ASN REPORT

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

2021

The French Nuclear Safety Authority presents its report on the state of nuclear safety and radiation protection in France in 2021.

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

ROLES
OPERATIONS
KEY FIGURES
ASN ORGANISATION CHART

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

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

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

2006 15 2021
YEARS

ROLES

REGULATING

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

AUTHORISING

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

MONITORING

ASN is responsible for ensuring compliance with the rules and requirements applicable to the facilities and activities within its field of competence. Since the Energy Transition for Green Growth Act of 17 August 2015, ASN's roles now include protecting ionising radioactive sources against malicious acts. Inspection is ASN's primary monitoring activity. More than 1,900 inspections were thus performed in 2021 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 of the nuclear facilities.

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

IN EMERGENCY SITUATIONS

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

REGULATION AND MONITORING OF DIVERSIFIED ACTIVITIES AND FACILITIES

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

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

EXPERT SUPPORT

When drawing up its decisions and regulations, 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 its eight Advisory Committees of Experts, who come from a variety of scientific and technical backgrounds.

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	Sylvie CADET-MERCIER (*) Commissioner	Géraldine PINA JOMIR Commissioner	Laure TOURJANSKY (*)(**) Commissioner	Jean-Luc LACHAUME (*) Commissioner
from 13 November 2018 to 12 November 2024	from 21 December 2016 to 9 December 2023	from 15 December 2020 to 9 December 2026	from 21 April 2021 to 9 December 2023	from 21 December 2018 to 9 December 2026

APPOINTED BY the President of the Republic (Bernard Doroszczuk, Sylvie Cadet-Mercier, Géraldine Pina Jomir)

APPOINTED BY the President of the Senate (Laure Tourjansky)

APPOINTED BY the President of the National Assembly (Jean-Luc Lachaume)

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

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

Impartiality

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

Independence

The Commissioners perform their duties on a full-time basis. Their mandate is for a six-year term. It is not renewable. The duties of a Commissioner can only be terminated in the case of impediment or resignation duly confirmed by a majority of the Commissioners. The President of the Republic may also terminate the duties of any member of the Commission in the event of 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, covering the entire country and the overseas territories. The regional divisions conduct most of the oversight in the field of 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 regional 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.

PERSONNEL

519
staff members

85% management

48% women

317 inspectors

BUDGET

€67.15 M
budget for ASN (programme 181)

€83 M
IRSN budget devoted to expert assessment work on behalf of ASN

ASN ACTIONS

1,881
inspections of which 5% were carried out remotely

26,733
inspection follow-up letters available on *asn.fr* as at 31 December 2021

393
technical opinions sent to ASN by IRSN

1,917
individual licensing and registration resolutions issued

8
plenary meetings of the Advisory Committees

INFORMATION

550
replies to queries from the public and stakeholders

63
information notices

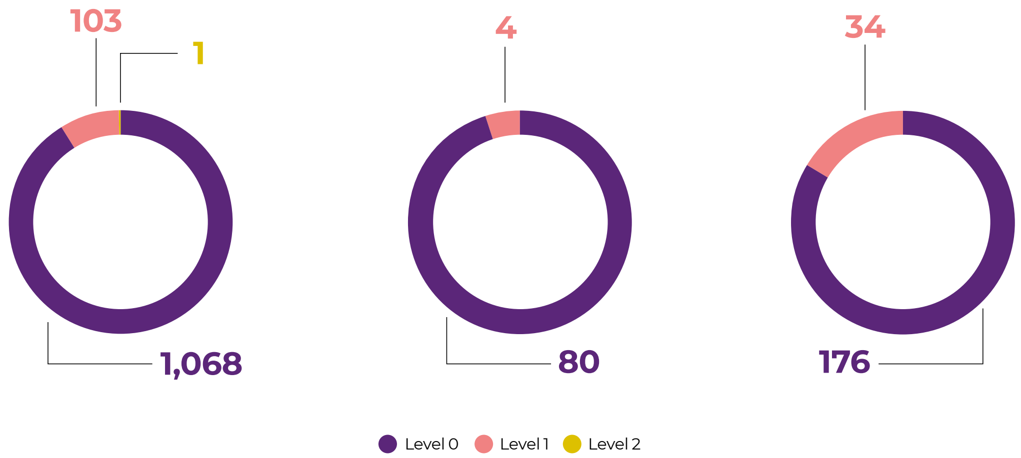
11
press conferences

NUMBER OF SIGNIFICANT EVENTS RATED ON THE INES SCALE(*)

1,172
events in the Basic Nuclear Installations

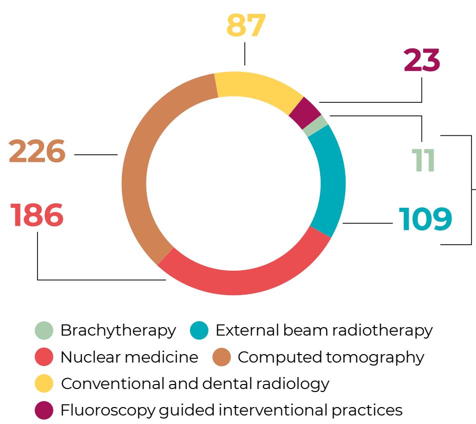
84
events in the transport of radioactive substances

210
events in small-scale nuclear facilities (medical and industrial)

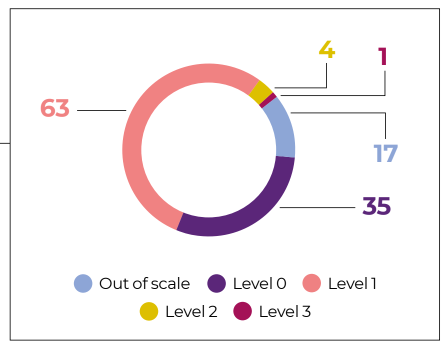


NUMBER OF SIGNIFICANT EVENTS IN THE MEDICAL FIELD(*)

642
significant events per area of exposure



120
significant events in external beam radiotherapy and brachytherapy
according to the rating on the ASN-SFRO scale



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

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

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

COMMISSION

CHAIRMAN
Bernard DOROSZCZUK

COMMISSIONERS
Sylvie CADET-MERCIER
Géraldine PINA JOMIR
Jean-Luc LACHAUME
Laure TOURJANSKY

HEAD OF PRIVATE OFFICE
Sylvie RODDE

ADMINISTRATIVE ENFORCEMENT COMMITTEE
CHAIRMAN
Maurice MÉDA

GENERAL DIRECTORATE

DIRECTOR GENERAL
Olivier GUPTA

ETHICS OFFICER
Alain DORISON

DEPUTY DIRECTORS GENERAL
Julien COLLET
Daniel DELALANDE
Anne-Cécile RIGAIL

CHIEF INSPECTOR
Christophe QUINTIN

DIRECTOR OF PRIVATE OFFICE
Vincent CLOÎTRE

MANAGEMENT AND EXPERTISE OFFICE
Adeline CLOS

REGULATION AND OVERSIGHT SUPPORT MISSION
Julien HUSSE

GENERAL SECRETARIAT
Brigitte ROUÈDE

DEPARTMENTS

NUCLEAR POWER PLANTS
Rémy CATTEAU

NUCLEAR PRESSURE EQUIPMENT
Corinne SILVESTRI

WASTE, RESEARCH, FACILITIES AND FUEL CYCLE
Cédric MESSIER

TRANSPORT AND SOURCES
Fabien FÉRON

IONISING RADIATION AND HEALTH
Carole ROUSSE

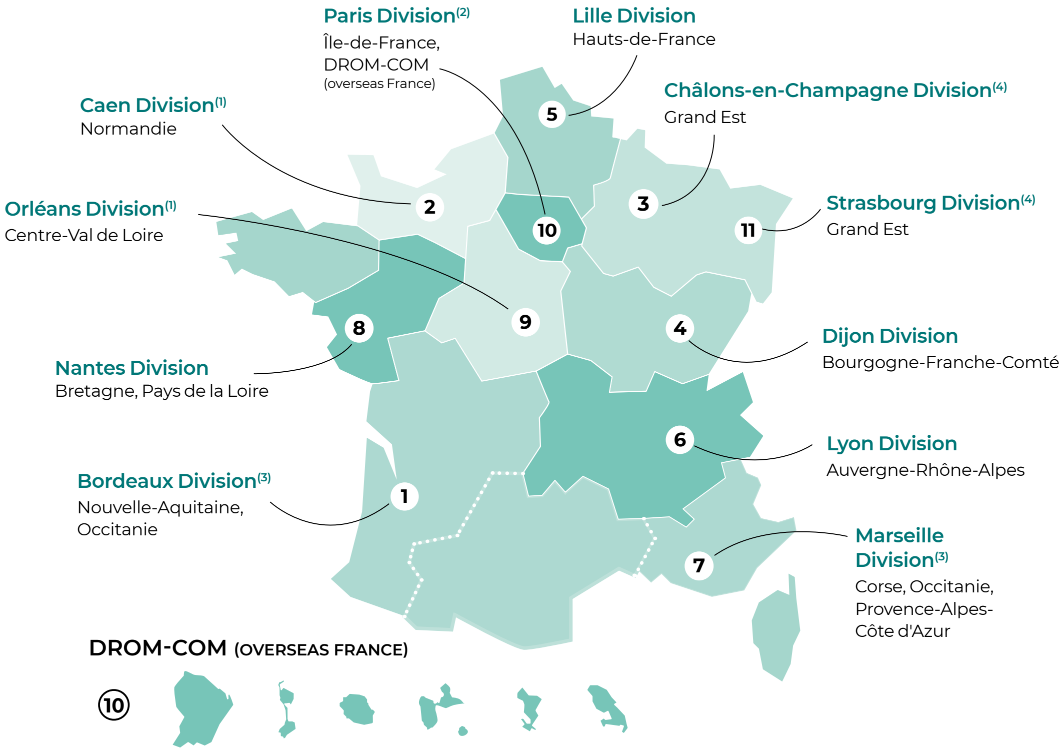
ENVIRONMENT AND EMERGENCY SITUATIONS
Olivier RIVIÈRE

INTERNATIONAL RELATIONS
Luc CHANIAL

LEGAL AFFAIRS
Olivia LAHAYE

INFORMATION, COMMUNICATION AND DIGITAL USAGES
Céline ACHARIAN

ORGANISATION CHART(*)



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

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

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

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

REGIONAL DIVISIONS

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

2 CAEN
REGIONAL REPRESENTATIVE
Olivier MORZELLE
REGIONAL HEAD
Adrien MANCHON

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

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

5 LILLE
REGIONAL REPRESENTATIVE
Laurent TAPADINHAS
REGIONAL HEAD
Rémy ZMYSLONY

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

7 MARSEILLE
REGIONAL REPRESENTATIVE
Corinne TOURASSE
REGIONAL HEAD
Bastien LAURAS

8 NANTES
REGIONAL REPRESENTATIVE
Anne BEAUVAL
REGIONAL HEAD
Émilie JAMBU

9 ORLÉANS
REGIONAL REPRESENTATIVE
Hervé BRÛLÉ
REGIONAL HEAD
Arthur NEVEU

10 PARIS
REGIONAL REPRESENTATIVE
Emmanuelle GAY
REGIONAL HEAD
Agathe BALTZER

11 STRASBOURG
REGIONAL REPRESENTATIVE
Hervé VANLAER
REGIONAL HEAD
Pierre BOIS

(*)As at 1 March 2022.

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 "Réglementer".

EDITORIAL BY THE COMMISSION

Nuclear safety concerns must lie at the heart of energy policy decisions

From left to right: **Jean-Luc LACHAUME,** Commissioner; **Laure TOURJANSKY,** Commissioner; **Bernard DOROSZCZUK,** Chairman; **Géraldine PINA JOMIR,** Commissioner; **Sylvie CADET-MERCIER,** Commissioner.

Montrouge, 1 March 2022

In 2021, the safety of nuclear facilities and radiation protection in the medical, industrial and radioactive substances transport sectors remained at a satisfactory level, in line with the level observed in 2020.

What are most striking about 2021, in particular its second part, are the industrial vulnerabilities affecting all nuclear facilities and the debate concerning energy policy choices and the position of nuclear power in these choices.

On these subjects, ASN has four key messages:

1. The French electricity system today faces an unprecedented two-fold vulnerability in availability, affecting both the "fuel cycle" facilities and the fleet of nuclear power reactors. This vulnerability is compounded by the unexpected discovery of a stress corrosion phenomenon on several EDF reactors, which is a serious event from the viewpoint of safety.

These situations and vulnerabilities, most of which stem from the lack of margins and inadequate anticipation, must serve as lessons for the entire nuclear sector and the public authorities.

2. Nuclear safety concerns must lie at the heart of energy policy decisions, in the same way as concerns regarding the decarbonisation of electricity production by 2050.

In the coming 5 years, EDF will have to examine and individually justify the ability of the older reactors to continue to operate beyond 50, or even 60 years, so that lessons can be learned as soon as possible regarding any provision to be made for additional production capacity.

At the same time, given the foreseeable growth in the electrification of usages, and given the need to maintain margins in the electricity system, the public authorities will have to carefully weigh its decision to shut down an additional 12 reactors by 2035, except of course for safety reasons.

Finally, by the end of the decade at the latest, the Government will have to decide on whether or not to continue with the reprocessing of spent fuel after the 2040 time-frame, in order to anticipate the consequences, with regard either to the refurbishment of the existing facilities, or alternative solutions to be adopted for spent fuel management.

3. The prospect of an energy policy comprising a long-term nuclear component must be accompanied by an exemplary policy for the management of waste and legacy nuclear facilities.

A policy such as this implies that decisions be taken before the end of the next National Radioactive Materials and Waste Management Plan (PNGMDR), so that operational management solutions are available for all types of waste within the coming 15 to 20 years, and so that the nuclear licensees are more committed to meeting the specified deadlines for legacy nuclear waste retrieval and conditioning projects for which they are responsible.

4. ASN reaffirms that the new energy policies perspectives, whatever they are, imply a considerable industrial effort, in order to tackle the industrial and safety challenges.

If nuclear power is among the choices made to ensure a decarbonised energy mix by the 2050 time-frame, the nuclear sector will have to implement its own "Marshall Plan" to make this perspective industrially sustainable and have the skills it needs to tackle the scale and duration of the projects concerned.

Quality and rigour in the design, manufacture and oversight of nuclear facilities, which were not up to the required level in the latest major nuclear projects conducted in France, constitute the first level of "Defence in Depth" in terms of safety.

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A weakened fuel chain, putting pressure on the electricity system

The "fuel cycle" industry consists of all the facilities contributing to the production of fresh fuel, the reprocessing of spent fuels and the reuse of products from reprocessing. These non-redundant facilities are the links in a chain, the operation of which can be disrupted if one of them experiences a long-term failure.

A series of events is currently weakening the entire "fuel cycle" chain and is a major strategic concern for ASN requiring particularly close attention, in that an unanticipated build-up of radioactive materials or waste could lead to storage conditions that are unsatisfactory from the safety standpoint.

Construction of the centralised spent fuel storage pool being planned by EDF to address the risk of saturation of the existing pools by 2030, the need for which was identified as of 2010, has not yet begun. This pool will not be available before 2034 at best. This delay will require interim measures to increase existing storage capacity. The solution chosen by Orano, which consists in increasing the storage density in the existing pools at the La Hague facility, cannot be considered a long-term one, given the required storage periods of about a hundred years, and in the light of the most recent safety standards.

Furthermore, the operating issues experienced by the Orano Melox plant in recent years, which worsened in 2021, are leading to the saturation of plutonium-bearing materials storage capacity as of 2022, owing to the production of a large quantity of manufacturing scrap. These issues are already leading to the "demoxing" of some of the 900 MWe reactors, which used MOX as fuel. They could also lead to saturation of the spent fuel pools at the La Hague facility earlier than 2028-2029.

Finally, the detection of corrosion in the existing evaporators in Orano's La Hague facility earlier than expected in the design has reduced reprocessing capacity until new fission product evaporators-concentrators are commissioned and could further degrade the saturation margins of the pools at La Hague.

Overall, these situations reflect a lack of anticipation and precaution owing to the absence of margins, which is weakening the entire "fuel cycle" chain and which could, in turn, have consequences on the operation of the Nuclear Power Plants (NPPs).

Pressure on the availability of the NPP fleet, underscoring the need to maintain margins for safety

The winter of 2021-2022 was marked by a lower than anticipated availability of the NPP fleet.

This was for a number of reasons, some of which could be foreseen, others less so.

The postponed commissioning of the Flamanville EPR, the 2020 shutdown of the two Fessenheim reactors and the schedule of heavy maintenance operations ("major overhaul"), as of 2018, were known.

In addition to this lower availability –which was predictable as of 2018, there was the unexpected impact of the Covid-19 pandemic– notably the first lockdown, identified as of mid-2020. This lockdown led to reactor maintenance and refuelling operations being spread out over a longer period, with the consequence of reducing production capacity margins over several consecutive winters.

Finally, this winter, the four N4 series reactors of Civaux and Chooz, plus one reactor at Penly were either shut down or kept shut down, for in-depth inspections and repairs, following the detection of stress corrosion anomalies on welds on the reactors' safety injection system. An inspection program for the reactors of the NPP fleet likely to be the most severely affected, extending over several months, has been proposed by EDF.

This build-up of events illustrates the absolute need –as ASN has pointed out to the public authorities and nuclear sector stakeholders numerous times– to maintain design-basis margins for the electricity system and the installations, in order to deal with unexpected events and avoid having to resort to a trade-off between the safety of installations and the availability of electricity supply.

New energy policy prospects which must address safety concerns at once

Five of the six scenarios presented in the *Réseau de transport d'électricité* (RTE) report, produced at the request of the Government, on "Energies of the future", aiming to achieve a decarbonised economy by 2050, are based on continued operation of the existing NPP fleet.

At this stage, no conclusion on the continued operation of all these reactors beyond 50 years can be drawn from the information available to ASN during the generic examination of the fourth periodic safety review of the 900 MWe reactors, for which it issued its decision in February 2021. Due to the specific features of some reactors, it might not be possible, with the current methods, to demonstrate their ability to operate up to 60 years.

Furthermore, over the longer term, one of the scenarios envisaged by RTE presents an electricity mix with a nuclear electricity share close to 50% in 2050. Consultation with industry revealed that the rate of construction of new nuclear reactors in order to achieve such a level would be hard to sustain, which led RTE also to base this scenario on the operation of some reactors beyond 60 years and the continued operation of the others until 60 years.

This scenario, which is based on fundamental hypotheses of an operating lifetime which cannot at present be confirmed with regard to safety, also entails the risk of leading the electricity system into a dead-end, if the number of reactors able to operate until or indeed beyond 60 years proves to be insufficient, and if this were only known belatedly. Moreover, the shutdown in a few years of a large number of reactors built during a short period of time in the 80s, could have "cliff-edge" consequences for electricity production capacity.

ASN considers that the energy policy choices for the 2050 time-frame must be based on hypotheses that are robust and which can be justified in terms of safety.

The choice of operating the current NPP fleet beyond 50 years and up to 60 years should include a step to justify this possibility, with sufficient margins for dealing with major or generic unexpected scenarios.

In any case, if the hypothesis of continued operation of certain reactors beyond 60 years were to be an option, this should involve an examination, in advance, so that there is enough time –at least 15 years– to be able to adjust the energy policy choices in the light of its conclusions and avoid a situation in which the lack of forward planning leads to continued operation of the nuclear reactors based on a decision dictated purely by electricity needs or which is hazardous in terms of safety.

The strong mobilisation of EDF must continue with a view to commissioning of the Flamanville EPR reactor

The activities concerning weld repairs on the secondary systems (main steamlines and steam generator feedwater lines) of the Flamanville EPR, involved considerable efforts of EDF. Because of the deviations observed, about a hundred secondary system welds needed to be repaired. EDF produced specific mock-ups and tests to qualify the repair processes. ASN carried out reinforced oversight of these worksites to ensure the quality of the new welds. According to the EDF schedule, repair of the welds on the secondary systems will continue until August 2022. Other work to correct deviations still has to be carried out ahead of commissioning, in particular concerning the primary system set-in nozzles.

Moreover, ahead of the reactor commissioning authorisation, considerable work is still to be done on numerous topics with major safety implications, already identified several years ago. In particular, EDF must carry out numerous analyses, including tests, to justify the design of certain equipment, notably the reliability of the pressuriser valves and the performance of the filters for the water reinjected from the bottom of the reactor building in an accident situation. In some cases, this could require modifications being made ahead of commissioning.

EDF must also complete the required test programme for reactor commissioning and supplement it, in order to carry out requalification of the installation after the modifications and repairs.

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Finally, ASN is paying close attention to how EDF learns the lessons gained from the EPRs commissioned in Finland and China. In particular and in addition to the in-depth technical dialogue initiated with EDF, anomalies on fuel, in particular those affecting the Taishan reactor core, are the subject of experience feedback exchanges between ASN and its Chinese counterpart.

Management of waste and materials which must, more than ever, be exemplary

Following the public debate in 2019, a draft PNGMDR covering the period 2021-2025 has been produced. Further to its opinions on each of the waste management routes, ASN issued an opinion on this draft. It considers that on the whole it meets the main goal: to allow the necessary decisions to be taken before its end, so that safe management routes are operational within the coming 15 to 20 years, for all types of radioactive waste. Within the framework of the oversight committee which it jointly chairs, ASN will pay particular attention to compliance with the strategic milestones.

ASN underlines the simultaneous occurrence of short-term safety issues, related to the malfunctions observed in certain "cycle" facilities, and longer-term issues. At this stage, the multi-year energy plan has not determined that reprocessing policy will continue beyond 2040. Whatever the option chosen, either cessation or continued reprocessing of spent fuels, the design and examination of the resulting facilities requires extensive forward planning.

At ASN's request, CEA and Orano have drawn up strategies to conduct several major decommissioning projects on old facilities. These are part of a prioritisation effort to address the safety issues. ASN therefore underlined the need to prioritise retrieval of waste and decommissioning of the facilities representing the greatest risk for people and the environment, and to comply with the defined scheduled. The retrieval and conditioning of legacy waste are preliminary but complex steps, because they require that appropriate techniques be developed. They more specifically entail a risk of delay. When the feasibility of final conditioning cannot be demonstrated within the planned time-frame, ASN requests that an alternative solution be developed, with safe retrieval of the waste, regardless of its conditioning.

With the possibility of a new nuclear future, the entire sector must be mobilised in order to implement concrete solutions to manage the situations inherited from the past, as rapidly as possible.

In the medical field, the level of radiation protection is maintained despite the Covid-19 pandemic

In 2021, medical exposure still represents the first cause of exposure to artificial ionising radiation, with the particularity of providing benefits for the patient, provided that prescription of the procedure is justified. Justification is thus a fundamental principle of radiation protection, hence the importance of implementing and overseeing it. When, for example, a new technique or procedure emerges, good collaboration is needed between the various medical and institutional actors.

When a long-duration, unexpected crisis appears and exerts pressure on the health care structures, as was the case during the Covid-19 pandemic, mastering the fundamentals of radiation protection culture becomes the best guarantee of the high level of radiation protection expected in the medical field. With this in mind, ASN's decisions and inspections aim to implement a quality management system increasing the accountability of each individual, from decision-maker to actor, that is proportionate to the radiation protection issues for all the diagnostic, interventional and therapeutic fields. Eventually, this system should incorporate the methods for performing external peer reviews and, for radiotherapy, if a new technology or new type of practice is used, the recording and analysis of data concerning the expected benefits to the patient and the corresponding risks. ASN stresses the importance of learning lessons from undesirable events (Significant Radiation protection Events –ESR), which enhance the study of potential risks and contributes to continuous improvement of the safety of practices by looking for the root causes of the ESRs, regardless of origin (material, human, organisational, etc.).

Faced with growing technical complexity in a field where innovations are major and rapid, compliance with the principle of optimisation in radiation protection constitutes a major concern. ASN recalls the importance of forward planning for change and compliance with the learning curve when new equipment arrives or when new techniques are adopted. In therapeutic nuclear medicine, the growth of internal targeted radiotherapy requires anticipation of the arrival of new molecules and the increase in the number of patients treated.

Preparation for post-accident management based on innovative partnership-based approaches

The work done in 2021 by the the Steering Committee for the management of the post-accident phase (Codirpa), under the mandate given to ASN by the Prime Minister on 18 June 2020, led to a number of tangible advances, built around listening to and involving the stakeholders concerned.

The "Q&A for health professionals" regarding the consequences of an accident was prepared with the health professionals, both locally and nationally, as they were identified as trusted third parties in the event of an emergency. This method ensures that the questions dealt with are pertinent and the answers given are of high quality, thus fostering a good level of assimilation.

Along the same lines, the drafting of guidelines regarding foodstuffs in a post-accident situation relied on the work done by a pluralistic expert group, followed by a debate with four panels of citizens living near the NPPs. This was an initial trial to test the understanding of the subjects and the pertinence of the areas of work, and to collect the opinions of the populations concerned.

Finally, the work done on the necessary information and awareness-raising in order to reinforce the safety and radiation protection culture focused on target public. Given the extensive work already done, an inventory of good practices will form the basis of the Codirpa report. It will enable to identify how to mobilise the various actors to implement the most effective measures in each area.

These partnership-based approaches will help to inform decisions and adopt a pragmatic approach to the essential development of the safety and radiation protection culture. The Codirpa recommendations to the Prime Minister will be based on all of this feedback collection and expert work. ■

Responsible oversight, combining consistency with adaptability

Montrouge, 1 March 2022

The last decade has been marked by the follow-up to the Fukushima Daiichi accident and the problems experienced by the french nuclear industry. During this period, the stakeholders asked that safety and inspections be reinforced. Today, the security of electricity supply is the focus of everyone's attention, raising questions about the cost of safety or the potentially excessive nature of the regulations.

Over and above the cycles in which nuclear power falls into or out of favour and regardless of those who say that there is too much or too little safety, ASN has always sought to adapt its oversight to the challenges of the moment, without ever deviating from its fundamental principles.

These fundamental principles are unwavering, because they correspond to convictions about how to exercise oversight and because nuclear power, in which time-scales are very long, requires a stable framework: stop and go and a lack of visibility are hardly the best guarantors of safety.

Adaptability is needed because the installations, licensees and network of subcontractors change, whether in technical, human resources, financial or industrial terms. In 2017, ASN therefore defined a strategic plan to exercise oversight that was as efficient as possible in a context where the nuclear industry was faced with colossal investments, at a time when the licensees were also faced with budgetary or financial difficulties.

Five years later, as ASN is drafting a new strategic plan, what changes have been made in the field of oversight? What are the new challenges?

ASN has consolidated the fundamental principles of its oversight

Oversight promoting more accountability

ASN's conviction has always been that a good level of nuclear safety and radiation protection can only be achieved if the nuclear licensees fully assume their prime responsibility for it. ASN's action aims to ensure that they do so effectively.

Before issuing a ruling on the restart of nuclear reactors following maintenance outages, ASN used to examine numerous documents in which EDF justified maintaining the equipment as-is, despite the anomalies observed. In recent years, ASN made changes to its oversight of reactor outages by replacing this systematic documentary review with targeted on-site inspections, while at the same time, EDF has placed emphasis on rectifying the anomalies as early as possible, rather than justifying their acceptability. This approach illustrates a more responsible attitude on the part of the licensee, as encouraged by ASN's oversight, with safety being the winner.

Oversight that is more proportionate to the stakes

The internationally recognised principle of the proportionality of the resources to the issues means that licensees and professionals are focusing their resources, which are by definition finite, on subjects with the greatest nuclear safety or radiation protection implications. Application of this principle is a constant concern in that ASN directs the allocation of the licensee's resources through the requests it makes or the questions it poses.

ASN has ramped up its efforts in favour of a "graded approach" to oversight. In the field of small-scale nuclear activities, the overhaul of the administrative regimes carried out in recent years has thus reduced the burden in terms of the files requested and the examinations carried out for those activities with lower radiation protection implications. Similarly, ASN has

Olivier GUPTA

"Without ever deviating from its fundamental principles, ASN has always sought to adapt its oversight to the challenges of the moment."

refocused its inspections on the activities with greater implications.

This necessary proportionality with the stakes is not always understood with respect to the large nuclear installations, as any subject concerning a Nuclear Power Plant (NPP) could be seen as being important: this sometimes creates a distortion between the actual issues and the media coverage. However, in the interests of safety, realism and pragmatism dictate that the proportionate approach should continue to be used and that it should even be taken further in the coming years.

Reinforced technical dialogue

Contrary to popular belief, french nuclear safety regulations are not particularly voluminous and are focused on the objectives to be achieved: only rarely do they specify means requirements. They have the advantage of allowing each licensee to define the most appropriate provisions and do not stand in the way of innovation.

Nuclear safety is not therefore built around the regulations, but more on an in-depth technical dialogue between the licensee and ASN, with the support of its Advisory Committees of Experts and the Institute for Radiation Protection and Nuclear Safety (IRSN). Between 2018 and 2022, ASN deployed a plan to reinforce its control of technical examinations and its involvement in this dialogue, placing technical considerations at the heart of its decisions and resolutions.

However, it is clear that over the years, the way in which the regulations are applied has become more complex, and the technical dialogue has led to a multiplication of the internal rules drafted by the licensees, to the extent that they have become hard to apply or have even lost part of their meaning for the operatives in the field. One of the challenges for the coming years will be to control this inflation in the number of rules.

Public participation in the drafting of decisions

Public involvement in the process of drafting decisions and resolutions opens up an area for dialogue, not only on the protection objectives but also on how they are to be technically achieved by the licensee. This involvement must lead to a lasting improvement in the understanding of the issues, increase trust in the decision-making process and, whenever possible, enhance it by making it possible to comprehend the questions considered to be priorities by the stakeholders and provide answers to them. Together with IRSN, ASN thus set up technical dialogue and consultation sessions on key subjects such as the fourth periodic safety reviews for the NPPs, or the densification project for the spent fuel storage pools at La Hague.

ASN has deployed new means of oversight

Experience feedback from the Creusot affair

Following the discovery – starting in 2016 – of irregularities in the manufacturing files (sometimes dating back some time) for certain nuclear reactor parts at Framatome's Le Creusot plant, ASN implemented a system for the prevention, detection and handling of fraud and falsification, in line with its undertaking to Parliament: creation of an on-line form to facilitate whistle-blowing; creation of a unit for systematic analysis of these reports, leading to investigations whenever necessary; performance of inspections targeted on fraud, with a specific investigation methodology enabling information to be cross-checked.

Oversight of the security of radioactive sources

An Ordinance of 2016 entrusted ASN with oversight of protection against malicious acts concerning the radioactive sources used outside the installations monitored by other authorities. An Order, published in 2019, defines the provisions to be followed by those in possession of sources and acts as a framework for inspections. On this basis, ASN was thus able to incorporate source security into the inspections it carries out in the small-scale nuclear activities. This oversight complies with the rules applicable to protection of the confidentiality of sensitive information.

Oversight of complex projects

ASN wished to overhaul its oversight of decommissioning and legacy waste retrieval projects, which suffer from repeated delays on the part of the licensees, partly owing to their complexity and the need to constantly adapt the operations to the new situations discovered. Rather than reinforce the level of technical detail of the inspections, and drawing inspiration from the practices of its british counterpart, ASN developed an inspection methodology for these projects designed to identify any potential drifts early on and to urge the licensees to take corrective measures in good time. Inspections were thus conducted at Orano and EDF accordingly. They will soon be extended to projects managed by CEA and the French National Radioactive Waste Management Agency (Andra).

ASN has changed how it works in-house

Skills reinforcement

ASN observes that, year after year, it is faced with increasingly complex subjects. This can be the analysis of physical phenomena not anticipated in the design, or the use by the licensees of increasingly sophisticated calculations to prove the safety of their facilities. At a different level, this can also concern ASN's ability to monitor the supply chain.

These issues require specific skills which take a long time to acquire, along with growth in the cumulative experience of ASN's personnel in the hazards and nuclear fields. In recent years, ASN thus developed its career paths, to ensure that it has personnel who have worked for a greater number of years in the oversight of nuclear safety and radiation protection. In addition to simply the question of numbers, it also devotes efforts to recruiting staff with more experience than previously for the "senior" positions. These approaches must be continued.

A well-advanced digital transformation

As early as 2017, ASN launched an ambitious digital transformation programme. It won a number of calls for project proposals from the State's Digital Division, which enabled it to benefit from support in developing data processing: for example, a data mining tool used for more than 26,000 follow-up letters now enables the inspection findings on a given topic to be collated, with identification of the early warning signs which were hitherto hard to detect.

The digital transformation also aims to simplify the procedures for the licensees: ASN has thus developed an online services portal to make it easier to submit notification or registration files for small-scale nuclear activities.

The Covid-19 pandemic crisis accelerated this process and led to the development of new practices, such as remote inspections, which do not aim to replace on-site inspection, but simply complement it.

ASN has begun to consider the future challenges and the changes for which it must begin to prepare

In conjunction with the internal analysis work, ASN conducted an "external consultation" to collect the viewpoints of its main interlocutors. Four main issues were identified by this preliminary work.

First of all, ASN will have to oversee a fleet of installations and nuclear activities undergoing a period of transition, given that many of them are faced with the question of their continued operation and consequently the need to plan ahead for their shutdown. Projects for new facilities to replace some of the older ones, in addition to the construction work already in progress, means that ASN will have to oversee a number of new facilities (under design or under construction) unlike anything that has been seen for some considerable time: the Jules Horowitz research reactor, ITER, the *Cigéo* waste disposal repository, the spent fuel centralised storage pool, and possibly a number of EPR2 reactors or Small Modular Reactors (SMRs). ASN must prepare for this, so that it can examine the corresponding requests without delay and without compromising on safety.

In the medical field, the major challenges are linked to questions of organisation and competence in a context of pressure in terms of staffing levels: as in the nuclear installations, social, organisational and human factors issues are predominant and ASN must further reinforce its skills and its oversight methods in this field.

A new challenge is the demand from our fellow citizens for the State to be more willing to listen and to explain. In the fields of risk management, it is clear that better results are obtained when the State encourages everyone to be a contributor to their own safety. This implies good understanding of the measures taken: strict policing alone is no longer sufficient and the activity managers, decision-makers and local players must truly take on board the nuclear safety and radiation protection issues.

At an international level, a key aspect of the coming period is geopolitical change. On the one hand, the nuclear centre of gravity is shifting towards Asia. On the other, some countries are preferring a national approach and the Covid-19 pandemic made international exchanges more difficult. ASN, together with its European partners, will have to redouble its efforts to ensure that there is an ambitious vision for nuclear safety internationally.

Finally, ASN must continue to adapt its operating methods in order to remain attractive, and acquire skills to address the new challenges.

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Many changes have been made in recent years to adapt both ASN and its oversight to the context, itself in a constant state of flux. The Covid-19 pandemic crisis, which weighed heavily on the ASN personnel in the same way as all our fellow citizens over the past two years, did not stop ASN from issuing the most urgent decisions in good time, nor from conducting examinations and inspections which attracted less media coverage, but which constitute the basis of its work and underpin the credibility of its oversight. I wish to thank all the ASN personnel for their commitment and indeed all the personnel of IRSN and the members of ASN's Advisory Committees of Experts, whose expertise is of valuable assistance during our examination work.

Preparing ASN for the oversight of new installations, ensuring that the nuclear safety and radiation protection challenges are addressed with sufficient forward planning and that all the actors involved take them on board, guaranteeing a high level of safety in Europe and worldwide, attracting the talents we need: the ASN teams will be capable of stepping up and tackling all these new challenges. ■

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

For EDF, the year was particularly dense in terms of industrial activity, after a 2020 which was disrupted by the Covid-19 pandemic. ASN nonetheless considers that the quality of operation of the installations remained at a satisfactory level. However, the safety performance of some of the Nuclear Power Plants (NPPs) appears to be falling short continually. Progress was observed with regard to radiation protection, after two years of regression; this should be confirmed in 2022. The end of 2021 was marked by the discovery of cracks on systems connected to the main lines of the primary system of several reactors.

OPERATION

The quality of the monitoring of operating parameters in the control room remained at a satisfactory level in 2021. The improvements observed in 2020 continued, despite an increase in the industrial activity of the NPPs. However, there was a rise in the number of situations in which the reactor was operated outside the planned limits, with their number in 2021 being equivalent to that observed in 2019.

To control the fire risk, EDF must further improve management of equipment temporary storage sites and warehouses, which represent significant calorific potential, along with management of sectorisation in order to contain any outbreak of fire.

The organisation put into place to manage skills, qualifications and training remained on the whole satisfactory in 2021, despite the training difficulties owing to the Covid-19 pandemic.

In 2021, ASN observed good management of accident situation operating procedures. EDF took measures to remedy the errors and ambiguities contained in the operating documents used by the operating crews in these situations.

The ASN inspections focusing on the emergency organisation and resources confirmed that the organisation, preparedness and management principles for emergency situations covered by an On-site Emergency Plan (PUI) have been correctly assimilated. However, EDF needs to continue its efforts regarding response times in the event of an emergency situation.

The analyses conducted by the sites further to significant events are generally relevant and the identification of organisational causes continues to progress. ASN observes that the origin of many events lies in problems with the quality of the documentation placed at the disposal of the teams in charge of reactor operation or maintenance; problems are continuing with the creation and updating processes for this documentation.

THE CONFORMITY OF THE FACILITIES

For several years now, ASN has found that the management of deviations affecting the facilities has improved. More specifically, EDF is placing greater emphasis on remedying any deviations rapidly. The efforts must be continued so that the new process implemented can be a lasting one. However, as in previous years, ASN considers that the compliance of the facilities with the rules applicable to them needs to be significantly improved. EDF must continue the targeted inspection actions it has been gradually deploying over the last few years. More particularly, the specific inspections implemented during the fourth ten-yearly outages are enabling a large number of deviations to be detected. Some of these deviations date back to the construction of the reactors, while others arose when making modifications to the facilities.

At the end of 2021, EDF detected stress corrosion cracking on systems connected to the main lines of the primary system on several reactors. This subject will lead to a large-scale inspection and repair programme.

MAINTENANCE

Generally speaking, the organisation adopted by the NPPs for large-scale maintenance operations was relatively satisfactory in 2021. ASN finds that EDF is giving greater priority to ensuring a calm climate for maintenance and modification work during reactor outages, which contributes to safety.

However, in 2021, ASN still found areas for improvement with regard to reactor maintenance, such as the consideration of various hazards generated by the activities, their correct preparation, and the quality of technical oversight. With regard to the numerous maintenance activities resulting from the continued operation of the reactors and the major overhaul work, 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.

Concerning EDF's monitoring of the subcontracted activities, the improvements observed in 2019 and 2020 were confirmed in 2021, even if weak points remain present on certain sites.

ENVIRONMENTAL PROTECTION

ASN considers that management of discharges from the various NPPs is on the whole handled satisfactorily.

In 2021, ASN's inspections with situational exercises showed that most of the NPPs are capable of ensuring the containment of a large volume of hazardous liquid substances in an accident situation. They also identified corrective measures to be taken. Inspections were also carried out by ASN on the prevention of leaks of sulphur hexafluoride, a gas with a significant greenhouse effect. The action plan defined by EDF to prevent, detect and reactively repair leaks is satisfactory and its implementation should continue.

ASN considers that corrective measures must be taken regarding waste management, notably in terms of signage, compliance with the baseline requirements for operation of outdoor areas and storage in unauthorised areas.

WORKER RADIATION PROTECTION AND OCCUPATIONAL SAFETY

In 2021, ASN found improvements in the handling of the issues related to worker radiation protection in several NPPs, after the deteriorations observed in 2019 and 2020. However, behavioural anomalies persist and the situation remains a subject of concern on certain sites. EDF must continue with the steps taken to improve the way in which radiation protection is handled.

The occupational health and safety situation degraded in the second half of 2021, as the number of accidents and events with potentially serious consequences actually increased. Progress is expected in 2022 to improve the management of situations that are hazardous for the workers, notably with regard to working equipment and lifting gear, explosion and fire hazards and electrical hazards in particular.

CONTINUED OPERATION OF THE REACTORS

The ambitious modifications EDF intends making to the facilities and the operational methods within the framework of the reactor periodic safety reviews are significantly improving the safety of the facilities and will enable 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.

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

The pace of the fourth ten-yearly outages of the 900 MWe reactors has accelerated: in 2021, EDF started four ten-yearly outages, which took place satisfactorily, and began preparatory work for the subsequent ones.

INDIVIDUAL NPP ASSESSMENTS

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

With regard to safety, the NPPs of Saint-Alban and Civaux stood out favourably in 2021. The NPPs of Golfech, Gravelines and, to a lesser extent, Flamanville, under-performed by comparison with the other reactors operated by EDF.

With regard to radiation protection, the NPPs of Civaux, Paluel and Saint-Alban stood out positively. ASN considers that the NPPs of Dampierre-en-Burly, Gravelines and, to a lesser extent, Cruas-Meysse, under-performed.

With regard to environmental protection, the Saint-Laurent-des-Eaux NPP stood out positively. On the other hand, the NPPs of Dampierre-en-Burly and, to a lesser extent, Chinon and Cruas-Meysse, under-performed.

The Flamanville EPR reactor under construction

In 2021, EDF continued with work to complete the installation, to make modifications to certain equipment and to draw up the various documents needed for the future operation of the reactor. The repairs on the main secondary systems welds also continued in good conditions. EDF is devoting considerable resources to these repairs.

EDF has taken the necessary measures to protect the installed equipment up until commissioning. It also continued with the inspections forming part of the equipment quality review, initiated after the detection of anomalies in the main secondary systems welds. The organisation put into place by EDF for performance and monitoring of these activities is satisfactory.

Considerable works and examinations still remain before commissioning of the reactor. This in particular concerns the design and reliability of the primary system valves, repairs to the main secondary system welds, with anomalies on three nozzles of the main primary system and post-weld heat treatment of the nuclear pressure equipment, the performance of the filtration system on a containment internal water tank, and the various anomalies detected on the cores of the Taishan EPR reactors, including the fuel clad ruptures observed in 2021.

Nuclear power plants being decommissioned and waste management facilities

ASN considers that the decommissioning and waste management operations were carried out in safety conditions there were on the whole satisfactory in 2021.

EDF gave priority to risk reduction in its installations that had been definitively shut down. 2021 was notably marked by the removal of all the fuel from Fessenheim reactor 1, which had been shut down in February 2020. The fuel from reactor 2 should for its part be removed before the end of 2023. The other reactors (Brennilis, Superphénix, Gas-Cooled Reactors –GCRs) no longer contain any 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.

2021 was marked by the resumption of most of the decommissioning worksites, which had been partially interrupted in 2020 owing to the Covid-19 pandemic.

The "outside pressure vessel" decommissioning work on the Saint-Laurent A, Bugey 1 and Chinon A3 sites is continuing in satisfactory conditions of safety. For these operations, EDF will have to be vigilant in meeting the deadlines stipulated in the resolution of 3 March 2020[1]. ASN asked EDF to continue with its reactor pressure vessel diagnostic and monitoring programme, in order to monitor the ageing of the civil engineering structures and ensure their long-term integrity. The first results of these investigations should be presented in the decommissioning files to be submitted at the end of 2022. In these files, EDF will also be required to demonstrate that the GCRs are being decommissioned "as rapidly as possible, in economically acceptable conditions".

With regard to worker radiation protection, the "alpha" action plan implemented on the Chooz A installation in 2020 is resulting in a positive trend in the number of contaminations detected. Efforts in this field must however be continued on all the decommissioning worksites, in order to confirm this trend over the course of 2022.

A few worksites requiring the use of remote-operated cutting systems were interrupted owing to equipment unavailability problems. EDF will need to ensure correct maintenance of this equipment to avoid delaying the progress of the decommissioning operations. The decommissioning of the reactor pressure vessels of Superphénix and Chooz A is continuing with the stipulated deadlines, notably with the removal of the first R73 packages containing waste –resulting from cutting up of the Chooz A vessel internals– to Iceda, where the first packages were conditioned and stored at the end of 2021. The Iceda restart completion file, expected in 2022, will provide feedback regarding these initial conditioning operations.

EDF is required to improve the periodic safety review process for definitively shut down installations, in particular regarding the approach for evaluating the conformity of the installations.

ASN notes EDF's involvement in the public inquiry on the Brennilis decommissioning file and, more generally, its efforts regarding transparency and communication.

1. *ASN Chairman's resolution CODEP-CLG-2020-021253 of 3 March 2020, setting binding requirements concerning the preparation fosr decommissioning of reactors Chinon A1 and A2 and the next steps in the decommissioning of reactors Bugey 1, Chinon A3, Saint-Laurent A1 and A2.*

ORANO

ASN considers that the safety level of the facilities operated by Orano remained overall at a satisfactory level in 2021. ASN however notes that malfunctions in the Melox plant are leading to a faster than anticipated saturation of storage capacity for plutonium-bearing materials, requiring urgent action by the industry in 2022. ASN notes progress in the management of complex projects, such as radioactive waste retrieval and conditioning operations. It however considers that Orano must analyse the causes of delays to the priority projects and ensure the adequacy of the resources devoted to these projects.

The facilities operated by Orano are located on the sites of La Hague, Marcoule and Tricastin. They present significant implications for safety but of different types, both chemical and radiological.

The organisation of the Orano group changed on 1 January 2021. Three group subsidiaries were thus created:
- *Orano Chimie-Enrichissement*, operating nuclear facilities for the production of enriched uranium;
- *Orano Recyclage*, operating nuclear facilities for the reuse of materials derived from spent fuel;
- *Orano Démantèlement*, subsidiary specialising in the decommissioning of nuclear facilities, which does not operate any nuclear facility.

This organisational change came on top of other organisational modifications ongoing within the Orano facilities at La Hague ("Convergence" Project) and Tricastin ("Single licensee" Project). ASN considers that maintaining a high level of safety in the facilities in parallel with the implementation of these organisational changes is a major challenge for Orano.

INSTALLATIONS IN OPERATION

Orano's management of the safety of the nuclear installations in operation is on the whole satisfactory.

The measures designed to combat ageing phenomena in the equipment of the installations, some of which were commissioned more than 30 years ago, or its replacement by new equipment, represent a major challenge for their continued safe operation.

These reviews are an opportunity for Orano to propose improvements, notably concerning management of the fire risks and the safe storage of materials and waste.

ASN considers that Orano must demonstrate greater rigorousness in operation and in compliance with the binding requirements and undertakings made further to the reviews of the installations.

LEGACY WASTE RETRIEVAL AND CONDITIONING, DECOMMISSIONING AND WASTE MANAGEMENT

Large quantities of legacy waste at La Hague are not stored in accordance with current safety requirements and present major safety risks. The Retrieval and Conditioning of this Legacy Waste (RCD) determines the progress of decommissioning in the definitively shut down plants.

With regard to the organisation of complex project management, ASN notes progress, such as assimilation of the objectives of immediate dismantling, the creation of the major projects department, the use of project maturity evaluations, or the development of project progress oversight tools. This progress must however be made more widespread and be consolidated for all the decommissioning and RCD projects. ASN observes that the complexity of the RCD operations had led Orano on several occasions to revise the retrieval and processing scenarios and announce significant postponements, sometimes of several decades.

STORAGE CAPACITY

In 2021, problems at the Melox plant led to faster than anticipated saturation of the storage capacity for plutonium-bearing materials at La Hague.

ASN considers that the deterioration of the available margins in the storage facilities at La Hague is all the more worrying as, were these difficulties to persist, it would be impossible to rule out saturation of the spent fuel storage pools far faster than expected.

OUTSIDE CONTRACTORS

ASN considers that the licensee must continue with its efforts to improve the monitoring of outside contractors, by ensuring that in-house technical skills are maintained in order to guarantee the quality of the services provided. Orano must also ensure that appropriate monitoring is maintained on operation of the workshops placed under the responsibility of industrial operators.

PERSONNEL RADIATION PROTECTION

Radiation protection issues are taken seriously by Orano. Particular vigilance is however required with regard to the Melox facility, owing to the increase in the number of preventive and corrective maintenance operations carried out on the facility's equipment, against a backdrop of significant production difficulties. This situation is leading to significant exposure, although within the regulation limits, of a large number of personnel in this facility.

The significant radiation protection events reported for the Orano group sites are primarily linked to the radiological cleanliness of the premises.

RISK MANAGEMENT

With respect to fire, ASN notes significant progress in the work done to reinforce fire detection and protection. However, considerable inadequacies remain in the facilities. Furthermore, the safety analyses presented are sometimes incomplete, or insufficient from the technical standpoint, and ASN has therefore asked that they be extensively revised. The licensee must improve and more regularly update its incident response instructions, so that they are more appropriate and operational, and carry out periodic exercises to test them.

ENVIRONMENTAL PROTECTION

For the year 2021, control of the detrimental effects and impact of the Orano sites on the environment is on the whole satisfactory.

The measures to prevent spillage/leaks and the environmental dispersal of radioactive or hazardous liquid substances, including those liable to result from actions taken to combat a possible incident, must still be improved.

With regard to protection of the ozone layer, ASN took enforcement measures against Orano in 2021, owing to the lack of forward planning in the replacement of certain automatic fire extinguishing installations containing halon.

INDIVIDUAL FACILITY ASSESSMENTS

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

CEA

ASN considers that the safety of the facilities operated by the Alternative Energies and Atomic Energy Commission (CEA) remains on the whole satisfactory. CEA must nonetheless clarify its vision regarding the continued operation of some of the older facilities. It must also reinforce its project management, notably for those projects concerning the decommissioning of definitively shut down facilities, or the retrieval and conditioning of legacy waste. The emergency situation management organisation also needs to be improved.

MANAGEMENT OF NUCLEAR SAFETY AND RADIATION PROTECTION

ASN considers that CEA must remain vigilant in ensuring that all the nuclear safety and radiation protection aspects are correctly taken into account at all levels of the organisation and are led by people who have the necessary resources, skills and authority.

ASN asked CEA to propose a strategic vision for the management of nuclear safety and radiation protection. This roadmap must be based on an analysis of feedback from the numerous organisational changes made in recent years, present an evaluation of the policy to protect CEA's interests, describe its strategy for guaranteeing the availability of rare and critical skills in the light of the safety issues and draw on the observations made by its internal general inspectorate.

ASN considers that the implementation of "major safety commitments", managed at the highest level and enabling the most important nuclear safety and radiation protection issues to be monitored, is on the whole satisfactory. It will be necessary to ensure that the reduction in resources allocated to CEA has no impact on its ability to meet other commitments.

FACILITIES IN OPERATION

Faced with the ageing of the facilities in operation and the uncertainty surrounding the projects to replace some of them, CEA developed a medium/long-term strategy in 2019 concerning the utilisation of its experimental civil nuclear research facilities and its waste and materials management facilities. ASN finds that uncertainties remain regarding the continued operation of some of the older facilities. ASN considers that CEA must precisely clarify the options adopted (abandon or optimise operation, works to be carried out, etc.).

FACILITIES UNDERGOING DECOMMISSIONING

ASN finds that, despite CEA's clear intention to carry out facilities decommissioning and RCD operations, this licensee is experiencing major difficulties in handling all these complex projects at the same time.

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

In 2021, ASN found that certain deadlines were thus pushed back by several decades, even though they concern ordinary decommissioning projects, based on sound operating experience feedback (notably the decommissioning of the research reactors). ASN also notes substantial changes to the priority projects, with numerous postponements, scope reductions or even some projects being abandoned.

RADIOACTIVE WASTE MANAGEMENT

ASN finds that the management of radioactive waste in the CEA facilities is satisfactory, even though the situation differs from one facility to another. Although progress was observed on certain facilities, notably with regard to the updating of procedures and waste inventories, the situation in other facilities is more contrasted.

CEA must remain vigilant with respect to the storage conditions for its waste (operation of collection areas, demarcation and signage), the pertinence of and compliance with waste zoning and tracking of the radioactive waste produced in the facilities.

In 2020, ASN noted that the provisions of the protocol between the National Radioactive Waste Management Agency (Andra) and CEA regarding Andra's monitoring of CEA waste packages liable to be disposed of in *Cigéo* were overly restrictive of Andra's scope of action and therefore failed to fully meet the provisions of ASN resolution 2017-DC-0587. Even though progress was observed in 2021, ASN will remain attentive to this subject in 2022.

THE CONFORMITY OF THE FACILITIES

ASN recognised the efforts made by CEA to improve the conformity of the facilities on the occasion of the periodic safety reviews. This trend must be maintained in the coming years, so that CEA is able to comply with the schedule for implementation of the actions it has identified.

MANAGEMENT OF DEVIATIONS

ASN finds that progress in the management of deviations is required in certain facilities, notably with regard to analysis of causes or of trends concerning repeated deviations of a similar nature.

In 2021, CEA informed ASN of the fall of a "medium activity" waste package into a storage pit of the Cedra facility (BNI 164) as well as the fall of a basket containing sections of fuel rods during placement in a storage pit in the STAR BNI. ASN hopes that CEA will learn the lessons from these handling problems, so that they do not occur in other facilities.

CHANGE MANAGEMENT

ASN considers that the quality of the safety analyses sent to ASN when CEA submits an authorisation application for a noteworthy modification is on the whole satisfactory. ASN also observes that the changes made in the field do effectively correspond to the information provided by CEA in its authorisation applications.

MAINTENANCE AND THE SCHEDULING OF PERIODIC INSPECTIONS AND TESTS

Maintenance work and the scheduling of the periodic inspections and tests, their performance and their monitoring within the CEA facilities are on the whole satisfactory. As these operations are generally subcontracted, CEA must however remain attentive to the level of technical competence. Moreover, ASN still observes disparities between the facilities. In addition, the traceability of the inspections performed must be further improved. CEA must also implement a harmonised materials ageing and obsolescence management strategy for all its facilities. The new methodology developed by CEA to manage the ageing of the Cabri reactor (BNI 24) represents a step forward.

OUTSIDE CONTRACTORS

Although the monitoring of outside contractors has been reinforced in recent years, ASN still notes the need for the CEA to reinforce the monitoring of the entire chain of outside contractors, particularly its contractors' subcontractors. Lastly, there are still disparities in the quality of this monitoring between the various facilities operated by CEA, and harmoni–sation is thus required.

RISK CONTROL AND EMERGENCY MANAGEMENT

ASN considers that CEA must continue its efforts to improve protection against the fire risk. Management of the technical devices (fire doors and dampers, detection systems, etc.), must be improved and fire loads limited, particularly on worksites.

CEA's emergency organisation and resources still need to be significantly improved, in order to make up the delay in meeting the current requirements. The national organisation in particular needs to be reinforced, paying very close attention to the coordination between the national level, the sites and the facilities. ASN noted that the teams in the field, notably the local safety force, are engaged and motivated in the performance of emergency exercises. Coordination between the local safety force and the facilities in the CEA centres however still needs to be improved with regard to the management of permanent resources (retention areas, automatic shut-off devices, etc.), as the priority of the local safety force is to extinguish fires.

ASN also observes significant delays in the construction of the emergency management buildings for the Cadarache and Saclay centres, designed to take account of the lessons learned from the Fukushima Daiichi NPP accident.

PERSONNEL RADIATION PROTECTION

Within the various CEA centres, radiation protection is on the whole dealt with satisfactorily. ASN remains vigilant with regard to the identification of items and activities important for protection, management of measuring instrument ageing and monitoring of outside contractors (handling of deviations, traceability and application of the "As Low As Reasonably Achievable" –ALARA approach).

Most of the significant radiation protection events reported by CEA are linked to failure to wear a passive dosimeter and problems with the radiological cleanliness of the premises. Of these events, only one was rated level 1 on the International Nuclear and Radiological Event Scale (INES) and concerned the failure by an outside contractor to wear personal protection equipment.

In 2022, ASN will ensure that CEA reinforces the worker radiation protection provisions, monitoring of their application, and of the outside contractors in its facilities.

ENVIRONMENTAL PROTECTION

For the year 2021, control of the detrimental effects and impact of the CEA facilities on the environment is on the whole satisfactory. The number of deviations in 2021 is approximately the same as in previous years. ASN considers that CEA must continue to implement measures on a number of subjects relating to environmental protection, management of the ageing of liquid effluent networks and repair of the network of piezometers, all of which will require long-term action.

INDIVIDUAL FACILITY ASSESSMENTS

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

ANDRA

Andra is continuing with the design of the *Cigéo* deep geological disposal project. ASN notes that Andra is firmly committed to public information and consultation. ASN also considers that the operation of the disposal BNIs by Andra, which is the sole licensee of this type of BNI in France, is satisfactory.

ANDRA'S PREPARATION FOR SUBMISSION OF THE *CIGÉO* CREATION AUTHORISATION APPLICATION

ASN notes that Andra has changed its organisation in order to ensure successful completion of the *Cigéo* deep geological disposal project. Owing to the scale of this project, adapting the organisation of the Agency is a very real challenge.

In the same way as the exploratory approaches to monitoring the progress of complex projects at EDF and Orano, ASN entered into discussions with Andra at the end of 2021 in order to gain a clearer understanding of the licensee's baseline requirements for the project, with a view to a subsequent inspection on the *Cigéo* project.

ASN considers that dialogue between ASN, Andra and the Institute for Radiation Protection and Nuclear Safety (IRSN) on the technical subjects identified following examination of the *Cigéo* safety options is fruitful.

In order to prepare for and facilitate the creation authorisation application examination process, ASN also urges Andra to submit all the documents providing additional justifications or presenting optimisations of the facility's concept, as early as possible.

Finally, ASN underlines the efforts made by Andra to conduct consultations around the *Cigéo* project, notably concerning the governance of the project and the pilot industrial phase.

PROGRESS OF THE STUDIES FOR THE LLW-LL WASTE DISPOSAL FACILITIES PROJECT

Discussions between ASN and Andra concerning the project for a low-level, long-lived waste (LLW-LL) disposal facility continued in 2021. ASN considers that this positive trend must be maintained in order to meet the deadlines that will be defined by the fifth National Radioactive Materials and Waste Management Plan (PNGMDR).

OPERATION OF ANDRA'S EXISTING FACILITIES

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

ASN assessments **by activity sector**

THE MEDICAL SECTOR

On the basis of the inspections carried out in 2021 and despite the impact of the Covid-19 pandemic on the working of the health services, ASN considers that the state of radiation protection in the medical sector is comparable to that of the years 2019 and 2020, reflecting the fact that the departments were able to adapt and maintain a good level of radiation protection. No major deficiency was therefore detected in the areas of radiation protection of medical professionals, patients, the public or the environment. However, owing to the impact of the pandemic, delays were observed in the radiation protection technical checks for Fluoroscopy-guided Interventional Practices (PIR), leading to a failure to comply with the regulation frequencies of these checks, designed to ensure the radiation protection of the workers. In addition, coordination of the prevention measures during external interventions, in particular by private practitioners, must be reinforced in the field of nuclear medicine and PIR. Finally, the awareness of the operating theatre personnel, who are non-specialist users of ionising radiation –such as surgeons, must be raised to ensure a clearer perception of the issues and the adoption of radiation protection measures in this sector where, moreover, the premises are being brought into conformity far too slowly. The events reported to ASN underline that the formalisation of practices, the explanation of validations, the management of maintenance services, the notification and analysis of malfunctions, and the evaluation of the impact of degraded situations, are all essential to ensuring that practices are safe.

In radiotherapy, the inspections carried out in 2021 in nearly one-quarter of the radiotherapy departments confirmed that the safety fundamentals are in place: organisation of medical physics, equipment checks, training in patient radiation protection, deployment of quality assurance procedures, collection and analysis of events and production of preliminary risk analyses. However, there is as yet little widespread use of the evaluation of the effectiveness of the corrective measures and the preliminary risk analysis still remain relatively incomplete and insufficiently updated before any organisational or technical change, or following experience feedback from events. The occurrence of events such as laterality or patient identification errors, reveals persistent organisational weaknesses and the need to assess practices regularly. The lessons learned from these events also illustrate the fact that calibration of medical devices is a critical step in health care safety.

In brachytherapy, the radiation protection of professionals and the management of high-level sealed sources are considered on the whole satisfactory. The training effort for professionals in possession of a high-level source must be maintained and reinforced for certain centres. ASN finds that new requirements concerning secure access to high-level sources are being deployed gradually, in particular measures preventing unauthorised access to these sources. The events reported underline the importance of event registration systems in order to identify malfunctions early on, as well as the need to evaluate the risks in a degraded situation (insufficient staffing levels) and to formalise and record equipment quality controls.

In nuclear medicine, the inspections reveal that radiation protection is correctly taken into account in the vast majority of departments. However, improvements are needed in effluent management, in order to control discharges into the sewage networks, in formalising the coordination of prevention measures with outside contractors (for maintenance, upkeep of premises, intervention by private practitioners, etc.) and in training of professionals. ASN observes a significant commitment on the part of the nuclear medicine departments to deploy high-quality management systems and underlines the good culture of undesirable events reporting in most of the departments inspected in 2021. The events reported however underline the fact that the drugs administration process needs to be regularly evaluated, in particular for therapeutic procedures, owing to the potentially serious consequences of any administration error.

In the field of fluoroscopy-guided interventional practices, ASN is still observing delays in premises being brought into conformity in order to comply with the technical design rules, more particularly in operating theatres, and recalls that these modifications are fundamental to preventing occupational hazards. Breaches of the regulations are still frequently observed, with unsatisfactory situations involving the radiation protection training of workers and patients, and preventive measures during concomitant activities, in particular with private practitioners. Non-conformities were found in 2021 in relation to non-compliance with radiation protection technical verification frequencies, as the departments had been unable to perform them in 2020 owing to the Covid-19 pandemic. Even if the deployment of medical physicists and the formalisation of the medical physics organisation plan would appear to be under way, progress is needed in the implementation of the optimisation approach, in particular in the operating theatres, where there is still insufficient analysis of the doses received by the patients.

However, a reporting culture is spreading, with the adoption of event registration systems. The reporting of significant radiation protection events underlines the fact that maintenance operations, which can have repercussions on the doses delivered, must be correctly managed and that practitioner training in the use of medical devices is essential to dose control. Extensive work to raise the awareness of all the medical and paramedical professionals in the centres is still necessary to give them a clearer perception of the issues, especially for operating theatre staff. This is why recommendations to improve radiation protection in the operating theatres, issued in 2020, are still valid.

In computed tomography, during its 2021 inspections, ASN still observes a lack of traceability of justification for the examinations and of the difficulties medical professionals encounter in implementing it. The lack of training of the referring practitioners, and of the use of the guide to good medical imaging practices, and the lack of justification protocols for the most common procedures partly explains the fact that the justification principle is not always applied. Furthermore, the lack of availability of other diagnostic methods (Magnetic Resonance Imaging –MRI, ultrasonography) and of health professionals limit the replacement of irradiating procedures by non-irradiating procedures. Elsewhere, ASN finds that examination protocols are optimised, quality controls of medical devices are performed at the required regulation frequency and the medical physics resources are appropriate to the tasks to be performed.

THE INDUSTRIAL, VETERINARY AND RESEARCH SECTOR

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 considers that the risks are addressed to varying extents depending on the companies, even though worker dosimetric monitoring is generally carried out correctly. If the risk of incidents and the doses received by the workers are on the whole well managed by the licensee when this activity is performed in a bunker in accordance with the applicable regulations, ASN is still concerned by the observed shortcomings in terms of the signage of the operations area during site work. In 2021, in order to raise licensee awareness, ASN drew their attention –in a letter sent out to each company performing industrial radiography– to the deviations most commonly identified during inspections and urged them to exercise greater vigilance in signage of the operations area. ASN also recalls the need for regular maintenance and periodic checks on the correct working of the safety devices built into the bunkers, so that the line of defence they represent in preventing inadvertent exposure remains effective. More generally, ASN considers that the ordering parties should 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. However, two cyclotron licensees informed ASN that their annual radioactive gas discharge limits had been exceeded, although the resulting impact remains very small. With regard to suppliers, ASN considers that the areas in which practices still need to be improved are advance preparations for the expiry of the sources administrative recovery period (which by default is ten years), information for the purchasers regarding future source recovery procedures, and the checks prior to delivery of a source to a customer.

The actions carried out by the licensees in recent years are continuing to improve radiation protection within the **research laboratories**. The conditions for the storage and elimination of waste and effluent remain the primary difficulties encountered by the research units, including with regard to the performance and traceability of checks prior to elimination or the recovery of "legacy" unused sealed radioactive sources. Finally, the licensees must be more attentive, notably in the event of modifications to research projects or experimental procedures, to compliance with certain requirements in their authorisations, notably those regarding the premises in which sources of ionising radiation are allowed to be kept or used.

With regard to the **veterinary uses of ionising radiation**, ASN can see the result of the efforts made by veterinary bodies over the past few years to comply with the regulations, notably in conventional radiology activities on pets.

For practices concerning large animals such as horses, or performed outside veterinary facilities, ASN considers that the implementation of radiological zoning and the radiation protection of persons from outside the veterinary facility who take part in the radiographic procedure, are points requiring particular attention.

With regard to the **protection of sources of radiation against malicious acts**, more particularly when high-level radioactive sources or batches of equivalent sources are used, the inspections conducted by ASN show that the licensees are beginning to implement the measures needed to comply with the requirements set out in the Order of 29 November 2019. Thus, the categorisation of sources, an essential step in identifying the applicable requirements and in implementing an approach proportionate to the risks, has been done by nearly 75% of the facilities concerned. Similarly, the issue of nominative permits for access to sources is progressing, even if it still needs to be implemented in nearly half the industrial facilities and the vast majority of health facilities. ASN therefore considers that significant progress is still needed, in particular because in mid-2022, the requirements regarding the presence of physical systems to prevent unauthorised access to sources will become applicable, offering intrusion resistance compliant with that stipulated by the Order. In 2022, ASN will continue its actions to raise licensee awareness on these subjects.

TRANSPORT OF RADIOACTIVE SUBSTANCES

ASN considers that in 2021, the safety of transport of radioactive substances is on the whole satisfactory. 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 involving the transport of radioactive substances on the public highway (84 events reported to ASN in 2021) is slightly up on 2020, even if the number of events rated level 1 on the INES scale remained stable and the number of events concerning the transport of radiopharmaceutical products fell significantly. The events mainly comprise:

- material non-conformities affecting a package (notably damaged packaging) or its stowage on the conveyance, thereby weakening the strength of the package (whether or not an accident occurs). These cases do not concern transports of spent fuels or highly radioactive waste and primarily concern transports for small-scale nuclear activities;
- exceeding of the limits set by the regulations, usually by a small amount, for the dose rates or unfixed contamination of a package;
- errors or omissions in package labelling, mainly for transports concerning small-scale nuclear activities.

