bring together international experts from the industry and representatives of the competent authorities and research organisations for scientific and technical discussions on all aspects related to the packaging and transport of radioactive materials. The 18th edition of the PATRAM symposium was held at Juan-les-Pins (Alpes-Maritimes *département*) in France, from 11 to 16 June 2023. ASN chaired or co-chaired a few technical sessions and presented its positions on the regulations applicable to transports.

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; called *Agence fédérale pour le contrôle nucléaire* – AFCN – in French) 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 options dossiers and the checks on the requirements associated with the correct utilisation of these transport packages.

CONTENTS

10

The EDF Nuclear Power Plants

10

The electricity generating reactors are at the heart of the nuclear industry in France. Many other installations described in other chapters of this report produce the fuel intended for the Nuclear Power Plants (NPPs) or reprocess it, store thewaste from NPPs or are used to study physical phenomena related to the operation or safety of these reactors.

The French reactors are technically very similar and thus form a standardised fleet operated by EDF. Although this uniformity means that the licensee and 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 rigorousness 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. Its expanded scope of intervention means that at each stage, it examines the fields of nuclear safety, environmental protection, radiation protection, occupational safety and the application of social laws. For each of these fields, it monitors all aspects, whether technical, organisational, or human. This approach requires that it take account of the interactions between these fields and that it define its monitoring actions accordingly. The resulting integrated overview enables ASN to fine-tune its assessment of the state of nuclear safety, radiation protection, environmental protection and worker protection within the NPPs.

1 General information about Nuclear Power Plants

1.1 GENERAL PRESENTATION OF A PRESSURISED WATER REACTOR

By transferring heat from a hot source to a heat sink, an electricity generating thermal power plant produces mechanical energy that it converts into electricity. Conventional thermal power plants use the heat given off by the combustion of fossil fuels (fuel oil, coal, gas). NPPs use that given off by the fission of uranium or plutonium atoms. The heat produced in a Pressurised Water Reactor (PWR) leads to the creation of steam, which does not come into contact with the nuclear fuel. The steam is then expanded in a turbine which drives a generator producing a three-phase electric current with a voltage raised to 400,000 volts (V) by a transformer. After expansion, the steam passes through a condenser where it is cooled on contact with tubes circulating cold water from the sea, a water course (river) or an atmospheric cooling circuit. The condensed water is reused in the steam production cycle.

Each reactor comprises a nuclear island, a conventional island, water intake and discharge structures and possibly a cooling tower.

The nuclear island mainly comprises the reactor vessel, the reactor coolant system, the Steam Generators (SGs) and the systems ensuring reactor operation and safety: the chemical and volumetric control, residual heat removal, safety injection, containment spray, SG feedwater supply, electrical, Instrumentation & Control (I&C) and reactor protection systems. These elements are also associated with systems providing support functions: monitoring and processing of primary effluents, water supply, ventilation and air-conditioning, back-up electricity supply (diesel electricity generating sets).

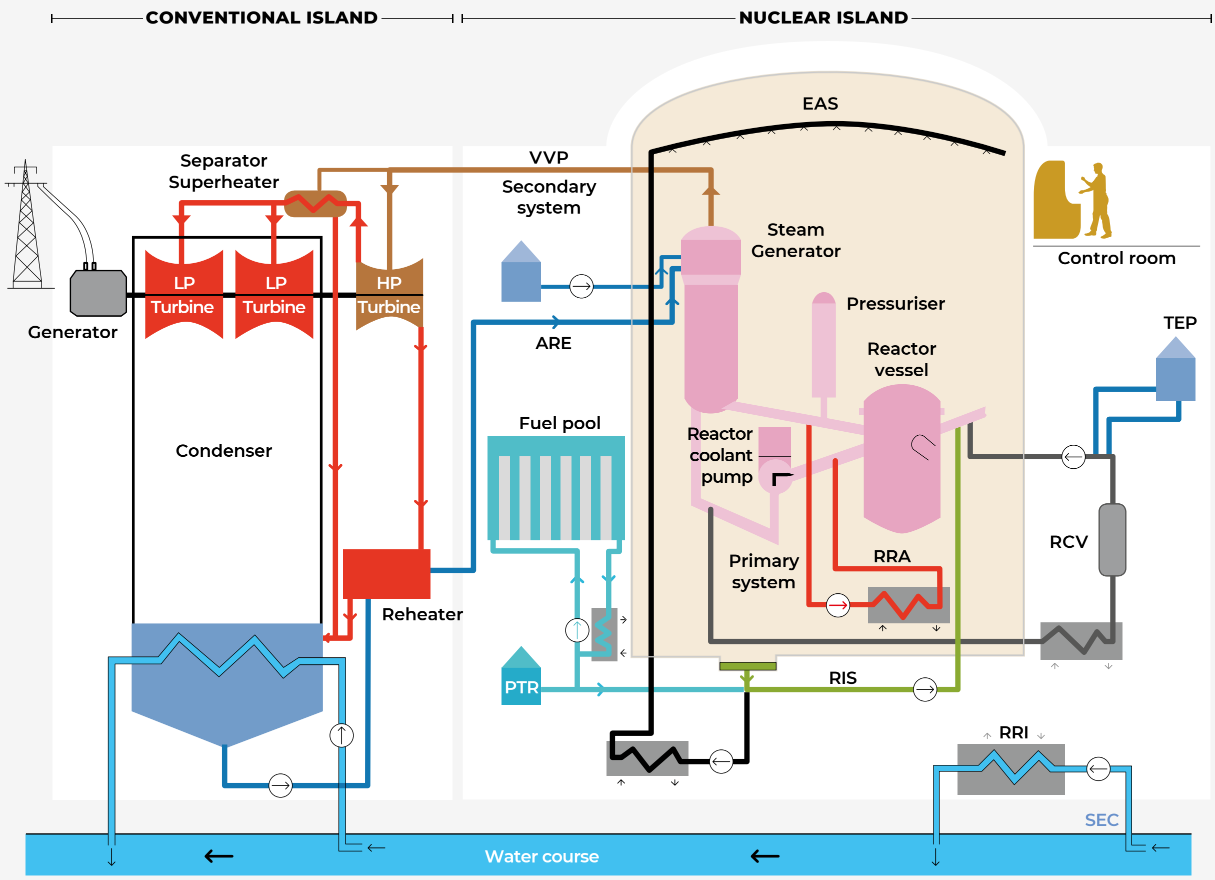
The nuclear island also comprises systems for the evacuation of steam to the conventional island, as well as the building housing the fresh and spent fuel storage and cooling pool (BK). When mixed with boric acid, the water in this pool helps absorb the neutrons emitted by the nuclei of the fissile elements in the spent fuel, to avoid sustaining nuclear fission, to cool the spent fuel and to provide the workers with radiological protection.

The conventional island notably comprises the turbine, the generator and the condenser. Some components of these items take part in reactor safety. The secondary system is partly in the nuclear island and partly in the conventional island.

1.2 SAFETY PRINCIPLES

The design of the nuclear reactors is based on safety principles aimed at ensuring the safety functions:
- control of core reactivity, that is control of the nuclear chain reactions;
- removal of the thermal power produced by the radioactive substances and nuclear reactions;
- containment of radioactive substances. The aim is to prevent the dispersal of radioactive substances into the environment and to protect people and the environment from ionising radiation.

Pressurised water reactor operating principle



ARE: Feedwater Flow Control System
ASG: Steam Generators Auxiliary Feedwater System
EAS : Reactor Building Containment Spray System
PTR : Reactor Cavity and Spent Fuel Pit Cooling and Treatment System
RCV : Chemical and Volume Control System
RIS : Safety Injection System
: Exchanger
RRA: Residual Heat Removal System
RRI: Component Cooling System
SEC: Essential Service Water System
TEP: Boron Recycle System
LP or HP turbine: Low-Pressure or High-Pressure Turbine
VVP: Main Steam Systems
: Pump

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_2) 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 uranium oxide and plutonium oxide (MOX). MOX fuel is produced by Orano's Melox plant. The maximum authorised plutonium content is currently set at 9.08% (average per fuel assembly) giving an energy performance equivalent to UO_2 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 (DACs) 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 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 bars by the pressuriser, to prevent boiling. The primary system is entirely situated within the containment.

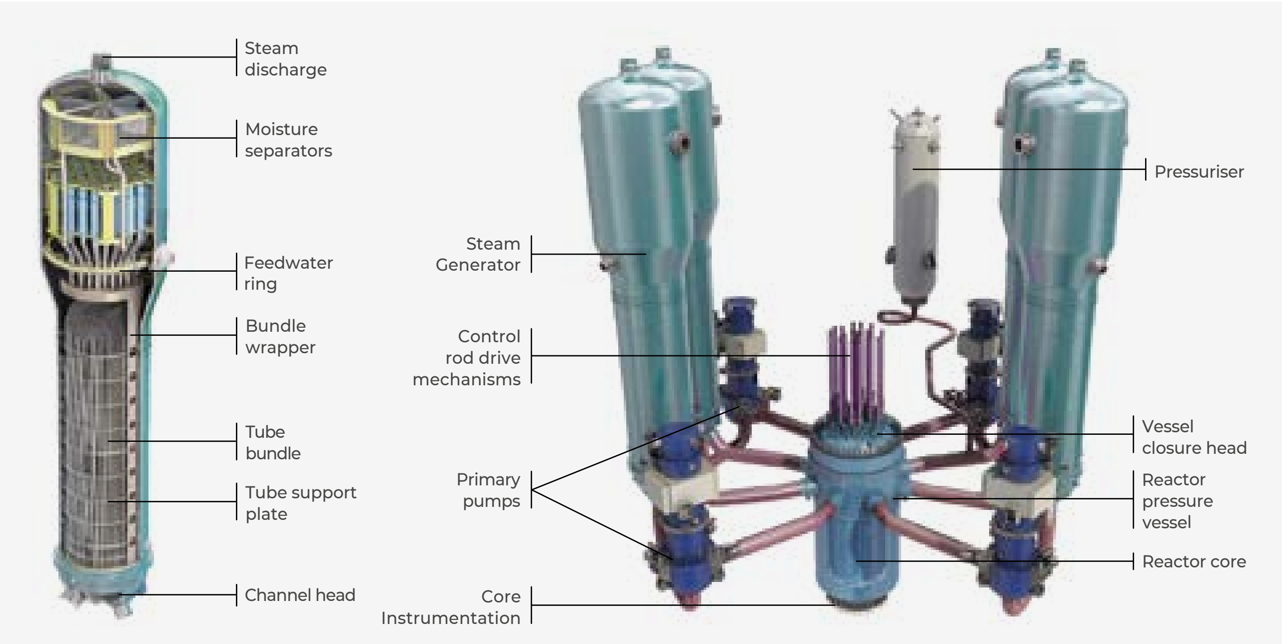
The primary system coolant transfers its heat to the water of the secondary systems in the SGs. The SGs are heat exchangers which contain from 3,500 to 6,000 tubes, depending on the model, through which the primary reactor coolant water circulates. These tubes are immersed in the secondary system water, 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.

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).

A steam generator and a main primary system of a 1,300 MWe reactor



Reactor containments

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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 nuclear reactor containment performs two functions:

- the containment of radioactive substances liable to be dispersed in the event of an accident; to do this, the containments were designed to withstand the temperatures and pressures that would result from a primary or secondary system rupture and to ensure satisfactory leaktightness in these conditions;
- reactor protection against external hazards.

There are three containment model designs:

- Those of the 900 MWe reactors comprise a single pre-stressed concrete wall (concrete comprising steel tendons tensioned to compress the structure in order to increase its tensile strength). This wall provides mechanical pressure resistance and ensures the integrity of the structure in the event of an external hazard. Tightness is provided by a metal liner covering the entire internal face of the concrete wall.
- Those of the 1,300 and 1,450 MWe reactors are made of two walls: the inner pre-stressed concrete wall and the outer reinforced concrete wall. Leaktightness is provided by the inner wall and by a Ventilation System (EDE) which, between the two walls, collects and filters residual leaks from the inner wall before discharge. Resistance to external hazards is primarily provided by the outer wall.
- That of the 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 (RIS), the role of which is to inject water into the primary system in the event of it leaking;
- the reactor building Containment Spray System (EAS), the role of which is to reduce the temperature and thus the pressure in the containment, in the event of a major primary system leak;
- the SGs Auxiliary feedwater System (ASG), which supplies water to the SGs if the normal feedwater system is lost, thus enabling heat to be removed from the primary system. This system is also used in normal operation during reactor outage or restart phases. After the Fukushima Daiichi NPP accident (Japan), the decision was taken to install a diversified water source, called the "ultimate water source", which can be used in an extreme situation to supply the SGs with water when the water reserves in the ASG system are empty and the various resupply solutions are no longer available.

1.8 THE OTHER SYSTEMS IMPORTANT FOR SAFETY

The other main systems important for safety and required for reactor operation are:

- the Component Cooling System (RRI) which cools a certain number of nuclear equipment items. This system functions in a closed loop between the auxiliary and safeguard systems on the one hand and the systems carrying water from the river or sea (heatsink) on the other;
- the Essential Service water System (SEC) which cools the RRI system with water from the river or sea (heatsink). This is a backup system comprising two redundant lines. In certain situations, each of its lines is capable of removing heat from the reactor to the heatsink;

- the Reactor Cavity and Spent Fuel Pit Cooling and Treatment System (PTR), which in particular removes residual heat from the fuel elements stored in the fuel building pool. The design of the ultimate water source installed in the wake of the Fukushima Daiichi NPP accident, can also – in an extreme situation – inject water into the fuel building pool, if the PTR system and the water make-up systems are lost;
- the ventilation systems, which ensure containment of radioactive materials by creating negative pressure in the rooms and by filtering discharges;
- the fire-fighting water systems;
- the I&C system, which processes the information received from all the sensors in the NPP. It uses transmission networks and sends orders to the actuators from the control room, through the programmable logic controllers or operator actions. Its main role with regard to reactor safety is to monitor reactivity, control the removal of residual heat to the heatsink and take part in the containment of radioactive substances;
- the electrical systems, which comprise sources and electricity distribution. The French nuclear power reactors have two external electrical sources: the step-down transformer and the auxiliary transformer. These two external sources are supplemented by two internal electrical sources: the backup diesel generators. In the event of total loss of these external and internal sources, each reactor has another electricity generating set comprising a turbine generator and each NPP has an ultimate backup source, the nature of which varies according to the plant in question. Finally, following the Fukushima Daiichi NPP accident, these resources were supplemented by an "Ultimate back-up" Diesel generator set (DUS) for each reactor.

2 Monitoring the nuclear safety of the reactors in operation

2.1 FUEL

2.1.1 Fuel in the reactor

The leaktightness of the cladding of the fuel rods, tens of thousands of which are present in each core and which constitute the first containment barrier, receives particularly close attention.

In normal operation, leaktightness is monitored by EDF through permanent measurement of the activity of the radionuclides contained in the primary system. Any significant increase in this activity is a sign of a loss of leaktightness in the fuel assemblies. If the activity of the primary system exceeds a predetermined threshold, the General Operating Rules (RGEs) require shutdown of the reactor before the end of its normal cycle.

At each outage, EDF is required to search for and identify the assemblies containing leaking rods: reloading of fuel assemblies containing leaking rods is not authorised.

EDF conducts examinations of leaking rods in order to determine the origin of the failures and prevent them from reoccurring. The preventive and corrective measures may concern the design of the rods and assemblies, their manufacture or the reactor operating conditions.

The conditions of fuel assembly handling, of core loading and unloading, as well as prevention of the presence of foreign objects in the systems and pools are also covered by operating specifications, in order to prevent the risks of fuel rods leaking.

2.1.2 Assessment of the condition of the fuel in the reactor

In 2023, all the NPPs satisfactorily managed the integrity of the first barrier, consisting of the fuel rod cladding.

There were fuel leaktightness defects in three reactors. This figure is very low, notably as a 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 held with EDF on the subject of the generalised corrosion of certain M5 alloy fuel cladding, enabled the compensatory operational measures implemented over the past few years to be lifted for all the reactors following justification. Pending the generalised use in all the reactor cores of cladding with an increased iron content, which could prevent this type of corrosion, EDF is maintaining measures to monitor the fuel at each unloading and each selection of assemblies for the next cycles.

In addition, errors with calibration or parameter settings in the IT applications monitoring the core were brought to light in 2023. Most of these errors were down to human factors (forgetfulness, use of incorrect procedure). They had no consequences for either humans or the environment.

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 must define and apply the provisions that enable it to demonstrate compliance with these requirements.

The industrial firms, EDF and Framatome in particular, initiated major changes to their industrial processes in 2015 to 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 NSSS Design, Construction and Monitoring Rules (AFCEN), which involves the majority of the profession. The work done led to the AFCEN publishing methodology guides and several revisions of the RCC-M code (design and construction rules for mechanical equipment of PWR nuclear islands), on which ASN issued a position statement. ASN in particular recognised that the 2018 edition of the RCC-M code was on the whole appropriate. This position statement will soon be updated and supplemented by a position statement on the 2020 edition.

AFCEN's work also led to the definition of a process to incorporate OEF into the RCC-M, and this is currently being reviewed by ASN. This is an essential area of work for the profession, in that this code is to be used as the basis for the design and manufacture of all the NPE for the EPR 2 programme.

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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 for 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 NPE. It involves 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 2023, with regard to NPE design and manufacture, the approved organisations carried out about 5,000 checks on the NPE intended for the Flamanville EPR reactor and about 5,200 checks on the replacement NPE intended for the NPP reactors in operation. These checks are performed under ASN supervision.

In 2023, Framatome reinforced its quality improvement actions in its three plants, as part of the start of the EPR 2 programme. Framatome and EDF continued to deploy an approach to monitor the most sensitive industrial processes, such as the welding and heat treatment processes, along with supplier approval, evaluation and surveillance. Through its inspections, ASN assessed the results of these actions. It underlines the scale of the programmes implemented.

Similarly, Westinghouse continued to apply its quality system and internal surveillance improvement plan in its SG manufacturing plant in Italy. As a result of the progress made, ASN considers that the particular surveillance in place in this plant can be lifted.

ASN also finds that the approved organisations, the manufacturers and the licensees are currently deploying organisations and resources in their structures for preventing and detecting fraud. Although progress has been observed in this respect, the actual implementation of these action plans still needs to be continued by all stakeholders in the sector.

2.2.3 Operation of Nuclear Pressure Equipment

The reactor MPS and MSS, which contribute to the containment of the radioactive substances, to cooling and to controlling reactivity, operate at high temperature and high pressure.

The monitoring of the operation of these systems is regulated by the Order of 10 November 1999 relative to the monitoring of operation of the MPS and the MSS of PWRs. These systems are thus the subject of monitoring and periodic maintenance by EDF.

These systems are subject to periodic requalification 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.

Some of the safety issues of the components of the primary or secondary systems are detailed below.

The reactor pressure vessels

The reactor pressure vessel is an essential component of a PWR and contains the reactor core and its instrumentation.

In normal operating conditions, the vessel is entirely filled with water, at a pressure of 155 bars 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 some of the reactors of the French fleet comprises several austenitic-ferritic stainless steel cast elbow assemblies. The ferritic phase of this steel 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.

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 the Stress Corrosion (SC) phenomenon. 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.

ANOMALIES LINKED TO CARBON SEGREGATIONS IN CERTAIN STEAM GENERATOR CHANNEL HEADS

In 2016, the carbon segregation anomaly in the Flamanville EPR reactor vessel revealed that the SG channel heads on 17 EDF reactors were also concerned by the issue. These channel heads were manufactured by the Creusot Forge plant and the Japan Casting and Forging Corporation (JCFC).

Following this discovery, EDF carried out non-destructive tests on the channel heads concerned, notably those prescribed by ASN on 18 October 2016. These inspections were completed in early 2017. They demonstrated that the reactors concerned could be kept in service.

In addition, a wide-ranging programme of tests was carried out between 2017 and 2021 on channel heads representative of the components in operation on the French reactors, in order to confirm the design hypotheses. ASN convened the Advisory Committee of Experts for Nuclear Pressure Equipment (GPESPN) on 17 November 2023 for a ruling on EDF's conclusions, the results of the thermohydraulic, chemical and metallurgical analyses and the mechanical tests carried out. These data indicate that the mechanical properties of the steel are not affected by the carbon segregation in the channel heads manufactured by JCFC. With regard to the channel heads manufactured by the Creusot Forge plant, the hypotheses adopted by EDF regarding a reduction in the mechanical properties, to take account of the presence of segregation, were considered to be sufficiently penalising. These calculations confirmed the serviceability of these channel heads.

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 reviewed by ASN, which verifies that the performance and frequency of the checks put into place 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.

Since the 1990s, EDF has been running a programme to replace those 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 reactors in which the tube bundle is made of heat treated Inconel 600 (22 reactors are still concerned).

2.2.4 Assessment of operation of Nuclear Pressure Equipment

Monitoring the operation of reactor main primary and secondary systems

ASN considers that EDF's surveillance of the operation of the MPP and MPS, which constitute the reactors' second containment barrier, remains a point warranting particular attention. 2023 was again particularly marked by the SC phenomenon affecting the auxiliary lines of these systems (see box next page). This phenomenon illustrates the point that unexpected degradation modes can appear on these systems, including in the absence of international OEF on similar phenomena.

THE PRINCIPLES OF THE REACTOR VESSELS IN-SERVICE STRENGTH DEMONSTRATION

The risk of fast fracture of a reactor pressure vessel depends on the joint presence of three factors: the presence of a flaw (such as a crack), thermomechanical loading and insufficient mechanical strength of the material.

The analysis of the fast fracture risk on the reactor pressure vessels therefore comprises the following steps:
- a determination of the dimensions of the flaws to be studied;
- evaluation of the characteristics of the material, taking account of steel embrittlement under the effect of irradiation;
- evaluation of the loadings liable to initiate the flaw, in all reactor operating situations (normal or accident).

The analysis approach to the risk of fast fracture consists in comparing the peak fault load with the mechanical strength of the irradiated material. Safety coefficients are considered at this stage. This approach is applied, considering both the existing flaws detected and a hypothetical flaw, corresponding to the largest crack that cannot be detected by the non-destructive tests performed and positioned at the location where the material is the most embrittled by irradiation.

The implementation of the in-service surveillance programmes on these systems, along with their adaptation to take account of changing OEF and knowledge of degradation modes, are thus the subject of particular attention by ASN. In this respect, ASN is attentive to ensuring that EDF uses appropriate non-destructive test means for which performance has been qualified, and that it carries out reactive inspections, which may not necessarily be qualified, to obtain greater knowledge of particular risks.

The reactor pressure vessels

During the periodic safety reviews, ASN examines the demonstration of the in-service strength of the reactor pressure vessels every ten years. The generic approach implemented by EDF is to use a worst-case approach to verify that all the vessels of a type of reactor offer sufficient resistance to fast fracture, taking account of the loads to which they are subjected in operation (whether during routine, incident or accident operating situations) and their embrittlement under irradiation. During this phase, account is taken of the mechanical properties of each vessel and the presence of a hypothetical flaw positioned in the worst possible place. For vessels with particular flaws, EDF also checks the mechanical strength of these flaws.

Following its review, ASN reached a favourable conclusion regarding the ability of the 900 MWe reactor vessels to continue to function until their fifth ten-yearly outage. It is currently examining the justifications provided by EDF for the pressure vessels of the 1,300 MWe reactors.

During the ten-yearly outage inspection of each reactor, EDF also carries out checks to ensure that the existing flaws have not developed further, or that prejudicial flaws have not appeared in the steel of the vessels. It also carries out a hydraulic pressure test of the primary system.

ASN issues reports following the checks carried out during each ten-yearly outage inspection of the primary system, and in particular with regard to the pressure vessels. In 2023, the results of the checks carried out were satisfactory.

Cast elbow assemblies

The files produced by EDF to justify maintaining the cast elbow assemblies and nozzles of the primary system in service beyond the fourth ten-yearly outage of the 900 MWe and 1,300 MWe reactors were reviewed by ASN. In order to support its position regarding this approach, ASN convened the GPESPN Advisory Committee on two occasions. The review concluded that virtually all the elbow assemblies can be kept in service at least until the fifth ten-yearly outage. It focused in particular on the case of a few elbow assemblies that would be hard to replace. Only the case of one elbow assembly on Paluel NPP reactor 2 needs to be examined further. EDF must propose a strategy to justify continued operation of this elbow assembly.

Following this analysis, ASN asked EDF to continue with its investigations regarding the possibility of removing, repairing and performing non-destructive test on the most sensitive elbow assemblies, in order to define a strategy sufficiently well in advance of the fifth ten-yearly outages for the elbow assemblies which could not be justified for operation beyond that date.

The Steam Generators

For ASN, the situation of the SGs remains a point for particular attention in 2023. The significant fouling detected in certain SGs, liable to alter their operating safety, entails the scheduling of preventive cleaning. Maintenance in order to guarantee satisfactory cleanness has been insufficient in the past and should now be considered 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.

RESULTS OF EDF ANALYSES AND REPAIRS AND ASN IN-DEPTH INSPECTIONS SINCE THE DISCOVERY OF STRESS CORROSION CRACKS

In 2023, EDF continued to deploy the action plan defined following the discovery of SC cracks at the end of 2021. EDF continued to mobilise significant resources to identify the causes and carry out checks on the reactors and repair the lines affected.

EDF thus continued to implement the in-depth inspection and appraisal programme which had been started in 2022 on the different types of reactors. Part of this programme is devoted to welds which were repaired during manufacturing and which are liable to be subject to greater risks. 301 welds were therefore inspected in 2023, and 170 were repaired. Inspection of these welds revealed four large cracksxwhich could have led to a risk of leaks in the event of high mechanical loading.

In parallel with this inspection programme, the lines felt to be most susceptible to the SC phenomenon were replaced. Thus, the cold leg safety injection lines on the P'4 type reactors underwent this work in 2023.

In 2023, the inspection programme also revealed the presence of a few thermal fatigue cracks on the same types of lines. EDF drew up an investigation programme in order to improve the understanding of the SC phenomenon itself, but also the competition between this phenomenon and thermal fatigue. The inspection programme is compatible with the detection of the two phenomena.

ASN continued its monitoring of the action taken by EDF. By the end of 2023, it had carried out more than 65 inspections devoted to this issue since the end of 2021. These inspections notably took place as part of the lines verification or replacement operations in the EDF engineering departments, in the NPPs and at its subcontractors.

ASN also continued its discussions with its foreign counterparts, some of whom carried out inspections on this same subject.

By the end of 2025, EDF will have checked the RIS and RRA systems lines on all of its reactors. In 2024, it will expand its inspections to the repaired welds on the other lines connected to the MPS.

With the technical support of the French Institute for Radiation Protection and Nuclear Safety (IRSN), ASN will remain focused on this issue in 2024 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.

The latest information on the subject is available on *asn.fr*.

SG replacement operations are scheduled at the rate of one reactor per year over the coming years, starting in 2024.

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 P'4 reactors, in the immediate vicinity of certain welds. They led to a very large number of destructive assessments and repairs (see box previous page).

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).

Other equipment takes part in the containment function, such as the systems for accessing the interior of the containment (airlocks and equipment hatch), the circuit depressurising the annulus between the double-wall containments or the control room ventilation system.

2.3.2 Assessment of the containments

Overall management of the containment function
EDF's management of the containment function is on the whole relatively satisfactory. ASN however still observes occasional but recurring unavailabilities affecting certain equipment participating in the containment function. These unavailabilities notably concern the containment penetrations pressurisation system and leak monitoring system, as well as the control room ventilation system.

Since 2014, EDF has 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 equipment and ducts. As necessary, EDF carries out repairs and improvements and adjusts the ventilation flow rates. The final phase of this national action plan includes a programme to ensure the lasting nature of the adjustments made. ASN will issue a position statement in 2024 on the pertinence of this programme.

Single-wall containments with an internal metal sealing liner
The ten-yearly tests on the 900 MWe reactor containments carried out since 2019 as part of their fourth ten-yearly outages did not bring to light any generic problems liable to compromise their operation.

In 2023, five single-wall containment reactors carried out their containment tests and the results were satisfactory.

Double-wall containments
The tests on the double-wall containments performed during the first ten-yearly outages of the 1,300 MWe reactors detected a rise in the leak rate from the inner wall of some of them, under the combined effect of concrete deformation and a loss of pre-stressing of certain tendons, that was greater than anticipated at the design stage.

EDF then initiated major work consisting in locally applying a resin sealing coating to the interior and exterior surfaces of the inner wall of the containments of the most severely affected 1,300 MWe reactors, as well as to the 1,450 MWe reactors.

For all the reactors on which it was carried out, this work enabled the leak rate criteria to be met during the containment pressure tests.

On Civaux NPP reactor 1, a sealing coating was applied to a large part of the inner containment. Despite this work, the leak rate found during the second ten-yearly outage test remained high, although lower than the specified criterion to be met. This is why ASN will remain vigilant with regard to changes in the situation of this containment and, more broadly, to changes in the leaktightness of all the containments and to maintaining the long-term effectiveness of the coatings.

2.4 ORGANISATION FOR REACTOR OPERATIONS

2.4.1 Reactor operations

The Order of 7 February 2012 stipulates that the licensee must have the technical skills needed to manage the activities involved in operation. Furthermore, this Order requires that the licensee define and implement an Integrated Management System (IMS) to ensure that the requirements concerning nuclear safety and protection of the environment are systematically considered in any decision concerning the facility. This IMS must specify the steps taken with regard to organisation and to resources of all kinds, in particular those adopted to control the activities important for the protection of persons and the environment.

Normal operation
The EDF NPPs are permanently monitored from a control room by a control team which is also in charge of controlling the installations.

The operating limits within which the teams must keep the installation are defined in the RGEs. The licensee ensures that this is done using normal operation documentation, in particular the operating instructions and alarm data sheets. The licensee is regularly required to modify the installation's configuration to allow intervention by the maintenance crews, to test the availability of a system or to change the status of the reactor.

Tests are regularly performed to check the correct working of the systems which could be required in an incident or accident situation and to check the correct behaviour of the reactor's core. Some tests are performed with the reactor operating, while others can only be carried out during reactor outages. The control teams perform some of these tests themselves, while others require intervention by specialised teams.

Operation in the event of an incident or accident
The operating strategies and practices to be implemented in an incident or accident situation are developed in various documents (operating rules and instructions) placed at their disposal. They specify what action is to be taken by the control team. To manage these situations, the organisation of the control team changes and each person has a specific role. The control teams are regularly trained in the implementation of these control strategies.

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In addition to the control strategies, an On-site Emergency Plan (PUI), implemented by the emergency crews, is triggered to help the control teams in incident or accident situations with a risk of consequences for outside the site.

Following an accident, if the safety functions (control of reactivity, cooling and containment) are not guaranteed owing to a series of failures, the situation is liable to develop into a severe accident with severe fuel damage. When faced with such situations, the installation control strategies place emphasis on preserving the integrity of the containment in order to minimise releases into the environment. The implementation of these strategies mobilises the expertise of the local and national emergency teams.

2.4.2 Assessment of reactor operations and operational documentation

ASN reviews the content of the RGEs before they are implemented and checks that they are correctly applied by means of inspections.

More broadly, it ensures that the measures taken by EDF for operation of the reactors are appropriate to the risks created by this operation.

ASN focuses on the conditions which are favourable or prejudicial to the contribution to NPP safety by the operators and worker groups. It defines Organisational and Human Factors (OHFs) as being all the aspects of working situations and the organisation which have an influence on the work done by the operators.

The general organisation

The organisation set up by EDF to control risks is on the whole satisfactory but could still be improved in a few NPPs. In particular, ASN regularly observes that OEF is insufficiently taken into account and that the risk assessments prior to the activities need to be improved. Changes are thus required in terms of preparation of activities. The managerial echelons need to be involved on this subject if concrete, satisfactory results are to be obtained.

The shortcomings identified in recent years regarding coordination between disciplines and projects or within the maintenance departments, continued in 2023. The faults observed are often linked to complex organisations, to the large number of parties involved, to undefined or informal interfaces between the entities (shift changes, relations between the shift crews or between the licensee and the contractors), geographical remoteness and failure to plan ahead for concomitant activities.

Normal operation

During its NPP inspections, ASN notably verifies that the licensee complies with the RGEs and, if applicable, the compensatory measures associated with any temporary modifications. It also checks the consistency between the control documentation and any modifications that have been made to the installations. It also ensures that the procedures used to configure the systems or lock out equipment do actually take account of the requirements arising from the RGEs.

Finally, it is attentive to the good understanding and correct application of these various documents by the control teams and the correct management of sensitive activities, which are regularly the cause of anomalies. To do this, it holds interviews with the control teams and attends operations needed for the NPPs to function.

Failures to comply with the RGEs constitute significant events which are to be reported to ASN. ASN analyses the origin and consequences of these events and, during its inspections, checks that measures have been taken by the licensee to correct the deviations and prevent them from happening again.

In terms of reactor operations and control, ASN considers that performance improved in 2023. The action plans covering operational rigour initiated in recent years by the NPPs appear to be effective. The number of situations for which the reactors were operated outside the prescribed limits remained stable in 2023, even though industrial activity was denser than in 2022 (which was reduced owing to management of SC on many reactors). ASN however finds that the quality of monitoring in the control room once again deteriorated in 2023. ASN reinforced its inspections on the topics of systems configuration management (see box page 301). Even if it observed a fall in the number of Significant Safety Events (ESS) in 2023, linked to systems configuration errors, ASN considers that the management of systems configurations needs to be improved.

GENERAL OPERATING RULES

The RGEs are one of the items making up the commissioning authorisation application for a nuclear reactor. They present the provisions the licensee intends to implement to operate its installation in compliance with the safety case. They notably specify the rules to be followed in normal operation, the periodic tests to be carried out and the control operations required in an incident or accident situation.

The operating technical specifications included in the RGEs define the parameters required in normal operation. They identify the systems essential to maintaining the safety functions and specify what to do in the event of momentary unavailability of a required system or if a limit is exceeded.

With regard to periodic tests, the RGEs detail the checks to be carried out, their frequency, and the criteria for acceptance of the results. Tests are notably required to verify that the reactor core is in conformity with the design baseline requirements and the safety case, as well as to calibrate the automatic control and protection systems.

The incident or accident situation control procedures, which are included in the RGEs, detail the steps to be taken by the control teams in these situations in order to restore normal operation or, in the event of an accident, to return the installation to a safe state and limit its consequences.

EDF regularly updates these documents in order to incorporate OEF and take account of the modifications made to the reactors. Temporary amendments can also be made. They require justification and the definition of compensatory measures to control any associated risks. Depending on their significance, RGEs noteworthy modifications that could affect the safety of the installation require either submission of an authorisation application to ASN or notification to ASN before they are implemented.

ASN checks that the periodic tests of safety-important equipment items do effectively check their operation and level of performance. It carries out this verification during the review of RGE modification authorisation applications. During inspections, it also verifies that these periodic tests are carried out in accordance with the test programmes stipulated in the RGEs.

As in previous years, the periodic tests were the origin of several ESS. The main causes of these significant events are incorrect specification of the test rules in the operating documents, errors in application of the test procedure when performing tests, inconsistencies between documents, or periodic test programming errors.

Further to OEF from these events, EDF is adapting its organisations to ensure better sharing of information between the various actors responsible for defining, programming and carrying out tests.

Skills management

In 2022, ASN ran an inspection campaign on the skills management of the teams in charge of operating the installations. In 2023, it again carried out inspections on the sites it considered to be in the greatest difficulty and saw improvements in the working of the training departments (team reinforcements, revitalization of training and skills committees, clarity and relevance of processes, increase in training equipment). Persistent weaknesses in the skills acquisition process for operating personnel were however still observed during the inspections or during analysis of significant events, which raises questions regarding the effectiveness and scope of the training. ASN observed frequent use of self-training through on-line e-learning, or by means of a questionnaire for refresher courses. Practical work in the field is limited or completely absent with this type of arrangement. Shortcomings in mentoring of newcomers is also observed.

In 2023, ASN also observes a continued lack of mentoring and training 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 operational documentation

In 2023, as in previous years, the significant event reports regularly spotlight insufficient documentation quality. This has been an underlying problem for a number of years. The difficulties identified are of various types (documentation not concise enough, not explicit, incomplete, or even non-existent). This situation 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). Operational documentation faults impair the effectiveness of the documentation as a line of defence.

These recurring anomalies in the operational documentation remain to a large extent linked to organisational problems. Failures in oversight of the documentary management process are present at all steps in the lifecycle of the documents, from identification of requirement up to document archival.

The Independent Safety Organisation

During its inspections, ASN examines the actions of the Independent Safety Organisation (FIS – see box below) and checks that its opinions are correctly taken into account by the operational departments. The inspectors found that the FIS on the various sites inspected in 2023 were competent, functional and independent. Some sites are still experiencing resourcing problems, as the number of safety engineers is sometimes lower than the number required for lengthy periods. EDF took steps to ensure that there would be sufficient numbers of safety engineers in the future, so that they can calmly perform their independent verification of reactor safety.