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 "fuel cycle" transports and, more generally, the BNIs, ASN finds that the licensees carry out numerous checks and are therefore better able to detect any deviations. It considers that the consignors must further improve how they demonstrate that the contents actually loaded into the packaging comply with the specifications of the package model approval certificates and the corresponding safety files. This more specifically concerns transports relating to research facilities or the removal of legacy radioactive waste.

More particularly 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 quality management system, actual compliance with the procedures put into place and the content and actual implementation of the worker radiation protection programme.

At a time when the uses of radionuclides in the medical sector are generating a high volume of transport traffic, progress is still needed in 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. ASN considers that the radiation protection of carriers of radiopharmaceutical products, who are significantly more exposed than the average worker, needs to be improved.

Finally, for transport operations involving packages that do not require ASN approval, progress is observed with respect to the previous years, along with better application of the recommendations given in ASN Guide No. 7 (volume 3). The improvements still to be made generally concern the description of the authorised contents by 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.

NOTABLE EVENTS 2021

MANAGEMENT OF RADIOACTIVE MATERIALS AND WASTE

ASN opinion on the draft fifth plan

Planning Act 2006-739 of 28 June 2006 on the sustainable management of radioactive materials and waste stipulated the periodic drafting of a National Radioactive Materials and Waste Management Plan (PNGMDR). This gives a detailed inventory of radioactive materials and waste management systems, whether operational or to be deployed, and then makes recommendations or sets targets to develop these systems.

Disposal of a concrete container in a cell at the Aube repository

For the first time, the drafting of the 5th edition of the PNGMDR was preceded by a public debate, the conclusions of which were published in November 2019. On 21 February 2020, the Ministry in charge of energy and ASN published a joint decision further to this public debate. The management of the plan also changed in the light of the conclusions of this debate. In particular, as the PNGMDR is a governmental policy document, ASN is therefore no longer jointly responsible for production of the work. It nonetheless remains involved and, with the Ministry for Ecological Transition, co-chairs the working group responsible for monitoring implementation of the plan. In 2020 and 2021, ASN also issued seven opinions on the management of radioactive materials and waste as contributions to the drafting of the fifth PNGMDR, covering the period 2021-2025.

The implementation of the orientations included in the 21 February 2020 decision was the subject of "guiding principles" established by the Ministry for Ecological Transition, which were debated at meetings of the pluralistic "Guidance Committee" chaired by an independent qualified personality. **This Committee issued 11 opinions summarising the debates concerning each management route and each subject on which it worked**. These "guiding principles" were also submitted to the public during the consultation following the public debate.

In September 2021, the Ministry for Ecological Transition asked the Environmental Authority for its opinion on the draft fifth PNGMDR. It submitted its opinion 2021-96 on the draft plan on 18 November 2021.

In addition, at the end of September 2021, the Ministry for Ecological Transition asked ASN for its opinion on this same draft plan. In response to this request, ASN's opinion 2021-AV-0390 of 9 November 2021 considers that **the PNGMDR 2021-2025 must, prior to its conclusion, enable the necessary decisions to be taken** so that operational solutions are available within the coming 15 to 20 years for all types of radioactive waste.

ASN considers that the draft PNGMDR 2021-2025 is in line with this approach, but that particular attention must be paid to compliance with the deadlines for each action it contains. It therefore issued a favourable opinion for the draft PNGMDR 2021-2025 with the following provisos:

• **given the malfunctions observed in 2021 in certain facilities vital to the working of the "fuel cycle",** the licensees will have to study worst-case operating scenarios for this "cycle" in terms of quantities of materials and waste produced, and as applicable propose appropriate remedies. They will also have to regularly report on the anticipated time-frames for saturation of the spent fuel storage capacities. In any case, the estimated prospects for saturation of spent fuel storage capacities produced pursuant to the draft plan must not be based on the hypothesis of any long-term densification of the storage pools envisaged by Orano on its La Hague site. This is not a technical solution that meets current safety standards;

• **given the forward planning needed for the actions involved in a decision to cease or continue with reprocessing of spent fuels after 2040**, studies of technical and safety options will have to be carried out by the industry with regard to the impact of such a decision on existing or future Basic Nuclear Installations;

• **with regard to actions concerning the safe management of high-level waste (HLW) and intermediate-level, long-lived (ILW-LL) waste**, the recommendations of the PNGMDR "Guidance Committee", formulated in its opinion of 19 March 2021, must now be incorporated into the PNGMDR 2021-2025. This more particularly entails:

– updating of the waste package delivery records at the very least at each new edition of the plan, with a first deadline for the end of 2023,

– provision of a preliminary version of the *Cigéo* acceptance specifications, no later than the deadline for submission of the creation authorisation application,

– explanation of the toxic, chemical and radiological substances inventories of the waste in the *Cigéo* reserve inventory, along with the conditioning methods adopted or, failing which, the ongoing or envisaged studies,

– by mid-2023, the transmission of a progress report on the studies carried out on the processing of bituminised waste, explaining the health and environmental impacts of each of the processes studied;

• **the work aiming to implement specific management solutions for certain waste, in the light of its properties, must be continued and supported by the PNGMDR 2021-2025**. This in particular concerns waste containing tritium, disused sealed sources, organic oils and liquids and activated waste from small producers. In this respect, ASN recalled the recommendations made in its opinion 2021-AV-0379 of 11 May 2021, aiming to improve the inventory of this waste and knowledge of its characteristics, as well as to identify and deploy appropriate management solutions.

ASN also considers that the ambition of that part of the draft plan requiring the development of recovery plans from the owners of radioactive materials is insufficient with regard to certain materials, such as depleted uranium, or the heavily depleted uranium which could result from the re-enrichment of depleted uranium, spent fuel from reactor EL4 (Brennilis' Nuclear Power Plant) and thorium-bearing substances. **ASN stresses the need to assess the recoverable nature of the radioactive materials**, taking account of the quantities concerned and the time-frames within which industrial solutions for using these materials will be available. In this respect, it recalls the analysis framework it proposed in its opinion 2020-AV-0363 of 8 October 2020, which includes the notion of a time-frame for the envisaged recovery.

In this opinion, ASN also makes a number of recommendations concerning the management of low-level, long-lived waste (LLW-LL) and ILW-LL waste, as well as on how to involve the public.

Following the submission of the above-mentioned opinions from the Environmental Authority and from ASN, the Ministry for Ecological Transition will submit an amended draft of the PNGMDR 2021-2025 for public consultation, along with draft regulatory texts issued pursuant to this plan, on which ASN will also issue an opinion.

NUCLEAR POWER PLANTS BEYOND 40 YEARS

Oversight of the fourth periodic safety reviews of EDF's 900 MWe reactors

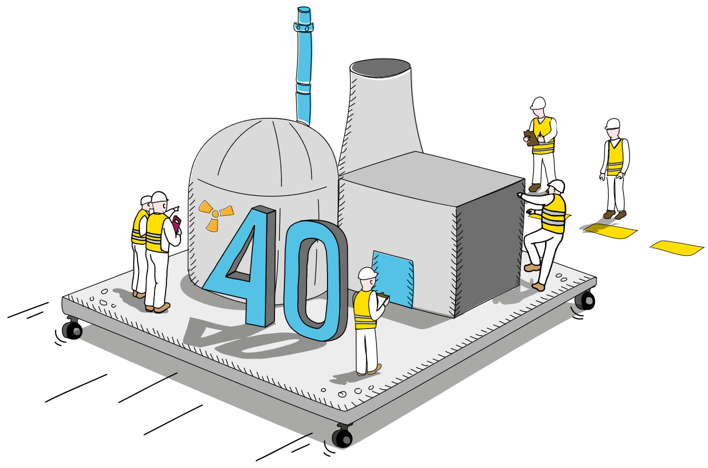

Aerial view of the Bugey Nuclear Power Plant

The fourth periodic safety review of the 900 Megawatts electric (MWe) reactors results in significant safety improvements, the deployment of which is mobilising the entire nuclear sector. ASN considers that so far, the fourth ten-yearly outages have been conducted relatively satisfactorily.

In France, the authorisation to create a nuclear facility is issued by the Government, after consulting ASN. This authorisation is issued without time limit. An in-depth examination, called the "periodic safety review", is performed every 10 years to evaluate the conditions for the continued operation of the installation for the next 10 years.

EDF's 900 MWe reactors are the oldest reactors in operation in France. Their fourth periodic safety review is of particular significance, because their design postulated an operating lifetime of 40 years. Their continued operation beyond this period requires the updating of design studies and equipment replacements.

"The generic phase of the periodic safety review concerns the 900 MWe reactors, the oldest reactors in operation in France."



The generic review phase, common to the 32 reactors of 900 MWe, enabled the safety improvements to be deployed on all the reactors to be determined

ASN considers that these safety improvements will make it possible to bring the level of safety of the 900 MWe reactors close to that of the most recent reactors (third generation), in particular:

• **by improving the way potential hazards** (earthquake, flooding, explosion, fire, etc.) are taken into account. The reactors will also be able to cope with more severe hazards than those hitherto considered;

• **by reducing the risk of accident with core melt** and mitigating any consequences of this type of accident. These provisions will thus lead to a significant reduction in environmental releases during this type of accident;

• **by mitigating the radiological consequences** of the accidents studied in the safety report. This will significantly reduce the occurrence of situations that involve implementing population protection measures (sheltering, evacuation, taking iodine tablets);

• **by improving the provisions for managing accident situations affecting spent fuel pools**.

In its resolution 2021-DC-0706 of 23 February 2021, ASN prescribed the implementation of the major safety improvements planned by EDF, along with additional measures it considers necessary to achieve the objectives of the safety review. ASN underlines the ambitious objectives of the fourth periodic safety review of the 900 MWe reactors and the substantial work carried out by EDF in the generic phase. It also underlines the scale of the modifications planned by EDF, the implementation of which will bring about significant safety improvements.

In 2019, EDF began to deploy these improvements during the fourth ten-yearly outages

The provisions determined during the generic stage of the safety review and those that will be defined in the studies specific to each site, will have to be applied on each reactor with a view to its continued operation. ASN asked EDF to carry out the majority of the safety improvements before submitting the safety review concluding report, and in practice during the ten-yearly outage of each reactor. At the end of 2021, EDF had carried out or initiated seven of these ten-yearly outages.

ASN is conducting reinforced oversight of these ten-yearly outages, with regard to both EDF's verification of the conformity of the installations with the safety rules, and deployment of the safety improvements. ASN considers that **these ten-yearly outages are being conducted relatively satisfactorily**. EDF is devoting considerable human resources to preparing and conducting them.

Considerable industrial capacity to be mobilised

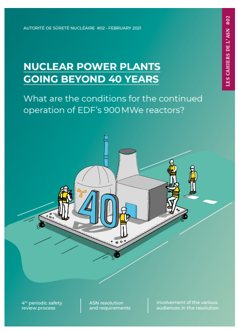
Every year, EDF has to carry out the fourth ten-yearly outages for four to five 900 MWe reactors. This work entails a significant increase in the industrial workload in the sector. ASN asked EDF to report annually on the industrial capacity of both itself and its suppliers to complete the modifications to the facilities on schedule.

The public is involved throughout the review process

The measures set out by EDF during the generic phase of the review underwent public participation from September 2018 to March 2019, under the aegis of the High Committee for Transparency and Information on Nuclear Safety. ASN also consulted the public regarding the objectives of the review in 2016 and the conclusion of the generic phase at the end of 2020.

Finally, the measures set out by EDF in the periodic safety review concluding report for each reactor shall be subject to a public inquiry. That of Tricastin Nuclear Power Plant reactor 1 took place in early 2022.

Read online *Le Cahier de l'ASN #02* on ***french-nuclear-safety.fr***



DECOMMISSIONING

Orano decommissioning and waste management strategy

Monitoring of decommissioning of the former Eurodif plant at Tricastin

The decommissioning of old nuclear facilities is a major challenge for Orano which –over the coming decades– will be required to carry out several large-scale decommissioning projects: the first generation fuel reprocessing plant at La Hague, called UP2-400, with its support facilities (STE2 Effluent Treatment Station and AT1 spent fuels reprocessing Unit, ELAN IIB radioactive sources fabrication unit and HAO "Oxide High Activity" unit), as well as the Tricastin uranium enrichment and conversion units.

The Legacy Waste Retrieval and Conditioning operations (referred to as RCD) are among the first steps in decommissioning. These are 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. RCD projects are characterised by major safety and radiation protection challenges, as well as by considerable industrial complexity. The general decommissioning of these facilities will also create a large quantity of waste, which will need to be safely managed.

Since 2005, ASN has been regularly evaluating Orano's decommissioning and waste management strategy for the La Hague and Tricastin sites. At ASN's request and given the complexity of these subjects, their interdependance and the delays observed in

"Despite progress observed in its decommissioning strategy, ASN asks Orano to improve certain points."

certain priority projects, the licensee updated its strategy in 2016. ASN examined this strategy and, following discussions with the licensee, observed progress in the assimilation of the objectives of immediate dismantling, monitoring the governance of complex projects[1], progress in the operations on several installations at Tricastin, and the definition of final waste conditioning processes for the La Hague site.

However, ASN asks Orano to improve its strategy in the following four areas:

1. The implementation of the decommissioning and waste management strategy must be prioritised according to the risks (existing pollution or high dispersible inventory[2]). The construction of new effluent and waste conditioning, storage, transport and treatment capacity will be needed to enable this strategy to be implemented, given the existing weak points (storage facilities that do not meet current safety standards, uncertainties regarding the medium-term saturation of certain storage facilities, etc.);

2. The implementation of the clean-up strategy must be based on sufficient knowledge of the current state of the facilities, and more particularly the civil engineering structures and soils. If complete clean-out is not possible, an appropriate clean-out strategy taken as far as is reasonably achievable, taking account of the technical and economic feasibility of the measures, shall be deployed;

3. The implementation of the RCD strategy must be better managed and the dispersible inventory must be reduced as early as possible. The characterisation of the waste and qualification of the processes envisaged must be actively pursued in order to define the required processes and demonstrate their feasibility within a time-frame compatible with implementation of the RCD projects. The waste currently stored in temporary facilities and for which there is no operational solution or which requires preliminary treatment, shall be transferred as rapidly as possible to storage facilities compliant with current safety requirements;

4. The oversight of complex projects must be improved by analysing the causes of delays to the priority projects and by examining the adequacy of the resources devoted to these projects.

ASN also underlines the need for the licensee to inform the public of the progress of its programmes.

It is up to Orano to ensure that this strategy is implemented and to report on it regularly to ASN. Given the safety and radiation protection issues encountered, ASN very regularly checks progress, by means of dedicated investigations, inspections, technical meetings and a project oversight approach.

Thanks to this heightened oversight, ASN adapts its methods for these high-stakes projects. Its intention is to transition from a "static" approach –in which the project completion deadline is set out in the regulations, often a long time in the future, and with calendar drift that is detected too belatedly– to a "dynamic" approach, focused on a precise analysis of the actions planned by the licensee over the coming 5 years.

In this new approach, having strengthened its RCD projects programming and oversight methods, the licensee submits detailed schedules to ASN, including milestones for which it makes a binding commitment to ASN. This may consist of safety studies or studies to develop certain aspects of the project, placing of industrial contracts or the completion of actual physical steps in the progress of the project, such as the beginning of construction of new equipment. On the basis of this detailed 5-year programme, ASN will specify key milestones for this period and will check that they are reached. This sliding process will continue until the final waste retrieval and conditioning result is achieved.

1. *Creation of a major projects department, a procedure to evaluate project maturity and develop project progress monitoring tools.*
2. *Corresponds to the quantity of radiological activity that could be involved in an incident or accident.*

Read online *Le Cahier de l'ASN #04* on ***french-nuclear-safety.fr***

REGULATORY NEWS

2021 was a particular year for work in the field of standards, notably owing to several Ministerial Orders and ASN resolutions as a result of the Decrees transposing European Council Directive 2013/59/Euratom of 5 December 2013 setting out Basic Standards for Health Protection against the dangers arising from exposure to ionising radiation.

National news

1.1 Acts and Ordinances

▶ Act 2021-401 of 8 April 2021 improving the effectiveness of local justice and the penal response

The purpose of this text is to encourage the use of alternatives to prosecution and settlement, in order to provide a faster response to violations of lesser importance. It also aims to create more fluid use of sentences involving community service and improve the collection of fixed penalty fines.

Its goals are to reinforce the proximity of the penal response for minor misdemeanours, to bring the justice process closer to the citizens and to speed up the judicial procedures.

In order to reinforce the effectiveness of the penalties pronounced for violations and to facilitate collection of fixed-penalty fines, the text creates a reduction in the amount of the fine for fifth category fixed-penalty fines. Article 9 of the Act thus stipulates that when a violation is category five, or when the regulation so provides, the fixed-penalty fine is reduced if the offender pays the amount of the reduced fixed-penalty fine, either to the officer issuing the fine at the moment the violation is detected, or within fifteen days from detection of the violation or, if notification of the violation is sent subsequently to the party concerned, within fifteen days from this notification. The purpose of this procedure is to encourage voluntary payment of the fine (within 15 days).

▶ Act 2021-1104 of 22 August 2021 combating climate change and reinforcing resilience to the effects thereof

The 22 August 2021 Act comprises legislative provisions adopted by Parliament, contributing to implementation of the proposals of the "Citizens climate Convention", concerning the following question: "*By 2030, how to reduce greenhouse gas emissions by at least 40% in comparison with 1990, while protecting social justice?*"

Article 86 of this Act introduces a provision into the Energy Code (I bis of Article L. 100-4) which, notwithstanding the provisions taken to ensure nuclear security, requires that the State take account of the objectives of security of supply and reduction in greenhouse gas emissions when it decides to cease the operation of a nuclear reactor in order to achieve national energy policy objectives.

The purpose of Title VII of the Act is to "*reinforce the legal protection of the environment*" and it comprises provisions which, within the Environment Code, defines new violations, or aggravates existing violations within this same Code or in the Transport Code. The purpose of these provisions is to reinforce the criminal prosecution of environmental offences and thus contribute more effectively to protection of the environment. These provisions include the following:

Penalty for exposure to risk with the creation of an offence of endangerment of the environment

The Act introduces provisions into the Environment Code (new Article L. 173-3-1) and into the Transport Code (II of Article L. 1252-5) which aggravate the penalties applicable to the circumstances set out respectively in Articles L. 173-1 and L. 173-2 of the Environment Code and Article L. 1252-5 of the Transport Code, when these circumstances directly expose the fauna, flora, or water quality to an immediate, serious and lasting risk. The Act stipulates that lasting refers to damage liable to persist for at least 7 years.

The penalties incurred are three years of imprisonment and a fine of 250,000 euros, which could be raised to three times the benefit gained from the offence committed.

The same penalties are incurred in the event of a further offence, created in X of Article L. 541-46 of the Environment Code, for non-compliance with formal notice served regarding the regulations governing the dumping of waste or its management, when this failure to comply "*directly exposes the fauna, flora, or water quality to an immediate serious and lasting risk*".

Within their sphere of competence, the nuclear safety inspectors are authorised to investigate and record these new violations.

Penalty for damage and creation of an offence of ecocide
A general offence of pollution of the environment and an offence of ecocide for the more serious cases (new Articles L. 231-1 to L. 231-3 of the Environment Code) are created.

Article L. 231-1 punishes the fact –in clear and deliberate violation of a particular obligation of prudence or safety set out by law or the regulations– of emitting into the air or releasing into the water a substance leading to serious and lasting harmful effects on health, flora, fauna, or serious modifications to the normal water supply system. The scope of this Article excludes emissions into the air complying with the limit values set out in a decision by the competent administrative authority, authorised discharge operations and the use of authorised substances when the binding requirements set by the competent administrative authority are adhered to. It defines lasting effects as those liable to persist for at least 7 years. The offences set out in the new Article L. 231-1 are punishable by a penalty of 5 years of imprisonment and a fine of one million euros, which could be raised to five times the benefit gained from the offence committed.

The new Article L. 231-3 of the Environment Code states that intentionally committing an offence as defined in Article L. 231-1 and intentionally committing offences set out in Article L. 231-2, when they lead to serious and lasting harm to health, flora, fauna, or air, soil or water quality, are considered to be crimes of ecocide. This crime of ecocide is punishable by 10 years of imprisonment and a fine of 4.5 million euros, an amount which can raised to ten times the benefit gained from the violation. Article L. 231-3 specifies that lasting effects are those harmful effects on health, flora, fauna or the quality of soils or surface or groundwater, which are liable to persist for at least 7 years.

Pursuant to the new Article L. 231-5, the nuclear safety inspectors, within their sphere of competence, are authorised to investigate and record the offences thus created.

The Act creates a new technical investigation system (Articles L. 501-1 to L. 501-19 of the Environment Code) which can apply to any accident occurring in the installations, mines, networks and products and equipment listed in Article L. 501-1, at the initiative of the head of the industrial risks investigation and analysis office or at the request of the Minister in charge of the environment.

II of this Article L. 501-1 states that, by way of derogation, ASN's special policing installations and activities are exclusively subject to the technical inquiries set out in Articles L. 592-35 to L. 592-40 of the Environment Code.

▶ Act 2021-1109 of 24 August 2021 consolidating compliance with the principles of the Republic

Article 12 of the Act of 24 August 2021 consolidating compliance with the principles of the Republic inserts an Article 10-1 into Act 2020-321 of 12 April 2000 on the rights of the citizens in their relations with the administrations, stipulating that any association or foundation applying for a public subsidy must sign a contract of commitment to the values of the Republic. The obligations arising from this contract are to respect the principles of liberty, equality, fraternity and the dignity of the human person, as well as the symbols of the Republic as defined in Article 2 of the Constitution, that is the national emblem, the national anthem and the motto of the Republic; not to call into question the secular nature of the Republic and, finally, to abstain from any action prejudicing public order. As a result of work in Parliament, this latter obligation concerns actions liable to lead to serious threats to public peace and security.

In the event of any breach of this contract of commitment, the public subsidy shall be revoked, following an adversarial procedure, with a fully substantiated decision by the authority or organisation, and with the association being given a period of six months in which to return the funds paid to it.

1.2 Decrees and Orders

▶ Decree 2021-286 of 16 March 2021 designating the regional centres specialising in environmental prejudice pursuant to Articles 706-2-3 of the Code of Criminal Procedure and L. 211-20 of the Judicial Organisation Code and adapting the Code of Criminal Procedure to the creation of specialised environmental assistants

The Decree determines the seat and the jurisdiction of the judicial tribunals with competence to investigate the most complex environmental offences, as well as actions regarding ecological prejudice founded on Articles 1246 to 1252 of the Civil Code, civil liability suits stipulated by the Environment Code and civil liability suits founded on the special environmental liability conditions resulting from the European regulations, international Conventions and Acts passed to implement these conventions.

The Decree also adapts the provisions regarding the specialised environmental assistants in the regional and interregional centres, pursuant to Articles 706-2 and 706-2-3 of the Code of Criminal Procedure, in their drafting derived from Articles 15 and 20 of Act 2020-1672 of 24 December 2020 relative to the European Prosecutor's Office, environmental justice and specialised criminal justice.

▶ Decree 2021-759 of 14 June 2021 creating an interministerial Delegate to assist the regions with their energy transition

The Decree creates an interministerial Delegate to assist the regions with their energy transition. It specifies the missions within the scope of his or her competence, updates the missions of the Delegate for the future of the Fessenheim region and the regions in which coal-fired power plants are located and supplements them for the other regions undergoing energy transition. It repeals Decree 2019-67 of 1 February 2019 creating an interministerial Delegate for the future of the region of Fessenheim and the regions in which coal-fired power plants are located.

▶ Decree 2021-837 of 29 June 2021 constituting various reforms regarding environmental assessments and public participation in the environmental field

The Decree is an implementing Decree of Act 2018-148 of 2 March 2018 which ratifies the following two Ordinances:
- Ordinance 2016-1058 of 3 August 2016 relative to modification of the rules applicable to the environmental assessment of projects, plans and programmes: the end-purpose of this ordinance is to bring french law into conformity with European law regarding environmental assessments;
- Ordinance 2016-1060 of 3 August 2016 reforming the procedures designed to ensure public information and participation in the drafting of certain decisions liable to have an effect on the environment: this ordinance reinforced the consultation phase upstream of any decisions with an effect on the environment.

Article 7 of the Decree modifies the annex of Article R.122-2 of the Environment Code, by creating three new categories of Installations Classified for Protection of the Environment (ICPEs) subject to a systematic environmental assessment:
- integrated ironworks and steel mills;
- facilities for the disposal of hazardous waste –as defined in Article 3, point 2, of European Parliament and Council Directive 2008/98/EC of 19 November 2008 relative to waste– by incineration, chemical treatment, as defined in Annex I, D 9, of said Directive, or landfill dumping;
- the facilities intended for the extraction of asbestos and the treatment and transformation of asbestos and products containing it.

Article 9 of the Decree creates an Annex to Article R. 122-3-1 of the Environment Code, which lists the criteria used to decide whether a project subject to a case by case examination must undergo an environmental assessment; these criteria are those set out in Annex III to Directive 2011/92/EU of 13 December 2011 concerning the assessment of the impacts of certain public and private projects on the environment, as modified by Directive 2014/52/EU of 16 April 2014, incorporated in full.

Article 10 of the Decree modifies Article R. 593-5 of the Environment Code, to specify that the impact assessment must take account of the opinion issued by the authority with competence to take the authorisation decision, when it has been solicited by the project owner, on the basis of Article R. 122-4 of the same Code. The project owner must take account of the available results of other pertinent assessments of the effects on the environment, required pursuant to other applicable legislations.

Article 26 of the Decree modifies Article R. 123-46-1 of the Environment Code, to specify the content of the file for the projects which are to undergo an environmental assessment and which, although not requiring a public inquiry, are subject to online public consultation on the basis of Article L. 123-19 of the same Code. It is now specified that the file subject to public participation on the basis of Article L. 123-19 must contain the same items as those mentioned in Article R. 123-8 of the Environment Code. Article R. 123-8 of the Environment Code specifies the items to be contained in a public inquiry file; this notably comprises the updated impact assessment, the opinion from the environmental authority and the licensee's response, other mandatory opinions, the licensee's response, an indication of the texts governing the consultation and of how this consultation fits into the administrative procedure, the decision(s) which could be adopted further to the consultation and the authorities with competence to take the authorisation decision, as well as any indication that the project is subject to a transboundary assessment.

It is also now specified that the references to the public inquiry in this Article R. 123-8 of the Environment Code are replaced, for application of Article R. 123-46-1 of the same Code, by those relative to online public participation and that the request for consultation on a paper version of the file, as applicable, set out in point II of Article L. 123-19 of the Environment Code, is made in the conditions stipulated in Article D. 123-46-2 of the same Code.

▶ Decree 2021-903 of 7 July 2021 supplementing Section 9 of Chapter III of Title IX of Book V of the Environment Code

Article L.593-19 of the Environment Code states that the provisions for remedying the anomalies found or for improving the protection of the interests mentioned in Article L. 593-1 of the same Code, proposed by the licensee during the reviews beyond the 35th year of operation of a Nuclear Power Plant (NPP) reactor, are the subject of a public inquiry. The Decree clarifies the NPP reactor review process beyond their 35th year of operation and specifies the scope and organisational arrangements for the public inquiry and consultations planned as part of these reviews. The Decree thus specifies the methods for implementing the legislative measures by supplementing Section 9 of Chapter III of Title IX of Book V of this Code (regulatory part):
- on the one hand, to make its implementation legally secure;
- on the other, to promote effective public participation, by enabling it to assess those safety improvements already made and those planned by the licensee for continued operation of its facility.

Article R. 593-62-1 of the Environment Code makes it possible for the licensee of several NPP reactors of similar design to carry out a part of their periodic safety reviews that is common to all of them, even if they are located on different sites. This possibility is in fact already used for the French NPP reactors owing to the standardisation of the fleet operated by EDF (the generic phase of the periodic safety review is conducted per plant series). The benefit of the provision is to manage this possibility and enshrine it in the regulations. The text specifies that in this case and for the periodic safety review of each reactor, the licensee incorporates the conclusions of this common part in the review report, together with any follow-up measures decided on by ASN. Prior to each review, the licensee checks that the conclusions of this common part remain valid with regard to changing knowledge and operating experience feedback.

Article R. 593-62-1 of the Environment Code stipulates that this possibility can only be used for NPP reactors (its application to Basic Nuclear Installations –BNIs– other than NPP reactors would not appear to be appropriate owing to their diversity) and for each periodic safety review (not only as of the fourth review).

The Decree creates a specific sub-section (1 bis) within Section 9 of Chapter III of Title IX of Book V of the Environment Code, comprising Articles R. 593-62-2 to R. 593-62-9, applicable to periodic safety reviews of NPP reactors beyond their 35th year of operation.

These Articles set the organisational arrangements for the public inquiry and the consultations planned as part of these reviews.

Even if the legislative provisions do not so require, the decision has been made to apply the common law regulatory provisions relating to the procedure and the performance of the "environment" public inquiry (Section 2 of Chapter III of Title II of Book I of the regulatory part of the Environment Code), with the necessary adaptations (Articles R. 593-62-2 to R. 593-62-8).

It is first of all stipulated that the public inquiry covers the provisions proposed by the licensee and what the Prefect transmits to the Chair of the administrative tribunal when he or she asks them to appoint an inquiry commissioner or a board of inquiry (Article R. 593-63-3).

This provision removes all ambiguity regarding the scope of the public inquiry and the procedure applicable to it. According to the actual terms of the law, the public inquiry covers "*the provisions proposed by the licensee*".

Article R. 593-62-4 sets the composition of the file submitted to the public inquiry (which therefore is not that of Article R. 123-8 of the Environment Code).

▶ Decree 2021-1000 of 30 July 2021 containing various provisions implementing the public action acceleration and simplification and environmental simplification Act

The Decree implements the provisions of Title III of the public action acceleration and simplification and environmental simplification Act. It:

- modifies the table in Article R. 121-2 of the Environment Code listing the categories of operations involved in development and equipment projects referred to the National Commission for Public Debate (CNDP);
- modifies the provisions concerning the case of ICPEs located within the perimeter of a BNI but not necessary for this BNI, for which ASN has competence (authorisation, registration, time-frame);
- adds that, in the same way as the manufacturers, the representatives are now subject to certain pressure equipment obligations.

This concerns the State services, professionals, private individuals, project owners, associations, design offices.

It entered into force on 1 August 2021, but does contain interim provisions.

Pursuant to these provisions, Article R. 121-2 of the Environment Code contains a table listing the categories of operations concerning development or equipment projects which are automatically referred to the CNDP and those concerning development or equipment projects made public and for which this referral is optional.

Articles 2 to 6 of the Decree modify numerous procedural provisions, notably regarding the licensing and registration of ICPEs located within the perimeter of a BNI but not necessary for this BNI and for which ASN has competence.

In the same way as the manufacturers, the representatives are now subject to certain pressure equipment obligations. With regard to the obligations of the economic operators, the term "representative" is added to that of "manufacturer". It is now the manufacturers or, as applicable, their representatives, who give their name, their corporate name or their trade mark and the postal address at which they can be contacted, on the product or equipment or, when this is not possible, on its packaging or in a document accompanying the product or equipment (Article R. 557-2-5 of the Environment Code).

▶ Decree 2021-1096 of 19 August 2021 modifying various provisions concerning polluted soils and the cessation of activity by ICPEs

Article 57 of Act 2020-1525 accelerating and simplifying public action modified Articles L. 512-6-1, L. 512-7-6 and L. 512-12-1 of the Environment Code, by creating an obligation for the licensees –as part of the cessation of activity procedure for an ICPE– to have a company that is certified in the field of polluted sites or soils, or with equivalent competence in the provision of services in this field, confirm the implementation of operations to make the site safe plus, as applicable, the adequacy of the measures proposed for rehabilitation of the site and then implementation of said measures.

The Decree of 19 August 2021 defines the means of application of this Article 57 and revises the cessation of activity procedure accordingly. It also modifies certain provisions regarding the soil hazard information sectors. Finally, it specifies the means of applying the transfer from a third-party applicant to another third-party applicant, created by this same Article 57.

As with all regulations regarding ICPEs, these provisions apply to ICPEs within the perimeter of a BNI but not necessary for it, with ASN exercising the powers regarding individual resolutions and oversight vested in the Prefect.

Article 2 of this Decree modifies Article L.125-43 of the Environment Code. In the new Article R. 125-43, the BNIs no longer appear explicitly in the exclusions "*of the soil hazard information sectors defined in Article L. 125-6*". However, the new formulation "*the land on which nuclear activities mentioned in Article L. 1333-1 of the Public Health Code are carried out*" includes nuclear activities carried out in BNIs and "nuclear" ICPEs.

The Decree of 19 August 2021 enters into force on 1 June 2022, with the exception of Articles 2, 3, 4, 21 and 27, which enter into force the day following its publication.

▶ Decree 2021-1802 of 23 December 2021 concerning the civil service secularity coordinator

Act 2021-1109 of 24 August 2021 confirming compliance with the principles of the Republic created a secularity coordinator within the State's administrations, regional authorities and public health establishments, who is more particularly responsible for providing all necessary advice regarding the principle of secularity for any civil servant or department head wishing to consult him or her. This coordinator is also responsible for organising a secularity day on 9 December of each year.

The Decree determines the duties, the methods and the criteria for appointing this secularity coordinator.

Article 1 of the Decree states that the secularity coordinators are appointed at a level enabling them to effectively carry out their duties. These authorities designated by the Decree may make provision for a secularity coordinator common to several departments or establishments. In this case, the secularity coordinators are then appointed by the competent head of department at the level determined, for a duration set by this latter. Article 5 of the Decree stipulates that the secularity coordinator advises the heads of department and civil servants with regard to implementing the principle of secularity, notably by analysing and responding to queries from these latter regarding individual situations or more general questions, raises civil servants' awareness of the principle of secularity and disseminates information regarding this principle within the administration concerned, at his or her level and, as applicable, in coordination with other secularity coordinator, and organises the secularity day on 9 December of each year.

At the request of the authority which determined the level at which the secularity coordinator is appointed, this latter may be called on in the event of difficulty in application of the principle of secularity between a civil servant and users of the public service. The same authorities may specify the means whereby these duties are carried out.

▶ Decree 2021-1947 of 31 December 2021 implementing Article 10-1 of Act 2000-321 of 12 April 2000 and approving the contract of Republican commitment by associations and foundations receiving public subsidies or State approval

The Decree determines the content of the contract of Republican commitment by associations and foundations receiving public subsidies or State approval. It determines how this commitment is made and specifies the conditions surrounding any revocation of public subsidies.

Its Article 5 specifies that the association or foundation ensures that the contract of Republican commitment is adhered to by its managers, its staff, its members and its volunteers. This same Article indicates that any violations committed by its managers, staff, members or volunteers acting in this capacity are attributable to the association or foundation, along with any violation committed by them and directly linked to the activities of the association or foundation, if its management –although informed of these actions– failed to take the necessary to ensure their cessation, taking account of the means at their disposal. A violation of the undertakings made under the contract of republican commitment is such as to justify revocation of a subsidy, in cash or in kind.

▶ **Order of 30 June 2021 creating a protected zone**

In accordance with the provisions of Article 413-7 of the Penal Code, a protected zone is created at the ASN headquarters, located 15-21, rue Louis-Lejeune in Montrouge (92120). The result of the creation of such a protected zone is to prohibit entry into the ASN premises without authorisation, under penalty of prosecution (Articles 413-7 and 413-8 of the Penal Code).

1.2.1 Radiation protection

TEXTS ISSUED PURSUANT TO THE PUBLIC HEALTH CODE

General provisions for all nuclear activities

▶ **Order of 27 January 2021 setting a list of categories of nuclear activities considered to be justified**

The Order, issued pursuant to Article R. 1333-9 of the Public Health Code, sets the list of categories of nuclear activities which are considered justified as stated in 1° of Article L. 1333-2 of the Public Health Code. Thus, notwithstanding the general provisions, when a nuclear activity falls within a category on this list, the party responsible for the nuclear activity, if it can establish that this activity meets the criteria for inclusion in this category, is not required to provide further evidence of justification.

Radon

▶ **Order of 30 June 2021 relative to specific workplaces which could expose workers to radon**

The text defines specific workplaces, other than buildings, where the radon risk assessment for workers occasionally or regularly present in these premises cannot be primarily based on zones with a radon potential originating in the soil. Moreover, it sets certain procedures to be adopted by the employers in their radon risk assessment.

TEXTS ISSUED PURSUANT TO THE LABOUR CODE

▶ **Decree 2021-1091 of 18 August 2021 relative to the protection of workers against the hazards of ionising and non-ionising radiation**

The Decree modifies the Labour Code, notably by extending the duration of the transitional period for the implementation of the new radiation protection organisation and the certification and accreditation of the necessary organisations. It also specifies the provisions applicable to workers subject to lasting exposure as a result of a major nuclear accident. It also make a number of modifications to the provisions applicable to radon: modification of the scope of the Order concerning the specific premises mentioned in Article R. 4451-4 of the Labour Code, to enable the provisions of the Labour Code to be adapted in these premises, obligation of training of workers exposed solely to radon, elimination of the possibility of resorting to an ASN-approved organisation to measure radon for the initial verification of "radon zones" as of 1 January 2022.

List of categories of nuclear activities considered to be justified by the Order of 27 January 2021

SOURCES OF IONISING RADIATION	PURPOSE	TYPES OF SOURCES OR TECHNIQUES CONCERNED
Electrical devices emitting X-rays[(1)]	• Computed tomography scanners for diagnostic purposes • Fluoroscopy-guided interventional practices	Computed tomography devices, including: • computed tomography devices coupled with single photon emission computed tomography devices • computed tomography devices coupled with positron emission tomography devices
	• Fluoroscopy-guided interventional practices	Fixed or mobile devices
	• Conventional imaging or examinations for diagnostic purposes	Fixed or mobile devices, including mammography devices and quantitative computed tomography bone density scanners
	• Conventional imaging or examinations for screening purposes	2D digital mammography devices
	• Dental imaging for diagnostic purposes	Fixed or mobile intra-oral radiography, dental panoramic radiography, with or without cone beam computed tomography

(1) Electrical device designed to emit X-rays or inadvertently emitting them. In the case of an electrical device designed to emit X-rays, it comprises at least a high-voltage generator, an X-ray emitting device and a control system or any other equivalent device.

▶ **Order of 12 November 2021 modifying the Order of 18 December 2019 relative to the procedures for training the Radiation Protection Expert-Officer (RPE-O) and the certification of training organisations and Radiation Protection Organisations (OCR) and the Order of 23 October 2020 regarding measurements taken for the assessment of risks and checks on the effectiveness of the prevention means put into place for the protection of workers against the hazards of ionising radiation**

The procedures for entry into force of these two Orders are brought into conformity with the provisions of the above-mentioned Decree. The Order of 18 December 2019, issued pursuant to Article R. 4451-126 of the Labour Code, defines the conditions for performance of the duties of the Radiation Protection Adviser (RPA). The Order of 23 October 2020, issued pursuant to Article R. 4451-51 of the Labour Code, specifies the methods for taking measurements for risk assessments. It reorganises the procedures and the conditions for performance of technical inspections, henceforth called "verifications", by making them proportional to the scope of the implications for worker radiation protection. Calling on an accredited organisation is only required at commissioning of the installation and the working equipment, as well as after any major modification of them liable to affect the health and safety of the workers. Finally, the employer may use the company's own resources for the periodic verifications, notably by or under the supervision of its Radiation Protection Adviser.

The radiation protection competence centres

▶ **Order of 28 June 2021 concerning the radiation protection competence centres**

The Order is issued pursuant to Article R. 4451-126 of the Labour Code. For the BNIs, it allows the implementation of the new Radiation Protection Organisation introduced by Decree 2018-437 of 4 June 2018, which contributes to the transposition of Council Directive 2013/59/Euratom of 5 December 2013 setting the Basics Standards for Health Protection against the hazards resulting from exposure to ionising radiation.

The competence centres are the RPAs for the employer and the licensee of a BNI.

The Order defines the roles and the organisational requirements of the radiation protection competence centres mentioned in Article R. 4451-113 of the Labour Code and Article R. 593-112 of the Environment Code, and the procedures and conditions for approval of these centres. It in particular states that the employer and the licensee of a BNI must submit their request for approval of the ASN competence centres before 2 January 2022. Pending their approval, the employer and the licensee must set up provisional competence centres.

1.2.2 Basic Nuclear Installations

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

The work to revise this Order continued in 2021.

1.3 ASN resolutions

▶ **ASN resolution 2021-DC-0707 of 2 March 2021 concerning the procedures for remote hearing by the Commission of persons from outside ASN**

This resolution organises the procedures for remote hearings by the ASN Commission. The ASN Chairman may decide that persons from outside ASN will be given a hearing by the Commission by telephone or audiovisual means, or by any process allowing the electronic exchange of written documents, in the conditions set out by Ordinance 2014-1329 of 6 November 2014 regarding the remote deliberations of collegial administrative bodies and Decree 2014-1627 of 26 December 2014 concerning the procedures for the organisation of remote deliberations by collegial administrative bodies.

▶ **Resolution of 19 October 2021 adopting the internal regulations of the ASN administrative enforcement Committee**

The internal regulations of the ASN administrative enforcement Committee were adopted by the members of the Committee on 19 October, during the session instituting the latter. It comprises provisions regarding the working of the Committee, how it investigates requests for issue of a fine referred to it, summons procedures, the running of sessions, deliberations, as well as a reminder of the references of the texts governing incompatibilities and the professional ethics obligations of its members.

The internal regulations of the ASN administrative enforcement Committee were published in the *Official Journal* on 5 November 2021 and in the ASN *Official Bulletin* on 8 November 2021.

1.3.1 Radiation protection

▶ **ASN resolution 2020-DC-0694 of 8 October 2020 concerning the qualifications of physicians or dental surgeons who perform procedures using ionising radiation for medical or research purposes involving humans, the qualifications required in order to be appointed a coordinating physician of a nuclear activity for medical purposes or request a license or registration as a natural person**

ASN updated the qualifications required for physicians or dental surgeons using ionising radiation for medical or research purposes involving humans, in order to adapt the regulatory provisions to changing techniques and performance conditions.

This resolution repeals the previous one dating from 2011 (ASN resolution 2011-DC-0238) and clarifies the definition of the qualifications:
1. of the physician or dental surgeon performing procedures using ionising radiation for medical or research purposes involving humans;
2. of the physician coordinating the steps taken to ensure radiation protection of the patients (Article 1333-131 of the Public Health Code);
3. of the natural person responsible for a nuclear activity for medical purposes, in other words a physician who reports a nuclear activity to ASN or a physician who requests ASN authorisation for radiotherapy, nuclear medicine or computed tomography.

It entered into force on 7 July 2021, after publication of its approval order of 5 July 2021 in the *Official Journal*.

▶ ASN resolution 2021-DC-0703 of 4 February 2021 establishing the list of nuclear activities using sources of ionising radiation for industrial, veterinary or research purposes (other than research involving humans) subject to the registration system, and the binding requirements applicable to these activities

A third administrative system, registration, was introduced into the Public Health Code by Decree 2018-434 of 4 June 2018; it corresponds to a simplified authorisation and applies to nuclear activities not needing specific individual requirements. Resolution 2021-DC-0703 implementing Articles L. 1333-8 and R. 1333-113 (*et seq.*) of the Public Health Code, notably specifies:
- the list of nuclear activity categories now subject to the registration system and previously requiring authorisation (appendix 1);
- the practicalities for submitting an initial application, a modification application or registration renewal application, and the list of information and documents to be provided for a registration application (appendix 2);
- the general requirements specific to the different nuclear activity categories (appendix 3) which are binding on the nuclear activity manager and any breach of which can be punished;
- the interim provisions applicable to authorised activities switching from the authorisation system to the registration system. In the absence of any modification to the authorised nuclear activity, the authorisations issued before the date this resolution enters into force Act as the registration up until their expiry date (an initial registration application shall be submitted no later than six months before the authorisation expiry date).

It entered into force on 1 July 2021, after publication of its approval order of 15 June 2021 in the *Official Journal*.

▶ ASN resolution 2021-DC-0704 of 4 February 2021 establishing the list of medical activities using medical devices emitting ionising radiation subject to the registration system and the requirements relative to these activities

Transposition into French law of Directive 2013/59/Euratom (known as the “BSS” Directive) led to modification of the Public Health Code. This was notably done through publication of Decree 2018-434 of 4 June 2018 introducing various provisions concerning nuclear activities. This resolution modifies and repeals ASN resolution 2018-DC-0649 of 18 October 2018 implementing 2° of Article R. 1333-109 and Article R. 1333-110 of the Public Health Code, setting the list of nuclear activities subject to the notification system and the information to be mentioned in these notifications.

This results in a significant change concerning fluoroscopy-guided interventional practices. Article 12 of the resolution concerning the interim provisions applicable to fluoroscopy-guided interventional practices requires that “*for fluoroscopy-guided interventional practices which have been notified to ASN, a description of the types of procedures carried out, according to the list given in Article 1, along with the references of the notification concerned, shall be transmitted within twelve months following entry into force of this resolution*”.

To enable this information to be transmitted to ASN, a notification form was created.

The facilities are asked to notify their activities *via* an online form available on the Framaforms website.

The registration is only valid if it complies with the specific general requirements concerning the medical devices emitting X-rays used (maintenance, loan for test purposes, organisation of patient radiation protection for fluoroscopy-guided interventional practices). The provisions to be implemented are formally set out in the quality management system put into place pursuant to ASN resolution 2019-DC-660 of 15 January 2019.

It entered into force on 1 July 2021, after publication of its approval order of 15 June 2021 in the *Official Journal*.

▶ ASN resolution 2021-DC-0708 of 6 April 2021 setting quality assurance obligations for procedures using ionising radiation for therapeutic care purposes

Following the transposition of Directive 2013/59/Euratom[1], ASN entirely revised the regulatory arrangements regarding the quality assurance obligations for medical procedures utilising ionising radiation.

ASN resolution 2021-DC-0708 applies to the four therapeutic fields using ionising radiation, preparatory and monitoring computed tomography examinations and research involving humans:
- external radiotherapy, including contact therapy and pre-operative radiotherapy;
- brachytherapy;
- therapeutic nuclear medicine (Targeted Internal Radiotherapy);
- radiosurgery.

The resolution repeals resolution 2008-DC-0103 of 1 July 2008 and expands the scope of procedures using ionising radiation for therapeutic purposes subject to the quality assurance obligation.

The requirements are harmonised with the medical imaging sector (resolution 2019-DC-0660).

This resolution prescribes new applicable quality assurance requirements:
- extension of quality assurance obligations to therapeutic nuclear medicine (art. 1).

The following points must be formalised:
- the procedures for training of professionals in radiation protection of patients and the use of a new medical device or a new technique (art. 7);
- the tasks to be performed by an internal procedure for qualification on the workstation by new arrivals, for all professions or when changing positions or medical devices (art. 7);
- project management for any change affecting the quality and safety of patient care (medical devices, information systems, premises, treatment practices, etc.) by means of a procedure (art. 8);
- the respective responsibilities of the ordering party and the service provider if the activity is out-sourced (subcontracted tasks, medical devices or operations concerned, technical measures taken), for example in the form of a contract (art. 3);
- the responsibilities, authorities and delegations of professionals, including in the event of intervention by external service providers (art. 5).

The quality management system shall make provision for the performance of the audits defined.

It entered into force three months after publication of its approval order of 17 May 2021 in the *Official Journal*.

1. Ordinance 2016-128 of 10 February 2016 for the legislative part and Decree 2018-434 of 4 June 2018 for the regulatory part.

1.3.2 Pressure Equipment

▶ **ASN resolution 2021-DC-0702 of 26 January 2021 modifying resolution 2020-DC-0688 of 24 March 2020, concerning the qualification of organisations tasked with the inspection of Nuclear Pressure Equipment**

This resolution corrects an error in the 2020 resolution; the conformity evaluation which takes place when installing a Nuclear Pressure Equipment (NPE) or nuclear assembly (mentioned in 4.1 a) in Annex V of the Order of 10 December 2015 having been omitted from the scope of qualification. The modifying resolution corrects this error.

It entered into force on 27 February 2021, after publication of its approval order of 16 February 2021 in the *Official Journal*.

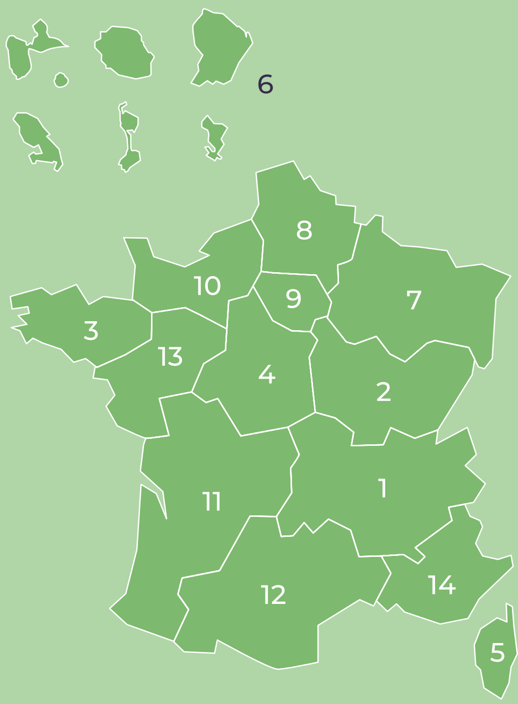
1.4 The professional guidelines approved by ASN

▶ **ASN resolution 2021-033633 of 12 July 2021 by the ASN Chairman accepting professional guidelines regarding the installation of in-service leak plugging systems on Nuclear Pressure Equipment**

This is a resolution accepting the EDF professional guidelines reference D450712014967 index 5 regarding the installation of in-service leak plugging systems on NPE. Article 10-4 of the Order of 30 December 2015 regarding NPE and some of its protection accessories enables the licensee to fit a leak plugging system to the NPE during operation, in accordance with the procedures of professional guidelines submitted to ASN for acceptance. The specified resolution approves the guidelines proposed by EDF.

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 2021, the ASN regional divisions totalled 226 employees, of whom 169 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 operations and of small-scale nuclear activities; they examine the majority of the licensing applications submitted to ASN by the persons/entities responsible for nuclear activities within their regions. The regional divisions check application within these installations of the regulations relative to nuclear safety and radiation protection, to pressure equipment 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*(*), who is responsible for protection of the population. To ensure emergency situation preparedness, they help draw up the emergency plans established by the Prefects and take part in the periodic exercises.

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

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

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

IMPORTANT

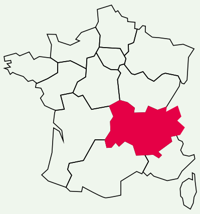
Oversight of small-scale nuclear activities (medical, research and industry, transport) is presented in chapters 7, 8, and 9.

MEDICAL FIELD > **07**

RESEARCH AND INDUSTRY > **08**

TRANSPORT > **09**

(*) *Administrative region headed by a Prefect.*



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 2021, ASN carried out 328 inspections in the Auvergne-Rhône-Alpes region, comprising 117 in the Bugey, Saint-Alban, Cruas-Meysse and Tricastin Nuclear Power Plants (NPPs), 92 in plants and installations undergoing decommissioning, 104 in small-scale nuclear activities and 15 in the radioactive substance transport sector.

ASN also carried out 40 days of labour inspections in the four NPPs and on the Creys-Malville site.

In 2021, ASN was notified of 26 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 5 in small-scale nuclear activities. One significant radiation protection event that occurred on the Cruas-Meysse site was rated level 2 on the INES scale.

BUGEY SITE

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

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

Lastly, the site accommodates one of the regional bases of the special 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.

Bugey nuclear power plant

Reactors 2, 3, 4 and 5 in operation

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

ASN considers that the nuclear safety performance of the NPP is in line with ASN's general assessment of EDF plant performance, but remains contrasted. The weaknesses observed in 2020 concerning the implementation of practices to increase the rigour of system configuring persisted in 2021. Furthermore, shortcomings have been found in the local application of the test rules applicable as of the fourth ten-yearly reactor outages, in emergency situation management and in the control of fire-related risks. On the other hand, ASN conducted a series of unannounced control room inspections which revealed improvements in monitoring and compliance with the operating technical specifications.

With regard to maintenance, in a particularly busy industrial context with the fourth ten-yearly outage of reactor 4 continuing until June 2021 and that of reactor 5 beginning in July 2021, ASN noted weaknesses in the planning and preparation of the maintenance activities. In addition, concerning the integration of modifications, difficulties relative to the updating of the set of reference documents and integration of the operating experience feedback from reactor 2 were observed in the fourth ten-yearly outages conducted in 2021. The management of conformity deviations, however, has improved. ASN therefore expects an improvement in the management of outages in 2022, which represent a smaller activity workload than in 2021.

With regard to radiation protection, ASN considers that the Bugey NPP's performance is in line with the general assessment of the EDF plants. As far as the conditions of operations in controlled areas are concerned, despite some improvements, recurrent fragilities are observed in the radiological cleanliness of the facilities, in the containment of worksites with contamination dispersal risks, and the provision of radiation protection equipment. Furthermore, ASN expects to see improvements in the prevention of contamination of the site road systems.

ASN considers that the environmental protection performance of the NPP is in line with its general assessment of the EDF plants. The overall standard of waste management remains satisfactory. Some deviations observed in 2020 concerning control of the conformity of the ultimate retention systems, which contribute to environmental protection, were again noted in 2021, but EDF has now put in place a special organisation for addressing the deviations affecting these equipment items.

Concerning labour inspection, ASN considers that the site's accident results are satisfactory, despite the very intense programme of activities in 2021. Improvements are nevertheless expected in the licensee's control of risks associated with work at height and chemicals.

Reactor 1 undergoing decommissioning

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

In March 2016, in view of the technical difficulties encountered, EDF announced a complete change of decommissioning strategy for its definitively shut down reactors. In this new strategy, the planned decommissioning scenario for all the reactor pressure vessels involves decommissioning "in air" rather than "under water" as initially envisaged. Through ASN Chairman's resolution CODEP-CLG-2020-021253 of 3 March 2020, further to the change in EDF's decommissioning strategy, ASN requires EDF to complete the decommissioning operations on the building and equipment that are not necessary for decommissioning of the reactor pressure vessel by 2024 at the latest.

In 2020, ASN authorised the creation of a new effluents storage facility at the Bugey 1 reactor to replace the old station, which will be put out of service, decommissioned and cleaned out.

ASN considers that the Bugey 1 reactor decommissioning and vessel characterisation operations are proceeding with a satisfactory level of safety. The licensee ensures rigorous monitoring of the equipment and the ongoing decommissioning works. After analysing the periodic safety review concluding report for the GCRs, ASN stated in December 2021 that it had no objection to continuing the decommissioning of this reactor.

Activated waste packaging and interim storage installation

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

- low-level, long-lived (LLW-LL) graphite waste 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;

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 Operational Hot Unit (BCOT) at Tricastin operated by EDF;**
- **The High Flux Reactor (RHF) operated by the Laue-Langevin Institute in Grenoble;**
- **the Activated waste packaging and storage facility (Iceda) on the Bugey nuclear site and the Bugey Inter-Regional Warehouse (MIR) for fuel storage, operated by EDF;**
- **reactor 1 undergoing decommissioning at the Bugey NPP operated by EDF;**
- **the Superphénix reactor undergoing decommissioning at Creys-Malville and its auxiliary installations, operated by EDF;**
- **the Ionisos irradiator in Dagneux;**
- **the Effluents and Solid waste Treatment and decay storage Station (STED) of the CEA in Grenoble, which is waiting to be delicensed following decommissioning;**
- **the CERN international research centre located on the Swiss-French border;**
- **small-scale nuclear activities in the medical sector:** p. 202
  - 22 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 23 nuclear medicine departments,
  - 121 facilities using fluoroscopy-guided interventional procedures,
  - 154 scanners within 115 facilities,
  - some 10,000 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - 1 synchrotron,
  - about 700 veterinary practices (surgeries or clinics),
  - 35 industrial radiology agencies,
  - about 600 users of industrial equipment,
  - about 70 public or private research units;
- **activities associated with the transport of radioactive substances;** p. 260
- **ASN-approved laboratories and organisations:**
  - 3 organisations and 7 agencies approved for radiation protection controls.

- **some low-level or intermediate-level, short-lived waste (LL/ILW-SL), called "deferred transfer" waste, intended for above-ground disposal but requiring a period of radioactive decay ranging from several years to several decades before being accepted at the Aube repository (CSA –BNI 149), operated by the French national agency for radioactive waste management (Andra).**

On 28 July 2020, ASN authorised the commissioning of Iceda and regulated operation of the facility through requirements relative to the operating range, the maximum storage durations for radioactive waste, the defining of criteria for activating the On-site Emergency Plan (PUI), the content of the end-of-startup file, compliance with waste package qualification heights, and the conditions of reception of source rods from Chooz A. The first activated waste package was received in late September 2020. By letter of 5 May 2021, EDF submitted to the Minister responsible for nuclear safety a request to amend the Iceda's Creation Authorisation Decree (DAC), to allow the acceptance of decommissioning waste from the Fessenheim NPP.

The inspections conducted in 2021 in this facility reveal that the periodic inspections and tests and the monitoring of the service providers performing them must be 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.

MIR presented a satisfactory overall level of safety in 2021, a year in which its activities remained restricted to allow the renovation of various items of equipment. ASN noted an increase in the operational monitoring of the activities.

Saint-Alban nuclear power plant

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

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

With regard to nuclear safety, ASN notes that the Saint-Alban NPP maintained its good performance in 2021, which is at a higher level than ASN's general assessment of the EDF plants. The site has made progress in the lockout/tagout and system configuring operations in particular. There are still areas for improvement in the monitoring of the work plans issued to workers. With regard to the integrity of the fuel assembly cladding, which constitutes the first barrier, ASN notes that accelerated corrosion of some assemblies has been identified on the two reactors and has been subject to special monitoring.

Packaging of ILW-LL in C1PG^{SP} packages in Iceda

Intermediate-level, long-lived waste (ILW-LL) is activated operational waste from the nuclear reactors and activated waste from the dismantling of certain NPPs. This waste is intended for deep geological disposal in application of Article L. 542-1-2 of the Environment Code.

The radioactive waste produced during BNI operation and decommissioning phases must be managed safely right through to their transfer to an appropriate disposal facility. Each of these steps must therefore be compatible with the subsequent steps, especially the disposal. Article 6.7 of the Order of 7 February 2012 setting the general rules for BNIs thus stipulates that the packaging of waste intended for radioactive waste disposal facilities currently being studied and provided for in Articles 3 and 4 of the Act of 28 June 2006 and not having acceptance specifications is subject to the approval of ASN.

On 23 November 2018 EDF submitted an application file for approval of the packaging of ILW-LL waste in a package model baptised "C1PG^{SP}". After being sorted, characterised, cut up if necessary, and placed in a basket, the ILW-LL waste is blocked with a "blocking" cementitious slurry, filling the voids in the basket between the pieces of waste and ensuring the mechanical resistance of the block of waste. Once the blocking slurry has set, the baskets are washed and dried, then immobilised in a concrete shell using an "immobilising" slurry. Once the immobilising slurry has set, the packages are capped with concrete of the same formulation as the shell. The package then undergoes inspections and radiological measurements and is transferred to an Iceda storage hall.

On completion of the examination of this file, ASN considered that the process envisaged by EDF would allow the production of waste packages that will be able to be stored and then disposed of safely. ASN therefore authorised EDF to package its waste in the C1PG^{SP} package through resolution CODEP-DRC-2021-013808 of 19 July 2021. It nevertheless noted that complementary studies were still in progress and decided, in its authorisation, to limit the thermal power released by each package and within each storage hall and to limit the validity of its packaging agreement to 31 December 2023. The extension of this agreement is conditional upon submittal of the abovementioned additional studies no later than 31 December 2022 and the agreement of ASN following their examination.

On 6 September 2021, EDF started production of the first packages of decommissioning waste from Chooz A and operational waste from Fessenheim. The first C1PG^{SP} package was thus produced in October 2021 in Iceda and has been stored there.

With regard to maintenance, the site's two reactors were shut down in 2021 for scheduled maintenance and partial refuelling. ASN considers that EDF competently carried out the planned activities and complied with the corresponding safety requirements.

With regard to worker radiation protection, ASN considers that the operational results were satisfactory. The availability of radiation protection equipment and monitoring of the entry areas of contamination-prone work sites have continued to improve. ASN has observed the improvement in the estimated dosimetry evaluations, particularly of the operational management service teams. Nevertheless, ASN is still waiting to see an improvement in the display of, and compliance with, work site access rules and strengthening of the radiation protection culture in work site preparation.

ASN considers that the environmental protection performance of the Saint-Alban NPP is in line with its general assessment of the EDF plants. Although the simulated liquid pollution event organised on the site by ASN as part of a national inspection campaign confirmed that each responder had a sound knowledge of the applicable procedures, it nevertheless showed that the preparation and speed of the responses planned for such situations could be improved.

With regard to labour inspection, ASN considers the site's results to be relatively satisfactory. Although the site suffered no serious or critical risk-related accidents, accident levels, particularly during reactor outages, remain higher than on other comparable NPPs.

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 nuclear safety performance of the Cruas-Meysse NPP is in line with ASN's general assessment of EDF plant performance. The environmental and radiation protection performance levels of this NPP, however, are slightly below average.

With regard to nuclear safety, ASN notes a satisfactory position of the independent safety organisation and an improvement in operating rigour. ASN moreover considers that the performance in fire risk management is improving.

With regard to maintenance of the facilities, ASN considers that the monitoring of outside contractors, application of the maintenance baseline requirements and the physical conformity of the facilities with respect to the applicable requirements must be improved. This is because several ASN inspections and significant events reported reveal anomalies further to maintenance operations. The site has also had difficulties in demonstrating to ASN at the end of the outage that these anomalies had been duly resolved.

With regard to radiation protection, ASN observes that shortcomings persist in the radiological cleanliness of the facilities and control of the contamination risk during reactor outage periods. In 2021, one site employee received a skin dose exceeding the authorised annual limit, entailing the reporting of a significant radiation protection event rated level 2 on the INES scale.

With regard to environmental protection, ASN considers that the performance of the Cruas-Meysse NPP must also be improved, particularly concerning effluent containment and the actions taken in pollution situations.

With regard to labour inspection, the site's results are on the whole satisfactory. ASN's inspections have confirmed that the site has met its commitments regarding the electrical conformity of the facilities and the measures taken to guarantee conformity of the ventilation of premises subject to specific pollution. The vigilance and the efforts must nevertheless be maintained with regard to electrical risks and the risks associated with the use of machinery during handling operations.

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 NPP comprising four 900 MWe reactors, nuclear fuel cycle facilities, and lastly the Tricastin Operational Hot Unit (BCOT), which fulfilled maintenance and storage functions.

Tricastin nuclear power plant

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

ASN considers that the overall performance of the Tricastin NPP with regard to nuclear safety, radiation protection and environmental protection in 2021 is in line with ASN's general assessment of EDF plant performance.

ASN considers that the nuclear safety performance of the NPP, which has been improving since 2019, is in line with the general assessment of the EDF plants. From the maintenance aspect, the four reactors of the Tricastin NPP were shut down in 2021 for scheduled maintenance and partial refuelling, reactor 2 having undergone its fourth ten-yearly outage, which represents tightened maintenance. ASN considers that these outages are managed with rigour, particularly in the planning and preparation of the maintenance activities. The modifications planned to reinforce safety during the fourth ten-yearly outage of reactor 2 were integrated satisfactorily. Control of the integrity of the first barrier, that is to say the fuel assembly claddings, is also improving. The attentiveness of the independent safety organisation, assessed in 2021, is deemed satisfactory and the quality of the significant events analysis remains good. Weaknesses are nevertheless still observed in some areas, such as the monitoring of control room activities and system configuring.

With regard to radiation protection, ASN considers that the NPP's performance is in line with the general assessment of the EDF plants and has improved with respect to 2020, continuing the momentum that began in 2019. The dosimetry received by the personnel of EDF and outside contractors alike seems under control, and significant progress has been made in establishing the forecast dosimetric evaluations of the outages. As stated in 2020 however, the radiological cleanliness of the premises during reactor outages could be improved.

ASN considers that the environmental protection performance of the NPP is down compared with 2020 and slightly below its general assessment of the EDF plants in this area. The liquid pollution containment exercise organised by ASN showed that the preparation and the speed of the responses planned for these situations needed to be reinforced. The pollution of groundwater at the end of the year by effluents containing tritium and the reactive inspection by ASN demonstrated the need to improve the management of effluent transfers and interim storage. ASN expects to see improvements in this area in 2022.

With regard to labour inspection, ASN considers the site's results show a distinct improvement. Accident prevention, particularly during reactor outages, has been well managed, with a drop in the number of accidents not necessitating lost-time. ASN nevertheless notes that one serious accident occurred this year during the intervention of a diver.

THE "NUCLEAR FUEL CYCLE" FACILITIES

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

The site comprises:
- **the TU5 facility** (BNI 155) for converting uranyl nitrate $UO_2(NO_3)_2$ resulting from the reprocessing of spent fuels into triuranium octoxide (U_3O_8);
- **the W plant** (ICPE within the perimeter of BNI 155) for converting depleted 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 uranium hexafluoride (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 and 179) for storing uranium in the form of oxides or UF_6;
- **the maintenance, liquid effluent treatment and waste packaging facilities** (IARU –BNI 138);
- **the Atlas process samples analysis and environmental monitoring laboratory** (BNI 176);
- **a Defence Basic Nuclear Installation** (DBNI), which more specifically accommodates former facilities undergoing decommissioning, radioactive substance storage yards and a liquid effluent treatment unit.

Following the inspections it conducted in 2021, ASN considers that the level of safety of the Orano facilities on the Tricastin site is improving. The year 2021 was marked by the change of licensee planned for through the PEARL project, with Orano Cycle –the single licensee of the platform– becoming *Orano Chimie-Enrichissement* on 1 January 2021. The Philippe Coste plant has reached more stable operating conditions. ASN has updated its requirements and monitored continuation of the starting of this plant's support functions. Trident, the new waste treatment unit of BNI 138 also gradually started operating in 2021. Construction of "FLEUR", the new reprocessed uranium storage facility, began at the same time as the examination of its license. Lastly, ASN continued examination of the creation authorisation application for the future containers maintenance unit (AMC2). It will take over from the existing unit (AMC), which is to stop operating in 2024. This authorisation application was the subject of a public inquiry from 10 December 2021 to 12 January 2022.

In 2021, ASN conducted a campaign of simultaneous unannounced inspections in BNIs 93, 105, 138, 155, 168 and 178 focusing on the periodic inspections and tests and maintenance, with the aim of checking Orano's organisation in these areas. The inspectors were thus able to attend more than ten periodic inspections and tests or maintenance operations and visit the spare parts stores. The overall assessment of these inspections is satisfactory.

Orano has submitted to ASN its strategy for changing the industrial scheme for managing all the site's liquid effluents. ASN has set up regular monitoring of implementation of this strategy, which is necessary to plan ahead for the technical developments. To check the progress of treating the backlog of diverse radioactive substances stored on the site, ASN has also asked Orano to present an annual statement on the progress of its action plan for the treatment of these substances.

In 2022, ASN will also ensure that Orano improves its organisation for analysing the conformity of the facilities with the regulations and further improves its follow-up of the commitments made to ASN.

Orano uranium chemistry plants TU5 and W

BNI 155, called TU5, can handle up to 2,000 tonnes of uranium per year, which enables all the uranyl nitrate ($UO_2(NO_3)_2$) from the Orano plant in La Hague to be processed for conversion into U_3O_8 (a stable solid compound that can guarantee storage of the uranium under safer conditions than in liquid or gaseous form). Once converted, the reprocessed uranium is placed in storage on the Tricastin site. The W plant situated within the perimeter of BNI 155 can process the depleted UF_6 from the Georges Besse II plant, to stabilise it as U_3O_8.

ASN considers that the safety of operation of the facilities situated within the perimeter of BNI 155 is satisfactory, but it notes an increase in significant events related to occupational radiation protection.

For the TU5 plant, ASN made public its analysis of the facility's periodic safety review report in 2021. It is continuing to check implementation of the commitments made in this context.

ASN will be attentive to the licensee's actions in 2022 on the theme of the safety and radiation protection culture and will remain vigilant with regard to maintaining sufficient rigour in the operation and maintenance actions and in the monitoring of detected deviations.

Orano uranium fluorination plants

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

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

In 2021, ASN also inspected the continuation of the upgrading of the Philippe Coste plant, whose facilities are classified Seveso high threshold and replace those of BNI 105 (formerly Comurhex). The main units of this plant were commissioned in 2019, but in 2020 the licensee had to replace all the crystallising containers and solve various technological difficulties. This upgrading of the process core restored more stable and therefore safer functioning in 2021, producing fewer minor atmospheric discharges associated with operating transients. The new fluorine production unit has also been commissioned. ASN will be attentive in 2022 to the maintaining of operating conditions, particularly those of the old conversion effluent treatment units. This is because the new effluent treatment unit of the Philippe Coste plant has to be modified in depth and will not be available for several years.

Furthermore, as regards the shut down facilities, ASN considers that the package repackaging projects have not made sufficient progress and expects the licensee to make greater efforts to ensure the repackaging of the packages containing radioactive and hazardous substances on areas 61 and 79 within the assigned times.

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 by the gaseous diffusion process.

After stopping production at this plant in May 2012, the licensee carried out, from 2013 to 2016, the Eurodif "Prisme" process of "intensive rinsing followed by venting", which consisted in performing repeated rinsing of the gaseous diffusion circuits with chlorine trifluoride (ClF_3), a toxic and dangerous substance. These operations, which are now completed, allowed the extraction of virtually all the residual uranium deposited in the diffusion barriers.

The licensee submitted its application for final shutdown and decommissioning of the facility in March 2015. The Decree ordering Orano to proceed with the decommissioning of the Georges Besse 1 plant was published on 5 February 2020.

The decommissioning issues particularly concern the large volume of very low-level waste (VLLW) produced, including 160,000 tonnes of metal waste which are undergoing specific studies (see "Orano's decommissioning and waste management strategy", in "Notable events" in the introduction to this report). In 2021, ASN carried out a tightened inspection of the action plan resulting from the periodic safety review file. ASN considers that the actions are carried out correctly but tracking of the action plan updates should be reinforced. 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 facility. These yards should ultimately be attached to the Tricastin uranium storage yards (BNI 178).

Georges Besse II enrichment plant

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

The standard of safety of the plant's facilities in 2021 was satisfactory. The technologies utilised in the facility enable high standards of safety, radiation protection and environmental protection to be reached. ASN considers that the licensee is duly following its commitments to ASN.

The outdoor gantries for handling the UF_6 cylinders have been out of service since October 2020 due to damage to their running tracks. The licensee moves the cylinders using handling equipment and is still looking into the repairability of the gantries. In 2021, ASN also inspected the actions taken by the licensee to reduce discharges of refrigerant into the atmosphere. Compliance with the examined requirements proved satisfactory and the licensee is continuing its efforts to control discharges of this type.

ASN issued an authorisation in 2021 allowing the mode of operation of certain enrichment cascades to be changed. ASN will check that these modifications are carried out safely.

Maintenance, effluent treatment and waste packaging facilities

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

ASN considers that the efforts made by the licensee in 2021 to improve the level of operational safety and the rigour of operation of BNI 138 must be continued. In 2021, ASN checked compliance with the numerous fire-related commitments made to ASN in 2020. Improvements were observed but actions still have to be accomplished. ASN moreover conducted a tightened inspection of the action plan and the studies associated with the periodic safety review, as well as an inspection dedicated to the surface treatment activities, which led to numerous upgrading requests.

Decree 2019-113 of 19 February 2019 authorised substantial modification of the BNI, in particular to create "Trident", a unit for processing the site waste, some of whose modules started in 2021 following on from the first modules the previous year.

The technical examination of the updating of the discharge resolutions for the entire BNI 138 was carried out in 2021, with a public consultation from 15 November to 6 December 2021, and the regulatory procedure should be concluded in 2022.

ASN will be attentive in 2022 to the continuation of the measures taken by the licensee to reinforce operating rigour. ASN will also examine the integration of the conclusions of the periodic safety review, including prevention of the fire risk and upgrading of the surface treatment activities.

Tricastin uranium-bearing material storage yards and P35

Following the delicensing of part of the Pierrelatte DBNI by decision of the Prime Minister, the Tricastin uranium-bearing materials storage yards (BNI 178) have been created. This facility groups the uranium storage yards and the new emergency management premises of the Tricastin platform. Following on from this delicensing process, facility P35 (BNI 179) was created. It groups together ten uranium storage buildings. A complementary storage project called "FLEUR" is in progress; the creation authorisation application was the subject of a public inquiry from 2 November to 3 December 2020 and its examination continued in 2021.

The overall level of safety of BNIs 178 and 179 operated by Orano was satisfactory in 2021. The standard of upkeep and cleanliness of the facilities has remained good. More generally, the licensee must always take care to meet the deadlines for the commitments made to ASN. ASN inspected the construction of the future additional storage buildings associated with the FLEUR project and found no deviations. With regard to the emergency management building and its equipment, the licensee has continued the efforts aiming to guarantee operation of the emergency centre and the various mobile emergency equipment items. Technical difficulties were nevertheless encountered in 2021, with some population alert sirens out of service.

Tricastin analysis laboratory

Authorised by Decree 2015-1210 of 30 September 2015 and commissioned in May 2017, Atlas, the Tricastin analysis laboratory, constitutes BNI 176. The facility represents a significant improvement in safety compared with the old laboratories it replaces.

Whereas difficulties were encountered until 2020 on one of the UF_6 analysis and sampling benches, all three are now functioning correctly.

More generally, ASN's inspections in 2021 found improvements in the area of fire prevention and criticality. The commitments the licensee made to ASN are being met and are well tracked, and the management of deviations has also been improved.

Tricastin Operational Hot Unit (BCOT)

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

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

The last operating activity consisted in finishing cutting up the used fuel cluster guide tubes from the PWRs operated by EDF. The facility is now being prepared for decommissioning, for which the review procedure is in progress. ASN considers that the level of safety of the BCOT is satisfactory.

ROMANS-SUR ISÈRE SITE

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

Framatome nuclear fuel fabrication plants

The fabrication of fuel for electricity generating reactors involves the transformation of UF_6 into uranium oxide powder. The pellets fabricated from this powder in Framatome's Romans-sur-Isère plant, called "FBFC" (formerly BNI 98), are placed in zirconium metal clads to constitute the fuel rods, then brought together to form the assemblies for use in the NPP reactors. In the case of experimental reactors, the fuels used are more varied, with some of them using, for example, highly-enriched uranium in metal form. These fuels are also fabricated in the Romans-sur-Isère plant, called "Cerca" (formerly BNI 63).

The former BNI 63 includes building F2, which houses the "uranium zone" where compacted powder cores placed in aluminium frames and plates are produced. The licensee has undertaken to replace this uranium zone by a new uranium zone called "NZU", in order to improve more specifically the containment of the premises, the process and the prevention of risks in the event of an extreme earthquake. The NZU construction work began in late 2017. These new buildings shall accommodate the current activities of the uranium zone of building F2 before 31 December 2022. This is because as from that date, which is stipulated in ASN resolution 2019-DC-0670 of 4 June 2019 relative to the periodic safety review of former BNI 63, the presence of radioactive substances in the uranium zone of building F2 shall be prohibited. Construction of the NZU continued in 2021, notably with the manufacture and installation of new equipment and performance of the first operating tests. The update of the safety report and the new general operating rules associated with the NZU were submitted to ASN in the first half of 2021, leading to complementary information requests on its part.

A request for a modification of the Order of 22 June 2000 governing water intakes, discharges and environmental monitoring of the Romans-sur-Isère nuclear site was also submitted to ASN in July 2020. This request follows on from several changes, including in particular the modification of the DAC of former BNI 98 to increase its production capacity, the stopping of certain activities, the taking into account of the changes made to the liquid effluent treatment facilities, and the changeover from continuous discharging of liquid effluents to discharging into tanks. This file will give rise to the publication of two ASN resolutions: the first stipulating the requirements relative to the conditions of effluent discharge, water intakes and consumption and environmental monitoring, the second stipulating the environmental discharge limits. The draft resolutions were made available for public consultation from 14 July to 29 August 2021.

By a resolution of 20 December 2021, ASN authorised the "Training, Research, Isotopes, General Atomics" (TRIGA) unit, intended for the production of fuels for american-designed research reactors, to be put back into operation.

A substantial modification request submitted for former BNI 98 in December 2020 aims to allow increased production of fuels based on enriched reprocessed uranium. It is currently being examined.

Given that the buildings of former BNIs 98 and 63 are very closely interlinked on the same site, a request to unite the two BNIs was submitted in 2020. On 23 December 2021, the two BNIs were merged by Decree 2021-1782 into a single BNI 63-U, called "Nuclear fuel fabrication plant".

Six significant events relating to control of the criticality risk and rated level 1 on the INES scale by Framatome were reported in 2021. These events are not inter-related and concern both BNIs. ASN performed a reactive inspection for two of these events and remains vigilant regarding the implementation of effective measures to prevent such events from recurring.

The inspections performed in 2021 confirmed the integrity of the facilities during the summer works and compliance with commitments, particularly concerning the control of maintenance. However, the inspection concerning the checking of laboratory L1's approval for taking environmental radioactivity measurements highlighted shortcomings for which the licensee established a major action plan. These improvements were verified in the last quarter of 2021 with satisfactory conclusions through an unannounced inspection.

ASN will be attentive to the progress of the NZU construction site in 2022, and to maintaining operating rigour and deploying a good questioning attitude, a guarantee of operational safety, in a context of major movements within the safety and radiation protection teams and continuation of the modifications to the facilities. Furthermore, the waste management rules must continue to be applied and brought to people's attention in the various facilities of the site.

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. Employing some 500 persons, this BNI occupies a surface area of 12 hectares situated between the rivers Isère and Drac, just upstream of their confluence, near the CEA Grenoble centre.

ASN considers that safety management of the RHF in 2021 is satisfactory. The ILL confirmed the improvements noted since 2019 regarding compliance with the requirements concerning protection of people and the environment.

In 2021, the ILL continued progressing with the action plan established for its third periodic safety review and enriched by the commitments made further to the examination of its conclusions. The year-end saw the beginning of the first works of a major outage forecast to last 14 months. They concern in particular the replacement of technological equipment constituting the reactor pressure vessel, reinforcement of the reactor building external air intake and the installation of anchors for the future renovation work on the main polar crane.

ASN consulted the public in 2021 on a draft resolution governing the continued operation of this facility further to its periodic safety review. It will be particularly attentive in 2022 to the deployment of the ILL's action plan resulting from the safety review, especially regarding the management of fire-related and handling-related risks. The continuation of preparation of the residual radioactive inventory pre-clean-up operations in the former detritiation facility shall also be verified.

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, prostheses) and polymerising plastic materials.

The level of safety of the facility was found to be satisfactory in 2021.

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

An authorisation for recovery of the sludge from pool D1 (operated until November 1996) was issued by ASN in the third quarter of 2021.

CERN accelerators and research centre

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

Two joint visits by the Swiss and French nuclear Authorities took place in 2021 on the theme of emergency situation preparedness and putting back into service the beam line called "n-TOF" –Neutron Time of Flight– after its modernisation. These visits found the practices to be satisfactory.

SITES UNDERGOING DECOMMISSIONING

Superphénix reactor and fuel storage facility

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

EDF has submitted the periodic safety review concluding reports for BNI 141 and BNI 91. ASN made public its conclusions concerning the Superphénix periodic safety review on 28 July 2021 and has approved continuation of the decommissioning operations. It made a draft resolution governing continued operation of APEC available for public consultation from 23 September to 8 October 2021.

ASN considers that the safety of Superphénix decommissioning operations and of APEC operation is on the whole satisfactory. In 2018, ASN authorised commencement of the second Superphénix decommissioning phase, which consists in opening the reactor pressure vessel to dismantle its internal components, in dedicated facilities constructed in the reactor building, by direct or remote manipulation. The site has fallen behind schedule with the "core cover plug" cutting operations, due to technical difficulties with the cutting robot. The safety and radiation protection measures implemented by EDF for these operations are on the whole satisfactory.

In 2020, ASN carried out a reactive inspection further to a fire outbreak that led EDF to activate its PUI. Shortcomings had been discovered at various levels in the course of the procedures. An unannounced night-time fire exercise carried out by ASN in September 2021 revealed the persistence of certain malfunctions in the licensee's organisation.

Concerning the management of facility obsolescence, EDF reported difficulties in procuring certain items of equipment and significant delays in the replacement and repair of parts. ASN has asked the licensee to carry out a site-level diagnosis and to draw up an action plan on this subject. An inspection carried out in the first quarter of 2021 revealed that the plan had effectively been initiated but there were delays in its application.

ASN will be particularly attentive in 2022 to the improvement of the site's emergency organisation and to the management of deviations, judged unsatisfactory in the course of several inspections.

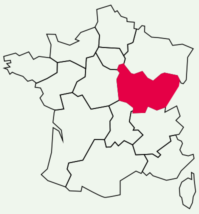
Siloette, Siloé, LAMA reactors and effluents and solid waste treatment station – *CEA Centre*

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

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

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

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



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.

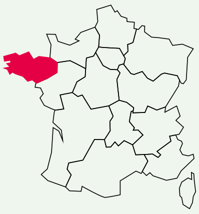
ASN conducted 62 inspections in small-scale nuclear activities in the Bourgogne-Franche-Comté region in 2021, comprising 23 in the medical sector, 24 in the industrial research and veterinary sectors, 2 concerning radon exposure, 6 to monitor approved organisations and laboratories, and 7 in the transport of radioactive substances.

One significant event rated level 1 on the INES scale was reported to ASN in 2021.

ASN also devoted particular attention to the Framatome manufacturing plants situated in the Bourgogne-Franche-Comté region. The actions conducted by ASN in this context are described in chapter 10. In Bourgogne-Franche-Comté in 2021, ASN carried out 2 inspections of Nuclear Pressure Equipment (NPE) manufacturers in their plants and 4 inspections of organisations accredited for the inspection of NPE.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- **small-scale nuclear activities in the medical sector:** p. 202
  - 8 external-beam radiotherapy departments,
  - 4 brachytherapy departments,
  - 14 nuclear medicine departments, of which 3 practise internal targeted radiotherapy,
  - 35 centres performing fluoroscopy-guided interventional procedures,
  - 55 computed tomography scanners for diagnostic purposes,
  - about 800 medical radiology devices,
  - about 2,000 dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - about 250 veterinary practices, 4 of them equipped with scanners,
  - about 400 industrial research centres, including 32 companies with an industrial radiography activity,
  - 1 industrial irradiator per radioactive source,
  - 1 computed tomography scanner dedicated to research,
  - 2 accelerators, one for industrial irradiation, the other for research and the production of drugs for medical imaging;
- **activities associated with the transport of radioactive substances;** p. 260
- **ASN-approved laboratories and organisations:**
  - 3 organisations approved for radiation protection controls,
  - 8 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 Monts d'Arrée NPP (Brennilis), currently undergoing decommissioning.

ASN carried out 47 inspections in 2021, comprising 2 at the Monts d'Arrée NPP undergoing decommissioning, 2 for monitoring approved organisations, 11 in the transport of radioactive substances and 32 in small-scale nuclear activities (22 in the medical sector and 10 in the industrial, veterinary or research sectors).

No significant event in 2021 was rated level 1 or higher on the INES scale or level 2 or higher on the ASN-SFRO scale.

The Brennilis nuclear power plant

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

Decree 2011-886 of 27 July 2011 authorised the NPP decommissioning operations, with the exception of the reactor block. In July 2018, EDF submitted an application file for the complete decommissioning of its facilities, and this file was subject to a public inquiry from 15 November 2021 to 3 January 2022. ASN notes the involvement of EDF in the conduct of the public inquiry on the Brennilis decommissioning file and, more generally, its efforts regarding transparency and communication.

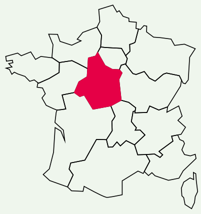
During 2021 EDF continued its decommissioning preparation work:

- completion of the reactor block sampling operations, authorised by ASN resolution of 20 September 2019,
- continuation of the preparations prior to decommissioning of the reactor block, such as the removal of unused equipment from the reactor containment; production of a detailed radiological mapping of the reactor containment premises and the asbestos removal operations;
- continuation of the repair work on the site's stormwater collection networks.

ASN considers that the licensee is conducting its work in compliance with the safety, radiation protection and environmental protection requirements and is demonstrating transparency in the detection, handling and analysis of the malfunctions and events occurring on its site.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- **the Basic Nuclear Installation:**
  - the Monts d'Arrée NPP (Brennilis), undergoing decommissioning;
- **small-scale nuclear activities in the medical sector:** p. 202
  - 10 external-beam radiotherapy departments,
  - 5 brachytherapy departments,
  - 9 nuclear medicine departments,
  - 39 centres performing fluoroscopy-guided inerventional procedures,
  - 54 computed tomography scanners,
  - some 2,500 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - 1 cyclotron,
  - 12 industrial radiography companies, including 3 performing gamma radiography,
  - 28 research units,
  - about 400 users of industrial equipment;
- **activities associated with the transport of radioactive substances;** p. 260
- **ASN-approved laboratories and organisations:**
  - 13 organisations approved for measuring radon,
  - 3 head-offices of laboratories approved for taking environmental radioactivity measurements.



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.

ASN conducted 151 inspections in the Centre-Val de Loire region in 2021, of which 119 were in nuclear facilities of the EDF sites of Belleville-sur-Loire, Chinon, Dampierre-en-Burly and Saint-Laurent-des-Eaux and 32 in small-scale nuclear activities.

ASN also carried out 51 days of labour inspections in the four nuclear power plants.

In 2021, 12 significant events rated level 1 on the INES scale were reported to ASN.

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

Belleville-sur-Loire nuclear power plant

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

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

In the operational management of the facilities, the site maintained the generally satisfactory performance levels of 2020 with regard to nuclear safety. ASN nevertheless considers that improvements are required in performance of the periodic tests and the quality of the documentation used by the operational management teams.

With regard to maintenance of the facilities, the performance of the NPP has to be improved, particularly in view of the unexpected events detected in 2021, most of which resulted from the preceding shutdowns, particularly during the ten-yearly outages of 2019 and 2020. Improvements in management of the fire risk on the site were made in 2021.

The site had only one reactor refuelling outage in 2021. With two outages in 2022, one of which is a maintenance one outage, ASN considers that the site must be attentive to the maintenance of the facilities and management of the fire risk, areas in which recurrent deviations had been observed during the ten-yearly outages of the preceding years.

ASN considers that the radiation protection performance of the Belleville-sur-Loire NPP is satisfactory and has improved since last year. It underlines the integration of experience feedback in the shutdown of reactor 2 and the defining of the monitoring programmes, the appropriateness of the radiation protection actions and the site's responsiveness in dealing with the problems of radiological cleanliness during the reactor outages. It nevertheless emerges that the optimisation of activity dosimetry can be improved, as can the management of radiological cleanliness as a whole. The recommendations of the radiation protection skills centres are not yet applied to sufficient effect.

In the area of the environment, ASN considers that effluent management, waste management and the monitoring of discharges in normal operating conditions are satisfactory. The inspections conducted in 2021 also revealed improvements in the management of fire extinguishing water retention, despite the need for further progress in this area. A public inquiry into the site's request to implement a new system to prevent the proliferation of pathogenic organisms and to change the authorised limits of certain discharges was opened in December 2021.

With regard to labour inspection, and in a context of stabilisation of the Covid-19 pandemic, the monitoring of accidents and near-accidents and the performance of the regulatory electrical inspections (and lifting of the anomalies detected) were the predominant subjects in 2021, the latter being part of a collective country-wide procedure. They revealed firstly a need to analyse some accidents or near-accidents in greater depth, and secondly, weaknesses in the site's organisation to permit the smooth running of the electrical inspections or to coordinate these inspections between the different EDF entities (particularly as concerns the tertiary buildings).

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 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. Its role is to intervene in pre-accident or accident situations, on any NPP in France, by providing additional human resources and emergency equipment.

ASN considers that the nuclear safety performance of the Dampierre-en-Burly NPP is in line with its general assessment of the EDF plants. Environmental and radiation protection performance, for their part, remain below the national average.

With regard to nuclear safety, although normal operational management of the facility remains satisfactory on the whole (improvements in periodic test management are to be underlined), organisational deficiencies linked to shortcomings in the documents and communication between the management teams were the cause of several significant events during the year 2021. As far as maintenance of the facilities is concerned, the site's performance is considered satisfactory, particularly in an industrial context where a first reactor on the site is undergoing its fourth ten-yearly outage. Although improvements in management of the explosion risk were observed in 2021, fire risk management remains sub-standard and will be a priority area of ASN action in 2022.

The radiation protection performance of the Dampierre-en-Burly NPP remains seriously inadequate, as has been the case for several years. Although the outside contractor monitoring programmes and verifications conducted by the independent safety organisation are found appropriate, numerous deviations were again observed in 2021, particularly in the control of radiological cleanliness and the dispersion of contamination on the work sites in controlled areas. A plan of rigour was put in place on the site in 2017, but it has not yet restored the expected levels of performance. Given this situation, ASN will maintain targeted monitoring of the site's radiation protection in 2022.

Lastly, the environmental protection performance of the Dampierre-en-Burly NPP also remains insufficient. Although the discharge limits for gaseous effluents are respected and a significant improvement in management of the microbiological risk compared with the preceding years was noted in 2021, cases of exceeding the liquid effluent discharge limits for certain chemical parameters were observed. Furthermore, the national action concerning management of the containment of dangerous substances conducted by ASN in 2021 on several EDF sites revealed the Dampierre-en-Burly site to be very far below average in this area. The necessary corrective actions in this area are therefore expected in 2022. An administrative procedure to modify the environmental resolutions governing the site's discharges engaged in 2021 will continue in 2022 to allow the implementation of a new treatment against the proliferation of pathogenic organisms and changing of the discharge limits of several substances.

Lastly, with regard to labour inspection, further to the actions conducted in 2021, management of the electrical risk will remain a priority in 2022 in view of the organisational difficulties detected in this respect on the Dampierre-en-Burly site. ASN nevertheless notes that the site has put in place a schedule for performing the regulatory electrical inspections. Inspections were moreover carried out on diverse themes such as handling, lifting devices, activities and works taking place during reactor outages. Organisational difficulties discovered during these inspections oblige the licensee to put in place corrective actions, which shall be specifically monitored in 2022.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- **Basic Nuclear Installations:**
  - the Belleville-sur-Loire NPP (2 reactors of 1,300 MWe),
  - the Dampierre-en-Burly NPP (4 reactors of 900 MWe),
  - the Saint-Laurent-des-Eaux site: the NPP in operation (2 reactors of 900 MWe), and the 2 Gas-Cooled Reactors (GCRs) undergoing decommissioning and the irradiated graphite sleeve storage silos,
  - the Chinon site: the NPP in operation (4 reactors of 900 MWe), the 3 GCRs undergoing decommissioning, the Irradiated Material Facility (AMI) and the Inter-Regional Fuel Warehouse (MIR);
- **small-scale nuclear activities in the medical sector:** p. 202
  - 8 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 11 nuclear medicine departments,
  - 32 centres performing fluoroscopy-guided interventional procedures,
  - 38 computed tomography scanners,
  - some 2,700 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - 10 industrial radiography companies,
  - about 330 industrial, veterinary and research radiography devices;
- **activities associated with the transport of radioactive substances;** p. 260
- **ASN-approved laboratories and organisations:**
  - 2 organisations approved for radiation protection controls,
  - 4 laboratories approved for taking environmental radioactivity measurements.

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 shut down or undergoing decommissioning. On the south side of the site, the Chinon B NPP comprises four in-service 900 MWe reactors; the first two –constituting BNI 107– were commissioned in 1982-1983, while the second two –constituting BNI 132– were commissioned in 1986-1987. To the north, the three old graphite-moderated GCRs designated Chinon A1, A2 and A3, are currently being decommissioned. The site also accommodates the Irradiated Materials Facility (AMI), designed for the expert assessment of activated or contaminated materials, whose assessment activities have now ceased and been entirely transferred to a new laboratory called "the Lidec", and to the 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 is in line with its general assessment of the EDF plants in the areas of nuclear safety and radiation protection. The environmental performance, which was below average at the beginning of 2021, improved significantly in the course of the year. Although progress was observed in 2021, particularly in terms of safety, the results in the areas of the environment and radiation protection must be consolidated.

With regard to safety, ASN considers that the incident and accident management situation is once again satisfactory, even if it noted difficulties in the management of the On-Site Emergency Plan (PUI) documentation. Alongside this, although ASN observes a drop in the number of significant events resulting from noncompliance with the reactor General Operating Rules (RGE) by the operational management teams, the analysis of deviations that can affect safety can be further improved.

ASN considers that the radiation protection performance of the Chinon NPP remains relatively satisfactory. The ASN inspections conducted in 2021 showed that progress had been made, which was expected further to the 2020 assessment, but also that organisational improvements were still required. In view of the site's good performance in this area before 2020, ASN considers that it must be a priority for the site in 2022.

The environmental protection performance of the Chinon NPP must be improved. The gaseous and liquid effluent discharges are well below the national average. ASN nevertheless considers that management of the hydrocarbons leaving the oil filters is a point requiring particular attention in 2022. In addition, waste management is poorly compliant with best practices and must be improved in 2022.

In 2021, labour inspection revealed the site's weaknesses in the prevention of risks of falling from height, in the legibility of some asbestos identification/location files, or even the exhaustiveness of the checks carried out, due to the organisational set-ups between various EDF entities. Inspection of the electrical risk continued in 2021 (and will remain a priority in 2022); it revealed several shortcomings, particularly concerning the knowledge of the premises and installations to inspect, the initial regulatory verifications and the correction of the identified deviations. Lastly, several accidental exposures of employees to asbestos led ASN to challenge EDF on the quality and legibility of the asbestos identification/location files, by asking the licensee to work on the subject in 2022.

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 houses the GIE Intra (which operates robotised machines for interventions on accident-stricken nuclear installations). Complete decommissioning of the Chinon A3 reactor was authorised by the Decree of 18 May 2010, with a decommissioning "under water" scenario.

In March 2016, EDF announced a complete change of decommissioning strategy for its definitively shut down reactors. In this new strategy, the planned decommissioning scenario for all the reactor pressure vessels is decommissioning "in air" and the Chinon A2 reactor pressure vessel would be decommissioned first (see chapter 13). In this context, ASN has analysed the periodic safety review concluding reports submitted by EDF for the six GCRs, supplemented further to the requests from ASN. On completion of its analysis, ASN indicated in December 2021 that it has no objection to the continued operation of BNI 133 (Chinon A1 reactor), BNI 153 (Chinon A2 reactor) and BNI 161 (Chinon A3 reactor). It will verify during the examination of the decommissioning files for these reactors, which are to be submitted by EDF in late 2022, that the decommissioning operations are carried out under suitable conditions of safety and radiation protection, within controlled time frames.

For the Chinon A2 reactor, EDF has continued the decommissioning preparation operations situated outside the reactor pressure vessel, particularly as concerns removal of the shells from the heat exchanger premises, and continued the investigations inside the pressure vessel. EDF has also continued decommissioning the Chinon A3 heat exchangers;

decommissioning the South Heat Exchangers room is finished and all the cylinders have been transferred to the Industrial centre for grouping, storage and disposal (Cires).

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 2021 revealed in particular good emergency management in an on-site exercise situation, and good tracking of the inspections of fire-related equipment. This being said, improvements are expected in the knowledge of the premises and the equipment on the part of the personnel attached to the in-service NPP who might have to intervene in the facilities undergoing decommissioning.

"NUCLEAR FUEL CYCLE" FACILITIES

Inter-Regional Fuel Warehouse

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

The facility 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.

RESEARCH FACILITIES UNDERGOING DECOMMISSIONING

Irradiated Materials Facility

The Irradiated Materials 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 primarily intended for performing examinations and expert assessments on activated or contaminated materials from the PWRs.

The analysis and expert assessment activities were entirely transferred in 2015 to a new facility on the site, the Ceidre integrated laboratory (Lidec).

Decree 2020-499 for AMI decommissioning was published on 30 April 2020 and the new RGEs were approved by ASN in April 2021, thereby enabling the Decree to enter into application.

The legacy waste treatment and removal activities continued in 2021. The legacy magnesian waste has been packaged and recharacterised. The characterisation results were not as expected, making it necessary to apply to the French national agency for radioactive waste management (Andra), for a waiver to allow acceptance of the waste. The waste removal work was therefore stopped pending the outcome of this procedure.

ASN considers that the management of the periodic inspections and tests, particularly those concerning the fire risk, is satisfactory. Particular attention must nevertheless be paid to tracking of the fire door inspections and monitoring of the ageing of the facility's civil engineering structures.

SAINT-LAURENT-DES-EAUX SITE

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

Saint-Laurent-des-Eaux nuclear power plant

Reactors B1 and B2 in operation

ASN considers that the performance of the Saint-Laurent-des-Eaux NPP with regard to radiation protection is in line with its general assessment of the EDF plants, and stands out positively for the environment. The performance in the area of safety, however, has deteriorated. In the middle of the year site senior management presented a reactive action plan, whose effect will be checked by ASN in 2022, particularly during the site in-depth inspection.

ASN considers that the site's nuclear safety performance deteriorated in 2021 and is inadequate. The safety management plan put in place in 2020 has not restored the expected level of performance. Numerous events have revealed a lack of both safety culture and a questioning attitude on the part of the workers, deviations in the handling of anomalies and conformity deviations in particular, as well as shortcomings in the integration of experience feedback, in the quality of the documentation and in the monitoring of work performance. ASN nevertheless underlines the good overall upkeep of the worksites and satisfactory apparent condition of the inspected equipment. It does however expect to see significant improvements on the part of the licensee in 2022.

Generally speaking, the management of radiation protection at the Saint-Laurent-des-Eaux NPP meets ASN expectations. The site's performance is considered stable compared with 2020, even if organisational improvements are required, particularly through the setting up of the radiation protection skills centre, which will take place in 2022.

The site's organisation to meet the regulatory environmental protection requirements is considered highly successful, particularly in view of the quantities of effluents discharged.

The management of an accidental spillage situation, checked during an exercise, is appropriate and the various retention systems inspected are well kept. Some improvements are nevertheless required in the knowledge of hazardous substances volumes and the volumes to be contained.

The labour inspections carried out in 2021 under national or local initiatives revealed some weaknesses in the site's organisation and the correction of deviations, and in the management of risks of falling from height. They have also prompted the labour inspectorate to ask for additional information in several areas, such as the optimisation of radiation protection on work sites, the cleaning and filtration of the air in certain rooms presenting particular risks and the management of risks associated with the Covid-19 pandemic.

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 are to be submitted by EDF in late 2022 to set out the new "in air" decommissioning strategy, that the decommissioning operations are carried out under suitable conditions of safety and radiation protection, within controlled time frames.

In 2021, EDF resumed the decommissioning work sites that were stopped on account of the restrictions laid down to combat the Covid-19 pandemic. ASN considers that the level of safety of the Saint-Laurent-des-Eaux A reactors is satisfactory. ASN's inspections found that the overall upkeep of the premises and worksites was good. In addition, the organisation put in place to meet the commitments made further to the inspections and significant events is satisfactory, as is waste management. However, improvements are required in the management of fire-extinguishing waters and the traceability of the monitoring of outside contractors working in the facility.

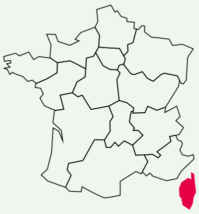
Saint-Laurent-des-Eaux silos

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, but whose behaviour in the event of an earthquake needs to be assessed. 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 BNI 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 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.

ASN is waiting for EDF to declare final shutdown of the facility. Submission of the decommissioning file, which will take into account the emptying, post-operational clean-out and demolition of the existing silos, is planned for the end of 2022.



Corse
Collectivity

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

In 2021, ASN carried out 4 inspections in Corse, of which 3 were in the medical sector and 1 in the industrial sector.

During 2021, one significant event occurring in the industrial sector and rated level 1 on the INES scale was reported.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- **small-scale nuclear activities in the medical sector:** p. 202
  - 2 external-beam radiotherapy departments,
  - 2 nuclear medicine departments,
  - 7 centres performing fluoroscopy-guided interventional procedures,
  - 9 computed tomography scanners,
  - about 330 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - 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;** p. 260
- **ASN-approved laboratories and organisations:**
  - 2 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 2021, 21 inspections were carried out in the small-scale nuclear activities sector in the French Overseas *départements*, regions and collectivities. Four on-site inspection campaigns were carried out by the ASN Paris division.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- **small-scale nuclear activities in the medical sector:** p. 202
  - 4 external-beam radiotherapy departments,
  - 1 brachytherapy department,
  - 3 nuclear medicine departments,
  - 24 centres performing fluoroscopy-guided interventional procedures,
  - about 30 centres holding at least 1 computed tomography scanner,
  - about 100 medical radiology practices,
  - about 1,000 dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - more than 70 users of veterinary radiology devices,
  - 3 industrial radiology companies using gamma radiography devices,
  - 1 cyclotron;
- **activities associated with the transport of radioactive substances.** p. 260

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 2021, ASN conducted 186 inspections in the Grand Est region, of which 63 were in the NPPs in service, 11 in radioactive waste disposal facilities and on the sites of the Fessenheim and Chooz A NPPs currently being decommissioned, 87 in the small-scale nuclear activities sector, 14 in the transport of radioactive substances and 11 concerning approved organisations or approved laboratories.

ASN also carried out 22 days of labour inspections in the NPPs.

During 2021, 16 significant events reported by nuclear installation licensees in the Grand Est region were rated level 1 on the INES scale.

One significant event in small-scale nuclear activities (industrial sector) was rated level 1 on the INES scale, while the event concerning the discovery of radiological contamination in an old building of the Strasbourg civil hospital was revised to level 2.

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 located in Soulaines-Dhuys in the Aube *département*;
- **the *Cigéo* geological disposal project for long-lived high- and intermediate-level radioactive waste;**
- **small-scale nuclear activities in the medical sector:** p. 202
  - 14 external-beam radiotherapy departments,
  - 5 brachytherapy departments,
  - 22 nuclear medicine departments,
  - 96 computed tomography scanners,
  - 80 centres performing fluoroscopy-guided interventional procedures,
  - some 2,100 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - 277 industrial and veterinary activities subject to the licensing system,
  - 24 companies exercising an industrial radiography activity,
  - 47 research laboratories situated primarily in the universities of the region;
- **activities associated with the transport of radioactive substances;** p. 260
- **5 head offices of organisations approved in radiation protection.**

Cattenom nuclear power plant

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

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

ASN considers that the safety performance of the Cattenom NPP is in line with its general assessment of the EDF plants following the improvements observed in 2020. As in the preceding years, the environmental protection and radiation protection performance are situated within the average, but progress is still expected.

With regard to operation and reactor management, ASN considers that the results confirm the start of improvement noted in 2020, despite several areas in which progress can still be made. The inspections have found that the operational management teams are proficient and the periodic tests meet expectations on the whole, despite a few deviations in the documents and recurrent contrasts in the indicators. More specifically, the number of significant events rated level 1 on the INES scale is higher than in preceding years.

The maintenance workload in 2021 was relatively higher than in 2020, with three reactor outages, including the third ten-yearly outage of reactor 3. The work undertaken by the site to improve the quality of maintenance, through the plan of rigour applied since 2020 is starting to produce effects. ASN notes in particular improved technical monitoring of the work sites, the insourcing of certain activities and the deployment of measures to prevent the risk of fraud. Despite this, the year was again marked by a number of technical deficiencies which could not always be detected during the requalification of the equipment items concerned.

The hydrostatic test of the primary system and the test of reactor 3 containment during its ten-yearly outage ran smoothly; the results comply with the safety requirements. Damage to the turbo charger of an emergency diesel generator set had a major impact on the duration of the refuelling outage of reactor 2 at the end of the year. Lastly, during reactor 2 and 3 outages, an abnormal corrosion phenomenon –not related to maintenance– was observed in the fuel assemblies; it required the implementation of compensatory measures and complementary analyses which are still in progress.

The total number of significant events reported remains within the average for the EDF reactors, but an unusually high proportion of them were rated level 1 on the INES scale, without this trend being able to be interpreted as a drift. As in 2020, the Cattenom site is prompt in its reporting of significant events. ASN notes that the significant events management process is well mastered on the whole and effectively mobilises the site players up to senior management level.

In the area of fire risk prevention, the findings of the inspections reveal many deviations. ASN considers that this entire subject needs to be brought back under control, as regards, for example, the calorific potential in the premises, sectorisation, fire permit management, or the time taken to remedy anomalies.

The site's emergency management was assessed through an unannounced exercise with a scenario of accidental spillage of soda into the stormwater system. The ability of the site to set up the required emergency organisation, which was put to the test by kinetics of the scenario, proved to be robust. Areas for improvement were nevertheless identified in the choice of measures to deploy on the ground to cope with the speed of the simulated event.

With regard to environmental protection, gaseous and liquid effluent discharges and waste management are well controlled, but the site still has weaknesses which are illustrated by the relatively high number of events. It was found that the management of deviations and threshold overshoots can be improved, notably because the times and the analysis parameters were not appropriate for the implementation of relevant and effective corrective actions. Controlling the risk of proliferation of microorganisms in the cooling towers still necessitates reinforced biocide treatments which have consequences on the aqueous discharges.

Lastly, in the areas of radiation protection and occupational safety the picture remains contrasted: although some deviations observed in preceding years, such as the control of accesses in prohibited areas, have not been repeated, the number of events remains high, including concerning radiation protection fundamentals, such as the marking out of limited stay areas. The relative improvement in the second half of the year compared with the first, possibly linked to the awareness-raising efforts the site made with the outside contractors, must be confirmed on the ground and last over time. A few events occasionally highlighted weaknesses in the occupational safety culture.

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 overall performance of the Chooz B NPP with regard to nuclear safety, radiation protection and environmental protection is in line with ASN's general assessment of the EDF plant performance.

At the end of 2021, EDF detected stress corrosion-related cracks in the circuits connected to the main pipes of the primary system of the two reactors. This issue will lead to a large-scale inspection and repair programme in 2022.

With regard to nuclear safety, ASN notes that despite a promising start to the year, the dynamic of progress in reactor operation observed for several years now was not fully maintained, with more specifically a deterioration in the conducting of reactor management operations in the second half of the year, which led to a significant rise in the number of significant events. The efforts made by the licensee in its plan to regain operating rigour must be maintained. Particular vigilance must be applied to the quality of work preparation and management of the transient operating phases.

With regard to maintenance and the works associated with the reactor 2 refuelling outage, ASN considers that the inspection activities ran satisfactorily, over and beyond the problem linked to the spalling of the cladding of several fuel rods –which prolonged the outage and necessitated the implementation of specific reactor control measures.

In the area of radiation protection, progress has been noted in the dose optimisation procedure. This trend must nevertheless be analysed in the context of a relatively low maintenance work load in 2021, which is more conducive to good results. It therefore remains to be confirmed. Inappropriate individual behaviours in terms of radiation protection culture and observance of the basic principles have moreover been observed.

ASN considers that the site's environmental protection organisation is on the whole satisfactory. Improvements are however required in the management of hazardous substances.

The labour inspections focused on the conformity of the work equipment and the electrical installations. An initiative concerning the prevention of the risk of falling from height was also conducted. EDF must be particularly attentive to the meeting of commitments and to the compliance work on the electrical installations.

Reactor A undergoing decommissioning

Decommissioning of the equipment inside the reactor vessel was completed in 2021. The next step is the emptying of the reactor building pool with a view to decommissioning the reactor vessel. An evaporator is currently being installed to treat the pool water prior to discharge, with start of operation planned for the second quarter 2022.

The decommissioning work on all the equipment still present in the bunkers of the "auxiliary" cavern has resumed after a long interruption due to technical problems. This work is carried out mainly by remote operation using a robotic arm.

In addition to this, decommissioning of the effluent treatment station equipment that is not necessary for treating the water from the rock or floor drains is in progress.

The site's organisation with regard to fire risk management is satisfactory on the whole.

In the area of radiation protection, the organisation set up for managing the risk of contamination with alpha particles seems satisfactory, even if interactions with the outside contractors can be further improved. The increase in cases of internal contamination during the second quarter of 2021 shows that the licensee must remain fully vigilant with respect to this risk.

Lastly, with regard to occupational safety, the nuclear safety inspection on the theme of fire was used to verify compliance with the provisions of the Labour Code on this subject. No significant deviation was observed.

Fessenheim nuclear power plant

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

ASN considers that the site has maintained a robust level of seriousness and vigour in the monitoring of operation of the facilities, despite the significant reduction in the operating and maintenance activities compared with the period when it was in production.

The year 2021 was thus primarily taken up by the continuation of the decommissioning preparation activities, such as the preparation of the decontamination activity files, installation of new effluent treatment capacities, removal of a large number of spare parts and the work to develop new organisational baseline requirements for the site, such as the emergency plans. The site has moreover undertaken an effective drive to remove the legacy waste from the site, along with chemical products that are no longer necessary.

These activities are proceeding satisfactorily, in accordance with the submitted schedules. Major milestones have been reached, such as the finalising of removal of the fuel from reactor 1, and the first shipping of upper sections of the old steam generators, for decontamination and recycling by a melting process in the Cyclife facilities in Sweden.

Several major work sites will be continuing in 2022, notably with removal of the fuel from the second reactor, the decontamination of the primary systems of the two reactors and the creation in the turbine hall of the facility for managing the waste resulting from the decommissioning.

With regard to radiation protection, despite confirmation of the improvement in the prevention of contamination of the site road systems and a strongly downward trend in the overall dosimetry of the works carried out in the facilities, vigilance must be maintained given the occurrence of several events revealing a lack of precautions by certain workers with respect to the conditions for leaving controlled areas, for marking out controlled areas, or individual dosimetry.

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 and the environment. This assessment also concerns the areas of radiation protection, but with a reservation on account of a number of improvements that are required.

ASN notes that the licensee has progressed in the area of nuclear safety, particularly in its mastery of the reactor operating technical specifications. ASN nevertheless considers that this progress remains fragile and that EDF must continue its efforts to further improve the rigour of operation of the reactors. Some significant events still reveal shortcomings in staff training and in the monitoring of the facilities. Specific action must also be taken to restore an adequate headcount in the independent safety organisation.

With regard to maintenance, ASN considers the situation satisfactory on the whole, even if the preparation of activities, especially unscheduled activities, and the management of deviations during works performance can be improved.

In the area of occupational radiation protection, the year was marked by a deterioration in the radiation protection culture of workers, mainly outside contractors. An increase in situations of non-compliance with the elementary radiation protection measures, such as wearing a dosimeter, was observed. ASN has moreover regularly noted shortcomings in the risk analysis of work sites and in the implementation of the defences planned for by these analysis during maintenance activities, which have led in particular to internal exposures of workers. Effective measures are required in order to restore proper consideration of the radiation protection issues.

With regard to environmental protection, ASN considers that the site's good results of the preceding year have been confirmed. The licensee must nevertheless be vigilant regarding control of the volume of waste present in the effluents treatment building.

The labour inspection actions focused essentially on the conformity of the electrical installations and the prevention of the risk of falling from height. EDF must be particularly attentive to the meeting of commitments and to the compliance work on the electrical installations.

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 which ceased its activities in July 1994, while benefiting from the experience gained with 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.

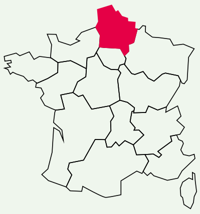
At the end of 2021, the volume of waste in the facility had reached about 363,000 m^3, or 36% of the authorised capacity. According to the estimates made by Andra in 2016 in the concluding report on the CSA periodic safety review, the CSA could be completely filled by 2062 rather than 2042 as initially forecast, this estimate being based not only on better knowledge of the future waste and the waste delivery schedules, but also an optimisation of waste management through the compacting of certain packages.

In 2021, the activity of the centre facilities returned to normal (post-crisis due to the Covid-19 pandemic). The construction of new disposal structures for the future waste continued at the same time.

ASN considers that the CSA is operated satisfactorily in the areas of safety, radiation protection and the environment. The inspections conducted in 2021 revealed more specifically:
- satisfactory management of modifications;
- appropriate implementation of the commitments made concerning control of the fire risk following the second periodic safety review;
- the quality and rigour of the CSA's dosimetric monitoring and the availability and regulatory conformity of the means of verification.

Deep geological disposal repository project

ASN considers that the scientific experiments and work conducted by Andra in the underground laboratory at Bure continued in 2021 with a good standard of quality, comparable with that of the preceding years.



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.

ASN carried out 150 inspections in the Hauts-de-France region in 2021, of which 30 were in the Gravelines NPP, 106 in small-scale nuclear activities, 12 in the transport of radioactive substances, and 2 at suppliers of equipment for BNIs.

ASN also carried out 14.5 days of labour inspection in the Gravelines NPP.

In the course of 2021, 11 significant events rated level 1 on the INES scale were reported by the Gravelines NPP, including one concerning radiation protection.

In small-scale nuclear activities, 3 events were rated level 1 on the INES scale. In radiotherapy, 2 events were rated level 1 on the ASN-SFRO scale.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- **Basic Nuclear Installation:**
  - the Gravelines NPP (6 reactors of 900 MWe) operated by EDF;
- **small-scale nuclear activities in the medical sector:** p. 202
  - 19 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 31 nuclear medicine departments,
  - 92 centres performing fluoroscopy-guided interventional procedures,
  - 127 computed tomography scanners,
  - some 4,600 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - 1 accelerator for the inspection of freight trains,
  - 600 industrial and research organisations, including 29 companies exercising an industrial radiography activity, 3 particle accelerators including 2 cyclotrons, 38 laboratories, mainly located in the universities of the region, and 19 companies using gamma ray densitometers,
  - 340 veterinary surgeries or clinics practising diagnostic radiology;
- **activities associated with the transport of radioactive substances;** p. 260
- **ASN-approved laboratories and organisations:**
  - 3 agencies of organisations approved for radiation protection controls.

Gravelines nuclear power plant

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

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

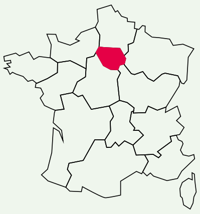
Nuclear safety performance did not improve in 2021, particularly with regard to the rigour of work interventions. The first measures taken by the licensee have not put an end to inappropriate practices or behaviours. The site must therefore continue its efforts to federate all the protagonists. ASN will conduct an interim assessment in mid-2022.

With regard to maintenance, the year 2021 was marked by significant increases in the refuelling and maintenance outage times. This situation increased the workload of an already very intense industrial programme, involving more specifically the fourth ten-yearly outage of reactor 1, replacement of the Steam Generators (SGs) of reactor 6 and the work on the peripheral protection against external flooding, implemented further to the lessons learned from the Fukushima Daiichi NPP accident.

Concerning environmental protection, ASN considers that the Gravelines NPP must continue its efforts in the maintenance of equipment that uses the insulating greenhouse gas (SF_6) and the facilities for treating the radioactive effluents produced by reactor operation.

ASN considers that the situation regarding radiation protection remains sub-standard and that the site is still not managing to restore a satisfactory level, despite putting in place preventive measures at the beginning of the year. The efforts made must be increased in order to rapidly and sustainably restore satisfactory performance in occupational radiation protection in 2022. Radiation protection will be subject to a tightened inspection in 2022.

The labour inspection actions conducted in 2021 on the Gravelines NPP were split between the inspections on the maintenance work sites, particularly during reactor outages, and specific inspections focusing on subjects such as lifting, electrical risks and work times. Regular meetings were organised with senior management, members of the health, safety and working conditions committee, and personnel representatives. The number of workplace accidents increased in 2021 despite the measures taken by the licensee. Deficiencies in taking on board the risks associated with the activities, failure of individuals to comply with basic safety rules and lack of proficiency in electrical equipment lockouts/tagouts figure among the recurrent causes recorded. The labour inspectorate will be particularly attentive to these aspects in its next inspections.



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 272 inspections in the Île-de-France region in 2021, of which 84 were in the field of nuclear safety, 135 in small-scale nuclear activities, 24 in the transport of radioactive substances and 29 concerning approved organisations or laboratories.

In the small-scale nuclear activities sector, 2 significant events were rated level 2 on the ASN-SFRO scale, and 8 were rated level 1 on the INES scale.

CEA SACLAY SITE

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

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

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

THE INDUSTRIAL AND RESEARCH FACILITIES

Osiris and Isis reactors

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

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

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- **Basic Nuclear Installations regulated by the Orléans division:**
  - the CEA Saclay site of the CEA Paris-Saclay centre,
  - the Artificial Radionuclide Production Plant (UPRA) operated by CIS bio international in Saclay,
  - the CEA Fontenay-aux-Roses site of the CEA Paris-Saclay centre;
- **small-scale nuclear activities in the medical sector regulated by the Paris division:** p. 202
  - 26 external-beam radiotherapy departments,
  - 12 brachytherapy departments,
  - 39 *in-vivo* nuclear medicine departments and 13 *in-vitro* nuclear medicine departments (medical biology),
  - 148 centres performing fluoroscopy-guided interventional procedures,
  - more than 200 centres possessing at least 1 computed tomography scanner,
  - about 850 medical radiology practices,
  - about 8,000 dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors under the oversight of the Paris division:** p. 232
  - some 650 users of veterinary radiology devices,
  - 6 industrial radiology companies using gamma radiography devices,
  - some 120 licenses concerning research activities involving unsealed radioactive sources;
- **activities associated with the transport of radioactive substances;** p. 260
- **ASN-approved laboratories and organisations:**
  - 9 organisations approved for radiation protection controls.

Given the old design of this facility by comparison with the best available techniques for protection against external hazards and for containment of materials in the event of an accident, the Osiris reactor was shut down at the end of 2015. The Isis reactor was definitively shut down in March 2019. Following submission of the decommissioning file for the entire facility in October 2018, ASN requested and received additional information giving more details on the operations planned at each stage of decommissioning and substantiating more precisely the initial state envisaged at the start of decommissioning and the results of the impact assessment.

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

Control of the fire risk is characterised by good fire permit management and constructive improvement measures in view. However, the monitoring of fire loads, especially the waste accumulated in the facility, is inadequate. The monitoring of outside contractors performing the periodic inspections and tests is not sufficiently formalised. The electrical equipment maintenance operations are performed correctly, despite some shortcomings in the verifications performed by outside contractors. Improvements are expected in the follow-up of the recommendations for protection against lightning-related risks. Management of the decommissioning preparation operations is satisfactory from the technical aspects, but delays are observed, as in the previous years.

ASN considers that the licensee must be attentive to control of the decommissioning preparation operations and improving waste management.

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.

Based on the facility inspections and monitoring carried out in 2021, ASN considers that the level of safety of the Orphée reactor is on the whole satisfactory. Nevertheless, some aspects in the management of radioactive sources and pressure equipment require particular attention, and individual assessments of exposure to ionising radiation at the work station must be established. The management of fire loads, the management of a waste storage area and the conformity of waste zoning must be improved. Although the preparation of the decommissioning preparation operations is satisfactory, delays are observed. Progress in fulfilling the commitments following the periodic safety review is satisfactory. The significant events nevertheless show that vigilance is required with the organisation of equipment maintenance.

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

Spent fuel testing laboratory

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

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

Further to the last periodic safety review, ASN issued the resolution of 30 November 2016 (amended on 26 June 2017) regulating the continued operation of the facility through technical prescriptions, relating in particular to the improvement plan that CEA had undertaken to implement. Some of the CEA's commitments have not been fulfilled within the deadlines. In particular, the CEA has requested pushing back of the deadlines for removal of the radioactive substances whose utilisation cannot be justified, and for the implementation where necessary of measures to place and maintain the BNI in a safe condition in the event of fire in the areas adjacent to the nuclear areas. The decommissioning of Célimène (unit formerly intended for the examination of fuels from reactor EL3) is also concerned by this request. ASN is therefore still waiting for the CEA to submit a robust action plan.

In the years to come, BNI 72 will no longer accept irradiating waste from the CEA Saclay site. Consequently, the CEA has started the clean-out work on a unit of the LECI which will be dedicated to the overpacking of the waste from BNI 50. ASN will check the progress of the associated work.

Operational management of the Organisational and Human Factors (OHF) is satisfactory, despite a high staff turnover. Improvements are however expected in the management of the criticality risk, in the integration of the lightning-related risk and the monitoring of outside contractors, notably with the adaptation of the BNI monitoring programme to the activities entrusted to these contractors.

Poséidon irradiator

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

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

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

ASN considers that the facility is operated satisfactorily and with the aim of continuously improving its safety. ASN has effectively observed that the licensee provides adequate responses within the set deadlines to its commitments resulting from the preceding periodic safety review (commitments made by licensee, technical requirements or requests from ASN). The periodic inspections and tests are suitably monitored, and any corrective measures required further to these inspections are duly implemented. ASN nevertheless considers that improvements must be made in the management of radioactive sources, particular in the tracking of expiry dates. Lastly, the license must conduct work to determine the cause of a recent increase in tritium activity observed in the Poséidon pool water.

SOLID WASTE AND LIQUID EFFLUENT TREATMENT FACILITIES

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

Solid radioactive waste management zone

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

In view of the "dispersable 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 13).

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

In 2017, in view of the delays in the removal from storage operations, the CEA requested that the deadlines prescribed in ASN resolution 2010-DC-0194 of 22 July 2010 for removal of the irradiated fuel from storage and removal of the waste stored in the "40 wells" area be pushed back by several years. In 2020, the CEA asked that the deadline for the removal of the waste stored in the "40 wells" area be further pushed back to 31 December 2030, a request which was validated by ASN Chairman's resolution CODEP-CMG-2022-05822 of 2 February 2022.

In order to be able to continue using the BNI for managing the radioactive waste from the Saclay BNIs, the CEA in 2017 asked for a change in the date of final shutdown of the facility, postponing it until the first of the following two terms was reached: either the effective date of the Decommissioning Decree or the date of 31 December 2022. It is also requesting certain arrangements for the management 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-2022-05822 of 2 February 2022.

ASN considers that the safety of the facility is acceptable, while at the same time noting numerous delays in the operations to remove the fuel and waste from storage. ASN nevertheless takes positive note of the removal of three strontium sources from the facility in 2021, which contributes to the gradual reduction of its "dispersible inventory".

In 2021, ASN inspected the organisation and measures implemented by the CEA to remove the irradiated fuels from block 108 and from the pool. Despite the observed delays, ASN underlines the CEA's ability to adapt to the various contingences encountered. Nevertheless, the action plans to ensure compliance with the stated schedules must be more rigorous. ASN underlines that projects that contribute to reducing the "dispersible inventory" within facilities constitute priorities for safety.

Alongside this, ASN's inspections find the facility to be in good overall condition. ASN nevertheless notes insufficient tracking of the periodic regulatory verifications of electrical equipment.

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.

Liquid effluents management zone

The liquid effluents management zone constitutes BNI 35. Declared by the CEA by letter of 27 May 1964, this facility is dedicated to the treatment of radioactive liquid effluents. CEA was authorised by a Decree of 8 January 2004 to create "Stella", an extension in the BNI for the purpose of treating and packaging low-level aqueous effluents from the Saclay centre. These effluents are concentrated by evaporation then immobilised in a cementitious matrix in order to produce packages acceptable by Andra's above-ground waste disposal centres.

The evaporation facility used to treat the radioactive effluents has been out of service since 2019, due to technical anomalies on an equipment item. Its return to service requires the preparation of a specific safety assessment file which ASN is waiting to receive. At present the facility is no longer capable of fulfilling its functions (evaporation of effluents, encapsulation of concentrates in cement, collection of effluents from the Saclay effluent producers).

The production of packages by cement encapsulation is subject to a robust and operational inspection plan. This process, which is 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. In view of the work to be carried out by the CEA to remedy this situation, the cement encapsulation activity is not expected to start again in the short term.

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 (LL and IL) radioactive effluents produced by the Saclay site production sources are now directed to the Marcoule Liquid Effluent Treatment Station (STEL).

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

Several other issues of major importance for the BNI are currently being discussed or examined. These include in particular the emptying of the tanks containing organic effluents in pit 99 - 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 facility has a good fire-response organisation which undergoes regular exercises. Alongside this, the tracking of commitments made to ASN is satisfactory. On the other hand, improvements are required in fire risk management, with regard to the upkeep of several fire protection devices, the limiting of the fire loads present in certain premises and proper performance of the control inspections after hot spot work.

FACILITIES UNDERGOING DECOMMISSIONING

The decommissioning operations performed on the Saclay site concern two finally shut down BNIs (BNIs 18 and 49) and three BNIs in operation (BNIs 35, 40 and 72), parts of which have ceased activity and in which operations in preparation for decommissioning are being carried out. They also concern two Installations Classified for Protection of the Environment –ICPEs– (EL2 and EL3), previously classified as BNIs but which have not been completely decommissioned due to the lack of a disposal route for the low-level long-lived waste (LLW-LL). Their downgrading from BNI to ICPE status in the 1980's, in compliance with the regulations of that time, could not be done today.

Broadly speaking, the CEA's decommissioning and waste management strategy has been examined by ASN, which stated its position in May 2019 on the priorities defined by the CEA (see chapter 13).

Ulysse reactor

Ulysse was the first French university reactor. The facility, which constitutes BNI 18, has been in final shutdown status since February 2007 and has contained no fuel since 2008. The BNI Decommissioning Decree was published on 21 August 2014 and provides for a decommissioning duration of five years. This facility presents limited safety risks.

On 8 August 2019, the CEA announced the end of the decommissioning operations provided for in the Decommissioning Decree, with the completion of final post-operational clean-out. The facility therefore no longer has any areas regulated on account of radiation protection, or areas where nuclear waste can be produced.

After declaring the delicensing of the facility's waste zoning in September 2020, the CEA sent ASN a delicensing application file in February 2021, with a view to deleting the Ulysse reactor from the list of BNIs. After analysing this file, ASN made complementary information requests in April 2020, more specifically concerning the analysis of the soils and groundwater. As the CEA took these requests into account in its file update in July 2021, ASN was able to initiate the consultations of the Essonne *département* Prefecture and the Saclay Local Information Committee in September 2021. The examination of this delicensing application file should lead to an ASN position statement in 2022. As the clean-out targets have been reached and the facility has no residual pollution (chemical or radioactive), ASN at this stage is considering delicensing of the facility without active institutional controls.

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 continued in 2021. In this respect, the last irradiated fuels were removed from BNI 40 in October 2021.

The decommissioning and waste recovery and packaging operations continued to fall behind schedule in 2021. ASN considers that the progress of the decommissioning projects is one of the major safety challenges for the shutdown installations and that the management of the waste from the decommissioning operations is crucial for the smooth running of the decommissioning programmes. The majority of the CEA Saclay centre BNIs are concerned, either directly or indirectly, by decommissioning or decommissioning preparation operations. ASN therefore expects the CEA to continue its efforts to make its implementation schedules for these operations more robust. ASN will maintain particular vigilance in monitoring the progress of the decommissioning and waste retrieval and packaging projects, with the aim of ensuring control of the schedules.

Particular attention must be paid to management of very-low level (VLL) waste and liquid radioactive effluents. In effect, following the temporary suspension of acceptance of VLL waste by one of the centre's facilities at the start of 2021, management of VLL waste within the BNIs had to be modified for a transient period. In addition to this, the liquid radioactive effluents produced on the Saclay site have been directed to the Marcoule STEL for several years now, given the difficulties encountered by the liquid effluent management zone (BNI 35).

The projected schedule for retrieval of the effluents in BNI 35 is not clearly defined at present.

During 2021, an abnormally high tritium content was discovered in the Fontainebleau Sands aquifer, at a new piezometer installed on the site. Identifying the precise origin of this pollution and how it will evolve over the medium and long term necessitates complementary investigations, which ASN will specifically monitor.

On another note, further to the Fukushima Daiichi NPP accident, 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.

With regard to the emergency organisation and means, the CEA submitted an update of its On-site Emergency Plan (PUI) in late 2021. ASN conducted an unannounced inspection which found that the emergency management organisation implemented by the CEA Saclay site is satisfactory.

Management of the pressure equipment and the NPE has improved. The management of on-site and off-site transport of radioactive substances is satisfactory. ASN has nevertheless observed that the monitoring of the main and backed-up electrical power supplies needs to be improved, as does the monitoring of outside contractors working on several BNIs on the site.

High Activity Laboratory

The High Activity Laboratory (LHA) comprises several laboratories which were intended for research or production work on various radionuclides. It constitutes BNI 49. On completion of the decommissioning and clean-out work authorised by Decree of 18 September 2008, only three cells, including 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 during the examination of this file.

The year 2021 was marked chiefly by the continuation of the soil investigations and studies, which enabled the CEA to finalise the decommissioning modification application file submitted at the end of 2021. The clean-out and decommissioning operations, suspended since the end of 2018, are expected to start again in 2022.

ASN considers that the level of safety of BNI 49 undergoing decommissioning is on the whole satisfactory. The commitments made by the facility are followed up satisfactorily. The conclusions of the fire risk analysis resulted in the rapid implementation of an action plan. The inventory of ionising radiation sources currently in use is kept duly up to date.

On the other hand, the inspections revealed deficiencies in the management of disused sources within the packaging and storage facility for the recovery of sources with no identified use, leading to two significant events linked to the presence of unauthorised sources or sources with activities exceeding the authorised limits. The management of sources used within the perimeter undergoing decommissioning must therefore be improved. Lastly, improvements are required in the management of the maximum permissible fire loads in each room of the facility, and in the sealing of certain roofs.

During its inspections, ASN will check the conditions for resuming, in the future, the decommissioning work on the TOTEM shielded system, which constitutes the predominant radiological inventory of BNI 49 (contaminated soils excluded).

Artificial Radionuclide Production Plant of CIS bio international

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

The Curium group is an important player on the French and international market for the production and development of radiopharmaceutical products. The products are mainly used for the purposes of medical diagnoses, but also for therapeutic uses. Until 2019, the role of BNI 29 was also to recover disused sealed sources which were used for radiotherapy and industrial irradiation. Removal of these sources, which have been stored in the facility, is well advanced. The group moreover decided to stop its iodine-131-based productions on the Saclay site at the end of 2019, which has significantly reduced the consequences of accident situations.

Broadly speaking, ASN finds that the drive to improve the safety of the facility, already observed in the preceding two years, continued in 2021 despite the disruptions caused by the Covid-19 pandemic. The stability of the organisation and better skills management were factors that favoured this approach.

Several projects bringing significant improvements in safety have been completed or should be completed in the short term. Nevertheless, the time frames for carrying out the major actions undertaken by CIS bio international, some of which are difficult to deploy, must be better controlled. The emergency organisation undergoes efficient preparation exercises. The equipment modification and qualification management processes are found to be appropriate. Control of the work sites involving dosimetric risks and the deployment of the legacy waste removal operations are satisfactory. The organisation for managing transport operations, which are numerous and involve packages with varied contents, is also efficient; quality assurance and document management have been improved.

The overall improvement in liquid effluent management following the deviations observed in the last few years is continuing, reflecting an appropriate response which is checked during the ASN inspections.

However, management of the periodic inspections of pressure equipment needs to be improved.

Although the number of significant events is stable, there are still numerous organisational or human failings. Consequently, compliance with the operational management rules, the operating range, the performance of maintenance and the integration of experience feedback must be further improved. ASN also expects to see improvements in the identification of significant events.

Improvements are moreover still necessary to meet the licensee's commitment deadlines.

To conclude, ASN observes that CIS bio international is maintaining the recovery drive it initiated in the preceding years. Areas for improvement on which CIS bio international must continue to focus its efforts include the cross-cutting functioning of the organisation, compliance with the facility baseline requirements, schedule control and operations monitoring, while remaining vigilant with regard to operating rigour and improving the safety culture.