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 2023 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 2023, 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. During the situational exercises, ASN nonetheless found that the operating documents still contained errors and inaccuracies, even though regular checks are normally scheduled to prevent these anomalies. ASN therefore remains attentive to ensuring correct implementation of the processes to verify the operating documents and process the anomalies detected. ASN also found errors in application of the procedures during certain transient incidents. EDF must analyse the origin of these application errors and, if necessary, modify the documentation, the organisation or the training of the parties involved, so that they do not happen again.

Emergency organisation

When the situation in the installation deteriorates or additional means are needed to manage the situation, the incident or accident operating procedures provide for activation of the PUI, which leads to deployment of an emergency organisation.

THE INDEPENDENT SAFETY ORGANISATION

At EDF, the Independent Safety Organisation (FIS) verifies the actions and decisions taken by the departments in charge of operating the installations, from the viewpoint of safety. On each NPP, the FIS comprises safety engineers and auditors, who notably 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.

INSPECTION CAMPAIGN ON THE CONTROL OF SYSTEM CONFIGURATIONS

Ensuring the correct configuration of the hydraulic and electrical systems of nuclear reactors contributes to the safety of the installations. Controlling the configuration of systems covers line connection activities (configuration of a set of devices enabling a system to function in the way it was designed, or meet a particular operating objective), lock-out (configuration of a set of devices in defined and locked positions in order to guarantee the required safety conditions for maintenance work) and administrative lock-out (physical immobilisation of a set of devices, which must be kept in this position for the safety of the installation).

At the end of 2022, ASN observed a rise in the number of line connection and lock-out errors, compromising the safety of the installations or leading to risk of personnel accidents. It therefore decided to run a campaign of inspections to check the steps taken by the licensees to ensure the correct configuration of the systems in the installations.

In 2023, ASN carried out ten dedicated inspections. On each NPP inspected, ASN examined the oversight of all the processes contributing to control of systems configuration. The inspectors also carried out checks on the conformity of the configurations of the installations and were able to observe the performance of certain activities. Finally, the inspectors conducted explanatory interviews with the personnel in charge of these activities.

These inspections revealed the quality of the monitoring of the processes related to these topics by the bodies concerned in the NPPs. However, the inspectors identified several subjects requiring improvement on the part of EDF.

Errors in preparation and a lack of rigour in the assimilation and performance of the activities are major contributors to systems configuration faults. Some workers also experience difficulty in perceiving the potential safety impact of incorrect performance of certain actions on the equipment.

ASN favourably noted the reactivity of certain sites which, being aware of their problems, implemented action plans notably to safeguard the time allotted to preparation and performance of the activities.

This inspection campaign also identified a lack of coordination between the teams in charge of installation maintenance and those in charge of its operation. The operations teams are regularly called on to configure systems so that the maintenance teams can carry out their work safely. In some cases, these maintenance operations are not in fact actually carried out. In a situation such as this, equipment is unnecessarily made unavailable whereas it could have been of use in managing an incident or accident.

After each of these inspections ASN sent improvement requests to EDF. This campaign will continue in 2024 to cover all the NPPs.

In 2023, four NPPs activated their emergency organisation, described in the PUI:
- for a fire in the controlled area of the Cattenom NPP, on 3 March;
- for a fire outside the controlled area, that is in an industrial building containing no radioactive substances, on three occasions: on 14 April in the Flamanville NPP, on 30 July in the Bugey NPP and on 17 October in the Blayais NPP.

These four situations had a limited impact inside the installation and required no population protection measures.

In 2023, in order to test the emergency organisation of EDF and the public authorities, ASN took part in national exercises. Four exercises of this type were held on a number of NPPs (Saint-Laurent-des-Eaux, Golfech, Chooz and Nogent-sur-Seine) and were able to test the emergency organisation on these sites and the exchanges with the authorities.

ASN also carried out several inspections on the EDF emergency organisation and resources. These inspections, some of which are based on unscheduled situational exercises leading to activation of the site's emergency organisation, were also an opportunity to test the operational nature of the system on specific subjects (resilience of the organisation, emergency premises equipment, documentation, training, etc.). Overall, these exercises and inspections demonstrated that the EDF sites have assimilated the principles of organisation, preparedness and management of emergency situations to the extent that they can take the required action in the event of an emergency. ASN also underlines the professionalism and motivation of the on-call personnel mobilised. However, EDF will have to continue its efforts to maintain the good operational condition of certain equipment that could be called on in an emergency and must be more vigilant with respect to the work done in the emergency premises or in the vicinity of equipment needed in an emergency. Finally, EDF must continue its efforts regarding preparedness for emergency situations of non-radiological origin.

2.4.3 The Operating Experience Feedback process

It is essential for EDF to take account of OEF from the operation of its installations and those of other licensees if safety is to be continuously improved. This is based on the collection and analysis of events.

Significant events are analysed individually. This analysis aims to identify their root causes and the changes required to prevent them from happening again. Analyses of trends and weak signals are regularly performed by EDF to identify the deterioration of installations safety as far upstream as possible.

EDF pays particular attention to detecting and analysing potentially generic significant events detected on one reactor, but which could affect others.

2.4.4 Assessment of the Operating Experience Feedback process

The Operating Experience Feedback process

ASN analyses the significant event notifications and reports transmitted by EDF to ensure that they are pertinent. It also carries out inspections on the NPPs to ensure that the OEF process is correctly implemented.

The quality and availability of the resources assigned to the in-depth analyses of significant events are satisfactory on all the sites, which is a positive point. With regard to technical aspects, the analyses reveal that the apparent causes and the root causes are correctly identified and dealt with using appropriate measures. ASN considers that EDF needs to make further progress on evaluating the effectiveness of the corrective measures and the conditions for closure of these measures. Building on lessons learned and sharing OEF remain points to be monitored.

With regard to investigation of causes in terms of OHF, ASN considers that the analyses all too often simply focus on human failures without sufficiently investigating the influence of the working situation or the organisational processes involved. Even if improvements have been observed since 2022 in the ESS analyses, the involvement of OHF specialists differs widely and is insufficient on several sites.

Notification of significant events by EDF

Pursuant to the rules for the notification of significant events (see chapter 3, point 3.3), ASN received 714 Significant Safety Events (ESS) reports from EDF in 2023, along with 140 Significant Radiation Protection Events (ESRs) reports and 46 Significant Environmental Protection Events (ESEs) reports. The number of significant events rose by about 2.4% in 2023 by comparison with the previous year, in particular the ESS (740 in 2020, 762 in 2021, 687 in 2022).

Graph 1 presents the trend in the number of significant events notified by EDF and rated on the International Nuclear and Radiological Event Scale (INES), which is graded from 0 to 7 in increasing order of severity, since 2013.

Graph 2 shows the trend since 2013 in the number of significant events according to the notification field. 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 2023, 16 events of this type were reported in the field of nuclear safety (26 in 2020, 31 in 2021, 21 in 2022).

In 2023, two significant events rated level 2 were notified by EDF. The first event is linked to the discovery of major SC cracks. The second event concerned the external contamination of a worker in the Cattenom NPP (see box page 313).

2.4.5 Protection against internal and external hazards

The NPPs must be able to withstand a variety of hazards, originating either inside or outside the installations. The main hazards constituting a risk for safety are detailed below.

Fire risks

A fire can lead to failure of the equipment needed to control the fundamental safety functions. Steps must thus be taken to protect the sensitive parts of the facility against fire.

In the same way as the other BNIs, NPPs are covered by ASN resolution 2014-DC-0417 of 28 January 2014, relating to the rules applicable to BNIs for controlling fire risks.

The way the fire risk is taken into account in the NPPs is based on the “Defence in Depth” principle built around three levels, that is the design of the facilities, fire prevention, fire detection and firefighting.

Design rules aim to prevent a fire from spreading and mitigate its consequences; they are based primarily on “fire sectorisation”. This involves dividing the facility into sectors and containment areas designed to keep the fire within a given perimeter bounded by items (doors, walls and fire dampers) offering a specified fire resistance duration. The main purpose is to prevent a fire from spreading to two redundant equipment items performing a fundamental safety function.

Explosion risks

An explosion can damage the items essential for maintaining safety or lead to rupture of the containment and the dispersal of radioactive materials into the facility, or even into the environment. Steps must thus be taken by the licensee to protect the sensitive parts of the installation.

Internal flooding risks

An internal flood, that is originating inside the facility, can lead to failure of the equipment needed to control the fundamental safety functions. Flooding may in particular be caused by an earthquake. Steps are therefore taken to prevent internal flooding (maintenance of piping carrying water, etc.), or mitigate its consequences (presence of floor drains and water extraction pumps, installation of sills or leaktight doors to prevent the flood from spreading, etc.).

Seismic risks

Although seismic activity in France is moderate, EDF’s inclusion of this risk in the safety case for its nuclear power reactors is the subject of constant attention on the part of ASN, given the potential consequences for the safety of the facilities. Seismic protection measures are designed into the facilities. They are periodically re-examined in the light of changing knowledge, on the occasion of the periodic safety reviews.

Basic Safety Rule (RFS) 2001-01 of 31 May 2001 defines the methodology used to determine the seismic risk for surface BNIs.

This RFS is supplemented by ASN Guide No. 2/01 of May 2006 which defines acceptable calculation methods for a study of the seismic behaviour of nuclear buildings and particular structures such as embankments, tunnels and underground pipes, supports or tanks.

The design of the buildings and the equipment important for safety in the NPPs must thus enable them to withstand earthquakes of an intensity greater than the strongest earthquakes that have occurred in the region. EDF’s NPPs must thus be able to withstand seismic levels incorporating the local geological features specific to each one.

As part of the periodic safety reviews, the seismic reassessment consists in verifying the adequacy of the seismic design of the facility, taking account of changing knowledge about seismic activity in the region of the site or the methods for assessing the seismic behaviour of elements of the facility. The lessons learned from international experience feedback are also analysed and integrated into this framework. The seismic reassessments regularly lead EDF to reinforce the strength of its installations.

Heatwave and drought risks

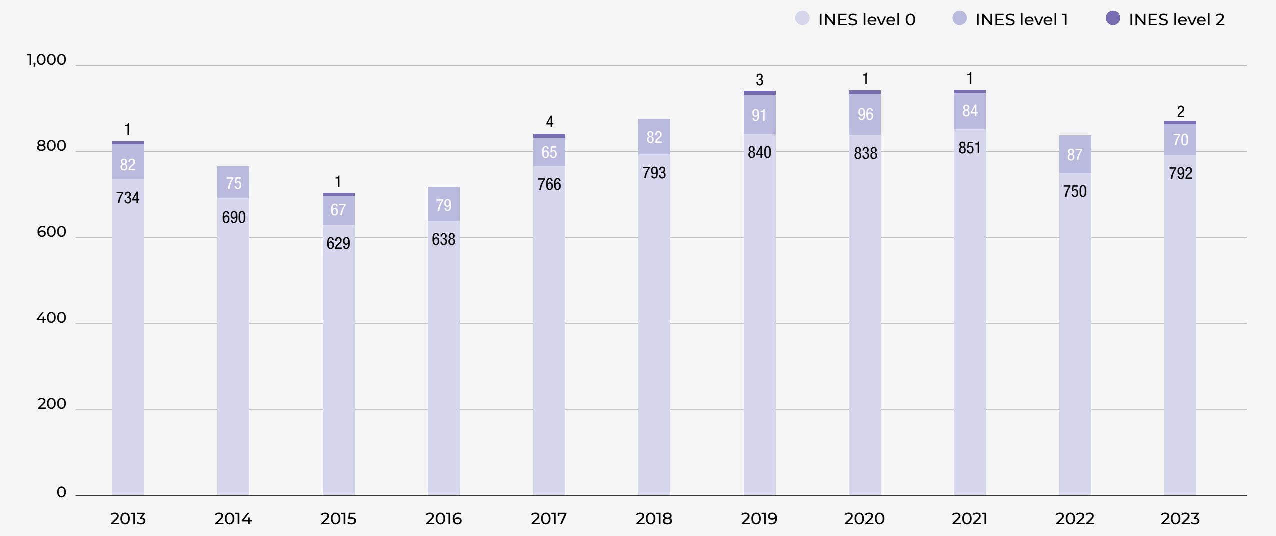
During the heat waves in 2003 and 2006, some of the watercourses used to cool NPPs experienced a reduction in their flow rate and significant warming. Significant temperature rises were also observed in certain NPP premises housing heat-sensitive equipment.

EDF took account of this OEF and carried out reassessment studies 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 modified its installations (such as the increase in the capacity of certain heat exchangers) and implemented operating practices optimising the cooling capacity of the equipment and improving the resistance of equipment susceptible to high temperatures.

During the reactors' periodic safety reviews, EDF takes account of climate change and is continuing to improve the capacity of its installations to deal with the effects of a heat wave. The capacity of certain cooling systems for equipment required for the nuclear safety case will in particular be improved. EDF has also initiated a climatic monitoring programme to anticipate climate changes which could compromise the temperature hypotheses adopted in its baseline requirements.

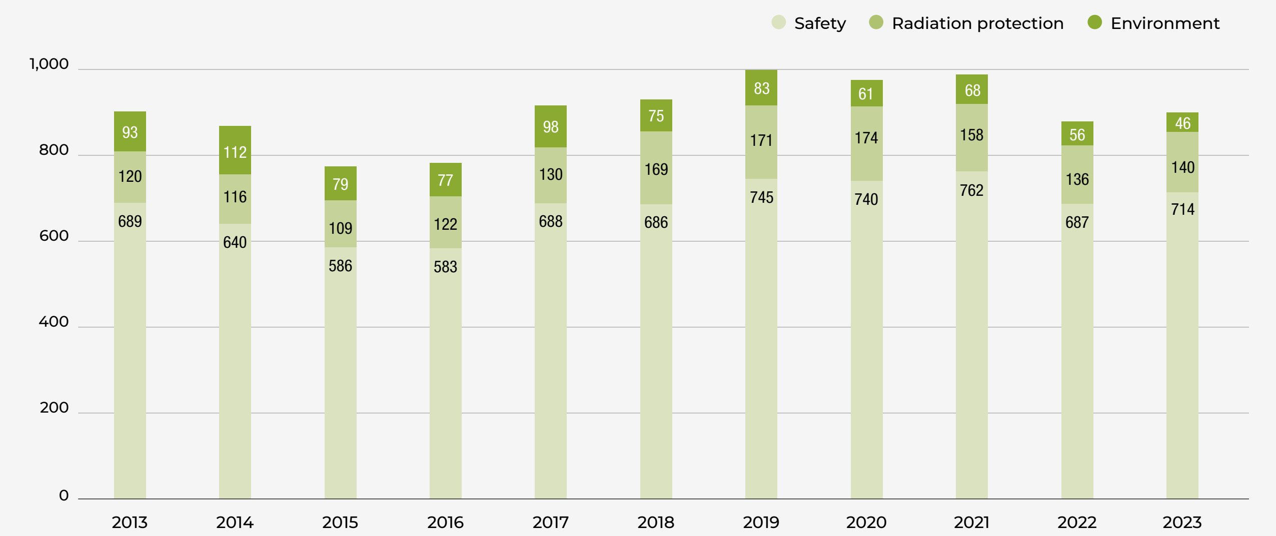
As for the other hazards, ASN asks EDF to learn the lessons from the various heatwave events, along with their effects on the installations.

GRAPH 1 Trend in the number of significant events rated on the INES scale in the EDF Nuclear Power Plants



This graph includes data for the Fessenheim NPP up until 2020.

GRAPH 2 Trend in the number of significant events by domain in the EDF Nuclear Power Plants



This graph includes data for the Fessenheim NPP up until 2020.

Consideration of natural hazards of extreme intensity
Following the accident that struck the Fukushima Daiichi NPP on 11 March 2011, stress tests led ASN to prescribe the installation of a hardened safety core of material and organisational provisions to deal with situations arising from external natural hazards of extreme intensity, the severity of which exceeds that considered hitherto in the baseline safety requirements of each installation. The external natural hazards considered for the design of the hardened safety core are the following: earthquake, flooding (including extreme rainfall) and associated phenomena (extreme winds, lightning, hail) as well as tornados.

2.4.6 Assessment of the risk prevention measures relating to hazards

ASN checks that risks linked to hazards in the NPPs are taken into account, notably based on the reassessment of the design of the installations during the periodic safety reviews, analysis of the licensee's baseline safety requirements, examination of significant events and the inspections performed on the sites.

The Fukushima Daiichi NPP accident led EDF to reinforce its organisation for the management of risks relating to hazards. More specifically, networks of coordinators were set up 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 still needed on most of the sites to improve how hazard risks are dealt with, in particular with regard to:
- the maintenance of equipment (sluice gates, fire doors, sensors, floor drains, etc.);
- risk assessments during maintenance operations and in the event an equipment malfunction is detected;
- compliance with the corrective action deadlines identified by the annual reviews;
- training of the coordinators and awareness-raising among the EDF and contractor personnel.

Fire risks
ASN finds no significant change with regard to control of fire risks within the NPPs. Even if progress is noted on some sites, most of them remain stable, with an overall level of performance below what is expected. The number of fire outbreaks in 2023 is similar to that in 2022. Four outbreaks of fire that occurred in 2023, including one in a controlled area, led to activation of the PUI on the site concerned.

ASN has observed certain improvements in the management of the fire risk in the NPPs, notably in management of detection and in personnel training. However, ASN also noted the need to improve certain areas, such as monitoring sectorisation equipment and handling of anomalies concerning it, or the temporary storage of combustible materials during worksites and maintenance operations. 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.

Finally, ASN notes that EDF is working on deploying a new firefighting organisation on its site, so that it can more effectively tackle fires and prevent them from spreading. Changes are thus planned with regard to personnel individual protection equipment, training and organisation with the Departmental Fire and Emergency Services (SDIS), which as of 2024 will be deployed on the NPPs. On several sites, this will result in an improved intervention capacity in conjunction with the SDIS.

Explosion risks
ASN checks the prevention and monitoring measures taken by EDF with regard to the risk of explosion. As part of its labour inspectorate duties, ASN also ensures compliance with the "EXplosive ATmospheres" (ATEX) regulations to ensure worker protection.

ASN considers that the level of explosion-related risk management is not yet up to the required standard for all sites. EDF's maintenance and inspection doctrine is not always applied satisfactorily, notably with regard to the risks related to the presence of hydrogen in the installations. ASN however notes the efforts made by EDF to reduce the deviations found, notably through the implementation of reinforced monitoring and deployment of specific action plans. ASN considers that EDF must continue to pay particular attention to this subject and ensure that it is dealt with using all necessary rigour on all the sites.

Internal flooding risks
In 2019, ASN asked EDF to supplement its approach in order to better control the internal flooding risk, notably to 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.

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. EDF implemented the operating procedure required in the event of an earthquake on the Cruas-Meysse 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-Meysse NPP sites. After field investigations, EDF defined a new design response spectrum for the Cruas-Meysse 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-Meysse NPPs.

OVERSIGHT OF SUPPLIERS OF EQUIPMENT IMPORTANT FOR NUCLEAR SAFETY

In 2023, ASN carried out 53 inspections of the procurement chain for safety-important equipment intended for NPPs. They evaluated the control of manufacturing by these suppliers, along with the surveillance carried out by EDF.

Of these inspections, 38 were related to the manufacture of NPE and the procurement of large forged components intended for the first EPR 2 reactors and the EDF reactors in operation. These inspections took place in France, Spain, Italy and Japan, primarily in the manufacturing plants. ASN was thus able to check the quality of manufacturing and verify how responsibilities were assumed by NPE manufacturers, organisations approved for evaluating NPE conformity and EDF in terms of its surveillance of NPE procurement.

These inspections identified a number of good practices in the performance of the activities entrusted to the suppliers. However, they also revealed a lack of familiarity with certain regulatory requirements within the subcontracting chain, a lack of expertise in certain special processes, and a need for improvement to the quality of EDF's surveillance of its suppliers.

During these inspections, ASN was able to evaluate the steps taken to mitigate the risk of falsification and counterfeiting during equipment manufacturing. ASN finds that the identified number of cases of irregularity is on the rise.

These findings were shared with EDF, so that improvements can be made.

In 2024, ASN will continue with its international commitments regarding supplier oversight, within the Committee on Nuclear Regulatory Activities (CNRA) of the Nuclear Energy Agency (NEA). This commitment entails active participation in the Working Group on Supply Chain (WGSUP) involving the nuclear safety regulators.

Within this working group, ASN shares the conclusions of its inspections with its counterparts and takes part in joint inspections, such as the international inspection overseen by the British Office for Nuclear Regulation (ONR) in 2023 at a nuclear equipment supplier in Japan.

On 16 June 2023, an earthquake occurred in the municipality of La Laigne, between La Rochelle and Niort. This earthquake was felt on the NPPs of Civaux, Blayais and Chinon. The intensity of this earthquake did not trigger the reactor building shaking alarms. However, as a precaution, the safety patrols on the installations confirmed that there were no civil engineering anomalies.

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 demonstration of the qualification of this equipment.

The OEF carried out by EDF following the heatwaves of the summer of 2022 identified no need to modify the measures already in place.

2.5 CONFORMITY AND MAINTENANCE OF THE INSTALLATIONS

2.5.1 Maintenance of the installations and management of subcontracted activities

Maintenance of the installations

Preventive maintenance is an essential line of defence in ensuring the conformity of a facility with its baseline safety requirements.

In order to improve the reliability of the safety-important equipment but also the industrial performance, EDF is optimising its maintenance activities, drawing on practices used in conventional industry and by the licensees of NPPs in other countries. In 2008, EDF decided to deploy the maintenance methodology called "AP913", developed by the American nuclear licensees and built around two main points: organisational changes to enhance monitoring of the reliability of the equipment and systems and implementation of a new type of preventive maintenance programmes.

The AP913 implementation diagnostic performed by EDF in mid-2016 revealed difficulties with implementing performance monitoring and with the increase in the maintenance tasks generated by the AP913 maintenance programmes.

In 2017, EDF thus defined strategic guidelines for maintenance and reliability. It specified the roles of the various departments and professions related to the performance of maintenance, by reaffirming that the maintenance departments are responsible for the project ownership of the equipment they maintain, in particular in a context of continued operation of the reactors beyond 40 years. EDF also adopted function reviews to obtain an integrated view of the equipment and systems participating in each function, as well as implementing a new phase of its project to control the volume of maintenance.

Management of subcontracted activities

Reactor maintenance operations are to a large extent subcontracted by EDF to outside contractors. EDF justifies the use of subcontracting by the need to call on specific or rare expertise, as well as the highly seasonal nature of reactor outages and thus the need to absorb workload peaks.

EDF's decision to resort to subcontracting must not compromise the technical skills it must retain in-house in order to exercise its responsibility as licensee with regard to the protection of people and the environment and to be able to effectively monitor the quality of the work performed by the subcontractors. Poorly managed subcontracting is liable to lead to poor quality work and have a negative impact on the safety of the facility and the radiation protection of the workers involved.

EDF takes the necessary steps to control the risks associated with the subcontracted activities and regularly updates them. EDF has thus reinforced the preparation of reactor outages, more particularly to guarantee the availability of human and material resources.

2.5.2 Assessment of maintenance and subcontracted activities

Maintenance of the installations

Maintenance is also subject to regular checks by ASN during its inspections in the NPPs. The organisation in the NPPs for large-scale maintenance operations was relatively satisfactory in 2023.

In this respect, through its inspections, ASN found that the various sites did on the whole deploy the maintenance policy changes initiated by EDF as of 2016. However, ASN finds that the considerable industrial workload on some sites is sometimes an obstacle to the implementation of these changes. In addition, there are still areas for improvement, such as addressing various hazards, preparing activities and the monitoring of activities entrusted to outside contractors.

In 2023, spares management also remains a source of shortcomings 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.

In 2022, ASN had found several anomalies concerning inspection programmes performed for maintenance of certain equipment (self-blocking devices, anchors). These anomalies sometimes led EDF to initiate complete programmes for new inspections on certain reactors. After the initial delay in implementation of these programmes, it should be noted that in 2023 improvements were observed in their implementation, even if some difficulties persist.

Finally, there were still a large number of 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.

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.

The organisation for performance of maintenance

ASN notes that there are still problems of coordination 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.

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 2023 in quality management of subcontracted activities. 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. EDF is implementing tangible measures, such as the increase in the provision of spaces for preparation work on a mock-up.

REACTOR OUTAGES

The nuclear power reactors must be periodically shut down for replacement of the fuel depleted during the electricity production cycle. One third or one quarter of the fuel is thus renewed at each outage.

These outages mean that certain parts of the installations which are not accessible during the production phase then become temporarily accessible. They are thus put to good use by EDF to carry out checks, tests and maintenance, as well as to perform works on the facility.

These 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 reassessments.

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.

Pursuant to the provisions of resolution 2014-DC-0444 of 15 July 2014 relative to PWR outages and restarts, ASN performs spot-checks. These mainly concern the activities with the most significant safety implications, as well as the processing of any unforeseen events. It consists of on-site inspections and documentary checks, for the duration of the outage and in particular prior to restart of the reactor. It is after this inspection that ASN may or may not approve reactor restart.

2.5.3 Regulation of the conformity of facilities with the applicable requirements

Maintaining the conformity of the facilities with their design, construction and operating requirements is a major issue insofar as this conformity is essential for ensuring compliance with the safety case. The processes employed by the licensee, notably during reactor outages, contribute to maintaining the conformity of the facilities.

The identification and processing of deviations

The checks initiated by EDF within the framework of its operating baseline requirements and the additional verifications requested by ASN, on the basis more particularly of operating experience feedback, can lead to the detection of deviations from the defined requirements, which must then be processed. These deviations can have a variety of origins: design problems, construction errors, insufficient expertise in maintenance work, deterioration through ageing, organisational shortcomings, etc.

The steps taken to detect and correct deviations, specified in the Order of 7 February 2012, play an essential role in maintaining the level of safety of the facilities.

"Real-time" checks

Carrying out periodic test and preventive maintenance programmes on the equipment and systems contributes to identifying deviations. Routine visits in the field and technical inspection and verification of activities considered to be important for the protection of people the environment are also effective means of detecting deviations.

Verifications during reactor outages

EDF takes advantage of nuclear reactor outages to carry out maintenance work and inspections which cannot be performed when the reactor is generating electricity. These operations more particularly correct already known deviations, but can also lead to the detection of new ones. Before each reactor restart, ASN asks EDF to list any deviations not yet remedied, to take appropriate compensatory measures and to demonstrate the acceptability of these deviations with respect to the protection of people and the environment for the coming production cycle.

Ten-yearly verifications: conformity checks

EDF carries out periodic safety reviews of the nuclear reactors every ten years, in accordance with the regulations (see point 3.2). EDF then carries out an in-depth review of the actual state of the facilities by comparison with the applicable safety requirements, more particularly on the basis of the in-service monitoring hitherto carried out, and lists any deviations. These verifications are supplemented by a programme of additional investigations, the aim of which is to check parts of the facility for degradation modes which are not covered by the inspections involved in the preventive maintenance programme.

The additional verifications in response to ASN requests

In addition to the steps taken by EDF with regard to its operating baseline requirements, additional checks are carried out at the request of ASN, whether, for example, with regard to OEF about events which have occurred on other facilities, after inspections, or after examination of the provisions proposed within the context of the periodic safety reviews.

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 proportionality principle. This is based more specifically on an assessment of the potential or actual consequences of any deviation identified and on the licensee's ability to guarantee the safety of the reactor in the event of an accident, by taking appropriate compensatory measures. The Guide also recalls the principle of the correction of compliance deviations as soon as possible and in any case defines the maximum times allowed.

2.5.4 Assessment of oversight of facilities compliance with the applicable requirements

Condition of equipment and conformity

In the past, ASN has found that the organisational measures taken by EDF to deal with deviations comprised shortcomings and that the time taken to characterise, check and process the deviations did not always comply with the requirements of the Order of 7 February 2012. In 2019, EDF therefore revised its internal baseline requirements for management of deviations, in order to improve how they are processed and provide ASN with reactive information proportionate to the safety implications. Since these new internal baseline requirements have been applied, ASN finds that in most situations, EDF corrects the deviations within the required time. These efforts will need to be continued in the coming years, notably on the occasion of the ten yearly outages.

Significant events concerning several reactors were once again reported in 2023 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 2024 and will in this respect continue its inspections of the condition of equipment and systems.

2.6 PREVENTION AND MANAGEMENT OF ENVIRONMENTAL AND HEALTH IMPACTS AND NON-RADIOLOGICAL RISKS

2.6.1 Discharges, waste management and health impacts

Limiting water intake and environmental discharges

NPPs discharge liquid and gaseous effluents. The origin of these effluents, which can be radioactive or chemical, is the actual operation of the reactor, primarily the operations designed to ensure the radiochemical quality of the main primary 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 chosen by the licensee and taking into consideration the characteristics of the installation, its location and the local environmental conditions. It verifies that these limits have acceptable environmental and health impacts.

ASN also sets the rules concerning the management of detrimental effects and the impact on health and the environment of the reactors. These 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 operating experience feedback 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 2023, ASN updated the resolutions regulating the conditions of water intake, consumption, discharge into the environment, and the effluent discharge limits for the Blayais and Tricastin NPPs.

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 liquid effluents into watercourses or the sea, either directly, from those NPPs operating with "once-through" cooling, or after cooling of these effluents in cooling towers, enabling some of the heat to be dissipated to the atmosphere. These thermal discharges lead to a temperature rise in the natural environment between the points upstream and downstream of the discharge which, depending on the reactors, can range from a few tenths of a degree to several degrees. These thermal discharges are regulated by ASN resolutions specific to each NPP.

Since 2006, provisions have been incorporated into the ASN resolutions for advance definition of the operations of NPPs in exceptional climatic conditions leading to significant warming of the watercourses upstream of the NPPs. These special provisions are 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 of the waste produced or to be produced, an estimation of the waste traffic volumes and a waste zoning plan.

In addition, every year, each site sends ASN a summary report on its production of waste and the corresponding disposal routes, a comparison with the results of previous years, a summary of the site organisation and the differences observed with respect to the management procedures specified in the waste management study, the list of significant events which have occurred and the outlook for the future.

Prevention of the health impacts caused by the growth of legionella and amoeba in certain cooling systems of the NPP secondary systems

The secondary cooling systems of nuclear reactors equipped with a cooling tower are environments favourable to the development of legionella and other amoeba. EDF monitors the legionella and amoeba concentrations and takes preventive measures and, if necessary, remedial measures in accordance with the provisions of ASN resolution 2016-DC-0578 of 6 December 2016 on the prevention of risks resulting from the dispersion of pathogenic micro-organisms (legionella and amoeba) by the cooling installations of the systems.

For most of these reactors, preventive and remedial measures to limit the development of legionella and amoeba are based on the injection of a biocidal product (monochloramine) into the cooling system.

2.6.2 Prevention and control of the non-radiological risks

Prevention of non-radiological risks with airborne effects

The accidents with effects said to be "non-radiological" are those which can arise from the release of hazard potentials not specific to the nuclear activity, insofar as they not concern radioactive substances. These hazard potentials, which can also be present in other industries covered by the system for Installations Classified for Protection of the Environment (ICPEs), are associated with storage facilities and processes using gaseous or liquid chemical substances.

The consideration of these non-radiological accidents is included in the nuclear safety case in accordance with the provisions of Title III of the Order of 7 February 2012, through a specific study known as the non-radiological risks study. This study is drawn up using the methodology applicable to ICPEs. The purpose of this study is to justify the thermal and toxic effects, projectiles or over-pressure effects generated by release of the hazard potentials present on the site and leading to no effects beyond the perimeter of the site. This justification is based, on the one hand, on identification of the hazard potentials (storage facilities or processes) and their potential hazard sources and, on the other, on characterisation of the possible dangerous phenomena and the specific prevention measures for reducing both probability and effects.

Each NPP thus has a study of non-radiological risks which analyses and as necessary identifies the possible dangerous phenomena, as well as the specific material and organisational provisions for preventing these phenomena or limiting their effects.

Prevention of liquid pollution resulting from accidental spillage of dangerous substances

As with numerous industrial activities, the operation of a NPP involves the handling and storage of dangerous liquid chemical substances. The management of these substances and the prevention of pollution, which are the responsibility of the licensee, are regulated by the Order of 7 February 2012 and ASN resolution 2013-DC-0360 of 16 July 2013 and must also comply with the requirements of the European texts. The licensee has obligations regarding the operational management of these substances and the identification of the corresponding potential hazards. It must also be able to take the necessary steps in the event of any incident or accident situations which would lead to pollution.

The licensee must thus for instance precisely identify the location of each dangerous substance on its site, along with the corresponding quantities. Drums and tanks must be labelled in compliance with the European Classification, Labelling, Packaging (CLP) regulation and there must be retention areas designed to collect any spills.

The NPPs must also adopt an organisation and resources to prevent pollution of the natural environment (groundwater, river, 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.

2.6.3 Assessment of control of environmental and health impacts and non-radiological hazards

ASN monitors the organisational and material measures put into place by EDF to prevent non-radiological risks and the liquid pollution that could result from the dangerous substances present in its installations. It also checks those designed to guarantee control of the detrimental effects arising from the operation of the installations, such as water intake, effluent discharges into the natural environment, and pathogenic hazards. As each year, ASN carried out inspections on these measures in 2023.

ASN in particular carried out a campaign of tightened inspections in the Dampierre-en-Burly, Belleville-sur-Loire and Gravelines NPPs on these topics. During these inspections, the inspectors carried out field checks and situational exercises, and examined the organisation of the NPPs.

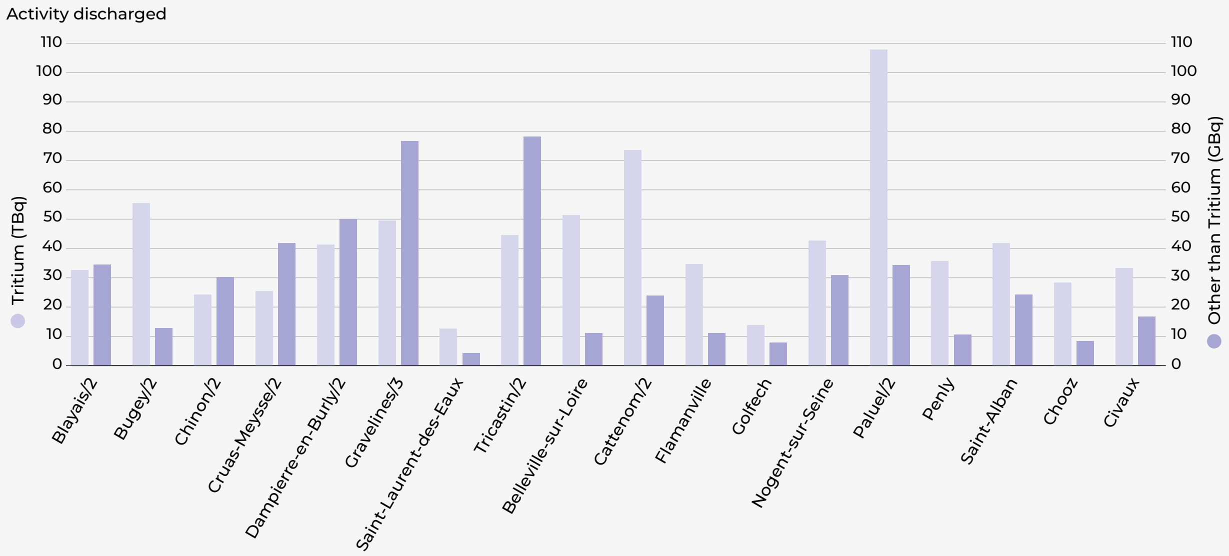
With regard to the control of non-radiological risks, and even though a number of areas for improvement were identified, in particular in terms of preparedness for the risk of release of dangerous substances, in order to protect people inside and outside the site, the inspectors noted the considerable commitment made in this field by the EDF teams. This point, confirmed by other specific inspections on this topic, represents a step forwards by comparison with ASN's findings in 2022. In 2024, ASN will maintain its vigilance on this subject.

With regard to the control of intakes and discharges, the inspectors observed the ageing of certain equipment involved in the management of radioactive and chemical effluents, such as the equipment used to treat the effluents, produce demineralised water and treat the sludges resulting from this production. This ageing and the associated malfunction of certain equipment could have consequences for availability, effectiveness of treatment, quality of effluents discharged, water consumption and use of the effluent storage tanks prior to discharge into the environment. Moreover, a number of incidents that occurred in 2023, related to chemical product leaks inside the facilities of some NPPs, are also the result of equipment ageing.