THE CEA FONTENAY-AUX-ROSES SITE

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

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

Broadly speaking, the CEA's decommissioning and waste management strategy has been examined by ASN, which stated its position in May 2019 on the priorities defined by the CEA (see chapter 13).

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

Procédé and Support facilities

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

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

Assessment of the CEA Fontenay-aux-Roses site

The licensee must maintain its efforts to ensure the operational safety of its facilities. Safety is considered acceptable, even if areas for improvement have been identified in a number of technical subjects. The points requiring particular attention concern more specifically control of the lightning-related risk for BNI 165 and the prolonged unavailability of the fire extinguishing systems of the shielded systems of said BNI.

The management process for noteworthy modifications of the facilities is appropriate. Tracking of the maintenance and inspections of the power generating sets must nevertheless be improved.

The CEA also reported one environment-related significant event in 2021, following the discovery of legacy pollution in an inspection port linked to old pipes of the CEA Fontenay-aux-Roses site effluents system (traces of plutonium in sediments). ASN conducted a reactive inspection on this subject. The CEA took action to remove the pollution, which included cleaning operations and post-clean-out inspection. In the light of the elements given to ASN by the CEA, no consequences for people or the environment have been identified.

Broadly speaking, ASN concedes that the CEA is encountering real technical difficulties in retrieving the legacy waste currently stored in these facilities, but it again underlines the delays in performing the studies and in the scheduling of these projects. In 2021, as in the preceding year, the CEA presented ASN its forecasts concerning the coordination of the studies and work planned on the site to reduce the "dispersible inventory" within the facilities. The new organisation deployed since September 2020 for the periodic safety reviews and work on the facility decommissioning files is found to be robust but must continue to prove its effectiveness. ASN expects the CEA to continue to implement proactive measures to control and render reliable the time frames associated with these projects, particularly the deadlines announced for the submission of the decommissioning worksite preparatory studies.

Normandie
Region

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

In 2021, ASN carried out 212 inspections in Normandie, comprising 81 inspections in the NPPs of Flamanville, Paluel and Penly, 13 on the Flamanville 3 EPR reactor construction site, 64 on fuel cycle facilities, research facilities and facilities undergoing decommissioning, 48 in small-scale nuclear activities and 6 in the transport of radioactive substances.

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

In 2021, 18 significant events rated level 1 on the INES scale were reported to ASN.

In the context of their oversight duties, the ASN inspectors issued one violation report. ASN also served formal notice on two nuclear facility licensees to comply with the regulations.

Flamanville nuclear power plant

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

ASN considers that the performance of the Flamanville NPP with regard to nuclear safety, despite the observed improvements, remains slightly below its general assessment of EDF plant performance. As far as radiation protection and the environment are concerned, ASN considers that the performance is in line with its general assessment of the EDF plants.

ASN has observed improvements in nuclear safety resulting from implementation of the action plan requested as part of the tightened surveillance of the site. The inspections have more specifically revealed several organisational changes, greater attention in the monitoring of the condition of the facilities, and greater compliance with the procedures and rules of good workmanship by the workers, which leads to an improvement in the operating results. Nevertheless, the difficulties encountered when restarting reactor 1 following an outage to save fuel show that this progress must still be consolidated, particularly as concerns operational management of the reactors. Lastly, ASN notes that the time taken to characterise deviations after their detection must be shortened.

With regard to emergency management, ASN served formal notice on EDF to comply with the applicable regulations relative to emergency situation preparedness and the on-site emergency plan. Following this decision, ASN checked the measures taken to comply with the regulations and considers them to be satisfactory, as the licensee is now capable of managing an emergency situation with partial deployment of the emergency response teams. ASN also considers that improvements must be made in the management and operation of the emergency response centre, which was the subject of several anomalies during the year.

ASN notes that the situation in radiation protection is improving, more particularly with the reorganisation of the risk prevention department. Broadly speaking, the number of events concerning radiation protection reported in 2021 remains at the same level as in 2020, but with lower risks. Nevertheless, work site preparation and monitoring are still areas requiring attention in which ASN expects EDF to continue its efforts. In effect, numerous deviations are still detected due to failure to comply with work conditions and the conditions of access to controlled areas. ASN still considers that the preparation of operations involving high radiological risks must be improved.

With regard to protection of the environment, ASN notes an improvement in the organisation and good command of the activities on the part of the personnel tasked with nuclear waste management. ASN will nevertheless remain attentive to the maintaining of the efforts to clear the backlog of legacy waste stored on the site, the continuation of the action plan to reduce emissions of the greenhouse gas used for electrical isolation (SF_6), and to the operational control of the conditions of discharge into the environment and monitoring of the discharges.

ASN placed the Flamanville NPP under tightened surveillance in September 2019. In accordance with ASN's request, EDF submitted a first assessment of the practices improvement plan in early 2021 along with a projection of the actions remaining to be accomplished over the year. During the year, ASN observed various changes in the organisational methods that led to improved results. A finalised assessment of all the improvement actions was also submitted to ASN at the end of 2021. This assessment will be examined by ASN and undergo specific checks in 2022 to decide whether to maintain tightened surveillance or not.

With regard to labour inspection, ASN considers that the licensee must make improvements in the verification of the electrical installations and the protection of certain areas against the risk of falling from height.

Paluel nuclear power plant

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

The site accommodates one of the regional bases of the Nuclear Rapid Intervention Force (FARN) created by EDF in 2011, further to the Fukushima Daiichi NPP accident. 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 performance of the Paluel NPP with regard to nuclear safety and environmental protection is broadly in line with the general assessment of the EDF plants. ASN considers that the radiation protection performance stands out positively with respect to its general assessment of the EDF plants.

The last two ultimate backup diesel generator sets were commissioned for the NPP reactors 1 and 2 in early 2021, in compliance with ASN resolution 2020-DC-0692 of 28 July 2020.

With regard to operation and operational management of the reactors, ASN considers that the knowledge and command of the general operating rules during the restarting phases must be improved. For this reason, ASN will be particularly attentive to the depth of the analyses performed when anomalies are encountered on safety important components. Along with this, various significant events related to equipment lockout/tagout deficiencies should make the licensee question the rigour of its practices. ASN does nevertheless observe a notable drop in significant safety events related to control of the reactors. The fire outbreak on the main transformer of reactor 1 also showed the fast response of the operating teams to an incident situation, despite shortcomings in the management of the extinguishing water.

With regard to maintenance, ASN considers that the site's performance in 2021 remains below average. Several inspections during maintenance outages highlighted deviations concerning the fastening and installation of equipment which the licensee had nonetheless deemed compliant. In addition, the analysis of several safety-related significant events, one of which led to a retained primary system leak, revealed a lack of preparation and shortcomings in the analyses of the risks of the activities. Improvements are therefore required, firstly through more rigorous preparation of the work interventions, and secondly by the operators duly appropriating the activities before carrying them out. Lastly, the reactor 1 refuelling and maintenance outage was marked by the discovery of traces of corrosion on the steam generator tubes. ASN inspected the specific installation operations of new welded plugs caps and considers that they were carried out properly.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- **Basic Nuclear Installations:**
  - the NPPs operated by EDF, namely Flamanville (2 reactors of 1,300 MWe), Paluel (4 reactors of 1,300 MWe) and Penly (2 reactors of 1,300 MWe),
  - the Flamanville 3 EPR reactor construction site,
  - the Orano spent nuclear fuel reprocessing plant at La Hague,
  - the Andra Manche repository (CSM),
  - the National large heavy ion accelerator (Ganil) in Caen;
- **small-scale nuclear activities in the medical sector:** p. 202
  - 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 veterinary, industrial and research sectors:** p. 232
  - about 450 industrial and research centres, including 20 companies with an industrial radiography activity,
  - 5 particle accelerators, including 1 cyclotron,
  - 21 laboratories located chiefly in the universities of the region,
  - 5 companies using gamma ray densitometers,
  - about 260 veterinary surgeries or clinics practising diagnostic radiology, 1 equine research centre and 1 equine hospital centre;
- **activities associated with the transport of radioactive substances;** p. 260
- **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 radiation protection performance, ASN notes an improvement compared with 2020. The overall doses received by the workers during maintenance outages in 2021 were all below the initial estimated evaluations. The inspections confirmed the good upkeep of the work sites and, more generally, satisfactory management of the contamination risk. Nevertheless, improvements are required in the compliance with procedures for accessing limited stay areas and in the preparation of activities with high radiation exposure risks.

With regard to environmental protection, ASN notes stable performance and a reduction in uncontrolled greenhouse gas discharges. Given shortcomings observed in fire extinguishing water management during the fire on the main transformer of reactor 1, ASN carried out an on-site exercise simulating a spillage of hazardous substances. This exercise revealed improvements in the prevention of uncontrolled flows in the facility. Moreover, EDF must now endeavour to define the material modifications necessary to ensure greater robustness in the management of accidental spillages combined with heavy rainfall.

With regard to labour inspection, ASN observes on the whole that the workers know and comply with the safety requirements, but that continued improvements are necessary in this area. The ASN inspections have also evidenced deviations concerning, for example, compliance with work times, the electrical installation verifications and the management of risks of tripping and falling.

Penly nuclear power plant

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

ASN considers that the performance of the Penly NPP with regard to nuclear safety, radiation protection and environmental protection is on the whole in line with its general assessment of EDF plant performance. At the end of 2021, EDF detected stress corrosion-related cracks in the circuits connected to the main pipes of the primary system of reactor 1. This issue will lead to a large-scale inspection and repair programme in 2022.

With regard to nuclear safety, ASN considers that operating rigour dropped in 2021. Several notable events linked to the operational management activities were observed. Greater attention must thus be paid to the preparation of operational management activities in order to enhance their proper appropriation by the personnel tasked with performing them. ASN also considers that the licensee must ensure that a calm atmosphere is maintained in the control room under all circumstances.

With regard to the maintenance operations, ASN considers that greater rigour is required in the management of the work files and that the monitoring of outside contractors must be further improved. Moreover, recurrent difficulties are found in the characterisation of deviations and their monitoring over time. Lastly, on several occasions during its inspections ASN has observed deficiencies in the summary reports of the Nuclear Pressure Equipment (NPE) inspections. The licensee must be attentive to the quality of the files submitted to ASN before they are put back into service.

The maintenance operations carried out during the reactor 2 refuelling outage were well managed on the whole. On the other hand, the start of the ten-yearly outage of reactor 1 was marked by a leak on the main primary system following the rupture of a flow meter during a valve tightness check. ASN conducted a reactive inspection which found deficient preparation and a lack of rigour in the development of the work intervention risk analyses.

In the area of radiation protection, ASN considers that the site must continue the ongoing actions to correct the deviations observed in the last few years. ASN observes recurrent anomalies in the preparation of activities in controlled areas and in the radiation protection culture of the operators. The licensee must in particular try to review the procedures for the reception and awareness briefing of outside contractors. ASN also considers that particular attention must be paid to control of the contamination risk.

With regard to environmental protection, the improvements made by the licensee have to be consolidated. More specifically, ASN considers that the Penly NPP has obtained satisfactory results in waste monitoring and management. EDF must nevertheless continue and finalise its action plan to significantly reduce its emissions of greenhouse gas (SF_6) used to insulate electric lines.

With regard to labour inspection, ASN considers that the licensee must improve its management of electrical installation conformity and the preparation of activities. ASN observed an increase in accidents in the second half of the year and will be attentive to the way the situation evolves and the measures taken by the licensee.

Flamanville 3 EPR reactor construction worksite

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

On 8 October 2020, ASN authorised partial commissioning of the Flamanville EPR reactor to allow the entry of nuclear fuel into the reactor perimeter and the performance of particular operating tests of the facility requiring the use of radioactive gases. Between 26 October 2020 and 24 June 2021, all the fuel assemblies were delivered for storage in the fuel building pool. In 2021, ASN conducted an inspection on the conditions of storage of these fuel assemblies and considers them satisfactory.

In the first half of 2021, ASN inspected the first utilisation of radioactive gases within the facility. This inspection showed that the test in question was well prepared and the authorisation conditions granted by ASN for the utilisation of these radioactive tracer gases were satisfied. The preparation for the overall requalification phase that EDF plans carrying out after repairing the Main Secondary Systems (MSS) was also inspected. ASN considers at this stage that it is conducted under satisfactory conditions.

Alongside this, ASN has continued the verification of the equipment quality review which was requested in 2018 due to the serious shortcomings observed in EDF's monitoring of its outside contractors. ASN ascertained at periodic meetings in 2021 that a programme of complementary verifications was established and implemented. ASN also carried out two inspections on this subject, which found that the conditions of performance of these verifications appeared on the whole to be good. EDF must nevertheless provide additional proof of the adequacy of the programme carried out. In 2022, ASN will examine the results of this review and the conclusions EDF draws from it.

Numerous systems, structures and components were shut down during the work carried out on the MSS's in 2020. After reviewing the preservation doctrine defined by EDF, ASN conducted several inspections in 2021 to check its implementation. These inspections confirmed the quality of the coordination and the measures taken to monitor the preservation actions. EDF was however sometimes obliged to make adjustments to the initially defined strategies. The inspections did not reveal any deviations linked to these adjustments, but EDF must be more attentive to the checks when bringing out of preservation.

ASN also continued its inspection of the MSS weld repairs through two field inspection campaigns and one specific inspection of EDF, four inspections of the manufacturer Framatome and three inspections of the notified body mandated by ASN to monitor these activities. ASN considers that the various parties involved have set up an organisation and a system for monitoring the activities conducive to achieving, with confidence, a high standard of quality in the production of these welds. ASN will continue to monitor these welding activities in 2022 and will be attentive to ensuring that the resources and the organisation are adequate to carry out a larger volume of repairs at the same time.

A large amount of work and examinations still have to be carried out before the reactor is commissioned (see chapter 10), as well as preparation for future operation of the facility. Concerning this latter point, a follow-up mission to the suggestions and recommendations expressed during an Operational Safety Review Team (OSART) international audit mission conducted by IAEA experts in 2019 was carried out at the end of 2021. ASN will monitor the actions implemented by the site further to this review.

With regard to labour inspection, apart from checking that the companies working on the site comply with the provisions of labour law, ASN has checked the measures taken by the licensee further to the occurrence of several workplace accidents. ASN notes that the safety organisation is progressing and seems to be generally appropriate with regard to the regulations. Nevertheless, in view of the numerous low-level events, ASN will be attentive to compliance with the safety rules in 2022 in the transfers of equipment and premises to the future licensee.

Manche waste repository

The Manche waste disposal facility (CSM), which entered service 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 periodic safety review guidance file had resulted in ASN formulating specific demands at the end of 2017, concerning the justification of the technical principles of deployment of the long-term cover, the CSM memory system and the updating of the impact study. In this context, ASN is currently examining the CSM periodic safety review report submitted by Andra in 2019. ASN performed a specific inspection on this subject in 2021, and notes that the review process was conducted satisfactorily by the licensee, as regards the organisational set-up, the methodology used, the resources allocated to the various studies and the quality of the documents submitted to ASN. Nevertheless, points requiring particular attention are noted, concerning the need to finalise the technical qualification of a spare geomembrane if it is necessary to perform one-off repairs, formalisation of the in-house check of documents and the level of precision of the periodic safety review follow-up action plan.

With regard to operation of the facilities, ASN considers that the measures taken by the licensee to guarantee environmental monitoring were satisfactory. The licensee must nevertheless be more rigorous in the performance of its network maintenance operations.

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 therefore constitutes the main risk of 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.

The year 2021 was marked by the submission of the facility's second periodic safety review report. A substantial modification application was also filed for the facility and is currently being examined. This concerns the setting up of the Desintegration, Excitation and Storage of Radioactive Ions (DESIR) facility, whose main purpose is to create new experimentation areas based on radioactive ion beams from the SPIRAL1 and S3 facilities (experimental areas of the SPIRAL2 phase 1 facility). This project involves modifying the BNI perimeter.

ASN considers that the Ganil's performance in 2021 in the implementation of the periodic inspections and tests, control of ageing and fire-fighting is satisfactory. ASN moreover considers that the licensee has made improvements –still to be consolidated– in its documentation management, particularly in the updating of its safety baseline requirements. Improvements are still expected in the completeness of the analyses submitted in support of its various requests.

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. This site is situated about fifteen kilometres from the Channel Islands.

THE *ORANO RECYCLAGE* REPROCESSING PLANTS IN OPERATION AT LA HAGUE

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

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

The Decrees of 10 January 2003 set the individual reprocessing capacity of each of the two plants at 1,000 tonnes per year, in terms of the quantities of uranium and plutonium contained in the fuel assemblies before burn-up (in the reactor), and limit the total capacity of the two plants to 1,700 tonnes per year. The limits and conditions for discharges and water intake by the site are defined by ASN resolutions 2015-DC-0535 and 2015-DC-0536 of 22 December 2015.

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 first stored in pools to cool them down.

They are then sheared and dissolved in nitric acid to separate the pieces of metal cladding from the spent nuclear fuel. The pieces of cladding, which are insoluble in nitric acid, are removed from the dissolver, rinsed in acid and then water, and transferred to a compacting and packaging unit.

The nitric acid solution comprising the dissolved radioactive substances is then processed in order to extract the uranium and plutonium and leave the fission products and other transuranic elements.

After purification, the uranium is concentrated and stored in the form of uranyl nitrate $UO_2(NO_3)_2$. 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 precipitated by oxalic acid, dried, calcined into plutonium oxide, packaged in sealed containers and stored. The plutonium is then intended for the fabrication of Mixed OXide (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 assembly cladding are compacted and packaged in standard compacted waste packages (CSD-C).

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

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

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 installations at La Hague

SHUT DOWN INSTALLATIONS UNDERGOING DECOMMISSIONING

BNI 80 – Oxide High Activity facility (HAO):
- **HAO/North**: Facility for “under water” unloading and storage of spent fuel elements,
- **HAO/South**: Facility for shearing and dissolving spent fuel elements;

BNI 33 – UP2-400 plant, first reprocessing unit:
- **HA/DE**: Facility for separating uranium and plutonium from fission products,
- **HAPF/SPF (1 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 of fission product solutions (including the UCD: centralised alpha waste conditioning unit),
- **SPF (4, 5, 6)**: Fission product storage facilities,
- **R4**: Facility for purification, conversion to oxide and initial packaging of plutonium oxide,
- **BST1**: Facility for secondary packaging and storage of plutonium oxide,
- **R7**: Fission products vitrification facility,
- **AML • AMEC**: Packaging reception and maintenance facilities;

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.

Marking events of the year 2021

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 context of this special surveillance, thickness measurements taken in September 2021 on evaporator 4120.23 of the T2 facility showed that the operational criterion for shutting down the evaporator had been reached. In view of this, Orano decided not to restart this evaporator.

To replace these evaporators, Orano has built 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.

Storage of plutonium-bearing materials

Orano filed a noteworthy modification authorisation application in September 2021 aiming to increase the plutonium-bearing materials storage capacities in the BST1 facility. This application is part of the more general procedure conducted by Orano in response to the saturation of the storage capacities for these materials, which is linked to the operating difficulties experienced by the Melox plant. This problem gave rise to a specific hearing of Orano by the ASN Commission on 28 September 2021 and was also examined during the joint hearing of Orano and EDF relative to the balance of the "nuclear fuel cycle" on 10 February 2022.

Noncompliance with the halon substitution deadlines for certain fire-fighting devices

At the end of 2020, Orano informed ASN that the deadline of 31 December 2020 set by the European regulation governing the use of ozone-layer depleting substances could not be met for the disconnection of the halon fire-extinguishing system of facility AD2 due to contractual and technical difficulties in finding an alternative solution using another extinguishing agent. ASN conducted an inspection on 27 January 2021 to examine the industrial options chosen by the licensee to ensure compliance with the regulations and the project management steps since the regulation was published. The inspection confirmed that the fire-protection equipment using halon 1301 was still in service in the AD2 facility. It also revealed shortcomings in the leak detection methods used on these systems.

In view of these factors, ASN decided to regulate the time frames for modifying the fire-extinguishing system of the AD2 facility, by issuing a compliance notice dated 22 April 2021.

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. In 2021, ASN continued the examination of these files and remains particularly vigilant about the justification for the various decommissioning stages and the reassessment of the safety of the facilities that are maintained in their current condition.

ASN notes that the schedule push-backs requested are significant and largely due to the delays in legacy waste retrieval and packaging. Consequently, ASN will continue to monitor the management of these projects in 2022.

LEGACY WASTE RETRIEVAL AND PACKAGING OPERATIONS

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

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

Retrieval and packaging of the STE2 sludges

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

The scenario for the retrieval and packaging of the STE2 sludges presented in 2010 was broken down into three steps:
- retrieval of the sludges stored in the silos of STE2 (BNI 38);
- transfer and treatment, initially envisaged by drying and compaction, in STE3 (BNI 118);
- packaging of the resulting pellets into C5 packages for deep geological disposal.

ASN authorised the first phase of the work to retrieve the sludges from STE2 in 2015. The Creation Authorisation Decree for the STE3 effluents treatment station 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 Recyclage* 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. Orano submitted an update of the DOS to ASN in July 2020. This file is currently being examined.

At present, the technical discussions with Orano highlight the need to further the studies of the sludge treatment and packaging processes, and the possibility of interim storage of the retrieved sludge under suitably safe conditions so that this step can be separated from their final packaging.

Silo 130

Silo 130 is a reinforced concrete underground storage facility, with a carbon steel liner, used for dry storage of solid waste from the reprocessing of Gas-Cooled Reactor (GCR) fuels, and the storage of technological waste and contaminated soils and rubble. The silo received waste of this type as from 1973, until the 1981 fire which forced the licensee to flood the waste. The leak-tightness of the water-filled silo is only ensured at present by a single containment barrier consisting of a steel "skin". Today, the civil engineering structure of Silo 130 is weakened by ageing and by a 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, which at present is the only containment barrier.

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 waste retrieval and packaging scenario comprises four steps:
- retrieval and packaging of the solid GCR waste;
- retrieval of the liquid effluents;
- retrieval and packaging of the residual GCR waste and the sludges from the bottom of the silo;
- retrieval and packaging of the soils and rubble.

Orano has built a retrieval unit above the pit containing the waste and a new building dedicated to the storing and packaging operations. The works carried out on Silo 130 in 2021 allowed the retrieval of about twenty waste drums. These operations were initially carried out manually, then in semi-automatic mode. In view of the various technical problems encountered, the industrial commissioning step with waste retrieval in automatic mode could not be accomplished in 2021. Orano envisages carrying out this step in early 2022.

HAO silo and Organised Storage of Hulls

The Oxide High Activity Facility –HAO (BNI 80) ensured the first steps of the spent nuclear fuel reprocessing process: reception, storage, then shearing and dissolution. The dissolution solutions produced in BNI 80 were then transferred to the UP2-400 industrial plant in which the subsequent reprocessing operations took place.

BNI 80 comprises:
- HAO North, spent fuel unloading and storage site;
- HAO South, where the shearing and dissolution operations were carried out;
- the "filtration" building, which accommodates the filtration system for the HAO South pool;

- the HAO silo, in which are stored the hulls and end-pieces (fragments of cladding and fuel end-pieces) in bulk, fines coming primarily from shearing, and resins and technological waste from the operation of the HAO facility between 1976 and 1997;
- the Organised Storage of Hulls (SOC), comprising three pools in which the drums containing the hulls and end-pieces are stored.

In 2021, Orano continued the operations prior to retrieval of the waste from the HAO silo (notably the fitting out of the future waste retrieval unit) and the tests important to safety which began in 2019. On completion of the in-depth analysis of hard spots identified during the functional tests conducted in early 2021, Orano made organisational improvements and started significant material modifications. Implementing these modifications significantly pushes back the estimated date of waste retrieval.

Assessment of the La Hague site

ASN considers that the performance of the *Orano Recyclage* La Hague site in 2021 is satisfactory in the areas of nuclear safety, radiation protection and environmental protection.

With regard to nuclear safety, Orano must endeavour to continue the improvements underway in the formalising of operator authorisations and the deployment of the operational management teams. Particular attention must also be paid to the training and appointing of the operators ensuring the local response group functions, and to the rigour in the traceability of the various operational tracking registers.

ASN considers that the licensee has improved its aids for monitoring outside contractors, but must now try to be more rigorous in the filling out of these tracking documents. It would also seem necessary to conduct a cross-site reflection on the precision with which the monitoring stop points are defined during operations carried out by outside contractors and on the rigour of their validation. The licensee must also be attentive to the proper deployment of the teams of certain facilities placed under the responsibility of industrial operators, such as the asbestos laboratory, in order not to induce delays in the decommissioning and legacy waste retrieval operations.

ASN also considers that the licensee has satisfactorily carried out the required work to reinforce fire detection and protection. Orano has also adapted the human resources provided during unannounced fire-fighting exercises conducted by ASN. The licensee must nevertheless be vigilant regarding its rigour in the management of fire permits, fire loads and fire-fighting means specific to work sites.

ASN considers that Orano must reinforce its forward-looking initiatives for managing the capacities of certain storage areas, such as those for plutonium–bearing materials, in order to define storage arrangements and solutions offering a high level of safety.

Lastly, ASN considers that the licensee must be more rigorous when gathering the results of investigations associated with the corrosion phenomena on the fission product evaporators-concentrators, and take care to maintain a questioning attitude when analysing the results.

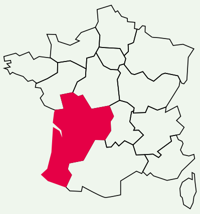
With regard to radiation protection, the year 2021 was marked by the continued implementation of the new radiation protection organisation. ASN notes that the La Hague site's organisation and results are satisfactory, particularly regarding compliance with the site's estimated dosimetric evaluations and control of exposure levels. However, ASN considers that Orano must be more rigorous with the traceability of radioactive sources and the management of outside contractors tasked with performing the regulatory technical verifications.

With regard to environmental protection, in June 2021 ASN carried out a tightened inspection of the measures adopted and implemented by the licensee to prevent and control the detrimental effects and environmental impact of the site's activity. This inspection revealed satisfactory control of the liquid and gaseous effluent discharges, and several recent improvements relating to the control of risks in the chemical product storage areas and the operational procedures for managing accidental pollution on the site. Orano must nevertheless be vigilant with regard to the conformity of equipment and facilities presenting a risk for protection of the environment, particularly the identification of the related requirements and the correct performance of the associated inspections.

As far as the management of decommissioning and legacy waste retrieval and packaging projects is concerned, progress was made in 2021, with Orano gradually implementing, as from early 2021, major improvements in project organisation and management, such as the putting in place of a collaborative tool that provides all the elements relating to decommissioning project management in digital format, or the use of readiness matrices for the various project steps. These improvements, which promote greater robustness, must nevertheless still be generalised and consolidated.

ASN does however observe that several legacy waste retrieval and packaging projects are facing difficulties leading to new delays (see the waste retrieval and packaging project observatory –chapter 13).

ASN considers that Orano must guarantee that governance decisions are taken on the basis of soundly argued and formalised hypotheses. It must also plan ahead to define alternative solutions in the event of uncertainties in project implementation.



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 2021, ASN carried out 143 inspections in the Nouvelle-Aquitaine region, comprising 60 in the Blayais and Civaux NPPs, 66 in small-scale nuclear facilities, 7 in the area of radioactive substance transport and 10 concerning approved organisations and laboratories.

ASN also carried out 13 days of labour inspection at the Blayais NPP and 15.5 days at the Civaux NPP.

During 2021, 9 significant events rated level 1 on the INES scale were reported by the NPP licensees of Nouvelle-Aquitaine. In small-scale nuclear activities, 5 significant radiation protection events rated level 1 on the INES 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. This NPP comprises four 900 MWe PWRs. Reactors 1 and 2 constitute BNI 86, and reactors 3 and 4 BNI 110.

ASN considers that the performance of the Blayais NPP with regard to nuclear safety, radiation protection and environmental protection is in line with ASN's general assessment of the EDF plants. However, despite this assessment, ASN considers that improvement measures are necessary to overcome the current deterioration in nuclear safety performance.

The nuclear safety performance of the Blayais NPP was variable during 2021. In the operational management of the reactors, the deployment of an action plan in the first half of the year to improve the quality of operation and supervision of control room activities resulted in satisfactory performance. A drop in performance during the summer and at the end of the 2021 however resulted in the reporting of numerous significant events. ASN considers it is necessary to take measures regarding the organisation and distribution of responsibilities in the control room. ASN also observes persistent deficiencies in the quality of the operational documentation covering the preparation and performance of the activities. On the other hand, in the area of maintenance, ASN notes a good command of the activities carried out during the reactor outages and appropriate handling of anomalies encountered.

A tightened inspection in the area of occupational radiation protection in 2021 showed that improvements were required. ASN considers that performance levels have improved compared with 2020 and underlines the deployment of an ambitious action plan in this area. Nevertheless, ASN's inspections still find numerous deviations in the way this risk is taken into account on the facilities, indicating a lack of radiation protection culture on the part of certain workers. It is therefore necessary to continue monitoring, training and providing information on this subject. Lastly, ASN notes that a number of detected events should have been reported and analysed in greater depth to prevent their recurrence.

With regard to environmental protection, ASN considers that the situation has significantly improved in various areas noted in the last few years, such as the treatment of legacy pollution of the soils and the confined aquifers of the site, or the reinforcement of the sealing of the liquid discharge pipes in the Gironde Estuary. ASN nevertheless notes that investigations are still necessary to characterise the exact origin of the liquid tritium pollutions, and that depollution actions must be continued in 2022. It observes moreover that work remains to be carried out to guarantee the containment of accidental liquid spillages on the site under all circumstances. ASN underlines with approval the licensee's transparency on these subjects and its drive in 2021 to remove waste that has been waiting to be removed for many years.

Concerning labour inspection, ASN considers that there is a deterioration in worker safety results. ASN has observed risk situations for personnel working at height, and the occurrence of events affecting safety linked to hand-held power tools. ASN has nevertheless noted positively the setting up of work site protection reviews. On 1 October last, the Bordeaux division and the Regional Directorates of the economy, employment, labour and solidarity of Nouvelle-Aquitaine and Occitanie held a half-day meeting with employers, ordering customers and employees of companies performing work that could cause the emission of asbestos fibres, in order to raise awareness on the prevention of this risk.

Civaux nuclear power plant

The Civaux NPP is operated by EDF in the Vienne *département*, 30 km south of Poitiers in the Nouvelle-Aquitaine region. It comprises two 1,450 MWe PWRs. Reactor 1 constitutes BNI 158 and reactor 2 BNI 159. 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 nuclear safety and radiation protection performance of the Civaux NPP stand out positively with respect to its general assessment of EDF plant performance, and that its environmental protection performance is in line with this general assessment. At the end of 2021, EDF detected stress corrosion-related cracks in the circuits connected to the main pipes of the primary system of the two reactors. This issue will lead to a large-scale inspection and repair programme in 2022.

ASN considers that the nuclear safety performance of the Civaux NPP remained stable in 2021. ASN considers that the reactor management operations are on the whole conducted with rigour and that the NPP is capable of preventing, detecting and correcting inappropriate operating actions. ASN nevertheless considers that the licensee must improve its management of the system for treating and cooling the water of the fuel storage pools and the reactor pools, which was the subject of several significant safety event reports in 2021.

With regard to maintenance, ASN considers that, on the whole, the licensee proficiently handled performance of the scheduled activities during the reactor 2 refuelling and maintenance outage and that its management of contingencies was satisfactory. Nevertheless, the activities programme was significantly delayed by maintenance operations on the emergency generators; proficiency in these operations must be improved. ASN considers it necessary to maintain these levels of performance in 2022, given the forthcoming second ten-yearly outage of the two reactors.

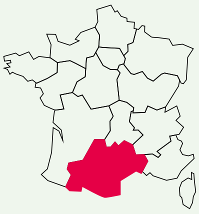
With regard to radiation protection, ASN considers that the radiological cleanliness of the premises is one of the Civaux NPP's strong points. In 2021, ASN conducted a tightened radiation protection inspection which concluded that the limitation of occupational exposure to ionising radiation was satisfactory, except in industrial radiography work. Nevertheless, deficiencies in the purification of the primary system during the reactor 2 shutdown had a significant impact on the collective dosimetry received by the workers.

With regard to environmental protection, ASN considers that the Civaux NPP's management of radioactive waste and radiological effluents in 2021 was satisfactory. The licensee has defined a lasting solution for preventing run-offs and unplanned dispersion of radioactive or hazardous liquid substances into the environment. Nevertheless, an ultimate containment pond must be built to guarantee on-site containment of accidental spillages of liquid effluents or fire extinguishing water in the event of a fire combined with heavy rainfall.

With regard to labour inspection, ASN considers that the results in occupational safety are improving and notes positively the setting up of work site protection reviews and a good standard of activity preparation. ASN has nevertheless observed recurrent deficiencies in the control of the asbestos-related risk, which resulted in accidental exposures in 2021. ASN notes several events relating to occupational safety linked to hand-held power tools and risk situations for workers relating to work at height and electrical work. ASN considers that the regulatory monitoring of the electrical installations of the industrial and tertiary buildings must be improved.

THE INSTALLATIONS AND ACTIVITIES TO REGULATE COMPRISE:

- **Basic Nuclear Installations:**
  - the Blayais NPP (4 reactors of 900 MWe),
  - the Civaux NPP (2 reactors of 1,450 MWe);
- **small-scale nuclear activities in the medical sector:** p. 202
  - 19 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 24 nuclear medicine departments,
  - 85 centres performing fluoroscopy-guided interventional procedures,
  - 116 computed tomography scanners,
  - some 6,000 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - about 700 industrial and research centres, including 55 companies with an industrial radiography activity,
  - 1 cyclotron particle accelerator,
  - 55 laboratories located chiefly in the universities of the region,
  - about 500 veterinary surgeries or clinics practising diagnostic radiology;
- **activities associated with the transport of radioactive substances;** p. 260
- **ASN-approved laboratories and organisations:**
  - 4 organisations approved for radiation protection controls,
  - 14 organisations approved for measuring radon,
  - 6 laboratories approved for taking environmental radioactivity measurements.



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 2021, ASN carried out 125 inspections in the Occitanie region, comprising 52 inspections in BNIs, 62 in small-scale nuclear activities, 6 in the transport of radioactive substances and 5 concerning organisations and laboratories approved by ASN.

ASN also carried out 14 days of labour inspection at the Golfech NPP.

During 2021, four significant events rated level 1 on the INES scale were reported by the licensees of the nuclear installations in Occitanie. In small-scale nuclear activities, 4 significant radiation protection events rated level 1 on the INES scale were reported to ASN (3 in the industrial sector and 1 in the medical sector).

Golfech nuclear power plant

The Golfech NPP operated by EDF is located in the Tarn-et-Garonne *département*, 40 km west of Montauban. This NPP comprises two 1,300 MWe PWRs. Reactor 1 constitutes BNI 135 and reactor 2 BNI 142.

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

With regard to nuclear safety, ASN considers that deployment of the Safety rigour plan since 2019 demonstrates senior management's commitment to improving the site's nuclear safety performance. Nevertheless, the actions and efforts undertaken in this context have not yet produced visible results on the Golfech NPP indicators. The reactor 2 maintenance and refuelling outage in 2021 revealed shortcomings in operational management, already identified in preceding years: skills deficiencies and insufficient serenity and organisation in the control room. These shortcomings resulted in the reporting of numerous significant safety events, three of which were rated level 1 on the INES scale. ASN considers that in 2022 the licensee must improve the monitoring of control room activities by enhancing the operators' skills and defining the role of each player, particularly as regards supervision of the activities.

The NPP's maintenance performance must be improved, particularly in view of the numerous unexpected events induced by operations performed during the reactor 2 outage, which overran the initial schedule by four and a half months. The deviations in the maintenance operations performed on the valves and the emergency diesel generator sets in particular, revealed deficiencies in proficiency and command of the activities. Despite an improvement in the handling of deviations detected on the equipment in 2021, ASN considers that the licensee must step up its efforts in this area to reach the required standard.

With regard to occupational radiation protection, ASN considers that the efforts made by the site in 2021 have borne fruit, more specifically through an improvement in the workers' attitude with respect to radiation protection rules. ASN noted that the collective dosimetry objectives were met during the reactor 2 outage, despite its prolongation. Two tightened inspections conducted in 2021 concluded that the situation regarding the limitation of occupational exposure to ionising radiation was satisfactory.

In the area of environmental protection, ASN considers that the Golfech NPP obtained satisfactory results. The Golfech site must nevertheless progress in its strategy for preventing run-offs and unplanned dispersion of radioactive or hazardous liquid substances into the environment, particularly as concerns the sealing of the containment pond and of the valves shutting off liquid discharges into the natural environment.

With regard to labour inspection, ASN considers that coordination of the risks associated with the interface between different activities must be improved, as must the quality of activity preparation and risk analyses. ASN considers that the occupational safety results for the site are improving. Nevertheless, an accidental exposure to asbestos in 2021 shows that this risk must be more seriously taken into account, as must the risk situations relating to work at height. ASN also noted recurrent deficiencies in the regulatory monitoring of the electrical installations.

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 Mixed Oxide (MOX) fuels, the processing of radioactive waste and the irradiation of materials. The majority of the site moreover consists of Defence Basic Nuclear Installations (DBNIs), 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 expand the research activities, equipment and activities from the CEA Cadarache centre's Laboratory for research and fabrication of advanced nuclear fuels (Lefca) were transferred there in 2017.

On completion of the analysis of the facility's periodic safety review report submitted in December 2016, ASN made available for public consultation a draft resolution intended to regulate the continued operation of the BNI. The CEA's improvement action plan in this context notably includes reinforcement of control of the fire risk.

In June 2021, laboratory L6 –which had been closed since an event of 19 December 2018, rated level 1 on the INES scale, involving the shattering of a flacon containing a radioactive liquid during handling in a glove box– was reopened by the licensee after having performed the periodic inspections and tests that were suspended following the accident. The licensee was thus able to carry out the operations to neutralise the reagents and retrieve the waste contained in the glove box in question. ASN considers that the follow-ups to this event were managed satisfactorily.

In 2020, ASN had observed shortcomings in radiation protection, in the management of deviations and the operational management of accident situations, as well as in the emergency organisation and means. ASN considers that efforts were made during 2021 to comply with the regulations in these areas.

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 plant producing MOX nuclear fuel,
  - the Centraco low-level radioactive waste processing facility,
  - the Gammatec industrial ioniser;
  - the facility for storing Écrin waste on the Malvési site;
- **small-scale nuclear activities in the medical sector:** p. 202
  - 14 external-beam radiotherapy departments,
  - 6 brachytherapy departments,
  - 21 nuclear medicine departments,
  - 99 centres performing fluoroscopy-guided interventional procedures,
  - 126 computed tomography scanners,
  - some 5,000 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - about 800 industrial and research centres, including 4 cyclotron particle accelerators, 31 companies exercising an industrial radiography activity and 65 laboratories situated mainly in the universities of the region,
  - about 560 veterinary surgeries or clinics practising diagnostic radiology;
- **activities associated with the transport of radioactive substances;** p. 260
- **ASN-approved laboratories and organisations:**
  - 4 laboratories approved for taking environmental radioactivity measurements,
  - 6 organisations approved for measuring radon,
  - 7 organisations approved for radiation protection controls.

ASN considers that the overall level of safety is satisfactory in the areas of deviation management, consideration of organisational and human factors and the meeting of commitments, which are followed up and have good traceability, with technical actions that are carried out and checked. ASN remains vigilant regarding occupational radiation protection and compliance with the regulations concerning the use of hazardous substances.

Assessment of the CEA Marcoule centre

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

In 2021, ASN inspected the management of on-site transport and the measures taken to deliver the modification authorisations to the nuclear installations of the centre. Control of the modification management procedures and the application of modifications within the BNI is satisfactory on the whole. ASN nevertheless remains attentive to the quality of the checks carried out prior to transport operations.

In 2021, ASN conducted an in-depth inspection to assess the CEA's ability to apply its new waste management and decommissioning strategy both nationally and locally. ASN more specifically checked the measures implemented by the licensee to conduct, in accordance with the commitments made, the priority operations of reducing the dispersible inventory in the facilities undergoing decommissioning.

With regard to environmental protection, the CEA submitted a study in 2020 relative to the sanitary and environmental assessment of the liquid and gaseous chemical discharges from the Marcoule platform. ASN has asked the licensee to supplement its study and propose a third-party expert to appraise this assessment. ASN will make sure that the action plan to bring the piezometers of the CEA Marcoule centre into compliance with the Order of 11 September 2003 by 2024 is implemented. In addition, the CEA continued the initiative to improve management of the Phénix stormwaters in 2021. It informed ASN that the work initiated further to the technical-economic study on this subject should be completed by the end of the first half of 2022.

Phénix reactor – *CEA centre*

The Phénix NPP (BNI 71) is a demonstration fast breeder reactor cooled with liquid sodium. This reactor, with an electrical power rating of 250 MWe, was definitively shut down in 2009 and is currently being decommissioned.

The major decommissioning phases are regulated by Decree 2016-739 of 2 June 2016. ASN resolution 2016-DC-0564 of 7 July 2016 sets the CEA various milestones and decommissioning operations.

Removal of the spent fuel and equipment continued in 2021 in accordance with the ASN requirements and the licensee's commitments made during the facility's periodic safety review and transition to the decommissioning phase. Uncertainties concerning the future and the processing of the spent fuel from Phénix (see chapter 11) nevertheless remain.

ASN considers that the level of nuclear safety and radiation protection of the Phénix NPP is satisfactory on the whole, particularly regarding the meeting of commitments and the monitoring of outside contractors, and that deviations are well managed. Progress has been made in bringing the facility into compliance with certain articles of resolution 2013-DC-0360 of 16 July 2013 and with the resolution that specifically regulates the discharges from the Phénix NPP. The facility has also begun a campaign of detailed radiological mapping of some of its premises, in order to optimise its waste zoning and thus direct the waste produced to appropriate management routes.

Construction of the NOAH facility, which will treat the sodium from Phénix and other CEA installations, progressed in 2021 and the operating tests prior to commissioning are continuing. ASN has however been informed of contractual difficulties on one of the site work packages, which will push back commissioning of the NOAH facility.

The licensee is currently redefining the reference scenario for facility decommissioning, in line with the decommissioning strategy for all the CEA facilities. These changes in the reference scenario will lead to a request to modify the decree, which requires NPP decommissioning to follow a predetermined schedule. The next periodic safety review report is moreover expected at the end of 2022.

Diadem facility – *CEA centre*

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

ASN considers that there are numerous shortcomings in the organisational set-up for project control, for exercising the responsibility of nuclear licensee and for processing deviations. The CEA must thus take all necessary measures to guarantee compliance with the regulatory requirements in these areas. The procedures undertaken by the licensee to restore an acceptable situation, further to ASN's oversight action concerning the processing of deviations or its responsibilities as nuclear licensee, are satisfactory on the whole, even if a considerable amount of work still has to be accomplished.

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 waste packages it is to receive.

The CEA filed a request to modify the Creation Authorisation Decree (DAC) in 2021 further to change in the package closure technology. It also filed its commissioning authorisation application file for the facility in 2021. The operations necessary for its commissioning, today planned for 2024, must be a priority for the CEA.

Melox plant

Created in 1990 and operated by *Orano Recyclage*, the Melox plant (BNI 151) produces MOX fuel which consists of a mix of uranium and plutonium oxides.

ASN considers that the level of nuclear safety and radiation protection is satisfactory on the whole, particularly in the areas of maintenance, control of the fire risk, management of internal authorisations and the management of waste and the cooling functions.

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. As one of the identified causes of these ruptures is the perforation of gloves in glove boxes, the licensee has developed specific reinforced gloves.

In addition, for several years now the licensee has had difficulties in producing the planned quantities of fuel in accordance with the safety specifications of the nuclear reactors. These difficulties seem to originate from the characteristics of the uranium powders used. The licensee has therefore decided to qualify a new type of powder whose production requires the creation of a new facility situated on Orano's Malvési site (see chapter 11). This situation results in the production of a large quantity of fabrication rejects which are sent to La Hague for interim storage, leading in the short term to the site's plutonium storage areas being filled to maximum capacity. If these difficulties continue, they could have major consequences for the fuel cycle as a whole. This issue was discussed with the ASN Commission at the hearings of 28 September 2021 and 10 February 2022.

This situation induces significant maintenance needs at Melox, which have consequences in terms of radiation protection, with a growing reliance on outside contractors and a very high collective dosimetry.

The solutions envisaged at present to 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. With this aim in view, research and development work has started on the processes for cleaning the facility equipment and on the materials to protect the workers. More particularly, the dosimetry at the lens of the eye remains high. Substantial research and development work has led to the gradual introduction of ergonomic radiation-proof glasses, adapted to the sight of the workers (including outside contractor employees), with the aim of complying with the new downwardly-revised regulatory limits. Furthermore, a vast Machinery Repair Programme (PPRM project) began in 2021.

Construction of the emergency centre has fallen behind schedule for reasons linked to the technical and contractual difficulties encountered. At the request of the licensee, ASN has modified the requirement of the resolution concerning the deadline for commissioning of the emergency centre accordingly, which is now set at 2023.

Centraco plant

The Centraco plant (BNI 160), was created in 1996 and is operated by Cyclife France, a 100% subsidiary of EDF. The purpose of the Centraco plant is to sort, decontaminate, reuse, treat and package –particularly by reducing their volume– waste and effluents with low and very low levels of radioactivity. The waste resulting from the plant's processes is then routed to Andra's CSA repository. The facility comprises:
- **a melting unit, melting a maximum of 3,500 tonnes of metallic waste per year;**
- **an incineration unit, in which the incinerable waste is burned, with a maximum of 3,000 tonnes of solid waste and 2,000 tonnes of liquid waste per year;**
- **and storage areas.**

ASN considers that the level of safety of the facility is satisfactory on the whole, particularly with regard to meeting commitments, deviation management, water take-ups and effluent discharges, and the monitoring of discharges and the environment. ASN does however note an increase in the number of significant events reported in 2021.

A new version of the On-Site Emergency Plan (PUI) was authorised by ASN in April 2021, to render it compliant with resolution 2017-DC-0592 of 13 June 2017 relative to the obligations of BNI licensees regarding emergency situation preparedness and management.

Furthermore, Cyclife France sent ASN modification requests for its facility in 2020 to allow the treatment of particular types of waste in Centraco, with specific sorting put in place for this waste. ASN considers that the technical and organisational provisions presented by the licensee for this prior sorting operation in dedicated units are satisfactory in principle, but double-checking of the conformity of the waste introduced into the incineration or melting furnaces must be maintained without fail. ASN thus modified the requirements of ASN resolution 2008-DC-0126 of 16 December 2008 through resolution CODEP-CLG-2022-003400 of 19 January 2022.

The monitoring and control of ageing of the facility, especially as concerns the fire-risk protection equipment, are one of the major challenges of the periodic safety review, the conclusions of which were submitted by the licensee in 2021. In 2021, the licensee more specifically implemented corrective measures to prevent the risk of jamming of the incineration furnace waste introduction chamber flaps further to a fire outbreak in this chamber in 2020.

Gammatec ioniser

The Gammatec ioniser (BNI 170) is an industrial irradiator operated by the company Stéris since 2013. Gammatec treats products by ionisation (emission of gamma radiation), with the aim of sterilising them or improving the performance of the materials. The installation consists of an industrial bunker and an experimental bunker. Both bunkers contain sealed sources of cobalt-60, which provide the radiation necessary for the facility's activity.

ASN considers that the level of safety of the instrumentation and control system and radiation protection are satisfactory on the whole in 2021.

The licensee must remain attentive to the formalisation of the periodic inspection and test results and the currency of the personnel authorisations to enter the experimental bunker.

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 entire plant is subject to the system governing Seveso high-threshold Installations Classified for Protection of the Environment (ICPEs).

The Écrin BNI consist of two storage basins (B1 and B2) containing the legacy sludge from the plant. These two basins have BNI classification, due to the presence of traces of artificial radioisotopes. This BNI was authorised by Decree of 20 July 2015 for the storage of radioactive waste, for a period of 30 years.

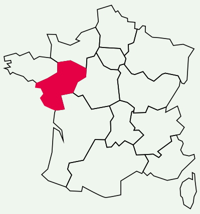
The Ecrin facility was commissioned by ASN resolution 2018-DC-0645 of 12 October 2018. This authorisation enabled the licensee to start the work defined in the DAC, which it effectively began in February 2019.

The activities continued in 2021 with the installation of a bituminous cover over the entire BNI apart from PERLE ("Project for reversible storage of lagoons"), which is a cell dug in the Écrin BNI to the south of basin B2 and allowing the storage of materials emptied from basins B5 and B6. The activities on this cell are still in progress.

An unannounced inspection was held in May 2021. ASN has noted that the sludge transfer work is well organised and considers that the activities are carried out satisfactorily.

On 12 February 2021, in application of Article 7 of the Decree of 20 July 2015, the licensee submitted the progress report for the 2015-2020 studies and investigations conducted to assess the feasibility of the disposal options for the waste currently stored within 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 2021, ASN carried out 36 inspections, comprising 2 inspections in the facilities of the company Ionisos (Pouzauges and Sablé-sur-Sarthe), 2 inspections of approved organisations, 2 in the transport of radioactive substances and 30 in small-scale nuclear activities (16 in the medical sector and 14 in the industrial, research and veterinary sectors).

One significant event in the industrial sector was rated level 1 on the INES scale in 2021.

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:** p. 202
  - 7 external-beam radiotherapy departments,
  - 2 brachytherapy units,
  - 11 nuclear medicine departments,
  - 40 centres performing fluoroscopy-guided interventional procedures,
  - 55 computed tomography scanners,
  - some 2,500 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - 1 cyclotron,
  - 26 industrial radiography companies, including 10 performing gamma radiography,
  - 20 research units,
  - about 400 users of industrial equipment;
- **activities associated with the transport of radioactive substances;** p. 260
- **ASN-approved laboratories and organisations:**
  - 9 organisations approved for measuring radon,
  - 1 head-office of a laboratory approved for environmental radioactivity measurements.

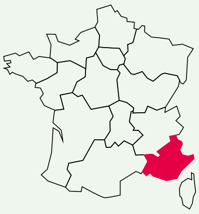
Ionisos irradiator

The company Ionisos operates two industrial ionisation installations on the sites of Pouzauges (Vendée *département*) and Sablé-sur-Sarthe (Sarthe *département*). These installations constitute BNIs 146 and 154 respectively.

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

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

ASN considers that the operation of the Pouzauges and Sablé-sur-Sarthe irradiators is generally satisfactory with regard to nuclear safety and radiation protection, with improvements in waste management and the integration of operating experience feedback. Improvements must nevertheless be made in the management of modifications, the management of emergency situations and operating rigour. Two modifications of the Pouzauges facility were authorised in 2021, concerning the extension of the facility and the installation of equipment and provisions for checking the integrity of radioactive sources.



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 2021, ASN carried out 130 inspections in the Provence-Alpes-Côte d'Azur (PACA) region, comprising 61 inspections in BNIs, 59 in small-scale nuclear activities, 5 in the transport of radioactive substances and 5 concerning organisations and laboratories approved by ASN.

During 2021, 9 significant events rated level 1 on the INES scale were reported by the nuclear installation licensees.

In small-scale nuclear activities, 2 significant events in the industrial sector and rated level 1 on the INES scale were reported to ASN. In the medical sector, 2 significant events rated level 2+ and 3 respectively on the ASN-SFRO scale were reported to ASN.

In the exercise of their oversight duties, the ASN inspectors served notice on one BNI licensee to comply with Regulation (EC) 1005/2009 of the European Parliament and Council of 16 September 2009 on substances that deplete the ozone layer.

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.

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 Solid Waste Treatment Station (STD –BNI 37-A);
- the Active Effluent Treatment Station (STE –BNI 37-B);
- the Plutonium Technology Facility (ATPu –BNI 32);
- the Masurca research reactor (BNI 39);
- the Éole research reactor (BNI 42);
- the enriched Uranium Processing Facilities (ATUe –BNI 52);
- the Central Fissile Material Warehouse (MCMF –BNI 53);
- the Chemical Purification Laboratory (LPC –BNI 54);
- the High-Activity Laboratory LECA-STAR (BNI 55);
- the solid radioactive waste storage area (BNI 56);
- the Phébus research reactor (BNI 92);
- the Minerve research reactor (BNI 95);
- the Laboratory for research and experimental fabrication of advanced nuclear fuels (Lefca –BNI 123);
- the Chicade laboratory (BNI 156);
- the Cedra storage facility (BNI 164);
- the Magenta storage warehouse (BNI 169);
- the Effluent advanced management and processing facility (Agate –BNI 171);
- the Jules Horowitz Reactor (JHR –BNI 172), under construction.

At the Cadarache centre, 10 installations are in final shutdown status, 10 are in operation and one is under construction. The CEA Cadarache centre operates numerous installations, which vary in their nature and their safety implications. ASN has moreover started or is continuing the examination of the periodic safety review guidance files or the conclusion reports for 15 of the 21 installations: Pégase-Cascad, Cabri, Rapsodie, STD, STE, ATPu, Éole, LPC, STAR, the Storage area, Phébus, Minerve, Chicade, Cedra and Magenta, and has given its conclusions on the periodic safety reviews of the ATUe facilities and the MCMF. 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.

In November 2021, the CEA provided additional elements for the Pégase facility decommissioning file, which was submitted in 2019 and is currently being examined.

With the aim of meeting the new deadlines of resolution CODEP-CLG-2020-062379 of 21 December 2020 concerning the removal of the radioactive substances present in the Pégase pool, the CEA submitted two authorisation application files to ASN in June 2021 concerning the setting up of the DECAP project for removal from storage of the araldite-encapsulated fuels of Pégase, for transfer to the Cascad facility. These applications are currently being examined by ASN.

In the course of the document verifications relative to the removal of the fuels stored in the Pégase BNI for transfer to the Cadarache DBNI, the CEA discovered a deviation concerning the physical-chemical nature of a fuel assembly transported between the two facilities in 2016. This gave rise to a significant event report in 2021 rated level 1 on the INES scale by ASN, for noncompliance with the conditions of use of the transport packaging.

ASN considers that the transfers of fuel from the Cascad facility to La Hague continued in accordance with the objectives set by the CEA in its last letter applying for renewal of the storage authorisation.

ASN considers that the nuclear safety and radiation protection of the Pégase and Cascad facilities for 2021 is on the whole satisfactory. ASN notes the continued satisfactory performance of the actions resulting from the last periodic safety review, particularly concerning the reinforcement and redundancy work on the two discharge outlets and the fire protection work.

The inspections in 2021 have also revealed proficiency in the modification management procedures and proper application of ASN resolution 2017-DC-0592 of 30 November 2017 on the management of emergency situations within the BNI.

Cabri research reactor – *CEA centre*

The Cabri reactor (BNI 24), created on 27 May 1964, is intended for conducting experimental programmes aiming to achieve a better understanding of the behaviour of nuclear fuel in the event of a reactivity accident. The reactor has been equipped with a pressurised water loop since 2006, in order to study the behaviour of the fuel at high combustion rates in accident situations of increasing reactivity in a PWR. Since January 2018, the CEA has been conducting a programme of tests called "CIP" (Cabri International Program), which began in the early 2000's and necessitated substantial modification and safety upgrading work on the facility.

On 25 September 2020, the licensee reported a significant event concerning a leak detected and collected in the "core water" system containment, and a second event on 17 February 2021 relative to a leak concerning a hodoscope, which is one of the neutron measuring instruments. ASN examined the safety of the reactor taking into consideration the action plan and the compensatory measures proposed by the CEA to deal with these two leaks. Resuming of the tests will thus be subject to ASN authorisation.

In this context, ASN is also examining a request, submitted in 2019, to modify the facility's Creation Authorisation Decree (DAC) with the aim of performing irradiation tests on electronic equipment.

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 currently under construction,
  - the ITER installation construction site, adjacent to the CEA Cadarache centre,
  - the Gammaster industrial ioniser;
- **small-scale nuclear activities in the medical sector:** p. 202
  - 13 external-beam radiotherapy departments,
  - 3 brachytherapy departments,
  - 16 nuclear medicine departments,
  - 112 centres performing fluoroscopy-guided interventional procedures,
  - 118 computed tomography scanners,
  - some 8,200 medical and dental radiology devices;
- **small-scale nuclear activities in the veterinary, industrial and research sectors:** p. 232
  - about 400 industrial and research centres, including 3 cyclotron particle accelerators and 21 companies with an industrial radiography activity,
  - about 460 veterinary surgeries or clinics practising diagnostic radiology;
- **activities associated with the transport of radioactive substances;** p. 260
- **ASN-approved laboratories and organisations:**
  - 2 laboratories approved for taking environmental radioactivity measurements,
  - 1 organisation approved for measuring radon,
  - 7 organisations approved for radiation protection controls.

ASN considers that emergency management and the management of internal authorisations are satisfactory on the whole. The level of safety of the reactor is relatively satisfactory, but the observed faults require appropriate action before it is restarted.

Rapsodie research reactor – *CEA centre*

The Rapsodie reactor (BNI 25) is the first sodium-cooled fast-neutron reactor built in France. It operated from 1967 to 1978. A sealing defect in the reactor pressure vessel led to its final shutdown in 1983. Decommissioning operations were subsequently undertaken, but have been partially stopped further to a fatal accident in 1994 during the washing of a sodium tank. At present, the core has been unloaded, the fuel evacuated from the installation, a large part of the fluids and radioactive components have been removed and the reactor vessel is contained. The reactor pool has been emptied, partially cleaned out and decommissioned, and the waste containing sodium has been removed.

The Decree governing the Rapsodie decommissioning operations was signed on 9 April 2021. This Decree sets a new perimeter for the facility and regulates, until 2030, the next phase of reactor life, consisting in the treatment of the sodium from the reactor and introducing air into the tank containing it. The subsequent decommissioning operations, such as decommissioning of the reactor block or of the civil engineering structures, shall be covered by a new decommissioning file.

ASN has attached two resolutions to this Decree. Resolution 2021-DC-0712 of 3 August 2021 requires the CEA to obtain ASN's consent to start the operations to neutralise the sodium in the tank. Resolution CODEP-CLG-2021-037079 of 3 August 2021 details the content of the application file to be submitted for these operations and sets requirements for limiting the safety impact of a fire.

Furthermore, on this occasion, ASN ruled on the conclusions of the facility's periodic safety review. It considered that, subject to compliance with these two resolutions, it had no objection to the continued decommissioning of the facility.

ASN considers that the level of nuclear safety and radiation protection of this facility in 2021 is on the whole satisfactory. The licensee must nevertheless remain attentive to the monitoring of outside contractors.

Solid waste treatment station *– CEA centre*

BNI 37 of CEA Cadarache historically comprised the active Effluents Treatment Station (STE) and the Waste Treatment Station (STD), grouped into a single installation. As the CEA wishes to ensure continued operation of the STD and proceed with the final shutdown of the STE, BNI 37 was divided into two BNIs: 37-A (STD) and 37-B (STE) by ASN resolutions CODEP-DRC-2015-027232 and CODEP-DRC-2015-027225 of 9 July 2015. These records were made further to the Orders of 9 June 2015 defining the perimeters of these two BNIs.

At present, the STD is the CEA's only civil BNI licensed for the packaging of intermediate-level, long-lived (ILW-LL) radioactive waste before it is stored in the Cedra facility (BNI 164) pending transfer to a deep geological repository. This situation makes the STD an indispensable part of the CEA's decommissioning and waste management strategy.

The continued operation of the STD necessitates renovation work –particularly on the civil engineering structures, which has been prescribed by ASN Chairman's resolution CODEP-CLG-2016-015866 of 18 April 2016. ASN authorised these works on 20 January 2022. In view of the lateness in starting the works, which necessitated a complex examination process, the CEA could not meet the prescribed completion deadline of 2021 and requested an extension.

After in-depth analysis of the technical and organisational provisions proposed by the licensee, ASN gave authorisation in October 2021 for retrieval of the package which fell into the ILW-LL waste storage pit in 2017. The CEA carried out the retrieval operations on 15 December 2021. This return to normal should make it possible to increase the waste packaging rates in the STD and allow removal of the waste before operation of the facility is stopped temporarily for works. The lessons the licensee learned from this event regarding HOFs and the reliability of suction systems for handling packages must be taken into account in the operation of the facility.

ASN considers that the level of safety and radiation protection is satisfactory on the whole. Process management and the monitoring of outside contractors involved in operation have improved. However, more rigorous documenting of internal authorisation processing is necessary, and the work deployment organisation must be better formalised.

On 12 March 2021, ASN gave the CEA its opinion on the periodic safety review guidance file submitted on 23 September 2020. ASN will be particularly attentive to any actions required further to the last safety review and not yet carried out when the conclusions of the new periodic safety review are submitted, which is scheduled for in 2022.

Active effluents treatment station *– CEA centre*

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

As part of the decommissioning file preparation, the licensee started characterising the soils and the equipment, in order to determine the initial radiological condition of the facility. This characterisation work revealed the presence of artificial radionuclides outside the identified contaminated areas and in the stormwater network. These contaminations were reported to ASN as significant events and gave rise to a stormwater management action plan, the effectiveness of which is monitored by the CEA.

Furthermore, the monitoring of outside contractors must be improved, particularly in view of the identified shortcomings, revealed by the detection of containment deficiencies on certain external tanks which had been inadequately inspected by an outside contractor.

ASN considers that the level of nuclear safety of BNI 37-B in 2021 is on the whole satisfactory with regard to the follow-up of commitments and significant events. Improvements are required in the monitoring of outside contractors and the management of legacy pollutions.

Plutonium Technology Facility and Chemical Purification Laboratory *– CEA centre*

The Plutonium Technology Facility (ATPu –BNI 32) produced plutonium-based fuel elements intended for fast neutron or experimental reactors as from 1967, then, from 1987 until 1997, for PWRs using MOX 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.

With regard to the ATPu, the campaigns for processing the drums containing alpha emitting radionuclides from BNI 56 have been finalised, in accordance with the last schedule proposed by the CEA in November 2020. A quarterly progress report shall be sent to ASN until the last waste has been removed from this site, planned for late December 2022.

As for the LPC, the cryotreatment process removal operations continued in 2021.

ASN considers that the monitoring of the containment barriers, the application of ASN resolution 2017-DC-0592 of 30 November 2017 relative to emergency situation management, the methodological procedure put in place for performing the periodic safety reviews and the tracking of the associated action plans by the two facilities are satisfactory on the whole. ASN will remain attentive to bringing the discharge outlet sampling points into compliance.

Masurca research reactor *– CEA centre*

The Masurca reactor (BNI 39), whose construction was authorised by a Decree of 14 December 1966, was intended for neutron studies, chiefly on the cores of fast neutron reactors, and the development of neutron measurement techniques. The reactor has been shut down since 2007.

Final shutdown of the facility was declared by the CEA on 31 December 2018. The licensee submitted the facility decommissioning file in December 2020 and in the interim has carried out decommissioning preparation work, such as removal of asbestos from the premises, rehabilitation of buildings and removal of conventional equipment.

The licensee's organisation for managing deviations is satisfactory on the whole. The license must nevertheless make progress in the detection and analysis of low-level events.

ASN considers that the level of nuclear safety and radiation protection of the Masurca BNI in 2021 is satisfactory on the whole.

Éole and Minerve research reactors *– CEA centre*

The experimental reactors Éole and Minerve are very-low-power (less than 1 kW) critical mock-ups that were used for neutron studies, in particular to evaluate the absorption of gamma rays or neutrons by materials.

The Éole reactor (BNI 42), whose construction was authorised by a Decree of 23 June 1965, was intended primarily for neutron studies of moderated arrays, in particular those of PWRs and boiling water reactors. The Minerve reactor (BNI 95), whose transfer from the Fontenay-aux-Roses studies centre to the Cadarache studies centre was authorised by a Decree of 21 September 1977, is situated in the same hall as the Éole reactor. Teaching and research activities were carried out on these mock-ups until their final shutdown on 31 December 2017.

The CEA submitted the update of its decommissioning file in July 2021, further to the complementary information requests made in 2019. Pending decommissioning, preparatory operations aiming to remove the fissile materials and better characterise the remaining radioactive equipment, in order to determine the necessary clean-out operations, continued in 2021.

ASN considers that the level of nuclear safety and radiation protection of the Éole and Minerve reactors is satisfactory on the whole.

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 enrichment plants into sinterable oxide, and ensured the chemical reprocessing of waste from the manufacture of fuel elements. Decommissioning of this facility was authorised by Decree in February 2006.

The first decommissioning phases, which consisted in removing the process equipment and the ventilation, effluent and electrical infrastructures, were completed in 2008. The only activities in the facility today are the maintenance and regulatory periodic inspection operations. The licensee has fallen substantially behind the initial schedule in the decommissioning operations, especially the civil engineering structure clean-out. It requested a modification of its Decree in 2010 and 2014, to take account of the true radiological condition of the facility. The new Decommissioning Decree was published on 16 April 2021. ASN has regulated the performance of certain decommissioning operations by two resolutions of 14 October 2021.

Alongside this, ASN made public its analysis of the periodic safety review of the facility on 7 September 2021. It has no objection to the continuation of the decommissioning operations.

ASN considers that the level of safety of BNI 52 (ATUe) in 2021 is satisfactory on the whole. The commitments made further to the preceding significant events and the periodic safety review are correctly implemented.

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, and ASN is currently examining it.

The decommissioning preparation operations initiated in 2018, notably the chemical and radiological characterisations of the facility, continued in 2021.

ASN considers that the chemical and radiological characterisation of the facility is well managed on the whole.

ASN made public its conclusions on the last periodic safety review of the facility in June 2021. It has no objection to the continuation of the decommissioning preparation operations.

LECA-STAR High Activity Laboratory

– CEA centre

BNI 55 accommodates the Active Fuel Examination Laboratory (LECA) and its extension, the Treatment, Clean-out and Reconditioning Station (STAR), which constitute the CEA's expert assessment facilities for the analysis of irradiated fuels. Commissioned in 1964, the LECA laboratory enables the CEA to carry out destructive and non-destructive examinations of spent fuel from the nuclear power, research and naval propulsion sectors. As the facility is old, it was partially reinforced in the early 2010's to improve its earthquake resistance.

To ensure the long-term continuity of the facility, the CEA has undertaken to reduce the dispersible inventory of the LECA laboratory. During the inspection carried out in 2021 on compliance with the requirements and commitments made following the periodic safety review of 2013, ASN noted the good organisation deployed by the licensee to meet the requirements set by ASN.