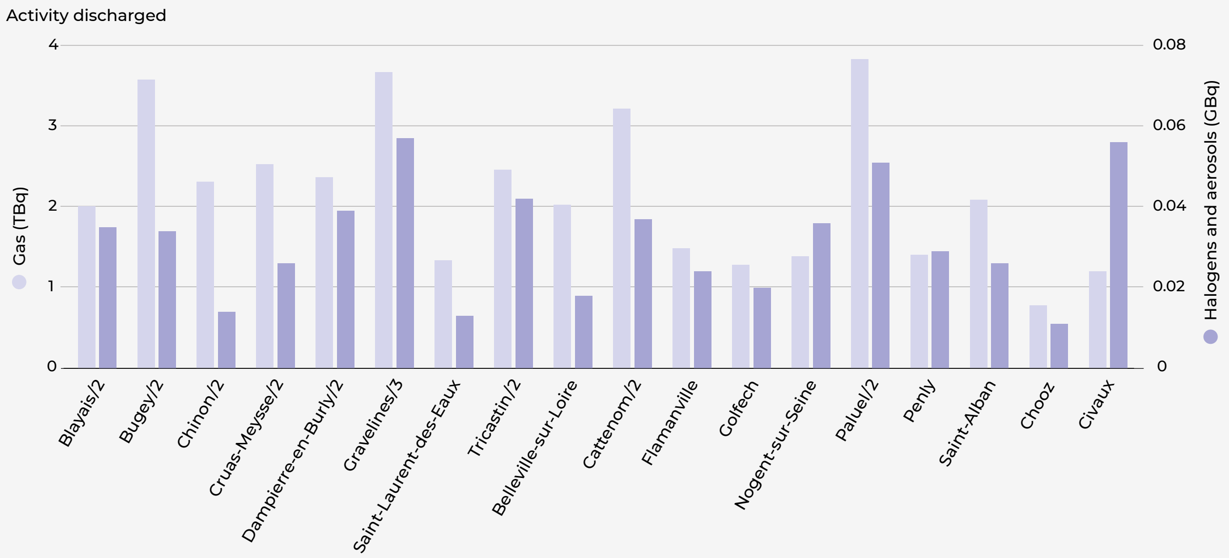
Finally, with regard to NPP adaptation to climate change, the campaign of tightened inspections revealed the need for each site to draw up a medium and long-term strategy taking account of its specific issues (condition of effluent-related equipment, sizing and availability of effluent storage tanks prior to discharge, constraints associated with water intakes during low-water periods, etc.). With regard to OEF from certain NPPs, this strategy must also address the issues of groundwater consumption, notably to better identify and prevent leaks which could affect the underground networks.

This campaign of in-depth inspections will be repeated in 2024 on three other NPPs, on the topics of controlling the containment of liquid pollution incidents. Several incidents of this type also occurred in 2023.

GRAPH 3 **Liquid radioactive discharges for the NPPs in 2023 (per pair of reactors)**



GRAPH 4 **Gaseous radioactive discharges for the NPPs in 2023 (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.

OPERATION OF NUCLEAR REACTORS DURING HEAT WAVES

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

Heatwaves lead 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 prevents this temperature from being exceeded. The temperatures that nuclear reactors are required to deal with are regularly reassessed, notably during the periodic safety reviews. These reassessments take account of climate change.

Removal of the heat produced by the reactors in a situation with high watercourse temperatures

To help cool its reactors, an 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 some of the heat to be discharged to 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 apply limit values for 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.

Since 2006, ASN has incorporated measures into the regulations covering NPP discharges, to ensure advance definition of the operations of NPPs in exceptional climatic conditions leading to significant warming of the watercourse. These special provisions are applicable if the security of the electricity grid is at stake. Temporary relaxation of the limit values for the thermal discharges may also be authorised by ASN, at EDF's request, if needed by the electricity grid, as was the case during the heat waves of 2003, 2006 and 2022. In this case, environmental monitoring is reinforced.

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. ASN must issue prior approval before they can be used.

More generally, and as in previous years, ASN in 2023 observed that discharges remain well managed on most of the sites. However, certain events are indicative of weaknesses reflecting operating defects in certain equipment such as the oil removers or cooling tower anti-scaling treatment installations using sulphuric acid.

With regard to waste management, the checks carried out by ASN reveal that its operational management needs to be further improved, even if the positive trend observed in 2022 continued in 2023. During its inspections, ASN still finds cases of non-compliance with the operating baseline requirements, in particular with regard to storage durations and inventory-keeping, as well as non-conforming storage facilities.

2.7 RADIATION PROTECTION OF WORKERS

2.7.1 Exposure of workers to ionising radiation

Exposure to ionising radiation in a nuclear power reactor comes primarily from the activation of corrosion products in the primary system and fission products in the fuel. All types of radiation are present (neutrons, α, β and γ), with a risk of internal and external exposure. In practice, most of the doses received come from external exposure to β and γ radiation and are primarily linked to maintenance operations during reactor outages.

During the course of 2023, maintenance work related to the SC problem on the primary system auxiliary lines continued on several reactors and contributed to the increase in the average collective dosimetry (see Graph 5 next page) and the average dose received by the workers for one hour of work in the controlled area (see Graph 6 next page) in relation to 2022.

Graph 7 (see page 312) shows the breakdown of the workers according to whole body external dosimetry. In 2023, 76% of workers were exposed to a dose of less than one millisievert (mSv), which is comparable to the previous years. The annual regulation limit for whole body external dosimetry (20 mSv) was exceeded on no occasion in 2023.

Graph 8 (see page 312) shows the trend in whole body average individual dosimetry according to the categories of disciplines of the workers in the NPPs. As in previous years, those workers most exposed are the personnel in charge of heat insulation.

The other categories of disciplines most exposed also remain unchanged: welders, personnel in charge of non-destructive tests, mechanical and ancillary activities. For these latter categories, the average individual dose increased in 2023, in particular for those workers in charge of non-destructive tests (33% increase in the average individual dose by comparison with 2022) and welders (13% increase) who were particularly in demand owing to the work related to the SC problem.

Significant contamination events

In 2023, EDF notified two significant worker contamination events in the NPPs, as against six in 2022. The first involved exposure greater than one quarter the annual regulation limit for the skin and was rated level 1 on the INES scale. The second concerned exposure greater than the annual regulation limit for the skin and was rated level 2 on the INES scale (see box page 313). In both situations, the workers concerned by these events were given care and the radioactive particles responsible for their contamination were removed.

2.7.2 Assessment of worker radiation protection

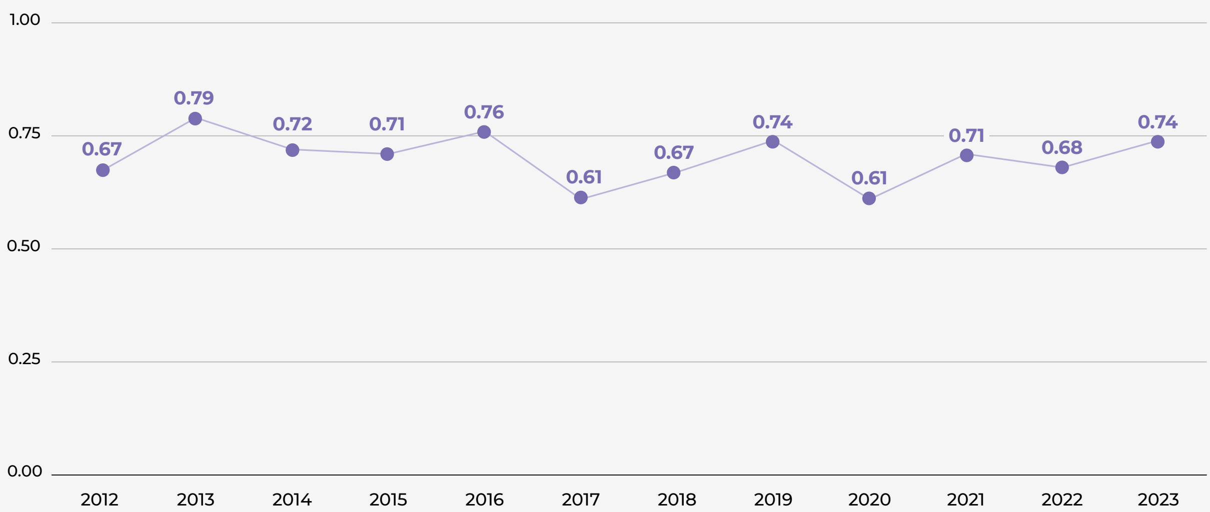
ASN monitors compliance with the regulations relative to the protection of workers liable to be exposed to ionising radiation in NPPs. In this respect, ASN is attentive to all the workers on the sites, both EDF personnel and those of contractors.

This monitoring is performed on each NPP during inspections, either on the specific topic of radiation protection, or during maintenance operations carried out during reactor outages, or as a result of specific events. This monitoring is also carried out during examination of the worker radiation protection files (significant event reports, design, maintenance or modification files, documents implementing the regulations produced by EDF, etc.).

During inspections carried out in 2023, in particular during tightened inspections performed on the Tricastin, Cruas-Meysse and Bugey NPPs, ASN found that the operation of the radiation protection competence centres approved at the end of 2022 on all the NPPs, was on the whole satisfactory. The approach used in preparing for work and optimising doses is also considered to be satisfactory on most of the NPPs.

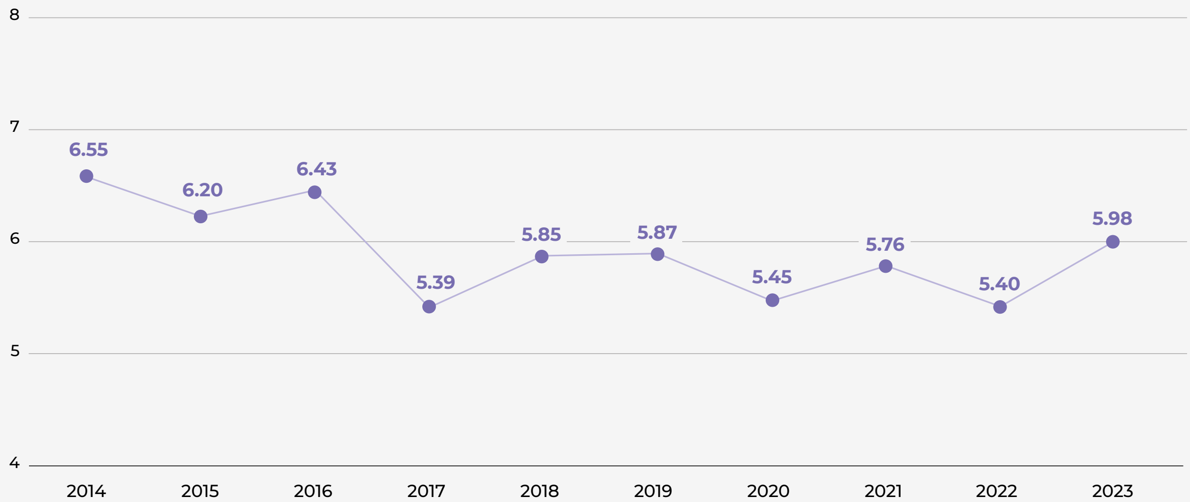
Nonetheless, on several NPPs, ASN observed deviations concerning compliance with the particular prevention rules for risks of exposure to ionising radiation applicable to the most vulnerable workers (young workers aged under 18, personnel on short-term contracts) and will be vigilant with regard to how they are dealt with.

GRAPH 5 **Mean collective dose per reactor (Man.Sv/reactor)**



This graph includes radiation protection data for the Fessenheim NPP until 2020.
Source: EDF.

GRAPH 6 **Collective dose for one hour of work in a controlled area (in µSv)**



Source: EDF.

ASN notes that difficulties with industrial radiography work observed in 2022 are persisting, in the light of the number of significant events notified with respect to these worksites, despite the action taken by EDF in this field.

The inspections were also able to identify points on which improvements are required in controlling the risk of the dispersal of contamination within and outside the installations, in particular in the "auxiliary" premises (such as waste conditioning buildings, units dedicated to contaminated equipment or buildings for final inspection of packages prior to shipment).

During the inspections scheduled in 2024, notably as part of a new campaign of tightened inspections, ASN will be particularly vigilant with respect to all of these points.

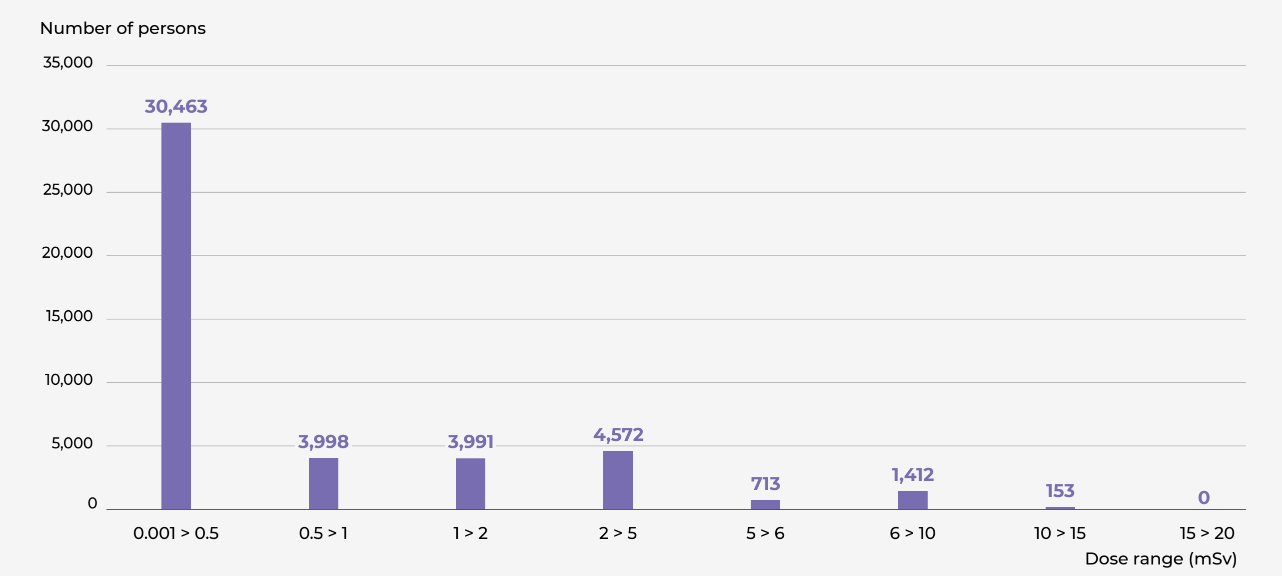
2.8 LABOUR LAW IN THE NUCLEAR POWER PLANTS

2.8.1 Oversight of work in the Nuclear Power Plants

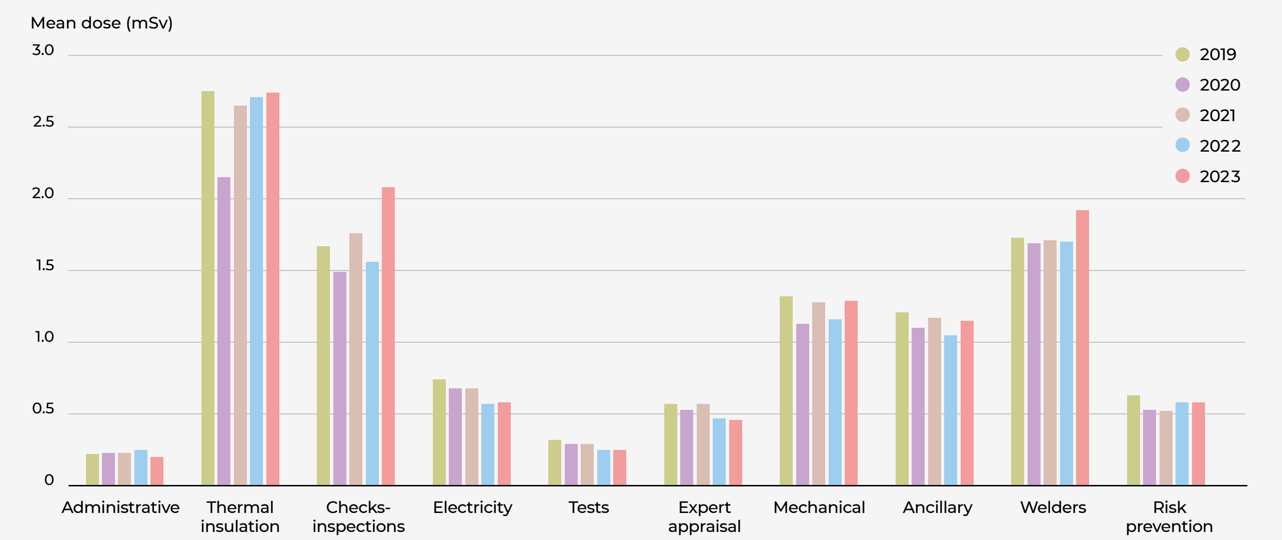
ASN is responsible for labour inspectorate duties in the 18 NPPs, the EPR reactor under construction at Flamanville and 11 other installations, most of which are reactors undergoing decommissioning. 800 to 2,000 people work in each NPP. About 23,000 EDF employees and 11,000 employees from outside contractors are thus assigned to these nuclear sites.

The role of the labour inspectorate is to ensure that the Labour Code as a whole is applied by the employers, whether EDF or its contractors.

GRAPH 7 **Number of workers per dose range (in mSv) for 2023**



GRAPH 8 **Trend in mean individual dosimetry according to the categories of trades of the workers**



This graph includes data for the Fessenheim NPP up until 2020.

Source: EDF.

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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 2022, the labour inspectors carried out checks in all the NPPs on the verifications of the electrical installations EDF is required to perform in accordance with the Labour Code. The various inspections carried out by the labour inspectors brought to light weaknesses in the organisation on the sites for the correct performance of these checks or for coordination of these checks between the various EDF entities.

They also carried out inspections during two campaigns covering all the NPPs on the topic of prevention of risks linked to work performed by an outside contractor, as well as mobile working equipment and lifting equipment.

At the same time, the labour inspectors continued their checks on maintenance operations with risks linked to the non-conformity of working equipment, lifting equipment in particular.

Finally, the labour inspectors followed up all the events compromising worker safety that had occurred on the sites, systematically initiating inquiries in the event of serious accidents or near accidents. They were also called on to deal with cases relating to psychosocial and working hours risks.

2.8.2 Assessment of health and safety, professional relations and quality of employment in the Nuclear Power Plants

ASN notes that, according to EDF data on the first nine months of 2023 as compared with the same period in 2022, the overall accident rate is up 10% (+17% for accidents with time lost, +3% for accidents without time lost) but with more hours worked in 2023.

These labour accidents mainly concern tripping (44%), handling of objects or tools (22%), manual handling (9%) and feeling unwell (7%). This accident rate on the site, 54% of which concerned the outside contractors in 2023, has fallen (63% in 2022).

With regard to near accidents, more than half concern critical risks (represented 33% by lifting, 18% by electrical risks, 12% by falls from height). Certain occupational risk contexts, such as those linked to working equipment, notably lifting equipment, asbestos, or electrical risks, need to be further improved. In 2024, ASN will continue its oversight of these fields.

In 2023, 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 also experienced labour movements at the beginning of the year, as part of the pension reform protests.

The labour inspectors also issued reminders regarding extreme heat working conditions, work on 1 May and compliance with maximum working hours.

EXTERNAL CONTAMINATION OF A WORKER IN THE CATTENOM NPP

On 2 February 2023, contamination of a worker from an EDF contractor was detected during the checks performed at the exit from the controlled area of the reactor 3 building of the Cattenom NPP. The medical service immediately took charge of the person and located the radioactive particle causing the contamination on the cheek. The particle was removed.

The person concerned was fitting heat insulation on the valves of various systems in the reactor building, which was shut down as part of the inspection and repair activities relating to the SC phenomenon.

The evaluation of the dose received by the worker exceeds the regulation limit for the dose equivalent on the skin, set at 500 millisieverts (mSv) for a skin surface area of 1 cm^2.

EDF reported an ESR. Owing to the regulatory occupational exposure limit being exceeded, this event was rated 2 on the INES scale.

Following this event report, ASN carried out an inspection on the Cattenom NPP, to check that EDF had taken all necessary steps for adequate management of the event and for analysis of its causes.

The previous level 2 ESR reported by an EDF NPP dates back to 2021.

3 Continued operation of the Nuclear Power Plants

3.1 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 2023, the average age of the 56 reactors in operation, calculated from the dates of first divergence, can be broken down as follows:

- 41 years for the 32 nuclear power reactors of 900 MWe;
- 36 years for the 20 nuclear power reactors of 1,300 MWe;
- 26 years for the four nuclear power reactors of 1,450 MWe.

3.2 THE PERIODIC SAFETY REVIEW

The principle of the periodic safety review
Every ten years, EDF must carry out a periodic safety review of its installations. The periodic safety reviews of nuclear power reactors comprise the following two steps:

- A check on the condition and conformity of the facility: this first step aims to assess the situation of the installation with respect to the rules applicable to it. It is based on a range of inspections and tests in addition to those performed in real-time. These verifications may comprise design reviews, 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. Following this periodic safety review, and in accordance with the provisions of Article L. 593-19 of the Environment Code, the licensee sends ASN a periodic safety review concluding report. In this report, the licensee states its position on the conformity of its facility and details the modifications made to remedy deviations observed or to improve the safety of the facility and, as necessary, specifies the additional improvements that it will be making.

ASN analysis
ASN examines the periodic safety reviews in several stages. It first of all issues a position statement on the objectives of the review and the guidelines of the generic programmes to verify the state of the facility and the safety reassessment proposed by EDF, after obtaining the opinion of the Advisory Committees of Experts (GPEs).

On this basis, EDF carries out safety reassessment studies and defines the modifications to be made. ASN then issues a position statement on the results of these studies and on these modifications, after again consulting the GPEs. This position statement closes the generic phase of the periodic safety review, common to all the reactors.

This generic review does not take account of any specific individual aspects and ASN gives a ruling on the suitability of each nuclear power reactor for continued operation, notably on the basis of the results of the conformity checks and the assessment made in the periodic safety review concluding report for the reactor submitted by EDF. Following examination of 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.

A public inquiry is held concerning the concluding report for the periodic safety reviews beyond the 35th year of operation of a nuclear power reactor. Five years after submission of the review concluding report, the licensee sends ASN an interim report on the implementation of the requirements stipulated by the review, as a result of which ASN may add to these requirements.

3.3 ONGOING PERIODIC SAFETY REVIEWS IN THE NUCLEAR POWER PLANTS

The 900 MWe reactors

The fourth periodic safety 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 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 GPEs, ASN released a position statement on these objectives and issued additional requests in April 2016. EDF supplemented its programme of work and in 2018 presented ASN with the measures it envisages taking in response to these requests.

In 2020, with the support of IRSN, ASN finalised its examination of the generic studies linked to this review. At the beginning of 2021, ASN issued a position statement on the conditions for continued operation of the reactors. ASN considered that the measures planned by EDF combined with those prescribed by itself open up the prospect of continued operation of these reactors for the ten years following their fourth periodic safety review.

In October 2023, EDF asked ASN for postponement of the deadlines for some of the requirements in the resolution adopted in February 2021. Unexpected technical issues during implementation of some of the requirements, changes in the refuelling outages schedule, notably linked to the discovery of SC on the auxiliary lines, unexpected long-duration shutdowns or the needs of the electricity grid during the winter period, as well as a logjam with other periodic safety reviews, creating pressure on its engineering capacity, led EDF to revise its ability to carry out the activities needed to comply with the requirements, on time. ASN considered EDF's request to be acceptable in the light of the explanations provided.

Deployment of the periodic safety review on the site
EDF carried out the first of the fourth ten-yearly outages in 2019 (Tricastin NPP reactor 1). At the end of 2023, EDF had carried out or initiated 17 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.

In 2023, the public inquiries were held relating to the fourth periodic safety reviews of Bugey NPP reactors 2, 4 and 6 and of the Dampierre-en-Burly NPP.

Finally, on 29 June 2023, ASN issued its position statement on the continued operation of Tricastin NPP reactor 1. This is ASN's first position statement on a reactor in the light of the conclusions of its fourth periodic safety review.

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.

The fifth periodic safety review

In 2023, EDF sent ASN the envisaged guidelines for the generic phase study programme for the fifth periodic safety review of the 900 MWe reactors.

ASN will issue a position statement on these guidelines in 2024, after consulting the Advisory Committee of Experts for Nuclear Reactors (GPR). The ASN position statement will also be submitted to the public for consultation in autumn 2024.

The 1,300 MWe reactors

The third periodic safety review

At the beginning of 2015, ASN issued a position statement on the generic aspects of the continued operation of the 1,300 MWe reactors beyond thirty years of operation. On this occasion, ASN underlined the importance of the modifications made by EDF following their third periodic safety review. Within the framework of this review, EDF is notably deploying material and operational modifications in order to mitigate the consequences of an SG tube break accident, to prevent the occurrence of severe accidents with early loss of containment, and to reduce the risk of uncovering the fuel assemblies present in the spent fuel pool. With regard to hazards, EDF is modifying its installations in order to guarantee operation of the equipment needed for the safety of these reactors in the event of a heatwave, to protect the safety-important equipment against projectiles created by strong winds and to prevent the risks of explosion further to an earthquake.

To help conclude the generic phase of this review, ASN issued additional requests in 2021 applicable to all the 1,300 MWe reactors, with the aim of reinforcing their safety.

The third ten-yearly outages for the 1,300 MWe reactors will run until 2024.

The fourth periodic safety review

In July 2017, EDF produced a file giving the guidelines envisaged for the generic phase of the fourth periodic safety review of the 1,300 MWe reactors. In 2019, ASN issued a position statement on these guidelines, after involving the public and consulting the GPR: ASN considered that the general objectives set by EDF for this review are acceptable in principle. 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. The modifications associated with this periodic safety review will also incorporate those linked to deployment of the "hardened safety core" (see point 2.4.5).

In 2023, ASN continued with the examinations performed for the generic phase of this periodic safety review. After primarily looking at methods, the examinations in 2023 concerned the application studies, in particular concerning the containments, the studies of accidents with or without core melt, evaluation of the robustness of the installations to hazards and the methods for implementing certain systems involved in the "hardened safety core". EDF 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.

THE AGEING OF NUCLEAR POWER PLANT EQUIPMENT

As in any industrial installation, the equipment in NPPs experiences ageing. This ageing is the result of physical phenomena (corrosion of metals, hardening of polymers, hardening of certain steels under the effect of irradiation or temperature, swelling of certain concretes, etc.) which can degrade their characteristics according to their age or their operating conditions. This degradation obliges the licensee to repair or replace the equipment or to limit the lifetime of non-replaceable equipment, such as the reactor pressure vessel (see point 2.2.4).

The ageing management process implemented by EDF is based on three main points: anticipating the effects of ageing as of the design stage, monitoring the actual condition of the facility and repairing or replacing equipment degraded by the effects of ageing. Before being installed, safety-important equipment more particularly undergoes a qualification process to ensure its ability to perform its functions in conditions corresponding to the situations in which it will be needed, accident situations in particular.

The management of equipment ageing, and of the risk of obsolescence – which refers to difficulties linked to guaranteeing the procurement of spares over time – are essential to maintaining a satisfactory level of safety. They also contribute to reactor conformity with the applicable rules being maintained over time.

The control of ageing is given particular attention by ASN during the fourth periodic safety reviews. The provisions adopted or planned by EDF are examined and inspected, to ensure that the risks associated with ageing and obsolescence are controlled satisfactorily.

EDF will begin the first ten yearly outage associated with this review at the end of 2025. ASN will issue a position statement on the generic phase of this periodic safety review six months in advance.

The 1,450 MWe reactors

The second periodic safety review

In 2011, EDF transmitted the envisaged guidelines for the generic study programme for the second periodic safety review of the 1,450 MWe reactors, notably concerning the prevention of core melt and mitigation of the consequences of severe accidents.

ASN issued a position statement in February 2015 regarding the guidelines for 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.

The four 1,450 MWe reactors submitted their review concluding reports between 2020 and 2023.

The third periodic safety review

After consulting the public and obtaining the opinion of the GPR regarding the guidelines proposed by EDF for its study programme of the generic phase of the third periodic safety review of the 1,450 MWe reactors, ASN issued a position statement in July 2023. The periodic safety review will allow definition of the conditions for continued operation of these reactors for up to 40 years. ASN considered that the general objectives set by EDF for this review were acceptable in principle. These objectives are consistent with those set for the fourth periodic safety reviews of the 900 MWe and 1,300 MWe reactors. However, ASN asked EDF to add to or clarify some of these general objectives, in the same way as it had done for the 900 MWe and 1,300 MWe reactors. The safety reassessment of these reactors and the resulting improvements will be carried out in the light of the safety objectives of the new-generation reactors, such as the EPR, the design of which meets significantly reinforced safety requirements. In addition, the modifications associated with this periodic safety review will incorporate those linked to deployment of the “hardened safety core”.

INVOLVEMENT OF THE PUBLIC IN THE 4th PERIODIC SAFETY REVIEW OF THE 1,300 MWe REACTORS

ASN reinforced the involvement of the public in the various steps of the fourth periodic safety review of the 900 MWe reactors. It is currently doing the same for the generic phase of the fourth periodic safety review of the 1,300 MWe reactors.

After consulting the public in 2019 on the guidelines for this review, ASN – together with the National Association of Local Information Committees and Commissions (Anccli) – in 2023 organised technical dialogue days for the main issues covered by the review. Four meetings thus offered an opportunity for discussions with representatives from the Local Information Committees (CLIs) and environmental associations on accidents with and without core melt, the hazards faced by the reactors, equipment ageing, environmental protection, pressure vessel strength and OHF.

In 2023, ASN also took part in preparing the national consultation to be held under the aegis of the High Committee for Transparency and Information on Nuclear Security (HCTISN) in the first half of 2024. This consultation will cover the provisions proposed by EDF for the generic phase of the periodic safety review. It will notably rely on a website, public meetings and webinars. ASN will take account of its conclusions in preparing its position on the generic phase of this periodic safety review scheduled for 2025.

4 Regulation and oversight of the safety of the Flamanville EPR reactor

The EPR is a PWR using a design that contains a number of changes by comparison with that of the reactors currently in operation in France. It meets reinforced safety objectives: reduction in the 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 DAC and the building permit, construction of the Flamanville EPR reactor began in September 2007. The first concrete was poured for the nuclear island buildings in December 2007.

Fuel loading is scheduled for the first half of 2024.

4.1 EXAMINATION OF THE AUTHORISATION APPLICATIONS

Examination of the commissioning authorisation application

In March 2015, EDF sent ASN a first commissioning authorisation application for the installation, containing all the items required by the regulations. This application was renewed in June 2021 and the file was supplemented and updated.

During the review, ASN obtained the opinion of the GPR on several topics and a session was devoted to examining the safety case. ASN's review also takes account of the results of the tests performed on the site and OEF from EPR reactors commissioned abroad. For this purpose, ASN maintained regular relations with the Finnish, Chinese and British safety regulators in order to benefit from their experience of start-up tests, preparation for operation and the actual working of the EPR reactors.

The commissioning authorisation application file underwent a public consultation.

4.2 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:
- in a manner proportionate to the issues, checking the quality of equipment manufacturing and installation construction, in order to be able to issue a position statement on the safety of the installation;
- 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 players draw on the OEF from the construction and start-up test phase, including the upstream phases (supplier selection and monitoring, construction, procurements, etc.), in order to improve the management of these safety-important activities;
- 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 nuclear steam supply system.

In 2023, 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 correct anomalies. It in particular completed the repairs of the secondary systems welds. 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. Finally, EDF also continued to carry out the reactor start-up test programme and, at the end of 2023, completed the hot requalification phase of the equipment prior to reactor commissioning. Since December 2023, the site has entered a reactor fuel loading preparation phase.

4.3 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 2023, EDF continued with the examinations linked to the commissioning authorisation application and reached a favourable conclusion on several high-stakes technical subjects. This is in particular the case with the design of the primary system safety valves, the performance of the containment internal water tank filtration system, 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.

The latest examinations in progress will be able to take account of the results of the overall requalification tests in order to check that the reactor as-built and operated complies with its baseline safety requirements.

Assessment of nuclear pressure equipment conformity
The NPE of the Flamanville reactor includes that making up the main primary and secondary systems presented in points 1.4 and 1.5 (reactor pressure vessel, SG, pressuriser, reactor coolant pumps, piping, safety valves) but also that constituting other parts of the Nuclear Stream Supply Chain System Design (NSSS).

During the course of 2023, ASN continued to assess the conformity of the NPE design. The main topics raised by these assessments, along with their conclusions, were presented during sessions of the GPESPN on 20 and 21 June 2023. The subjects relating to repair of the welds on the main steam letdown lines (covered by the break preclusion baseline requirements), and the operations performed on other piping not subject to these requirements, to post-weld heat treatment, or the prevention of SC risks, were presented at these sessions. ASN considered that ultimately these various subjects were dealt with in such a way that it could rule that the equipment concerned was conforming. On some subjects, such as SC, or the coating of certain valves, follow-up work will nonetheless be carried out by EDF during the first years of operation.

In addition, several cases of irregularities during equipment manufacturing were reported to ASN. ASN systematically analyses their potential consequences for the safety of the installation.

Oversight of construction, start-up tests and preparation for operation
In 2023, ASN carried out an inspection campaign on EDF, Framatome, and the organisation it mandated to perform checks, focusing on repair of the secondary systems welds. ASN considers that this work was carried out rigorously, with a good level of monitoring by EDF, leading to confidence that a high level of production quality will be achieved.

Oversight of construction has repeatedly revealed faults in construction quality, requiring corrective measures. At ASN's request, EDF carried out additional checks during an equipment quality review. In 2023, ASN reviewed the results, which confirmed the quality of equipment production and identified areas for improvement to be addressed during the EPR 2 project.

Given the numerous scheduling delays, EDF implemented an equipment conservation strategy pending commissioning. The conservation activities were inspected on the site by ASN in 2023, which found that EDF's strategy was satisfactory in the light of the additional maintenance work performed and the checks conducted on the equipment at the end of the conservation phase.

Since 2022, ASN has also initiated a campaign of inspections regarding the 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 processing, etc.) and has scheduled them prior to commissioning of the reactor. ASN considers that significant work has been done in recent years to obtain a satisfactory level of finishing. It will nonetheless remain vigilant with regard to completion of the remaining activities before commissioning.

WELDS ON THE SECONDARY SYSTEMS OF THE FLAMANVILLE EPR REACTOR

Major repairs were required on 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.

Most of the other welds on the main steam lines to be repaired, of which there are about fifty, are located in an environment with no access difficulties.

At the same time, EDF analysed the quality of other welds, in particular those on the SG feedwater lines. This work led it to make the decision to repair ten or so additional welds.

The work done on all of these welds was completed in 2023 with post-weld heat treatment and non-destructive tests, as well as the performance of hydraulic testing. This last step is the key step in the final verification of these repair activities.

ASN carried out checks at each step in these repairs, with the support of an approved organisation.

ASN continued with the examination of the installation startup test results in order to check that the as-built facility complies with the assumptions used in the safety case. This examination will continue in 2024, notably on the basis of the results of the tests to prepare for fuel loading and the reactor startup tests.

ASN continued its checks on preparations for operation and notably carried out a five-day in-depth inspection in May 2023, which involved 15 inspectors and 11 IRSN experts. During this inspection, ASN found that the operating organisations were defined and most of them were already in use and the personnel had a good understanding of the installation. ASN nonetheless noted that considerable work was still to be done on the production of operational documentation for the control and maintenance of the installation. In 2024, ASN will carry out a follow-up inspection before commissioning, to ensure that the steps taken in response to its requests have indeed been implemented and meet the objectives set.

Overall, in 2023, ASN carried out 10 inspections of EDF on the Flamanville site, including one in-depth inspection on preparation for operation and a tightened inspection on the hot requalification tests, plus three inspections in the engineering departments. ASN also carried out Labour Code inspections. The conclusions of these inspections are presented in the Regional Overview in the introduction to this report.

5 Regulation and oversight of the EPR 2 reactors project

EDF has started a programme to build EPR 2 type reactors in France. A first pair of reactors is planned for the Penly site in the Seine-Maritime *département*, a second on the Gravelines site in the Nord *département* and a third on the Bugey site in the Ain *département*. EDF aims to commission the EPR 2 reactors on the Penly site by about 2035-2037. With this in mind, a public debate was held from 27 October 2022 to 27 February 2023, following which EDF submitted a DAC application to the Minister responsible for nuclear safety at the end of June 2023. This application is currently being examined by ASN, with the technical support of IRSN. This examination follows on from the evaluation of the EPR 2 reactor safety options.

EPR 2 reactors safety options

The EPR 2 is a new reactor which aims to incorporate the lessons learned from the design, construction and commissioning of the EPR reactors, along with OEF from the reactors currently in service. In the same way as the EPR reactors, it aims to meet the general safety objectives for third-generation reactors. Furthermore, this reactor will integrate all the lessons learned from the Fukushima Daiichi NPP accident, as of the design stage. This more specifically entails reinforcing the design against 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 considered that the general safety objectives, the baseline safety requirements and the main design options are on the whole satisfactory and, in its opinion and in a supplementary letter sent to EDF in July 2021, identified the subjects to be considered in greater detail for a future DAC.

Technical reviews carried out in 2023

Following examination of the EPR 2 safety options, ASN - with the support of IRSN – continued with the technical evaluation of this reactor model, notably on the basis of a preliminary version of the safety analysis report EDF sent it in February 2021. In 2023, ASN informed EDF of its requests regarding the study approach for accidents, with or without fuel melt, presented in it. The response from EDF to these requests will be examined during the review of the DAC application.