Commissioned in 1999, the STAR facility is an extension of the LECA laboratory, designed for the stabilisation and reconditioning of spent fuel.

The licensee reported two significant events in April and July 2021, one rated level 1 on the INES scale, linked to malfunctions of lifting and grasping devices in the STAR shielded cells. The action plan established after analysing the root causes of the events, particularly the OHFs, and conducting an expert assessment of the failure of the handling devices and the operating experience feedback from these systems, should prevent their recurrence.

Further to the inspections carried out in 2021, ASN will be attentive to ensuring that the CEA meets its commitments relating to the inspections and the processing of significant events.

ASN considers that the level of nuclear safety and radiation protection of the LECA-STAR facility in 2021 is generally satisfactory, particularly the licensee's organisation for controlling nuclear chain reactions, the fire-fighting means and the maintaining of static and dynamic containment.

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 3 pools, 6 pits, 5 trenches and hangars, which contain in particular ILW-LL waste from the operation or decommissioning of CEA facilities. BNI 56 is one of the priorities identified by the CEA in its new decommissioning and waste management strategy.

The facility decommissioning file, submitted in 2018, was supplemented in 2021.

In view of the conclusions of the examination of the facility's safety review, ASN has also set new technical requirements aiming to regulate its continued operation through resolution CODEP-CLG-2021-013405 of 15 March 2021.

The operations to retrieve the waste contained in the recent pits, to remove the waste that is stored in the hangars and to put in place the static containment of trench T2 continued. The waste retrieval and repackaging targets for the year 2021 were broadly achieved. ASN will however remain attentive to the schedule shift for performing certain decommissioning preparation operations.

ASN considers that the level of nuclear safety and radiation protection of the CEA Cadarache storage area in 2021 is broadly satisfactory, particularly with regard to pollution prevention, control of nuisance factors and waste management. Improvements have more specifically been observed in the facility's stormwater management, but these actions must be taken through to completion. The licensee must continue its studies to identify and open disposal routes for waste that does not have a disposal route at present.

Phébus research reactor *– CEA centre*

The Phébus reactor (BNI 92) is an experimental pool-type reactor with a power rating of 38 MWth which functioned from 1978 to 2007. Phébus was designed for the study of serious accidents affecting light water reactors and for defining operating procedures to prevent core melt-down or to mitigate its consequences.

The licensee submitted its decommissioning file to the Minister in February 2018 and its periodic safety review report to ASN in October 2017. The Environmental Authority issued its opinion on the decommissioning file in July 2021 and the CEA submitted its memorandum in response in November 2021.

One of the priorities of the decommissioning preparation operations was the removal of the irradiated fuel from the reactor, and this was completed in January 2019. The decommissioning preparation operations continued in 2021, in particular with the removal of used radioactive sources and the characterisation of certain equipment items. The last non-irradiated fuels were removed in December 2021.

ASN considers that the CEA's organisation for performing the periodic inspections and tests and for occupational radiation protection is satisfactory on the whole.

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.

The CEA submitted the final shutdown declaration for the facility in April 2019. However, in December 2021, the CEA informed ASN of its decision to keep the Lefca facility in operation and conduct new activities in it. An action plan with a schedule for this industrial and strategic change of direction was submitted to ASN on 28 January 2022. The forthcoming periodic safety review must integrate this change of strategy.

ASN considers that the level of nuclear safety and radiation protection of the facility in 2021 is broadly satisfactory, particularly as regards meeting commitments and external hazards. ASN has nevertheless found a need for improvements in the conformity and integrity of the piezometers of the water table verification system.

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.**

On the basis of the inspections carried out in 2021, ASN considers that the facility broadly meets its commitments, ensures good traceability of its modifications, and that the action plan following the conclusions of the safety review is progressing. Improvements are required in the collection of radioactive waste and the management of the radioactive samples produced by the facility.

With regard to environmental protection, the CEA has undertaken to submit, by the end of 2022, a request to modify the facility's DAC, to take into account gaseous discharges of tritium, not provided for in its current baseline requirements.

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 2027. The studies concerning a project to double the storage capacity began in 2020.

ASN considers that the main steps of this project need to be better defined and that CEA must look ahead to all the procedures in order to have the necessary storage capacities for overall management of its waste.

The CEA put the package examination unit into operation in 2021. This allows the inspection of packages and the overpacking of any damaged or contaminated packages.

ASN considers that the licensee's verifications for package acceptance in the Cedra facility, the management of modifications and the meeting of its commitments are satisfactory on the whole.

The year 2021 was marked by the reporting of significant events of level 1 concerning:

- exceeding of the authorised mass of fissile material in a package stored in the BNI, further to an error in the composition of a waste package in the producing facility;
- the fall of a waste package, an event that has already occurred several times on the Cadarache site, in BNI 37-A and BNI 56.

ASN considers that the licensee must draw all the necessary conclusions from these events, particularly regarding integration of the feedback from preceding events, the monitoring of waste producers and management of the interfaces between the various people likely to use the transport packages.

One significant event concerning damage to the metallic casing of a package was also reported by the facility. ASN has asked the CEA to conduct the necessary expert assessments to determine the cause and mechanism of the damage to this package.

Magenta storage warehouse – *CEA centre*

The Magenta facility (BNI 169), which replaces the MCMF currently being decommissioned, has been dedicated since 2011 to the storage of non-irradiated fissile material and the non-destructive characterisation of the nuclear materials received.

The licensee submitted its safety review conclusion report in February 2021. ASN has started the examination of this file and will focus in particular on the impact that pushing back glove box commissioning has on the maintenance operations of certain primary material containers.

One significant event rated level 1 on the INES scale was reported to ASN on 5 February 2021. This event concerned the unauthorised storage of material in the form of a uranium/aluminium alloy in one of the facility's storage blocks. The licensee is currently deploying corrective measures to prevent the causes of such events. In the interim, the storage block in question has been padlocked.

ASN considers that the operational management of the facility in 2021 is generally satisfactory.

Effluent advanced management and processing facility – *CEA centre*

The Effluent Advanced Management and Processing Facility (Agate –BNI 171), commissioned in 2014 to replace BNI 37-B which is now shut down, uses an evaporation process to concentrate radioactive liquid effluents containing mainly beta- and gamma-emitting radionuclides.

ASN considers that the licensee's verifications for the acceptance of effluents in the facility and the meeting of the commitments it has taken are on the whole satisfactory in the Agate facility. The evaporator has been out of service since December 2020 following a failure on the superheated water system. The evaporator's return to service is planned for the first quarter of 2022. The facility's activity in 2021 consisted chiefly in collecting the producers' effluents in buffer tanks upstream of the facility and repairing the failure of the superheated water system. ASN will be attentive to the conditions of resuming the operations and the filling status of the effluent storage capacities prior to their processing.

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 construction activities continued in 2021 on the work site and on the suppliers' sites, with the supply of handling equipment, hot cell equipment and the manufacture of pool equipment. The lining of the pools and channels of the nuclear auxiliaries building is well advanced. The hot cell windows have been installed and their leak-tightness has been tested.

The JHR project reorganisation, initiated in 2020, is now effective and raises no particular remarks from ASN.

The excessive vibrations encountered in 2020 during the qualification tests of certain equipment items inside the reactor pile block are still being studied and analysed by the CEA, in order to determine appropriate technical solutions to limit the equipment wear rates.

Signs of corrosion were detected in 2021 on one of the reactor pool welds. Analyses were carried out to identify the potential causes of this deviation and determine the appropriate corrective action. The progress of these actions was verified in the course of several inspections and additional data are to be received in 2022. ASN has asked to be kept regularly informed by the CEA on this subject.

ASN considers that the organisation in place for construction of the JHR is satisfactory and that technical problems are followed up rigorously, with a commitment to transparency.

Assessment of the CEA Cadarache centre

ASN considers that the level of nuclear safety of the CEA Cadarache centre in 2021 is on the whole satisfactory.

ASN considers that the BNIs are operated satisfactorily on the whole, especially the control of the condition of the equipment, the meeting of commitments and modifications management. Improvements are nevertheless required in the sharing of operating experience feedback, notably concerning the risk of heavy objects falling during handling operations.

The monitoring of outside contractors, whose contracts are followed up by the centre's technical service, hasimproved, with a more clearly defined division of responsibilities between the centre's services and the BNIs, and more rigorous formalising of the monitoring plans. The CEA must periodically assess the appropriateness andeffectiveness of its monitoring of outside contractors.

With regard to the containment of radioactive substances, the monitoring of the first containment barrier is well ensured on the whole. Monitoring of the other barriers highlighted in the safety cases of the BNIs (walls of premises, ventilation and filtration systems) must be stepped up, in order to ensure their good performance.

The commitments made by the facilities and the centre, further to the inspections and significant events, are broadly met.

ASN notes progress in deviation management for the centre as a whole. Improvements are however required in certain services in the analysis of the causes or trends relating to recurrent deviations of similar types.

ASN considers that the organisation put in place to conduct the reassessment and conformity check of the facility periodic safety reviews is satisfactory, but, where action plans are implemented, that the scheduling of the actions and their traceability must be further improved.

With regard to emergency situation management, ASN considers that the overall organisation of the centre has improved, particularly in view of the conclusions of the inspection of 10 October 2018. A large amount of work nevertheless remains to be done in the facilities to define the functions of the emergency situation responders. Greater rigour is required in the activation of the On-site Emergency Plan (PUI) and the alerting of the public authorities. ASN underlines that the compensatory measures proposed by the CEA pending the availability of an emergency centre that is robust to extreme hazards will have to be kept operational. Complementary elements concerning the qualification of some of these measures are still to be received.

ASN considers that the radiation protection situation of the CEA Cadarache centre is satisfactory. It notes positively the putting in place of internal self-checks, which allow thesharing of best practices and have also enabled the vulnerability of the operational radiation protection documents to falsification to be analysed.

ASN observes that the standard of environmental protection has progressed. Improvements are nevertheless still required in the monitoring of the industrial effluents network, in rendering compliant the centre's piezometer base, in the storage of hazardous products and the management of the centre's stormwater, particularly regarding network maintenance and discharge monitoring.

ITER

The ITER installation (BNI 174), under construction on the Cadarache site since 2010 and adjacent to the CEA facilities, will be a fusion experimental reactor used for the scientific and technical demonstration of the control of thermonuclear fusion energy, obtained by magnetic confinement of a deuterium-tritium plasma during long-duration experiments with a significant power level (500 MW developed for 400 seconds). This international project enjoys financial support from China, South Korea, the United States, India, Japan, Russia and the European Union, who make in-kind contributions by providing equipment for the project.

The large quantities of tritium that will be brought into play in this installation, the intense neutron flow and the resulting activation of materials have serious implications regarding radiation protection and will represent true challenges for the safe management of waste during the operation and decommissioning of the installation.

The works on the site and the manufacture of equipment are continuing, having pushed back the previously announced objective of deploying the first hydrogen plasma by 2025. The revised schedule, integrating the assessment of the impact of the Covid-19 pandemic, has not yet been received and should be formalised in the course of 2022.

The year 2021 was marked in particular by the preparation of the first sector of the vacuum chamber, with the installation of its equipment and thermal protections in the assembly hall, so that it can be subsequently transferred to the well of the Tokamak building. A second sector has arrived on site and must also be equipped.

ITER organisation requested approval to start the vacuum chamber assembly phase in March 2020, in accordance with the requirement of the amended ASN resolution of 12 November 2013. On completion of the technical examination, ASN found that the state of progress of the vacuum chamber design and the associated equipment did not yet enable this assembly phase to be started.

ASN draws up a relatively satisfactory overall assessment of the construction site, but underlines the potential impact of the nonconformities concerning the vaccum chamber sector welds and weld inspections. These nonconformities had not been reported to ASN, which moreover noted difficulties during one inspection in obtaining all the requested documents.

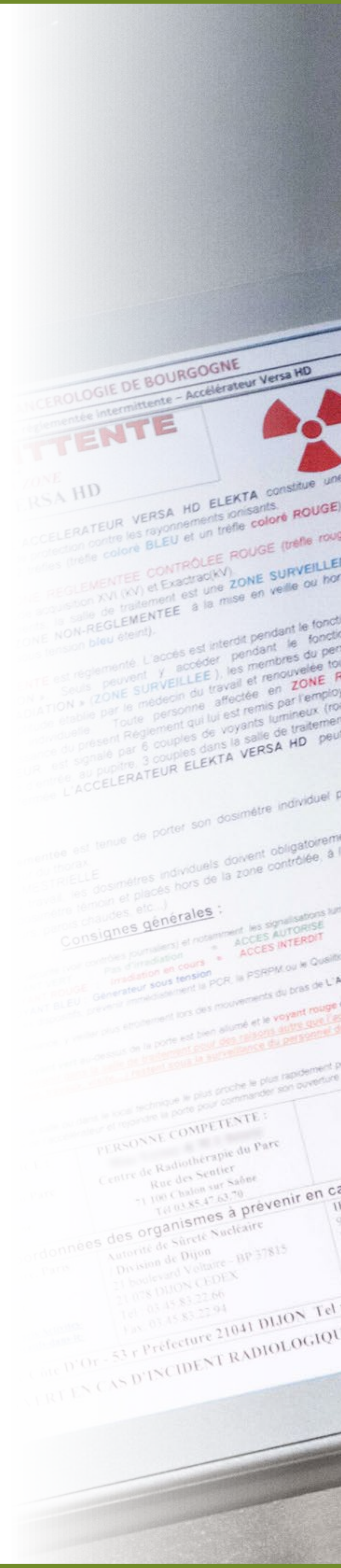
The complexity of this project and the regular developments of the facility make it necessary to ensure great rigour and transparency in the development of the technical configuration and the demonstration of effective compliance with the planned criteria for protection of people and the environment.

Gammaster ioniser

Since 2008, the company Steris has been operating an industrial irradiator called "Gammaster", situated on the land of the municipality of Marseille. Gammaster treats products by ionisation (emission of gamma radiation) with the aim of sanitising, sterilising or improving the performance of materials. The facility is made up of an industrial bunker and houses sealed sources of cobalt-60, which provide the radiation necessary for its activity.

The licensee was served formal notice through resolution CODEP-MRS-2021-020797 of 5 May 2021 to comply with Regulation (EC) 1005/2009 of the European Parliament and Council of 16 September 2009 relative to substances that deplete the ozone layer. The licensee possessed and was using a fire extinguishing gas whose use has been prohibited since 2020. The licensee has brought the facility into conformity and the compliance notice was lifted following an ASN inspection carried out on 5 July 2021.

ASN considers that the organisation of Steris for radiation protection and meeting its commitments is relatively satisfactory. The management of radioactive sources must be improved and the licensee must remain attentive to the waste management operations and to deviations.



Consignes générales :
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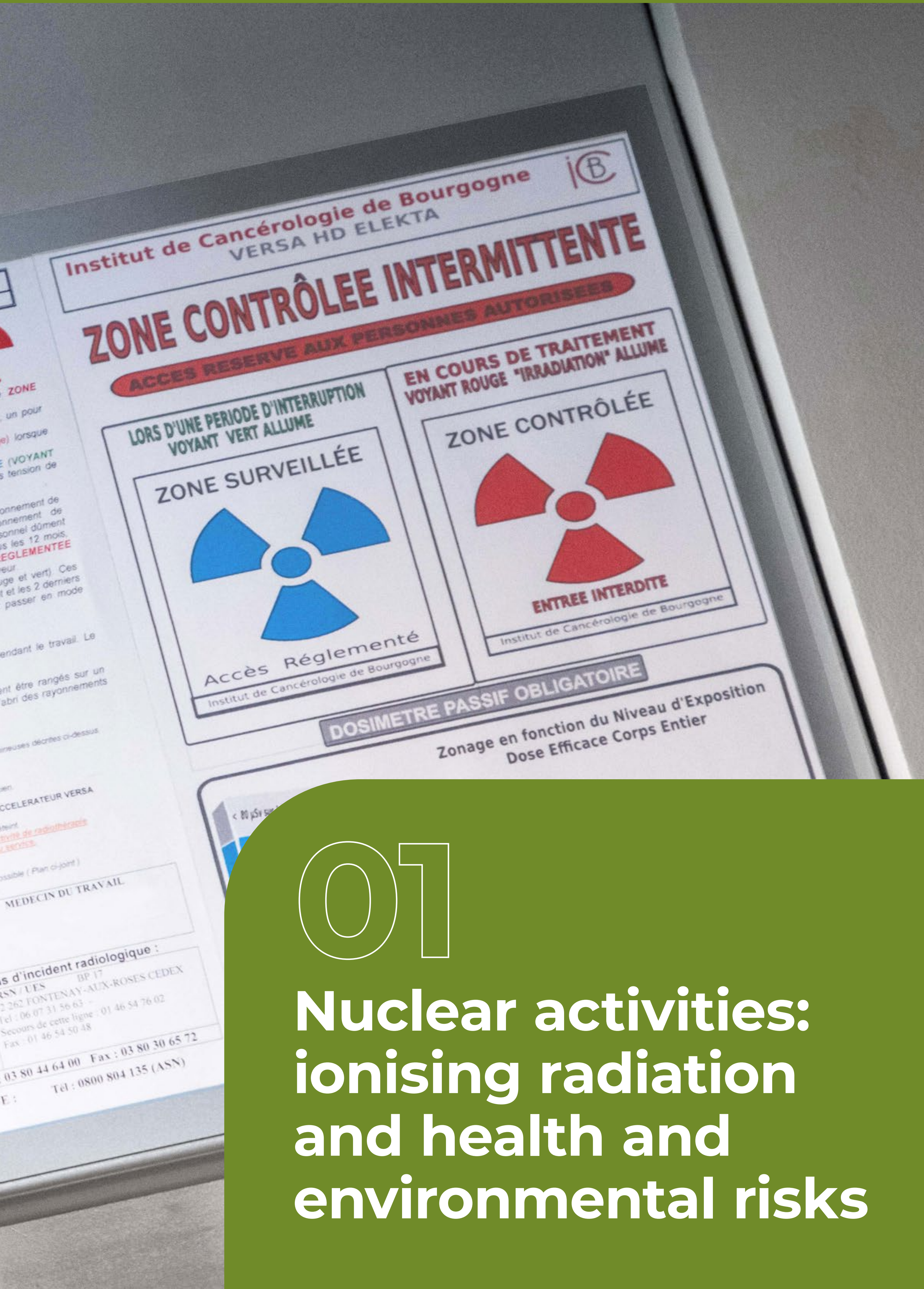


01

Nuclear activities: ionising radiation and health and environmental risks

01 NUCLEAR ACTIVITIES: IONISING RADIATION AND HEALTH AND ENVIRONMENTAL RISKS

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.

The various principles with which the nuclear activities must comply, particularly those of nuclear safety and radiation protection, are set out in chapter 2.

In addition to the effects of ionising radiation, BNIs are similar to all industrial installations in that they are the source of non-radiological risks and detrimental effects such as the discharge of chemical substances into the environment or noise emission.

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 interacts with the molecules making up the cells of living matter and alters them chemically. Of the resulting damage, the most significant concerns the DNA of the cells and this damage is not fundamentally different from that caused by certain toxic chemical substances, whether exogenous (external to the organism) or endogenous (resulting from cellular metabolism).

When not repaired by the cells themselves, this damage can lead either to cell death or to the appearance of harmful biological effects if tissues are no longer able to carry out their functions.

These effects, called "deterministic effects", have been known for a long time, as the first effects were observed with the discovery of X rays by W. Roentgen (in the early 1900's). They depend on the nature of the exposed tissue and are certain to appear as soon as the quantity of radiation absorbed exceeds a certain dose level. These effects include, for example, erythema, radiodermatitis, radionecrosis and cataract formation. The higher the radiation dose received by the tissue, the more serious the effects.

Cells can also repair the damage thus caused, although imperfectly or incorrectly. Of the damage that persists, that to DNA is of a particular nature because residual anomalies in the chromosomes can be transmitted by successive cellular divisions to new cells.

A single genetic mutation is far from being sufficient to cause the transformation into a cancerous cell, but this damage due to ionising radiation may be a first step towards cancerisation which appears after a variable lapse of time (five to twenty 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).

Subsequently, several types of cancers were observed in occupational situations, including certain types of leukaemia, bronchopulmonary cancers (owing to radon inhalation) and jawbone sarcomas. Outside the professional area, the monitoring for more than sixty years of a cohort[1] of about 85,000 people irradiated at Hiroshima and Nagasaki (Japan) has allowed the morbidity and mortality due to cancer following exposure to ionising radiation to be regularly assessed and the dose-effects relationships –which form the basis of current regulations– to be described. Other epidemiological work has revealed a statistically significant rise in cancers (secondary effects) among patients treated using radiotherapy and attributable to ionising radiation We can also mention the Chernobyl accident (Ukraine) which, as a result of the radioactive iodine released, caused in the areas near the accident an excess in the incidence of thyroid cancers in young people exposed during their childhood. The consequences of the Fukushima Daiichi accident (Japan) on the health of the neighbouring populations are not yet sufficiently known and analysed to draw epidemiological lessons from them.

The risk of radiation-induced cancer appears at different levels of exposure and is not linked to the exceeding of a threshold. It is revealed by an increase in the probability of cancer in a population of a given age and sex. Such cases are referred to as probabilistic, stochastic (produced by chance) or random effects.

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 related to radiation protection aim to prevent the appearance of deterministic effects and to reduce the probabilities of cancers arising from exposure to ionising radiation, which are also known as radiation-induced (or radio-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*(2) 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). However, the registers do not necessarily cover the areas close to nuclear installations.

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, as is the case in particular with low exposure levels of a few tens of millisieverts (mSv), must be borne in mind.

Cohorts such as those of Hiroshima and Nagasaki have clearly shown an excess of cancers, with the average exposure being about 200 mSv; studies on nuclear industry workers published in recent years suggest a risk of cancer at lower doses (cumulative doses over several years) cannot be excluded.

These results support the justification of radiation protection of populations exposed to low doses of ionising radiation (nuclear industry workers, medical personnel, medical exposure for diagnostic purposes, etc.).

Due to insufficient data on the impact of low doses on the occurrence of a cancer, estimates are provided by making Linear No-Threshold (LNT) extrapolations of the observed effects described for high doses. These models give estimations of the risks run during exposure to low doses of ionising radiation, which nevertheless remain scientifically controversial. Studies on very large populations are currently underway to enrich these models.

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(3) is based on a large number of epidemiological studies conducted directly in the home, in France and on an international scale. These studies have revealed 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 46,363). A national plan for managing radon-related risks has been implemented since 2004 on the initiative of ASN and is updated periodically. The fourth plan (2020-2024) was published in early 2021 (see point 3.2.2).

1.3 Scientific uncertainties and vigilance

The action taken in the fields of nuclear safety and radiation protection to prevent accidents and limit detrimental effects has led to a reduction in risks but not to zero risk, whether in terms of the doses received by workers or those associated with discharges and releases 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. *Administrative region headed by a Prefect.*
3. *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 persons suffering from genetic diseases affecting the repair of DNA and cellular signalling; in these individuals they can lead to "radiological burns". 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 (Multi-disciplinary European Low Dose Initiative –MELODI) and in the medical field (European platform for research activities in medical radiation protection –Euramed) is continuing on this subject. The ICRP task group (TG111) dedicated to this subject has published a review of the state of knowledge on individual radiosensitivity and the possibilities of predicting it with a view to developing international radiation protection recommendations. At this stage however, no valid biomarker allowing such a prediction has been identified. The individual response to ionising radiation remains an important subject of research and application in radiobiology and radiation protection (Euratom 2021-2022), while at the same time raising ethical and societal questions.

1.3.2 Effects of low doses

The Linear No-Threshold (LNT) relationship

The hypothesis of this relationship, adopted to model the effects of low doses on health (see point 1.2), albeit practical from the regulatory standpoint and albeit conservative from the health standpoint, is not as scientifically well-grounded as might be hoped for. 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. But faced with the complexity of the DNA repair and mutation phenomena, and the methodological limitations of epidemiology, uncertainties remain and the public authorities must exercise caution.

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[(4)] of ionising radiation. The studies carried out in the countries most affected by the Chernobyl accident (Belorussia, Ukraine and Russia) were also able to improve our understanding of the effects of radiation on health caused by exposure through internal contamination (internal exposure), more specifically through radioactive iodine. Studies on nuclear industry workers have given a clearer picture of the risk associated with chronic exposures at low doses established over many years, whether as a result of external exposure or internal contamination.

Hereditary effects

The appearance of possible hereditary effects from ionising radiation in humans remains uncertain. Such effects have not been observed among the survivors of the Hiroshima and Nagasaki bombings. However, hereditary effects have been documented in experimental work on animals: mutations induced by ionising radiation in embryonic germ cells can be transmitted to descendants. The recessive mutation of one gene on one chromosome

ASSESSMENT OF EXPOSURE DUE TO RADON: THE RECOMMENDATIONS OF THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION (ICRP)

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), entitled *Occupational intakes of radionuclides –Part 3*, concerns 14 radionuclides, including radon.

The doses delivered by radon and its progeny depend on many parameters (variability of exposure situations, individuals, etc.).

ICRP Publication 115 (2010) updated the risk of lung cancer associated with radon exposure on the basis of new epidemiological studies. The ICRP had concluded that the risk of death from lung cancer in adults having been chronically exposed to low concentrations of radon was nearly two times higher than that estimated on the basis of the knowledge available in 1993 (Publication 65).

These coefficients were based on an epidemiological approach. In its Publication 137, the ICRP proposes new coefficients based on a dosimetric approach, in the same way as for the other radionuclides.

For an equal given level of exposure to radon and its progeny, they lead to a significant increase in the annual effective dose received by workers exposed to radon (nearly two times higher).

Pending updating of the regulations[(*)], the French Institute of Radiation Protection and Nuclear Safety (IRSN) has assessed the consequences of adopting the new dose coefficients provided by the ICRP in its Publication 137 on exposure of the population to radon[(**)]. These calculations lead to an average annual effective dose in France of 3.5 mSv with a variation of 0.75 millisieverts per year (mSv/year) to 47 mSv/year depending on the municipalities. The average overall exposure of the population would thus increase from 4.5 mSv/year to 6.5 mSv/year, with exposure to radon representing 54%of the overall exposures compared with 33% at present.

(*) Order of 1 September 2003 defining the methods for calculating effective doses and equivalent doses resulting from human exposure to ionising radiation.

(**) Exposure of the French population to ionising radiation –Results for 2014-2019, IRSN, 2021.

4. *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.*

will produce no clinical or biological indications as long as the same gene carried by the other counterpart chromosome is not affected. Although it cannot be absolutely ruled out, the probability of this type of event nonetheless remains low.

Environmental protection

The purpose of radiation protection is to prevent or mitigate the harmful effects of ionising radiation on individuals, 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 has been the subject of several publications since 2008 (ICRP 108, 114, 124 and 148).

1.3.3 Molecular signature in radiation-induced cancers

It is currently impossible to distinguish a radiation-induced cancer from a cancer that is not radiation induced. The reason for this is that the molecular lesions caused by ionising radiation seem no different to those resulting from the normal cellular metabolism, with the involvement of free radicals –oxygenated in particular– in both cases. Furthermore, to date, neither anatomopathological examinations nor research for specific mutations have been able to distinguish a radiation-induced tumour from a sporadic tumour.

It is known that in the first stages of carcinogenesis (process of cancer formation) a cell develops with a particular combination of DNA lesions that enables it to escape from the usual control of cellular division, and that it takes about ten to one hundred DNA lesions (mutations, breaks, etc.) at critical points to pass through these stages. All the agents capable of damaging cellular DNA (tobacco, alcohol, various chemical substances, ionising radiation, high temperature, other environmental factors, notably nutritional and free radicals of normal cellular metabolism, etc.) contribute to cellular ageing and to carcinogenesis.

Consequently, in a multi-risk approach to carcinogenesis, can we still talk about radiation-induced cancers? Yes we can, given the quantity of epidemiological data which indicate that cancer frequency increases when the dose increases, with the other main risk factors taken into account. However, the radiation-induced event can also in certain cases be the only event responsible (radiation-induced cancers in children).

Workers ("radium girls") painting the pointers of luminous dials with radium in the US Radium (United States Radium Corporation) plant in Orange, New Jersey –1922

Highlighting a radiological signature of cancers, that is to say the discovery of markers that could indicate whether a tumour has a radiation-induced component or not, would be of considerable benefit in the evaluation of the risks associated with exposure to ionising radiation, but has not been demonstrated to date.

The multifactorial nature of carcinogenesis pleads in favour of a precautionary approach with regard to all the risk factors, since each one of them can contribute to DNA impairment. This is particularly important in persons displaying high individual radiosensitivity and for the most sensitive organs, such as the breast and the bone marrow, and all the more so if the persons are young. Here, the principles of justification and optimisation are more than ever applicable (see chapter 2).

2 // The different sources of ionising radiation

2.1 Natural ionising radiation

In France, exposure to the different types of natural radioactivity (cosmic radiation, terrestrial radiation such as that linked to the incorporation of natural radionuclides contained in foodstuffs and drinking water and that associated with the presence of radon in the home) represents on average 66% of the total annual exposure[(5)].

2.1.1 Cosmic radiation

Cosmic radiation is essentially made up of ions. They have a directly ionising component and an indirectly ionising component due to the presence of neutrons (the "neutron component"), which vary according to altitude and longitude.

Considering the altitude of each municipality, the average time spent inside the home and a housing protection factor of 0.8 (housing attenuates the ionic component of cosmic radiation), IRSN evaluates the average individual effective dose per person in France at 0.31 mSv, with a variation of 0.3 to 1.1 mSv/year depending on the municipalities.

Passengers and flight crew are exposed during air travel, depending on the flight altitude and the journey, to exposure varying from a few microsieverts (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.

5. *Exposure of the French population to ionising radiation –Results 2014-2019, IRSN, 2021.*

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.

The levels of natural radionuclides in soils are extremely variable. The external exposure dose rate values in the open air in France, depending on the region, range from a few nanosieverts per hour (nSv/h) to 100 nSv/h.

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 dose rate of terrestrial origin outside the home and inside the home, and d) assumptions on the time spent by the population indoors and outdoors (92% and 8% respectively), IRSN estimates that the average annual effective dose due to external exposure to gamma radiation of terrestrial origin in France is about 0.63 mSv per person per year. It varies from 0.30 mSv/year to 2.0 mSv/year depending on the municipaly.

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*).

Based on the available measurement results and the mapping of the geogenic radon potential of the territory, the average time spent inside the home and assumptions on the type of housing concerned (collective or individual), IRSN has estimated the average radon concentration for each municipality: the average concentration of radon-222 inside housing in metropolitan France, weighted for the population and type of housing, is 60.8 Bq/m^3. Using the dose factor of ICRP 65 currently in effect, the effective average does per inhabitant is estimated at 1.45 mSv/year. The effective dose varies from 0.31 mSv/year to 19 mSv/year depending on the municipality. IRSN has moreover published an assessment of the consequences of the adoption of new coefficients published by the ICRP in its publication 137 (see box on page 102).

The new obligation for radon detector analysis laboratories to send IRSN the measurement results and the expected results of action 7 of the fourth French Action Plan for Management of the Radon Risk (see point 3.2), relative to the defining of organisation methods for collecting the radon measurement data, should improve knowledge of radon exposures in France.

2.2 Ionising radiation resulting 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;
- transport of radioactive substances;
- small-scale nuclear activities;
- removal of radioactive waste;
- management of contaminated sites;
- activities enhancing natural ionising radiation.

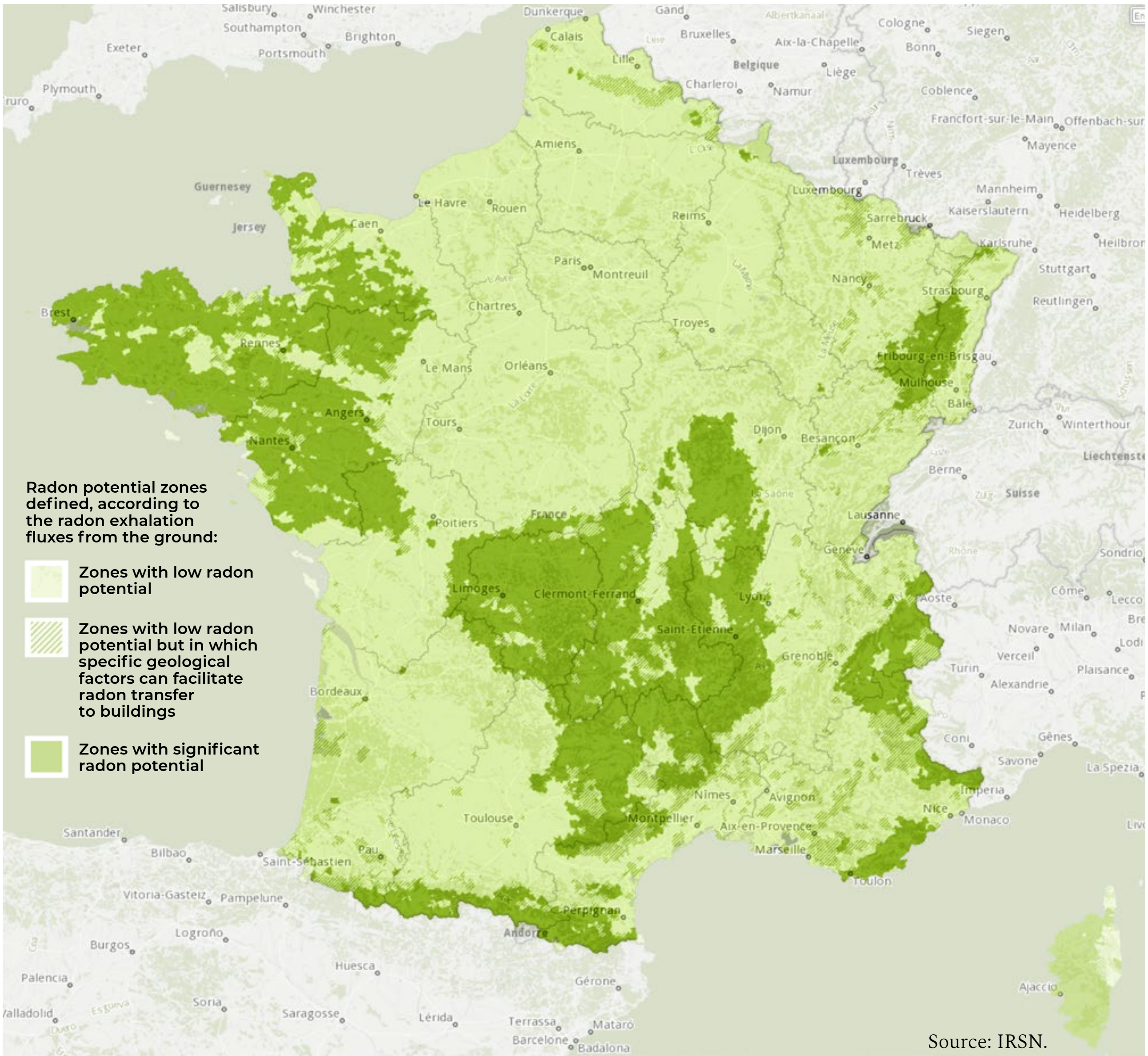
2.2.1 Basic Nuclear Installations

Nuclear activities are highly diverse, covering any activity relating to the preparation or utilisation of radioactive substances or ionising radiation. These activities are subject to the general provisions of the Public Health Code and, depending on their nature and the risks that they involve, to a specific legal system: BNIs are defined in Article L. 593-2 of the Environment Code:
1. Nuclear reactors.
2. Facilities, corresponding to characteristics defined by Decree of the Council of State, for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels, or for the treatment, storage or disposal of radioactive waste.
3. Facilities containing radioactive or fissile substances and meeting characteristics defined by Decree of the Council of State.
4. Particle accelerators meeting characteristics defined by Decree of the Council of State.
5. Deep geological repositories for radioactive waste mentioned in Article L. 542-10-1 of the Environment Code.

The installations and facilities are subject to the BNI System, governed by Chapters III and VI of Title IX of Book V of the Environment Code and their implementing texts.

The list of Basic Nuclear Installations as at 31 December 2021 figures in the appendix to this report.

RADON POTENTIAL ZONES IN METROPOLITAN FRANCE DEFINED BY THE ORDER OF 27 JUNE 2018



Source: IRSN.

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 a vital role and must withstand the foreseeable transport conditions.
- 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), biology, research, industry, but also in veterinary applications and the conservation of foodstuffs.

The employer is required to take all necessary measures to protect workers against the hazards of ionising radiation. The facility licensee must also implement the provisions of the Public Health Code for the management of the ionising radiation sources in its possession (radioactive sources in particular) and, where applicable, manage the waste produced and limit discharges of liquid and gaseous effluents. In the case of use for medical purposes, patient protection issues are also taken into account.

2.2.4 Radioactive waste management

Like all industrial activities, nuclear activities can generate waste, some of which is radioactive. The three fundamental principles on which strict radioactive waste management is based are the accountability of the waste producer, the traceability of the waste and informing the public.

The technical management provisions to be implemented must be tailored to the hazard presented by the radioactive waste. This hazard can be assessed primarily through two parameters: the activity level, which contributes to the toxicity of the waste, and the half-life, the time after which the activity level is halved.

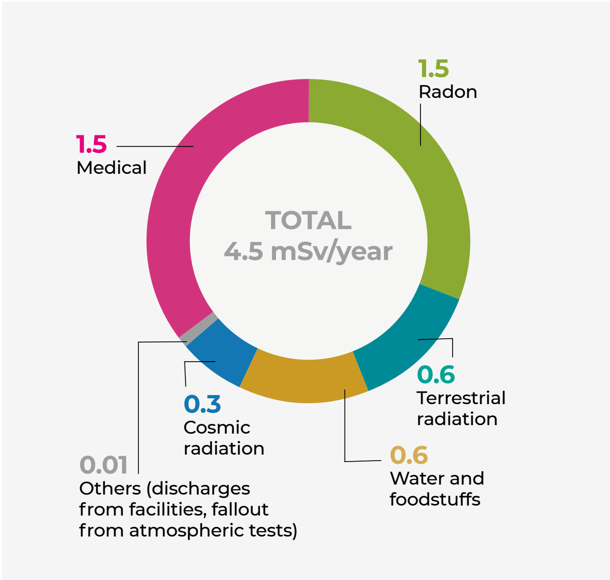
Lastly, management of radioactive waste must be determined prior to the creation of any new activities or the modification of existing activities in order to:
- ensure the availability of processing channels for the various categories of waste likely to be produced, from the front-end phase (production of waste and its placing in packages) to the back-end phase (storage, transport and disposal);
- optimise the waste management routes.

2.2.5 Management of contaminated sites

Management of sites contaminated by residual radioactivity resulting either from a past nuclear activity or an activity which generated deposits of natural radionuclides warrants specific radiation protection actions, in particular if rehabilitation is envisaged.

Depending on the current or future uses of the site, decontamination objectives must be set. The removal of the waste produced during post-operation clean-out of the premises and removal of the contaminated soil must be managed from the site through to storage or disposal. The management of contaminated objects also follows these same principles.

DIAGRAM 1 Average exposure of the French population to ionising radiation (mSv/year)



Source: IRSN, 2021.

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 exposure to ionising radiation

Given the difficulty in attributing a cancer solely to the ionising radiation risk factor, "risk monitoring" to prevent cancers in the population is performed by measuring ambient radioactivity indicators (measurement of dose rates for example), internal contamination or, failing this, by measuring values (activities in radioactive effluent discharges) which can then be used –by modelling and calculation– to estimate the doses received by the exposed populations.

The entire population of France is exposed to ionising radiation of natural or anthropogenic origin, but to different extents across the country. The average exposure of the French population is estimated at 4.5 mSv per person per year, but this exposure is subject to wide individual variability, particularly depending on the place of residence (radon potential of the municipality, level of terrestrial radiation), the number of radiological examinations the person undergoes, consumption (smoking, foodstuffs) and living habits (air travel). The average annual individual effective dose can thus vary from 1.6 mSv to 28 mSv[(6)]. Diagram 1 represents an estimate of the respective contributions of the various sources of exposure to ionising radiation for the French population.

3.1 Doses received by workers

3.1.1 Monitoring the exposure of persons working in nuclear facilities

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 (month or quarter) for each worker, including those from outside contractors. They are grouped together in the Ionizing 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 2020 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 three preceding years, the IRSN 2020 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 2020 are not directly comparable with those of 2019, 2018 and 2017. Nevertheless, in order to establish trends, the results for the years 2015 and 2016 have been retroactively reassessed applying the new methodological approach (see Table 3).

Tables 1 and 2 present, per area of activity and for the year 2020, the breakdown of the populations monitored, the collective dose (*i.e.* 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 and veterinary activities sector, which comprises a significant share of the population monitored (59%), accounts for only 11% of the collective dose; on the other hand, the civil nuclear industry, which represents just 22% of the headcount, accounts for 52% of the collective dose and the sector concerned by exposure to natural radioactivity, which represents only 5.9% of the total headcount, accounts for 31% of the collective dose. The industrial sector, which represents 4.2% of the headcount, accounts for 3.5% of the collective dose.

Table 3 shows that the total number of workers monitored by external passive dosimetry increased by about 1% per year from 2015 until 2019. In 2020, the number of workers monitored dropped by 1.9%.

The collective dose for 2020 (all sectors combined) is 72.43 man-Sv[(7)], a value that has fallen by 35.5% compared with 2019 and which has never been as low since 2015. This drop concerns all areas of activity and can be explained primarily by the drop in air traffic resulting in lower exposure of flight crew to cosmic radiation, and spreading of the volume of maintenance work in the nuclear sector, both linked to the consequences of the Covid-19 pandemic.

For these same reasons, the average annual individual dose, which was 0.78 mSv in 2020, is 35% lower than that observed in 2019.

Five cases of exceeding the effective dose regulatory limit of 20 mSv were recorded in 2020 (see Diagram 2), of which four were related to external exposure and one to internal exposure. The four cases linked to external exposure concern 2 workers in the medical sector, 1 in the veterinary sector and 1 in the non-nuclear industry sector. A fifth case of exceeding the effective dose limit in the medical sector must nevertheless be noted in addition to these four cases, corresponding to a cumulative dose over 12 sliding months from June 2019 to May 2020 and not over the calendar year. Only one case was confirmed by the occupational physician, the others being retained by default in the absence of a response from the occupational physician on the survey conclusions.

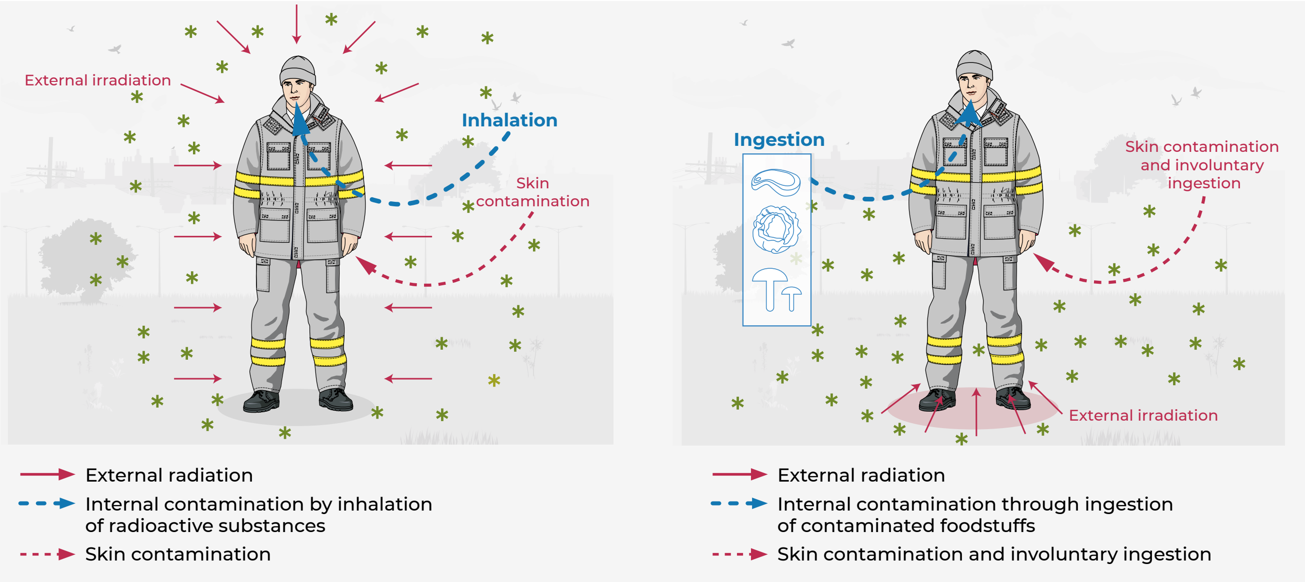
Exceeding of the regulatory limit of 20 mSv for internal exposure concerns the nuclear domain in the fuel fabrication sector.

With regard to the dosimetry of the extremities (fingers and wrist), 27,437 workers were monitored in 2020 (*i.e.* 7% of the total number of persons monitored). Out of all the persons monitored, there was one case –in the medical sector– where the 500 mSv regulatory equivalent dose limit at the extremities was exceeded (975.8 mSv).

Alongside this, 4,429 workers were subject to monitoring of exposure of the lens of the eye (compared with 4,830 in 2019), probably reflecting a drop in activity due to the health crisis, after a strong increase in the preceding years. Four workers (in the medical radiology sector) received an equivalent dose exceeding 20 mSv. The maximum recorded dose is 37.74 mSv. This value

6. *Exposure of the French population to ionising radiation –Results for 2014-2019, IRSN, 2021.*
7. *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.*

SOURCES AND ROUTES OF EXPOSURE TO IONISING RADIATION



should be compared with the future regulatory dose limit for the lens of the eye of 20 mSv/year as from 2023.

To conclude, as in the preceding years, the assessment of monitoring of workers exposed to ionising radiation in France in 2020, published by IRSN in June 2021, shows the overall effectiveness of the prevention system introduced in facilities where sources of ionising radiation are used, because for 94% of the population monitored, the annual dose remained below 1 mSv (effective annual dose limit for the public due to nuclear activities). Exceeding the regulatory limit values remains the exception (five cases exceeding the annual limit of 20 mSv).

Monitoring of exposure of the lens of the eye with, for this tissue, compliance with the new limit, constitutes the main objective of radiation protection in the immediate years and more specifically in the area of fluoroscopy-guided interventional medical practices.

3.1.2 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).

The results of the studies conducted in France between 2005 and 2009, published by ASN in January 2010, and the studies published in 2018, show that 85% of the doses received by workers in the industries concerned remain below 1 mSv/year. The industrial sectors in which worker exposure is liable to exceed 1 mSv/year are the following: titanium ore processing, heating systems and recycling of refractory ceramics, maintenance of parts comprising thorium alloys in the aeronautical sector, chemical processing of zircon ore, mechanical transformation and utilisation of zircon and processing of rare earths.

In 2020, the individual monitoring of worker exposure in industrial activities leading to exposure to radioactive substances of natural origin or to radon of geological origin concerned about 450 workers, of whom 21 were exposed to more than 1 mSv (internal exposure to the natural radionuclides of the uranium and thorium decay chains).

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 2020, *SievertPN* had transmitted to Siseri all the flight crew doses for 12 airlines having subscribed to the system, giving a total of 21,949 flight crew members monitored by this system. In 2020, nearly 55% of the individual annual doses were below 1 mSv and 45% of the individual annual doses were between 1 mSv and 5 mSv. The maximum individual annual dose was 4.17 mSv.

The collective dose in 2020 fell by 58% compared with 2019, whereas it had been increasing regularly over the last few years. This reduction can be explained by the health crisis which caused a significant drop in air traffic.

3.2 Doses received by the population

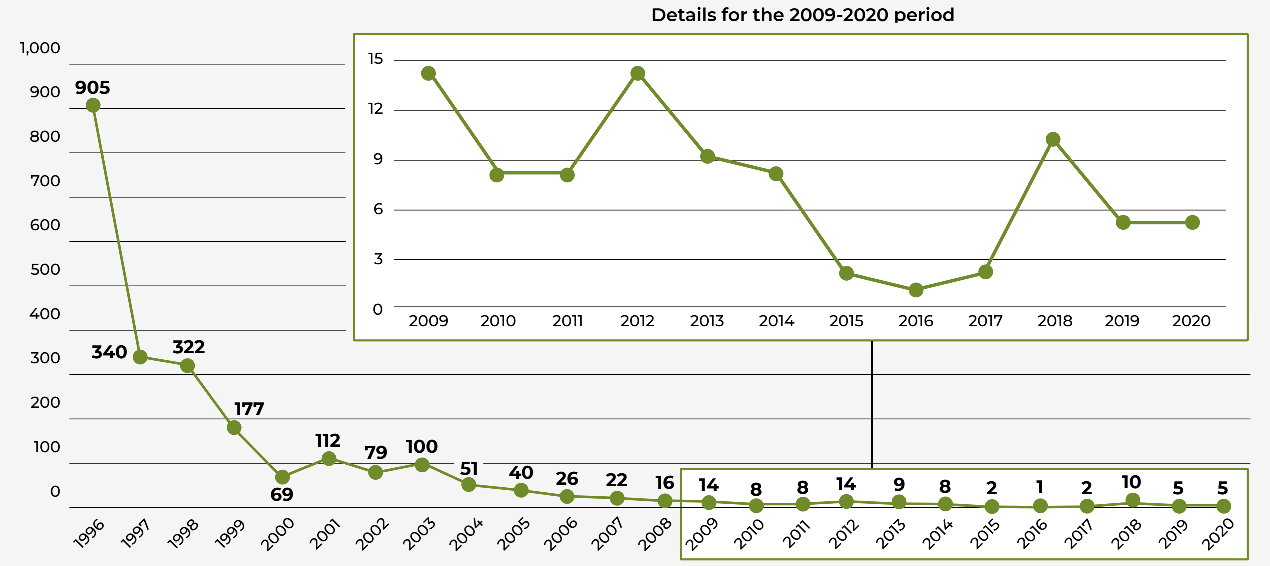
3.2.1 Exposure of the population as a result of nuclear activities

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).

However, there is no overall monitoring system able to provide an exhaustive picture of the doses received by the population as a result of nuclear activities. Consequently, compliance with the population exposure limit (effective dose set at 1 mSv per year) cannot be controlled directly. However, for BNIs, there is detailed accounting of radioactive effluent discharges and radiological monitoring of the environment is implemented around the installations. On the basis of the data collected, the dosimetric impact of these discharges on the populations in the immediate vicinity of the installations is then calculated using models simulating transfers to the environment. The dosimetric impacts vary, according to the type of installation and the lifestyles of the chosen reference groups, 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 reference population groups.

There are no known estimates for nuclear activities other than BNIs owing to the methodological difficulties involved in identifying the impact of these facilities and in particular the impact of discharges containing small quantities of artificial radionuclides resulting from the use of unsealed radioactive sources in research or biology laboratories, or in nuclear medicine units. To give an example, the impact of hospital discharges could lead to doses of a several tens of microsieverts per year for the most exposed persons, particularly for certain jobs in sewage networks and wastewater treatment plants (IRSN studies 2005 and 2015).

DIAGRAM 2 **Changes in the number of monitored workers whose annual dose exceeds 20 mSv, from 1996 to 2020**



Source: IRSN.

RESULTS OF DOSIMETRY MONITORING OF WORKER EXTERNAL EXPOSURE TO IONISING RADIATION (EXPOSURE TO NATURAL RADIOACTIVITY INCLUDED) IN 2020

(Source: IRSN 2020 report, June 2021 –"*Worker radiation protection: occupational exposure to ionising radiation in France*")

- Total population monitored: 387,452 workers
- Monitored population for whom the annual effective dose remained below the detection threshold: 295,080, *i.e.* more than 76%
- Monitored population for whom the annual effective dose remained between the detection threshold and 1 mSv: 70,324 workers, *i.e.* about 18%
- Monitored population for whom the annual effective dose remained between 1 mSv and 20 mSv: 22,044 workers, *i.e.* more than 5.6%
- Monitored population for whom the annual effective dose exceeded 20 mSv: 4 workers(*)
- Monitored population for whom the equivalent dose to the extremities exceeded 500 mSv: 1 worker
- Collective dose (sum of the individual effective annual doses): 72.43 man-Sv
- Average annual individual effective dose in the population which recorded a dose higher than the detection threshold: 0.78 mSv

Results of internal exposure monitoring in 2020 (natural radioactivity excluded)

- Number of routine examinations carried out: 197,485 (of which 0.4% were considered positive)
- Population for which a dose estimation was made: 724 workers
- Number of special monitoring examinations or verifications performed: 7,773 (of which 15% are higher than the detection threshold)
- Population having recorded a committed effective dose exceeding 1 mSv: 1 worker

Results of monitoring of internal exposure to natural radionuclides from the uranium and thorium decay chains in 2020

- Internal exposure:
  - collective dose for 334 workers: 83.95 man-mSv
  - Average annual individual effective dose in the population which recorded a dose higher than the detection threshold: 0.45 mSv

(*) A fifth case not included in this summary can be added to these four cases: case in the medical sector corresponding to a cumulative dose over 12 sliding month from June 2019 to May 2020 and not over the calendar year.

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 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, the results published for France by IRSN in 2011 showed the presence of radioactive iodine at very low levels, resulting in estimated effective doses for the populations of less than 2 µSv/year in 2011.

TABLE 1 **Monitoring of external exposure of workers in the civil nuclear field (year 2020)**

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv (*))	INDIVIDUAL DOSE > 20 mSv
Reactors and energy production (EDF)	23,603	5.65	0
"Fuel cycle"; decommissioning	12,417	3.4	0
Transport	638	0.09	0
Logistics and maintenance (contractors)	31,807	25.42	0
Effluents, waste	789	0.1	0
Others	6,501	1.1	0
Total civil nuclear	75,755	35.76	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: IRSN report, June 2021 – "*Worker radiation protection: occupational exposure to ionising radiation in France*")

TABLE 2 **Monitoring of external exposure of workers in small-scale nuclear activities (year 2020)**

	NUMBER OF PERSONS MONITORED	COLLECTIVE DOSE (man-Sv (*))	INDIVIDUAL DOSE > 20 mSv
Medicine	163,633	6.28	2 (1)
Dental	43,510	1.2	0
Veterinary	21,442	0.36	1
Industry	16,439	2.59	1
Research and education	10,844	0.26	0
Natural (**)	22,838	22.46	0
Total small-scale nuclear activities	278,706	33.15	4

(1) Added to these two cases is a third case detected in May 2020 in the medical sector for a cumulative dose of 21.1 mSv over 12 sliding months from June 2019 to May 2020 and not over the calendar year.
(*) 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: IRSN report, June 2021 – "*Worker radiation protection: occupational exposure to ionising radiation in France*")

TABLE 3 **Development of number of persons monitored and average collective and individual doses in the exposed population from 2015 to 2020(*) 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

(*) For comparison purposes, the results for 2015 and 2016 have been retroactively reassessed applying the new methodological approach.
(Source: IRSN report, June 2021 – "*Worker radiation protection: occupational exposure to ionising radiation in France*")

TABLE 4 **Radiological impact of BNIs since 2015 calculated by the licensees on the basis of the actual discharges from the installations and for the most exposed reference groups (data provided by the nuclear licensees)**

LICENSEES/SITE	REFERENCE GROUP MOST EXPOSED IN 2020	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)					
			2015	2016	2017	2018	2019	2020
Andra / CSA	Multi-activity Ville-aux-Bois	1.7	2.10^{-6}	2.10^{-6}	2.10^{-6}	3.10^{-7}	3.10^{-7}	4.10^{-7}
Andra's Manche repository	Hameau de La Fosse	2.5	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}
CEA / Cadarache (b)	Saint-Paul-lez-Durance	5	1.10^{-3}	$<2.10^{-3}$	$<2.10^{-3}$	$<3.10^{-3}$	$<2.10^{-3}$	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^{-5}	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$
CEA / Saclay (b)	Le Christ-de-Saclay	1	2.10^{-3}	$<2.10^{-3}$	$<2.10^{-3}$	$<2.10^{-3}$	$<4.10^{-3}$	$<2.10^{-3}$
EDF / Belleville-sur-Loire	Beaulieu-sur-Loire	1.8	5.10^{-4}	4.10^{-4}	3.10^{-4}	4.10^{-4}	4.10^{-4}	3.10^{-4}
EDF / Blayais	Braud et Saint-Louis	2.5	5.10^{-4}	5.10^{-4}	4.10^{-4}	5.10^{-4}	4.10^{-4}	5.10^{-4}
EDF / Bugey	Vernas	1.8	2.10^{-4}	9.10^{-5}	2.10^{-4}	2.10^{-4}	2.10^{-4}	9.10^{-5}
EDF / Cattenom	Kœnigsmacker	4.8	7.10^{-3}	9.10^{-3}	8.10^{-3}	9.10^{-3}	1.10^{-2}	7.10^{-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	6.10^{-4}	6.10^{-4}	4.10^{-4}	5.10^{-4}	5.10^{-4}	3.10^{-4}
EDF / Civaux	Valdivienne	1.9	9.10^{-4}	2.10^{-3}	8.10^{-4}	8.10^{-4}	2.10^{-3}	1.10^{-3}
EDF / Creys-Malville	Creys-Mépieu	0.95	2.10^{-6}	3.10^{-4}	1.10^{-4}	2.10^{-5}	2.10^{-5}	8.10^{-6}
EDF / Cruas-Meysse	Savasse	2.4	2.10^{-4}	2.10^{-4}	4.10^{-4}	3.10^{-3}	3.10^{-4}	2.10^{-4}
EDF / Dampierre-en-Burly	Lion-en-Sulias	1.6	5.10^{-4}	5.10^{-4}	5.10^{-4}	5.10^{-4}	5.10^{-4}	3.10^{-4}
EDF / Fessenheim	Fessenheim	1.3	4.10^{-5}	3.10^{-5}	2.10^{-5}	5.10^{-5}	4.10^{-5}	3.10^{-5}
EDF / Flamanville	Flamanville	0.8	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	7.10^{-5}	2.10^{-5}
EDF / Golfech	Valence	3.4	3.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	1.10^{-4}
EDF / Gravelines	Grand-Fort-Philippe	2.5	4.10^{-4}	4.10^{-4}	5.10^{-4}	8.10^{-4}	1.10^{-3}	8.10^{-4}
EDF / Nogent-sur-Seine	Saint-Nicolas-la-Chapelle	2.3	4.10^{-4}	7.10^{-4}	5.10^{-4}	5.10^{-4}	4.10^{-4}	4.10^{-4}
EDF / Paluel	Paluel	1.1	4.10^{-4}	3.10^{-4}	3.10^{-4}	4.10^{-4}	3.10^{-4}	3.10^{-4}
EDF / Penly	Berneval-le-Grand	3.1	4.10^{-4}	4.10^{-4}	5.10^{-4}	5.10^{-4}	4.10^{-4}	3.10^{-4}
EDF / Saint-Alban	Saint-Maurice-l'Exil	1.7	2.10^{-4}	3.10^{-4}	2.10^{-4}	2.10^{-4}	3.10^{-4}	2.10^{-4}
EDF / Saint-Laurent-des-Eaux	Lestiou	1.7	1.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}	1.10^{-4}
EDF / Tricastin	Bollène	1.3	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	2.10^{-4}	1.10^{-4}
Framatome Romans	Ferme Riffard	0.2	3.10^{-4}	3.10^{-4}	2.10^{-5}	2.10^{-5}	3.10^{-5}	1.10^{-5}
Ganil / Caen	IUT	0.6	$<2.10^{-3}$	$<2.10^{-3}$	8.10^{-3}	8.10^{-3}	7.10^{-3}	7.10^{-3}
ILL / Grenoble	Fontaine (gaseous discharges) and Saint-Égrève (liquid discharges)	1 and 1.4	2.10^{-4}	2.10^{-4}	5.10^{-5}	2.10^{-5}	3.10^{-5}	5.10^{-5}
Orano Cycle / La Hague	Digulleville	2.8	2.10^{-2}	2.10^{-2}	2.10^{-2}	2.10^{-2}	2.10^{-2}	1.10^{-2}
Orano / Tricastin (Areva NC, Comurhex, Eurodif, Socatri, SET)	Les Girardes	1.2	3.10^{-4}	2.10^{-4}	2.10^{-4}	9.10^{-5}	8.10^{-5}	4.10^{-5}

(a) For the installations operated by EDF, only the "adult" values were calculated until 2008. From 2010 to 2012, the dose of the most exposed 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 microsieverts, the values indicated are preceded by the "less than (<)" sign.

(c) As the site has no longer had radioactive discharges since 2014, the radiological impact caused by radioactive discharges has been nil since 2014.

3.2.2 Exposure of the population to Naturally Occurring Radioactive Materials

Exposure due to natural radioactivity in drinking water

The results of the monitoring of the radiological quality of the tap water distributed to consumers carried out by the Regional Health Agencies (ARS) between 2008 and 2009 (DGS/ASN/IRSN report published in 2011) showed that 99.83% of the population receives tap water whose quality complies at all times with the total indicative dose of 0.1 mSv/year set by the regulations. This generally satisfactory assessment also applies to the radiological quality of bottled water produced in France (DGS/ASN/IRSN report published in 2013).

Since 2019, measurement of the radon content of tap water and bottled water has been compulsory. To assist the introduction of this new provision, an instruction was drawn up in consultation with ASN and issued in 2018 to the ARS by the General Directorate for Health (DGS) (ASN opinion 2018-AV-0302 of 6 March 2018 on radon management procedures in the sanitary control of water intended for human consumption).

Exposure due to radon

In France, the regulations relative to management of the radon risk, put in place in the early 2000's for certain Public Access Buildings (PAB), were extended to certain workplaces in 2008. In 2016, radon was introduced into the indoor air quality policy.

Transposition of Council Directive 2013/59/Euratom of 5 December 2013 laying down Basic Safety Standards for protection against the dangers arising from exposure to ionising radiation led to the amending of the provisions applicable to radon since 1 July 2018. A reference level of 300 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.
- In workplaces, the regulations have been extended to cover professional activities exercised on ground floor levels (only activities carried out in basements were concerned until now) and in certain specific workplaces. Whatever the radon potential zone in which the workplace is situated, radon must be considered in the risk assessment. A radon measurement can be carried out in this context if necessary. If there is a risk of reaching or exceeding the reference level of 300 Bq/m^3, the employer must take action to reduce the radon activity concentration. If the action turns out to be ineffective, the employer must identify potential "radon zones" 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 equal 1,000 Bq/m^3 or higher.

The results communicated by the ASN-accredited organisations for the 2018/2019 and 2019/2020 and 2020/2021 campaigns show that the majority of the screenings were carried out in educational institutions and healthcare and medical-social institutions (55% and 26% of screenings respectively). Day-care facilities for children aged under 6 years, which constitute a new category of PAB subject to management of the radon risk, represent 12% of the measurements taken during the 2019/2020 and 2020/2021 campaigns. The radon activity concentration is lower than the reference level of 300 Bq/m^3 in 75% of educational institutions and 90% of the day-care facilities for children aged under 6 years and 87% of healthcare and medical-social institutions screened.

The data collected in 467 PABs show that the corrective actions or works to reduce the radon concentration have lowered the concentration to below 300 Bq/m^3 in only 40% of these buildings. Consequently, "simple" corrective actions aiming to improve the sealing of a building or renew the air in the premises are not always sufficient. Furthermore, having a professional expert assessment of the building and, if necessary, complementary investigations by an ASN-approved organisation, prove to be essential steps to determine the remediation work to be undertaken.

More generally, the management strategy for the radon risk is set out in a national action plan. Implementation of this plan will improve the way the general public and the stakeholders concerned are informed and will enhance knowledge of radon exposure in the home and how it evolves.

The fourth French national plan for the 2020-2024 period was published in early 2021. It fits into the framework of the fourth National Health and Environment Plan which now coordinates all the sector-based plans concerning health or the environment, which is itself driven by the National Public Health Strategy 2018-2022, of which one action aims to reduce exposure to interior pollution. This action explicitly targets the effects of radon in the home: "*over and beyond the sanitary aspects, it is question of promoting a living environment that fosters health and of reducing the effects of exposure in the home (chemical pollution, radon, etc.)*".

This plan follows on from the preceding plans (the assessment of the third plan is available on *asn.fr*). It can be broken down into 13 actions focusing on three lines.

Line 1 aims to implement an information and awareness-raising strategy. The health issue that radon represents requires continuation of the awareness-raising and information measures directed towards all the players (regional authorities, employers, building professionals, health professionals, teachers, etc.) and the general public, both nationally and locally, with the promotion and accompanying of regional measures for the integrated management of the radon risk in the home.

A specific communication campaign shall target smokers, because they constitute the population the most at risk of developing lung cancer linked to cumulative exposure to radon and tobacco. The operational implementation of the information system incorporating all the radon monitoring results, as well as the consolidation and centralising of the existing measures, would appear moreover to be essential for informing the public.

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

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.*

RADON RISK: ASN PRIORITIES

Responsibility for the national strategy for managing the radon risk, and the regulations that depend on this, is shared between the Ministries responsible for risk prevention, health, labour and construction, assisted by ASN. ASN redefined its directions and priorities regarding management of the radon risk in 2021, which are now deployed along eight lines.

1. Continuation of the facilitation and coordination of the national radon action plan and assessment of the management policy for the radon risk

The French national radon action plan has been structuring the public policies regarding management of the radon risk since 2005. Its preparation and monitoring are co-managed by ASN, which also ensures the technical secretariat for the monitoring committee. ASN is also tasked with the co-management of several actions in the 2020-2024 plan.

ASN will consolidate its facilitation and coordination role at both national and regional level.

ASN will moreover participate in the work to assess the effectiveness of the radon risk management policy.

2. Support for the enhancement of scientific knowledge and involvement in international work

The assessment of the risks associated with exposure to radon has been the subject of recent publications allowing updating of the knowledge based on the available epidemiological and scientific studies and the dosimetric approach developed by the ICRP. At national level, the quantitative assessment of the health effect of radon in France was updated in 2018. Nevertheless, subjects remain to be investigated (risk of pathologies other than lung cancer for example).

ASN will participate in the international work on these subjects, particularly through the work of the Heads of the European Radiological Protection Competent Authorities (HERCA).

3. Development of a communication strategy

The radon risk and the corresponding regulations are still poorly known to the general public(*). Informing the various audiences of this risk and the associated means of prevention, as well as the applicable regulations, constitutes a major challenge for the success of the public policies for managing the radon risk. It constitutes the leading priority of the national radon action plan 2020-2024. ASN will examine any experimental and innovative initiative that fosters the development of a culture of prevention.

4. Assessment of the system for approving organisations performing radon activity measurements

At present, ASN issues the approvals for organisations tasked with measuring radon activity. A change in this system will be studied in consultation with the DGS, with the more specific aim of switching from a system of approval by ASN to a system of accreditation by the Cofrac for organisations taking measurements in PABs.

5. Completion of the regulatory system

ASN will complete the updating of the resolutions relative to the approved organisations (conditions of approval and operator training) and the resolution relative to the data centralisation information system (abandoning of the SISE-ERP(**) application in favour of the "simplified procedures" system).

6. Support for radon risk reduction actions at the construction stage

Current building construction standards make no particular provisions concerning consideration of the radon risk and no conclusions can be drawn at present from the studies on the effectiveness of these standards with respect to this risk. ASN will encourage any action that aims firstly to better assess the effectiveness of the standards in effect in the building sector with respect to the radon risk, and secondly to reduce the risk at source through, for example, obligations at the construction stage.

7. Continuation of the graded approach to oversight

For PABs, the oversight will target the property managers in priority. Point inspections shall be conducted in situations where set deadlines have been greatly exceeded and the owners have clearly taken no action. Where workplaces are concerned, for which the regulations have greatly evolved, ASN will also conduct targeted inspections of buildings with radiation exposure risks, where the radon concentrations can be high.

8. Development of a national framework for emergency situation management

In the last few years, situations where the reference radon level of 300 Bq/m^3 has been greatly exceeded in PABs, workplaces and private homes have been reported to ASN. Experience feedback reveals the need for nationwide coordination, as is already the case for radon of anthropogenic origin.

ASN will reflect on ways of defining national coordination procedures for these situations. ASN will moreover support the creation of specific funds to finance emergency actions in the most critical cases.

(*) IRSN barometer 2019: How the French perceive risks and safety.
(**) Health environment information system concerning PABs.

be improved so as to better integrate certain geological factors that could facilitate radon transfer to buildings (karst zones in particular). Furthermore, the fourth Radon Plan provides for the updating of knowledge of exposure of the French population by organising the collection of measurement data obtained in particular during the local awareness-raising operations organised by the ARS and the regional authorities to cover the areas for which insufficient data are available. These operations consist in proposing screening kits to the inhabitants of a given region to raise their awareness of the radon risk.

Lastly, **line 3** aims to take better account of the management of the radon risk in buildings. In order to help members of building trade organisations improve their skills, these organisations have recently developed training courses dealing with methods to prevent and reduce concentration levels and various media to address the needs. The various French-language aids have been listed. To complete the offering, a guide intended for professionals and private individuals will establish prevention recommendations for new constructions and remedial measures in existing buildings. The progress made in understanding the effectiveness of construction standards in reducing radon concentrations in indoor air shall be consolidated.

A system of specific indicators, chosen according to their relevance and the available data allowing them to be monitored, has been put in place to evaluate the effectiveness of the national strategy implemented under the national action plan. The way the indicators evolve will be analysed each year by the steering committee that monitors the new action plan.

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. Medical exposure has been increasing over the last thirty years or so due to the rise in the number of radiological examinations –and computed tomography examinations in particular, to the ageing of the population, and to the strategies implemented to ensure better patient care, particularly in the context of patient monitoring after cancer treatment and coronary diseases. It has been regularly reviewed by IRSN since 2002.

The average effective dose per inhabitant resulting from diagnostic radiological examinations has been evaluated at 1.53 mSv for the year 2017 (IRSN ExPRI study 2020) for some 85 million diagnostic procedures performed in 2017 (81.6 million in 2012), *i.e.* 1,187 procedures for 1,000 inhabitants per year. It is to be noted that as before, the individual exposure in 2017 is very varied. Consequently, although about 32.7% of the French population underwent at least one procedure (dental procedures excluded), half the patients received a dose of 0.1 mSv or less, 75% received 1.5 mSv or less, while the most exposed 5% of patients received a dose exceeding 18.1 mSv.

Conventional radiology (55.1%), computed tomography (12.8%) and dental radiology (29.6%) account for the largest number of procedures. It is the contribution of computed tomography to the effective collective dose that remains preponderant and more significant in 2017 (75%) than in 2012 (71%), whereas that of dental radiology remains very low (0.3%).

In adolescents, conventional and dental radiology procedures are the more 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 is noteworthy 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 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. A second plan of action was published in July 2018. This plan extends the first one (2011-2017), drawn up in collaboration with the stakeholders (institutional and professional).

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.

3.4 Exposure of non-human species (animal and plant species)

The international radiation protection system was created to protect humans against the effects of ionising radiation. Environmental radioactivity is thus assessed with respect to its impact on human beings and, in the absence of any evidence to the contrary, it is today considered that the current standards guarantee the protection of other species.

Protection of the environment against the radiological risk and more specifically the protection of non-human species, must however be guaranteed independently of the effects on humans. Pointing out that this objective is already incorporated in French legislation, ASN ensures that the impact of ionising radiation on non-human species is effectively taken into account in the impact assessments of nuclear facilities and activities. On the basis of the IRSN expert assessment report, the Advisory Committee for Radiation Protection in Industrial and Research Applications of Ionising Radiation and for the Environment (GPRADE) adopted an opinion in September 2015. Following the recommendations of this opinion, at the end of 2017 ASN set up a pluralistic and multi-disciplinary working group coordinated by IRSN to produce a methodological guide for assessing the impact of ionising radiation on the flora and fauna. The draft guide was submitted to ASN at the end of 2020 and presented to the GPRADE in June 2021. It is planned to publish the guide at the very beginning of 2022.

Actions of ASN regional divisions in the prevention of the radon risk in the regions

In 2021, the ASN regional divisions, along with the public authorities Dreal (Regional directorate for environment, planning and housing), ARS, Dreets (Regional directorate for the economy, employment, labour and solidarity) and the partner organisations (Cerema, trade associations, local authorities, etc.), continued the actions to raise the awareness of elected officials, building trade professionals, employers, managers of PABs and the general public to the regulatory changes made since 2018 (see point 3.2.2). This awareness-raising was accompanied by inspection actions. For the PABs, these inspections target the major property managers in particular.

AWARENESS-RAISING ACTIONS

BRETAGNE / PAYS DE LA LOIRE – **Nantes division**

- Between 65% and 93% of the municipalities in the *départements* (Sarthe excluded) of these regions are situated in **zones with significant radon potential**.
- Organisation by the Nantes division, the ARS and the Dreets of a "radon" webinar for PAB owners and employers, with a **dual goal**: reiterate the regulatory obligations and collect testimonies of radon risk reduction actions.
- Financing by ASN of **four new actions** in Pays de la Loire aiming to get private individuals to carry out voluntary radon measurement campaigns in their homes (the division participated in the campaign kick-off meetings).
- The Nantes division answered some **twenty demands** from PABs, employers and inhabitants concerning the radon issue.

BOURGOGNE-FRANCHE-COMTÉ – **Dijon division**

- Ongoing reflections on the creation of a **regional health/environment network** that would allow the coordination and facilitation of the players involved in management of the radon risk and air quality inside buildings.
- This network has several objectives in view: provide its member with an **overall view of the challenges**, create **synergies** between them, foster the application of national guidelines and accompany the **deployment of new collective projects**. It would be based on the digital platform stemming from the JURAD-BAT project and would contribute to its development.

NOUVELLE-AQUITAINE / OCCITANIE – **Bordeaux division**

- Setting up in 2020 of a **communication plan** by the Bordeaux division, the ARS, the Dreets and the Dreal for the elected officials and PAB managers with the aim of assisting with the implementation of the new regulatory provisions.
- **Action continued in 2021** with the response to the demands from the targeted audiences: town halls, health facilities, educational institutions, collectivities, etc.

GRAND EST – **Strasbourg and Châlons-en-Champagne divisions**

- **Awareness-raising actions** by the two regional divisions in the context of the Regional Health Environment Plan 3 (PRSE 3), particularly with the elected officials of the Vallées and Plateau d'Ardenne municipal federation (Ardennes *département*).

PROVENCE-ALPES-CÔTE D'AZUR / OCCITANIE – **Marseille division**

- During two meetings with the elected officials and the technical services of the city of Marseille, presentation of the regulations and, with the assistance of IRSN, the **methods of creating the radon mapping** on the municipal scale.

CENTRE-VAL DE LOIRE – **Orléans division**

- Participation on 1 December 2021 at an information meeting organised for the elected officials of four municipalities of the Cher *département* involved in the setting up of a screening campaign. This meeting provided the opportunity to **present the risks associated with radon in the home and to determine the methods of informing the inhabitants** in order to find volunteers prepared to have radon measuring kits installed in their home.

OVERSIGHT ACTIONS

BRETAGNE / PAYS DE LA LOIRE – Nantes division

- **Two inspections** of the actions taken by the towns of Rennes and la Roche-sur-Yon. Observation of **contrasting ways of taking into account** the radon risk in these municipalities: one had deployed measures and actions to reduce the radon risk for the public and workers, the other having initiated procedures in late 2021.

BOURGOGNE-FRANCHE-COMTÉ – Dijon division

- **Inspection and observation** of good management of the initial radon screening (in 2015) of the Spa of Saint-Honoré-les-Bains (Nièvre *département*) where four premises had moderately exceeded the reference level with the **implementation of remediation actions** (but nevertheless without the effectiveness of the renovation work having been verified). Furthermore, radon was not taken into consideration in the occupational risks assessment.
- **Inspection and observation** of good management of the initial radon screening with the departmental Council of Saône-et-Loire with the **effective implementation of screening and remediation actions** in all the secondary schools of the *département*; a few radon concentrations exceeding 300 Bq/m³ subsist in a few schools and expert assessments of the buildings are in progress. In addition, radon has been taken into account in the occupational risks assessment for the first time at two sites (Solutré Museum and the Azé Grotto), but remains to be deployed in all the other workplaces.

GRAND EST – Strasbourg and Châlons-en-Champagne divisions

- **Inspection** of two spas.
- **Continuation of the inspections** of PAB managers and workplaces in 2022.

PROVENCE-ALPES-CÔTE D'AZUR / OCCITANIE – Marseille division

- **Joint inspection** of the **town of Toulon** by the Marseille division and the ARS of Provence-Alpes-Côtes d'Azur (PACA).
- The division participated in the management of a case of where the reference level was significantly exceeded in a school in Meyrueis (Lozère *département*).

AUVERGNE-RHÔNE-ALPES – Lyon division

- **Inspection of the departmental Councils** of the Allier, Ardèche and Savoie *départements* and the metropolis of Lyon. Observation of the need **to follow up over the long term** the measures taken by these institutions to reduce exposure to radon.

NORMANDIE – Caen division

- **Inspection within the departmental Council** of Calvados which is responsible for all the secondary schools of the *département*. **The prevention measures** required by the new regulations have been **applied satisfactorily** by the manager of the institutions. Observation of the need **to continue this approach**.

In addition, the radiation protection inspections carried out in 2021 in medical or industrial facilities situated in municipalities with significant radon potential were used by some divisions to explain the regulatory obligations of employers in workplaces. In this respect, as in the year 2020, ASN found that radon is increasingly taken into account in the occupational risk assessments.

The regional divisions moreover contributed to the inspection of organisations approved for taking radon measurements in PABs (14 inspections).

Several other awareness-raising or oversight actions planned in 2021 were postponed due to the Covid-19 pandemic.

(*) 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.

02

The principles of nuclear safety and radiation protection and the regulation and oversight stakeholders

02 THE PRINCIPLES OF NUCLEAR SAFETY AND RADIATION PROTECTION AND THE REGULATION AND OVERSIGHT STAKEHOLDERS

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 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 below page 122 and chapter 6, point 3.1) implemented by the Convention on Nuclear Safety (see chapter 6, point 4.1), which establishes the international framework for the oversight of nuclear safety and radiation protection.

These various measures of differing origins extensively overlap. They can be grouped into the eight main principles presented below.

1.1.1 The principle of licensee responsibility

This principle, defined in Article 9 of the Convention on Nuclear Safety, is the first of IAEA's fundamental safety principles. It stipulates that responsibility for the safety of nuclear activities entailing risks lies with those who undertake or perform them.

It applies directly to all nuclear activities.

1.1.2 The "Polluter-pays" principle

The "Polluter-pays" principle, contained in Article 110-1 of the Environment Code, stipulates that the costs resulting from the measures to prevent, mitigate and fight against pollution must be borne by the polluter.

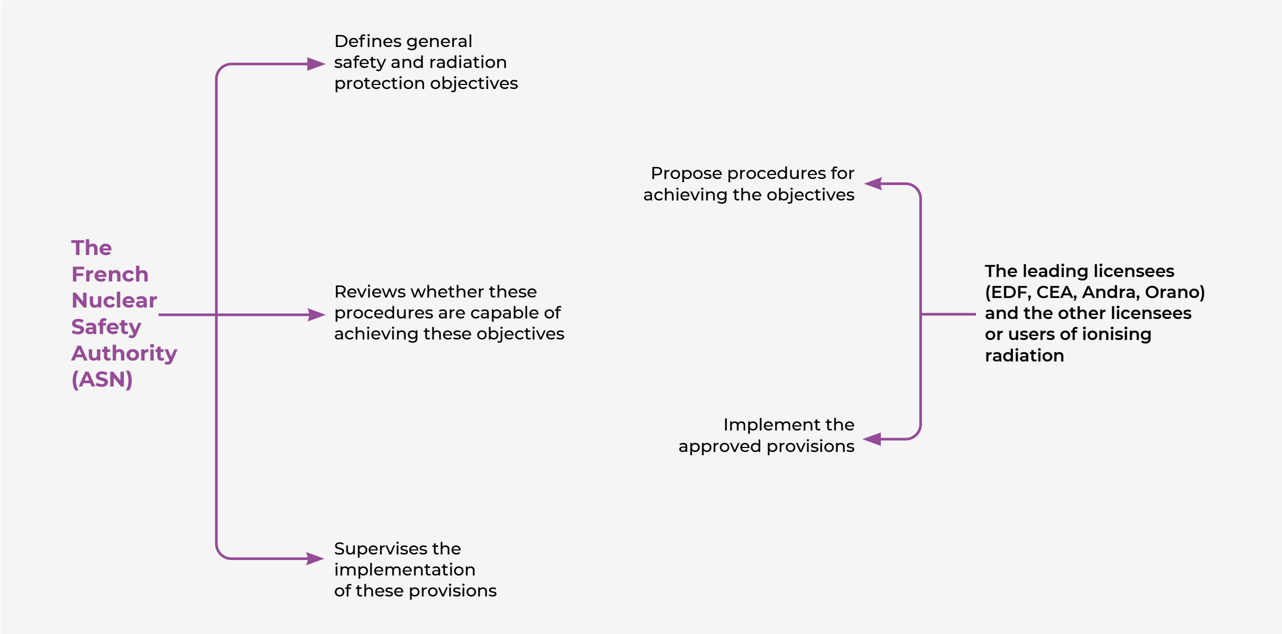
1.1.3 The precautionary principle

The precautionary principle, defined in Article 5 of the Environment Charter, states that "*the absence of certainty, in the light of current scientific and technical knowledge, must not delay the adoption of effective and proportionate measures to prevent a risk of serious and irreversible damage to the environment*".

Application of this principle results, for example, in the adoption of a linear, no-threshold dose-effect relationship where the biological effects of exposure to low doses of ionising radiation are concerned. This point is clarified in chapter 1 of this report.

01 02 03 04 05 06 07 08 09 10 11 12 13 14 AP

RESPONSIBILITY OF LICENSEES AND RESPONSIBILITY OF ASN



1.1.4 The public participation principle

This principle allows public participation in the decision-making process by 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. *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 30 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 International Atomic Energy Agency (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 radiological risks must be justified and optimised.

1.1.8 The prevention principle

To anticipate any environmental damage, the prevention principle, defined in Article 3 of the Environment Charter, stipulates the implementation of rules and measures, which must take account of "*the best available technology at an economically acceptable cost*".

In the nuclear field, this principle underpins the concept of "Defence in Depth", presented below.

1.2 Some aspects of the safety approach

The safety principles and approaches presented below were gradually implemented and incorporate the lessons learned from accidents. Absolute safety can never be guaranteed. Despite all the precautions taken in the design, construction and operation of nuclear facilities, an accident can never be completely ruled out. Willingness to move forward and to create a continuous improvement approach is thus essential if the risks are to be reduced.

1.2.1 Safety culture

Safety culture is defined by the International Nuclear Safety Advisory Group (INSAG), an international consultative group for nuclear safety reporting to the Director General of the IAEA, as that complete range of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance.

Safety culture therefore determines the ways in which an organisation and individuals perform their duties and assume their responsibilities with respect to safety. It is one of the key fundamentals in maintaining and improving safety. It commits organisations and individuals to paying particular and appropriate attention to safety. At the individual level it must be given expression by a rigorous and cautious approach and a questioning attitude making it possible to both obey rules and take initiatives. In operational terms, the concept underpins daily decisions and actions relating to activities.

1.2.2 The "Defence in Depth" concept

The concept of "Defence in Depth" consists in implementing a series of levels of defence based on the intrinsic characteristics of the installation, material, organisational and human measures and procedures designed to prevent accidents and then, if this fails, to mitigate their consequences. "Defence in Depth" is a concept which applies to all stages in the lifetime of a facility, from design to decommissioning.

These levels of defence are consecutive and independant, 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

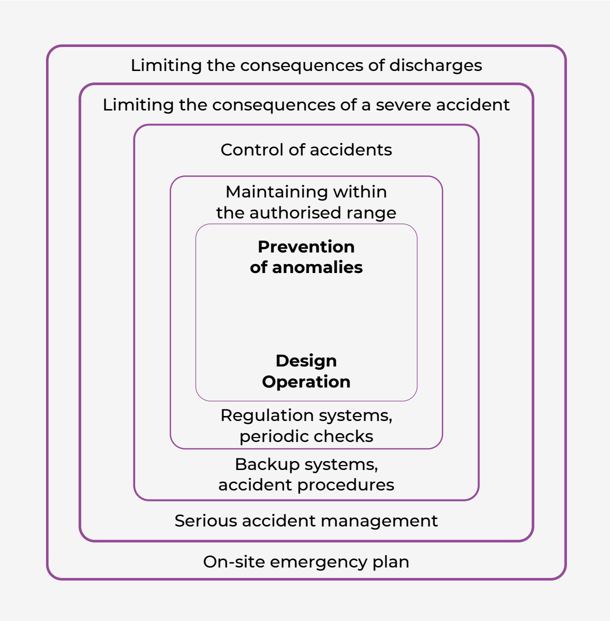
Regulation and governing systems must be designed, installed and operated such that the installation is kept within an operating range that is far below the safety limits. For example, if the temperature in a system increases, a cooling system starts up before the temperature reaches the authorised limit. 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.

THE 5 LEVELS OF DEFENCE IN DEPTH



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 –PWR (Evolutionary Power Reactor –EPR). The aim is to preclude such accidents or to design systems that can withstand them.

Level 5: Mitigation of the radiological consequences of significant releases
This entails implementing 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 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 Probabilistic Safety Assessments (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 of the organisation, which have an influence on the work done by the persons involved. The elements considered concern the individual (training received, fatigue or stress, etc.) and the organisation within which they work (functional and hierarchical links, joint contractor work, etc.), the technical arrangements (tools, software, etc.) and, more broadly, the working environment with which the individual interacts.

The working environment for instance concerns the heat, sound or light environment of the workstation, as well as the accessibility of the premises.

The variability in worker characteristics (vigilance varies with the time of day, the level of expertise varies according to the seniority in the position) and in the situations encountered (unexpected failure, social tension) explains that these workers constantly need to adapt how they work, in order to optimise effectiveness and efficiency. This goal must be achieved at an acceptable cost to the persons concerned (in terms of fatigue or stress) and provide a benefit to them (the feeling of a job well done, recognition by both peers and the hierarchy, development of new skills). Thus, an operating situation or a task achieved at very high cost to the operators is a potential source of risks: a small variation in the working context, human environment or working organisation can prevent the persons concerned from performing their tasks as expected.

Integration of 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 "*contracting party shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory provisions mentioned in Article 7, and provided with adequate authority, competence and financial and human resources to fulfill its assigned responsibilities*" and "*[...] shall take the appropriate steps to ensure an effective separation between the functions of the regulatory body and those of any other body or organisation concerned with the promotion or utilisation of nuclear energy*". These provisions were confirmed by European Council Directive 2009/71/Euratom of 25 June 2009 concerning Nuclear Safety, the provisions of which were in turn reinforced by the amending Directive of 8 July 2014.

The regulation of nuclear safety and radiation protection in France depends essentially on three players: Parliament, the Government and ASN.

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 Ministers responsible for nuclear safety and radiation protection

On the advice of and, as applicable, further to proposals from ASN, the Minister responsible for nuclear safety defines the general regulations applicable to BNIs and those concerning the construction and use of Pressure Equipment (PE) specifically designed for these installations.

Also, on the advice of and, as applicable, further to proposals from ASN, this same Minister takes major individual resolutions concerning:
- the design, construction, operation and decommissioning of BNIs;
- the design, construction, operation, closure and decommissioning, as well as the surveillance, of radioactive waste disposal facilities.

If an installation presents serious risks, the above-mentioned Minister can suspend the operation of an installation on the advice of ASN.

Furthermore –and on the basis of ASN proposals if necessary– the Minister responsible for radiation protection defines the general regulations applicable to radiation protection.

The regulation of worker radiation protection is the responsibility of the Minister for Labour, Employment and Integration. That concerning the radiation protection of patients is the responsibility of the Minister for Solidarity and Health.

The Ministers responsible for nuclear safety and for radiation protection approve the ASN internal rules of procedures 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 Defence and Security High Official (HFDS) administration 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.

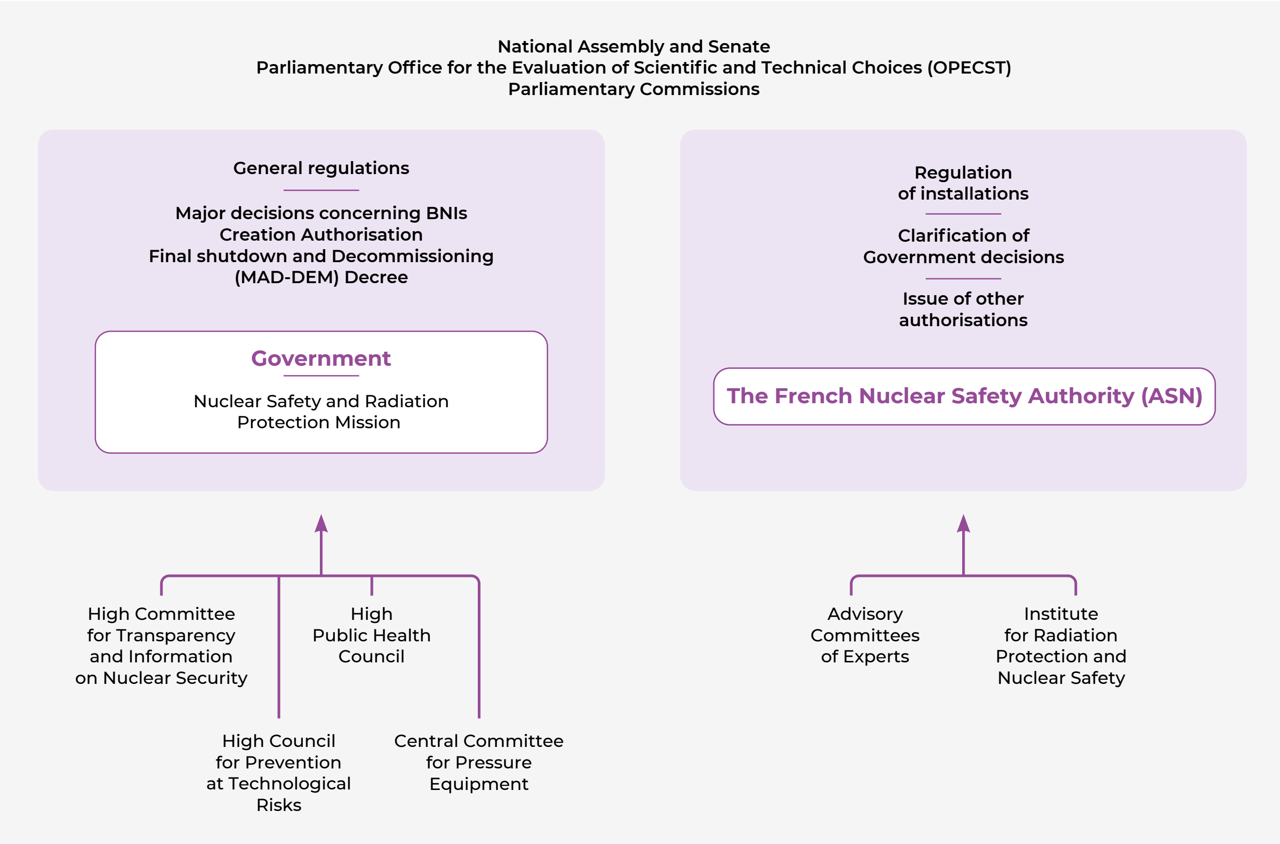
ASN maintains close relations with the Regional Directorates for the Environment, Planning and Housing (Dreal), the Regional and Interdepartmental Directorate for Public Works, Development and Transport of Île-de-France (Drieat), the Regional Directorates for the economy, employment, labour and solidarity (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 (GPE).

2.3.1 Role and duties

Regulation

ASN is consulted on draft decrees and Ministerial Orders of a regulatory nature dealing with nuclear safety as defined in Article L.591-1 of the Environment Code.

It can issue technical regulations to complete the implementing procedures for decrees and orders adopted in the nuclear safety or radiation protection field, except for those relating to occupational medicine. These regulations must be approved by the Minister responsible for nuclear safety or the Minister responsible for radiation protection. Approval orders and approved resolutions are published in the *Official Journal*.

Authorisation

ASN reviews BNI creation authorisation or decommissioning applications, issues opinions and makes proposals to the Government concerning the decrees to be issued in these fields. It authorises significant modifications to a BNI. It defines the requirements applicable to these installations with regard to the prevention of risks, pollution and detrimental effects. It authorises commissioning of these installations and pronounces delicensing following completion of decommissioning.

Some of these resolutions require approval by the Minister responsible for nuclear safety.

ASN issues the licenses, carries out registration and receives the notifications provided for in the Public Health Code concerning small-scale nuclear activities and issues licenses or approvals for radioactive substances transport operations. The ASN resolutions and opinions debated by its Commission are published in its *Official Bulletin* on its website (*asn.fr*).

Oversight

ASN verifies compliance with the general rules and specific requirements for nuclear safety and radiation protection applicable to BNIs, to the pressure equipment designed specifically for these facilities and to the transport of radioactive substances. It also regulates the activities mentioned in Article L. 1333-1 of the Public Health Code and the ionising radiation exposure situations defined in Article L. 1333-3 of the same Code. ASN organises a permanent radiation protection watch throughout the national territory.

From among its staff, it appoints nuclear safety inspectors, radiation protection inspectors and inspectors carrying out labour inspectorate duties.

ASN issues the required approvals and certifications to the organisations participating in the verifications and in nuclear safety or radiation protection monitoring, as well as with regard to Nuclear Pressure Equipment (NPE).

Ordinance 2016-128 of 10 February 2016, issued pursuant to the TECV Act, reinforces ASN's regulatory and enforcement powers and broadens the scope of its competences.

The effect of ASN's reinforced regulation, policing and enforcement powers will be to improve the effectiveness of the regulation of nuclear safety and radiation protection. These policing and enforcement powers are extended to the activities performed outside BNIs, and participating in the technical and organisational measures mentioned in the 2nd paragraph of Article L. 595-2 of the Environment Code, by the licensee, its suppliers, contractors or sub-contractors and in the same conditions as within the facilities themselves.

Administrative fines will be imposed by the administrative enforcement Committee, in order to comply with the principle of separation between the investigation, charging and sentencing functions instituted in French law and in international Conventions on the right to a fair trial. Chapter 3 of this report describes all of ASN's oversight actions, including enforcement.

Emergency situations

ASN participates in the management of radiological emergency situations. It provides technical assistance to the competent Authorities for the drafting of emergency response plans, taking account of the risks resulting from nuclear activities.

When such an emergency situation occurs, ASN verifies the steps taken by the licensee to make the facility safe. It assists the Government with all matters within its field of competence and submits its recommendations on the medical or health measures or civil protection steps to be taken. It informs the general public of the situation, of any releases into the environment and their consequences. It acts as the Competent Authority within the framework of international conventions, by notifying international organisations and foreign countries of the accident.

Chapter 4 of this report describes ASN actions in this field.

In the event of an incident or accident concerning a nuclear activity and, pursuant to Articles L.592-35 and R.592-23 *et seq.* of the Environment Code concerning technical inquiries into accidents or incidents concerning a nuclear activity, ASN may carry out a technical inquiry.

ASN ACTIONS IN THE FIELD OF RESEARCH

In the field of research, ASN set itself the objectives of identifying its needs, publishing them and making them known among the institutions, licensees and research laboratories, so that they are incorporated into the research programmes.

In order to reinforce its approach, ASN is also involved in steering committees, such as that of the Research in the fields of Nuclear Safety and Radiation Protection programme (RSNR) of the National Research Agency (ANR). ASN also takes part in selecting research projects financed by Euratom. These calls for project proposals helped numerous projects emerge in response to the research needs identified by ASN over the past ten years, on subjects such as non-destructive examinations, severe accidents, organisational and human factors, the biological and health effects of low doses of ionising radiation, or the conditioning of waste and its geological disposal.

ASN will continue its meetings with the authorities, institutions, research laboratories and licensees in France and abroad, for discussions on research needs.

Information

ASN participates in informing the public in its areas of competence. Chapter 5 of this report describes ASN actions in this field.

Definition of orientations and oversight of research

The quality of ASN's resolutions and decisions relies primarily on robust technical expertise which, in turn, requires the best and most up-to-date knowledge. In this field, Article L.592-31-1 of the Environment Code comprises provisions giving ASN competence to ensure that public research is tailored to the needs of nuclear safety and radiation protection.

On the basis of the work of its Scientific Committee (see point 2.5.3), ASN issued three opinions on research needs in 2012, 2015 and 2018. Since the publication of its third opinion, ASN has continued to strengthen its relations with research organisations and institutions in charge of programming and financing research nationally and at a European level. The 2020 and 2021 health context however limited the scheduled meetings, notably at an international level.

The Fukushima Daiichi NPP accident in Japan highlighted the need for more research in the field of nuclear safety and radiation protection. A Call for Project (AAP) proposals in these fields was therefore issued by the French National Research Agency (ANR) within the framework of the Investments for the Future programme. ASN takes part in the steering committee for this AAP, which has enabled research projects to be financed since 2013, up until mid-2023. An evaluation of these projects is planned as of 2022.

2.3.2 Organisation

ASN Commission

The ASN Commission comprises five full-time Commissioners. Their mandate is for a period of six years and may not be renewed. The Commissioners perform their duties in complete impartiality and receive no instructions from either the Government or any other person or institution. The President of the Republic may terminate the duties of any member of the Commission in the event of a serious breach of his or her obligations.

The Commission defines ASN's strategy. More specifically, it is involved in developing overall policy, *i.e.* the doctrines and principles that underpin ASN's main missions of regulation, inspection, transparency, management of emergency situations and international relations.

Pursuant to the Environment Code, the Commission submits ASN's opinions to the Government and issues the main ASN regulations and decisions. It decides on the public position to be adopted on the main issues within ASN's sphere of competence. The Commission adopts the ASN internal rules of procedure which set out its organisation and working rules, as well as its ethical guidelines. The Commission's decisions and opinions are published in ASN's *Official Bulletin*.

In 2021, the ASN Commission met 57 times. It issued 22 opinions and 17 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). ASN installed its Administrative Enforcement Committee 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

THE ASN ADMINISTRATIVE ENFORCEMENT COMMITTEE

From left to right: **Bernard Bureau, Françoise Farrenq-Nesi, Jacqueline Riffault, Maurice Méda, Denis Jardel, Olivier Yeznikian. *Absent:* Yves Gounin.**

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 Court of Cassation. It also comprises four deputy members, one of whom is currently being appointed. The duration of the members' mandate is 6 years.

At their first meeting, on 19 October 2021, the regular members elected Mr. Maurice Meda as Chairman of the Committee for the next three years. They also adopted the internal rules of procedure which were published in the *Official Journal* on 5 November 2021 and the ASN *Official Bulletin* on 8 November.

As set out by law, the Committee will meet exclusively when referred to by the ASN Commission. This latter may decide to open a procedure leading to issue of a fine after clearly determining that the person responsible for nuclear activities has not complied with a formal notice, in other words has not taken the measures required by this formal notice.

The fines will be proportional to the seriousness of the observed breaches and in particular take into account the extent of the impact on the environment. The maximum amount of the fines is set by law at 10 million euros, in the event of a breach of the provisions applicable to BNIs, one million euros for a breach of the provisions applicable to NPE, 30,000 euros in the field of transport of radioactive substances, and 15,000 euros for small-scale nuclear activities.

The administrative fine issue procedure includes compliance with the adversarial principle. No penalty can be imposed without the party concerned or their representative having been heard or summoned. The Committee's decision may be made public. The decisions pronounced by the Administrative Enforcement Committee may be referred to the administrative jurisdiction (Council of State) by the person concerned, by the ASN Chairman or by the third parties.

ASN head office departments

The ASN head office departments comprise an Executive Committee, a General Secretariat, a Management and Expertise Office, an Oversight Support Office and nine departments covering specific themes.

Under the authority of the ASN Director General, the Executive Committee organises and manages the departments on a day to day basis. It ensures that the orientations determined by the Commission are followed and that ASN's actions are effective. It oversees and coordinates the various entities.

The role of the departments is to manage national affairs concerning the activities under their responsibility. They take part in defining the general regulations and coordinate and oversee the actions of the ASN regional divisions:

- The Nuclear Power Plant Department (DCN) is responsible for regulating and monitoring the safety of the NPPs in operation, as well as the safety of future power generating reactor projects. It contributes to the development of regulation/oversight strategies and ASN actions on subjects such as facility ageing, reactor service life, assessment of NPP safety performance and harmonisation of nuclear safety in Europe. The DCN comprises six offices: "Hazards and Safety Reviews", "Equipment and Systems Monitoring", "Operation", "Core and Studies", "Radiation Protection, Environment and Labour Inspectorate" and "Regulation and New Facilities".
- The Nuclear Pressure Equipment Department (DEP) is responsible for monitoring the safety of pressure equipment 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

THE MEMBERS OF THE MANAGEMENT COMMITTEE

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, certification of packaging and of relevant organisations). It took charge of oversight of the security of radioactive sources. The DTS comprises two offices: "Transport Monitoring" and "Radiation Protection and Sources", plus a "Source Security" section.
- The Waste, Research Facilities and Fuel Cycle Department (DRC) is responsible for monitoring "nuclear fuel cycle" facilities, research facilities, nuclear installations being decommissioned, contaminated sites and radioactive waste management. It takes part in monitoring the Meuse/Haute-Marne underground research laboratory and the research facilities covered by international Conventions, such as the European Organisation for Nuclear Research (CERN) or the International Thermonuclear Experimental Reactor (ITER) project. The DRC comprises five offices: "Radioactive Waste Management", "Monitoring of Laboratories-plants-waste-decommissioning and Research Facilities", "Monitoring of Fuel Cycle Facilities", "Management of Reactor Decommissioning and the Cycle Front-end" and "Management of Cycle Back-end Decommissioning and Legacy Situations".
- The Ionising Radiation and Health Department (DIS) is tasked with regulating medical applications of ionising radiation and –in collaboration with IRSN and the various health authorities– organising the scientific, health and medical watch with regard to the effects of ionising radiation on health. It contributes to the drafting of the regulations in the field of radiation protection, including with respect to natural ionising radiation, and the updating of health protection measures should a nuclear or radiological event take place. The DIS comprises two offices: "Exposure in the Medical Sector" and "Exposure of Workers and the Public".
- The Environment and Emergency Department (DEU) is responsible for monitoring environmental protection and managing emergency situations. It establishes policy on nationwide radiological monitoring and on the provision of information to the public and helps to ensure that discharges from BNIs are "as low as reasonably achievable", in particular by establishing general regulations. It contributes to defining the framework of the organisation of the public authorities and nuclear licensees in the management of emergency situations. The DEU comprises two offices: "Safety and Preparedness for Emergency Situations" and "Environment and Prevention of Detrimental Effects".
- The Legal Affairs Department (DAJ) provides consulting, analysis and assessment and assistance services on legal matters. It assists the various departments and the regional divisions with drafting ASN standards and analyses the consequences of new texts and new reforms on ASN's actions. It takes part in drawing up ASN's enforcement and sanctions doctrine. It defends ASN's interests before administrative and judicial courts, jointly with the entities concerned. It takes part in the legal training of staff and in coordinating regulations steering committees.
- The Information, Communication and Digital Usages Department (DIN) implements ASN information and communication policy in the fields of nuclear safety and radiation protection. It coordinates ASN communication and information actions targeting different audiences, with a focus on handling requests for information and documentation, making ASN's position known and explaining regulations. It is responsible for the IT infrastructure, for overseeing the digital transformation and the development of digital services for the parties concerned and the ASN audiences. The DIN comprises two offices: "Communication and Information" and "IT and Digital Usages".
- The International Relations Department (DRI) coordinates ASN's bilateral, European and multilateral actions on the international stage, both formal and informal. It develops exchanges with ASN's foreign counterparts in order to promote

THE REGIONAL DIVISION HEADS

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 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. It ensures that ASN’s actions are coherent, by means of a quality approach and by overseeing coordination of the workforce. The MEA consists of six staff in charge of expert appraisals, research, quality and relations with IRSN. 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 inspection programme to check the approved organisations of the departments.

ASN regional divisions

For many years, ASN has benefited from a regional organisation built around its eleven regional divisions. These regional divisions operate under the authority of the regional representatives. The Director of the Dreal or of the Driee, 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 2021, ASN’s overall workforce stood at 519, distributed between the head office departments (291 staff), the regional divisions (226 staff) and various international organisations (2 staff).

This workforce can be further broken down as follows:

- 451 tenured or contract staff;
- 68 staff seconded by public establishments (National Radioactive Waste Management Agency –Andra, *Assistance publique*

THE REGIONAL REPRESENTATIVES

From left to right and from top to bottom: H. Brûlé, A. Beauval, J-P. Lestoille, A-A. Médard, J-P. Deneuvy, O. Morzelle, L. Tapadinhas, C. Tourasse, H. Vanlaer.
Absent: E. Gay.

– *Hôpitaux de Paris*, CEA, IRSN, Departmental Fire and Emergency Response Service).

ASN utilises a diversified hiring policy with the aim of ensuring that there are sufficient numbers of the qualified and complementary human resources needed to perform its duties.

Skills management

Alongside independence, transparency and rigour, 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 nuclear power plants, pursuant to Article R. 8111-11 of the Labour Code. For each of the inspectors concerned, the accreditation decision taken by ASN is based on the match between the skills acquired –both within and outside ASN– and those specified in the professional baseline requirements.

Training has been adapted to the Covid-19 pandemic context. As at 31 December 2021, ASN employed 321 nuclear safety or radiation protection inspectors holding at least one qualification, or nearly 62% of the 519 ASN staff.

Nearly 2,400 training days were given to ASN staff during the course of 156 sessions as part of 90 different in-person or video courses. A large volume of self-training hours should be added to these figures.

The training committee ensures that the training system matches the needs and strategic objectives set out in the multi-year Strategic Plan.

Social dialogue

As a State administration, ASN has three social dialogue bodies:
- the Social Dialogue Committee (SDC), with competence for all questions concerning the organisation and working of the departments, workforce and budget aspects;
- the Joint Consultative Commission (CCP) with competence for all individual or collective questions concerning ASN's tenured contract staff;
- the Health, Safety and Working Conditions Committee (CHSCT) with competence for all questions concerning the occupational health and safety of ASN staff.

These three bodies allow wide-ranging and regular internal discussions on all subjects affecting its organisation, its operations and the working environment of its personnel.

During the course of 2021, the ASN SDC met on three occasions to tackle various subjects and, for some of them, issued an opinion on texts presented by the administration: Covid-19 pandemic and the organisation of the continuity of activities; plan to relocate the Dijon regional division and the DEP; operation of the training committee; single social report; information concerning senior positions and professional elections in 2022. On the occasion of the last SDC of the year, a particular point was devoted to organising negotiations regarding home-working at ASN.

For its part, the CHSCT focused on ensuring that occupational health and safety aspects were taken into account in ASN's organisational and operational changes and in the performance of its duties. It met on three occasions in 2021. Regular remote meetings between the personnel representatives and the administration were held during the lockdown and post-lockdown periods, to share information and discuss adaptations to the organisational and operational instructions needed given the developing health context.

"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
- Inspections 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 licensee routine operations approach - Immersion
- BNI technical regulations

Specific PWR training
- Pressurised Water Reactor
- 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
- Pressurised Water Reactor
- Fire
- External hazards
- Ventilation

Qualifying professional experience

Joint nuclear safety inspectors qualifying experience
- Has followed two inspections as an observer
- Has played a hands-on role in three inspections

PWR inspectors qualifying experience (excluding Pressure Equipment –PE), LUDD
- Has taken part in three notification investigations of Article 26
- Has taken part in three significant event investigations (ASN regional divisions)

PWR inspectors qualifying experience with intervention limited to the 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

The debates and exchanges with the personnel representatives concerned Covid-19 pandemic and the prevention and evaluation of occupational risks during the pandemic, the organisation of the service competent in radiation protection and the procedure regarding the prevention of risks of exposure to ionising radiation for the ASN staff. A working group was set up and an inquiry was held for questions regarding home-working. The conclusions of the inquiry were presented to the CHSCT.

As every year, the CHSCT also examined the annual general health and safety situation, and the SST (occupational health services) results at CEA.

In addition, the CHSCT carried out two delegation visits, one to the headquarters (General Secretariat) and the other to a regional division (Paris).

Finally, in consultation with the members of the CHSCT and with the assistance of the network of prevention assistants, the administration continued its actions to improve the prevention of occupational risks and updated the Consolidated Occupational Risks Assessment Document (DUERP).

The CCP, which has competence for contract staff, met twice in 2021. The debates primarily concerned the situation of contract staff at ASN and the salary measures applicable to this population.

It should be noted that regarding the actions decided on by the CCP, and for the fourth consecutive year, the administration organised a meeting in October 2021, bringing together all the ASN contract staff.

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: contains provisions regarding the professional ethics of the commissioners and staff, while the second contains provisions concerning external analysis and assessment performed at the request of ASN, for example by the Advisory Committees (see below).

With the aim of preventing conflicts of interest, the rules in force at ASN more specifically include the following declaration obligations:

- Public Declaration of Interests (DPI) stipulated in Article L. 1451-1 (derived from Act 2011-2012 of 29 December 2011 on strengthening the safety of drugs and health products) and Articles R. 1451-1 *et seq.* of the Public Health Code: the 4 July 2012 decision CODEP-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). Until mid-July 2017, the DPI were posted on the ASN website. The DPI are henceforth declared on the single on-line declaration site. About 60 people are subject to the DPI;
- Declarations of Interests and assets to the High Authority for Transparency in Public Life (HATVP) derived from Act 2013-907 of 11 October 2013 on Transparency in Public Life: the members of the Commission submit their declarations on the HATVP website. The same applies to the Director General, the Deputy Director Generals, and the General Secretariat since 15 February 2017 following modification of the Act of 13 October 2013;
- "Civil service" Declaration of Interests introduced by Act 2016-483 of 20 April 2016 into Article 25 of Act 83-634 of 13 July 1983 and governed by Decree 2016-1967 of 28 December 2016: the professional ethics officer 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 or her financial instruments in conditions which preclude all right of review on his or her part, pursuant to Article 25 *quater* of the 13 July 1983 Act and Decree 2017-547 of 13 April 2017: the ASN Director General submitted justification data to the HATVP before 2 November 2017.

In a decision dated 28 January 2020, the ASN Chairman appointed Alain Dorison as professional ethics officer.

Procedures for collecting internal ethics alerts from ASN personnel, pursuant to Act 2016-1691 of 9 December 2016 and Decree 2017-564 of 19 April 2017 were also put into place. The alert concerns an ethical problem, but also the case of a staff member witnessing a misdemeanour or serious prejudice during the exercise of their duties.

In addition to the obligations recalled above, ASN defined a new internal monitoring procedure for staff wishing to work in the private sector or requesting permission to add a professional activity, in order to create or take over a company, in accordance with Act 2019-828 of 6 August 2019 on the transformation of the civil service and Decree 2020-69 of 30 January 2020. Actions to raise personnel awareness, in order to enhance the in-house ethics culture and prevent conflicts of interest were also carried out, such as placing practical documents on-line on the intranet (for example, on the prevention of conflicts of interest and the role of ethical supervision in the event of departures to the private sector), the inclusion of a module on professional ethics rules applicable to ASN staff during training sessions held for new arrivals and a video interview in which the professional ethics officer uses a few examples to explain professional ethics and which professional activities require particular vigilance.

Alain Dorison, Professional Ethics Officer, appointed by the ASN Chairman in January 2020

Financial resources

ASN's financial resources are presented in point 3.

In its opinions of 27 April 2021 and 23 September 2021, ASN considers that the current budgetary set-up dedicated to the IRSN's technical support for ASN is both fragile and lacking in transparency, and underlines the need to guarantee a level of the IRSN budget financing which enables it to continue to meet ASN's technical support requirements in good conditions (see point 3).

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 in the following 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.

Available on *asn.fr*, the PSP for the period 2018-2020 comprises the following five strategic points:

- reinforce implementation of a graded and efficient approach to our regulation and oversight;
- improve the running of technical investigations;
- reinforce the efficiency of our actions in the field;
- consolidate our operation to the benefit of regulation and oversight;
- promote the French and European safety approach on the international stage.

In the current context, this plan remains particularly valid and requires further action on each of the points recalled above. For example, the Covid-19 pandemic requires acceleration of the ASN's digital transformation actions, which naturally fall under point 4 of the PSP. This is why the PSP was extended for a further two years. Throughout 2022, ASN will conduct a strategic study, in order to prepare its new PSP for a five-year period (2023-2027).

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.

ASN INTERNATIONAL AUDITS (IRRS MISSIONS)

The IAEA's Integrated Regulatory Review Service (IRRS) missions are designed to improve and reinforce the efficiency of national nuclear regulatory frameworks, while recognising the ultimate responsibility of each State to ensure safety in this field. These missions take account of 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.

RECORD OF MISSIONS IN FRANCE

2006: ASN hosted the first IRRS mission concerning all the activities of a safety regulator.

2009: IRRS follow-up mission.

2014: new review mission extended to include management of security/safety interfaces.

2017: follow-up mission in October to assess the steps taken following the review carried out at the end of 2014, with the following findings and recommendations:

- implementation of measures to address 15 of the 16 recommendations;
- achievement of significant progress in improving its management system;
- drafting of general policy principles including safety culture aspects in training, self-evaluation and management;
- achievement of efficiency gains across all activities;
- need to continue improving resources management to ensure that they enable future challenges to be met, more particularly the periodic safety reviews, the NPP operating life extension, the graded approach to issues, plus new responsibilities, such as supervision of the supply chain and the security of radioactive sources.

The reports for the 2006, 2009, 2014 and 2017 IRRS missions are available for consultation on *asn.fr*.

ASN considers that by contributing to the adoption of the best international practices, the IRRS missions constitute a tool for the continuous improvement of safety worldwide.

At the request of ASN, a further IRRS mission is scheduled in France for Spring 2024.

In 2021, ASN experts also took part in IRRS missions in Denmark and Switzerland.

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 a High Committee for Transparency and Information on Nuclear Safety (HCTISN), an information, discussion and debating body dealing with the risks inherent in nuclear activities and the impact of these activities on human health, the environment and nuclear safety.

The HCTISN can issue an opinion on any question in these fields, as well as on controls and the relevant information. It may also examine all questions concerning the accessibility of information on nuclear safety and propose all measures such as to guarantee or improve nuclear transparency. It can be called on by the Government, Parliament, the Local Information Committees (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 in 2021 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 pressure equipment 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 pressure equipment. 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 Local Information Committees (CLIs) for BNIs are tasked with a general duty of monitoring, information and consultation on the subject of nuclear safety, radiation protection and the impact of nuclear activities on humans and the environment, with respect to the site or sites which concern them. They may request expert assessments or have measurements taken on the installation's discharges into the environment.

The CLIs, whose creation is incumbent upon the President of the General Council of the *département*, comprise various categories of members: representatives of *département* General Councils, of the municipal councils or representative bodies of the groups of communities and the Regional Councils concerned, members of Parliament elected in the *département*, representatives of environmental protection associations, economic interests and representative trade union and medical profession union organisations, and qualified personalities.

The status of the CLIs was defined by the TSN Act of 13 June 2006 and by Articles R.125-50 *et seq.* of the Environment Code. It was reinforced by the 2015 TECV Act.

The duties and activities of the CLIs are described in chapter 5.

The roles of the Local information Committees and the National Association of Local Information Committees and Commissions (Anccli) are to represent the CLIs in dealings with the national and European authorities and to provide assistance to the commissions with regard to questions of common interest.

2.5 ASN's technical support organisations

ASN benefits from the expertise of technical support organisations when preparing its decisions. 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 of 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 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 the 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.

The IRSN workforce

As at 31 December 2021, the IRSN's overall workforce stood at 1,725 employees, of whom 435 are devoted to ASN technical support.

The 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 Nuclear Safety Authority (ASN)" of Title IX of Book V of the Environment Code.
- It recalls that ASN benefits from the 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 the IRSN opinions.

2.5.2 Advisory Committees of Experts

In preparing its decisions, ASN relies on the opinions and recommendations of eight 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 2021, they were broken down according to their areas of expertise:

- The Advisory Committee for Decommissioning (GPDEM) created in October 2018,
- the Advisory Committee for Nuclear Reactors (GPR) renewed in October 2018,
- the Advisory Committee for Laboratories and Plants (GPU) renewed in October 2018,
- the Advisory Committee for Waste (GPD) renewed in October 2018,
- the Advisory Committee for Transport (GPT) renewed in October 2018,
- the Advisory Committee for Nuclear Pressure Equipment (GPESPN) renewed in October 2018,

- The Advisory Committee for the Radiation Protection of Workers and the Public for Industrial and Research Applications, as well as for ionising radiation of natural origin and in the environment (GPRADE) whose mandate expired on 31 December 2021 (see box below);
- The Advisory Committee for the Radiation Protection of Health Professionals, the Public and Patients for Medical and Forensic Applications of Ionising Radiation (GPMED) whose mandate expired on 31 December 2021 (see box below).

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.

COMPOSITION OF THE ADVISORY COMMITTEE FOR RADIATION PROTECTION AND OF A WORKING GROUP IN CHARGE OF RADIATION PROTECTION OF PATIENTS

In January 2022, ASN is setting up a single Advisory Committee for Radiation Protection (GPRP) to continue the roles performed by the Advisory Committees for Radiation Protection (GPRADE and GPMED), whose mandates expired on 31 December 2021.

The duty of this Advisory Committee is to inform ASN on questions regarding:

- 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);
- the radiation protection of patients.

Owing to the specific nature of the subjects regarding the radiation protection of patients, a specific Working Group (WG) has been created for these questions (GTRPP), and reports to the GPRP.

In order to create this Advisory Committee and this Working Group, whose mandate began on 15 January 2022 for a period of four years, a call for candidates was organised in 2021. The selection committee met on 26 November 2021 and, on the basis of its proposals, the ASN Director General defined the composition of the GP and WG, selecting 36 experts for the GPRP and 25 experts for the GTRPP (including nine experts common to the two groups).

For the GPRP, Mr. Jean-Luc Godet is appointed Chairman and Messrs. Pierre Barbey and Thierry Sarrazin, Vice-Chairmen. For the GTRPP, Mr. Thierry Sarrazin is appointed Chairman and Mr. Nicolas Stritt, Vice-Chairman.

TABLE 1 **Advisory Committee meetings in 2021**

GPE	DATE	MAIN TOPIC
GPD	23 March 2021	• Examination of the general safety guidance notice regarding the search for a site capable of accepting low level, long-lived waste (LLW-LL), published by ASN on 5 May 2008, with a view to its transformation to a Guidelines document.
GPDEM	11 March 2021	• Examination of the complete decommissioning file for BNI 62 on EDF's Monts d'Arrée site (Brennilis NPP).
GPR	10 June 2021	• Analysis of experience feedback from operation of the NPP reactors over the period 2018-2019.
GPRADE and GPMED	4 March 2021	• Update of the national Guidelines *Medical intervention in the case of a nuclear or radiological event.* • Draft methodological guidelines for evaluation of the radiological risk to wild fauna and flora (specific GPRADE subject).
GPRADE and GPMED	8 April 2021	• Recommendations on Advisory Committee on Radiation Protection changes.
GPMED	18 May 2021	• Results of inspections in radiotherapy, brachytherapy and Fluoroscopy-Guided Interventional Practices (FGIPs) and feedback from events reported. • Changes to the Advisory Committees for Radiation Protection and guidelines for the programme of work for the next mandate. • Exchanges and discussions concerning the modification of ASN resolution 2008-DC-0095 of 29 January 2008 setting the technical rules to be followed by the disposal of effluent and waste contaminated by radionuclides, or liable to be so, as a result of a nuclear activity [...].
GPRADE	18 June 2021	• Revision of the Order of 1 September 2003 concerning the calculation methods for effective doses and dose equivalents, and regulatory news. • Changes to the Advisory Committees for Radiation Protection and guidelines for the programme of work for the next mandate. • Exchanges and discussions concerning the modification of ASN resolution 2008-DC-0095 of 29 January 2008 setting the technical rules to be followed by the disposal of effluent and waste contaminated by radionuclides, or liable to be so, as a result of a nuclear activity [...]. • GPRADE opinion on the draft methodological guidelines for evaluation of the radiological risk to wild fauna and flora.
GPRADE and GPMED	7 December 2021	• Opinion of the GPRADE and GPMED concerning the guidelines for the programme of work for the next mandate of the Advisory Committees for Radiation Protection. • Progress of the procedure to appoint members of the Advisory Committee for Radiation Protection (GPRP) and the Working Group for the Radiation Protection of Patients (GTRPP). • Update of the national Guidelines *Medical intervention in the case of a nuclear or radiological event.*

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 rules of procedure. Each GPE member produces a Declaration of Interest (GPMED and future GPRP/GTRPP).

Internal rules of procedure common to all the GPEs are in force and notably provide a framework for identifying and managing links and conflicts of interest.

Since 2009, as part of its commitment to transparency in nuclear safety and radiation protection, ASN has published the GPE letters of referral, the opinions of the GPEs and ASN's position statements based on these opinions. IRSN for its part publishes the summaries of the technical investigation reports it presents to the GPEs.

Advisory Committee for Decommissioning (GPDEM)
Chaired by Michèle Viala, the GPDEM comprises 33 experts appointed for their competence in the field of BNI decommissioning. The GPDEM was consulted once on the project for complete decommissioning of the Brennilis NPP on EDF's Monts d'Arrée site.

Advisory Committee for Waste (GPD)
The GPD is chaired by Pierre Bérest and comprises 38 experts appointed for their competence in the nuclear, geological and mining fields. In 2021, the GPD was consulted on the draft guidelines for the disposal of LLW-LL waste.

Advisory Committee for Nuclear Pressure Equipment (GPESPN)
Since 2009, the GPESPN has replaced the Standing Nuclear Section of the CCAP. This latter was replaced as of 28 December 2016 by a standing sub-committee of the CSPRT (see point 2.4.3). The GPESPN has been chaired by Matthieu Schuler since 6 October 2018 and comprises 29 experts appointed for their competence in the field of PE. It did not meet in 2021.

Advisory Committee for Radiation Protection in Medical and Forensic Applications of Ionising Radiation (GPMED)
Chaired by Bernard Aubert, the GPMED comprises 30 experts appointed for their competence in the field of radiation protection of health professionals, the general public and patients and for medical and forensic applications of ionising radiation. In 2021, it held four plenary meetings, three of which were organised jointly with the GPRADE. In the summer of 2021, a call for candidates was issued for the creation of a single Advisory Committee for Radiation Protection (GPRP), with cross-cutting expertise, and a Working Group in charge of patient radiation protection (GTRPP) reporting to it, for which the mandates will begin in January 2022.

Advisory Committee for Radiation protection for industrial and research applications of ionising radiation and in the environment (GPRADE)
Chaired by Jean-Paul Samain, the GPRADE comprises 27 experts appointed for their competence in the fields of radiation protection of workers (other than health professionals) and the public, for industrial and research applications using ionising radiation and for exposure to ionising radiation of natural origin, and protection of the environment. In 2021, it held four plenary meetings, three of which were organised jointly with the GPMED. In the summer of 2021, a call for candidates was issued for the creation of a single Advisory Committee for Radiation Protection (GPRP), with cross-cutting expertise, and a Working Group in charge of Patient Radiation Protection (GTRPP) reporting to it, for which the mandates began in January 2022.

Advisory Committee for Nuclear Reactors (GPR)
The GPR is chaired by Thierry Charles and comprises 35 experts appointed for their competence in the field of nuclear reactors. In 2021, it held one meeting to analyse the experience feedback from operation of the NPP reactors over the period 2018-2019.

Advisory Committee for Transport (GPT)
The GPT currently has no Chair and comprises 25 experts appointed for their competence in the field of transport. It did not meet in 2021.

Advisory Committee for Laboratories and Plants (GPU)
The GPU is chaired by Alain Dorison and comprises 32 experts appointed for their competence in the field of laboratories and plants concerned by radioactive substances. It did not meet in 2021.

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. In decisions dated 6 November 2018 and 28 September 2021, the ASN Commission appointed the nine 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 comprises Christophe Badie, Benoît De Boeck, Jean-Marc Cavedon, Edward Lazo, Catherine Luccioni, Antoine Masson, Jean-Claude Micaelli and Marc Vannerem. The Scientific Committee maintained its two annual plenary meetings in 2021. It also continued its meetings with the research laboratories, notably with respect to the ageing of non-metallic materials and nuclear medicine for therapeutic purposes. It also drafted an opinion on the research to be carried out in relation to the ageing of non-metallic materials.

2.5.4 The ASN's other technical support organisations

To diversify its expertise and benefit from other particular skills, ASN committed credits of €76.5 thousand in 2021.

ASN notably published a framework agreement for the expert assessment work needed to examine the safety analyses submitted to ASN by CEA for the Cabri nuclear facility (Cadarache).

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 three years and serves to review the existing management procedures for radioactive materials and waste, to identify the foreseeable needs for storage and disposal facilities, to 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, to 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 Ecological Transition and by ASN.

The work of this Working Group is presented in greater detail in chapter 14. Information about the plan itself is given in "Notable Events" in the introduction to this report.

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,

TABLE 2 **Status and activities of the main civil nuclear safety regulators(*)**

COUNTRY/ REGULATORY AUTHORITY	STATUS			ACTIVITIES						
					RADIATION PROTECTION			SECURITY (PROTECTION AGAINST MALICIOUS ACTS)		
	ADMINISTRATION	GOVERNMENT AGENCY	INDEPENDENT AGENCY	SAFETY OF CIVIL FACILITIES	LARGE NUCLEAR INSTALLATIONS	OUTSIDE BNIS	PATIENTS	SOURCES	NUCLEAR MATERIALS	TRANSPORT SAFETY
Europe										
Germany/Bmub + *Länder*	■			■	■	■	■	■	■	■
Belgium/AFCN		■		■	■	■	■	■	■	■
Spain/CSN			■	■	■	■	■	■	■	■
Finland/STÜK		■		■	■	■	■	■	■	■
France/ASN			■	■	■	■	■	■(**)		■
United Kingdom/ ONR		■		■	■			■	■	■
Sweden/SSM		■		■	■	■	■	■	■	■
Switzerland/ENSI			■	■	■				■	■
Other countries										
Canada/CNSC			■	■	■	■	■	■	■	■
China/NNSA	■			■	■	■		■	■	■
Korea/NSSC		■		■	■	■		■	■	■
United States/ NRC			■	■	■	■	■	■	■	■(***)
India/AERB		■		■	■	■	■	■	■	■
Japan/NRA		■	■	■	■	■	■	■	■	
Russia/ *Rostekhnadzor*	■	■		■	■			■	■	■
Ukraine/SNRIU	■	■		■	■	■		■	■	■

(*) Schematic and simplified presentation 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.

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 99-1172 of 30 December 1999. The revenue generated by this tax, the amount of which is set yearly by Parliament, came to €560.3 million in 2021. The proceeds go to the central State budget.

In addition, for certain BNIs, said Act also creates three additional taxes, known as "research", "support" and "disposal" respectively. The revenue from these taxes is allocated to funding economic development measures and research into underground disposal and storage by the Andra. The revenue from these taxes represented €126.18 million in 2021, of which €3.30 million were paid in 2021 to the municipalities and the local public cooperation bodies situated around the disposal centre.

In addition, since 2014, ASN has been tasked with assessing and ordering payment of the special contribution on behalf of Andra created by Article 58 of the 2013 Budget Amendment Act 2013-1279 of 29 December 2013, which will be payable up until the date of the deep geological disposal facility's creation authorisation. In the same way as the additional taxes, this contribution is due by BNI licensees, as of the creation of their facility and up until the delicensing decision. The revenue from this contribution represented €80.7 million in 2021.

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 amounted to €61.3 million in 2021.

preparing for and implementing the necessary measures to manage a post-accident situation.

In order to develop a doctrine and after testing post-accident management during national and international exercises, ASN brought all the players concerned together within the Steering Committee responsible for Post-Accident Management (Codirpa). This Committee, headed by ASN, has representatives from the ministerial departments concerned, the health agencies, associations, the CLIs, and IRSN.

The work of the Codirpa is presented in greater detail in chapter 4.

2.6.3 The Committee for the Analysis of New Techniques and Practices using Ionising Radiation

The Committee for the Analysis of New Techniques and Practices using Ionising Radiation (Canpri) was created on 8 July 2019.

This Committee is chaired by ASN and comprises 16 experts appointed by ASN, from learned societies, along with representatives of the French health institutions. This Committee met on 13 April and 14 December 2021.

2.6.4 The other pluralistic working groups

Considering that it was necessary to move forward with regard to the reflections and 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 end-purposes of the Cofsoh are firstly to allow exchanges between the stakeholders on the difficult subject of social, organisational and human factors, and secondly to draw up documents proposing joint positions by the various members on given subjects, and to propose directions for studies to be undertaken, in order to clarify subjects that lack data or 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.

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 2021 Budget Act, the ASN budget (action 9 of programme 181 "Risk prevention") amounted to €67.15 million in payment credits. It included €49.41 million for personnel expenses and €17.74 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 Recovery (programme 218), the Ministry for Ecological Transition (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

TABLE 3 **Breakdown of licensee contributions**

LICENSEE	AMOUNT FOR 2021 (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	18.52	6.20	4.00	5.71
CEA	4.51	18.34	13.70	7.08
Andra	5.41	3.30	-	0.40
Others	1.26	1.67	-	0.71
Total	560.30	126.18	80.70	61.38 (*)

(*) The amount allocated to IRSN is capped at €61.38 M.

ASN support credits are part of action 11 "Research in the field of risks" of programme 190 "Research in the fields of sustainable energy, development and mobility".

The total IRSN budget for 2021 amounted for its part to €282 million, of which €83 million were devoted to the provision of technical support for ASN. The IRSN credits for providing ASN with technical support come in part (€41.8 million) from programme 190 (see below). The rest (€41.9 million) comes from a contribution from the nuclear licensees. This contribution was put into place by the budget amendment Act of 29 December 2010.

In total, in 2021, the State's budget for transparency and the regulation of nuclear safety and radiation protection in France amounted to €275.1 million.

By way of comparison, the amount of taxes collected by ASN in 2021 amounted to €767.18 million:
- €560.3 million from BNI taxes (paid into the State's general budget);
- €126.18 million from additional "support", "disposal" and "research" taxes (allocated to various establishments, including Andra, municipalities and Public Interest Groupings –GIP);
- €80.7 million from the special contribution for the management of radioactive waste (allocated to Andra).

This complex funding structure is detrimental to the overall clarity of the cost of regulation. It moreover leads to difficulties in terms of budgetary preparation, arbitration and implementation.

4 // Outlook

The year 2022 will again be marked by the analysis of the organisational lessons learned from the pandemic. A new home-working system will be implemented, to take advantage of these new working methods, while preserving the collective approach. The activity continuity plan will continue to be updated. With regard to the new inspection methods (on-site and remotely), the work already done on the framework for remote inspections will be continued, in order to clarify which subjects are suitable for a documentary approach, while aiming to avoid increasing the time spent on documentary analysis to the detriment of time spent in the field.

With regard to skills, ASN will continue to consolidate its skills, on the one hand by modifying its training methods, giving greater importance to evaluation and self-training and, on the other, by continuing with its policy of developing senior positions, which will be occupied by staff with solid professional experience in the fields of nuclear safety and radiation protection, or those which contribute to this (support or transverse functions).

In budgetary and financial terms, ASN's objectives are to consolidate the financing of both its operations and its expert assessment capacity, and to protect its budgetary independence.

In 2022, in terms of expert assessment, the new agreement between ASN and its technical support organisation, IRSN, will be implemented. The composition of six of the eight Advisory Committees (GPDEM, GPR, GPU, GPT, GPD, GPESPN) will be renewed. Meetings will be maintained and, depending on the health conditions, the interaction and contribution methods will be adapted.

In 2022, ASN will draw up its new Multi-year Strategic Plan, which will from now on cover a five-year period.