In January 2023, ASN convened the GPESPN concerning the baseline requirements for application of the break preclusion approach to non-breakable components, to the main lines of the primary and secondary systems of the EPR 2 reactors and concerning the definition of the NPE situations and loads for the main primary and secondary systems. The break preclusion approach is among the subjects for which ASN had requested additional data in its 2019 opinion.

ASN considers that, given the additional measures and justifications provided by EDF, the baseline requirements for applying the break preclusion approach to the non-breakable components and to the main lines of the primary and secondary systems of the 2-reactor project is acceptable. This position has yet to be confirmed by the completion of certain studies and validation of the choice of certain materials.

ASN also examined the options files of the main NPE for the EPR 2 reactors. ASN issued opinions concerning the reactor pressure vessel in 2021, the SGs in 2022 and the pressuriser and main steam lines in 2023.

In response to a request from EDF, ASN in June 2023 also expressed its requirements regarding the incorporation of the specific features of the Tricastin site, were this site to be chosen for the construction of EPR 2 reactors.

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The emergence of small modular reactor projects

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Several Small Modular Reactor (SMR) projects are currently being developed around the world. These are reactors with a power of less than 300 Megawatts electric (MWe), built mainly in a factory. They use a variety of technologies: that of the Pressurised Water Reactors (PWRs) or advanced technologies (high-temperature, molten salt, fast neutrons reactors, etc.).

The characteristics of SMRs, in particular their low power and compactness, contribute to their safety.

The French Nuclear Safety Authority (ASN) considers that the designers should take advantage of these characteristics to propose reactors aiming for more ambitious safety objectives than the existing third-generation high-power reactors.

ASN is also participating in international SMR working groups. Within this framework, it is holding discussions with its foreign counterparts in order to promote the definition of ambitious international baseline requirements, share its practices and benefit from experience feedback from its counterparts.

1 The Government's call for project proposals

In March 2022, the Government launched a call for project proposals for innovative nuclear reactors, aiming to create a new ecosystem of nuclear start-ups, in addition to the existing historical French large nuclear companies.

This call for project proposals is part of the France 2030 Plan to decarbonise the economy, in particular aiming to develop new nuclear reactor concepts which:
- in addition to producing electricity, will also meet the need for the production of heat with temperatures of several hundred degrees, offering an alternative to the use of gas for a large number of industrial processes;
- can help close the "nuclear fuel cycle[1]" and improve radioactive waste management, by helping to reduce its volume or its activity.

This was the context in which about ten new companies sponsoring SMR projects appeared in 2022 and 2023.

2 From power reactors to small modular reactors

The industrial nuclear reactors operated in France have until now only focused on the large-scale production of electricity. The French Nuclear Power Plant (NPP) fleet was thus gradually built with a regular increase in the power of these reactors, from 900 MWe initially, to 1,300 MWe, then 1,450 MWe and finally 1,600 MWe for the Flamanville EPR reactor.

By more specifically targeting the market to directly supply energy to industrial customers, the new reactor designers responding to the Government's call for project proposals are moving away from the traditional model, by developing reactors 10 to 400 times less powerful than the Flamanville EPR reactor (see Table 1).

This significant power reduction also implies a radical adaptation of the development business model for these small reactors, on the one hand by seeking to reduce construction times and, on the other, by relying on standardisation and mass production.

This new industrial model with mass production involving a large share of prefabrication in the factory is why these small reactors are referred to as "modular".

TABLE 1 **Comparative thermal power of the reactors**

	THERMAL POWER (*) OF THE REACTOR CORE
Flamanville 3 EPR reactor	4,300 Megawatts thermal (MWth)
Small Modular Reactors which responded to the call for project proposals	10 to 540 MWth

* In the light of the supply of energy which is now not exclusively in the form of electricity, the characteristic power of these SMRs is expressed in terms of the thermal power of their core.

1. France opted for a "nuclear fuel cycle" including the reprocessing of spent fuel. This reprocessing enables reusable materials (uranium and plutonium) to be recovered, while the other compounds (fission products and minor actinides) constitute the ultimate waste. At present, only a part of the reprocessed materials can actually be reused to fabricate new fuels. The notion of a "'closed' nuclear fuel cycle" corresponds to the goal of reprocessing the fuels several times and reusing all of the recovered materials or even, for some innovative reactor projects, also consuming the waste such as the fission produces and minor actinides.

01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 AP

TABLE 2 **SMR projects being studied**

TECHNOLOGY	PROJECT	POWER OF ONE REACTOR (MWth)	SHORT-TERM TARGET
Light water reactor	NUWARD	540	Industrial prototype
	CALOGENA	30	
Sodium-cooled reactor	OTRERA	300	
	HEXANA	400	
High-temperature reactor	JIMMY	10 to 20	
	BLUE CAPSULE	150	
Lead-cooled reactor	NEWCLEO	80 (then eventually 450)	Experimental reactor
Molten salt reactor	NAAREA	80	
	STELLARIA	250	
	THORIZON	250	

3 Overview per technology of the small modular reactor projects being monitored by ASN and IRSN

Table 2 presents the list of the ten SMR projects currently being monitored by ASN and the French Institute for Radiation Protection and Nuclear Safety (IRSN), ranked according to the degree of technological maturity of the reactor. A distinction must in particular be made between:

- **nuclear reactors cooled and moderated by light water**

This technology accounts for the vast majority of the reactors currently being operated worldwide.

- **reactors known as "Generation IV"**

These reactor technologies, already known and explored for many years now, had so far only led to the development of a few experimental or prototype reactors, with no industrial scale operation.

In 2015, IRSN evaluated the maturity of these various technologies and identified the needs for development of scientific and technical knowledge. IRSN had concluded that only sodium-cooled Fast Neutrons Reactors (SFRs – such as the Phenix and Superphenix reactors which were operated in France) and high-temperature gas-cooled reactors using graphite as a moderator, offered usable Operating Experience Feedback (OEF) for envisaging a transition to a possible industrial phase in the short term.

This difference in the maturity of the various technologies notably means that some projects are beginning with an experimental reactor development phase before envisaging the development of an industrial prototype.

4 Implementation of a framework of incremental technical exchanges with ASN and IRSN

In order to optimise preparations for any creation authorisation applications for these various innovative reactor projects, and in order to mobilise resources proportionate to the level of development maturity of each project, a four-phase framework of incremental technical exchanges (see Table 3) was set up:

PHASE 1 Screening phase

During a short meeting, the project developer is asked to present the following to ASN and IRSN:
- the main characteristics of its reactor project (technology, power, form of energy output, size of target market in number of reactors, type of site, etc.);
- the state of progress of the reactor design and its development schedule;
- the current technical and financial capacity of the company developing the project, along with its growth plan (calls for funds and staffing).

Following this screening phase, the project developer is asked to continue with its development in order to attain the following three objectives:

1. **Minimum maturity of the technical project:** the project developer has an initial complete conceptual design of its project.
2. **Project developer's capacity to conduct technical exchanges:** the project developer has a sufficient in-house technical team (estimated at about twenty engineers) to be able to carry out technical exchanges with ASN and IRSN on all the technical topics associated with the safety case of its reactor.
3. **Minimum financial security of the project developer:** the company developing the project has sufficient financial guarantees to back up its development for at least the coming 18 to 24 months.

TABLE 3 **Status of technical exchanges between the SMR project sponsors, ASN and IRSN**

PROJECT	SCREENING PHASE	PREPARATORY REVIEW	PRE LICENSING (SAFETY OPTIONS)	ASSESSMENT OF THE CREATION AUTHORISATION APPLICATION
NUWARD			In progress	
CALOGENA		Planned		
OTRERA	To be repeated			
HEXANA	To be repeated			
JIMMY		Finalised		
BLUE CAPSULE	To be repeated			
NEWCLEO		In progress		
NAAREA		In progress		
STELLARIA	To be repeated			
THORIZON	To be repeated			

PHASE 2 Project preparatory review

Once the project maturity is considered to be sufficient with respect to the three above-mentioned criteria, a cycle of thematic discussion meetings is scheduled.

By means of presentations and Q&A sessions, the purpose of this cycle of meetings is to obtain a precise overview of the project. These meetings more particularly help to obtain an understanding of its particular design, paint a picture of the knowledge both available and still to be acquired, and clearly identify the main safety orientations of the project.

This phase entails a first level of mobilisation by the IRSN specialists, but simply constitutes an exchange of information in preparation for future assessments. At this stage neither ASN nor IRSN expresses any technical position on the project.

PHASE 3 Pre-licensing of the fundamental safety options of the project

Pursuant to Article R. 593-14 of the Environment Code, before finalising the detailed design of its reactor, the project developer that intends to apply for a creation authorisation procedure can ask ASN for its opinion on some or all of the fundamental aspects of its project.

With regard to these innovative reactor projects, ASN recommends that the project developers take advantage of this pre-licensing step, which enables initial technical assessments to be started and enables the positions of the regulator to be obtained on a jointly agreed list of identified high-stakes subjects further to the preparatory review phase.

PHASE 4 Assessment of the creation authorisation application

Finally, once the detailed design of the reactor project is ready, a submission of a creation authorisation application can be envisaged.

This phase represents a new step in the increasing commitment of resources by ASN and IRSN. Following the complete technical evaluation of the project, there will also be an evaluation of the characteristics of the planned site and a programme of inspections of the applicant, who acquires the de facto status of licensee, notably with the aim of checking its management system and its ability to manage subcontracting.

5 New safety challenges and safety objectives to be adapted

Whereas the siting of a new power generating reactor is one of the aspects of the project which can to a certain extent be a choice, this is not the case for numerous SMR projects.

If the particular target is the industrial heat production market, then the siting of an SMR is determined by the location of the customer to whom it will be delivering the energy. Numerous SMR projects are thus aiming for deployment on industrial sites located near to or even within urban areas.

This type of siting near to densely populated or industrial areas is being envisaged by the project developers because these reactors are likely to be able to achieve safety levels significantly better than those of today's large power generating reactors. The low power to be removed in the event of an accident should make it possible to combine passive and active safety systems, leading to increased diversification of the safety provisions, longer grace periods[(2)] and better protection of the containment barriers. In addition, some of the new technologies proposed have specific characteristics (such as the intrinsic containment performance of the particular fuels of high-temperature reactors), which also make it possible to envisage a significant reduction in radioactive releases in the event of an accident, even the most severe.

Even if these reactors can in principle achieve a higher safety level than those of the high-power electricity generating reactors, ASN considers that the safety objectives to be attained must be defined before envisaging such siting close to population centres.

ASN thus set up a pluralistic working group to consider the reinforced safety objectives to be defined before envisaging such siting choices.

2. Time during which safety can be guaranteed with no intervention being required (for example the time for which – in the event of total loss of electrical power – safety can be guaranteed passively, pending the restoration of a back-up power source).

TABLE 4 **Presentation of technologies and corresponding fuels envisaged for the SMRs**

TECHNOLOGY	CURRENT AVAILABILITY OF THE ASSOCIATED SPECIFIC FUEL
Light water reactor	• Existing industrial capacity
Fast Neutron Reactor, sodium or lead-cooled	• Industrial production capacity to be developed
High-temperature reactor	• No industrial production capacity for this particular type of fuel (TRISO(*)) • Need for uranium enriched to nearly 20% (HALEU(**))
Molten salt reactor	• No industrial production capacity for this particular type of fuel (mixture of U and PU integrated into chloride salts) • Need to develop natural chlorine to chlore-37(***) enrichment capacity

* The particle fuel is referred to as "TRISO" for "Tri-Structural Isotropic". The kernel consisting of uranium oxide, carbon and oxygen is surrounded by three insulating layers acting as the first containment barrier to retain the fission products.

** High-Assay Low-Enriched Uranium (HALEU) type uranium is enriched to a higher level of the uranium-235 isotope (from 5 to 20%) than the conventional Low-Enriched Uranium (LEU) used in the fuel for PWRs and Boiling Water Reactors (BWRs).

*** Natural chlorine consists of two stable isotopes: chlorine-35 (75%) and chlorine-37 (25%). In the reactor core, the chlorine-35 is transformed by neutron capture into chlorine-36 which is a very long half-life radioactive isotope and whose solubility and mobility through geological layers make it waste that is hard to manage.

6 The need for a vision incorporating the "fuel cycle"

The development of these modular reactor projects is dependent on the availability of the fuel they need in order to operate. This availability refers not only to the existence of industrial production means for the fuels, but also the production capacity (see Table 4).

Two SMR project sponsors also initiated technical discussions with ASN and IRSN in 2023 on projects to develop fabrication plants for their fuel:
- JIMMY, concerning a project for a TRISO fuel fabrication plant;
- NEWCLEO, concerning a project for a MOX[3] fuel fabrication plant for a Lead-Cooled Fast Neutrons Reactor (LFR).

With regard to the molten salt reactor projects (NAAREA, STELLARIA and THORIZON), these project developers are working in collaboration with Orano, which could eventually envisage developing production means for this type of fuel.

Apart from the subject of fuel fabrication, ASN also underlines the need to have the transport systems approved for these fresh and used fuels, and to anticipate the development of technologies for reprocessing and for management of the associated waste.

7 Standardisation and international cooperation goals

Despite the already high level of harmonisation both internationally, with the safety standards from the International Atomic Energy Agency (IAEA), and at the European level, with the safety objectives and reference levels adopted by the Western European Nuclear Regulators' Association (WENRA), each project to build a reactor model in a new country generally leads to modification of the original design to adapt to the national regulatory context and the requirements of the local licensee.

Although the cost of these adaptations remains acceptable in the case of large nuclear power reactors, this is not necessarily the case for SMRs, for which the business model is based on mass production to reduce costs and achieve the profitability threshold, thus implying that a given model can be authorised by several countries.

In order to remove the potential obstacles to the development of these new reactors, a number of international initiatives have emerged. The IAEA is mobilising its members through an initiative called "NHSI" (Nuclear Harmonization and Standardisation Initiative) aiming to develop and encourage international cooperation modes for joint reviews of a given reactor model by several safety regulators, or to enable a country to familiarise itself with the evaluations already performed by other countries, in order to reduce its own review workload.

ASN is taking part in this work and at the International Convention on Nuclear Safety presented the concrete results of the Joint Early Review (JER) of the Nuward reactor (see box next page) conducted with the safety regulators from Finland (STUK) and Czech Republic (SUJB). In view of the interest in and success of this cooperation between three safety regulators, Nuward aimed to take this JER further by launching a second phase in which the nuclear safety regulators from the Netherlands (ANVS), Poland (PAA) and Sweden (SSM) joined the three regulators already involved.

3. MOX fuel is a nuclear fuel consisting of a mixture of depleted uranium oxide and plutonium.

IDENTIFICATION OF THE SAFETY ISSUES AND REGULATORY CHANGES NEEDED FOR SMRS THROUGH THE ACTUAL CASE OF THE NUWARD SMR

Nuward SMR small modular reactor project.

On 14 November 2023, together with five European counterparts, ASN initiated the second phase of the Nuward reactor project safety options review.

The Nuward SMR reactor is a small modular pressurised water reactor project developed by Nuward, a subsidiary of the EDF group, and its partners (Alternative Energies and Atomic Energy Commission – CEA, Naval Group, TechnicAtome, Framatome and Tractebel). Each unit consists of two modules of 170 MWe each, immersed and housed in the same building, which is partially underground. This concept comprises a number of major safety innovations, notably passive management of reactor cooling in the event of an accident.

Joint review conducted by several safety regulators

In the first quarter of 2022, ASN, together with its Czech (SUJB) and Finnish (STUK) counterparts, with the support of IRSN and its Czech counterpart (SÚRO), conducted a preliminary review of the main safety options for the Nuward project.

By means of a concrete example, this review identified the safety advantages of SMRs, along with the questions to which they could give rise. It also compared the various requirements, practices and experiences of the three regulators involved and identified the opportunities for changes to national regulations and practices. This review provided Nuward with data allowing the development of a more standardised design.

The closing report from this multilateral cooperation presented the programme and the working method adopted, along with the main lessons learned.

On 14 November 2023, ASN initiated the second phase of this review. On this occasion the Dutch (ANVS), Polish (PAA) and Swedish (SSM) regulators joined the initiative. This phase also involves the technical support organisations of these safety regulators.

Following on from the first phase, the aim of the second phase will be to use an actual project to identify the benefits of and the questions raised by SMRs in terms of safety and adaptation to the various national regulatory frameworks. During this new phase, the evaluation will be expanded to include new technical subjects. The review will notably concern the containment barriers, assessment of the radiological consequences of an accident and the architecture of the electrical and instrumentation and control systems.

ASN review of the reactor's safety options

In parallel with this joint review, EDF asked ASN in June 2023 for its opinion on the safety options of the Nuward SMR reactor, as provided for in Article R. 593-14 of the Environment Code. This review will cover the project as a whole. It will take account of the recommendations of ASN Guide No. 22 on PWR design. ASN will pay particular attention to assessment of the innovative approaches and systems of the Nuward reactor.

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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 packaging of the various 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 2023, on the La Hague site, Orano commissioned three New fission products evaporator-concentrators (NCPF T2) in the UP3-A plant, thus replacing the existing equipment which suffered from more advanced corrosion than foreseen in the design, plus a further expansion of the plutonium-bearing materials storage capacity. The situation of the Melox plant improved in 2023 by comparison with the previous years, in terms of quality and quantity of MOX fuel production (Mixture of OXides of uranium and plutonium). These factors are helping to stabilise the operation of the "fuel cycle", even if this still offers little margin for contingencies and the countermeasures to be put into place to offset the risk of saturation of the spent fuel storage pool are yet to be deployed.

With regard to the performance of the sites in 2023 and the measures taken by their licensees to improve them, ASN considers that the operation of the "fuel cycle" as a whole is improving, but 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_6) 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_6 enrichment between 3% and 6% is carried out by ultracentrifuges in the Georges Besse II (GB II) plant in Tricastin.

This enriched UF_6 is then transformed into uranium oxide powder in the Framatome plant in Romans-sur-Isère. The fuel pellets manufactured with this oxide are introduced into cladding to make fuel rods, which are then combined to form fuel assemblies.

These assemblies are then 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. In 2023, Framatome also took over the fabrication of fuel assemblies based on Enriched Reprocessed Uranium (URE) intended for the Cruas-Meysse Nuclear Power Plant (NPP).

After a period of use of about 3 to 4 years, the spent fuel assemblies are removed from the reactor and cooled in a pool, firstly on the site of the plant in which they were used and then in the Orano reprocessing plant at La Hague.

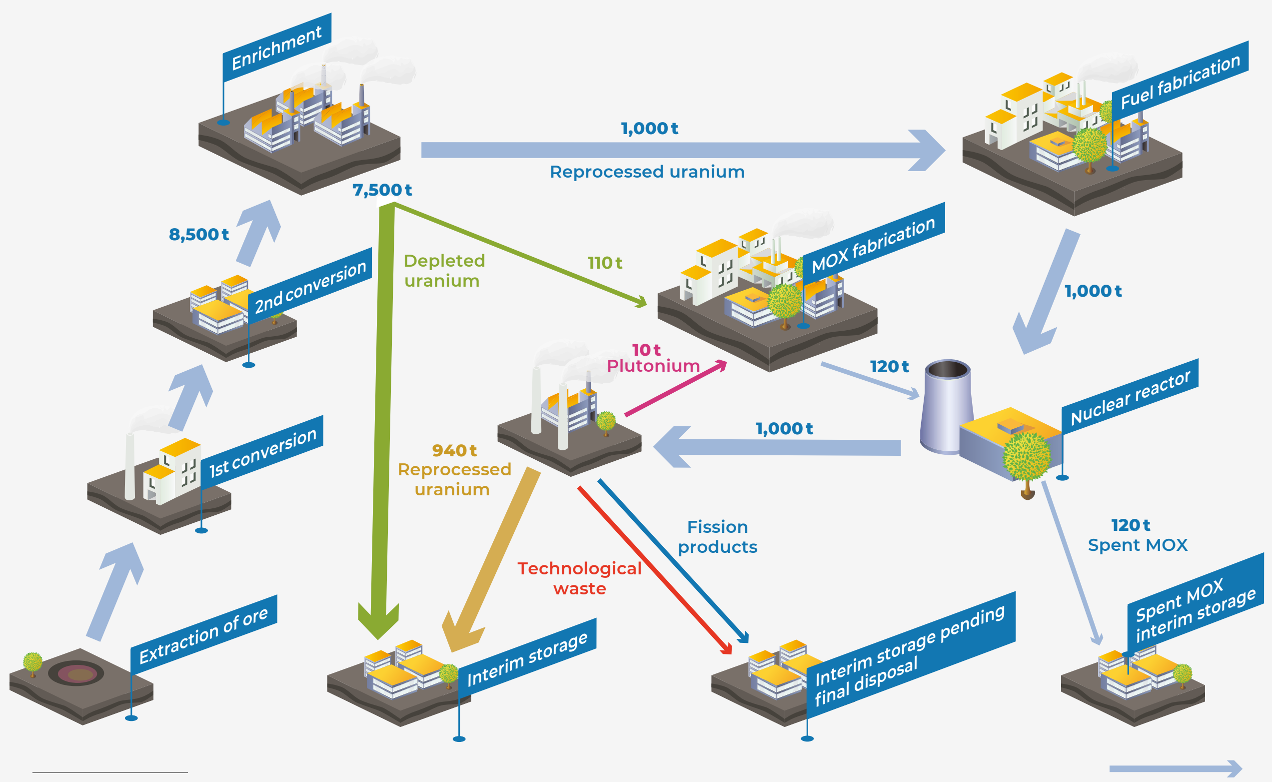
In this plant, the uranium and plutonium from the spent fuels are then separated from the fission products and other transuranic elements[1]. The uranium and plutonium are packaged and then stored for subsequent re-use.

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 2023

	PRODUCT PROCESSED			PRODUCT OBTAINED		PRODUCT SHIPPED	
INSTALLATION	ORIGIN	PRODUCT PROCESSED	TONNAGE	PRODUCT OBTAINED	TONNAGE	DESTINATION	TONNAGE
Orano Tricastin Conversion	Orano Malvési	UF_4	13,679	UF_6	14,879	Orano storage areas Tricastin	14,879
Orano Tricastin TU5 Unit	Orano La Hague	Uranyl nitrate	3,468	U_3O_8	1,048	Orano storage areas Tricastin	1,048
Orano Tricastin Usine W	Orano Tricastin GB II	UF_6 depleted	9,879	U_3O_8	7,880	Orano storage areas Tricastin	7,880
Orano Tricastin GB II	Orano Tricastin Conversion	UF_6	11,263	UF_6 depleted	9,451	Orano W plant Tricatin	9,451
				UF_6 enriched	1,426	Fuel fabrication plants	1,426
Framatome Romans	Orano Tricastin GB II	UF_6 enriched	518	Fuel assemblies	568	EDF	428
						Taishan (China)	70
	Urenco (Netherlands, Germany and United States)		90			Tihange (Belgium)	29
						Koeberg (South Africa)	28
						Goesgen (Switzerland)	7
	Tenex (Russia)		38			Rignhals (Sweden)	4
						Trillo (Spain)	2
	ANF Lingen (Germany)	Gadolinium rods	7	UO_2 and U_3O_8 powder	7	CEA	5
						Framatome Richland (United States)	3
Orano Melox Marcoule	WSE Vasteras (Sweden)	UO_2 depleted	81	MOX fuel elements	72	EDF	61
	Orano La Hague	PuO_2	8				
Orano La Hague	**Fuels reprocessed in the La Hague plant**						
	EDF and other licensees	UOX and MOX	882	Uranyl nitrate	998	Orano Tricastin	865
				PuO_2	12	Melox Marcoule	6
	Fuels stored in the La Hague plant pools						
	EDF and other licensees	Irradiated fuel elements	10,125	–	–	–	–

"Fuel cycle" diagram



The tonnages represented on the diagram correspond to "nominal" operation, which has not been the case in recent years.

Flows expressed in tonnes/year

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 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 (see previous page).

Other facilities are needed for the operation of the Basic Nuclear Installations (BNIs) mentioned below, more particularly the IARU facility (formerly Socatri), which is responsible for the maintenance and decommissioning of nuclear equipment, as well as the treatment of nuclear and industrial effluents from the Orano platform in Tricastin.

1.1 THE FRONT-END "FUEL CYCLE"

Before fuels are fabricated for use in the reactors, the uranium ore must undergo a number of chemical transformations, from the preparation of the Yellow Cake through to conversion into UF_6, the form in which it is enriched. These operations take place primarily on the Orano sites of Malvési, in the Aude *département*, and Tricastin in the Drôme and Vaucluse *départements* (also known as the Pierrelatte site).

On the Tricastin site, Orano operates:

- the TU5 facility (BNI 155) for conversion of uranyl nitrate ($UO_2(NO_3)_2$) produced by reprocessing spent fuel at La Hague into triuranium octoxide (U_3O_8);
- the W plant (ICPE within the perimeter of BNI 155) for converting depleted UF_6 into U_3O_8;
- the former Comurhex facility (BNI 105) for converting uranium tetrafluoride (UF_4) into UF_6, which contains the Philippe Coste plant;
- the GB II (BNI 168) UF_6 ultra-centrifuge enrichment facility;
- the Atlas analysis laboratory (BNI 176);
- areas for the storage of uranium and thorium in various forms (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 (t) 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 14).

The Philippe Coste plant is located inside its perimeter and is devoted to the fluorination of UF_4 into UF_6, to allow its subsequent enrichment in the GB II plant.

It has a production capacity of about 14,000 t of UF_6 from the UF_4 coming from the Orano facility in Malvési. It has ICPE status subject to authorisation with institutional controls ("Seveso" class installation) and is monitored by ASN accordingly.

The Georges Besse II ultra-centrifuge enrichment plant – BNI 168

BNI 168, called "GB II", for which creation was authorised in 2007, is a plant enriching uranium by means of gas ultra-centrifugation. This process involves injecting UF_6 into a cylindrical vessel rotating at very high speed. Under the effect of the centrifugal force, the heavier molecules (containing uranium-238) are separated from the lighter ones (containing uranium-235). By combining several centrifuges, creating a cascade, it is then possible to recover a stream of uranium enriched with fissile 235 isotope and a depleted stream. The GB II plant comprises two enrichment units (South and North units) and a support unit, REC II. On 19 June 2023, Orano send the Minister in charge of nuclear safety a substantial modification authorisation application, with the aim of increasing the nominal production capacity of the GB II plant by 30%.

Enrichment of the uranium resulting from reprocessing, which would require prior authorisation from ASN, is not currently carried out in this plant.

The Atlas facility – BNI 176

The purpose of the Atlas facility is:
- to carry out industrial physico-chemical and radio-chemical analyses;
- to monitor liquid and atmospheric discharges and monitor the environment of the Tricastin facilities.

The Atlas facility, commissioned in 2017, meets the most recent safety requirements.

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 2022-3091 of 18 March 2022 authorises the Orano Chimie-Enrichissement company to create a storage BNI called "Local Supply of Reprocessed Uranium Storage" (FLEUR acronym in French), intended for the storage of containers of depleted uranium mainly produced by reprocessing of spent fuels. It currently comprises two buildings and could eventually comprise up to four.

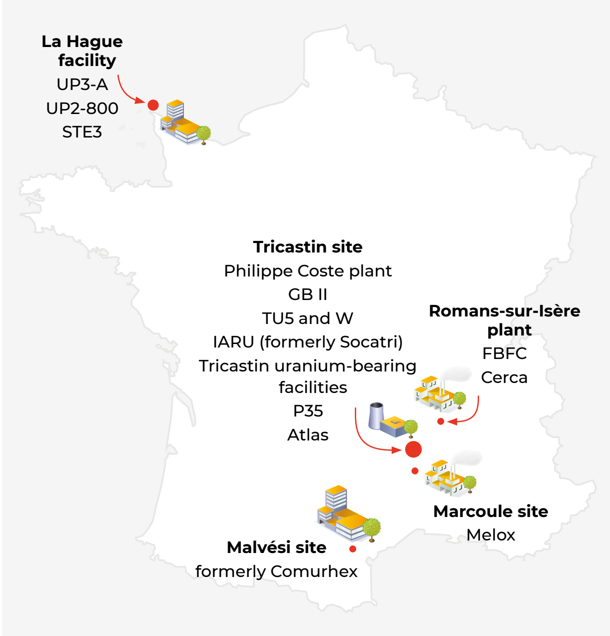
The IARU facility (formerly Socatri) – BNI 138

The facility primarily carries out repair, decontamination and dismantling of industrial or nuclear equipment, radioactive and industrial liquid effluent treatment and reprocessing and conditioning of radioactive waste.

1.2 FUEL FABRICATION

The fabrication of fuel for electricity generating reactors involves the transformation of UF_6 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 "fuel cycle" facilities in service



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 uranium oxide and plutonium oxide powder and sintering it into pellets, which are then placed in cladding and assemblies of the same geometry as those produced by FBFC.

1.3 THE BACK-END "FUEL CYCLE" – REPROCESSING

The Orano reprocessing plants in operation at La Hague

The La Hague plants, intended for reprocessing of spent fuel assemblies from nuclear reactors, are operated by Orano.

The various facilities of the plants reprocessing irradiated fuel elements from ordinary water nuclear reactors (UP3-A – BNI 116 and UP2-800 – BNI 117) and of the Effluent Treatment Station (STE3 – BNI 118) were commissioned from 1986 (reception and storage of spent fuel assemblies) to 2002 (R4 plutonium reprocessing facility), with most of the process facilities being commissioned in 1989-1990.

The Decrees of 10 January 2003 set the individual reprocessing capacity of each of the two plants at 1,000 tonnes per year (t/year), in terms of the quantities of uranium and plutonium contained in the fuel assemblies before burn-up (in the reactor), and limit the total capacity of the two plants to 1,700 t/year. The limits and conditions for water discharges and intake defined in 2015, were updated by two ASN resolutions of 16 June 2022 (resolution 2022-DC-0724 and resolution 2022-DC-0725). The resolutions notably modify the maximum monthly value of the activity concentration of the noble gases, including krypton-85, and regulate the limits and procedures for the discharge at sea of eleven chemical substances, detected by the licensee in small quantities in the discharges during a regulatory conformity evaluation.

Operations carried out in the plants
The reprocessing plants comprise several industrial units, each of which performs a specific operation. Consequently there are facilities for the reception and storage of spent fuel assemblies, for their shearing and dissolution, for the chemical separation of fission products, uranium and plutonium, for the purification of uranium and plutonium, for treating the effluents and for 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 in the form of $UO_2(NO_3)_2$. 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 Standard vitrified waste packages (CSD-V). The pieces of metal cladding are compacted and packaged in Standard compacted waste packages (CSD-C).

These reprocessing operations also use chemical and mechanical processes, the operation of which generates gaseous and liquid effluents as well as solid waste.

The 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 Soulaines (see chapter 15) or stored on the Orano site at La Hague, pending a final disposal solution; this is notably the case for the CSD-V and CSD-C, for which final disposal is envisaged in the planned *Cigéo* project (see chapter 15).

In accordance with Article L. 542-2 of the Environment Code, the radioactive waste from the reprocessing of spent fuel assemblies from abroad, is sent back to the producer country. It is however impossible to physically separate the waste according to the fuel from which it originates. In order to guarantee an equitable distribution of the waste resulting from the reprocessing of the fuels of its various customers, the licensee has proposed an accounting system that tracks the entries into and exits from the La Hague plant. This system, called "Exper", was approved by the 2 October 2008 Order from the Minister responsible for energy.

1.4 "FUEL CYCLE" CONSISTENCY IN TERMS OF NUCLEAR SAFETY AND RADIATION PROTECTION

The "nuclear fuel cycle" comprises the fabrication of the nuclear fuel used in the nuclear power plant reactors, its storage, its reprocessing after irradiation and management of the resulting waste. Several licensees are involved in the cycle: Orano, Framatome, EDF and the French National Radioactive Waste Management Agency (Andra).

ASN monitors the overall consistency of the industrial choices made with regard to fuel management and which could have consequences for safety. Over and above the safety issues specific to each facility, there are systemic safety issues affecting the "fuel cycle", notably from the viewpoint of balancing the operation of the various facilities and managing the inventories of radioactive substances and the corresponding storage needs.

On 18 October 2018, ASN issued its opinion 2018-AV-0316 on the "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 (PPE), or the operating contingencies of the plants involved in the "fuel cycle".

It underlines the need to anticipate any strategic change in the functioning of the "fuel cycle" by at least ten years so that it can be designed and carried out under controlled conditions of safety and radiation protection. It is a question for example – given the incompressible development times for industrial projects – of ensuring that the needs for the creation of new spent fuel storage facilities or for new transport packaging designs are addressed sufficiently early.

In December 2020, EDF, together with Framatome, Orano and Andra, updated its "fuel cycle" management outlook to take account of energy mix scenarios consistent with the PPE published in April 2020. This outlook was modified substantially in the light of subsequent French energy policy orientations; prospective simulation work is regularly presented to ASN by the licensees concerned, notably during joint hearings of Orano and EDF by the ASN Commission. In the light of the quantitative prospects resulting from the range of scenarios considered, and the reduced margins available in the pools on the La Hague site, it appears that there is a risk of saturation of the spent fuel storage capacity as of the early 2030s, or even before in the event of a major problem with one or more "cycle" facilities. ASN underlines the need for the "cycle" facilities and associated storage capacities to have significant margins with respect to the various energy scenarios envisaged and with regard to the contingencies liable to affect the operations.

In 2020, EDF announced postponement of the commissioning of its centralised storage pool project to 2034 at the earliest. This means that countermeasures will have to be deployed to deal with this delay to the 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 problems concerning certain steps in the “fuel cycle”, which had appeared and became worse in 2021, the situation in 2023 is improving, but remains fragile:

- An action plan has been implemented by Orano since 2019 to overcome the production difficulties at Melox. The use of a “wet process” depleted uranium powder was qualified in September 2022. The production by the Melox plant in 2023 was thus significantly higher than in 2022. The production of radioactive materials containing plutonium that was not compatible with use as fuel in the reactors, referred to as “MOX scrap” also fell. The use of this “wet process” powder thus helps improve the situation, pending the use of a comparable uranium powder from a new unit called “New Wet Process” (NVH) in Orano’s Malvési plant, qualification of which is scheduled for 2024.
- The problems with Melox production 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, a second in April 2023 and a third is currently being examined by ASN.
- Replacement of the fission products evaporator-concentrators (“NCPF” project) in the UP3-A plant was completed in 2023, while replacement of those in plant UP2-800 is scheduled for 2024.
- The La Hague pools densification authorisation application file, submitted at the end of December 2022, is currently being examined. 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 (DAC) of BNIs 116 and 117, constitutes one of the countermeasures identified to deal with the delay in commissioning of a centralised storage pool.

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. They were built and commissioned in accordance with the schedule set out by the licensee. The commissioning authorisation for three other evaporators (NCPF R2) is envisaged for 2024.

Construction of new storage capacity for waste packages on the La Hague site

To anticipate the saturation of storage capacity for CSD-V (units R7, T7 and E/EV/SE), construction work on new storage facilities, known as the “glass storage extension on the La Hague site” (E/EV/LH) began in 2007. These facilities are being built module by module, with the construction of identical units called “pits”. On 8 September 2022, ASN authorised the introduction of radioactive waste packages into pit 50 in the E/EV/LH2 unit. Pit 60 is under construction in order to boost storage capacity.

In addition, an extension of CSD-C storage, authorised by the Decree of 27 November 2020, is currently under construction; radioactive substances should be introduced into this extension for the first time in 2025, after authorisation by ASN.

In 2023, Orano submitted an application for a substantial modification to the DAC of BNI 116 (UP3-A) to increase the storage capacity for CSD-C waste packages and CSD-V waste packages. This application will be the subject of a public inquiry.

Extension project for the North unit of the George Besse II plant on the Tricastin site

In July 2022, Orano sent ASN a Safety Options Dossier (DOS) concerning a project to extend the North unit of the GB II plant, in order to increase the plant’s production capacity by about 30%. ASN issued a position statement on the file on 7 February 2023. A prior consultation was organised on this project by Orano, under the aegis of the National Commission for Public Debate (CNDP) from 1 February to 9 March 2023. The guarantors designated by the CNDP submitted the results of the consultation on 9 May 2023, to which Orano responded on 13 June 2023, indicating that it intended to continue with the project.

On 19 June 2023, Orano submitted an application for modification of the DAC in order to increase the production capacity of the GB II plant by about 30%. The application is currently being examined by ASN and will be the subject of a public inquiry in 2024.

EDF centralised storage pool project at La Hague

During the public debate held in 2019, prior to the 5th edition of the National Radioactive Materials and Waste Management Plan (PNGMDR), EDF reaffirmed that 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 reported a delay concerning this storage pool project, which should be located on the La Hague site, but will not be commissioned before 2034. In 2021, EDF referred to the CNDP regarding this project and a prior consultation under the CNDP’s aegis was organised by EDF from 22 November 2021 to 8 July 2022, although it was suspended from 2 February to 20 June 2022. The guarantors designated by the CNDP submitted the results of the consultation on 8 August 2022. EDF now announces that the creation authorisation application file for the facility will be submitted in the first half of 2024.

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ASN recalls the importance of obtaining new spent fuels storage capacity meeting the most recent safety standards as rapidly 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 the dossier in February 2022. 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.