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 2020 AE (€M)	INITIAL BUDGET ACT 2020 CP (€M)	INITIAL BUDGET ACT 2021 AE (€M)	INITIAL BUDGET ACT 2021 CP (€M)	BNI TAX 2021 (€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)	48.12	48.12	49.41	49.41	
			Operating and intervention expenditure	12.65	17.65	59.73	17.73	
			Total	60.77	65.77	109.14	67.14	
		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	60.92	65.92	109.29	67.29	
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	-	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				560.30
Interministerial mission **Management of public finances and human resources**	**Programme 218:** Implementation and oversight of economic and financial policy	-	Operation of the ASN head office departments					
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	41.15	41.15	41.80	41.80	
		Sub-action 11-2 (3 other areas): French Institute for Radiation Protection and Nuclear Safety	-	129.62	129.62	125.40	125.40	
Annual contribution on behalf of IRSN instituted by Article 96 of budget amendment Act 2010-1658 of 29 December 2010 dedicated to the IRSN's activities (apart from technical support for ASN)			-	19.50	19.50	19.40	19.40	
Annual contribution on behalf of IRSN instituted by Article 96 of budget amendment Act 2010-1658 of 29 December 2010 dedicated to the IRSN's activities in support of ASN			-	42.70	42.70	41.90	41.90	
			Sub-total	232.97	232.97	228.50	228.50	560.30
Grand Total (excluding IRSN and programmes 217, 218 and 354)				**144.77**	**149.77**	**192.99**	**150.99**	**560.30**
Grand Total ASN (excluding IRSN and programmes 217, 218 and 354)				**293.89**	**298.89**	**337.79**	**295.79**	

03

Regulation of nuclear activities and exposure to ionising radiation

03

REGULATION OF NUCLEAR ACTIVITIES AND EXPOSURE TO IONISING RADIATION

In France, the party responsible for a nuclear activity must ensure that this activity is safe. They cannot delegate this responsibility, and must ensure permanent monitoring of both this activity and the equipment used. Given the risks linked to ionising radiation for humans and the environment, the State regulates nuclear activities, a task it has entrusted to the French Nuclear Safety Authority (ASN).
With the aim of ensuring greater administrative efficiency, ASN has also been entrusted with the oversight of regulations concerning the environment and Pressure Equipment (PE) in Basic Nuclear Installations (BNIs).

Control and regulation of nuclear activities is a fundamental responsibility of ASN.

Its primary goal is to ensure that a party responsible for a nuclear activity effectively assumes its obligations. ASN has a vision of control and regulation encompassing material, organisational and human aspects. Following safety and radiation protection assessments in each activity sector, ASN implements its oversight action by issuing resolutions, binding requirements, inspection follow-up letters, plus penalties as applicable.

The oversight priorities are defined with regard to the risks inherent in the activities, the behaviour of those responsible for the activities and the means they deploy to control them. In the priority areas, ASN must reinforce its oversight. Conversely, for lower-risk areas, ASN must be able to explicitly scale-back its regulation and oversight.

1 // Verifying that the licensee assumes its responsibilities

1.1 The principles of ASN's oversight duties

ASN's oversight aims primarily to ensure that those responsible for an activity effectively assume their obligations and comply with the requirements of the regulations concerning nuclear safety and radiation protection, in order to protect persons and the environment from radioactivity-related risks.

It applies to all the phases in the performance of the activity, including the decommissioning phase for nuclear facilities:
- before the licensee exercises an activity subject to authorisation, by reviewing and analysing the files, documents and information provided by the licensee to justify its project with regard to safety and radiation protection. This verification aims to ensure that the information and demonstration supplied are both relevant and sufficient;
- during exercise of the activity, by visits, inspections, verification of licensee operations entailing significant potential consequences, review of reports supplied by the licensee and analysis of significant events. This oversight includes an analysis of any justifications provided by the licensee.

ASN applies the principle of proportionality when determining its actions, so that the scope, conditions and extent of its regulatory action are commensurate with the human and environmental protection implications involved.

When applicable, this oversight can call on the support of the French Institute for Radiation Protection and Nuclear Safety (IRSN).

1.2 The scope of regulation of nuclear activities

Article L. 592-22 of the Environment Code states that ASN must regulate compliance with the general rules and particular requirements of safety and radiation protection, applicable to:
- the BNI licensees;
- the manufacturers and users of Nuclear Pressure Equipment (NPE) used in the BNIs;
- those in charge of Radioactive Substances Transport (TSR);
- those in charge of activities entailing a risk of exposure of individuals and workers to ionising radiation;
- those in charge of implementing ionising radiation exposure monitoring measures, such as the approved organisations and laboratories;
- the nuclear licensees, their suppliers, contractors or 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 2021 concerning the inspection of the Nuclear Power Plants (NPPs) procurement chain.

In this chapter, these persons or entities are called the "licensees".

ASN also oversees the entities and laboratories that it approves, in order to take part in the inspections and oversight of nuclear safety and radiation protection. ASN carries out labour inspectorate duties in the NPPs (see chapter 10).

2 // Ensuring that regulation is proportionate to the implications

ASN aims to organise its regulatory work in a way that is proportionate to the implications of the activities. It follows a continuous improvement approach to its regulation and oversight practices, in order to consolidate the effectiveness and quality of its actions. ASN uses Operating Experience Feedback (OEF) from more than forty years of nuclear activity oversight and the exchange of best practices with its foreign counterparts.

The licensee is the key player in the regulation of its activities.

ASN regulates nuclear activities by various means:
- inspection, generally on the site, or in an inspected department, or at carriers of radioactive substances. It consists in performing spot checks on the conformity of a given situation with regulatory or technical baseline requirements but may also include an assessment of the licensee's practices by comparison with current best practices;
- authorisation, following analysis of the applicant's demonstration that its activities are satisfactorily managed in terms of radiation protection and safety;
- OEF, more specifically through analysis of significant events;
- approval of entities and laboratories taking part in radioactivity measurements and radiation protection inspections, as well as qualification of pressure equipment monitoring organisations;
- presence in the field, also frequently outside actual inspections;
- dialogue with the professional organisations (trades unions, professional orders, learned societies, etc.).

The performance of certain inspections by organisations and laboratories offering the necessary guarantees, as validated by ASN approval or qualification, contributes to the oversight of nuclear activities.

2.1 Oversight by ASN

The licensee is required to provide ASN with the information it needs to meet its regulatory responsibilities. The volume and quality of this information should enable ASN to analyse the technical demonstrations presented by the licensee and target the inspections. It should also allow identification and monitoring of the important events marking the operation of a nuclear activity.

Regulation and monitoring of Basic Nuclear Installations

Nuclear safety is the set of technical provisions and organisational measures related to the design, construction, operation, shutdown and decommissioning of BNIs, as well as the transport of radioactive substances, 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 convey pressurised fluids. In this respect, they are subject to the regulations applicable to pressure equipment, which include NPE.

The Environment Code states that ASN is the administrative Authority with competence for issuing individual resolutions and checking the in-service monitoring of the pressure equipment installed within the perimeter of a BNI.

The operation of pressure equipment is subject to regulatory oversight in particular covering in-service monitoring programmes, non-destructive testing, maintenance works, processing of anomalies affecting these systems and periodic requalifications.

ASN also assesses the compliance of the most important new NPE with the requirements of the regulations. It approves and monitors the organisations responsible for assessing the conformity of the other NPE.

Regulation and monitoring of the transport of radioactive substances

Transport comprises all operations and conditions associated with movements of radioactive substances, such as packaging design, manufacture, maintenance and repair, as well as the preparation, shipment, loading, carriage, including storage in transit, unloading and receipt at the final destination of the radioactive substance consignments and packages.

Regulation and monitoring of activities comprising a risk of exposure to ionising radiation

In France, ASN is in charge of drafting and monitoring technical regulations concerning radiation protection.

The scope of ASN's regulatory role in radiation protection covers all the activities that use ionising radiation. ASN exercises this duty, where applicable, jointly with other State services such as the Labour Inspectorate, the Inspectorate for Installations Classified for Protection of the Environment (ICPEs), the departments of the Ministry of Health and the French National Agency for Medicines and Health Products Safety (ANSM).

This action directly concerns either the users of ionising radiation sources, or organisations approved to carry out technical checks and inspections on these users.

The methods of regulating the radiation protection stakeholders 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 carries out 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 8.30 Full-Time Equivalent of which 2 are for the labour inspectorate mission) has been reinforced in the field since 2009, particularly during reactor outages, with inspection visits, advisory roles at the meetings of the Committee for Health, Safety and Working Conditions (CHSCT) and the Inter-company Committees on Safety and Working Conditions (CIESCT), as well as regular discussions with the social partners.

2.2 Internal checks performed by the licensees

2.2.1 Internal oversight 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 reorganised the procedures for the performance of technical monitoring, now referred to as “verifications”. They harmonise the relevant requirements with those applicable to other risks, notably the electrical risk (Article R. 4226-14), or more generally for work equipment (Article R. 4323-22), making the measures to be taken proportionate to the nature and scale of the risk. During the lifetime of the work equipment or the facilities, these verifications take the form of initial verifications (by an accredited organisation), which may be repeated, and periodic verifications (by the Radiation Protection Advisor –RPA). The Order of 23 October 2020, set out in Article R. 4451-51, notably determines the work equipment or work equipment categories and the type of radioactive sources for which the employer is required to conduct an initial verification and, as applicable, to repeat it, and the procedures and conditions for the performance of these verifications.

2.3 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*.

TABLE 1 **Methods of ASN regulation of the various radiation protection players**

	EXAMINATION/AUTHORISATION	INSPECTION	COOPERATION
Users of ionising radiation sources	• Examination of the dossiers 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 supervision inspections in the field	• Jointly with the professional organisations, drafting of rules of good practices for performance of radiation protection checks

TABLE 2 **Radiation protection verifications performed in 2020 by the organisations approved for radiation protection verifications**

	MEDICAL	VETERINARY	RESEARCH / TEACHING	INDUSTRY EXCLUDING BNIs	BNIs	TOTAL
Sealed sources	1,686	6	1,472	8,959	9,155	21,278
Unsealed sources	351	12	732	456	1,479	3,030
Mobile electrical generators of ionising radiation	2,247	245	130	650	36	3,308
Fixed electrical generators of ionising radiation	11,923	742	579	5,275	211	18,730
Particle accelerators	402	3	204	146	14	769
Total	16,609	1,008	3,117	15,486	10,895	47,115

ASN thus approves organisations so that they can perform the technical inspections or verifications required by the regulations in the fields within its scope of competence:
- radiation protection verifications;
- measurement of radon activity concentration in premises open to the public;
- assessment of NPE conformity and inspection of PE in service.

In order to approve the applicant organisations, ASN ensures that they perform the inspections in accordance with their technical, organisational and ethical obligations and in compliance with the rules of professional good practice. Compliance with these provisions should enable the required level of quality to be obtained and maintained.

ASN ensures that benefit is gained from the approval, in particular through regular exchanges with the organisations it has approved and the mandatory submission of an annual report.

In 2020, the Organisations Approved for Radiation Protection (OARP) verifications carried out 47,115 verifications, with the breakdown per type of source and per field being given in Table 2.

The reports of the verifications performed in each facility by the OARP verifications are at the disposal of and examined by ASN personnel on the occasion of:
- licence renewals or modifications requiring ASN authorisation;
- inspections.

Examination of these reports on the one hand makes it possible to check that the mandatory verifications have actually been carried out and, on the other, enables the licensees to be questioned about the steps taken to remedy any nonconformities.

ASN also approves laboratories to conduct analyses requiring a high level of measurement quality if the results are to be usable. It thus approves laboratories to monitor radioactivity in the environment (see point 4.3).

The updated list of approvals issued by ASN is available on *asn.fr*.

In addition, on the advice of the standing sub-committee in charge of the carriage of dangerous goods within the High Council for the Prevention of Technological Risks, ASN approved:
- the training organisations for drivers of vehicles carrying radioactive materials; two organisations have been approved;
- the organisations responsible for certifying the conformity of packagings designed to contain 0.1 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 packaging.

As at 31 December 2021, the following are approved or accredited by ASN:
- 29 organisations responsible for radiation protection verifications. Five approval renewals were delivered in 2021;
- 94 organisations tasked with measuring radon activity concentration in buildings. Eight of these organisations can also carry out measurements in cavities and underground structures, while 12 are approved to identify sources and means of radon ingress into buildings. In 2021, ASN issued 71 new approvals or approval renewals;
- 4 organisations qualified for NPE inspections as part of the new NPE conformity assessment;
- 2 organisations qualified for NPE inspections as part of in-service monitoring;
- 3 organisations qualified for PE and Simple Pressure Vessels (RPS) within the perimeter of BNIs (in-service monitoring);
- 17 inspection departments qualified for in-service monitoring of PE and RPS within the perimeter of NPPs;
- 67 laboratories for environmental radioactivity measurements covering 945 approvals, of which 148 are approvals or approval renewals delivered during 2021.

In 2022, the regulations concerning the verifications performed and services provided by the OARP and for radon measurement will change.

Since 1 January 2022, ASN resolution 2010-DC-0175 of 4 February 2010 defining the procedures for verification of the OARPs is no longer applicable with regard to verifications performed under the Labour Code. Current regulations defining the procedures for approval of OARP verifications (ASN resolution 2010-DC-0191 of 22 July 2010) and the verifications they perform under the Public Health Code (resolution 2010-DC-0175) will be modified in 2022:
- the rules that those in charge of nuclear activities will need to have verified by an OARP will primarily concern the management of effluent and waste, defined in ASN resolution 2008-DC-0095 of 29 January 2008, as well as the design, operation and maintenance of *in vivo* nuclear medicine facilities, defined in ASN resolution 2014-DC-0463 of 23 October 2014;
- ASN resolution 2010-DC-0191 of 22 July 2010 will be revised in 2022: the draft ASN resolution repealing this resolution was opened for public consultation in December 2021.

The ASN resolutions concerning the organisations approved for measurement of radon will also be updated in 2022 in order to take account notably of the recent changes to the Labour Code because, since 1 January 2022, only accredited organisations can conduct the initial verification of workplaces mentioned in Article R. 4451-44 of the Labour Code.

3 // Performing efficient regulation and oversight

3.1 Inspection

3.1.1 Inspection objectives and principles

The inspection carried out by ASN is based on the following principles:
- The inspection aims to verify compliance with the provisions that are mandatory under the regulations. It also aims to assess the situation with regard to the nuclear safety and radiation protection implications; it seeks to identify best practices, practices that could be improved and assess possible developments of the situation.
- The scope and depth of the inspection is adjusted to the risks inherent in the activity and the way they are effectively taken into account by those responsible for the activity.
- The inspection is neither systematic nor exhaustive; it is based on sampling and focuses on the subjects with the highest potential consequences.

3.1.2 Inspection resources implemented

To ensure greater efficiency, ASN action is organised on the following basis:
- inspections, at a predetermined frequency, of the nuclear activities and topics of particular health and environmental significance;
- inspections on a representative sample of other nuclear activities;
- inspections of approved organisations and laboratories.

The inspections may be unannounced or notified to the licensee a few weeks before the visit. They take place mainly on the site or during the course of the activities (work, transport operation, etc.). They may also concern the head office departments or design and engineering departments at the major nuclear licensees, the workshops or engineering offices of the subcontractors, the construction sites, plants or workshops manufacturing the various safety-related components.

ASN uses various types of inspections:
- routine inspections;
- reinforced inspections, which consist in conducting an in-depth examination of a targeted topic by a larger team of inspectors than for a routine inspection;
- in-depth inspections which take place over 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, created as of 2020 for EDF, 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, following 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.

During the Covid-19 pandemic, ASN implemented remote-inspection measures. This type of inspection has become one of the tools available to the inspectors and is suitable for certain inspection topics. On-site inspection however remains the preferred method.

The implementation of remote inspection measures required ASN to modify the inspection indicators. For this type of inspection, the critical review of documents transmitted by a nuclear activity manager, during the on-site inspection preparation phases, becomes the primary method. It is then no longer possible to differentiate between preparation of the inspection, involving this documentary examination, and the inspection itself.

The following paragraphs will therefore present the number of inspector.days corresponding to the on-site inspections and the number of remote inspections. The number of inspector.days in these paragraphs cannot therefore be directly compared with that of years before 2020, because it only reflects the time spent on the site and does not take account of the remote inspections.

In addition, Table 5 presents the total number of inspector.days devoted to inspections, whether performed on-site, remotely, or using a combination of the two.

ASN sends the licensee an inspection follow-up letter, published on *asn.fr*, which officially documents:
- deviations between the situation observed during the inspection and the regulations or documents produced by the licensee pursuant to the regulations;
- anomalies or aspects warranting additional justifications;
- best practices or practices to which improvements could be made, even if not directly constituting requirements.

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 an IRSN representative specialised in the facility checked or the topic of the inspection.

ASN inspectors
ASN has inspectors designated and accredited by its Chairman, pursuant to Decree 2007-831 of 11 May 2007 setting the procedures for appointing and accrediting nuclear safety inspectors, subject to their having acquired the requisite legal and technical skills through professional experience, mentoring or training courses.

1. The intervention is the unit representative of activity traditionally used by the labour inspectorate.

TABLE 3 **Breakdown of inspectors per inspection field as at 31 December 2021**

INSPECTOR CATEGORIES	DEPARTMENTS	REGIONAL DIVISIONS	TOTAL
Nuclear safety inspectors	128	125	253
including nuclear safety inspectors for transport	*27*	*49*	*76*
Radiation protection inspectors	40	106	146
Labour inspectors	2	18	20
Inspectors for all fields	148	169	317

TABLE 4 **Number of inspections per field**

BASIC NUCLEAR INSTALLATIONS (EXCLUDING PRESSURE EQUIPMENT)	PRESSURE EQUIPMENT	TRANSPORT OF RADIOACTIVE SUBSTANCES	SMALL-SCALE NUCLEAR ACTIVITIES	APPROVED ORGANISATIONS AND LABORATORIES	TOTAL
733	106	109	823	110	1,881

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 in at least one inspection performed in a different region. This rule was considerably relaxed in 2020 owing to the Covid-19 pandemic context and the need, at certain times, to avoid the spread of the virus between regions, but was restored in 2021.

Table 3 presents the headcount of inspectors, which stood at 317 on 31 December 2021. Some inspectors operate in several inspection areas, and all the operational entity heads and their deputies fulfil both managerial and inspection functions.

Most of the inspections are carried out by inspectors assigned to the regional divisions, who represent 53% of the ASN inspectors. The 148 inspectors assigned to the departments take part in ASN inspections within their field of competence; they represent 47% of the inspector headcount and carried out 16% of inspections in 2021, with most of their work being the examination of files.

As previously mentioned, ASN continuously improves the efficiency of its oversight by targeting and modulating its inspections according to the scale of the implications for the protection of persons and the environment.

In 2021, the ASN inspectors carried out a total of 1,881 inspections, representing 3,959 inspection man.days in the field. About 5% of the inspections were carried out remotely. The breakdown per field is given in Table 4.

ASN inspections programme

To guarantee a distribution of the inspection resources that is proportionate to the safety and radiation protection implications of the various facilities and activities, ASN drafts a planned inspections schedule every year, taking account of the inspection issues (see point 3.1). This programme is not communicated to either the licensees or the nuclear activity managers.

ASN monitors the performance of the programme and the follow-up given to the inspections, through periodic reviews. This follow-up enables the inspected activities to be assessed and contributes to the continuous improvement of the inspection process.

Information relative to the inspections

ASN informs the public of the steps taken following the inspections by posting the inspection follow-up letters on-line, on *asn.fr*.

Moreover, after each in-depth inspection, ASN publishes an information notice on *asn.fr*.

3.1.3 Inspection of Basic Nuclear Installations and pressure equipment

In 2021, 2,322 inspector.days were devoted to the on-site field inspection of BNIs and NPE, corresponding to 839 inspections. Of these, 17% were unannounced. Furthermore, 17 inspections were conducted remotely.

Inspection work in the field can be broken down into 1,216 inspector.days in the NPPs (426 on-site inspections), 819 inspector.days in the other BNIs (295 on-site inspections), that is mainly the "fuel cycle" facilities, research facilities and installations undergoing decommissioning, and 287 for NPE (101 on-site inspections).

The remote inspection work entailed 8 inspections for the NPPs, 4 inspections for the other BNIs and 5 inspections for NPE.

Two in-depth inspections were carried out in 2021, one on the Cattenom NPP and the other, on the Marcoule site, which corresponds to 98 days inspector.days.

The ASN labour inspectors also carried out 664 interventions during the 196 inspection days in the NPPs.

3.1.4 Inspection of radioactive substances transport

In 2021, 143 inspector.days were devoted by ASN to on-site inspection of transport activities, corresponding to 99 on-site inspections. Of these, 34% were unannounced. Ten remote inspections were also carried out.

3.1.5 Inspection in the small-scale nuclear activities

ASN organises its inspection activity so that it is proportionate to the radiological issues involved in the use of ionising radiation and consistent with the actions of the other inspection services.

In 2021, 1,355 inspector.days were devoted to on-site inspections of small-scale nuclear activities, corresponding to 766 on-site inspections, 9% of which were unannounced, plus 57 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 2021, 139 inspector.days were devoted to checking approved organisations and laboratories, corresponding to 97 inspections, 34% of which were unannounced, plus 13 remote inspections.

3.1.7 Checks on exposure to radon and naturally occurring radioactive material

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 Public Access Buildings (PAB) and in the workplace).

Monitoring exposure to radon

Article R. 1333-33 of the Public Health Code states that the activity concentration of radon in PAB is measured either by IRSN, or by organisations approved by ASN. These measurements are to be taken between 15 September of a given year and 30 April of the following year.

Article R. 4451-44 of the Labour Code stipulates that, whenever required, the initial checks on the radon activity concentration in areas identified owing to the radon risk must be carried out by accredited organisations or by organisations approved by ASN.

Monitoring natural radioactivity in water intended for human consumption

Monitoring the natural radioactivity in water intended for human consumption is the role of the ARS. The methods used for these checks take account of the recommendations issued by ASN and included in the circular from the General Directorate for Health of 13 June 2007.

The results of the checks are jointly analysed and utilised by ASN and the services of the Ministry of Health.

3.2 Analysis of the demonstrations provided by the licensee

The purpose of the files supplied by the licensee is to demonstrate compliance with the objectives set by the general technical regulations, as well as those that it has set for itself. ASN is required to check the completeness of the data and the quality of the demonstration.

The review of these files may lead ASN to accept or to reject the licensee's proposals, to ask for additional information or studies or to ask for work to be done to bring the relevant items into conformity.

3.2.1 Analysis of the files transmitted by BNI licensees

Reviewing the supporting documents produced by the licensees and the technical meetings organised with them are one of the forms of control carried out by ASN.

TABLE 5 **Breakdown of inspection days by topic in 2021 (including remote inspection days)**

PER FIELD	NUMBER OF INSPECTOR DAYS	NUMBER OF INSPECTIONS PERFORMED
Basic Nuclear Installation /Pressurised Water Reactor	1,216	434
Basic Nuclear Installation/Laboratories Plants Waste and Decommissioning	819	299
Basic Nuclear Installation/Pressure Equipment	287	106
Small-scale nuclear activities/Industry	412	272
Small-scale nuclear activities/Medical	784	429
Small-scale nuclear activities/Natural radioactivity	13	18
Small-scale nuclear activities/Polluted sites and ground	5	4
Small-scale nuclear activities/Research	106	75
Small-scale nuclear activities/Veterinary	33	23
Small-scale nuclear activities/Other	2	2
Transport of radioactive substances	143	109
Approved organisations/approved laboratories	139	110
Total	3,959	1,881

Whenever it considers it necessary, ASN requests an opinion from its technical support organisations, the most important of which is IRSN. The safety review implies cooperation by numerous specialists, as well as efficient coordination, in order to identify the essential points relating to safety and radiation protection.

The IRSN assessment is based on in-depth technical discussions with the licensee teams responsible for designing and operating the installations. It is also based on studies and research and development programmes focused on risk prevention and on improving our knowledge of accidents. For certain dossiers, ASN asks the competent Advisory Committee of Experts (GPE) for its opinion. For other matters, IRSN examines the safety analyses and gives its opinion directly to ASN. ASN procedures for requesting the opinion of a technical support organisation and, where required, of an Advisory Committee, are described in chapter 2.

At the design and construction stage, ASN –aided by its technical support organisation– assesses the safety analysis reports describing and justifying the design principles, equipment and system design calculations, utilisation rules and test procedures, and quality organisation provisions implemented by the prime contractor and its suppliers. It also analyses the facility's environmental impact assessment. ASN regulates and oversees the construction and manufacture of structures and equipment, in particular that of the main primary system and the main secondary systems of Pressurised Water Reactors (PWRs). In accordance with the same principles, it checks the packages intended for the transport of radioactive substances.

Once the nuclear facility has been commissioned, following ASN authorisation, all changes to the facility or its operation made by the licensee that could affect security, public health and safety, or the protection of the environment, are reported to ASN or submitted to it for authorisation. Moreover, the licensee must perform periodic safety reviews to update the assessment of the facility, taking into account any changes in techniques and regulations, as well as OEF. The conclusions of these reviews are submitted by the licensee to ASN, which can issue new binding requirements for continued operation.

The other files submitted by BNI licensees

A large number of files concerns specific topics such as fire protection, fuel management in PWRs, relations with the outside contractors, etc.

The licensee therefore also periodically provides activity reports as well as summaries of water intake, liquid and gaseous discharges and waste produced.

3.2.2 Review of the applications required by the Public Health Code

ASN is responsible for reviewing applications to possess and use ionising radiation sources in the medical and industrial sectors. ASN also deals with the specified procedures for the acquisition, distribution, import, export, transfer, recovery and disposal of radioactive sources. It in particular relies on the inspection reports from the approved organisations and the reports on the steps taken to remedy nonconformities detected during these inspections.

In addition to the verifications carried out under the responsibility of the facilities and the periodic checks required by the regulations, ASN carries out its own checks when examining the applications.

3.3 Lessons learned from significant events

3.3.1 Anomaly detection and analysis approach

Background

The international Conventions ratified by France (Article 19vi of the Convention on Nuclear Safety of 20 September 1994; Article 9v 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.

Based on thirty years of experience, ASN felt that it would be useful to transpose this approach, initially limited to nuclear safety, to radiation protection and protection of the environment. 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 and to on-site transport managers. It concerns significant events affecting the nuclear safety of BNIs, radioactive material transports taking place inside the perimeter of the BNI or an industrial site and without using the public highway, radiation protection and protection of the environment.
- Guide No. 11 of 7 October 2009, updated in July 2015, contains provisions applicable to those in charge of nuclear activities as defined in Article L. 1333-1 of the Public Health Code and to the heads of the facilities in which ionising radiation is used (medical, industrial and research activities using ionising radiation).
- Guide No. 31 describes the procedures for notification of radioactive substances transport events (see chapter 9). This guide has been applicable since 1 July 2017.

These Guides can be consulted on the ASN website, *asn.fr*.

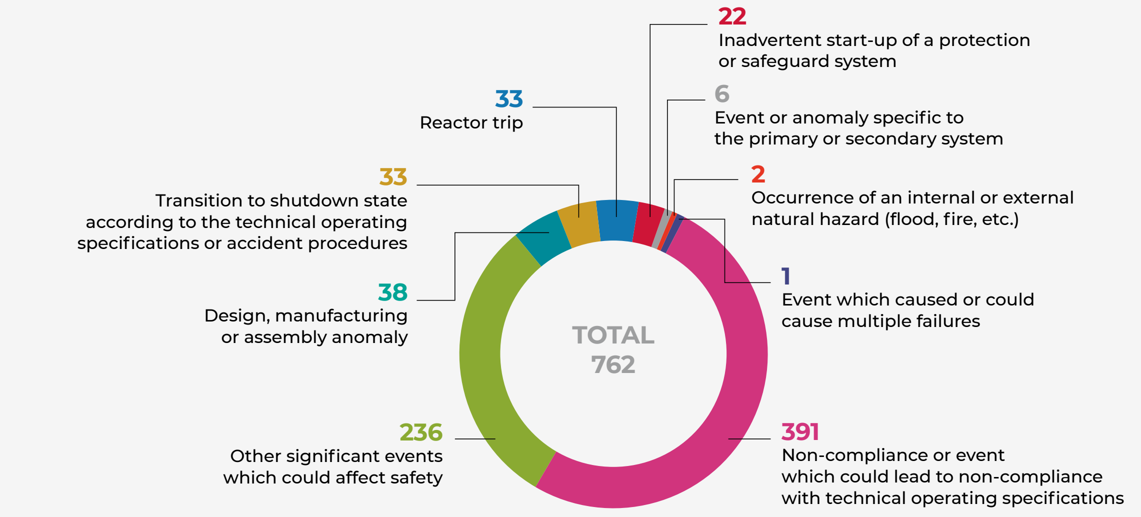
What is a significant event?

Detection of events (deviations, anomalies, incidents, etc.) by those in charge of the activities using ionising radiation, and implementation of corrective measures decided on after analysis, play a fundamental role in accident prevention. For example, the nuclear licensees detect and analyse several hundred anomalies every year, for each EDF reactor.

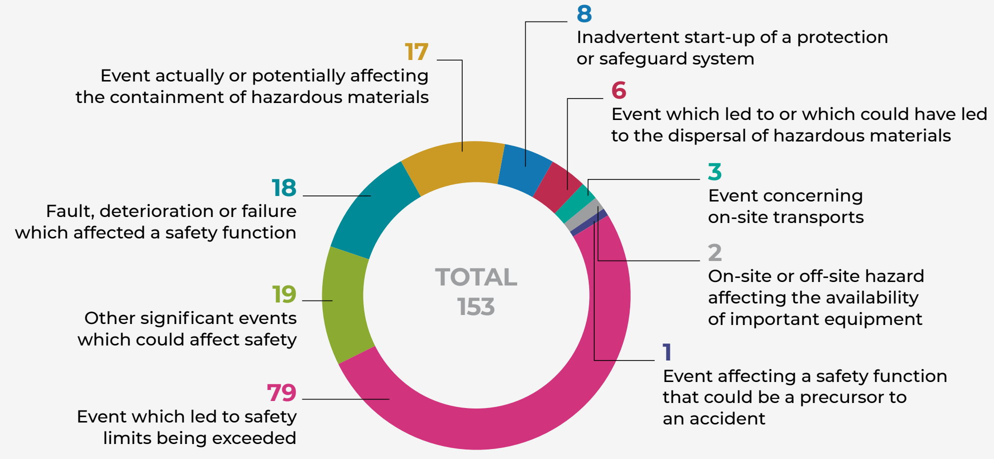
Prioritising the anomalies should enable the most important ones to be addressed first. The regulations have defined a category of anomalies called "significant events". These are events which are sufficiently important in terms of safety, the environment or radiation protection to justify that ASN be rapidly informed of their occurrence and subsequently receive a fuller analysis. Significant events must be reported to it, as specified in the Order of 7 February 2012 (Article 2.6.4), the Public Health Code (Articles L. 1333-13, R. 1333-21 and R. 1333-22), the Labour Code (Article R. 4451-74) and the regulatory texts applicable to the transport of radioactive substances (for instance, the European Agreement on the International Carriage of Dangerous Goods by Road –ADR).

The criteria for notifying the public authorities of events considered to be "significant" take account of the following:
- the actual or potential consequences for 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.

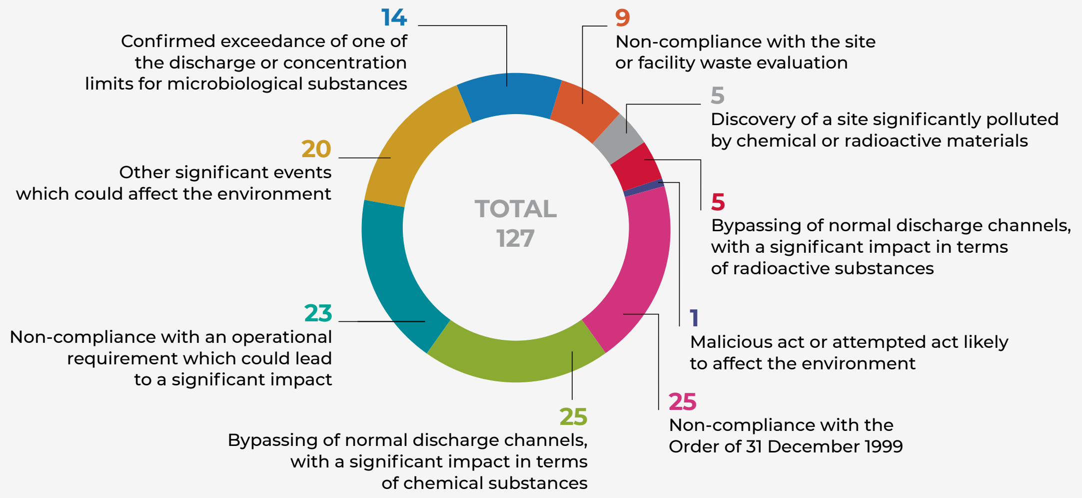
GRAPH 1 Events involving safety in NPPs reported in 2021



GRAPH 2 Events involving safety in BNIs other than NPPs reported in 2021



GRAPH 3 Significant environment-related events in BNIs reported in 2021



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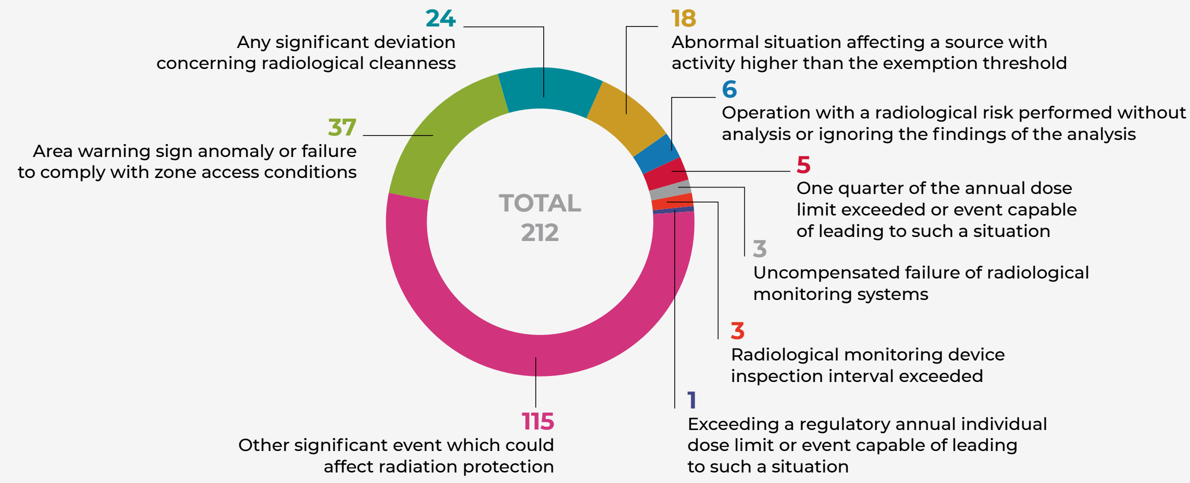
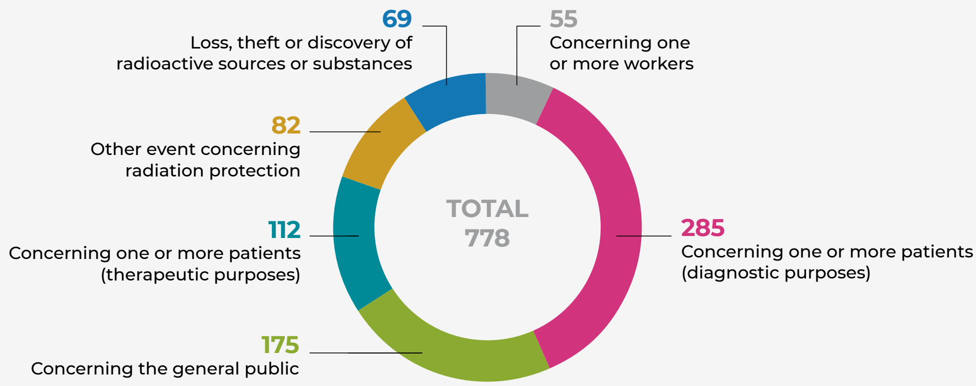
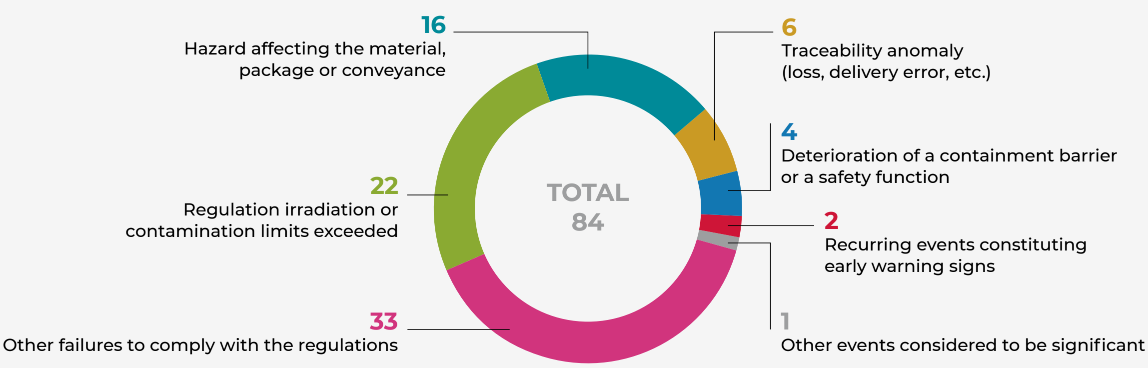
GRAPH 4 **Events involving radiation protection in BNIs reported in 2021**



GRAPH 5 **Events involving radiation protection (other than BNIs and TSR) reported in 2021**



GRAPH 6 **Events involving the transport of radioactive substances reported in 2021**



This notification process is part of the continuous safety and radiation protection improvement approach. It requires the active participation of all players (users of ionising radiation, carriers, etc.) in the detection and analysis of deviations.

It enables the authorities:
- to ensure that the licensee has suitably analysed the event and taken appropriate measures to remedy the situation and prevent it from happening again;
- to ensure that other parties responsible for similar activities benefit from experience feedback about the event.

The purpose of this system is not to identify or penalise any individual person or party.

Moreover, the number and rating on the International Nuclear and Radiological Event Scale (INES 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 transport of radioactive substances is obliged to notify ASN and, as applicable, the administrative authority, without delay, of any accidents or incidents that occur on account of the operation of that installation or the transport activity and which could significantly prejudice the interests mentioned in Article L. 593-1 of the Environment Code.

Similarly, the party responsible for a nuclear activity must notify 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 affecting salaried or non-salaried 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, 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 into a safe condition, and the pertinence of the submitted analysis.

TABLE 6 **Number of significant events rated on the INES scale between 2016 and 2021**

		2016	2017	2018	2019	2020	2021
Basic Nuclear Installations	Level 0	847	949	989	1,057	1,033	1,068
	Level 1	101	87	103	111	107 (*)	103
	Level 2	0	4	0	4	2	1
	Level 3 and +	0	0	0	0	0	0
	Total	**948**	**1,040**	**1,092**	**1,172**	**1,142**	**1,172**
Small-scale nuclear activities (medical and industry)	Level 0	111	144	143	142	135	176
	Level 1	30	36	22	35	24(*)	34
	Level 2	0	3	0	2	1(*)	0
	Level 3 and +	0	0	0	0	0	0
	Total	**141**	**183**	**165**	**179**	**160**	**210**
Transport of radioactive substances	Level 0	59	64	88	85	71	80
	Level 1	5	2	3	4	4	4
	Level 2	0	0	0	0	0	0
	Level 3 and +	0	0	0	0	0	0
	Total	**64**	**66**	**91**	**89**	**75**	**84**
	Grand Total	**1,153**	**1,289**	**1,348**	**1,440**	**1,377**	**1,466**

(*) For the year 2020 only the data concerning significant events rated level 1 and higher on the INES scale were updated (following the re-ratings carried out in 2021).

USING THE LESSONS LEARNED FROM THE LUBRIZOL FIRE

Following the fire that occurred on 26 September 2019 in the Lubrizol and Normandie Logistique facilities in Rouen, ASN initiated a number of actions with the BNIs, in order to learn lessons from this accident and, if necessary, initiate reinforcement of the measures to prevent and control non-radiological risks in BNIs.

More specifically, ASN sent a letter to all licensees in October 2019, asking them to conduct a review of the adequacy and effectiveness of the various barriers in place inside their facilities to control risks related to the storage of hazardous substances, as well as their knowledge of the nature and quantities of the hazardous substances present. After analysing the answers provided by the licensees to this letter, describing the provisions planned for their sites, ASN reinforced its inspections on the topic of non-radiological risks in 2020 and 2021. They brought to light the need for the BNI licensees to improve their organisation, in order to better guarantee the quality, exhaustiveness and robustness of the safety case regarding non-radiological risks, as well as its operational implementation. An effort to improve the inventories of hazardous substances present within the facility and the real-time stocks situation is also required. ASN will continue its inspections on this subject, notably through situational exercises in the facilities.

At the same time, ASN is continuing its work to reinforce the regulatory requirements applicable to the BNIs. ASN is therefore studying whether it would be opportune to revise the new regulatory provisions made applicable to ICPEs following the fire on 26 September 2019, or adapt them to the BNIs.

Finally, with regard to post-accident management, ASN ensures that the OEF from the various Ministries on this subject is incorporated into the considerations by the Steering Committee for the management of the post-accident phase (Codirpa). The General Directorate for the Prevention of Risks (DGPR) at the Ministry for Ecological Transition thus presented and shared the lessons learned from this event. The recommendations of the delegation on “transparency, information and participation by all in the management of major risks, whether technological or natural” ordered by the Ministry for Ecological Transition following the Lubrizol fire, were also presented to this committee in order to contribute to the deliberations of the Codirpa, in order to reinforce the safety and radiation protection culture around nuclear facilities.

ASN and IRSN also carry out a more wide-ranging examination of the OEF from the events. The significant event reports and the periodic reviews sent by the licensees, as well as the assessment by ASN and IRSN, constitute the basis of OEF. The examination of OEF may lead to ASN requests for improvements to the condition of the facilities and the organisation adopted by the licensee, but also to changes to the regulations.

OEF 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 2021, 2,116 significant events were reported to ASN:
- 1,254 significant events concerning nuclear safety, radiation protection, the environment and the on-site transport of hazardous materials within BNIs, 1,172 of which are rated on the INES scale (1,068 “level 0” events, 103 “level 1” events and 1 “level 2” event). Of these events, 31 significant events were rated as “generic events”, in other words concerning several reactors, including 2 at “level 1” on the INES scale;
- 84 significant events concerning the transport of radioactive substances on the public highway, including 4 events rated “level 1” on the INES scale;
- 778 significant events concerning radiation protection in small-scale nuclear activities, including 210 rated on the INES scale (34 “level 1” events).

In 2021, one event was rated “level 2” on the INES scale: it concerns the external contamination of a worker in the Cruas-Meysse NPP. This is described in detail in chapter 10.

In 2021, a significant event reported in 2020 and initially rated “level 1” on the INES scale was provisionally re-rated “level 2”. This event concerns the discovery of residual radioactive contamination in a building of the civil hospital of Strasbourg.

As indicated earlier, these data must be used with caution: they do not in themselves constitute a safety indicator. ASN encourages the licensees to report incidents, which contributes to transparency and the sharing of experience.

The breakdown of significant events rated on the INES scale is given in Table 6. As the INES scale does not apply to significant events concerning patients, the rating of significant events affecting one or more patients in radiotherapy on the ASN-SFRO scale[2] is specified in chapter 7.

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.*

Likewise, significant events concerning the environment but involving non-radiological substances are not covered by the INES scale.

Such events are classified as "out of INES scale" events.

Graphs 1 to 6 describe in detail the significant events reported to ASN in 2021, differentiating between them according to the various notification criteria for each field of activity.

3.4 Raising the awareness of professionals and cooperating with the other administrations

Regulation is supplemented by awareness-raising programmes designed to ensure familiarity with the regulations and their application in practical terms appropriate to the various professions. ASN aims to encourage and support initiatives by the professional organisations that implement this approach by issuing best practices and professional information guides.

ASN publishes "Avoiding accidents" sheets with the aim of sharing its OEF analyses.

Awareness-raising also involves joint actions with other administrations and organisations which oversee the same facilities, but with different prerogatives. One could here mention the labour inspectorate, the medical devices inspectorate work by the ANSM, the medical activities inspectorate work entrusted to the technical services of the Ministry of Health, or the oversight of small-scale nuclear activities at the Ministry of Defence entrusted to the Armed Forces General Inspectorate.

3.5 Information about ASN's regulatory activity

ASN attaches importance to coordinating Government departments and informs the other administration departments concerned of its inspection programme, the follow-up to its inspections, the penalties imposed on the licensees and any significant events.

To ensure that its inspection work is transparent, ASN informs the public by placing the following on its website *asn.fr*:
- its resolutions and decisions;
- inspection follow-up letters for all the activities it inspects;
- the approvals and accreditations it issues or rejects;
- incident notices;
- reactor outage summaries;
- thematic publications.

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 discharges. 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 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 water intake and discharge limits.

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 and gaseous effluents (monitoring of the activity of discharges, 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.). The results of this monitoring are recorded in registers transmitted to ASN every month.

The BNI licensees also regularly transmit a certain number of discharge samples to an independent laboratory for cross-analysis. The results of these "cross-analyses" are sent to ASN. This programme of cross-analyses defined by ASN is a way of ensuring that the accuracy of the measurements taken by the licensee laboratories is maintained over time.

The inspections carried out by ASN

Through dedicated inspections, ASN ensures that the licensees actually comply with the regulations binding on them with regard to the management of discharges and the environmental and health impact of their facilities. Every year, it carries out about 90 inspections of this type, split into three topics:
- prevention of pollution and management of detrimental effects;
- water intake and effluent discharge, monitoring of discharges and the environment;
- waste management.

Each of these topics covers both radiological and non-radiological aspects.

Every year, ASN carries out 10 to 20 inspections with sampling and measurement. They are generally unannounced and are run with the support of specialist, independent laboratories appointed by ASN. Effluent and environmental samples are taken for radiological and chemical analyses. Finally, every year, ASN carries out several reinforced inspections which aim to check the organisation put into place by the licensee to protect the environment; the scope of the inspection is then broadened to cover all of the above-mentioned topics. Within this context, situational exercises can be carried out to test the organisation implemented for pollution management (see chapter 10).

2016-2021 Micro-pollutants Plan

The 2016-2021 Micro-pollutants Plan[3] to preserve the quality of water and biodiversity, aims to protect surface waters, groundwaters, biota, sediments and waters intended for human consumption from all molecules liable to pollute the water resources. This plan meets the good water quality objectives

3. A micro-pollutant can be defined as an undesirable substance detectable in the environment at very low concentrations. Its presence is due, at least in part, to human activity (industrial processes, agricultural practices or day to day activities) and it may, at these very small concentrations, create negative effects on living organisms owing to its toxicity, its persistence and its bioaccumulation.

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set by the framework directive on water and contributes to those of the strategy framework directive for the marine environment, by limiting the input of pollutants into the marine environment from water courses.

For the NPPs, the campaigns to search for hazardous substances in water concluded that close monitoring of copper and zinc discharges was required. Under the Micro-pollutants Plan, the ASN action initiated in 2017 comprises three parts:
- monitor the effective implementation of the action plan proposed by EDF to reduce discharges of copper and zinc (gradual replacement of the brass condenser tubes with stainless steel or titanium tubes);
- monitor the discharge trends for these substances;
- if necessary revise the individual requirements applicable to NPPs, setting emission limits for these substances.

To allow a revision of the emission limits for copper and zinc, among other things, ASN is examining EDF's requests for modification of the requirements concerning water discharge and intake for the NPPs of Dampierre-en-Burly and Belleville-sur-Loire. Within this context, the Environmental Authority issued an opinion on the modification authorisation application file, submitted by the licensee of the Belleville-sur-Loire NPP, on 23 June 2021 and a public inquiry was held on it from 13 December 2021 to 28 January 2022.

The modification authorisation application file submitted by the licensee of the Dampierre-en-Burly NPP was the subject of numerous discussions between the licensee and ASN in 2021, in order to reach draft resolutions which will be submitted for public consultation during the course of 2022.

Accounting of BNI discharges

The rules for accounting of discharges, both radioactive and chemical, are set in the general regulations by amended ASN resolution 2013-DC-0360 of 16 July 2013 relative to control of the detrimental effects and the impact of BNIs on health and the environment. These rules were set so as to guarantee that the discharge values accounted by the licensees, notably those considered in the impact calculations, will in no case be under-estimated.

For discharges of radioactive substances, accounting is not based on overall measurements, but on an analysis per radionuclide, introducing the notion of a "reference spectrum", listing the radionuclides specific to the type of discharge in question.

The principles underlying the accounting rules are as follows:
- radionuclides for which the measured activity exceeds the decision threshold for the measurement technique are all counted;
- the radionuclides of the "reference spectrum" for which the measured activity is below the decision threshold (see box page 159) are counted at the decision threshold level.

For discharges of chemical substances with an emission limit value set by an ASN binding requirement, when the concentration values measured are below the quantification limit, the licensee is required by convention to declare a value equal to half the quantification limit concerned.

Monitoring discharges in the medical sector

Pursuant to ASN resolution 2008-DC-0095 of 29 January 2008, radioactivity measurements are taken on the effluents coming from the places that produce them. In hospitals that have a nuclear medicine department, these measurements chiefly concern iodine-131 and technetium-99m. In view of the difficulties encountered in putting in place the permits to discharge radionuclides into the public sewage networks, as provided for by the Public Health Code, ASN has created a working group involving administrations, "producers" (nuclear physicians, researchers) and sanitation professionals. The report from this working group formulating recommendations to improve the efficiency of the regulations was presented in October 2016 to the Advisory Committee for Radiation Protection (GPRADE), for industrial and research applications of ionising radiation and the environment. ASN consulted the stakeholders in 2017 on this subject. The report from the working group and a circular letter intended for the professionals concerned and constituting the applicable doctrine on the subject were published on the ASN website on 14 June 2019.

Since 2019, the CIDRRE tool (Calculation of the impact of radioactive discharges into the sewage networks) developed by IRSN, enables the licensees to evaluate the impact of their discharges. It is on-line on the Internet. Moreover, additional work has been started concerning the use of new radiopharmaceutical drugs and their environmental impact, as well as the definition of guideline levels enabling the sewage network managers to regulate the effluent discharges into the sewage networks.

In the small-scale industrial nuclear sector, few plants discharge 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.

4.1.2 Evaluating the radiological impact of nuclear activities

The radiological impact of effluents produced by medical activities

The radiological impact of the effluents or waste produced by the nuclear medicine departments underwent recent assessments, which concluded that these discharges represent a low dose impact for persons outside the health facility.

The radiological impact of BNIs

In accordance with the optimisation principle, the licensee must reduce the radiological impact of its facility to values that are as low as possible under economically acceptable conditions.

The licensee is required to assess the dosimetric impact of its activity. As applicable, this obligation is the result of Article L. 1333-8 of the Public Health Code, or the regulations concerning BNI discharges (Article 5.3.2 of ASN resolution 2013-DC-0360 of 16 July 2013, amended, concerning control of detrimental effects and the impact of BNIs on health and the environment). The result is to be assessed considering the allowable annual dose limit for the public (1 millisievert per year –mSv/year) defined in Article R.1333-11 of the Public Health Code, which corresponds to the sum of effective doses received by the public as a result of nuclear activities.

In practice, only traces of artificial radioactivity are detectable in the vicinity of the nuclear facilities; most measurements taken during routine surveillance are below the decision threshold or reflect the natural radioactivity. As these measurements cannot be used for dose estimations, models for the transfer of radioactivity to humans must be used, on the basis of measurements of discharges from the installation. These models are specific to each licensee and are detailed in the facility's impact assessment. During its assessment, ASN devotes efforts to verifying that these models are conservative, in order to ensure that the impact assessments are not underestimated.

In addition to the impact assessments produced on the basis of discharges from the facilities, the licensees are required to carry out environmental radioactivity monitoring programmes (aquatic environments, air, earth, milk, grass, agricultural produce, etc.), more specifically to verify compliance with the hypotheses used in the impact assessment and to monitor changes in the radioactivity level in the various compartments of the environment around the facilities (see point 4.1.1).

The doses from BNIs for a given year are estimated on the basis of the actual discharges from each installation accounted for the year in question. This assessment takes account of discharges from the identified outlets (stack, river or sea discharge pipe), the diffuse emissions not channelled to the outlets (for example tank vent) and the sources of radiological exposure to ionising radiation present in the installation.

The estimate is made in relation to one or more identified reference groups. These are uniform groups of people (adults, children, infants) receiving the highest average dose out of the entire population exposed to a given installation, following realistic scenarios (taking into account the distance to the site, meteorological data, etc.). All of these parameters, specific to each site, explain most of the differences observed between sites and from one year to another.

The Table entitled "Radiological impact of BNIs since 2015" in chapter 1 presents an assessment of the doses due to BNIs calculated by the licensees for the most exposed reference groups.

For each of the nuclear sites presented, the radiological impact remains far below, or at most represents about 1% of the limit for the public, this limit being 1 mSv/year. Therefore in France, the discharges produced by the nuclear industry have an extremely small radiological impact.

4.1.3 Monitoring within the European framework

Article 35 of the EURATOM Treaty requires that the Member States establish the facilities needed to carry out continuous monitoring of the level of radioactivity in the air, water and soil and to ensure compliance with the basic standards of health protection for the general public and workers against the hazards of ionising radiation. All Member States, whether or not they have nuclear facilities, are therefore required to implement environmental monitoring arrangements throughout their territory.

Article 35 also states that the European Commission may access the monitoring facilities to verify their operation and their effectiveness. During its verifications, it gives an opinion on the means implemented by the member states to monitor radioactive discharges into the environment and the levels of radioactivity in the environment around nuclear sites and over the national territory. It notably gives its assessment of the monitoring equipment and methodologies used and of the organisational setup.

Since 1994, the European Commission has carried out the following verification inspections:
- the La Hague reprocessing plant and the Manche disposal facility of the French national radioactive waste management agency, in 1996;
- the Chooz NPP in 1999;
- the Belleville-sur-Loire NPP in 1994 and 2003;
- the La Hague reprocessing plant in 2005;
- the Pierrelatte nuclear site in 2008;
- the old uranium mines in the Limousin *département* in 2010;
- the CEA Cadarache site in 2011;
- the environmental radioactivity monitoring facilities in the Paris area in 2016;
- the La Hague reprocessing plant in 2018.

From 14 to 16 December 2021, ASN took part in the verification visit by the European Commission on the environmental radioactivity monitoring system around the facilities operated by Orano at Malvesi in the Aude *département*. The conclusions of this visit will be written up in a report to be published on the European Commission's website in 2022.

4.2 Environmental monitoring

4.2.1 The French National Network for Environmental Radioactivity Monitoring

In France, many parties are involved in environmental radioactivity monitoring:
- the nuclear facility licensees, who perform monitoring around their sites;
- ASN, IRSN (whose duties as defined by Decree 2016-283 of 10 March 2016 include participation in radiological monitoring of the environment), the Ministries (General Directorate for Health, General Directorate for Food, General Directorate for Competition Policy, Consumer Affairs and Fraud control, etc.), the services of the State and other public players carrying out monitoring duties across the national territory or in particular sectors (foodstuffs controlled by the Ministry for Agriculture, for example);
- the approved air quality monitoring associations (local authorities), environmental protection associations and Local Information Committees (CLIs).

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 are decided by a network steering committee made up of representatives from all the stakeholders in the network: ministerial departments, ARS, representatives of nuclear licensee or association laboratories, members of the CLIs, IRSN, ASN, etc.

4.2.2 The purpose of environmental monitoring

The licensees are responsible for monitoring the environment around their facilities. The content of the monitoring programmes to be implemented in this respect (measurements to be taken and frequency) is defined in amended ASN resolution 2013-DC-0360 of 16 July 2013, and in the individual requirements applicable to each installation (Creation Authorisation Decree, discharge licensing orders or ASN resolutions), independently of the additional measures that can be taken by the licensees for the purposes of their own monitoring.

This environmental monitoring:
- contributes to understanding the radiological and 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 there are no facility malfunctions, notably by analysing the ground water and checking licensees' compliance with the regulations;
- contributes to transparency and information of the public through the transmission of monitoring data to the RNM.

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, Ag-110m, tellurium 123m, antimony-124, antimony-125, caesium-134, caesium-137);
- **Gaseous discharges:** tritium, carbon-14, iodines (iodine-131, iodine-133), other fission and activation products (cobalt-58, cobalt-60, caesium-134, caesium-137), noble gases: xenon-133 (permanent discharges from ventilation networks, when draining "RS" effluent storage tanks and at decompression of reactor buildings), xenon-135 (permanent discharges from ventilation networks and at decompression of reactor buildings), xenon-131m (when draining "RS" tanks), krypton-85 (when draining "RS" tanks), argon-41 (at decompression of reactor buildings).

4.2.3 Content of monitoring

All the nuclear sites in France that produce discharges are subject to systematic environmental monitoring. This monitoring is proportionate to the environmental risks or detrimental effects of the facility, as presented in the authorisation file, particularly the impact assessment.

The regulation monitoring of the environment of BNIs is tailored to each type of facility, depending on whether it is a nuclear power reactor, a plant, a research facility, a waste disposal centre, and so on. The minimum contents of this monitoring are defined by the amended Order of 7 February 2012 setting the general rules for BNIs and by the above-mentioned modified resolution of 16 July 2013. This resolution obliges BNI licensees to have approved laboratories take the environmental radioactivity measurements required by the regulations.

Depending on specific local features, monitoring may vary from one site to another. Table 7 gives examples of the monitoring performed by the licensee of an NPP and of a research centre (or plant).

When several facilities (whether or not BNIs) are present on the same site, joint monitoring of all these installations is possible, as has been the case, for example, on the Cadarache and Tricastin sites since 2006.

These monitoring principles are supplemented in the individual requirements applicable to the facilities by monitoring measures specific to the risks inherent in the industrial processes they use.

Each year, in addition to sending ASN the monitoring results required by the regulations, the licensees transmit nearly 120,000 measurements to the RNM.

4.2.4 Environmental monitoring nationwide by IRSN

IRSN's nationwide environmental monitoring is carried out by means of measurement and sampling networks dedicated to:

- air monitoring (aerosols, rainwater, ambient gamma activity);
- monitoring of surface water (watercourses) and groundwater (aquifers);
- monitoring of the human food chain (milk, cereals, fish, etc.);
- terrestrial continental monitoring (reference stations located far from all industrial facilities).

This monitoring is based on:

- continuous on-site monitoring using independent systems (remote-monitoring networks) providing real-time transmission of results. This includes:
  - the *Téléray* network (ambient gamma radioactivity in the air) which uses a system of continuous measurement monitors around the whole country. The density of this network is being increased around nuclear sites within a radius of 10 to 30 kilometres around BNIs;
  - the *Hydrotéléray* network (monitoring of the main watercourses downstream of all nuclear facilities and before they cross national boundaries);
- continuous sampling networks with laboratory measurement, for example the atmospheric aerosols radioactivity monitoring network;
- laboratory processing and measurement of samples taken from the various compartments of the environment, whether or not close to facilities liable to discharge radionuclides.

Every year, IRSN takes more than 25,000 samples in all compartments of the environment (excluding the remote-measurement networks).

The radioactivity levels measured in France are stable and situated at very low levels, generally at the detection sensitivity threshold of the measuring instruments. The artificial radioactivity detected in the environment results essentially from fallout from the atmospheric tests of nuclear weapons carried out in the 1960s, and from the Chernobyl (Ukraine) accident. Traces of artificial radioactivity associated with discharges can sometimes be detected near installations. To this can be added very local contaminations resulting from incidents or past industrial activities, and which do not represent a health risk.

On the basis of the nationwide radioactivity monitoring results published in the RNM and in accordance with the provisions of ASN resolution 2008-DC-0099 of 29 April 2008, as amended, IRSN regularly publishes a detailed *Summary of the Radioactive State of the French Environment*. The third edition of this summary was published at the end of 2018 and covered the period 2015-2017. The fourth edition of this summary, covering the period 2018-2020, was published in December 2021. The innovations of this last summary include the addition of a chapter devoted to installations classified for protection of the environment. In addition to this summary, IRSN also produces regional radiological findings to provide more precise information about a given area.

Finally, between November 2020 and April 2021, IRSN carried out a campaign to measure tritium in the Loire river. This campaign, the results of which were published at the beginning of 2022, was unable to determine the origin of the atypical value of 310 becquerels per litre (Bq/L) observed in Saumur in January 2019 but did reveal significant differences in the concentrations measured at different points downstream of the discharges. Indeed, depending on the hydraulic conditions, the discharges from the site can take time to disperse uniformly across the width of the river. As a result of these observations, ASN will take a fresh look at how discharges are monitored downstream of the NPPs, in particular the positioning of the stations located downstream of the environmental monitoring installations.

4.3 Laboratories approved by ASN to guarantee measurement quality

Articles R.1333-25 and R.1333-26 of the Public Health Code require the creation of an RNM and a procedure to have the radioactivity measurement laboratories approved by ASN. The RNM working methods are defined by the above-mentioned amended ASN resolution of 29 April 2008.

This network is being deployed for two main reasons:
- to pursue the implementation of a quality assurance policy for environmental radioactivity measurements by setting up a system of laboratory approvals granted by ASN resolution;
- to ensure transparency by making the results of this environmental monitoring and information about the radiological impact of nuclear activities in France available to the public on the RNM website (see point 4.2.1).

The approvals cover all environmental matrices for which regulatory oversight is imposed on the licensees: water, soil or sediment, biological matrices (fauna, flora, milk), aerosols and atmospheric gases. The measurements concern the main artificial or natural gamma, beta or alpha emitting radionuclides, as well as the ambient gamma dosimetry. The list of the types of measurements covered by an approval is set by the above-mentioned amended ASN resolution of 29 April 2008.

In total, an approval covers 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.

In order to produce OEF from the ILTs organised by IRSN, since they were set up in 2003, ASN and IRSN jointly organised a seminar in November 2021 bringing together all the environmental monitoring stakeholders (laboratories of nuclear facility licensees, public institutions, universities, private, association or foreign players, etc.).

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 Inter-laboratory Comparison Test (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.

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.

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 ILT programme, which now operates on a five-yearly basis, is updated annually. It is reviewed by the approval commission and published on the RNM's website. Up to 70 laboratories sign up for a type of test, including a number of laboratories from other countries.

The approval commission defines the evaluation criteria used for analysis of the ILTs. When the result obtained in an ILT by a laboratory is not conclusive enough, ASN may, on the advice of the approval commission, issue an approval for a trial period of one to two years for example, or make issue of the approval dependent on the provision of additional data, or even the participation in a further corroborating test.

In 2021, IRSN organised seven ILT and one cross-check test. Since 2003, 95 ILTs have been carried out, covering 59 types of approval. The most numerous approved laboratories (54) are in the field of monitoring of radioactivity in water. About thirty to forty laboratories are approved for measurement of biological matrices (fauna, flora, milk), atmospheric dust, air, or ambient gamma dosimetry. There are 28 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 2021, ASN issued 121 approvals or approval renewals and decided that 27 approvals would be continued. As at 1 January 2022, the total number of approved laboratories stood at 67, which represents 945 approvals of all types currently valid.

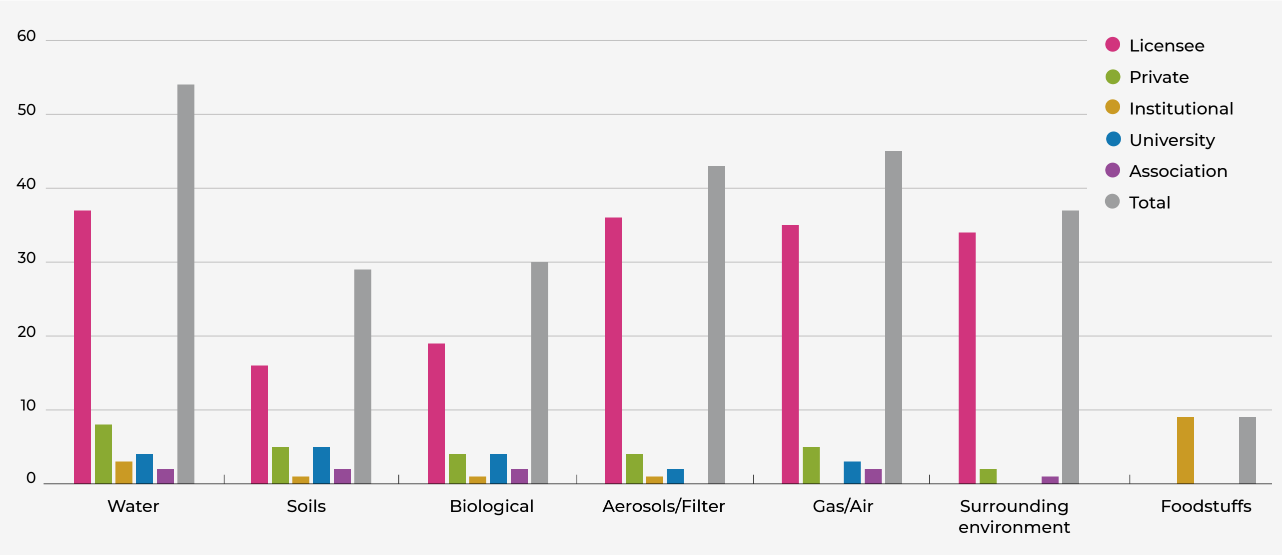
The detailed list of approved laboratories and their scope of technical competence is available on *asn.fr*.

TABLE 7 **Examples of radiological monitoring of the environment around BNIs**

ENVIRONMENT MONITORED OR TYPE OF INSPECTION	CATTENOM NPP (ASN RESOLUTION 2014-DC-0415 OF 16 JANUARY 2014)	ORANO LA HAGUE FACILITY (ASN RESOLUTION 2015-DC-0535 OF 22 DECEMBER 2015)
Air at ground level	• 4 stations continuously sampling atmospheric dust on a fixed filter with daily measurements of total β activity (βG): – γ spectrometry if βG > 2 mBq/m^{3} – Monthly γ spectrometry on groups of filters per station • 1 continuous sampling station downwind of the prevailing winds, with weekly measurement of atmospheric ^{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/m^{3} – Monthly α (Pu) spectrometry on grouped filters per station • 5 continuous sampling stations for halogens on specific adsorbent with weekly γ spectrometry to measure iodines • 5 continuous sampling stations with weekly measurement of atmospheric ^{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
Environment receiving 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
Groundwater	• 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.