Project for dry storage of spent fuels on the La Hague site

In November 2021, Orano submitted the first version of a DOS to ASN, which considers it to be insufficient at this stage to enable it to issue a ruling. The DOS update transmitted by Orano in 2023 is being examined by ASN.

2 ASN actions in the field of "fuel cycle" facilities: a graded approach

2.1 THE GRADED APPROACH ACCORDING TO THE RISKS OF THE FACILITIES

At each step in the "fuel cycle", the potential risks in the facilities are different:
- The conversion and enrichment facilities mainly entail toxic risks (owing to the chemical form of the radioactive substances they use), criticality risks (when they use enriched materials) and the risk of dissemination of radioactive substances (in powder, liquid or crystallised form).
- The fuel fabrication facilities mainly entail toxic risks (when they have conversion units), criticality, fire or explosion risks (processes using heating methods), as well as the risk of dissemination of radioactive substances (in powder form) and of exposure to ionising radiation (when they use reprocessed substances).
- The spent fuel reprocessing facilities mainly entail risks of dissemination of radioactive substances (the substances used are mainly liquids and powders), of criticality (the fissile substances employed change geometrical shape) and exposure to ionising radiation (the fuels contain highly irradiating substances).

Their common point is that they never seek to create chain reactions (prevention of the criticality risk) and that they use substances that are dangerous, owing to their radiological or chemical properties, in industrial quantities. Conventional industrial risks are often preponderant; certain plants, such as Orano at Tricastin and La Hague or Framatome at Romans-sur-Isère, are in this respect subject to the Seveso Directive.

ASN devotes efforts to applying oversight that is proportionate to the potential risks of each facility. These are thus classified by ASN in one of the three categories defined according to the scale of the risks and their impacts on safety, health and the environment. This BNI classification enables the oversight and monitoring of the facilities to be adapted, reinforcing the inspections and the scope of the reviews carried out by ASN for the higher risk facilities.

When the installations are substantially modified or when they are finally shut down, ASN is in charge of examining these modifications, which are the subject of an amending decree from the Government, after prior consultation of ASN. ASN also establishes binding requirements for these main steps. Finally, ASN also reviews the safety files justifying the operation of each BNI.

For each facility, ASN monitors the organisation and means chosen by the licensee to enable it to assume its responsibilities in terms of nuclear safety, radiation protection, emergency management in the event of an accident and protection of the environment and public health and safety. ASN monitors the working of the organisations put into place by the licensees mainly through inspections, more specifically those devoted to safety management.

2.2 PERIODIC SAFETY REVIEWS OF "FUEL CYCLE" FACILITIES

Since the publication of the Decree of 2 November 2007, all the BNI licensees must carry out periodic safety reviews of their facilities at least every ten years. These exercises were carried out gradually on the "fuel cycle" facilities. Defining the review procedures may be somewhat complex, because unlike nuclear power reactors, most of these facilities are in fact unique. There are thus few baseline requirements or other facilities with which a comparison can be easily made.

Examination of these periodic safety reviews confirmed the pertinence of an upstream definition, in the "guidance" phase, of the priority subjects for examination by the licensee during the periodic safety review, along with the associated methodologies. 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) ended with ASN issuing technical requirements for the continued operation of this BNI. For plant UP3-A (BNI 116), Orano transmitted its review concluding report at the end of 2020, and it will be examined by the Advisory Committee of Experts for Laboratories and Plants (GPU) during the course of several meetings scheduled between 2023 and 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 a review by the GPU in 2024. The concluding report for the periodic safety review of the FBFC and Cerca plants, combined in a single BNI (63-U) by the Decree of 23 December 2021, was submitted by Framatome in June 2023.

The periodic safety review of the uranium-bearing materials storage facilities at Tricastin (BNIs 178, 179 and 180) was completed, with ASN issuing technical requirements for the continued operation of these BNIs.

The periodic safety reviews show the importance of an *in situ* verification of the conformity of the Protection Important Elements (EIPs) that is as exhaustive as possible, or as representative as possible of the EIP that are not accessible. They also illustrate the need for a robust approach to the control of the ageing of fuel cycle facilities. This is notably the case for the facilities in the back-end of the "cycle", for which the control of ageing is a priority issue. This is the subject of dedicated inspections and increased vigilance when examining the ongoing periodic safety reviews.

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Nuclear research and miscellaneous industrial facilities

13

Nuclear research or industrial facilities differ from the Basic Nuclear Installations (BNIs) involved directly in the generation of electricity (nuclear power reactors and "fuel cycle" facilities) or waste management. Traditionally, most of these BNIs are operated by the Alternative Energies and Atomic Energy Commission (CEA), but also by other research organisations (for example the Laue-Langevin Institute – ILL, the ITER international organisation and the National Large Heavy Ion Accelerator – Ganil) or by industrial firms (for instance CIS bio international, Steris and Ionisos, which operate facilities producing radiopharmaceuticals, or industrial irradiators).

1 Research facilities, laboratories and other facilities in France

1.1 RESEARCH REACTORS

The purpose of research reactors is to contribute to scientific and technological research and to improve the operation of the Nuclear Power Plants (NPPs). Some of these facilities also produce radionuclides[1] for medical uses. They are facilities in which a chain reaction is created and sustained, to produce a neutron flux of varying density, used primarily for scientific experimentation purposes. Unlike in NPPs, the energy produced by research reactors is not 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.

The CIP and electronic components irradiation test programmes continued in 2023. In parallel with performance of these tests, the French Nuclear Safety Authority (ASN) is examining the request for underwater repair of the hodoscope, a dossier which completes the full repair of the reactor following the discovery of flaws in 2020. This repair should take place at the end of the currently ongoing test programme, towards the end of 2025. ASN checks correct performance of the actions initiated following the conclusions of the last periodic safety review of the facility, notably with regard to improving the measures to prevent the fire risk and the 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.

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.

After an outage period relating to the occurrence of significant events, the facility was able to resume its tests in September 2022.

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.

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

▲ Research reactors
Cadarache: Cabri
Grenoble: RHF

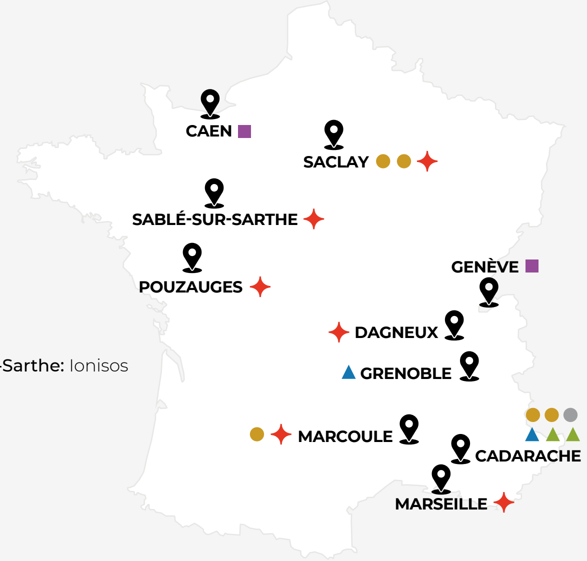
▲ Research reactors under construction
Cadarache: ITER, JHR

■ Particle accelerators
Caen: Ganil
Genève: CERN

● Laboratories and miscellaneous industrial facilities
Cadarache: LECA/STAR, Lefca
Saclay: LECI, UPRA
Marcoule: Atalante

● Storage of materials
Cadarache: Magenta

✦ Industrial ionisation facilities
Dagneux, Pouzauges, Sablé-sur-Sarthe: Ionisos
Marseille: Gammaster
Marcoule: Gammatec
Saclay: Poséidon



These research reactors are also significant sources for the production of certain radionuclides for medical uses.

The power of these reactors varies from a few tens to a hundred MWth. These reactors operate in cycles of about 20 to 30 days.

In France, since the final shutdown of the Osiris reactor (BNI 40) on CEA's Saclay site in 2015, there have been no technological irradiation reactors in operation.

The Jules Horowitz Reactor (JHR – BNI 172), which is intended to replace Osiris, is under construction at Cadarache. Commissioning of the facility, which comprises a number of milestones, is currently being examined by ASN. On 19 July 2023, the Nuclear Policy Council also ratified the continued investment by the State and the sector to finalise the construction of the JHR, so that France would have this new operational facility by 2032-2034. This reactor will be able to support research on extending the lifetime of the existing NPP fleet, on the EPR 2, but also on Small Modular Reactors (SMRs).

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.

Iter Organization began work in 2023 to redefine the facility's experimentation programme and develop a "new reference scenario". ASN underlines an improvement in the transparency of the exchanges on the corresponding safety issues. The hold points associated with the project, notably that relating to assembly of the tokamak, will be redefined within the context of the review associated with this new experimentation programme.

1.2 LABORATORIES AND MISCELLANEOUS INDUSTRIAL FACILITIES

1.2.1 Laboratories

The laboratories carrying out research and development work for the nuclear sector contribute to enhancing knowledge for nuclear power production, fuel fabrication and reprocessing, and waste management. They can also produce radionuclides for medical uses.

Principles and safety issues
The main challenges inherent in these facilities are protecting persons against ionising radiation, preventing the dispersal of radioactive substances, controlling fire risks and controlling the chain reaction (criticality).

The design principles for these laboratories are similar. Special areas, called "shielded cells" allow handling of and experimentation with radioactive substances, using appropriate handling systems. These shielded cells are designed with particularly thick walls and windows, to protect the operators against the ionising radiation. They also allow the containment of radioactive materials by means of a specific ventilation and filters system. The criticality risk is controlled 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.

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.

ASN checks the correct performance of the measures undertaken following the last periodic safety review.

Artificial Radionuclides Production Facility
The Artificial Radionuclides Production Facility (UPRA), situated in Saclay and operated by CIS bio international, is a nuclear facility designed according to the same principles as a laboratory (special areas for handling and experimenting with radioactive substances, using appropriate means), for the purposes of research and to develop radionuclides for medical uses. CIS bio international is a subsidiary of the Curium group, a manufacturer of radiopharmaceuticals.

ASN is currently examining the facility's periodic safety review, and it was also the subject of an opinion from the Advisory Committee of Experts for Laboratories and Plants (GPU) dated 16 March 2023.

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. Following the public inquiry held in 2023, publication of the Decree modifying the facility's Creation Authorisation Decree in order to integrate the "Désir" building, is expected by the end of 2024.

The CERN
The European Organisation 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.

FORMAL NOTICE SERVED ON THE SPENT FUEL TESTING LABORATORY (LECI)

In 2023, ASN served formal notice on CEA to implement operational measures on its LECI facility (BNI 50) to ensure that a safe state is achieved and maintained on the facility in the event of a fire in the areas adjacent to the nuclear areas. This technical requirement had been sent to CEA following the 2013 periodic safety review, with an initial deadline of 31 December 2019. Further to the finding by ASN's inspectors that this deadline had not been complied with, CEA requested a postponement to 31 December 2029. ASN considers this new request to be unacceptable, notably in the light of analysis of operating experience feedback from other licensees regarding fire reinforcement works, and thus served formal notice on the licensee, through resolution CODEP-DRC-2023-015452 of 4 July 2023, to comply with the technical requirement no later than 31 December 2026.

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 objection to the continued operation of BNI 154 for the next few years;
- the Steris group, which operates the Gammaster (BNI 147) and Gammatec (BNI 170) facilities in Marseille and Marcoule;
- CEA, which operates the Poséidon irradiator (BNI 77) on the Saclay site.

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 effluents released 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 the inspections and the reviews 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 2023, ASN continued to examine the periodic safety reviews of the Cabri (BNI 24), Poséidon (BNI 77) and Magenta (BNI 169) facilities operated by CEA, as well as the irradiators in Dagneux and Pouzauges (BNI 68 and 146) operated by Ionisos, the ion accelerator (BNI 113) operated by the Ganil and the artificial radionuclides production plant (BNI 29) operated by CIS bio international.

In 2023, ASN also finalised the analysis of the guidance files for the periodic safety review of three CEA facilities: LECI (BNI 50), LECA (BNI 55) and Lefca (BNI 123).

This step, in advance of the licensee’s transmission of the periodic safety review concluding report, sets out the methodology, the scope and the methods of the studies carried out for the forthcoming periodic safety review. ASN thus made a number of observations that CEA will have to take into account when preparing the periodic safety reviews of the above-mentioned facilities.

For example, these observations concerned the methodology used to take account of the risks linked to the chemical products in the facilities, notably with respect to the inventory of the substances to be considered.

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14

Decommissioning of Basic Nuclear Installations

14

The term decommissioning covers all the technical and administrative activities carried out after the final shutdown of a nuclear facility, following which it can be delicensed, in other words removed from the list of Basic Nuclear installations (BNIs). These activities comprise the removal of radioactive materials and waste still present in the facility and operations to dismantle the equipment and components used during operation, as well as clean-out of the premises and soils plus civil engineering structures demolition work as necessary.

The aim of the decommissioning and clean-out operations is to achieve a predetermined final state that allows prevention of the risks and impacts that the site may present for the environment and people, taking into account its possible future uses.

The decommissioning of a nuclear installation is prescribed by Decree issued after consulting 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 lengthy, produce large amounts of waste, and are costly; optimum forward planning is essential – especially given that they must be carried out within the shortest time frame possible, as stipulated in the regulations. The continuous changes that installations undergo in the course of decommissioning alter the nature of the risks and represent challenges for the licensees in terms of project management.

In 2023, 36 nuclear installations of all types (power and research reactors, laboratories, fuel reprocessing plants, waste treatment facilities, etc.) were shut down or are undergoing decommissioning in France, representing more than one quarter of the 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 within 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, and therefore by evolving risk levels. Although the reduction in the quantities of substances present in the facility tends to reduce the risks, the decommissioning work, which sometimes takes place very close to the radioactive substances, nevertheless presents significant radiation 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 large volumes of waste produced, which are usually very much greater than the volumes produced during its operation.

The decommissioning of the former facilities of the Alternative Energies and Atomic Energy Agency (CEA) and Orano's first generation plants (in particular the plants which were involved in France's deterrence policy, such as the gaseous diffusion facilities of the Pierrelatte Defence Basic Nuclear Installation (DBNI – defence sector) in Tricastin, and the UP1 facility at the Marcoule DBNI, will thus lead to the production of a very large quantity of very low level (VLL) waste. The scale and the difficulty of the work must be assessed as early as possible in the life of the installation, and as of the design stage for new facilities, in order to ensure that they can be decommissioned safely within as short a time frame as possible.

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 make prudent provision for the facilities necessary for the safe interim storage of this waste pending opening of the corresponding disposal route. The adequacy of the available interim storage capacities for the waste resulting from BNI operation and decommissioning, and the progress of the studies concerning the various definitive radioactive waste management options, are regularly examined in this respect under the French National Radioactive Material and Waste Management Plan (PNGMDR – see chapter 15).

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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 CEA, EDF and Orano (see point 4 and the *Cahiers de l'ASN* magazine issue No. 4).

1.2 THE ASN DECOMMISSIONING DOCTRINE

Many factors can influence the choice of one decommissioning strategy rather than another: national regulations, social and economic factors, financing of the operations, availability of waste disposal routes, decommissioning techniques and qualified personnel, knowledge of the operating history, exposure of the personnel and the public to ionising radiation resulting from the decommissioning operations, etc.

1.2.1 Immediate dismantling

The principle of decommissioning "within the shortest time frame possible under economically acceptable conditions" appears 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 with regard to BNI decommissioning and delicensing, was enshrined in legislation by Act 2015-992 of 17 August 2015 relative to Energy Transition for Green Growth (TECV Act). 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 the 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.

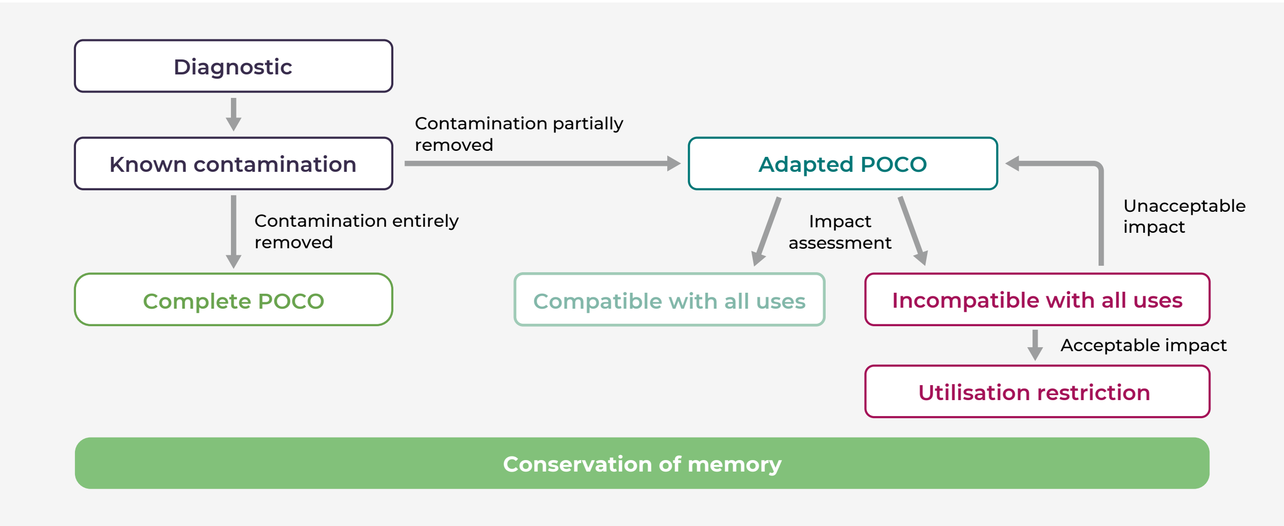
The decommissioning plan, which describes the operations the licensee intends to implement to decommission its facility, aims to ensure optimal preparation and forward planning for decommissioning. Since 2007, this document has been required as from commissioning of the facility, and is then updated regularly during its lifetime. It capitalises on Operating Experience Feedback (OEF) by identifying any impacts on the future decommissioning operations, and must enable the licensee to justify the chosen decommissioning strategy on the basis of technical and economic criteria.

1.2.2 Post operational clean-out and achieving the final state

The decommissioning and Post Operational Clean-Out (POCO) operations of a nuclear facility must lead to the gradual removal of the radioactive or hazardous substances from the structures and soils, with a view to delicensing the facility and its subsequent withdrawal from the list of 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.

Simplified flowchart of ASN's "contaminated sites and soils" doctrine



Phases in the life of a Basic Nuclear Installation

END OF OPERATION

Shutdown notification ⋯⋯> Transmission of decommissioning file

2 years maximum

At least two years before the planned date, the licensee must inform the Minister responsible for nuclear safety and ASN of its intention to definitively shut down its facility.

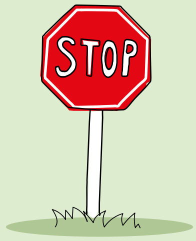
This notification is made public.

The licensee must submit its decommissioning file to the Minister no later than 2 years after shutdown notification.

This file sets out the decommissioning operations projected by the licensee and the measures it takes to limit the impacts on people and the environment.

DECOMMISSIONING PREPARATORY PHASE

⋯⋯> Final shutdown ⋯⋯



As of the date of final shutdown, the licensee is no longer authorised to operate its facility.

The license starts to prepare for the decommissioning of its facility.

The decommissioning preparation operations often consist in removing the radioactive and chemical substances present in the facility (spent fuel), reorganising the premises (to create storage areas) or adapting the utility networks (ventilation, electrical power distribution).

ASN asks the licensees of nuclear facilities to implement POCO practices that integrate the best available methods and techniques under economically acceptable conditions. The complete POCO scenario must always be envisaged as the reference scenario. This scenario, which leads to unconditional release of the buildings and sites, effectively enables the protection of people and the environment to be guaranteed over time with no reservations.

In the event of identified technical, economic or financial difficulties, the licensee may submit one or more appropriate POCO scenarios compatible with the site's futures usages (confirmed, planned and practicable) to ASN. Whatever the case, the licensee must provide elements proving that the reference scenario cannot be applied under acceptable technical and economic conditions and that the planned POCO operations constitute a technical and economic optimum. ASN then examines the scenarios proposed by the licensee and ensures that the POCO will be taken as far as reasonably possible in order to meet the objectives set out in the decommissioning Decree. If the POCO carried out does not allow unconditional release of the site, ASN may make administrative delicensing of the facility conditional upon the implementation of active institutional controls, limiting the right of ownership and use of the soil, instituted by the public authority at the request of the licensee (see flowchart previous page).

In any case, the regulations stipulate that the POCO strategy implemented by the licensee must lead to a final state of the BNI and its site that is compatible with administrative delicensing (see point 1.3).

In accordance with the general principles of radiation protection, the dosimetric impact of the site on the workers and public after delicensing must be as low as reasonably achievable (ALARA principle[1]). 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.

1. ALARA principle (As Low As Reasonably Achievable).

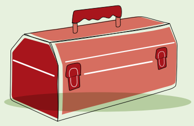
DECOMMISSIONING

Decommissioning Decree

On the basis of the decommissioning file submitted by the licensee, the Minister issues a Decree stipulating the decommissioning operations to be performed on the installation and the duration of decommissioning.

ASN may also impose technical requirements through a resolution in order to regulate the decommissioning operations more closely.

Decommissioning operations



Decommissioning concerns all the technical operations carried out with a view to achieving a final state that allows delicensing of the facility.

It concerns the electromechanical decommissioning and clean-out and remediation of soils and structures.

DELICENSING

Delicensing resolution

Delicensing consists in withdrawing a facility from the list of BNIs, which implies that from this point on the facility is no longer subject to the BNI legal and administrative system.

Delicensing takes place after completion of the decommissioning operations on the basis of a file presenting the final state of the facility.

When necessary, usage restrictions may introduced if it has not been possible to remove all the pollution.

ASN's role stops here

The doctrine implemented by ASN is specified in the guides (available on *asn.fr*) relative to clean-out operations on structures (Guide No. 14) and the management of contaminated soils in nuclear facilities (Guide No. 24). The provisions of these guides have already been implemented on numerous installations with varied characteristics, such as research reactors, laboratories, fuel manufacturing plants, etc.

1.3 DECOMMISSIONING REGULATORY FRAMEWORK

Once a BNI is definitively shut down, it must be decommissioned. Its purpose therefore has to change with respect to that for which its creation was authorised, as the Creation Authorisation Decree (DAC) specifies the operating conditions of the installation. Furthermore, the decommissioning operations imply a change in the risks presented by the installation. Consequently, these operations cannot be carried out within the framework set by the DAC. The decommissioning of a nuclear installation is prescribed by a new decree issued on the basis of an opinion from ASN. Among other things, this decree sets out the main decommissioning steps, the planned decommissioning end date and the final state to be achieved. As part of its oversight duties, ASN monitors the implementation of the decommissioning operations as directed by the Decommissioning Decree.

In order to avoid fragmentation of the decommissioning projects and to improve their overall consistency, the decommissioning file must explicitly describe all the planned operations, from final shutdown to attainment of the targeted final state and, for each step, describe the nature and scale of the risks presented by the facility as well as the means of managing them. The licensee must in its decommissioning file demonstrate that the decommissioning operations will be carried out within as short a time frame as possible. This file undergoes a public inquiry, during which the local residents, local authorities and Local Information Committee (CLI) are called upon to respond. Furthermore, the decommissioning files representing the most significant risks are examined by the Advisory Committee of Experts 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 "Phases in the life of a BNI" Diagram above 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 for example permits the removal of a portion of the radioactive and chemical substances (including the fuel of a nuclear reactor) as well as preparation 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 mapping, 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 ten 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.).

On completion of decommissioning, a nuclear facility can be delicensed by an ASN resolution approved by the Minister responsible for nuclear safety. It is then removed from the list of BNIs and is no longer subject to the BNI regulatory framework. Some twenty facilities, most of them old research reactors, have been decommissioned and delicensed to date.

As at 31 December 2023, ASN was examining 23 decommissioning files for definitively shut down facilities whose decommissioning has not yet been prescribed or whose decommissioning conditions have substantially changed.

1.4 THE FINANCING OF DECOMMISSIONING AND RADIOACTIVE WASTE MANAGEMENT

Articles L. 594-1 to L. 594-10 and D. 594-1 to D. 594-18 of the Environment Code define the system for ring-fencing funds to 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 ring-fencing of the funding of the nuclear costs.

This Order aims to secure the financing of nuclear costs, following the "polluter-pays" principle. It is therefore up to the nuclear licensees to take charge of this financing by setting up a dedicated portfolio of assets capable of covering the expected costs.

These costs must be evaluated conservatively, taking the various uncertainties into account. The licensees are thus obliged to submit three-yearly 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.

2 Situation of nuclear facilities undergoing decommissioning: specific challenges

At the end of 2023, 36 nuclear facilities in France are definitively shut down or undergoing decommissioning, that is to say about a quarter of the BNIs (see map page 352). These facilities vary considerably (nuclear power reactors, research reactors, "fuel cycle" facilities, support installations, etc.), and the decommissioning challenges differ from one facility to the next. These risks are nevertheless all linked to the large quantity of waste to be managed during decommissioning and the need to carry out work very close to contaminated or activated zones. The risks for safety and radiation protection are all the higher if the facilities contain legacy waste; this is in particular the case with the Orano former spent fuel reprocessing plants and 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 OEF from numerous projects around the world and the design of these reactors facilitates their decommissioning compared with other reactor technologies. The decommissioning of this type of installation presents no major technical challenges and its feasibility is guaranteed. Nevertheless, whatever the service life of the reactors in operation, EDF will be confronted with the simultaneous decommissioning of several PWRs. EDF will therefore have to organise itself to industrialise the decommissioning process in order to meet the requirement to decommission each installation in the shortest time possible.

The first PWR decommissioning worksite 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 finally shut down in 2020. These will be the first two 900 Megawatts electric (MWe) reactors to be decommissioned in France and are representative of the fleet of reactors currently operated by EDF. Decommissioning of the Fessenheim reactors will therefore also provide EDF with considerable experience feedback for its other PWRs (see "Regional overview" in the introduction of this report).

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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), as well as 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 prospect of their future decommissioning was not as fundamental a concern as it may have been for the more recent reactor series. In view of their unique nature, specific and complex operations have to be devised and carried out to decommission them. Furthermore, some of these reactors have been shut down for several decades, which has led to loss of knowledge of the installation and its operation and loss of the associated skills.

As with the PWRs, decommissioning begins with the removal of the nuclear fuel, which removes 99% of the radioactivity present in the installation. As 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 for 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 OEF concerning the decommissioning techniques to be used, and secondly due to difficulties concerning the Conditioning and Storage Facility for Activated Waste (Iceda – see the "Regional Overview" in the introduction to this report) which must take in some of this decommissioning waste. Given that Iceda is now in service and the reactor building decommissioning scenario has been established, decommissioning of the installation will resume in 2041, to achieve complete dismantling of the facility by the end of 2041, as regulated by Decree 2023-898 of 26 September 2023.

Decommissioning of the sodium-cooled reactors (Phénix and Superphénix) has met with no major technological obstacles. 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 intermediate-level long-lived waste (ILW-LL), waste without a disposal route (such as non-incinerable organic oils and liquids, or waste containing potentially water-soluble mercury compounds). Moreover, incidents occurred during their operation, contributing to the emission of radioactive substances inside and outside the containment enclosures and to the varying levels of pollution of the structures and soils, which makes the decommissioning and clean-out operations longer and more complex. One of the most important steps in the decommissioning of this type of facility, and which is sometimes rendered difficult due to incomplete archives, therefore consists in inventorying the waste and the radiological status of the facility as accurately as possible in order to define the decommissioning steps and the waste management routes.

2.2.2 Research reactors

Eight experimental reactors are in final shutdown status at the end of 2023: Rapsodie (sodium-cooled fast neutron reactor), Masurca, Éole and Minerve (critical mock-ups), Phébus (test reactor), Osiris and Orphée ("pool" type reactors) and Isis (teaching reactor). The Ulysse training reactor was delicensed in 2022. These reactors are characterised by a lower power output (from 100 Watts thermal – Wth – to 70 MWth) than the nuclear power reactors. When they were designed back in the 1960s to 1980s, the question of their decommissioning was not considered.

At the time of decommissioning, these installations usually present a low radiological source term, as one of the first operations after final shutdown consists in removing the spent fuel. One of the main challenges comes from the production and management of large volumes of VLL waste, which must be stored then disposed of via an appropriate route.

There is a considerable amount of OEF for the research reactors, given the decommissioning of numerous similar installations in France (Siloé, Siloette, Mélusine, Harmonie, Triton[2], the Strasbourg University Reactor – RUS, Ulysse) and abroad. Their decommissioning usually spans about ten years, but the large number of installations to be decommissioned simultaneously may lead to significantly longer prospective decommissioning durations for some of CEA's reactors. After clean-out of the activated or contaminated areas and subsequent removal of all the radioactive waste to appropriate disposal routes, the majority of these reactors were demolished and the waste sent to conventional waste disposal routes.

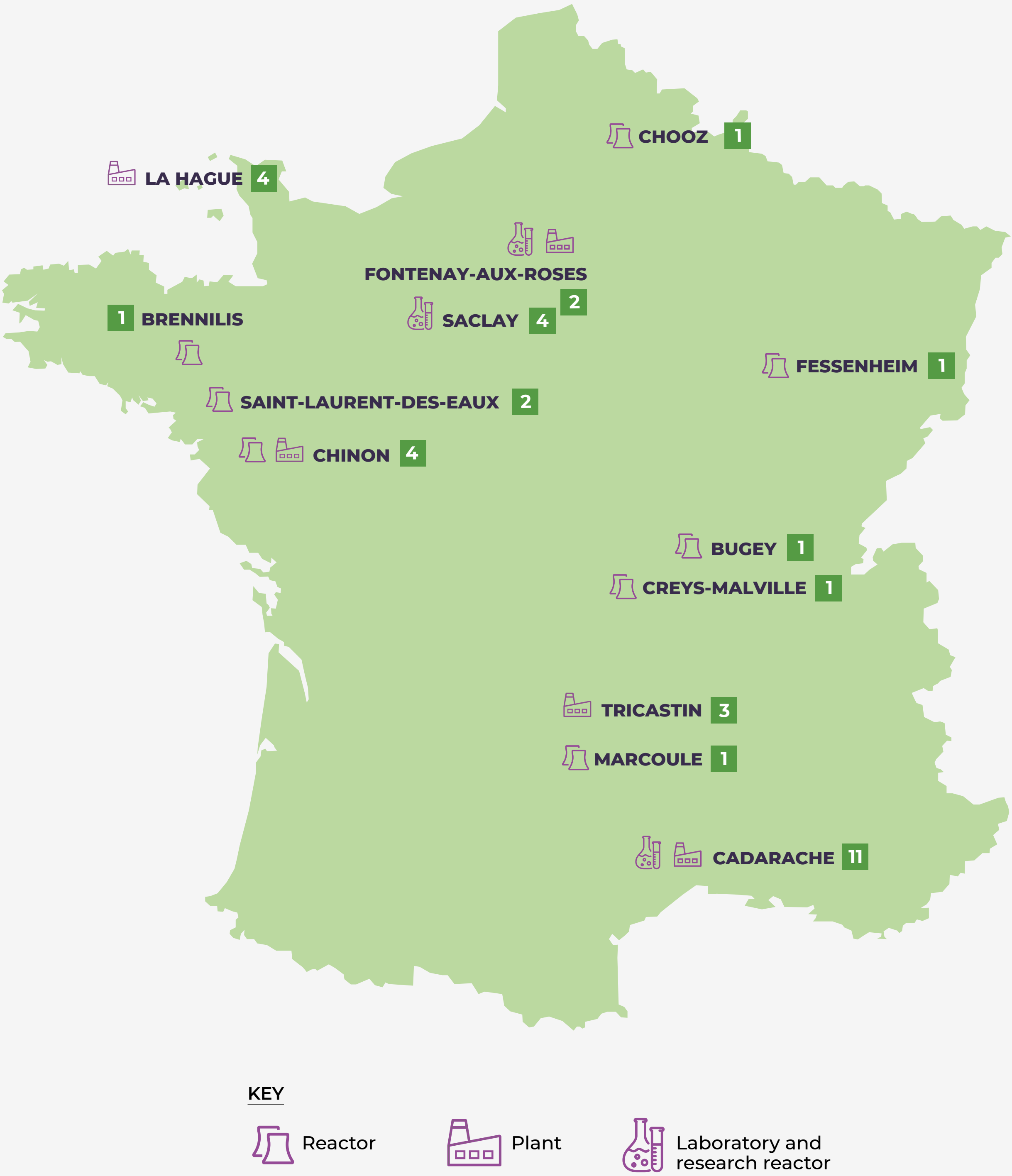
2.3 THE FRONT-END "NUCLEAR FUEL CYCLE" FACILITIES

Two front-end nuclear fuel cycle facilities are undergoing decommissioning. They are located on the Tricastin site, one specialising in uranium enrichment by gaseous diffusion (Georges Besse I plant – BNI 93), the other in uranium conversion (former Comurhex plant – BNI 105).

The only radioactive materials used in these plants were uranium-bearing substances. One of the particularities of these facilities therefore lies in the presence of radioactive contamination associated with the presence of "alpha" particle-emitting uranium isotopes. The radiation protection issues are therefore to a large extent linked to the risk of internal contamination.

2. *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.*

36 NUCLEAR FACILITIES DEFINITIVELY SHUT DOWN OR IN THE PROCESS OF DECOMMISSIONING AS AT 31 DECEMBER 2023



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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
- Decommissioning in progress

BNI 39 • Masurca
- Commissioned: 1966
- Final shutdown

BNI 42-U • Éole / Minerve
- Commissioned: 1965 / 1977
- Decommissioning in progress

BNI 92 • Phébus
- Commissioned: 1978
- Final shutdown

MANUFACTURE, TRANSFORMATION OR STORAGE OF RADIOACTIVE SUBSTANCES

BNI 22 • Pégase-Cascad
- Commissioned: 1964
- Final shutdown only for the Pégase facility

BNI 32 • Plutonium technology facility – ATPu
- Commissioned: 1962
- Decommissioning in progress

BNI 37-B • Effluent Treatment Station – STE
- Commissioned: 2015(*)
- Final shutdown

BNI 52 • Enriched uranium processing facility – ATUe
- Commissioned: 1963
- Decommissioning in progress

BNI 53 • Central fissile material warehouse – MCMF
- Commissioned: 1966
- Final shutdown

BNI 54 • Chemical Purification Laboratory – LPC
- Commissioned: 1966
- Decommissioning in progress

BNI 56 • Storage area
- Commissioned: 1968
- Final shutdown

CHINON

UTILISATION OF RADIOACTIVE SUBSTANCES — CEA

BNI 94 • Irradiated Material 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(**)
- Decommissioning in progress

EFFLUENT TREATMENT AND WASTE STORAGE FACILITY

BNI 166 • Support
- Commissioned: 2006(**)
- 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 / 1971
- Decommissioning in progress

BNI 74 • Saint-Laurent silos
- Commissioned: 1971
- Final shutdown

TRICASTIN

TRANSFORMATION OF RADIOACTIVE SUBSTANCES — Orano Chimie Enrichissement

BNI 93 • Georges Besse plant for separating uranium isotopes by gaseous diffusion
- Commissioned: 1979
- Decommissioning in progress

BNI 105 • Comurhex uranium hexafluoride preparation plant
- Commissioned: 1978
- Decommissioning in progress

UTILISATION OF RADIOACTIVE SUBSTANCES — EDF

BNI 157 • Tricastin operational hot unit (BCOT)
- Commissioned: 2000
- Decommissioning in progress

** This date is because of the separation of BNI 37 (commissioned in 1964) into two BNIs: 37-A and 37-B.*
*** This date results from the joining of former BNIs, commissioned in 1966 and 1968.*

Observatory of waste retrieval and conditioning and decommissioning projects

Given the large number of their facilities in final shutdown status or undergoing decommissioning, CEA, Orano and EDF must carry out various Waste Retrieval and Conditioning (WRC) and decommissioning projects simultaneously.

Some of these projects present particular difficulties owing to the extent of their radiological inventory or their unprecedented nature. In effect, progressing with these projects sometimes requires that specific processes be designed on the basis of technologies that are not yet tried and tested, or that management routes be put in place for radioactive waste for which there is as yet no disposal solution.

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 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 Waste Retrieval and Packaging (WRP) projects, along with the difficulties encountered in their implementation.

CEA Cadarache

	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY STEPS	ASN OBSERVATIONS
BNI 22	**Decommissioning** of Pégase facility	**Safety of storage pool with respect to a seismic hazard** **Limitation of dependency of Cascad in terms of active institutional controls**	• Retrieval and conditioning of araldite-encapsulated fuels from the Pégase facility (planned to start in 2025(*)). • Decoupling of Pégase and Cascad facilities (envisaged from 2030 to 2035).	In 2022, ASN authorises the “removal of araldite-encapsulated fuels from storage” (DECAP) process allowing reconditioning of the araldite-encapsulated cans for storage in the Cascad facility. BNI 22 comprises two facilities: the Pégase facility being decommissioned and the Cascad facility in operation. The end of decommissioning is scheduled for 2065(*).
BNI 37B	**Retrieval and conditioning** of all the residues in the facility’s tanks	**Safety of the pits containing waste with respect to seismic and fire hazards**	• Construction of a new building and commissioning of an entirely automated retrieval process requiring substantial preliminary operations (scheduled for 2052). • Definition of the definitive conditioning process.	The facility decommissioning file is currently being examined; its time frame targets are set for the very distant future, beyond 2100 for completion of decommissioning; these will be examined with particular attention.

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

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CEA Cadarache

BNI	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY STEPS	ASN OBSERVATIONS
BNI 54	**Decommissioning of the cryogenic treatment facility** for final clean-out and remediation of the structures and soils	**Safety of the operations with respect to the risk of dissemination of radioactive materials**	• Decommissioning of the cryogenic treatment process chambers. • Characterisation of the soils under the facility.	ASN is currently reviewing an application to modify the Decree authorising the decommissioning of BNI 54. The decommissioning of the cryogenic treatment facility takes priority in CEA's "DEM/Waste" strategy. It started in 2021. The end of decommissioning is scheduled for 2024 (*).
BNI 56	**Retrieval and packaging of the waste** stored in the trenches	**Risk of flooding by water table upwelling**	• Development of packaging routes for certain particular types of waste. • Design of automated means of retrieval.	The retrieval scenario for the waste in the trenches is to be transmitted to ASN at the beginning of 2024.
	Retrieval and packaging of all the intermediate level bulk waste present in the old pits ("vrac MI" – bulk IL – project)	**Safety of the pits containing waste with respect to a seismic hazard**	• Construction of new buildings and commissioning of an entirely automated retrieval process requiring substantial preliminary operations. • Definition of the definitive packaging process.	ASN is currently examining the decommissioning file. The "vrac MI" project is at the detailed design study stage. The "ATC" project is at the preliminary design study stage.
	Retrieval and packaging of all the waste present under the hangars ("ATC" project)	**Safety of the hangars containing waste with respect to a seismic hazard**		

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

CEA Fontenay-aux-Roses

BNI	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY STEPS	ASN OBSERVATIONS
BNI 165	**Packaging of the ILW-LL waste** in PETRUS drums and characterisation of the waste from the decommissioning of the PETRUS unit	**Access to the contaminated silos under the PETRUS unit**	• Construction of the new Waste transfer and packaging enclosure (ETCB). • Development work in order to accept and remove the waste drums from Decommissioning of the equipment of building 18 (EDB).	ASN is currently examining an application to modify the decrees authorising the decommissioning of BNIs 165 and 166, for which some deadlines have already expired. In view of the numerous technical and organisational difficulties, particularly regarding the 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. The end of decommissioning was scheduled for 2017 (*) and 2018 (*) for BNIs 165 and 166 respectively.
BNI 166	**Retrieval of waste** stored in the pits of building 58 of BNI 166	**Retrieval of waste to allow decommissioning of the facilities situated in a highly urbanised area**	• Construction of the new Measuring and conditioning equipment (EMC).	

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

CEA Marcoule

	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY STEPS	ASN OBSERVATIONS
BNI 71	**Sodium treatment**	**Risk of fire, pyrophoricity, explosion**	• Commissioning of the Noah sodium treatment facility (scheduled for 2037(*)). • Removal of fuel (scheduled as of 2025(*)).	Treating the sodium is a prerequisite for decommissioning the facility and significantly reduces the risks it represents. 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 STEPS	ASN OBSERVATIONS
BNI 35	**Emptying of tanks** MA3 to MA8 of room 98	**Safety of the operations with respect to the risk of dissemination of radioactive materials**	Investigations into the physical state of the tanks and their retention (end scheduled in 2026).	The investigations must also allow characterisation of the effluents in the tanks; the reliability of the packaging process must be ensured. All these operations shall be regulated by an ASN requirement.
	Clean-out of pit 99		Emptying tank-bottom contents present in the pit.	In October 2022, ASN authorised the drainage operations on tank 40/4 considered to be a priority.
	Treatment of the sludges of tanks MA501 to MA507		Characterisation of effluents and clean-out strategy to be consolidated.	ASN considers tank MA507 a priority.
BNI 72	**Retrieval and packaging of drums** containing a mixture of waste and fragments of fuel	**Safety of the storage areas with respect to containment and a seismic hazard**	• Construction of retrieval equipment (scheduled for 2029). • Adaptation of the retrieval equipment, whatever the envisaged state of the waste. • Commissioning of retrieval equipment (scheduled for 2029).	Commissioning of the retrieval equipment was initially scheduled for 2023. This deadline was pushed back to 2029 due to numerous technical and organisational difficulties. This commissioning deadline must be consolidated owing to the need to repeat the studies already carried out. The end of decommissioning is scheduled for 2059(*).
	Retrieval and packaging of all the solid waste, fuels, irradiated fuels and radioactive sources		Removal from storage and emptying of the pool (end scheduled for 2024(*)).	The removal operations are in progress. Given the numerous technical and organisational difficulties, the initial deadlines have been pushed back by several years. The removal from storage of blocks 108 and 116 was completed in 2022.
			40 pits zone – Removal of stored irradiating waste (end scheduled in 2030(*)).	
			Removal of stored sources from building 116 (end scheduled in 2025(*)).	

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

EDF

	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY STEPS	ASN OBSERVATIONS
BNI Chinon A2	**Decommissioning of reactor pressure vessel**	**"Pilot" project for the decommissioning of the other GCRs**	• Opening of pressure vessel and installation of the decommissioning platform. • Decommissioning of the graphite stack.	Removal of the fuel from the facility has significantly reduced the risks. The facility has moreover already been partly decommissioned. ASN will issue a position statement on the deadlines presented by EDF for decommissioning its GCRs, as part of the review of the decommissioning files submitted at the end of 2022.
BNI 74	**Retrieval and packaging** of the graphite sleeves	**Construction of a new storage facility that meets current safety standards**	Construction of the new storage building and of the retrieval and packaging equipment.	ASN will issue a position statement on the safety of the new storage facility project as part of the review of the decommissioning file submitted in 2022.

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

Orano La Hague

	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY STEPS	ASN OBSERVATIONS
BNI 33	**Decommissioning** of the "High Activity Dissolution Extraction" unit (HADE)	**Short-term safety with respect to the earthquake hazard**	Active commissioning of the DFG building (French acronym for "Fine granulometry waste") for retrieval of decladding waste (scheduled for 2028).	The decommissioning priority for this facility is given to the expeditious retrieval of the legacy waste, which represents a major risk for safety given the large radiological inventory and the fragility of the current storage conditions. The rinsing and treatment operations on the effluents in the solvent tanks in the HAPF unit could be postponed to about 2035 in the event of technical difficulties. The end of decommissioning is scheduled for 2046 (*).
	Decommissioning of the "High Activity Fission Product" unit (HAPF)		Rinsing and effluent treatment operations on the HAPF unit solvent tanks (scheduled for before the end of 2031).	
	Decommissioning of the "Medium Activity Plutonium" unit (MAPu)	**Short term safety of neighbouring units with respect to the earthquake hazard**	Dismantling of upper storeys to limit risks to the units in operation (scheduled before end of 2028).	

* Deadline as presented in the last file subject to public inquiry or the deadline stipulated by ASN.

Orano La Hague

	OPERATION AND DESCRIPTION	CHALLENGE	NEXT KEY STEPS	ASN OBSERVATIONS
BNI 38	**Retrieval and packaging of waste** from silo 130	**Short-term safety of the silo with respect to containment or a seismic hazard** **Packaging within time frames compatible with commissioning of the deep geological repository *Cigéo***	· End of retrieval of solid GCR waste (ILW-LL). · End of retrieval of active effluents and sludge. · End of conditioning of ILW-LL waste.	The retrieval of all the waste from silo 130 is currently scheduled for the end of 2025(*). However, the end-of-retrieval deadlines have been pushed back by a few years. Retrieval began in February 2020, but technical malfunctions require adjustments in order achieve industrial output rates. The sludge and effluents retrieval scenario has been determined. Studies into the possibility of retrieving the effluents along with the solid GCR ILW-LL waste are continuing. Packaging in definitive packages that meet the acceptance criteria for a deep geological repository is pushed back by several decades(**). The end of decommissioning is scheduled for 2043(*).
	Retrieval and packaging of the sludge stored in STE2 silos (“Sludge Retrieval and Packaging” project – RCB)	**Safety of the silos with respect to containment and a seismic hazard**	· Construction and commissioning of a new storage facility. · Definition of the sludge encapsulation matrix, development then commissioning of the sludge treatment process. · Definition of the definitive packaging process.	The new strategy for sludge retrieval and management was revised in 2022 and validated in April 2023. Orano has undertaken to build new silos to guarantee the sludge storage conditions. The beginning of sludge retrieval has been postponed to 2037. The deadlines for the start and end of retrieval are therefore pushed back significantly. The packaging in definitive packages acceptable in a deep geological repository will be pushed back by several decades(**). The end of packaging of the sludges from the silos is scheduled for the end of 2030(*)(**) (in accordance with Article L. 542-1-3 of the Environment Code).
BNI 80	**Retrieval and packaging of waste** from the HAO silo and Organised Storage of Hulls (SOC) pools	**Safety of the silo with respect to containment, a seismic hazard or resistance to an aircraft crash** **Packaging within time frames compatible with commissioning of the *Cigéo* deep geological repository**	· Commissioning of the ILW-LL solid waste and active effluents retrieval unit. · End of packaging of waste (scheduled before end 2022(*)).	In view of the difficulties associated with operation and maintenance of the planned process, the retrieval scenario was updated in 2021. ASN is reviewing the equipment active commissioning authorisation applications. The first tests are planned in the next few years. The deadline for the beginning of retrieval is now pushed back to 2027. The end of packaging deadline is also significantly postponed.
	Partial dismantling of the filtration building at the end of decommissioning	**Reduction of the interactions with the pools of the Spent fuel elements unloading and storage facility (NPH), in the event of an earthquake**	· Dismantling of the upper storeys. · Clean-out of the “900 cells”.	Completion of dismantling of the filtration building is envisaged for between 2031 and 2036, and clean-out of the “900 cells” around 2050; these deadlines must nevertheless be supported by additional files to be submitted in the coming years. ASN is currently reviewing an application to modify the Decree authorising the decommissioning of BNI 80. The end of decommissioning is scheduled for 2033(*).

* 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.

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Furthermore, these are older facilities whose operating history is poorly known. Determining the initial state, particularly the pollution present in the soils beneath the structures, therefore remains an important issue. Moreover, the industrial processes implemented back then involved the use of large quantities of toxic chemical substances (such as chlorine trifluoride and hydrogen fluoride, in addition to the uranium itself): the containment of these chemical substances therefore also represents a risk on these facilities and can necessitate the deployment of dedicated means (ventilation, containment air locks, respiratory protection masks, etc.).

2.4 THE BACK-END "NUCLEAR FUEL CYCLE" FACILITIES

The back-end facilities of the "nuclear fuel cycle" are the spent fuel storage pools, the spent fuel reprocessing plants and the facilities for storing waste from the treatment process. These facilities operated by Orano, are situated on the La Hague site.

The first processing facility at La Hague was commissioned in 1966, initially for reprocessing the fuel from the first-generation GCRs. This facility, BNI 33, called "UP2-400" standing for "Production Unit No. 2 – 400 tonnes", was definitively shut down on 1 January 2004 along with its support facilities: Effluent Treatment Station No. 2 (STE2) and the Spent fuel reprocessing unit (AT1 – BNI 38), the Radioactive sources fabrication unit (ELAN IIB – BNI 47) and the "High Activity Oxide" (HAO) unit, created for reprocessing fuels from the "light water" reactors (BNI 80). Some of these facilities experienced accidents which contaminated the premises and their near environment, such as the fire in silo 130 belonging to BNI 38, in 1981.

Unlike the direct on-line packaging of the waste generated by the plants in operation (plants treating irradiated fuel elements from light water nuclear reactors – UP2-800 and UP3-A), most of the waste generated by the first reprocessing plant was stored without treatment or conditioning. Decommissioning is therefore carried out concomitantly with the legacy WRC operations.

About ten projects of this type are currently in progress in the old facilities (silos STE2, 115 and 130 in BNI 38 and the HAO silo in BNI 80). They will span several decades and are a prerequisite to the complete decommissioning of these facilities, whereas the decommissioning of the process parts of the plant is continuing with more conventional techniques.

2.5 THE SUPPORT FACILITIES (STORAGE AND PROCESSING OF RADIOACTIVE EFFLUENT 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 are the silos at Saint-Laurent-des-Eaux (BNI 74), the pits, trenches and hangars of the radioactive waste storage area (BNI 56), the pits of the ZGDS (BNI 72) and the Support facility (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 either planned or actually under construction.

The STEs for their part have been shut down due to their ageing or because the facilities producing the effluents treated in these units have stopped functioning. Examples include BNI 37-B at Cadarache and STE2 at the La Hague plant (BNI 38). The difficulties associated with decommissioning of the 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 stored legacy waste and of the sludges or deposits 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. More specifically, the BNI System also applies to definitively shut down facilities. ASN implements an approach that is proportional to the extent of the risks or drawbacks inherent in the facility.

The risks with facilities undergoing decommissioning differ from those for facilities in operation. For example, the risks of significant off-site discharges decrease as decommissioning progresses because the quantity of radioactive substances decreases. Consequently, the requirements relating to the control of risks and impacts are proportionate to the risks inherent in the facilities. ASN thus considers that it is generally inappropriate to start significant reinforcement work on a facility undergoing decommissioning, on condition that the decommissioning operations reduce the sources of danger in the short term.

3.2 THE PERIODIC SAFETY REVIEWS OF FACILITIES UNDERGOING DECOMMISSIONING

Given the diversity of the facilities and the situations in question, each periodic safety review necessitates an appropriate examination method. Some facilities undergoing decommissioning warrant particular attention owing to the risks they present and may be reviewed by the GPDEM. For others presenting a lower level of risk, the extent of the inspections and examinations is adapted accordingly. These inspections are used to check the means implemented by the licensee to carry out its review, as well as compliance with the action plan resulting from its conclusions. These inspections led to several requests for corrective action and additional information.

3.3 FINANCING DECOMMISSIONING: ASN'S OPINION ON THE THREE-YEARLY REPORTS

The regulatory framework for ring-fencing the funds necessary for management of the long-term decommissioning and waste management expenses is presented in point 1.4.

In 2022, ASN examined the three-yearly reports submitted by the licensees, regarding the accounts closed at the end of 2021. It published opinion CODEP-CLG-2022-061286 of 14 December 2022 and forwarded its observations to the Ministry responsible for energy. The next three-yearly reports will be submitted in 2025.

More generally, ASN notes that the evaluation perimeter of the expenses considered in the majority of these reports must be supplemented because it does not take into account certain operations that could represent major financial issues, particularly the decommissioning preparation operations.

Moreover, ASN considers that the initial states of the sites at the beginning of their decommissioning must be described more precisely, taking account of any pollution present in the soils and structures and evaluating the associated clean-out costs. In effect, the assumptions concerning the initial state of the sites are not sufficiently robust on the whole, whereas it is of fundamental importance to have sound knowledge of the state of the sites in order to evaluate the decommissioning expenses conservatively.

Lastly, ASN underlines that the assumptions adopted for evaluating the complete costs must be reassessed in order to exercise reasonable prudence in the scheduling of the decommissioning projects and programmes, taking account of the risks related to the unavailability of storage, treatment and disposal facilities.

4 Assessment of the licensees' decommissioning strategies

In a context in which numerous facilities have been shut down for several decades, with concomitant loss of knowledge of the facilities, ageing structures and in some cases large quantities of waste still present, maintaining good progress with the decommissioning operations is of major importance for the safety of these facilities. Yet ASN has noted that the majority of these operations are falling significantly behind schedule. ASN therefore regularly asks CEA, EDF and Orano to present their decommissioning and radioactive waste management strategies, thereby providing an overall view of the decommissioning projects and the management routes necessary for removal of the radioactive waste resulting from the decommissioning operations.

As far as decommissioning is concerned, the licensees must justify the 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 15.

4.1 ASSESSMENT OF EDF'S DECOMMISSIONING STRATEGY

The first decommissioning strategy file for the EDF reactors definitively shut down (Chinon A1, A2, A3, Saint-Laurent A1 and A2, Bugey 1, EL4-D, Chooz A and Superphénix) was transmitted in 2001 at the request of ASN. Immediate dismantling was adopted as the reference strategy. This strategy has been updated regularly, in order to adjust the decommissioning schedule or incorporate the complementary studies requested by ASN and elements concerning the future decommissioning of the reactor fleet in service.

For the six first-generation GCRs (Chinon A1, A2 and A3, Saint-Laurent A1 and A2, and Bugey 1), EDF informed ASN of a complete change of strategy in March 2016, calling into question the technical principle (decommissioning "under water") chosen for the decommissioning of these reactors and the phasing of the operations, resulting in the decommissioning of all the GCRs being pushed back by several decades. ASN will rule on the decommissioning time frames put forward by EDF in the decommissioning files submitted at the end of 2022 (currently being reviewed by ASN), which may also be revised if it turns out in the coming decades that this scenario can be optimised in the light of the OEF acquired. This GCR decommissioning strategy is regulated by two ASN resolutions 2020-DC-0686 and CODEP-CLG-2020-021253 of 3 March 2020.

These resolutions set the next steps required for the change of decommissioning strategy, notably the definition 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.

ASN considers that it is appropriate for EDF to develop a graphite industrial demonstrator (commissioned in 2022 in Chinon) before decommissioning the reactor pressure vessels, but decommissioning of the various reactors must nevertheless begin within reasonable time frames in view of the obligation for dismantling to be carried out as rapidly as possible.

Regarding the other EDF facilities shut down (notably Chooz A, AMI Chinon, EL4-D and Superphénix), their decommissioning is under way and on the whole is meeting the objective of achieving as short a time frame as possible.

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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 legacy radioactive waste management strategy, given the quantity and the non-standard and hard to characterise nature of the waste produced during the prior operations phase and during the ongoing decommissioning operations.

Furthermore, Orano must carry out special WRC operations in old waste storage facilities. The deadlines for completion have been stipulated by ASN, particularly for the La Hague site. Completion of these WRC operations determines the progress of decommissioning on the UP2-400 plant, as WRP is one of the first steps of its decommissioning. The WRC 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, WRC projects are considerably complex owing to the interactions with the plants in operation on the site. Further to the difficulties observed in the examination of files relating to the WRP and decommissioning operations on the Orano La Hague site and failure to perform the operations within the prescribed deadlines, ASN and Orano agreed to set up regular monitoring in order to anticipate and address any blocking situations and determine practical measures to be put into place to accomplish the WRC 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 to the La Hague and Tricastin sites. In its position statement letter of 14 February 2022, ASN underlined the progress made by the licensee in taking on-board the decommissioning objectives prioritised according to the issues of the BNIs and the decommissioning phases and the Orano governance's oversight of complex WRP and decommissioning projects. ASN also favourably noted Orano's decision at the beginning of 2023 to build new silos for the sludges from the former STE (BNI 38) without waiting for a final conditioning process for these sludges. However, ASN considers that Orano should continue to improve its knowledge of the current state of the facilities and notably the soils, with a view to future POCO, make progress in enhancing the industrial reliability of the waste retrieval processes and ensure that the schedules for the various announced WRC and decommissioning projects are guaranteed.

4.3 ASSESSMENT OF CEA'S DECOMMISSIONING STRATEGY

Given the number and complexity of the operations to be carried out for all the nuclear facilities concerned, CEA is giving priority to reducing the "dispersible inventory" which is currently very high in certain facilities, particularly in some of the individual facilities of the Marcoule DBNI and in BNIs 56 and 72.

In their Position Statement Letter of 27 May 2019, ASN and the ASND considered that, given the resources allocated by the State and the large number of facilities undergoing decommissioning for which legacy waste retrieval and storage capacity will need to be built, it was acceptable for CEA to envisage staggering the decommissioning operations and that priority be given to the facilities with the greatest safety risks. The two Authorities have since observed changes in the WRC schedules presented by the CEA, particularly the pushing back of waste management deadlines, including for operations considered to be priorities. ASN and CEA have set up regular monitoring of these operations, notably by means of progress indicators.

However, ASN observes that CEA's decommissioning and materials and waste management strategies share certain vulnerabilities in particular relative to the availability of support facilities, which are often unique but are needed in order to run numerous projects. CEA's strategies rely on sharing of the resources by its centres and are based on the use of facilities, some of which are simply planned, while others are undergoing commissioning, or being refurbished. Most of them are unique and there is no obvious operational alternative in the event of a failure. All of these aspects underline the vulnerability of CEA's strategy.

Appendix

BNI List of Basic Nuclear Installations undergoing decommissioning or delicensed as at 31 December 2023

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	Dismantled at Fontenay-aux-Roses and reassembled at Cadarache
EL2 (Saclay)	(Former BNI 13)	Reactor (2,8 MWth)	1952	1965	Removed from BNI list	Partially decommissioned, remaining parts confined
EL3 (Saclay)	(Former BNI 14)	Reactor (18 MWth)	1957	1979	1988: Removed from BNI list and classified as ICPE	Partially decommissioned, remaining parts confined
Ulysse (Saclay)	(Former BNI 18)	Reactor (100 kWth)	1967	2007	–	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-RUCPE (*)
Siloette (Grenoble)	(Former BNI 21)	Reactor (100 kWth)	1964	2002	2007: Removed from BNI list	Decommissioned-RUCPE (*)
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 and High-level waste storage unit (Grenoble)	(Former BNI 36 and 79)	Waste treatment and storage plant	1964/1972	2008	2023: Removed from BNI list	Decommissioned
STED (Cadarache)	(Former BNI 37)	Transformation of radioactive substances	1964	2015	2015: Removed from BNI list	Integrated in BNIs 37-A and 37-B
Harmonie (Cadarache)	(Former BNI 41)	Reactor (1 kWth)	1965	1996	2009: Removed from BNI list	Destruction of the ancillaries building
ALI (Saclay)	(Former BNI 43)	Accelerator	1958	1996	2006: Removed from BNI list	Decommissioned-RUCPE (*)
Strasbourg University reactor	(Former BNI 44)	Reactor (100 kWth)	1967	1997	2012: Removed from BNI list	Decommissioned-RUCPE (*)
Saturne (Saclay)	(Former BNI 48)	Accelerator	1966	1997	2005: Removed from BNI list	Decommissioned-RUCPE (*)
Attila (**) (Fontenay-aux-Roses)	(Former BNI 57)	Reprocessing pilot	1968	1975	2006: Removed from BNI list	Integrated in BNI 165
LCPu (Fontenay-aux-Roses)	(Former BNI 57)	Plutonium chemistry laboratory	1966	1995	2006: Removed from BNI list	Integrated in BNI 165
BAT 19 (Fontenay-aux-Roses)	(Former BNI 58)	Plutonium metallurgy	1968	1984	1984: Removed from BNI list	Decommissioned
RM2 (Fontenay-aux-Roses)	(Former BNI 59)	Radio-metallurgy	1968	1982	2006: Removed from BNI list	Integrated in BNI 165
LCAC (Grenoble)	(Former BNI 60)	Fuels analysis	1975	1984	1997: Removed from BNI list	Decommissioned

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 BNI 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-SUP (***)
IRCA (Cadarache)	(Former BNI 121)	Irradiator	1983	1996	2006: Removed from BNI list	Decommissioned-RUCPE (*)
FBFC (Pierrelatte)	(Former BNI 131)	Fabrication of fuel	1990	1998	2003: Removed from BNI list	Decommissioned-RUCPE (*)
Uranium warehouse (Miramas)	(Former BNI 134)	Uranium-bearing materials warehouse	1964	2004	2007: Removed from BNI list	Decommissioned-RUCPE (*)
SNCS (Osmanville)	(Former BNI 152)	Ioniser	1983	1995	2002: Removed from BNI list	Decommissioned-RUCPE (*)
Pégase (Cadarache)	22	Reactor and storage of radioactive substances	1964	2017	–	Preparation for decommissioning
Rapsodie (Cadarache)	25	Reactor (40 MWth)	1967	1983	2021: Partial decommissioning Decree	Decommissioning in progress
ATPu (Cadarache)	32	Fuel fabrication plant	1962	2003	2009: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Spent fuel reprocessing plant – UP2-400 (La Hague)	33	Transformation of radioactive substances	1964	2004	2022: Partial decommissioning Decree	Decommissioning in progress
STE (Cadarache)	37-B	Effluent treatment facility (non-permanent part of former BNI 37)	2015	2016	–	Preparation for decommissioning
STE2 (La Hague)	38	Effluent treatment station	1964	2004	2022: Partial decommissioning Decree	Decommissioning in progress
Masurca (Cadarache)	39	Reactor (5 kWth)	1966	2018	–	Preparation for decommissioning
Osiris-Isis (Saclay)	40	Reactor (70 MWth)	1966	2015	–	Preparation for decommissioning
Éole / Minerve (Cadarache)	42-U	Reactor (1 kWth) and Reactor (100 Wth)	1965 and 1977	2017	2023: Decree for decommissioning and merging of the two BNIs (Éole and Minerve)	Decommissioning in progress
Bugey 1 (Saint-Vulbas)	45	Reactor (1,920 MWth)	1972	1994	2008: Final Shutdown and Decommissioning Decree	Decommissioning in progress
St-Laurent-des-Eaux A1 (St-Laurent-Nouan)	46	Reactor (1,662 MWth)	1969	1990	2010: Decommissioning Decree	Decommissioning in progress
St-Laurent-des-Eaux A2 (St-Laurent-Nouan)	46	Reactor (1,801 MWth)	1971	1992	2010: Decommissioning Decree	Decommissioning in progress
ELAN IIB (La Hague)	47	Manufacture of caesium-137 sources	1970	1973	2013: Decommissioning Decree	Decommissioning in progress
LHA (Saclay)	49	Laboratory	1960	1996	2008: Final Shutdown and Decommissioning Decree	Decommissioning in progress
ATUe (Cadarache)	52	Uranium processing	1963	1997	2021: Decree amending the Decommissioning Decree of 2006	Decommissioning in progress
MCMF (Cadarache)	53	Storage of radioactive substances	1968	2017	–	Preparation for decommissioning
LPC (Cadarache)	54	Laboratory	1966	2003	2009: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Storage yard	56	Storage of radioactive substances	1968	2023	–	Preparation for decommissioning
Phénix (Marcoule)	71	Reactor (536 MWth)	1973	2009	2016: Decommissioning Decree	Decommissioning in progress
ZGDS (Saclay)	72	Transformation of radioactive substances	1971	2022	2022: Decommissioning Decree	Preparation for decommissioning

INSTALLATION LOCATION	BNI No.	TYPE OF INSTALLATION	COMMIS-SIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
Saint-Laurent silos (St-Laurent-Nouan)	74	Radioactive waste storage	1971	2022	–	Preparation for decommissioning
Fessenheim NPP (Fessenheim)	75	Reactors (each of 2,660 MWth)	1977	2020	–	Preparation for decommissioning
HAO facility (La Hague)	80	Transformation of radioactive substances	1974	2004	2009: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Superphénix (Creys-Malville)	91	Reactor (3,000 MWth)	1985	1997	2009: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Phébus (Cadarache)	92	Reactor (40 MWth)	1978	2017	–	Preparation for decommissioning
Eurodif (Pierrelatte)	93	Transformation of radioactive substances	1979	2012	2020: Partial decommissioning Decree	Decommissioning in progress partiel
AMI (Chinon)	94	Utilisation of radioactive substances	1964	2015	2020: Decommissioning Decree	Decommissioning in progress
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
Tricastin Operational Hot Unit (Tricastin)	157	Laboratory	2000	2020	2023: Decommissioning Decree	Decommissioning in progress
Chinon A3 D – former Chinon A3 (Avoine)	161 (Former INB 7)	Reactor (1,360 MWth)	1966	1990	2010: Decommissioning Decree	Decommissioning in progress
EL4-D – former EL4 (Brennilis)	162 (Former BNI 28)	Reactor (250 MWth)	1966	1985	1996: Decree ordering decommissioning and creation of the EL4-D storage BNI 2006: Final Shutdown and Decommissioning Decree 2007: State Council decision cancelling the Decree of 2006 2011: Partial decommissioning Decree 2023: Complete decommissioning Decree	Decommissioning in progress
Ardennes NPP – former Chooz A (Chooz)	163 (Former BNI 1, 2, 3)	Reactor (1,040 MWth)	1967	1991	2007: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Procédé (Fontenay-aux-Roses)	165	Grouping of former research installations (BNIs 57 and 59) concerning reprocessing processes	2006	2006	2006: Final Shutdown and Decommissioning Decree	Decommissioning in progress
Support (Fontenay-aux-Roses)	166	Grouping of former installations (BNIs 34 and 73) for packaging and treating waste and effluents	2006	2006	2006: Final Shutdown and Decommissioning Decree	Decommissioning in progress

* Passive institutional controls.
** Attila: reprocessing pilot located in a unit of BNI 57.
*** Active institutional controls.

CONTENTS

15

Radioactive waste and contaminated sites and soils

15

This chapter presents the role and actions of ASN, 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 Minister responsible for energy. The waste comes from activities involving artificial or natural radioactive substances (nuclear installations, the medical or research sectors, contaminated sites and soils, etc.).

ASN has competence for the management of contaminated sites and soils linked to the Basic Nuclear Installations (BNIs). For the other radiological contamination situations, ASN may, at the request of the competent authorities, issue an opinion regarding their management procedures. ASN notably ensures that the waste resulting from contaminated site clean-up operations is directed to appropriate management routes.

As part of its oversight of the decommissioning and waste management strategies implemented by the major licensees, ASN in 2023 continued its monitoring of the strategies used by the Alternative Energies and Atomic Energy Commission (CEA) and Orano.

Finally, in 2023, ASN initiated its review of the Creation Authorisation Decree (DAC) application for *Cigéo*, the geological disposal project for the most highly radioactive waste, submitted on 16 January 2023 by the French National Radioactive Waste Management Agency (Andra).

1 Radioactive waste

Pursuant to the provisions of the Environment Code, the producers of spent fuel and radioactive waste are responsible for these substances, without prejudice to the liability of those who hold these substances in their role as persons or entities responsible for nuclear activities. Radioactive waste must be managed in accordance with specific procedures. Waste producers must pursue the objective of minimising the volume and harmfulness of their waste, both before production by appropriate design and operation of the facilities, and after production by appropriate sorting, treatment and packaging.

The types of radioactive waste differ widely in their radioactivity (specific activity, nature of the radiation, half-life) and their form (scrap metal, rubble, oils, etc.).

Two main parameters can be used to assess the radiological risk that radioactive waste represents: firstly the activity, which contributes to the toxicity of the waste, and secondly the half-life of the radionuclides present in the waste which determines the required waste containment time. A distinction is therefore made between very low, low, intermediate and high-level waste on the one hand and, on the other hand, very short-lived waste (whose activity level is halved in less than 100 days) resulting mainly from medical activities, short-lived waste (chiefly containing radionuclides whose activity level is halved in less than 31 years) and long-lived waste (which contains a large quantity of radionuclides whose activity level is halved in more than 31 years).

Each type of waste requires the implementation of an appropriate and safe management solution in order to control the risks it represents, particularly the radiological risk but also risks linked to its chemical composition.

1.1 MANAGEMENT OF RADIOACTIVE WASTE (WITH THE EXCEPTION OF MINING TAILINGS AND WASTE ROCK)

Defined in Article L. 542-1-1 of the Environment Code, the management of radioactive waste comprises all the activities associated with the handling, preliminary treatment, treatment, packaging, storage and disposal of radioactive waste, excluding off-site transportation.

ASN oversees the activities associated with the management of radioactive waste from BNIs or small-scale nuclear activities, other than those linked to national defence which are overseen by the Defence Nuclear Safety Authority (ASND) and those relative to Installations Classified for Protection of the Environment (ICPEs), which are placed under the oversight of the Prefects.

1.1.1 Management of radioactive waste in Basic Nuclear Installations

Two economic sectors are the major contributors to the production of radioactive waste in BNIs.

The nuclear power sector for its part comprises the 18 Nuclear Power Plants (NPPs) operated by EDF, and the plants dedicated to the fabrication and reprocessing of nuclear fuel operated by Orano and Framatome. Operation of the NPPs generates spent fuel, part of which is reprocessed to separate the recyclable substances from the fission products or minor actinides which are waste. Radioactive waste is also produced during the operational and maintenance activities in the NPPs and the fuel reprocessing plants, like the structural waste, the hulls and end-pieces constituting the nuclear fuel cladding, and the technological waste, and the waste from the treatment of effluents such as bituminised sludge. Furthermore, decommissioning of the facilities produces a large volume of radioactive waste.

TABLE 1 **Classification of radioactive waste**[1]

Activity	Level	VERY SHORT LIVED WASTE, CONTAINING RADIONUCLIDES WITH A HALF-LIFE < 100 DAYS	SHORT LIVED WASTE, IN WHICH THE RADIOACTIVITY COMES MAINLY FROM RADIONUCLIDES WITH A HALF-LIFE ≤ 31 YEARS	LONG LIVED WASTE, CONTAINING MAINLY RADIONUCLIDES WITH A HALF-LIFE > 31 YEARS
0 Bq/g (*)	Very low-level (VLL)	**Management by radioactive decay on production site** then disposal *via* disposal routes dedicated to conventional waste	**Recycling or dedicated above-ground disposal** (disposal facility of the industrial centre for collection, storage and disposal – Cires – in the Aube *département*)	
HUNDREDS Bq/g (*)	Low-level (LL)		**Surface disposal** (Aube waste disposal repository)	**Near-surface disposal** (being studied pursuant to the Act of 28 June 2006)
MILLIONS Bq/g (*)	Intermediate-level (IL)			
BILLIONS Bq/g (*)	High-level (HL)	Not applicable (**)	**Deep geological disposal** (planned pursuant to the Act of 28 June 2006)	

* Becquerel per gram (Bq/g).
** There is no such thing as high level, very short-lived waste.

Secondly, 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[2] in nuclear medicine, biomedical or industrial research creates solid or liquid waste: small laboratory equipment items used to prepare sources, medical sources 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[3] are used for medical, industrial, research and veterinary applications (see chapters 7 and 8). Once they have been used, and if their suppliers do not envisage their reuse in any way, they are considered to be radioactive waste and must be managed as such.

The management of sealed sources considered as waste, and their disposal in particular, must take into consideration both their concentrated activity and their potential attractiveness in the event of human intrusion after loss of the memory of a disposal facility at the end of its monitoring and surveillance phase after closure. These two factors therefore limit the types of sources that can be accepted in disposal facilities, especially surface facilities.

1.1.3 Management of waste containing natural radioactivity

Some professional activities using raw materials which naturally contain radionuclides, but which are not used for their radioactive properties, may lead to an increase in specific activity in the products, residues or waste they produce. The term "Naturally Occurring Radioactive Material" (NORM) is used when the activity exceeds the exemption thresholds figuring in Table 1 of Appendix 13-8 of the Public Health Code (for example the treatment of rare earths, the production of phosphate fertilizers and phosphoric acid, the combustion of coal in thermal power plants, etc.). NORM waste, for which there is no planned or envisaged use, is therefore considered to be radioactive waste within the meaning of Article L. 542-1-1 of the Environment Code. Waste containing radioactive substances of natural origin but which do not exceed the abovementioned exemption thresholds is directed to conventional waste management routes.

NORM waste can be stored in two types of facility depending on its specific activity:
- in a waste disposal facility authorised by Prefectural Order, if the acceptance conditions stipulated in the Circular of 25 July 2006[4] relative to waste disposal facilities, coming under sections 2760 of the ICPE classification are satisfied;
- in the Industrial centre for grouping, storage and disposal (Cires[5]) intended for the disposal of very low-level (VLL) 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).

1. Appendix 1 of the Order of 9 October 2008 amended relative to the nature of the information that the entities responsible for nuclear activities and the companies mentioned in Article L. 1333-10 of the Public Health Code are obliged to establish, keep up to date and periodically communicate to Andra.
2. Source for which the presentation and the normal conditions of use are unable to prevent all dispersion of the radioactive substance.
3. Source for which the structure or packaging prevents all dispersion of radioactive substances into the ambient environment, in normal use.
4. Circular of 25 July 2006 relative to classified installations – Acceptance of technologically enhanced or concentrated natural radioactivity in the waste disposal centres.
5. This name, which stands for "Centre industriel de regroupement, d'entreposage et de stockage" *(Industrial centre for grouping, storage and disposal) was given in October 2012. When commissioned in 2003 it was called the* "CSTFA – Centre de Stockage des déchets de très faible activité" *(Very Low-Level Waste Disposal Facility). Installation subject to licensing under the system of section 2797 of the ICPEs.*

Four hazardous waste disposal facilities are authorised by Prefectural Order to receive waste containing NORMs.

Furthermore, following the entry into force 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 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 share of the provisions of these Acts are codified in Chapter II of Part IV of Book V of the Environment Code.

The Act of 28 June 2006 more specifically sets a calendar for research into high- and intermediate-level, long-lived waste (HLW- and ILW-LL) waste and a clear legal framework for ring-fencing the funds needed for decommissioning and for the management of radioactive waste. It also provides for the drafting of the National Radioactive Materials and Waste Management Plan (PNGMDR), which aims periodically to asses and define the outlook for the radioactive substance management policy. It also reinforces the missions of 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 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 abroad and of radioactive waste resulting from the reprocessing of spent fuel and the treatment of radioactive waste from abroad, and detailing the conditions of application of this prohibition;
- define a procedure for the administrative authority to requalify materials as radioactive waste;
- reinforce the existing administrative and penal enforcement actions and provide for new enforcement actions in the event of failure to comply with the provisions applicable to the management of radioactive waste and spent fuel.

The conditions for creating a reversible deep geological repository for HLW- and ILW-LL radioactive waste are detailed in Act 2016-1015 of 25 July 2016.

1.2.1 Legal framework for the management of radioactive waste produced in Basic Nuclear Installations

In France, the management of radioactive waste in BNIs is governed in particular by the Order of 7 February 2012 setting the general rules relative to BNIs, of which 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 (RGEs) and the environmental impact assessment of their facility, the wastes produced by the facility, whether radioactive or not, indicating the volumes, types, harmfulness and the envisaged disposal routes. The measures adopted by the licensees must consist in reducing, through recycling and treatment processes, the volume and the radiological, chemical or biological toxicity of the waste produced so that only the ultimate waste has to go to final disposal.

ASN resolution 2015-DC-0508 of 21 April 2015 details the provisions of the Order of 7 February 2012, particularly concerning:
- the procedures for drawing up and managing the waste zoning plan;
- the content of the annual waste management assessment each BNI must transmit to ASN.

ASN Guide No. 23 presents the conditions of application of this resolution with regard to the drawing up and modification of the waste zoning plan.

Further to a modification of the regulatory requirements of the Environment Code in 2019, the waste management study is no longer required as a specific document. The provisions it contained must now be carried over to the environmental impact assessment and the BNI RGEs. ASN resolution 2022-DC-0749 of 29 November 2022, approved on 16 February 2023, modified resolution 2015-DC-0508 of 21 April 2015 to take account of this change in the regulations.

1.2.2 Legal framework for the management of radioactive waste produced by activities governed by the Public Health Code

Article R. 1333-16[6] of the Public Health Code states that the management of effluents and waste contaminated by radioactive substances originating from all nuclear activities involving a risk of exposure to ionising radiation must be examined and approved by the public authorities. This is the case in particular for activities using radioactive substances intended for medicine, human biology or biomedical research.

6. Formerly Article R. 1333-12.

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) for 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 be clarified. The "DECPAR.4" action of the PNGMDR 2022-2026 states that producers should conduct an inventory of sealed sources with ownership issues and that a work programme should be drawn up with Andra to develop management solutions. The volume of sealed sources awaiting management in a definitive disposal facility has been introduced as a new monitoring indicator in the PNGMDR 2022-2026.

Management by Andra of waste from small-scale nuclear activities
Article L. 542-12 of the Environment Code entrusts Andra with a public service mission for the management of waste produced by small-scale nuclear activities. Since 2012, Andra operates Cires, a facility situated in the municipalities of Morvilliers and La Chaise in the Aube *département*, designed for the collection and storage of waste from small producers that are not in the nuclear power sector. ASN considers that Andra's actions in this area are appropriate to fulfil its mission assigned under the abovementioned Article L. 542-12 and that they must be continued.

Nevertheless, the tritiated solid waste must be managed with the waste from International Thermonuclear Experimental Reactor (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 abovementioned storage facilities.

In its opinion 2021-AV-0379 of 11 May 2021, ASN reiterated that the storage of tritiated waste from small producers in a Defence Basic Nuclear Installation (DNBI) was not justified by a potential need to protect information in the interests of national 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.

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 (MTE). The Ministry has opted, in the light of the public debate of 2019, to rely on a pluralistic "Guidance Commission", in which ASN participates. This Commission is chaired by an independent qualified person. Monitoring of the technical and operational implementation of the PNGMDR is still ensured by a pluralistic working group co-chaired by ASN and the General Directorate for Energy and the Climate (DGEC), as described in chapter 2.

On its website, ASN also publishes the PNGMDR, its summary, the minutes of the abovementioned working group's meetings, the studies required by the plan and the opinions it has issued on these studies.

1.2.3 The National Inventory of radioactive materials and waste

Article L. 542-12 of the Environment Code assigns Andra the task of establishing, updating every five years and publishing the National Inventory of radioactive materials and waste. This Inventory constitutes an input database for preparing the PNGMDR. The last update was published in December 2023. The inventory provides information concerning the quantities, nature, and location of radioactive materials and waste at the end of 2021, categorised by type and economic sector. A prospective exercise was also conducted, based on four contrasting scenarios for France's energy policy, as envisioned in the 2019-2028 Multi-year Energy Plan (PPE).

1.2.4 The National Radioactive Materials and Waste Management Plan

Article L. 542-1-2 of the Environment Code, 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;
- organise research and studies into the management of radioactive materials and wastes, by setting deadlines for the implementation of new management modes, the creation of facilities or the modification of existing facilities.

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 edition was prepared by the MTE, based in particular on the work of a "Guidelines Commission". Introduced by the resolution of 21 February 2020, this Commission is chaired by an independent qualified personality and brings together, in addition to the legacy members of the pluralistic working group mentioned in chapter 2, elected officials and representatives of the regional authorities. This Commission gave opinions on various major subjects relating to the management of radioactive waste (management of VLL/LLW-LL waste, management of radioactive materials, etc.). ASN participates actively in the Guidelines Commission – albeit without voting rights – to provide its guidance on the safety and radiation protection issues.

Implementation of the plan is then followed up at periodic meetings of the PNGMDR working group jointly chaired by ASN and the DGEC.

In 2020 and 2021, ASN also evaluated the studies submitted for the 2016-2018 PNGMDR. On the occasion of the production of the 5th PNGMDR, ASN has thus issued seven opinions on the radioactive material and waste management routes, which identify a number of recommendations. In addition, on 9 November 2021, ASN issued a favourable opinion for the 5th PNGMDR, on condition that it is supplemented with a study of worst-case operating scenarios for the "fuel cycle", an assessment of the impact on the nuclear facilities of continuing the reprocessing of spent fuel beyond 2040 or not, the inclusion of measures relative to the safety of HL/ILW-LL waste management and the management of waste necessitating specific work, such as tritiated waste, and better assessing the recyclability of certain radioactive materials.

Finally, 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 (VLL) waste 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 451,259 m^3 of VLL waste, which represents 69% of its authorised capacity. According to the national inventory conducted by Andra, the amount of VLL waste resulting from decommissioning of the existing nuclear facilities will be about 2,200,000 m^3. According to current forecasts, the centre could reach its capacity around 2029. In April 2023, Andra submitted an application to increase the authorised capacity of this repository to more than 900,000 m^3 (Acaci project), for the same surface area (compared to the currently authorised 650,000 m^3).

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 VLL waste management must be based on the place of origin of the waste and guarantee its traceability; *via* specific routes, from production through to disposal, with the exception of metallic VLL waste that is to be recycled, as stated in the resolution of 21 February 2020.

The recycling of certain types of waste which will be produced in large volumes is encouraged, consistently with the waste management hierarchy defined in the Environment Code. ASN more specifically recommends 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 these draft regulations. In February 2022, the Government published the regulatory framework for issuing waivers to authorise the recycling of weakly radioactive metal substances after melting and decontamination. 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 abovementioned ASN opinion, the 5th PNGMDR contains the following objectives concerning the management of VLL waste:
- continue the studies aiming to deploy new centralised and decentralised storage capacities for VLL waste;
- continue looking into the recycling of VLL waste, particularly defining the conditions of implementation of metallic waste recycling;
- define VLL waste management scenarios, cast light upon their environmental, regional, health and safety issues, and use this to establish an overall management strategy;
- refine the perspectives for the production of VLL waste from the decommissioning of the nuclear installations, by explicitly identifying the waste associated with the clean-out of structures and contaminated soils.

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1.3.2 Low and intermediate-level, short-lived waste

Low-level and intermediate-level short-lived waste (LL/ILW-SL) – in which the radioactivity comes primarily from radionuclides with a half-life of less than 31 years – results essentially from the operation of nuclear facilities and more specifically from maintenance activities (clothing, tools, filters, etc.). It can also come from the post-operational clean-out and decommissioning of these facilities. The majority of LL/ILW-SL waste is placed in surface disposal facilities operated by Andra. Once these facilities are closed, they will be monitored for a period set at 300 years by Basic Safety Rule RFS-I.2. The facility safety analysis reports – which are updated periodically, including during the monitoring phase – must show that at the end of this phase, the activity contained in the waste will have reached a residual level such that human and environmental exposure levels are acceptable, even in the event of a significant loss of the containment properties of the facility. There are two facilities of this type in France, the Manche repository (CSM – BNI 66), which operated from 1969 until 1994 and is currently in the closure preparation phase, and the Aube repository (CSA – BNI 149) which is in operation (see "Regional overview" in the introduction to this report).

The quantity of LL/ILW-SL waste at the CSA amounted to 371,304 m^3 at the end of 2022, representing 37% of the facility's maximum authorised capacity. This quantity is supplemented by the waste emplaced in the CSM, or 527,225 m^3. Therefore, the total quantity of LL/ILW-SL waste stored in Andra's facilities is 898,529 m^3, to be compared with the amount produced at the end of 2021, which was 981,000 m^3. According to the data in the national inventory drawn up by Andra, these waste will represent a maximum volume of 2,000,000 m^3, following the decommissioning of the existing installations. 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 low-level long-lived waste (LLW-LL) waste initially comprised two main types: graphite waste resulting from operation of the Gas-Cooled Reactors (GCRs) and radium-bearing waste from the radium industry and its offshoots. Other types of waste have been added to this category such as certain bituminised wastes, substances containing radium, uranium and thorium with low specific activity, as well as certain disused sealed radioactive sources.

Furthermore, a fraction of the waste from the Écrin facility (BNI 175) operated by Orano in Malvési (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 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-bearing waste, and asked Andra to work on 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 were examined by the Advisory Committee of Experts (GPE) in March 2021. On this basis, ASN began technical discussions with Andra and IRSN in 2021, focusing in particular on the assessment of the long-term dosimetric impact of the disposal project.

In 2011 (as part of the PNGMDR 2013-2015 preparatory work) Orano submitted a study concerning the long-term management of the waste already produced by the Malvési site (known as "RTCU"), currently stored in the Écrin facility (BNI 175). Various disposal concepts are being 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.

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 was not in favour of continuing the development of an above-ground disposal facility, as it considers that it does not meet the long-term safety requirements. Since then, Orano has abandoned the option of an above-ground disposal facility.

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. In 2021, pursuant to Article 7 of the Decree of 20 July 2015, authorising the creation of BNI 175 Écrin, Orano submitted a report to ASN presenting the progress of studies and investigations conducted. Two disposal options envisaged for the radioactive waste on the Malvési site and its immediate environment are being considered. This report, which helped consolidate the waste inventories and acquired knowledge on the site's geological formations, is currently being reviewed.

ASN opinion 2020-AV-0357 of 6 August 2020 details the areas of work it recommends for the management of LLW-LL waste.

Based on this opinion, the 2022-2026 edition of the PNGMDR includes actions aiming to:

- ensure the reliability of the inventories (by including the legacy RTCU waste stored in Écrin) and the characteristics of the LLW-LL waste;
- clarify the saturation time-lines for the LLW-LL storage capacities;
- define LLW-LL waste management scenarios and assess their advantages and drawbacks;
- continue studies on an RTCU disposal facility, by involving the representatives of the affected or potentially affected localities.

It also requires that Andra submit a file presenting the technical and safety options adopted for disposal on the site of the Vendeuvre-Soulaines local authority.

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 high-level and intermediate-level long-lived radioactive waste (HL/ILW-LL) radioactive waste to be continued along three complementary lines: separation and transmutation of the long-lived radionuclides, interim storage and reversible deep geological disposal.

Separation/transmutation

The report of the Special Public Debates Commission (CPDP) of 25 November 2019 concerning the public debate prior to the 5th edition of the PNGMDR concludes in particular that "*there are two options, each one defended by a certain number of the actors: deep geological disposal and interim sub-surface storage for a sufficient length of time to allow progress to be made in transmutation research in order to reduce the radioactivity of the waste*".

Separation/transmutation processes aim to isolate and then transform the long-lived radionuclides in radioactive waste into shorter-lived radionuclides or even stable elements. The transmutation of the minor actinides contained in the waste would have an impact on the size of the disposal facility, by reducing both the heating power, the harmfulness of the packages placed in it and the repository inventory. Despite this however, the impact of the disposal facility on the biosphere, which originates essentially from the mobility of the radionuclides contained in the fission and activation products, would not be significantly reduced.

In its opinion 2020-AV-0369 of 1 December 2020, ASN recalls that the prospects for transmutation on an industrial scale of the waste already conditioned in 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 HLW-LL waste, 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 radioactive waste. Storage facilities are nevertheless indispensable pending commissioning of the deep geological disposal facility, to allow the cooling of certain types of waste and then to accompany the industrial operation of the disposal facility, which will develop in stages. Furthermore, if operations to remove emplaced packages were to be decided on in the context of the reversibility of the repository, storage facilities would be needed. Reception of the first radioactive waste packages for deep geological disposal is now scheduled for around 2040.

The Act of 28 June 2006 tasked Andra with coordinating the research and studies on the storage of HL- and ILW-LL waste, which are therefore part of the approach of complementarity with the reversible repository. This 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 HLW and situated in the UP3-A plant (BNI 116). This extension comprises three pits: 30, 40 and 50, commissioned in 2015, 2017 and 2022 respectively.

Within the framework of the PNGMDR 2013-2015, and after presenting the inventory of HL- and ILW-LL waste packages intended for *Cigéo* at the end of 2013, and the status of the existing storage locations, the producers more specifically analysed the fundamental elements enabling waste package storage needs to be identified.

The work carried out under the PNGMDR 2016-2018

The studies required by the PNGMDR 2016-2018 focus on the analysis of the storage needs for HL and ILW-LL waste packages and take up the broad lines of the ASN opinion of 25 February 2016.

Article D. 542-79 of the Environment Code, introduced by the Decree of 23 February 2017 relative to the provisions of the PNGMDR 2016-2018, stipulates that the holders of spent fuel and HL- and ILW-LL radioactive waste must keep up to date the availability status of the storage capacities for these substances by waste category and identify the future storage capacity needs for the next twenty years at least.

CEA, EDF and Orano have defined future storage needs for all the families of HLW and ILW-LL waste, for the 2040 time-frame. Within this context, CEA, EDF and Orano have also studied how sensitive the storage needs are to shifts in the *Cigéo* schedule.

In its opinion 2020-AV-0369 of 1 December 2020, ASN estimates in this respect that the dates of saturation of the existing storage capacities and the future storage needs until 2040 have on the whole been well identified by the producers.

Nevertheless, the storage capacity estimates must be consolidated by all the waste producers, incorporating margins to cope with any contingencies affecting the waste management routes concerned and thereby be able to anticipate the needs for additional storage capacities and the corresponding licensing procedures.

Based on a comparative study of the different types of storage submitted by Andra, ASN, in its opinion 2020-AV-0369 of 1 December 2020, confirmed that near-surface storage facilities did not present significant advantages in terms of nuclear safety and radiation protection over above-ground storage facilities.

The PNGMDR 2016-2018 set out several guidelines for the design of HL- and ILW-LL waste storage facilities (significant design margins, simple and modular architecture favouring passive systems, definition of provisions for controlling the ambient storage conditions in normal, incident and accident situations, definition of provisions for monitoring and management of deviations as of the design stage, provisions for preserving the memory, etc.). ASN will be attentive to the integration of these recommendations in the new facilities that will be necessary pending commissioning of *Cigéo*.

The work carried out under the PNGMDR 2022-2026

The PNGMDR 2022-2026 comprises measures to revive discussions on credible or complementary alternatives to deep geological disposal. Therefore, a Committee for assessment and dialogue on alternatives to deep geological disposal, in which ASN is involved, was set up in 2023 in order to provide recommendations for the next edition of the PNGMDR.

Reversible deep geological disposal

Deep geological disposal is stipulated in Article L. 542-1-2 of the Environment Code, which states that *"after storage, ultimate radioactive waste which, for nuclear safety or radiation protection reasons, cannot be disposed of on the surface or at shallow depth, shall be disposed of in a deep geological repository"*.

The codified Act of 28 June 2006 entrusts Andra with the mission of designing a project for a deep geological repository, which shall be a BNI and therefore, governed by this specific legal system.

The principle of this type of disposal

Deep geological disposal of radioactive waste consists in emplacing the radioactive waste in an underground facility specially designed for this purpose, complying with the principle of reversibility. The characteristics of the geological layer are intended to confine the radioactive substances contained in this waste. Such a disposal facility – unlike storage facilities – must be designed such that long-term safety is ensured passively, that is to say without depending on human actions (such as monitoring or maintenance activities) which require oversight, the durability of which cannot be guaranteed beyond a limited period of time. Lastly, the depth of the disposal structures must be such that they cannot be significantly affected by the expected external natural phenomena (erosion, climate change, earthquakes, etc.) or by human activities.

In 2008, ASN published a safety guide on the final disposal of radioactive waste in a deep geological formation (ASN Guide No. 1) which was an update of the RFS III 2 f of 1991.

The conditions for the creation of a reversible deep geological repository for HL- and ILW-LL radioactive waste were specified by the codified Act of 25 July 2016, which defines the principle of reversibility, introduces the industrial pilot phase before complete commissioning of *Cigéo* and brings schedule adaptations concerning the deployment of *Cigéo*.

This Act defines reversibility as *"the ability, for successive generations, to either continue the construction and then the operation of successive sections of a disposal facility, or to reassess previous choices and change the management solutions. Reversibility is materialised by the progressive nature of the construction, the adaptability of the design and the operational flexibility of placing radioactive waste in a deep geological repository which can integrate technological progress and adapt to possible changes in waste inventory following a change in energy policy. It includes the possibility of retrieving waste packages from the repository under conditions and over a time frame that are consistent with the strategy for operation and closure of the repository"*.

In its opinion 2016-AV-0267 of 31 May 2016 relative to the reversibility of the deep geological disposal of radioactive waste, ASN had considered that the principle of reversibility implied a requirement for adaptability of the facility and retrievability of the packages during a period governed by law.

The Decree of 9 December 2022, relative to the requirements of the PNGMDR 2022-2026 specifies certain principles applicable to *Cigéo*, and more particularly those set out in in Articles D. 542-91 and D. 542-92 of the Environment Code. These specify that the inventory to be adopted by Andra for the studies and research conducted for the design of the *Cigéo* disposal facility shall include a reference inventory and a reserve inventory. The reference inventory takes account of all HL- and ILW-LL waste already produced and to be produced by the existing nuclear facilities (nuclear power plants, research centres, etc.), as well as that to be produced by the authorised nuclear facilities (Flamanville EPR, ITER, Jules Horowitz experimental reactor), assuming an average reactor operating life of 50 years.

The reserve inventory considers uncertainties, particularly related to changes in energy policy. For waste from the future reactors which are planned for construction in France (in particular the first six EPR 2), Andra shall identify the waste liable to be included in the reserve inventory and ensure that the *Cigéo* adaptability studies are able to accommodate this waste, without compromising the fundamental assumptions of the project as outlined in the DAC application currently under review (see next page).

Underground laboratory of Meuse/Haute-Marne

Studies on deep geological disposal necessitate research and experiments in an underground laboratory. Andra has been operating such an underground laboratory within the Bure municipality since 1999.

In the context of the studies on the deep geological disposal, ASN issues recommendations concerning the research and experiments conducted in the laboratory, and by random sampling during follow-up inspections ascertains that they are carried out using processes that guarantee the quality of the results.

Technical reviews

Pursuant to the Act of 30 December 1991, and then pursuant to the Act of 28 June 2006 and the PNGMDR, Andra has carried out studies and submitted reports on deep geological disposal. These reports have been examined by ASN – referring in particular to the Safety Guide of 2008 – and it has issued an opinion on them.

ASN has thus more specifically examined the reports submitted by Andra in 2005 and 2009. It issued opinions on these reports on 1 February 2006 and 26 July 2011. Andra subsequently submitted various files to ASN presenting the progress of the studies and work carried out.

ASN thus issued a position statement:
- in 2013, on the documents produced between 2009 and 2013, the year of the public debate, and on the intermediate design milestone at the outline stage presented by Andra in 2012;
- in 2014, on the safety components of the closure structures and the expected content of the Safety Options Dossier (DOS) for the facility;
- in 2015, on the control of operating risks and the cost of the project;
- in 2016, on the components development plan;
- in 2018 on the *Cigéo* DOS;
- in 2022, on the seismic hazard to be considered in the design of the facility.

The *Cigéo* Safety Options Dossier

The filing of a DOS marks the start of a regulatory process[7]. ASN received the *Cigéo* DOS in April 2016. At the end of the technical review phase, the ASN draft opinion underwent public consultation, and ASN issued its opinion on 11 January 2018. ASN also sent a follow-up letter giving recommendations on the safety options to prevent or limit the risks and asked Andra for additional studies and justifications (corrosion phenomena, low-pH concretes, representativeness of the hydrogeological model, surveillance strategy, etc.). The demands made in this letter took account of the suggestions and comments received through the public consultation.

The examination of the *Cigéo* DOS highlighted several issues relating to specific aspects (architecture, definition of hazards, post-accident management, etc.). Among these issues, ASN pointed out that the management of bituminised waste required special attention.

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 requested additional information[8] from the waste producers and Andra, following the review of the study submitted pursuant to Article 46. These requests notably concern the effect of self-irradiation on the thermal behaviour of the bituminised waste packages, on the thermal reactivity of the bituminised coatings, on the swelling in the context of long-term behaviour of the *Cigéo* repository, and on the design development aimed at ensuring control of 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 issued opinion 2020-AV-0369 on 1 December 2020 regarding the conclusions of the third-party review on the management of bituminised waste and the studies on the design development of the *Cigéo* ILW-LL waste disposal cells, which highlight new technical factors since the publication of the opinion of 11 January 2018. ASN therefore considers it essential for the waste producers to implement an ambitious characterisation programme for bituminised waste packages. This programme is essential 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 launch in 2021 of a new "quadri-partite" 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

The *Cigéo* project was declared of public utility by Decree 2022-993 of 7 July 2022, published in the *Official Journal of the French Republic* on 8 July. During this process, ASN answered questions from the inquiry Commissioners concerning certain technical aspects of the *Cigéo* project.

In accordance with the resolution by the Minister responsible for energy and the ASN Chairman of 21 February 2020, following the public debate on the 5th edition of the PNGMDR, and through its "HAMAVL.6" (HLW/ILW-LL 6 action), this specifies the conditions for implementing disposal reversibility, particularly regarding the retrievability of packages, the *Cigéo* project's decision milestones, and the governance to be adopted, needed to periodically review the choices made. It is also planned to define the objectives and success criteria of the pilot industrial phase, the procedures for informing the public between two successive updates of the master operating plan as provided in Article L. 542-10-1 of the Environmental Code, and the procedures for involving the public in the key stages of the *Cigéo* project development.

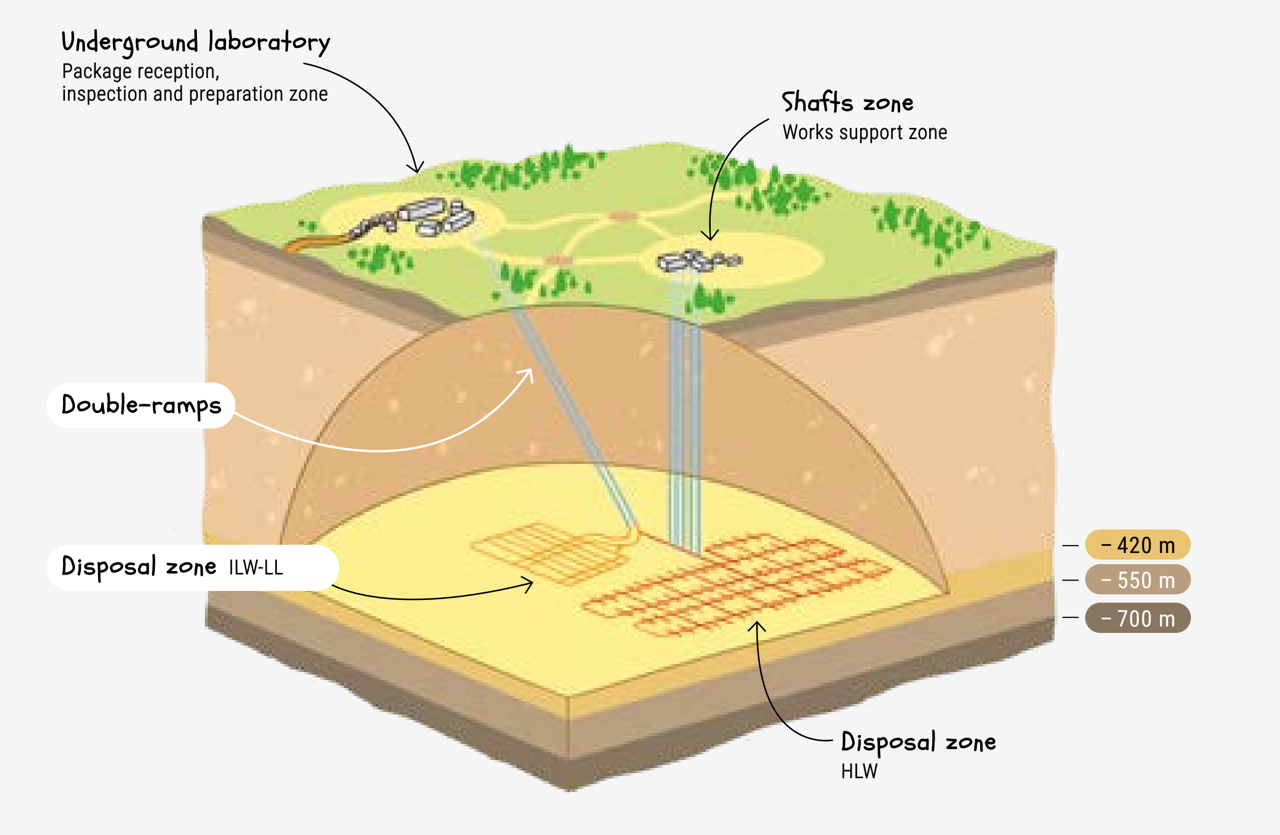
The review process for the Creation Authorisation Application filed in early 2023

Further to the filing of the *Cigéo* creation authorisation application on 16 January 2023, ASN initiated the DAC review process for this deep geological disposal facility, which is regulated by Section 4 of Chapter III of Title IX of Book V of the Environment Code and by Article L. 542-10-1 of the Environment Code, specific to this type of facility.

7. Article R. 593-14 of the Environment Code stipulates that "any person who plans operating a BNI can, before initiating the creation authorisation procedure, ask ASN for an opinion on all or part of the options it has chosen to protect the interests mentioned in Article L. 593-1. In an opinion issued and published in the conditions and forms it so determines, clarifies to what extent the safety options presented by the applicant as such as to prevent or limit the risks to the interests mentioned in Article L. 593.1, taking account of the technical and economic conditions of the time. ASN may define the additional studies and justifications that will be required for a prospective creation authorisation application. It can set a validity period for its opinion. This opinion is communicated to the applicant and to the Minister responsible for nuclear safety".

8. The follow-up letters are available on the ASN website under the heading "ASN informs", "Educational files", "Management of radioactive waste", "French National Radioactive Material and Waste Management Plan", "PNGMDR 2016-2018".

Schematic diagram of the *Cigéo* repository showing the surface and underground facilities



Following an initial analysis of the contents of the file, ASN informed the MTE that it was administratively acceptable in June 2023 and formally started the technical review process, for which it requested IRSN's support. This process is expected to last 30 months and will comprise three meetings of the "Waste" GPE. As necessary, experts from the "laboratories and plants" GPE and the "radiation protection" GPE will join these meetings. The review by the GPEs will initially cover the knowledge and the hypotheses used to design the facility and then review operational safety before finally assessing long-term safety. The first meeting of the GPEs is scheduled for April 2024. Following the technical review, ASN will issue the opinion provided for in Article L. 542-10-1 of the Environment Code. The duration of the entire authorisation process is estimated at about five years. Apart from the technical examination phase, it includes a consultation phase (local authorities, Environmental Authority, etc.), as well as a public inquiry.

Consultation actions

In order to address society's strong desire to take part in the *Cigéo* project, and consistently with the measures stipulated in this respect by the 5th PNGMDR, ASN has implemented an unprecedented system of consultation and discussion around the technical examination process. Various stakeholders (about twenty organisations, including the Local Information Committees (CLIs), the National Association of Local Information Committees and Commissions (Anccli) and environmental protection associations) were consulted as part of the drafting of the referral to IRSN about the *Cigéo* creation authorisation application, with the aim of identifying their expectations and concerns, as related to nuclear safety and radiation protection, so that they could be taken into account when framing the technical review. Following this exercise, the IRSN referral project was modified, for example, to incorporate aspects related to addressing climate change issues. To guarantee the continuity of participation by society throughout the technical review process, consultation measures will also be taken when drafting the GPE referrals on the three previously mentioned topics, and the public will be regularly informed, notably after each meeting of these GPEs.

The cost of the project

In accordance with the procedure stipulated in Article L. 542-12 of the Environment Code and after consideration of ASN's opinion of February 2015 and the comments of the radioactive waste producers, the Minister responsible for energy issued an Order on 15 January 2016 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 amount is being reassess and will be transmitted to the MTE before the public inquiry is held regarding the *Cigéo* creation authorisation application.

2 Nuclear safety of waste management support facilities, role of ASN and waste management strategies of the major nuclear licensees

2.1 RADIOACTIVE WASTE MANAGEMENT METHODS AND THEIR OVERSIGHT BY ASN

2.1.1 The graded approach

With regard to radioactive waste management, ASN's oversight aims on the one hand to verify correct application of the waste management regulations on the production sites (for example with respect to zoning, packaging or the controls performed by the licensee), and on the other hand to verify the safety of the facilities dedicated to radioactive waste management (waste treatment, packaging, storage and disposal facilities). This oversight is exercised in a manner proportionate to the nuclear safety issues associated with each waste management step and each facility. Thus, the waste management BNIs are classified in one of three categories, numbered from 1 to 3 in descending order of significance of the risks and adverse effects they present. This categorisation is taken into account in the preparation of the inspection schedule and helps to determine the level of expertise required for the examination of certain files submitted to ASN by the licensees.

The various facilities and ASN's assessment of their level of safety are presented in the introduction to this report.

2.1.2 Radioactive waste management support facilities

Treatment

Treatment is a fundamental step in the radioactive waste management process. This operation serves to separate the waste into different categories to facilitate its subsequent management and to significantly reduce the volume of waste.

The La Hague plants, which process and recycle the spent fuel assemblies, are involved in this process because they apply a dissolution and chemical treatment process to separate the cladding and the fission products. The hulls and end-pieces are then compacted to reduce their disposal footprint.

Centraco, 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 (BNI 171), with this same aim of volume reduction.

Packaging

Radioactive waste packaging consists in placing the waste in a package which provides a first containment barrier preventing radioactive substances from being dispersed in the environment. The techniques used depend on the physical-chemical characteristics of the wastes and their typology, which explains the large variety of packages used. These packages are subject to approval by Andra if they are intended for existing disposal facilities, and to packaging agreements by ASN if they are intended to be directed towards disposal facilities still under study.

In some cases the packaging operations are carried out directly on the site of waste production, but they can also take place in dedicated facilities, like the La Hague plants, which package spent fuel hulls and end-pieces in "Standard compacted waste containers" (CSD-C packages), and the fission products in stainless steel "Standard vitrified waste containers" (CSD-V packages), and the effluent treatment stations such as the Stella station in BNI 35. The conditioned waste packages are sometimes made up in the facilities where they are to be stored, such as for the ILW-LL type CIPG^{SP} packages in the Iceda facility, or directly in a disposal repository, such as the Cires and CSA which carry out these operations for some of the arriving packages.

Storage

Storage, as defined by Article L. 542-1-1 of the Environment Code, is a temporary management solution for radioactive waste. The waste is kept in storage for a limited period (which can extend to 50 years) pending its transfer to disposal, or in order to achieve a sufficient level of radioactive decay to enable it to be sent to conventional waste management routes in the particular case of very short-lived waste, which comes chiefly from the medical sector.

Some facilities (see map above) are specifically dedicated to the storage of radioactive waste, such as Écrin, commissioned in 2018, Cedra, commissioned in 2006, and Iceda, commissioned in 2020. This will also be the case of Diadem, once this facility is commissioned around 2026. CSD-C and CSD-V packages will be directly stored in the various facilities on the La Hague site, pending the commissioning of a deep geological repository for HL- and ILW-LL waste.

Research and Development

Support facilities are used for research and development work to optimise radioactive waste management.

Among these, the Chicade facility (BNI 156) operated by CEA on the Cadarache site conducts research and development work on 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

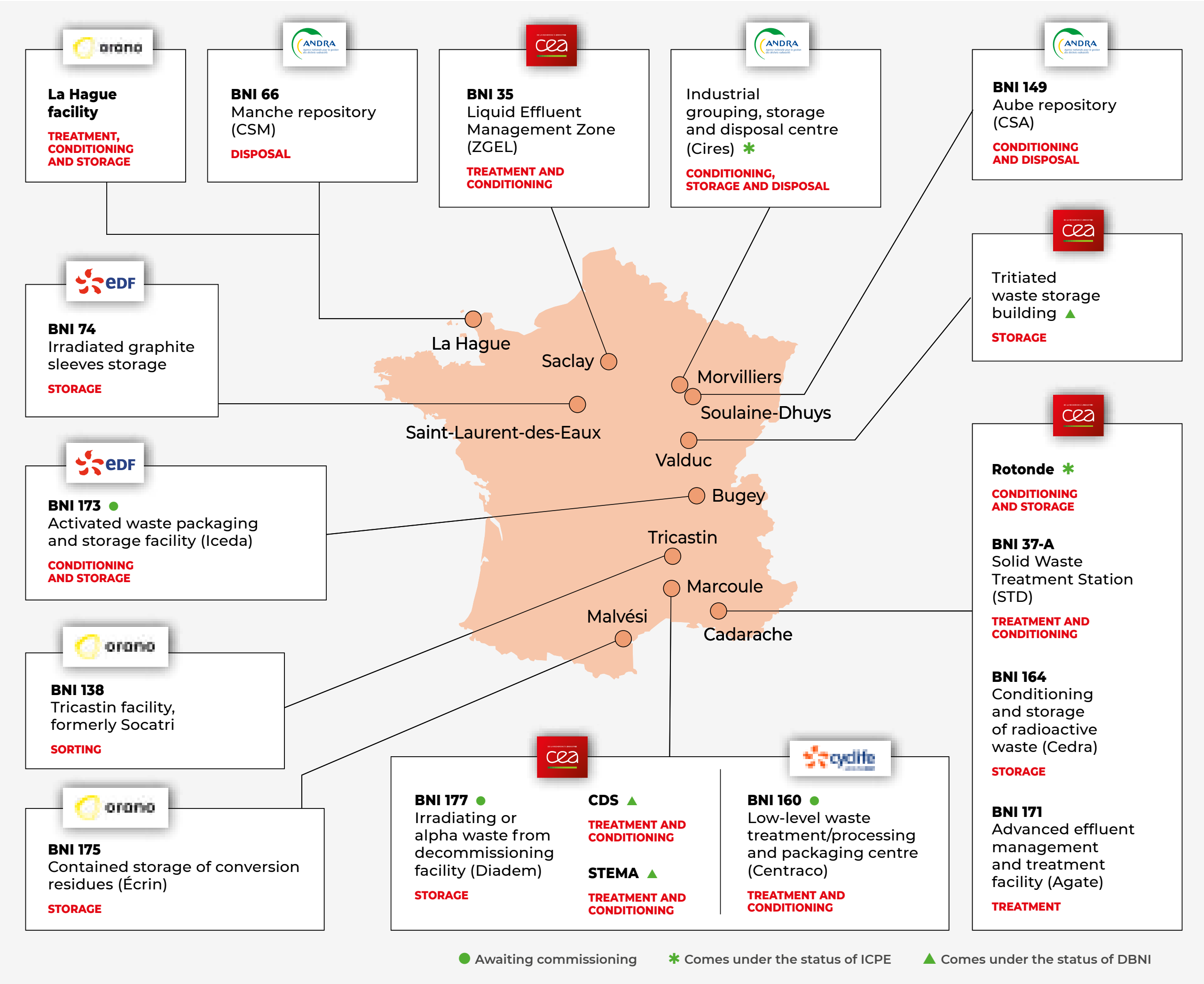
The Order of 7 February 2012 defines the requirements associated with waste packaging. Producers of radioactive waste are instructed to package their waste taking into account the requirements associated with their subsequent management, and more particularly their acceptance at the disposal facilities.

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.

The main support facilities for radioactive waste management



Waste packages intended for projected disposal facilities

With regard to disposal facilities currently being studied, the waste acceptance specifications have of course not yet been defined. Andra cannot therefore issue approvals to govern the production of packages for LLW-LL, HLW-LL or ILW-LL waste.

Under these conditions, the production of packages of these types of waste is subject to ASN approval on the basis of a file established by the waste producer called "packaging baseline requirements". This file must demonstrate that on the basis of existing knowledge and the currently identified requirements of the disposal facilities still under study, the packages display no unacceptable behaviour, and concerning, for example, the geometry and the maximum masses of the packages, waste that is prohibited or subject to restriction or the dose rate or radiological activity limits.

This provision notably also avoids delaying legacy Waste Retrieval and Packaging (WRP) operations in facilities being decommissioned (see chapter 14).

Within the framework of the PNGMDR 2016-2018, the waste producers were asked to study the acceptability of the waste packages intended for *Cigéo*. In its opinion 2020-AV-0369 of 1 December 2020, and in a letter of 23 July 2021, ASN made several observations relative to the methodology for producing these preliminary acceptance specifications for *Cigéo*, the chosen parameters and the envisaged modes of disposal.

It considered in particular that the methodology for producing these preliminary acceptance specifications for *Cigéo* was satisfactory. It nevertheless noted that several parameters, qualitative in particular, should be consolidated in order to facilitate their verification. Furthermore, as the producers' analysis of package acceptability could only be considered as partial, notably in view of the chosen mode of disposal, it will have to be carried out again on the basis of the version of the preliminary acceptance specifications for *Cigéo* incorporated into this facility's creation authorisation application, submitted in January 2023.

Checks and inspections

Alongside Andra's surveillance of approved packages, ASN checks the steps taken by the licensee to correctly implement the requirements of the 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.

Through inspections, ASN also ensures that Andra takes the necessary steps to verify the quality of the packages accepted in its disposal facilities. This is because ASN considers that Andra's role in the approvals issuing process and in monitoring the measures taken by the waste package producers is vital in guaranteeing package quality and compliance with the safety case of the waste repositories.

2.1.4 Developing the regulatory framework and issuing prescriptions to the licensees

ASN can issue resolutions of a regulatory nature. Thus, the provisions of the Order of 7 February 2012 which concern the management of radioactive waste have been set out in the ASN resolutions mentioned earlier relative to waste management in BNIs and the packaging of waste. To give an example, the resolution of 23 March 2017 addresses the packaging of radioactive waste and the conditions of acceptance of the radioactive waste packages in the disposal BNIs. Its aim is to specify the safety requirements at the various stages of a management route. This resolution has been applicable since 1 July 2018. Moreover, to ensure a consistent approach to the management of waste in BNIs and 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). Finally, ASN is consulted for its opinion on draft regulatory texts concerning radioactive waste management.

Regarding the subject of the disposal of radioactive waste, in 2023, ASN continued its work to draft a resolution regulating the disposal facilities, as well as a guide on near surface disposal. These texts aim to consolidate the requirements associated with the radioactive waste disposal facilities. From 20 October to 20 November 2023, ASN held a consultation on the Guidance and Supporting Document (DOJ) for this work, which will continue into 2024.

2.1.5 Evaluation of the nuclear financial costs

The regulatory framework designed to secure the financing of nuclear facility decommissioning costs or, for radioactive waste disposal facilities, the final shutdown, maintenance and surveillance costs, in addition to the cost of managing spent fuel and radioactive waste, is described in chapter 14 (see point 1.4).

2.2 PERIODIC SAFETY REVIEWS OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

BNI licensees, including for radioactive waste management facilities, carry out periodic safety reviews of their facilities in order to assess the situation of the facilities with respect to the rules applicable to them and to update the assessment of the risks or adverse effects, notably taking account of the state of the facility, the experience acquired during operation, and the development of knowledge and rules applicable to similar facilities. The diversity and frequently unique nature of each radioactive waste management facility lead ASN to adopt an examination procedure that is specific to each periodic safety review.

In this context, ASN is currently examining four periodic safety reviews of radioactive waste management facilities. They concern:
- two BNIs operated by CEA: the treatment and packaging facility (BNI 35) on the Saclay site and the Cedra facility on the Cadarache site;
- one BNI operated by EDF: BNI 74 comprising the Saint-Laurent-des-Eaux storage silos;
- one BNI operated by Cyclife France: 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 for some BNIs) are controlled.

For the most recent facilities, as is the case with Cedra and Chicade, the periodic safety reviews highlight more generic problems. The resistance of the buildings to internal and external hazards (earthquake, fire, lightning, flooding, aircraft crash) is one of the important aspects. ASN released its conclusions on the periodic safety review of the 37-A conditioning facility on 4 January 2023, and those for the BNI 118 safety review on 8 December 2022.

2.2.2 Periodic safety reviews of radioactive waste disposal facilities

The safety reviews of the CSM (BNI 66) and the CSA (BNI 149) have the particularity of addressing control of the risks and adverse effects over the long term, in addition to reassessing their operational control. Their purpose is therefore more specifically to update, if necessary, the scenarios, models and long-term assumptions in order to confirm satisfactory control of the risks and adverse effects over time. The periodic safety reviews of these two facilities thus highlight the need for increased knowledge of the long-term impacts associated with the toxic chemicals contained in some waste and of the impacts of the radionuclides on the environment (flora and fauna) ASN issued its conclusions on the second periodic safety review of the CSA on 25 July 2022. The periodic safety review of the CSM is currently being examined, following the review of this file by the Advisory Committee of Experts for Radioactive Waste (GPD) 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 CEA

CEA operates diverse types of facilities covering all the activities relating to the nuclear cycle: laboratories and plants associated with fuel cycle research, as well as experimental reactors.

CEA also carries out numerous decommissioning operations.

Consequently, the types of waste produced by CEA are varied and include more specifically:
- waste resulting from operation of the research facilities (protective garments, filters, metal parts and components, liquid waste, etc.);
- waste resulting from legacy waste retrieval and packaging operations (cement-, sodium-, magnesium- and mercury-bearing waste);
- waste resulting from final shutdown and decommissioning of the facilities (graphite waste, rubble, contaminated soils, etc.).

The contamination spectrum of this waste is also wide with, in particular, the presence of alpha emitters in activities relating to fuel cycle research and beta-gamma emitters in operational waste from the experimental reactors.

CEA has specific facilities for managing this waste (processing, packaging and storage). Some of them are shared between all the CEA centres, such as the Liquid Effluent Treatment Station (STEL) in Marcoule or the Solid Waste Treatment Station (STD) in Cadarache.

The issues and challenges

The main issues for CEA with regard to radioactive waste management are:
- renovation of the facilities (BNI 37-A for example);
- extension of the existing storage capacities (Cedra);
- commissioning future storage capacities (Diadem);
- conducting legacy WRP projects.

These various undertakings must permit the processing, packaging and storage of the effluents, spent fuel and waste under satisfactory conditions of safety and radiation protection and within time frames compatible with the commitments made for shutting down old facilities which no longer meet current safety requirements.

ASN's examination of CEA's waste management strategy

In response to a request from ASN and ASND in 2012, CEA submitted an overall review of its decommissioning and waste management strategy in December 2016. The review of this report enabled the two authorities to issue a joint opinion on this strategy in May 2019.

ASN and ASND consider that CEA's facility decommissioning strategy and its updating of the waste and material management strategy are the result of an in-depth review and analysis.

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 CEA with the aim of limiting these vulnerabilities, consolidating its strategy and detailing the operations schedule.

They demanded that CEA make regular progress reports on the decommissioning and waste management projects, and ensure regular communication with the public, applying procedures appropriate to the nature of the facilities, civil or defence. ASN, ASND and CEA have agreed to set up regular monitoring of these operations, through progress indicators in particular.

Monitoring implementation of CEA waste management strategy

ASN has engaged regular interchanges with the DGEC, ASND and CEA to reinforce progress monitoring on the priority projects. ASN has observed the difficulty CEA has in fully controlling the challenges associated with these projects, which must be carried out simultaneously and concern as much the management of the decommissioning operations as the operation of the waste management support facilities. It will continue to be particularly attentive to the management and monitoring of these projects. However, ASN emphasises 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 good alignment of the transportation master plan with CEA's storage capacities.

2.4 ORANO'S WASTE MANAGEMENT STRATEGY AND ITS ASSESSMENT BY ASN

The spent fuel reprocessing and recycling plant at the La Hague site presents major radioactive waste management issues. The waste on the La Hague site comprises on the one hand waste resulting from reprocessing of the spent fuel, which generally comes from nuclear power plants but also from research reactors, and on the other, waste resulting from operation of the various facilities on the site. Most of this waste remains the property of the licensees – whether French or foreign – who have their spent fuel reprocessed. French waste is directed to the management routes described earlier, whereas foreign waste is sent back to its country of origin. On the Tricastin site, Orano also produces waste associated with the front-end activities of the "cycle" (production of nuclear fuel), essentially contaminated by alpha emitters.

In 2016, Orano submitted a file to ASN and ASND, which was supplemented in 2017, presenting its decommissioning and waste management strategy for the group's French facilities, and its practical implementation on the La Hague and Tricastin sites. Moreover, Orano submitted general and particular commitments for the La Hague and Tricastin sites in 2018. ASN issued a position statement on the strategy on 14 February 2022.

Orano sent ASN further information in 2022 and 2023, in response to ASN's various requests in its letter of 14 February 2022. This information is currently being reviewed by ASN.

The issues and challenges

The main issues relating to the management of waste from the licensee Orano are:
- The safety of the legacy waste storage facilities. On the La Hague site, the facilities dedicated to legacy waste retrieval, conditioning and storage have to be designed, built and then commissioned. These projects are encountering technical difficulties which can make it necessary to adjust deadlines set by ASN (see chapter 14). Furthermore, the radioactive waste on-site storage capacities must be anticipated with conservative margins in order to prevent premature saturation. The legacy waste stored on the Tricastin site necessitates a large amount of work to characterise it and find management solutions. The storage conditions in some of the Tricastin site facilities do not meet current safety requirements and must be improved.
- The definition of solutions for waste packaging, in particular the legacy waste. The packaging procedures for 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). Compliance with 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 corresponding projects. 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.

Within the framework of the WRP operations, Orano is examining packaging solutions that necessitate the development of new processes, particularly for the following ILW-LL waste:
- the radioactive sludge from the La Hague STE2 facility;
- the alpha-emitting technological waste which comes primarily from the La Hague and Melox (Gard département) plants and is not suitable for above-ground disposal.

For other types of ILW-LL waste resulting from the WRP operations, Orano is examining the possibility of adapting existing processes (compaction, cementation, vitrification). Some of the associated packaging baseline requirements are currently being examined by ASN.

2.5 EDF'S WASTE MANAGEMENT STRATEGY AND ITS ASSESSMENT BY ASN

The radioactive waste produced by EDF comes from several distinct activities. It mainly comprises waste from the operation of the NPPs, which consists of activated waste from the reactor cores, and waste from their operation and maintenance. Some legacy waste and waste resulting from ongoing decommissioning operations can be added to this. EDF is also the owner, for the share attributed to it, of HL- and ILW-LL waste resulting from spent fuel reprocessing in the Orano La Hague plant.

Activated waste

This waste notably comprises control rod assemblies and poison rod assemblies used for reactor operation. This is ILW-LL waste that is produced in small quantities. At present this waste is stored in the NPP fuel storage pools pending transfer to the Iceda facility.

Operational and maintenance waste

Some of the waste is processed by melting or incineration in the Centraco facility, in order to reduce the volume of ultimate waste. The other types of operational and maintenance waste are packaged on the production site then shipped to the CSA or Cires repositories for disposal (see points 1.3.1 and 1.3.2). This waste contains beta and gamma emitters, and few or no alpha emitters. At the end of 2013, EDF submitted a file presenting its waste management strategy. After examining this file, ASN in 2017 asked EDF to continue its measures to reduce the uncertainties concerning the activity of the waste sent to the CSA, to improve its organisational arrangements to guarantee the allocation of sufficient resources to radioactive waste management, and to present the most appropriate process for the treatment of used steam generators.

Finally, the spent control rod cluster guide tubes from the EDF fleet could be disposed of directly in the CSA, following EDF's decision to abandon the Cyclife France reprocessing project in the Centraco facility, in order to reduce the volume of waste.

The issues and challenges

The main issues relating to the EDF waste management strategy concern:
- The management of legacy waste. This mainly concerns structural waste (graphite sleeves) from the GCR fuels. This waste could be disposed of in a repository for LLW-LL waste (see point 1.3.4). It is stored primarily in semi-buried silos at Saint-Laurent-des-Eaux. Graphite waste is also present in the form of stacks in the GCRs currently being decommissioned. In the context of the PNGMDR 2016-2018, EDF conducted a study of the reliability of the activity of this waste and submitted its conclusions in December 2019. Further to ASN's requests, additional information was provided in 2023 and will be reviewed by ASN.
- The changes linked to the "fuel cycle". EDF's fuel use policy (see chapter 10) has consequences for the "fuel cycle" installations (see chapter 12) and for the quantity and nature of the waste produced. ASN issued an opinion on the coherence of the "nuclear fuel cycle" in October 2018 (see chapter 12).

3 Management of mining residues and mining waste rock from former uranium mines

Uranium mines were worked in France between 1948 and 2001, producing 76,000 tons of uranium. Some 250 sites in France were involved in exploration, extraction and processing activities. The sites were spread over 27 *départements* in the eight regions: Auvergne-Rhône-Alpes, Bourgogne-Franche-Comté, Bretagne, Grand Est, Nouvelle-Aquitaine, Occitanie, Pays de la Loire and Provence-Alpes-Côte d'Azur. Ore processing was carried out in eight plants. The former uranium mines are now almost all under the responsibility of Orano. The working of uranium mines produced two categories of products:
- mining waste rock, that is to say the rocks excavated to gain access to the ore. The quantity of mining waste rock extracted is estimated at about 170 million tonnes;
- static or dynamic processing tailings, which are the products remaining after extraction of the uranium from the ore. In France, these tailings represent 50 million tonnes spread over 17 disposal sites. These sites are ICPEs and their environmental impact is monitored.

Redevelopment of the uranium processing tailings disposal sites consisted notably in placing a solid cover over the tailings to provide a geochemical and radiological protective barrier to limit the risks of intrusion, erosion, dispersion of the stored products and the risks of external and internal exposure of the neighbouring populations.

The regulatory context

The uranium mines, their annexes and their conditions of closure are covered by the Mining Code. The disposal facilities for radioactive mining tailings are governed by section 1735 of the ICPE classification system. The mines and the mine tailings disposal sites are not subject to ASN oversight.

In the specific case of the former uranium mines, an action plan was defined by Circular 2009-132 of 22 July 2009 from 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.

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.

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 recalled 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 shall now be taken into consideration by Orano to update its assessments of the stability of its structures encircling the mining residue disposal sites. In October 2023, Orano submitted the study concerning the Bernardan site and in December 2023 that of the Lodève site.
- Management of the water from the former uranium mining sites. With the aim of reducing the overall impact (radiological and chemical) of releases on people and ecosystems, the special technical working group in 2023 finalised the drafting of the methodology guide for drafting the multi-stakeholder, multi-criterion analysis methodology. This is a decision-making aid guide regarding the questions of maintaining, shutting down or modifying the treatment of mine water collected on a given site, which in some cases hosts uranium ore processing residue repository.

ASN has proposed creating a third working group which will focus on the updating of the methodology for assessing the long-term impact of the mining processing residue disposal sites. This working group will endeavour more specifically to detail the long-term deterioration scenarios for the covers of mining processing residue disposal facilities, in relation with the radioactive waste disposal site development scenarios and the work carried out by the pluralistic expert assessment group for the uranium mining sites of the Limousin region (GEP Limousin). This working group has not yet started, priority having been given to the work of the two working groups mentioned above.

The PNGMDR 2022-2026 plans to continue these actions concerning the long-term environmental and health impact of the management of the former uranium mines. These actions will notably take into consideration the ongoing update of the studies on structure stability applying the methodology proposed by the final report on maintaining the functions of the structures encircling the uranium ore treatment residue disposal areas and application of the methodology for management of the waters from former mining sites specified above.

4 Management of sites and soils contaminated by radioactive substances

A site contaminated by radioactive substances is defined as a site which, due to the presence of old deposits of radioactive substances or waste, or to the utilisation or infiltration of radioactive substances or radiological activation of materials, presents radioactive contamination that could cause adverse effects or a lasting risk for people or the environment.

Contamination by radioactive substances can result from industrial, craft, medical or research activities involving radioactive substances. It can concern the places where these activities are carried out, but also their immediate or more remote vicinity. The activities concerned are generally either nuclear activities as defined by the Public Health Code, or activities concerned by natural radioactivity.

However, most of the sites contaminated by radioactive substances and today requiring management have been the seat of past industrial activities, dating back to a time when knowledge of the radioactivity-related risks was not what it is today. The main industrial sectors that generated the radioactive contamination identified today were radium extraction for medical and para-pharmaceutical needs, from the early 1900s until the end of the 1930s, the manufacture and application of luminescent radioactive paint for night vision, and the industries working ores such as monazite or zircons. Sites contaminated by radioactive substances are managed on a case-by-case basis, which necessitates having a precise diagnosis of the site.

Several inventories of contaminated sites are available to the public and are complementary: Andra's national inventory, updated every five years, which comprises the sites identified as contaminated by radioactive substances (the 2023 edition is available on *andra.fr* as is the publication of the National Inventory Essentials 2023), as well as the databases devoted to contaminated sites and soils managed by 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) issues opinions on the utilisation of this subsidy, as much with respect to fund allocation priorities as to polluted site treatment strategies and the principles of assisted collection of waste.

Under Article D. 542-15 of the Environment Code, the composition of the CNAR is as follows:
- "members by right": representatives of the Ministries responsible for the environment and energy, of Andra, the French Environment and Energy Management Agency (Ademe), IRSN, CEA, ASN and the Association of Mayors of France;
- members mandated for four years by the Ministries responsible for energy, nuclear safety and radiation protection (the CNAR chair, two representatives of environmental associations and one representative of a public land management corporation).

The Commission met twice in 2023, 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.

Regarding the management of sites contaminated by radioactivity subject to the ICPE System and the Public Health Code, whether the responsible party is solvent or insolvent, in accordance with its validated doctrine regarding sites contaminated by radioactive substances (see chapter 14, point 1.2.2), ASN recalls that the clean-out practices must be implemented taking account of the best available methods and techniques, in economically acceptable conditions. The complete POCO scenario must always be envisaged as the reference scenario. This scenario, which leads to unconditional release of the buildings and sites, effectively enables the protection of people and the environment to be guaranteed over time by the removal of all contamination.

In the event of identified technical, economic or financial difficulties, the party responsible for the contamination (if solvent) or the owner of the site may propose one or more appropriate POCO scenarios compatible with the site's futures usages (confirmed, planned and possible) to the Prefect. In any case, elements proving that the reference scenario cannot be applied under acceptable technical and economic conditions and that the POCO operations envisaged constitute a technical and economic optimum shall be provided. In the event of incompatibility with the uses as a whole, usage restrictions or prohibitions and technical measures to limit exposure of the occupants, or prescribe surveillance measures may be adopted, through active institutional controls or a soil hazard information sector.

In all cases, the Prefect may rely on the advice of the classified installations inspectorate, ASN and the Regional Health Agency (ARS) to validate the site rehabilitation project, and issues a prefectural order to govern implementation of the rehabilitation measures. ASN may thus be called upon by the services of the Prefect and the classified installation inspectors to give its opinion on the clean-out objectives of a site.

APPENDIX

Overview of Basic Nuclear Installations as at 31 December 2023

To ensure the oversight of all the civil nuclear activities and installations in France, ASN – 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 (BNIs) in the Bretagne (Brittany) and Île-de-France regions respectively. The Paris division is responsible for oversight of the overseas regions and the *département* of Mayotte, while the Marseille division oversees radiation protection and radioactive substance transport in the Corse (Corsica) territorial collectivity.

A BNI is an installation which, by its nature or because of the quantity or activity of the radioactive substances it contains, is subject to a specific regulation and oversight system defined by the Environment Code (Title IX of Book V). These installations must be authorised by decree further to a public inquiry and the opinion of ASN. Their design, construction, operation and decommissioning are regulated.

The following are BNIs:
1. nuclear reactors;
2. large installations for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels, or for the treatment, storage or disposal of radioactive waste;
3. large installations containing radioactive or fissile substances;
4. large particle accelerators;
5. deep geological repositories for radioactive waste.

With the exception of nuclear reactors and any future deep geological repositories for radioactive waste, which are all BNIs, Section 1 titled "Classification of Basic Nuclear Installations" of Chapter III of Title IX of Book V of the regulatory section of the Environment Code sets the BNI System thresholds for entry into the BNI system for each category.

For technical or legal reasons, the BNI concept can cover different physical realities: thus, in a Nuclear Power Plant (NPP), each reactor may be considered to be a specific BNI, or a given BNI may be made up of two reactors. Similarly, a "fuel cycle" plant or a centre of the French Alternative Energies and Atomic Energy Commission (CEA) may be made up of several BNIs. These different configurations do not change the conditions of oversight in any way.

The following come under the BNI System:
- installations under construction, if they have formed the subject of a Creation Authorisation Decree (DAC);
- installations in operation;
- installations that are shut down or undergoing decommissioning, until they are delicensed by an ASN resolution.

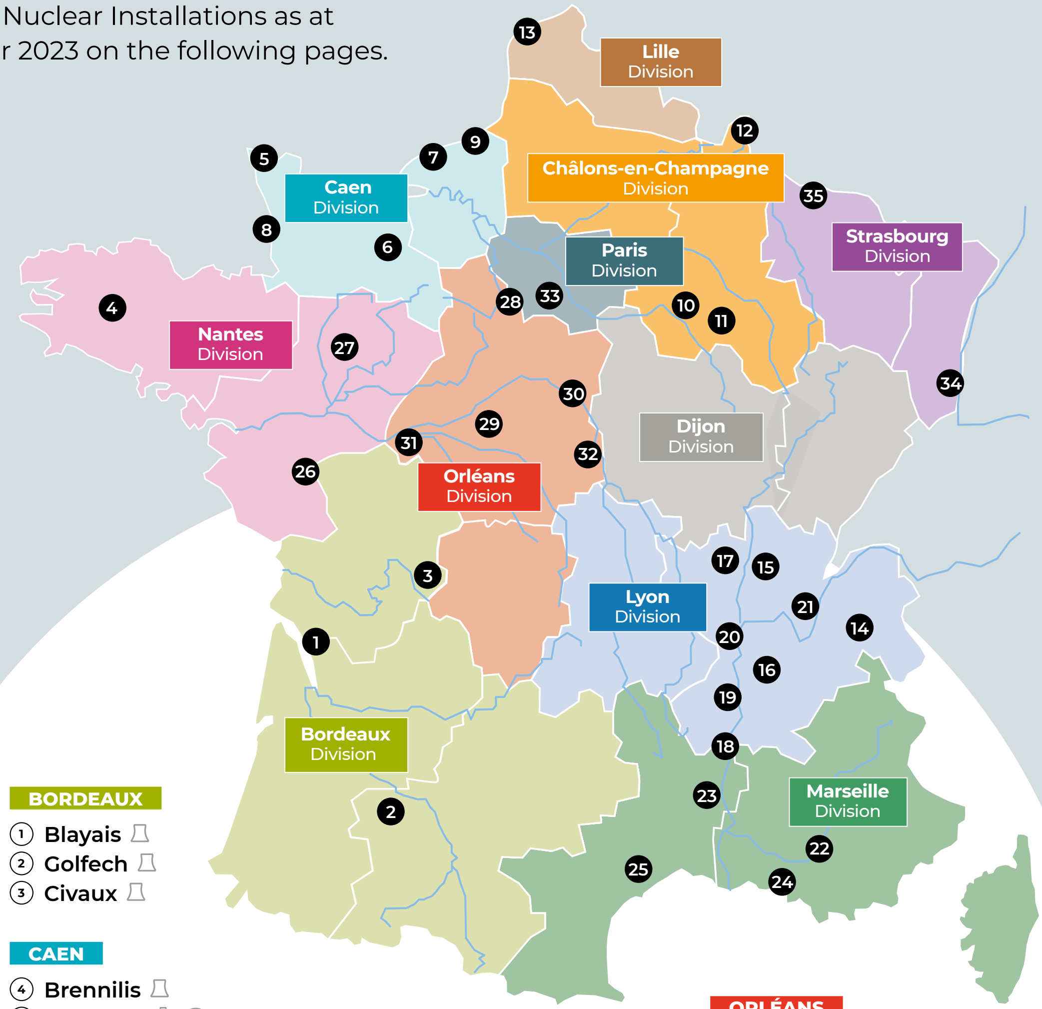
As at 31 December 2023, the number of BNIs (in the sense of legal entities) stood at 120.

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 14) or licensed as new BNIs (for example, further to the merging of BNIs 42 and 95 into a single BNI 42-U, the numbers "42" and "95" have been removed from the list and number "42-U" has been added).

FACILITIES OVERSEEN BY THE ASN REGIONAL DIVISIONS

List of Basic Nuclear Installations as at 31 December 2023 on the following pages.



BORDEAUX

1. Blayais
2. Golfech
3. Civaux

CAEN

4. Brennilis
5. La Hague
6. Caen
7. Paluel
8. Flamanville
9. Penly

CHÂLONS-EN-CHAMPAGNE

10. Nogent-sur-Seine
11. 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 facilities

- Nuclear power plants
- Plants
- Research facilities
- Waste disposal repositories
- Others

SITE NAME	LOCATION OF THE BASIC NUCLEAR INSTALLATIONS	LICENSEE	TYPE OF INSTALLATION	No.
BORDEAUX DIVISION				
1 **Blayais**	LE BLAYAIS NUCLEAR POWER PLANT (reactors 1 and 2) **33820 Saint-Ciers-sur-Gironde (Gironde)**	EDF	Reactors	86
1 **Blayais**	LE BLAYAIS NUCLEAR POWER PLANT (reactors 3 and 4) **33820 Saint-Ciers-sur-Gironde (Gironde)**	EDF	Reactors	110
2 **Golfech**	GOLFECH NUCLEAR POWER PLANT (reactor 1) **82400 Golfech (Tarn-et-Garonne)**	EDF	Reactor	135
2 **Golfech**	GOLFECH NUCLEAR POWER PLANT (reactor 2) **82400 Golfech (Tarn-et-Garonne)**	EDF	Reactor	142
3 **Civaux**	CIVAUX NUCLEAR POWER PLANT (reactor 1) **BP 1 – 86320 Civaux (Vienne)**	EDF	Reactor	158
3 **Civaux**	CIVAUX NUCLEAR POWER PLANT (reactor 2) **BP 1 – 86320 Civaux (Vienne)**	EDF	Reactor	159
CAEN DIVISION				
4 **Brennilis**	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 LIGHT WATER REACTORS (UP3-A) **50107 Cherbourg Cedex (Manche)**	Orano Recyclage	Transformation of radioactive substances	116
5 **La Hague**	PLANT FOR REPROCESSING SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP2-800) **50107 Cherbourg Cedex (Manche)**	Orano Recyclage	Transformation of radioactive substances	117
5 **La Hague**	LIQUID EFFLUENTS AND SOLID WASTE TREATMENT STATION (STE3) **50107 Cherbourg Cedex (Manche)**	Orano Recyclage	Transformation of radioactive substances	118
6 **Caen**	LARGE NATIONAL HEAVY ION ACCELERATOR (GANIL) **14021 Caen Cedex (Calvados)**	G.I.E. GANIL	Particle accelerator	113
7 **Paluel**	PALUEL NUCLEAR POWER PLANT (reactor 1) **76450 Paluel (Seine-Maritime)**	EDF	Reactor	103
7 **Paluel**	PALUEL NUCLEAR POWER PLANT (reactor 2) **76450 Paluel (Seine-Maritime)**	EDF	Reactor	104
7 **Paluel**	PALUEL NUCLEAR POWER PLANT (reactor 3) **76450 Paluel (Seine-Maritime)**	EDF	Reactor	114
7 **Paluel**	PALUEL NUCLEAR POWER PLANT (reactor 4) **76450 Paluel (Seine-Maritime)**	EDF	Reactor	115
8 **Flamanville**	FLAMANVILLE NUCLEAR POWER PLANT (reactor 1) **50340 Flamanville (Manche)**	EDF	Reactor	108
8 **Flamanville**	FLAMANVILLE NUCLEAR POWER PLANT (reactor 2) **50340 Flamanville (Manche)**	EDF	Reactor	109
8 **Flamanville**	FLAMANVILLE NUCLEAR POWER PLANT (reactor 3 – EPR) **50340 Flamanville (Manche)**	EDF	Reactor	167
9 **Penly**	PENLY NUCLEAR POWER PLANT (reactor 1) **76370 Neuville-lès-Dieppe (Seine-Maritime)**	EDF	Reactor	136
9 **Penly**	PENLY NUCLEAR POWER PLANT (reactor 2) **76370 Neuville-lès-Dieppe (Seine-Maritime)**	EDF	Reactor	140
CHÂLONS-EN-CHAMPAGNE DIVISION				
10 **Nogent-sur-Seine**	NOGENT-SUR-SEINE NUCLEAR POWER PLANT (reactor 1) **10400 Nogent-sur-Seine (Aube)**	EDF	Reactor	129
10 **Nogent-sur-Seine**	NOGENT-SUR-SEINE NUCLEAR POWER PLANT (reactor 2) **10400 Nogent-sur-Seine (Aube)**	EDF	Reactor	130
11 **Soulaines-Dhuys**	AUBE REPOSITORY (CSA) **10200 Bar-sur-Aube (Aube)**	Andra	Above-ground disposal of radioactive substances	149
12 **Chooz**	CHOOZ B NUCLEAR POWER PLANT (reactor 1) **08600 Givet (Ardennes)**	EDF	Reactor	139
12 **Chooz**	CHOOZ B NUCLEAR POWER PLANT (reactor 2) **08600 Givet (Ardennes)**	EDF	Reactor	144
12 **Chooz**	ARDENNES NUCLEAR POWER PLANT (CNA-D – CHOOZ A) **08600 Givet (Ardennes)**	EDF	Reactor	163

SITE NAME	LOCATION OF THE BASIC NUCLEAR INSTALLATIONS	LICENSEE	TYPE OF INSTALLATION	No.
LILLE DIVISION				
13 **Gravelines**	GRAVELINES NUCLEAR POWER PLANT (reactors 1 and 2) 59820 Gravelines (Nord)	EDF	Reactors	96
13 **Gravelines**	GRAVELINES NUCLEAR POWER PLANT (reactors 3 and 4) 59820 Gravelines (Nord)	EDF	Reactors	97
13 **Gravelines**	GRAVELINES NUCLEAR POWER PLANT (reactors 5 and 6) 59820 Gravelines (Nord)	EDF	Reactors	122
LYON DIVISION				
14 **Grenoble**	HIGH-FLUX REACTOR (RHF) 38041 Grenoble Cedex (Isère)	Institut Max Von Laue Paul Langevin (ILL)	Reactor	67
15 **Bugey**	BUGEY NUCLEAR POWER PLANT (reactor 1) BP 60120 – 01150 Saint-Vulbas (Ain)	EDF	Reactor	45
15 **Bugey**	BUGEY NUCLEAR POWER PLANT (reactors 2 and 3) BP 60120 – 01150 Saint-Vulbas (Ain)	EDF	Reactors	78
15 **Bugey**	BUGEY NUCLEAR POWER PLANT (reactors 4 and 5) BP 60120 – 01150 Saint-Vulbas (Ain)	EDF	Reactors	89
15 **Bugey**	BUGEY INTER-REGIONAL STORE (MIR) BP 60120 – 01150 Saint-Vulbas (Ain)	EDF	Fresh fuel storage	102
15 **Bugey**	ACTIVATED WASTE PACKAGING AND STORAGE FACILITY (ICEDA) 01150 Saint-Vulbas (Ain)	EDF	Conditioning, packaging and storage of radioactive substances	173
16 **Romans-sur-Isère**	NUCLEAR FUEL FABRICATION PLANT 26104 Romans-sur-Isère Cedex (Drôme)	Framatome	Fabrication of nuclear fuels	63-U
17 **Dagneux**	DAGNEUX IONISATION FACILITY Z.I. Les Chartinières – 01120 Dagneux (Ain)	Ionisos	Utilisation of radioactive substances	68
18 **Tricastin**	TRICASTIN NUCLEAR POWER PLANT (reactors 1 and 2) 26130 Saint-Paul-Trois-Châteaux (Drôme)	EDF	Reactors	87
18 **Tricastin**	TRICASTIN NUCLEAR POWER PLANT (reactors 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 et 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 et 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-Meysse**	CRUAS NUCLEAR POWER PLANT (reactors 1 and 2) 07350 Cruas (Ardèche)	EDF	Reactors	111
19 **Cruas-Meysse**	CRUAS NUCLEAR POWER PLANT (reactors 3 and 4) 07350 Cruas (Ardèche)	EDF	Reactors	112
20 **Saint-Alban**	SAINT ALBAN NUCLEAR POWER PLANT (reactor 1) 38550 Le Péage-de-Roussillon (Isère)	EDF	Reactor	119
20 **Saint-Alban**	SAINT ALBAN NUCLEAR POWER PLANT (reactor 2) 38550 Le Péage-de-Roussillon (Isère)	EDF	Reactor	120
21 **Creys-Malville**	SUPERPHÉNIX REACTOR 38510 Morestel (Isère)	EDF	Reactor	91
21 **Creys-Malville**	FUEL STORAGE FACILITY (APEC) 38510 Creys-Mépieu (Isère)	EDF	Storage of radioactive substances	141

SITE NAME	LOCATION OF THE BASIC NUCLEAR INSTALLATIONS	LICENSEE	TYPE OF INSTALLATION	No.
MARSEILLE DIVISION				
22 Cadarache	PROVISIONAL STORAGE FACILITY AND FACILITY FOR DRY STORAGE OF SPENT NUCLEAR FUEL (PÉGASE-CASCAD) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Storage of radioactive substances	22
22 Cadarache	CABRI 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	24
22 Cadarache	RAPSODIE 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	25
22 Cadarache	PLUTONIUM TECHNOLOGY FACILITY (ATPu) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Manufacture or transformation of radioactive substances	32
22 Cadarache	SOLID WASTE TREATMENT STATION (STD) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Transformation of radioactive substances	37-A
22 Cadarache	EFFLUENT TREATMENT STATION (STE) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Transformation of radioactive substances	37-B
22 Cadarache	MASURCA 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	39
22 Cadarache	ÉOLE / MINERVE 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	42-U
22 Cadarache	ENRICHED URANIUM PROCESSING FACILITY (ATUe) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Manufacture of radioactive substances	52
22 Cadarache	CENTRAL FISSILE MATERIAL WAREHOUSE (MCMF) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Holding of radioactive substances	53
22 Cadarache	CHEMICAL PURIFICATION LABORATORY (LPC) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Transformation of radioactive substances	54
22 Cadarache	ACTIVE FUEL EXAMINATION LABORATORY (LECA) AND SPENT FUEL TREATMENT, CLEAN-OUT AND RECONDITIONING STATION (STAR) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Utilisation of radioactive substances	55
22 Cadarache	SOLID RADIOACTIVE WASTE STORAGE AREA 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Storage of radioactive substances	56
22 Cadarache	PHÉBUS 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	92
22 Cadarache	LABORATORY FOR RESEARCH AND EXPERIMENTAL FABRICATION OF ADVANCED NUCLEAR FUELS (LEFCA) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Manufacture of radioactive substances	123
22 Cadarache	CHICADE BP 1 – 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Research and development laboratory	156
22 Cadarache	CEDRA 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Conditioning, packaging and storage of radioactive substances	164
22 Cadarache	MAGENTA 13115 Saint-Paul-lez Durance Cedex (Bouches-du-Rhône)	CEA	Reception and shipping of nuclear materials	169
22 Cadarache	ADVANCED EFFLUENT MANAGEMENT AND TREATMENT FACILITY (AGATE) 13115 Saint-Paul-lez Durance Cedex (Bouches-du-Rhône)	CEA	Conditioning, packaging and storage of radioactive substances	171
22 Cadarache	THE JULES HOROWITZ REACTOR (JHR) 13115 Saint-Paul-lez Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	172
22 Cadarache	ITER 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	ITER International Organisation	Experiments on nuclear fusion reactions in tritum and deuterium plasma	174
23 Marcoule	PHÉNIX 30205 Bagnols-sur-Cèze Cedex (Gard)	CEA	Reactor	71
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30 **Dampierre-en-Burly**	DAMPIERRE-EN-BURLY NUCLEAR POWER PLANT (reactors 3 and 4) 45570 Ouzouer-sur-Loire (Loiret)	EDF	Reactors	85
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ASN Report on the state of nuclear safety and radiation protection in France in 2023

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Publishing director: Bernard Doroszczuk, Chairman of ASN
Editor: Clémence Picart
Sub-editor: Lucas Patriat
Iconographer: Olivier Javay

ISSN 1967 – 5127

Printer number: 14063-7-2024 – **Legal deposit:** July 2024
Conception and production: BRIEF
Printer: Imprimerie Fabrègue

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