GRAPH 7 **Breakdown of the number of approved laboratories for a given environmental matrix as at 1 January 2022**



5 // Inspections concerning fraud and processing of reported cases

5.1 Monitoring of fraud

Since 2015, several cases of irregularities that could be considered to be falsifications have been brought to light at known manufacturers, suppliers or organisations who have been working for many years on behalf of the French nuclear industry. Confirmed cases of counterfeit or falsification have also been encountered in a number of other countries in recent years. The term of irregularity is employed by ASN to cover any intentional modification, alteration or omission of certain information or data. An irregularity detected by ASN can be dealt with by a judge in a case of criminal fraud.

The number of confirmed or suspected cases only represents a very small proportion of the nuclear activities, but these cases show that neither the robustness of the monitoring and inspection chain, for which the manufacturers, suppliers and licensees have prime responsibility, nor the high level of quality required in the nuclear industry, have been able to totally rule out the risk of counterfeit, fraud and falsification. Not all of these cases were detected by the licensee's monitoring process, which must now be more adequately tailored to the prevention, detection, analysis and processing of cases of fraud.

In 2016, ASN began to look at adapting BNI inspection methods in an irregularity context. In so doing, it questioned other regulation and oversight administrations, its foreign counterparts and the licensees with regard to their practices, in order to learn the pertinent lessons. This particular risk led to changes in the ASN oversight methods, but it continues to be dealt with using the existing procedures.

In 2018, ASN also reminded the BNI licensees and the main manufacturers of nuclear equipment that an irregularity is a deviation as defined by the BNI Order. The requirements of the BNI Order therefore apply to the prevention, detection and processing of cases that can be considered to be fraud. More generally, the regulatory requirements concerning the safety and protection of persons against the risks related to ionising radiation also apply. For example, applying a signature to certify that an activity has been correctly carried out, whereas in reality it has not, could –depending on the circumstances– be a breach of the rules of organisation, technical inspection of activities, skills management, etc.

In 2021, the search for irregularities constituting fraud was reinforced during routine inspections in the nuclear facilities. These inspections are of three types:
- inspections further to known subjects, resulting from irregularities discovered in other facilities, or to monitor the processing of a case previously detected;
- inspections including an in-depth search for proof in the performance of activities, for example with verification of the actual presence of a person who certified that they had carried out an activity on a given date;
- inspections with the purpose of raising awareness concerning the risks of fraud, notably during supplier inspections, where the risk of fraud in the subcontracting chain was dealt with.

About sixty inspections were carried out in this way in 2021, excluding the inspections which carried out verifications but with no discovery of suspicious cases and for which there is no traceability. They mainly take place on the nuclear sites. Inspections devoted to this topic were also carried out in the head office departments of the main nuclear licensees. The cases detected are first of all dealt with as deviations from the regulatory requirements. They are also the subject of discussions with the site management and the head office departments of the licensees, so that preventive action can be taken. Depending on the potential implications of the deviation, a report or notification is sent to the Public Prosecutor's Office. One report was sent in 2021.

In addition, the data integrity topic –linked to the risk of fraud in that traceability weaknesses can facilitate irregularities– is being covered with increasing frequency and is the subject of requests in certain inspection follow-up letters.

The detection of irregularities or suspicious cases is still very much an issue, both for the licensees themselves, within the context of their monitoring and internal checks, and for the ASN inspectors.

In the field of small-scale nuclear activities, ASN programmed a general verification in 2021 on the authenticity of the industrial radiology operator certificates (CAMARI) and the cards authorising the transport of radioactive materials, during inspections. This action is detailed in chapter 8.

ASN's actions to prevent, detect and process fraud type irregularities are not limited just to the inspections. For example, ASN has informed the main licensees and manufacturers of the cases detected and is analysing their responses. In 2021, ASN also sent out two information sheets to foreign safety regulators, through an international exchange channel that it actively helped to set up.

5.2 Processing of reported cases

At the end of November 2018, ASN set up an on-line portal to enable anyone wishing to report irregularities potentially affecting the protection of persons and the environment, potentially a whistle-blower, to do so.

By means of a system of pseudonyms for the reports received, ASN guarantees the confidentiality of anyone sending it a report. Only a request from a judicial authority could override this confidentiality, something which has not yet happened. It is however preferable for the person sending in the notification to leave their contact details so that ASN can:

- acknowledge receipt of the notification;
- contact them if clarification is required (this is frequently the case);
- inform them if action has been taken following their alert.

In 2021, 45 reports were sent to ASN: more than half (26) *via* the on-line portal, the others by alternative means of transmission, mainly (15 reports) by direct contact with the ASN division geographically competent or the technical department in charge of the subject. The reports received vary:

- in the field concerned: about one third concern BNIs, just under one quarter the medical field;
- in their content: they can report deterioration in the organisation of the entity which could affect radiation protection, poorly performed work, etc.

Some reports are forwarded by ASN to other administrations when it is not competent to deal with them. All reports are examined and dealt with. This can lead to an inspection, a technical analysis, a request for information from a nuclear activity manager, etc. It could for example concern information regarding the security of a BNI, which must be addressed by the High Defence and Security Official at the Ministry for Energy.

Twelve 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 2021 were anonymous (four), which make it easier to process them. Only one report could not be processed, because its content was extremely vague and it was impossible to contact the source.

6 // Identifying and penalising deviations

ASN implements enforcement measures, making it possible to oblige a licensee or party responsible for a nuclear activity to restore compliance with the regulations, along with penalties.

In certain situations in which the actions of the licensee or party responsible for a nuclear activity fail to comply with the regulations in force, or when it is important that appropriate action be taken by it to remedy the most serious risks without delay, ASN may resort to enforcement measures and impose the penalties provided for by law. The principles of ASN actions in this respect are:

- actions that are impartial, justified and appropriate to the level of risk presented by the situation concerned. Their scale is proportionate to the nuclear safety, health and environmental risks associated with the deviation identified and also take account of factors relating to the licensee (past history, behaviour, repeated nature), the context of the deviation and the nature of the requirements contravened (regulations, standards, "rules of good practice", etc.);
- administrative measures initiated on proposals from the inspectors and decided on by ASN or the administrative enforcement Committee, in order to remedy risk situations and non-compliance with the legislative and regulatory requirements as observed during its inspections.

Moreover, criminal infringement reports (violation, misdemeanour) can be issued by the ASN inspectors and transmitted to the competent local Public Prosecutor's Office, which will assess whether or not to initiate prosecution.

6.1 Enforcement measures and administrative sanctions

ASN has a range of tools at its disposal regarding the party responsible for a nuclear activity or a licensee, more particularly:

- the inspector's observations;
- the official letter from the ASN departments (inspection follow-up letter);
- formal notice from ASN to regularise the administrative situation or to comply with the regulations in force, within a time-frame determined by itself;
- enforcement measures or administrative sanctions, applied after formal notice has been served.

These measures, as set out in law, are as follows:

- deposit in the hands of a public accountant of a sum covering the total cost of the work to be performed;
- have the work carried out without consulting the licensee or the party responsible for the nuclear activity and at its expense (any sums deposited beforehand can be used to pay for this work);
- suspension of the operation of the facility or of the transport operation until conformity is restored, or suspension of the activity until complete performance of the conditions imposed and the adoption of interim measures at the expense of the person served formal notice, in particular in the event of urgent measures to protect human safety;
- a daily fine (an amount set per day, to be paid by the licensee or the party responsible until full compliance with the requirements of the formal notice has been achieved);
- administrative fine.

It should be noted that these last two measures are proportionate to the gravity of the infringements observed. With regard to administrative sanctions, the administrative enforcement Committee, when referred to by the ASN Commission, may hand down the administrative fine set out in 4° of II of Article L. 171-8 of the Environment Code, when a formal notice decision, issued beforehand by ASN against a licensee or nuclear activity manager to require compliance of the activity with the regulations in force, has not been met by the latter.

The meeting to set up the administrative enforcement Committee was held on 19 October 2021. On this occasion, the Committee appointed its Chairman and adopted its internal rules of procedure, which were published in the *Official Journal* of the French Republic in 5 November 2021.

TABLE 8 **Number of reports transmitted by the ASN inspectors between 2016 and 2021**

	2016	2017	2018	2019	2020	2021
Report excluding labour inspection in the NPPs	7	13	14	8	4	2
Labour inspection report in the NPPs	1	5	2	4	8	0

The law also makes provision for interim measures to safeguard security and public health and safety or protect the environment. ASN can therefore:
- provisionally suspend operation of a BNI, immediately notifying the Ministers responsible for nuclear safety, in the event of any serious and imminent risk;
- at all times require assessments and implementation of the necessary measures in the event of a threat to the above-mentioned interests;
- take decisions to temporarily or definitively revoke the administrative title (authorisation and soon registration) issued to the party responsible for the nuclear activity, after having informed the party concerned that it is entitled to submit observations within a given time, in order to comply with the exchange of views procedure.

In 2021, ASN sent out formal notice on five occasions: four for BNIs and one for small-scale nuclear activities.

6.2 The action taken following criminal violations

The texts also make provision for criminal infringements, misdemeanours or breaches. This will for example be non-compliance with the provisions concerning the protection of workers exposed to ionising radiation, non-compliance with formal notice served by ASN, performance of a nuclear activity without the required administrative title, non-compliance with the provisions of ASN resolutions or decisions, or irregular management of radioactive waste.

Any infringements observed are written up in reports by the nuclear safety and radiation protection inspectors and transmitted to the Public Prosecutor's Office, that decides on what subsequent action, if any, is to be taken.

The Environment Code makes provision for criminal penalties, a fine or even a term of imprisonment (up to €150,000 and three years in prison), depending on the nature of the infringement. For legal persons found to be criminally liable, the amount of the fine can reach €10M, depending on the infringement in question and the actual prejudice to the interests mentioned in Article L. 593-1.

The Public Health Code also makes provision for criminal penalties, consisting of a fine of from €3,750 to €15,000 and a term of imprisonment of six months to one year. Depending on the gravity of the offence, additional sentences may be applied to legal persons.

Class five penalties (fines) are stipulated in the field of nuclear safety for infringements mentioned in Article R. 596-16 of the Environment Code, as well as in the field of radiation protection for infringements mentioned in Articles R. 1337-14-2 to 5 of the Public Health Code, for example with regard to non-compliance with the requirements for notification of a significant event, to the administrative system (transmission of the title application file, compliance with general requirements, information concerning changes to the RPA).

With regard to pressure equipment, the provisions of Chapter VII of Title V of Book V of the Environment Code, which apply to products and equipment representing a risk, which covers pressure equipment, including that installed in BNIs, notably provide for the payment of a fine, plus a daily penalty payment as applicable, until compliance with the formal notice served on the licensees. This chapter also includes provisions applicable to the manufacturers, importers and distributors of such equipment, aiming to ban the marketing, commissioning or continued operation of an equipment item and to serve the licensee with formal notice to take all steps necessary to ensure conformity with the legislative and regulatory provisions applicable to its activity.

In the performance of their duties in NPPs, the ASN labour inspectors have at their disposal all the inspection, decision-making and enforcement resources of ordinary law inspectors (pursuant to Article R. 8111-11 of the Labour Code). Observation, formal notice, administrative sanction, report, injunction (to obtain immediate cessation of the risks) or even stoppage of the works, offer the ASN labour inspectors a broad range of incentive and constraining measures.

Finally, the inspector may record offences which do not fall within their scope of competence, such as an irregularity comparable to fraud (see point 5.1). In this case –and in the event of a misdemeanour this is mandatory– a report is sent to the Public Prosecutor's Office.

In 2021, two infringements were recorded by the ASN inspectors and two reports were transmitted to the Public Prosecutor's Office.

04
Radiological emergency and post-accident situations

04 RADIOLOGICAL EMERGENCY AND POST-ACCIDENT SITUATIONS

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 dealing with and managing a radiological emergency situation must be planned for, tested and regularly 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.

To take account of the lessons learned from the national emergency exercises and the Fukushima Daiichi NPP accident, this Committee proposed to the Government that changes be made to the post-accident management strategy for the consequences of a nuclear accident. These changes notably lead to new proposals for the population protection zoning strategy, in order to set up a system that is simpler and more operational.

In 2021, the Codirpa continued its work under a new mandate from the Prime Minister, to expand post-accident doctrine to new subjects such as waste management, preparedness and the involvement of the local stakeholders.

1 // Planning ahead

Four main principles underpin the protection of the general public against BNI risks:

- risk reduction at source, wherein the licensee must take all steps to reduce the risks to a level that is as low as possible in acceptable economic conditions;
- the emergency and contingency plans, designed to prevent and mitigate the consequences of an accident;
- controlling urban development around BNIs;
- informing the general public.

1.1 Looking ahead and planning

1.1.1 The Basic Nuclear Installation emergency and contingency plans

The emergency and contingency plans relative to accidents occurring at a BNI define the measures necessary to protect the site personnel, the general public and the environment, and to control the accident.

a) Major Nuclear or Radiological Accident National Response Plan

ASN took part in drafting the Major Nuclear or Radiological Accident National Response Plan (PNRANRM), which was published by the Government in February 2014. The Plan incorporates the lessons learned from the Fukushima Daiichi NPP accident and the post-accident doctrine drawn up by the Codirpa

SECNUC 2021 EXERCISE: SIMULATION OF THE CIC AND THE INTERMINISTERIAL ASPECTS OF A NUCLEAR EMERGENCY

On 18 and 19 May 2021, ASN took part in the SECNUC 2021 major emergency exercise under the supervision of and at the initiative of the General Secretariat for Defence and National Security (SGDSN). This type of exercise, involving the local and national levels of the various stakeholders, is held every three years. On this occasion, several ASN staff members took part in emergency management within the Interministerial Crisis Committee (CIC). The CIC is an organisation enabling the Prime Minister, in collaboration with the President of the Republic, to exercise his/her emergency management responsibilities.

It brings together all the ministries concerned, in order to collect all useful information and develop the analysis capacity required for decision-making. The exercise scenario was run three days after a fictitious accident which took place on 15 May in the EDF Saint-Laurent-des-Eaux NPP (*département* 41), leading to radioactive releases into the environment. The participants thus managed the post-accident phase of the nuclear accident, first of all with emergency management by role-playing two decision-making meetings of the CIC and then, the next day, jumping back four days in the exercise scenario to run a forward-planning situation. ASN thus mobilised about fifty people over these two exercise days.

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.

b) Off-site Emergency Plan
In the vicinity of the facility, the Off-site Emergency Plan (PPI) is established by the Prefect of the *département* concerned pursuant to Articles L.741-6, R.741-18 et *seq.* of the Domestic Security Code, "*to protect the populations, property and the environment, and to cope with the specific risks associated with the existence of structures and facilities whose perimeter is localised and fixed. The PPI implements the orientations of civil protection policy in terms of mobilisation of resources, information, alert, exercises and training*". These Articles also stipulate the characteristics of the facilities or structures for which the Prefect is required to define a PPI.

The PPI specifies the initial actions to be taken to protect the general public, the roles of the various services concerned, the systems for giving the alert, and the human and material resources likely to be engaged in order to protect the general public.

The PPI falls within the framework of the Disaster and Emergency Response Organisation (Orsec), which describes the protective measures decided on by the public authorities in large-scale emergencies. Therefore, beyond the application perimeter of the PPI, the *département* or zone Orsec plan is activated. ASN assists the Prefect, who is responsible for the drafting and approval of the PPI, by analysing the various aspects with its technical support organisation, IRSN, including those concerning the nature and scale of the radiological consequences of an accident.

The PPIs currently make it possible to plan the public authorities' response in the first hours of the accident, in order to protect the population living within a 20 km radius around the affected installation. The PPI comprise a "reflex" phase, in which the licensee immediately issues an alert to the populations situated within a radius of from a few hundred metres up to 2 km (for electricity generating reactors). Once alerted by activation of the "PPI" sirens, the populations situated within this radius must take shelter and listen to the media. The PPI are also able to prepare for an "immediate evacuation" response from a distance of a few hundred metres up to 5 km (for electricity generating reactors). Finally, in a radius of up to 20 km around the installations, the PPI provide for measures to restrict consumption in the event of an accident, plus reinforced information of the populations regarding the risks from the installation and the appropriate behaviour to be followed.

The additional measures to be taken beyond the zone covered by the PPI are specified, as applicable, through a joint approach which can be based on the Orsec arrangements, taking account of the characteristics of the accident and the weather conditions.

c) On-site Emergency Plan
As part of the BNI commissioning authorisation procedures, ASN examines and approves the On-site Emergency Plans (PUIs) and their updates (Article R. 593-31 of the Environment Code).

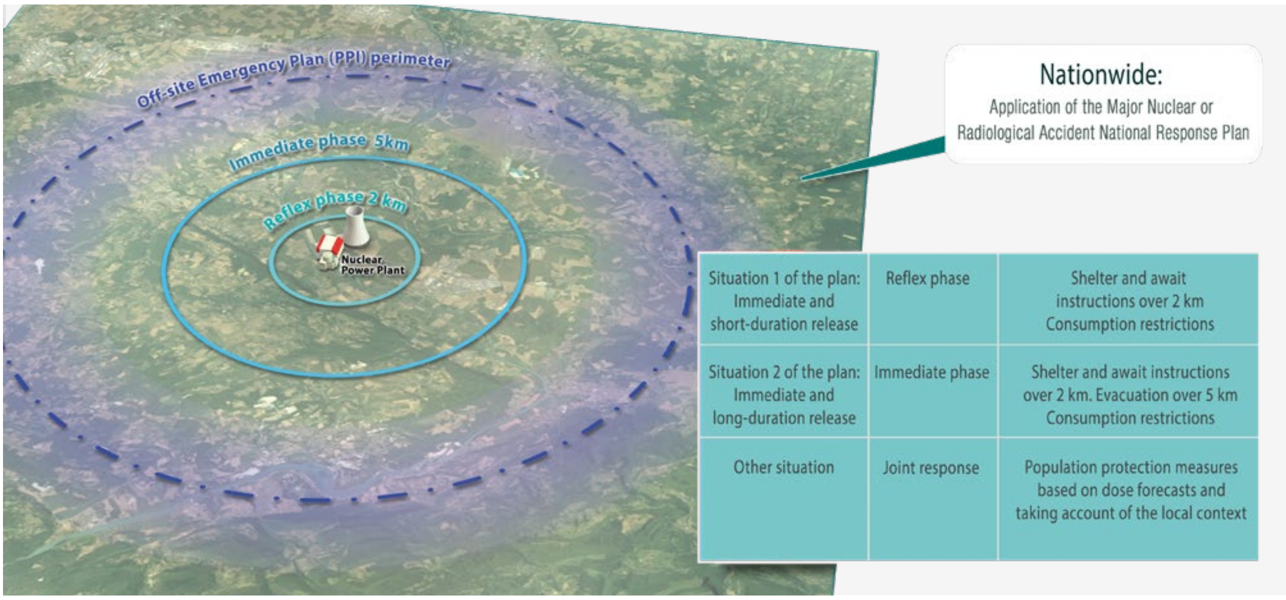
The PUI, prepared by the licensee, is designed to restore the plant to a controlled and stable condition and mitigate the consequences of an event. It defines the organisational actions and the resources to be implemented on the site. It also includes the provisions for rapidly informing the public authorities. The obligations of the licensee relative to the preparation for and management of emergency situations are defined in Title VII of the Order of 7 February 2012 setting the general rules for BNIs. The associated provisions were stipulated in ASN resolution 2017-DC-0592 of 13 June 2017 concerning the obligations of BNI licensees in terms of preparedness for and management of emergency situations and the content of the 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.

DIAGRAM 1 **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. Evacuation over 5 km Consumption restrictions
Other situation	Joint response	Population protection measures based on dose forecasts and taking account of the local context

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 Transport of Radioactive Materials (TMR) plan. Faced with the diversity of possible types of transport operations, this part of the plan defines the criteria and simple measures enabling the first respondents (Departmental Fire and Emergency Service –SDIS– and law enforcement services, in particular) to initiate the first reflex response measures to protect the general public and sound the alert, based on their findings on the site of the accident.

1.1.3 The response to other radiological emergency situations

Apart from the incidents or accidents which could affect nuclear installations or radioactive substances transport operations, radiological emergency situations can also occur:
- during performance of a nuclear activity for medical, research or industrial purposes;
- in the event of intentional or inadvertent dispersal of radioactive substances into the environment;
- if radioactive sources are discovered in places where they are not supposed to be.

In such cases, intervention is necessary to limit the risk of human exposure to ionising radiation. Together with the Ministries and the parties concerned, ASN therefore drafted Circular DGSNR/DHOS/DDSC 2005/1390 of 23 December 2005 relative to the principles of intervention in the case of an event that could lead to a radiological emergency, other than situations covered by a contingency plan or an emergency response plan. This Circular supplements the provisions of the Interministerial Directive of 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation presented in point 1.3 and defines the methods for the organisation of the State services in these situations.

Given the large number of potential originators of an alert and the corresponding alert circuits, all the alerts are centralised in a single location, which then distributes them to all the stakeholders: this is the fire brigade's centralised alert processing centre, the *Département* Operational Fire and Emergency Centre-Alert Processing Centre (CODIS-CTA), that can be reached by calling 18 or 112.

The management of accidents of malicious origin occurring outside BNIs are not covered by this Circular, but by the Government's "Nuclear, Radiological, Biological and Chemical" (NRBC) plan.

1.1.4 Controlling urban development around nuclear sites

The aim of controlling urban development is to limit the consequences of an accident for the population and property. An approach of this type has been in place since 1987 around non-nuclear industrial facilities and was reinforced following the AZF plant accident in Toulouse in 2001. Act 2006-686 of 13 June 2006 concerning Transparency and Security on Nuclear matters (TSN Act, now codified in Books I and V of the Environment Code), enables the public authorities to control urban development around BNIs, by implementing institutional controls limiting or prohibiting new constructions in the vicinity of these facilities.

The actions to control urban development entail a division of responsibilities between the licensee, the mayors and the State:
- The licensee is responsible for its activities and the related risks.
- The mayor is responsible for producing the town planning documents and issuing building permits.
- The Prefect informs the mayors of the existing risks, verifies the legality of the steps taken by the local authorities and may impose institutional controls as necessary.

ASN supplies technical data in order to characterise the risk, and offers the Prefect its assistance in the urban development control process.

The current approach to controlling activities around nuclear facilities exclusively concerns those subject to a PPI and primarily aims to preserve the operational nature of the contingency plans, in particular for sheltering and evacuation, while limiting the population numbers concerned as far as possible. It focuses on the PPI "reflex" zone, determined by the Circular of 10 March 2000 revising the PPIs for BNIs, the pertinence of which was confirmed by the instruction of 3 October 2016.

In this "reflex" zone, immediate steps to protect the population are taken in the event of a rapidly developing accident (see point 1.1.1 b).

A 17 February 2010 Circular from the Ministry responsible for the environment concerning the control of activities in the vicinity of BNIs liable to present dangers off the site asked the Prefects to exercise increased vigilance with regard to urban development in the vicinity of nuclear facilities. This Circular states that the greatest possible attention must be paid to projects that are sensitive owing to their size, their purpose, or the difficulties they could entail in terms of protection of the general public in the "reflex" zone.

ASN is consulted on construction or urban development projects situated within this zone. The opinions issued are based on the principles explained in ASN Guide No.15 on the control of activities around BNIs published in 2016. This Guide, drawn up by a pluralistic working group jointly overseen by ASN and the General Directorate for Risk Prevention (DGPR), comprising elected officials and the National Association of Local Information Commissions and Committees (Anccli), has the following basic objectives:
- preserve the operational nature of the contingency plans;
- give priority to regional development outside the "reflex" zone;
- allow controlled development that meets the needs of the resident population.

1.2 The emergency situation stakeholders

The response by the public authorities to a major nuclear or radiological accident is determined by a number of texts concerning nuclear safety, radiation protection, public order and civil protection, as well as by the emergency plans.

Act 2004-811 of 13 August 2004 on the Modernisation of Civil Protection, makes provision for an updated inventory of risks, an overhaul of operational planning, performance of exercises involving the general public, information and training of the general public, an operational watching brief and alert procedures. Several Decrees implementing this Act, codified in Articles L. 741-1 to L. 741-32 of the Domestic Security Code, more specifically concerning the Orsec plans and PPIs, clarified it in 2005.

How radiological emergency situations are dealt with is specified in the Interministerial Directive of 7 April 2005 on the action of the public authorities in the case of an event leading to a radiological emergency situation (see Diagram 1).

Thus, at the national level, ASN is an active participant in interministerial work on nuclear emergency management.

The Fukushima Daiichi NPP accident showed that it was necessary to improve preparation for the occurrence of a multifaceted accident (natural disaster, accident affecting several facilities simultaneously). The response organisations thus put into place must be robust and capable of managing a large-scale emergency over a long period of time. Better advance planning must be carried out for work done under ionising radiation and, in order to provide effective support for the country affected, international relations must be improved.

1.2.1 Local response organisation

In an emergency situation, several parties have the authority to take decisions:
- The licensee of the affected nuclear facilities deploys the response organisation and the resources defined in its PUI (see point 1.1.1).
- ASN has a duty to monitor the licensee's actions in terms of nuclear safety and radiation protection. In an emergency situation, it calls on assessments by IRSN and can at any time ask the licensee to perform any assessments and take any actions it deems necessary.
- The Prefect of the *département* in which the installation is located takes the necessary decisions to protect the population, the environment and the property threatened by the accident. Within the framework of the PPI, this comprises the Orsec plans or the Off-site Protection Plan (PPE) in the event of a malicious act. The Prefect is thus responsible for coordinating the resources –both public and private, human and material– deployed in the PPI. He/she keeps the population and the mayors informed of events. ASN assists the Prefect with managing the situation.
- The Prefect of the defence and security zone is responsible for coordinating reinforcements and the support needed by the Prefect of the *département*, for ensuring that the steps taken between *départements* are consistent, and for coordinating regional and national communications.
- Owing to his or her role in the local community, the Mayor has an important part to play in anticipating and supporting the measures to protect the population. To this end, the mayor of a municipality included within the scope of application of a PPI must draw up and implement a local safeguard plan to provide for, organise and structure the measures to accompany the Prefect's decisions. The Mayor also plays a role in relaying the information and heightening population awareness, more particularly during iodine tablet distribution campaigns.

1.2.2 National response organisation

In a radiological emergency situation, each Ministry –together with the decentralised State services– is responsible for preparing and executing national level measures within their field of competence.

In the event of a major crisis requiring the coordination of numerous players, a governmental crisis organisation is set up, under the supervision of the Prime Minister, with activation of the 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.

To supplement the pre-distribution in 2016 within the 0-10 km radius, the national campaign of iodine tablets distribution to the populations within the zone covered by the PPIs between 10 and 20 km around the NPPs, was launched in September 2019.

Outside the zone covered by a PPI, tablets are stockpiled to cover the rest of the country. In this respect, the Ministries for Health and for the Interior decided to create stocks of iodine tablets, positioned and managed by *Santé Publique France* (more particularly taking over the roles previously held by the Health Emergency Preparedness and Response Organisation –Eprus). Each Prefect defines the procedures for distribution to the population in their *département*, relying in particular on the mayors for this.

This arrangement is described in a Circular of 11 July 2011 concerning the storage and distribution of potassium iodide tablets outside the zones covered by a PPI. Pursuant to this circular, the Prefects implemented plans to distribute stable iodine tablets in a radiological emergency situation, which can involve exercises being held for the local implementation of the PNRANRM.

The Prefect may also take measures to ban the consumption of foodstuffs liable to have been contaminated by radioactive substances as of the emergency phase (until the facility has been restored to a controlled and stable state).

The purpose of these measures, taken before the releases cease, is to facilitate management of the post-accident phase. Once the releases are over and the facility has returned to a stable state, further population protection steps are decided on, according to the deposition of radioactive materials in the environment. Depending on the ambient radioactivity level, this could involve:
- evacuating the population for a variable length of time;
- restrictions on the self-consumption of foodstuffs produced locally;
- checks on foodstuffs prior to marketing, in accordance with the maximum allowable levels of radioactive contamination defined at European level for the sale of foodstuffs.

1.3.2 Care and treatment of exposed persons

In the event of a radiological emergency situation, a significant number of people could be contaminated by radionuclides. These persons shall be cared for by the emergency response teams duly trained and equipped for this type of operation.

The Circular of 18 February 2011 regarding national doctrine for the use of emergency resources and care to deal with an act of terrorism using radioactive substances, specifies the provisions which also apply to a nuclear or radiological accident, and which aim to implement a unified nationwide methodology for the use of resources, in order to optimise efficiency.

The *Medical intervention following a nuclear or radiological event Guide*, the drafting of which was coordinated by ASN and which was published in 2008, accompanies Circular DHOS/HFD/DGSNR No. 2002/277 of 2 May 2002 concerning the organisation of medical care in the event of a nuclear or radiological accident, giving all the information of use for the medical response teams in charge of collecting and transporting the injured, as well as for the hospital staff. Under the aegis of the General Secretariat for Defence and National Security (SGDSN), a new version of this Guide taking account of changes to certain practices, is currently under preparation.

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.

As part of its ongoing analysis of the management of the post-accident phase, the Codirpa, set up by ASN in 2005 at the request of the Prime Minister, worked to learn the lessons from the post-accident management employed in Japan after the Fukushima Daiichi disaster, but also the experience feedback from emergency exercises.

Following this work, the Codirpa recommended a number of changes to post-accident doctrine, which ASN transmitted to the Prime Minister, who accepted them in June 2020. The main one is simplification of the post-accident zoning, constituting the basis for the population protection measures:

PANELS OF CITIZENS TO INVOLVE THE POPULATION IN DEFINING POST-ACCIDENT DOCTRINE

The purpose of these panels, decided on by the Codirpa, is to assess the population's understanding of the proposed protection measures, to test their acceptability and to collect proposals.

ASN and the CLIs jointly organised these discussions with the public. The chosen topic concerns the management of the consequences of a nuclear accident, more particularly with regard to local fresh produce (vegetable gardens, orchards) and products from hunting, fishing and gathering.

Two workshops were held in 2021, one in Golfech in November, the other in Tricastin in December.

The discussions with the participants were constructive and the opinions collected were reported to the Cordirpa "foodstuffs" working group, with a view to updating national doctrine.

This approach, which aims to anticipate the consequences of a major accident, also enables a "safety culture» to be developed among the stakeholders concerned (regional authorities, public services, NGOs, population); this is a crucial area f or progress, as proven by recent emergencies (Lubrizol accident, Covid-19 pandemic).

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- To protect the population from the risk of external exposure, the population evacuation perimeter (uninhabitable zone) would be maintained, on the basis of an annual effective dose value of 20 millisieverts per year (mSv/year) for the first year, due to external exposure alone. The consumption and sale of foodstuffs produced locally would be prohibited within this zone.
- To limit exposure of the population to the risk of contamination through consumption, a non-consumption perimeter for fresh local produce is proposed. First of all, this perimeter would be defined from the largest of the population protection perimeters (sheltering, ingestion of iodine, etc.) determined during the emergency phase. It would then be refined using environmental contamination measurements and the available models.
- With regard to the sale of local produce, the Codirpa proposes adopting a regional approach per agricultural production and livestock sector, based on the maximum allowable radioactive contamination levels defined by the European authorities for the sale of foodstuffs. In order to involve the stakeholders in preparedness for the post-accident phase, ASN joined forces with the CLIs to propose participative discussions with the residents living within the perimeter of a PPI. This process involving an on-line forum with panels of citizens focuses on the restrictions on the use of fresh produce grown locally (vegetable gardens, etc.) which could be issued by the authorities in the wake of a nuclear accident (see box above).

Finally, to enable the doctrine to be disseminated in the regions, the Codirpa set up a working group involving numerous associations (including the Anccli), IRSN but also representatives of national and decentralised administrations. The work done led to:
- the creation of an Anccli/ASN/IRSN website raising post-accident awareness (*post-accident-nucleaire.fr*). This site enables elected officials, health professionals, associations, education personnel and economic players to access documents and information of use for preparing or managing life in a region contaminated by a nuclear accident;
- the publication of a practical guide intended for the inhabitants of a region contaminated by a nuclear accident;
- frequently asked questions/answers drawn up with and for health professionals on subjects concerning health and everyday life in the form of a Guide in December 2021;
- and the organisation of panels of citizens.

This initial information work will be continued on a long-term basis. The post-accident awareness-raising website will be enhanced with Codirpa outputs concerning information of the post-accident stakeholders.

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, offices of the Prefect, political authorities, general directorates of administrations, Anccli, CLIs, etc.;
- foreign nuclear safety regulators.

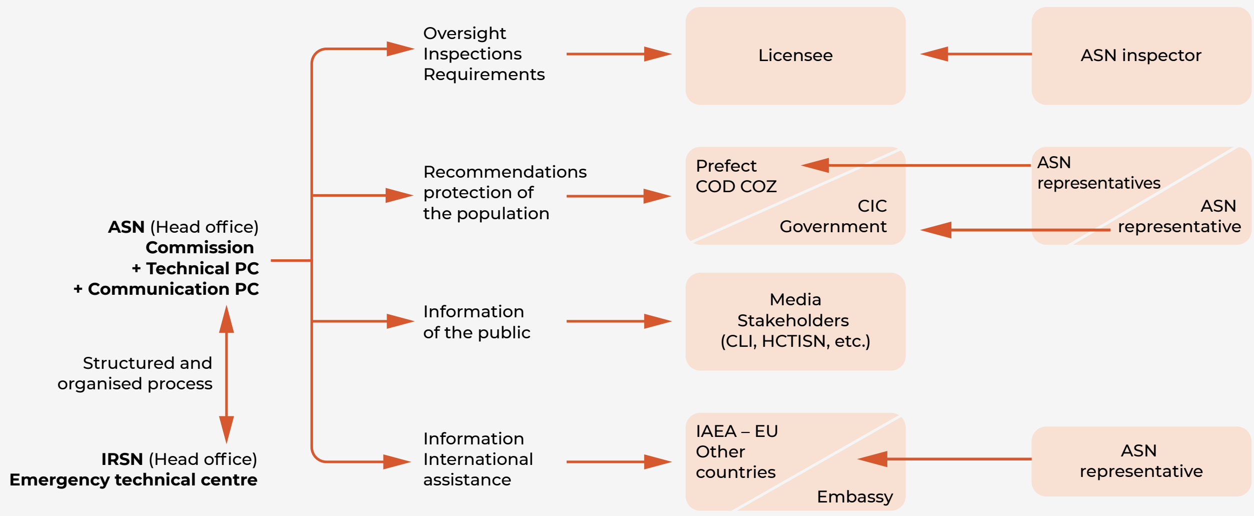
Function of Competent Authority as defined by international conventions

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;

DIAGRAM 2 **The role of ASN in a nuclear emergency situation**



COD: Departmental Operations Centre – **COZ:** Zone Operations Centre – **CIC:** Interministerial Crisis Committee – **CICNR:** Interministerial Committee for Nuclear or Radiological Emergencies – **CLI:** Local Information Committee – **HCTISN:** High Committee for Transparency and Information on Nuclear Safety – **PC:** Command Post

- a "protection of persons, the environment and property" unit, notably in charge of proposing population protection actions;
- an "internal and external communication" unit;
- an "international relations" unit;
- a "forward planning" unit.

The working of the Emergency Centre is regularly tested during national emergency exercises and is activated for actual incidents or accidents. At the local level, ASN representatives visit the *département* and zone Prefects to help them with their decisions and their communication actions. ASN inspectors may also go to the site affected; others take part in emergency management at the headquarters of the regional division involved.

In 2021, the ASN Emergency Centre was activated on nine occasions for seven national exercises, one major exercise (SECNUC –see box below) and one international exercise.

The ASN emergency response organisation was also partially activated on several occasions in 2021.

In the night of Sunday 4 to Monday 5 April 2021, the Paluel NPP in Seine-Maritime (*département* 76) triggered the ASN's general alert system owing to the fire on the main transformer of reactor 1, leading to activation of the installation's PUI.

On Saturday 21 October 2021, ASN was informed by IRSN on-call manager that a radioactivity detection alarm had been triggered in the foundry process of the LME company's plant at Trith-Saint-Léger (*département* 59) during the night of Saturday to Sunday.

For these events, and even without actually activating the Emergency Centre, the ASN on-call team was mobilised remotely in order to collect the information needed to monitor the situation and be ready to intervene if necessary.

During exercises, or in the event of a real emergency, ASN is supported by a team of analysts working in IRSN's Technical Emergency Centre.

ASN's alert system allows mobilisation of its Emergency Centre staff and those of IRSN. This automatic system sends an alert signal to the staff equipped with appropriate reception devices, as soon as it is remotely triggered by the BNI licensee originating the alert. It also sends the alert to the staff of the SGDSN, the General Directorate for Civil Security and Emergency Management, the Interministerial Emergency Management Operations Centre,

DURING INSPECTIONS, ASN TESTS THE CONCRETE IMPLEMENTATION OF THE LICENSEES' EMERGENCY ORGANISATION

For several years now, ASN has been testing the EDF emergency organisation in extreme situations during its inspections. These are organised with the help of the IRSN scenario writers, and enable the inspectors to conduct an on-site check of the correct working and resilience of the on-call teams mobilised. These inspections, which mobilise large numbers of inspectors, have notably been able to check the ability of several NPPs to manage an extreme climatic (or comparable) situation which prevented the licensee from having access to its full on-call team for at least several hours. These inspections are usually performed outside working hours and without prior warning of the inspected site and confirmed the good level of preparedness of the EDF teams for all types of emergency situations.

In 2021, ASN also carried out an inspection at CEA based on a situational exercise simultaneously mobilising the emergency response organisation of the Saclay site and the licensee's national emergency response organisation. Two teams of inspectors were deployed, one to the Saclay site and one to the CEA national emergency response centre at Fontenay-aux-Roses. The first team, on the Saclay site, simulated a fire in a facility using radioactive materials and then observed how the licensee managed this event. At the same time, the second team observed activation of CEA's national emergency organisation in response to this event. The inspectors deployed found a reliable and robust emergency response organisation enabling the licensee's local and national levels to deal with a radiological emergency situation.

Météo-France and the Ministerial operational monitoring and alert centre of the Ministry for Ecological Transition (CMVOA).

A radiological emergency toll-free number (0 800 804 135) 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. The information provided during the call is transmitted to the on-call team. Depending on the severity of the event, ASN may activate its Montrouge Emergency Centre by triggering the alert system. If not, only the ASN local level (regional division concerned) intervenes to perform its Prefect support and communication duties, if necessary calling on the expertise of the national departments. In order to enhance the graded nature of the ASN response and organisation in the event of an emergency, for situations not warranting activation of the Emergency Centre, the on-call team provides assistance to support the regional division concerned.

Since 2018, an on-call duty system reinforces the robustness and the mobilisation and intervention reactivity of the ASN staff.

Diagram 2 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, ASN together with the SGDSN, the General Directorate for Civil Security and Emergency Management and the ASND, prepared the 2021 programme of national nuclear and radiological emergency exercises concerning BNIs and radioactive substance transport operations. This programme was announced to the Prefects in the interministerial instruction of 26 June 2020.

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.

Under the aegis of the SGDSN, ASN also took part in the SECNUC 2021 major exercise (see box above). Many lessons were learned from this exercise, including the need to reinforce preparedness for managing the post-accident phase of a nuclear accident. This exercise illustrates the benefits of practicing with the system at interministerial level, by mobilising all the State services and the CIC decision-making level. A CIC simulation was thus run during the national exercises on EDF's Penly and Blayais NPPs.

Table 2 describes the key characteristics of the national exercises conducted in 2021.

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.

TABLE 1 **Positions of the various stakeholders in a radiological emergency situation**

	DECISION	EXPERT APPRAISAL	INTERVENTION	COMMUNICATION
Public authorities	Government (CIC) Prefect (COD, COZ)	–	Prefect (PCO) Civil protection	Government (CIC) Prefect (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:** *Départemental* Operations Centre – **COZ:** Zone Operations Centre – **CTC:** Emergency Technical Centre
PCO: Operational Command Post – **CU:** Emergency Centre

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 com-promise between the training of individuals and the time needed to effect changes to organisations.

In 2021, in addition to the general objectives of the exercises listed earlier, additional objectives were introduced into the schedule, taking account of lessons learned and the results of the exercises and experimental training carried out in 2021.

ASN is also heavily involved in the preparation and performance of other emergency exercises that have a nuclear safety component and are organised by other players such as:
- its counterparts for nuclear security (Defence and Security High Official –HFDS reporting to the Minister in charge of Energy) or for Defence-related facilities (ASND);
- international bodies (IAEA, European Commission, Nuclear Energy Agency);
- the Ministries for Health, the Interior, etc.

In October 2021, ASN thus took part in the ConvEx-3 exercise organised by IAEA. This exercise was held over several days and considered a reactor accident in the United Arab Emirates. It notably enabled ASN to test the tools for notification and the exchange of information internationally in the event of a nuclear accident abroad. Coordination with the Ministry of Foreign Affairs and the French embassy in the United Arab Emirates was tested and France's response to their assistance request was simulated.

The experience acquired during these exercises should enable the ASN personnel to respond more effectively in real emergency situations. Drawing on the lessons learned from previous feedback, the 2021 exercise simulating a radioactive substances transport accident tested a national emergency response orga–nisation better suited to the local organisations associated with management of risks other than the nuclear risk.

3.2 Assessing with a view to improvement

Assessment meetings are organised immediately after each exercise in each emergency centre and at ASN a few weeks after the exercise. ASN, along with the other players, endeavours to identify best practices and the areas for improvement brought to light during these exercises.

These assessment meetings enable the players to share their experience through a participative approach. They more specifically revealed:
- the importance of having scenarios that were as realistic as possible, in real meteorological conditions and that were technically complex enough to be able to provide useful experience feedback;
- the importance of communication in an emergency situation, in particular to inform the public and foreign authorities as rapidly as possible and avoid the spread of rumours liable to hamper good emergency management, in France and in other countries;
- the importance of providing the decision-makers with a clear view of the radiological impacts in the form of maps: the tool called "Criter" developed by IRSN gives a representation of the results of environmental radioactivity measurements.

TABLE 2 **National civil nuclear and radiological emergency exercises conducted in 2021**

NUCLEAR SITE	DATES OF EXERCISE	MAIN CHARACTERISTICS
Orano La Hague site (50)	2 and 3 February	• Decision-making process and simulated media pressure
EDF Saint-Laurent-des-Eaux NPP (41)	18 and 19 May	• SECNUC 2021 major exercise (mobilisation of the CIC) • Post-accident situation management • Decision and forward planning • Simulated media pressure
EDF Penly NPP (76)	24 March and 14 September	• Decision-making process • Simulation of the CIC decision-making cell • Post-accident workshop
EDF Gravelines NPP (59)	21 and 22 September	• Decision-making process • Simulation of the CIC decision-making cell • Simulated media pressure • Post-accident workshop
Transport of radioactive substances (48)	5 October	• Decision-making process • Simulated media pressure
EDF Blayais NPP (33)	20 and 21 October	• Decision-making process • ASN inspectors dispatched to the affected site
ConvEx-3 (IAEA)	26 and 27 October	• Accident at an NPP in the United Arab Emirates • Coordination with the Ministry for Foreign Affairs and the embassy of the country affected
Saint-Dizier Air Base (52)	28 and 29 October	• Coordination with ASND • Recommendations for post-accident management
Cherbourg Naval Base (50)	23 and 24 November	• Coordination with ASND

Emergency exercise on 15 September 2021 at the Penly NPP (76), view of the Seine-Maritime *département* Operations Centre

4 // Outlook

After a year 2020 marked by the Covid-19 pandemic, 2021 –even though still disrupted– saw nine emergency exercises being held, thus enabling the emergency teams and the other stakeholders to return to a normal pace of training. In addition, ASN reinforced the instruction and training of its staff, with continued situational exercises for its on-call teams, the production of internal instructional films and enhancement of its internal emergency training system.

2021 was also marked by ASN's participation in the SECNUC 2021 major nuclear exercise. In terms of preparedness, ASN made a significant effort to assist the various stakeholders with the new post-accident doctrine proposed by the Codirpa in 2019. This exercise also showed the importance of adapting emergency organisations specific to the nuclear sector (ASN, IRSN, licensee) so that they interface coherently with the CIC. Two national exercises were therefore held in 2021, with simulation of the CIC. ASN will continue its investment so that the CIC simulation can be included in the national exercises in 2022.

2022 will be an opportunity to implement the many lessons learned from this major exercise.

It will also see the continuation of Codirpa's work to propose changes to post-accident doctrine, as requested in the mandate from the Prime Minister. In order to improve the safety and radiation protection culture around the nuclear sites, ASN will continue to oversee the work of the specific working group and support the Government as needed with the action plan unveiled by the Ministry for Ecological transition, following the 2021 report from the risk culture modernisation mission.

In order to reinforce the safety culture in nuclear facilities, ASN agrees fully with the request to involve the population in the emergency exercises, as expressed by the Ministry of the Interior in its Circular INTE2134143J of 7 December 2021.

05

Informing the public and other audiences

05

INFORMING THE PUBLIC AND OTHER AUDIENCES

At the French Nuclear Safety Authority (ASN), informing the public and other audiences is the centre of its activities. The Acts of 2006 on Transparency and Security in the Nuclear Field and 2015 on Energy Transition for Green Growth entrusted ASN with the mission of making a statement on the state of nuclear safety and radiation protection in France. Consequently, throughout the year ASN informs the citizens, the media, the institutional and professional audiences of the situation of the Basic Nuclear Installations (BNIs) and small-scale nuclear activities with respect to the safety and radiation protection requirements. It presents its regulatory and oversight activity and the actions it takes in this respect, and widely disseminates its resolutions and position statements, explaining them where necessary. ASN publishes inspection follow-up letters which, after an inspection, set out its findings and the recommendations for the licensee: nearly 25,000 follow-up letters can thus be consulted on-line. It also publishes notices, guides and reports intended for the professionals and accessible to the public.

ASN promotes the involvement of civil society and enables citizens to make their contribution: it consults, for example, the stakeholders and the public on its draft resolutions. To this end, it ensures that the principles of nuclear safety and radiation protection are understood by the widest possible audience, it produces explanatory documents and endeavours to render the technical issues understandable.

In 2021, to continue its activity of informing the public and other audiences despite the constraints linked to the Covid-19 pandemic, ASN developed new ways of sharing information and having interchanges: remote press conferences, on-line presentation of the annual report, on-line hearings, etc. All these means, combined with putting new resources on line (especially the new website *asn.fr*) and increased presence on the social networks, have enabled the dialogue with the various audiences to be maintained throughout the year.

1 // Developing relations between ASN and the public

1.1 Informing the public at large

ASN works to ensure that citizens have reliable information on the nuclear risk and that they develop the right radiation protection reflexes in all circumstances (particularly with respect to the risks of exposure of medical personnel and patients during medical activities involving ionising radiation). To this end, ASN develops relations with its stakeholders and uses diverse vectors: printed publications, website, social networks, etc.

The *Cahiers de l'ASN* publications aim to provide an informative overview of major subjects relating to nuclear safety. With lots of illustrations (diagrams, photos, computer graphics) and short and airy texts, it is designed to make for easy reading. The *Cahiers* are distributed to nearly 10,000 subscribers and are available at *asn.fr*. Two *Cahiers de l'ASN* were published in 2021.

The first, entitled *Nuclear power plants beyond 40 years: what are the conditions for the continued operation of EDF's 900 MWe reactors?* (February 2021), reviews the situation concerning the future of the 32 reactors concerned –the oldest in operation in France– beyond their 40 years of operation. ASN reports on its conclusions and the generic decision it has taken for the reactors of this type.

The second, entitled *10 years after Fukushima: what safety improvements for nuclear facilities in France?* (March 2021) emphasises that the Fukushima Daiichi NPP accident highlighted the need to reinforce the resilience of nuclear facilities and organisations in the face of extreme situations. It proposes a "guided tour" of the main safety enhancements made to the facilities in France.

ASN sends its two-monthly *La Lettre de l'Autorité de sûreté nucléaire* (Nuclear Safety Authority Newsletter) to more than 5,000 subscribers. This publication provides a summary of the most noteworthy topical issues and information relative to ASN resolutions and actions. To subscribe to the ASN newsletter, simply register on *asn.fr*.

1.1.1 The website *asn.fr*

Receiving more than 55,600 visits per month on average, the *asn.fr* website is the pivotal component of the system for informing the different audiences. It posts the majority of draft opinions and resolutions for consultation.

The website is also a reference source of information for the more informed audiences: expert citizens, members of environmental associations and professionals. In all, more than 2.1 million pages of the website were viewed in 2021.

ASN translates the information notices, press releases and content concerning important issues. These English translations support ASN's work in large international organisations and foster a concerted global vision of nuclear safety and radiation protection.

In 2021, ASN put on line a new version of its website with the aim of facilitating access to the 20,000-odd pages it devotes to the oversight of nuclear safety and radiation protection, the regulations, and ASN's actions in the areas of health, industry and nuclear research. Content and functionalities are available under the same condition whatever the medium used (computer, telephone, tablet), in accordance with the accessibility standards in effect and the requirements of the Act for a Digital Republic of 7 October 2016.

A higher-performance search engine and a map of the facilities (nuclear power, industrial and medical) provide for a faster and more precise browsing experience.

This new version of the ASN website, the result of numerous tests conducted with users, endeavours to facilitate access to the desired information according to the audience:
- 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. 26 fraud reports were filed on *asn.fr* in 2021.

1.1.2 The social networks

The website content, which can be consulted on smartphones or tablets, is also shared on the main social media (primarily Twitter, Facebook and LinkedIn). The news feeds of the ASN social media accounts convey the main position statements. The major events in which ASN participates (parliamentary hearings, public meetings) are announced and can be followed in real time on the social networks.

Since 2011, the social media have been integrated in the "media pressure simulation" during the emergency exercises. The main question is to take into account the immediacy of the reactions and the urgency of the need for information.

ASN news is followed and passed on by more than 14,000 subscribers on Twitter, nearly 30,000 on LinkedIn and 4,300 on Facebook.

1.1.3 The ASN/IRSN exhibition

As part of their duty to inform the public, ASN and the Institute for Radiation Protection and Nuclear Safety (IRSN) have created educational content intended for high school pupils, students, employees, hospital personnel, patients, etc. and the citizens more broadly. Comprising 80 display boards covering ten themes, the exhibition is designed to provide information on radioactivity –whether natural or artificial– its uses, its implications and its effects on humans and the environment. This exhibition is made available on request, free of charge. It is modular and can be borrowed in whole or in part.

The exhibition can also be consulted on-line (*irsn.fr/expo-asn-irsn*).

1.1.4 The ASN Information Centre

Any citizen can address requests for information to ASN, either on-line (at the address *info@asn.fr*), by letter or by telephone. In 2021, the on-line information centre responded to more than 550 requests on diverse subjects (technical questions, requests for transmission of administrative documents, information relative to the environment, publications, documentary searches, etc.).

Cahiers de l'ASN **published in February and March 2021**

1.2 ASN and 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 the responsibilities and the implications of nuclear safety and radiation protection, and lastly to encourage the reporting of significant events.

1.2.1 Making known the regulations and enhancing the radiation protection culture

ASN considers that having clear regulations based on the best safety standards is an important factor for improving the safety of BNIs. Over the last few years it has thus undertaken a major overhaul of the technical and general regulations applicable to BNIs, while always being attentive to the clarity and completeness of the information delivered to the professionals concerning these regulations. The same goes for radiation protection of workers and patients in the medical and industry sectors: ASN makes guides, practical sheets and reference manuals available everyone.

A space for the professionals on *asn.fr*

The professionals have a dedicated space where they can find forms and regulatory texts, along with publications aiming to provide explanations or assistance in the application of the regulations.

In 2021, ASN published the series of medical sector inspection results for 2020 (radiotherapy, brachytherapy and Fluoroscopy-Guided Interventional Practices –FGIPs).

Practical tools for concrete application of the regulations

Radiation protection regulations have undergone major changes in the Public Health Code and the Labour Code alike. The *ASN Guides* give recommendations, present the means ASN considers appropriate for achieving the objectives set by the regulations, and share methods and good practices resulting from lessons learned from significant events.

The guide entitled *Main regulatory radiation protection provisions applicable in medical and dental radiology* was entirely updated in October 2021 in order to foster the appropriation of the applicable requirements by the persons in charge of medical activities, their Radiation Protection Expert-Officers (RPE-O) and their medical physicists.

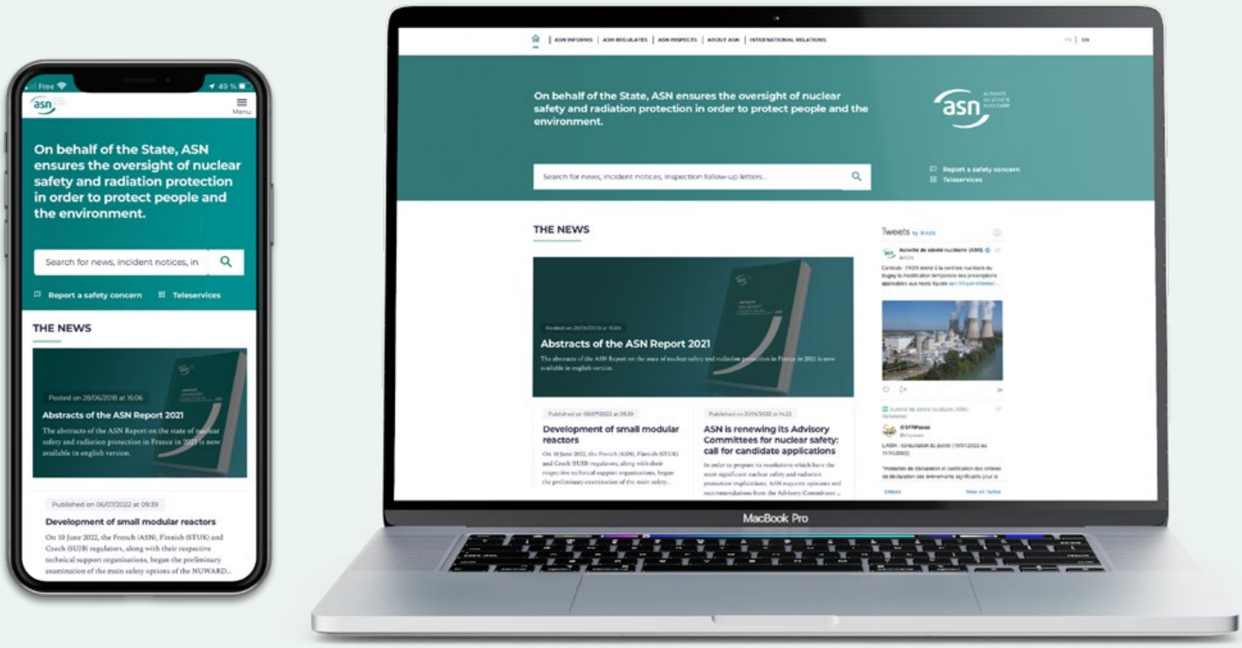
Still in the medical sector, a brochure entitled *Quality assurance in therapeutic procedures involving ionising radiation* accompanies entry into force of ASN resolution 2021-DC-0708 in external beam radiotherapy, brachytherapy, nuclear medicine for therapeutic purposes and in radiosurgery.

THE NEW

asn.fr

The website *asn.fr* evolved in 2021, unveiling a new interface which is the culmination of numerous tests conducted with internal and external audiences.

The objective: make an ever-greater contribution to ASN's prime duty of ensuring transparency.



Overview of the main changes to the website.

1. An optimised **user browsing path**
2. A renewed **graphic environment**
3. A higher performance **search engine**

22 years of history of the oversight of nuclear safety and radiation protection

Nearly 250 videos available (interviews, recordings of parliamentary hearings, educational films, etc.)

Nearly 27,000 inspection follow-up letters published

Thematic portfolios on-line

6,400 subscribers to the ASN newsletters

Open access free of charge to the publications (annual *reports on the state of nuclear safety and radiation protection in France*, issues of the *Les Cahiers de l'ASN* reviews)

News relayed over the social networks

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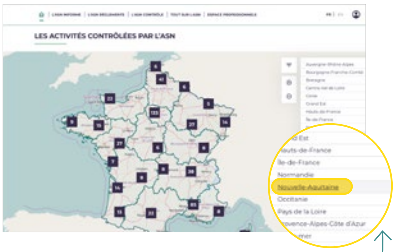
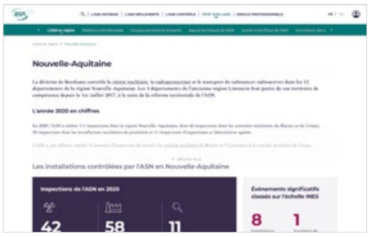
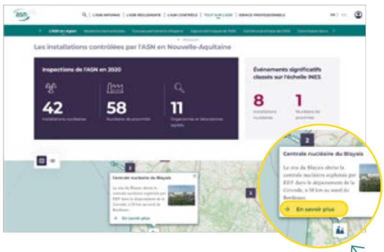
User browsing paths: 3 concrete examples

I am coming to live near the Blayais nuclear power plant
and I want to find out the latest news on the site in operation.





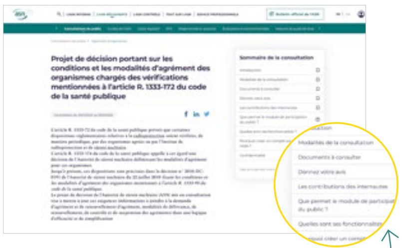


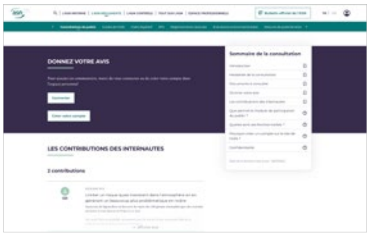
1 **I access the map of the activities regulated by ASN** at the bottom of the home page. (I click on the Nouvelle-Aquitaine region, on the right, in the choice of filters).

2 **Information relative to the selected region** (Nouvelle-Aquitaine) appears: key figures, news, related subjects.

3 **By clicking on the Blayais NPP icon** in the map, a window containing a description of the facility appears. By clicking on "**Find out more**", all the information relative to the facility is made available.

I want to contribute to the resolutions concerning nuclear safety and radiation protection.
How can I give my opinion on the draft resolutions of ASN?



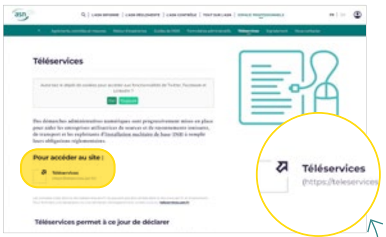


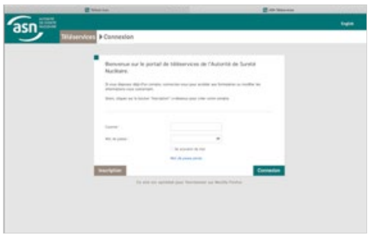
1 On the home page, I go to "**Public consultations**" and select the appropriate consultation.

2 The right-hand menu **gives access to all the useful information concerning the consultation** (procedures, documents to consult, contributions of the Internet users, FAQ, etc.).

3 At the bottom of the page, **I create my account**, after which I can readily make my contribution (with the possibility of adding files).

I want to declare the use of radionuclides to ASN
(products or devices containing them). How do I do this?





1 On the home page, I click on "**Teleservices**", the centralised on-line notification interface.

2 **An access link provides** access the **on-line services portal**.

3 **I can fill out a registration or connection form** to carry out my administrative procedures.

***Patient safety* newsletters published in September and October 2021**

Due to the Covid-19 pandemic, the medical sector and radiation protection meeting events in which ASN usually participates were postponed or held on-line. On the other hand, ASN was able to meet the radiology professionals during the French Radiology Days organised for the first time in a "hybrid" mode in October 2021.

1.2.2 A platform to facilitate on-line procedures

The regulatory procedures are gradually undergoing their digital transformation on *teleservices.asn.fr*, the on-line services portal. ASN thus aims to facilitate the procedures for professionals, which helps to promote the culture of safety. Twelve declaration and notification forms were already available (including the declarations for possessing devices and sources and reporting events in the transport of dangerous goods). As of 1 July 2021, entry into effect of the new simplified authorisation system –the registration system– has been accompanied by the placing on line of 12 new registration application forms available to nuclear activity supervisors in the industrial, medical, veterinary and research sectors. ASN was thus able to allow a dematerialised procedure, as soon as the new regulations came into effect.

1.2.3 A newsletter for sharing good practices

The newsletter *Patient safety –Paving the way for progress* was created in March 2011 to keep radiotherapy professionals informed of the lessons learned from significant radiation protection events. Since July 2019 it alternates between subjects devoted to radiotherapy, diagnostic medical imaging (conventional, computed tomography scanning and nuclear medicine) and FGIPs. Produced by multidisciplinary working groups coordinated by ASN, the newsletter offers a thematic presentation of the good practices of medical departments and the recommendations developed by the learned societies of the discipline concerned and the health and radiation protection institutions.

Two issues were published in 2021, *Ionising radiation: limiting the exposures of women unaware of their pregnancy* (September) and *Patient follow-up further to radiotherapy incidents –A review of the ASN-SFRO scale after 10 years of existence* (October).

Three events formed the subject of a "Lessons learned" sheet, namely *Jamming of the radioactive source during a Pulsed Dose-Rate (PDR) brachytherapy treatment* (February), *Error in the calibration of a linear particle accelerator* (October) and, in medical imaging, *Installation of a computed tomography scanner with spectral technology* (September).

These publications are available on *asn.fr*.

1.3 ASN and 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 majority of the press requests relate to specific facilities. Some nevertheless concern more general issues: continued operation of the reactors, safety improvements, radioactive waste management and decommissioning. 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. In 2021, due to the Covid-19 pandemic, ASN held regional video conferences between late May and mid-September which brought together 80 journalists.

At these meetings, the ASN regional divisions report on ASN's assessment of the safety of the facilities in the regions. The current regional news in the area of radiation protection is addressed, whether it concerns the medical and industrial sectors, sites contaminated by radioactive substances, population exposure to radon, or former mining sites, etc.

Lastly, ASN has a duty to inform the public in the event of an emergency situation[1]. In order to prepare for this, ASN staff receives specific training and take part in emergency exercises. Emergency exercises are held each year, with simulated media pressure from journalists designed to test ASN's responsiveness to the media, as well as the consistency and quality of the messages put across by the various players, both nationally and locally (see chapter 4).

THE SUBJECTS AT THE CORE OF MEDIA ATTENTION

A number of subjects received particular attention from the media and the public opinion in 2021: the construction site of the Flamanville EPR reactor, the fourth periodic safety review of the 900 Megawatts electric (MWe) reactors, the position of ASN concerning the break preclusion approach of the EPR 2 reactor, the safety improvements made to the French nuclear fleet further to the Fukushima Daiichi NPP accident, the incident that occurred on the Taishan EPR in China.

The year 2021 was also marked by the continuation of the Covid-19 pandemic. A great many questions were asked concerning the state of safety of the nuclear facilities and the organisation put in place by ASN to check them. The journalists moreover remained attentive to the question of the anomalies in the welds of certain nuclear equipment items, announced by EDF in 2018-2019. The anomalies in the Flamanville EPR reactor penetration welds in particular were the subject of numerous interactions with the press. The incidents that occurred on certain nuclear sites (Penly, Flamanville, Golfech, Bugey) also interested the local media.

With regard to current events in the medical sector, the press focused more particularly on dose optimisation, especially in the area of nuclear medicine, and exposure to radon.

1. *According to Article L. 592-32 of the Environment Code.*

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1.4 ASN's relations with 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 in the field of communication

ASN invests itself on the international scene to promote experience feedback and the sharing of best practices in informing the public. ASN participates in the Working Group on Transparency of the European Nuclear Safety Regulators Group (ENSREG); it participates regularly in the work of the International Atomic Energy Agency (IAEA). ASN is currently chairing 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[2]. ASN has published recommendations for the drafting of these reports in ASN Guide No. 3. The reports are often presented at the Local Information Committee (CLI) meetings (see point 2.3.4).

Access to information in the possession of the licensees

Since the Act on Transparency and Security in the Nuclear Field (called the "TSN Act") came into force, the nuclear sector has a system that fosters public access to information.

In application of the Environment Code, licensees must communicate to any person who so requests, the information they hold on the risks their activity presents for public health and the environment and on the measures taken to prevent or reduce these risks.

This right to information on the risks also concerns those responsible for the transport of radioactive substances when the quantities involved exceed the thresholds set by law.

The Commission for Access to Administrative Documents

If a licensee refuses to communicate a document, the requesting party can refer the issue to the Commission for Access to Administrative Documents (CADA), an independent administrative Authority. If the opinion of the CADA is not followed, the dispute may be taken before the administrative jurisdiction which will rule on whether or not the information in question can be communicated.

ASN is particularly attentive to the application of this right to information, in compliance with the protection of interests provided for in law (security, business confidentiality, etc.).

2.2 Information given to populations living in the vicinity of Basic Nuclear Installations

The Energy Transition for Green Growth Act (known as the "TECV Act") has instituted an obligation to regularly inform the people living in the vicinity of a BNI of the nature of the accident risks associated with that installation, the envisaged consequences of such accidents, the planned safety measures and the action to take in the event of an accident. This information is provided at the expense of the licensee.

2.3 Consultation of the public on draft opinions, guides and resolutions

Article 7 of the Environment Charter embodies the right of participation of any citizen in the framing of public decisions having an impact on the environment. This provision is applicable to a large proportion of the resolutions issued by ASN or decisions in which it participates by formulating opinions (draft decrees and orders issued by the Government, in particular).

In 2021, 91 draft guides, opinions and resolutions were thus submitted for public consultation, including the draft concerning the conditions for continued operation of the 900 MWe reactors beyond 40 years.

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 consultation of the public *via* the Internet on draft resolutions other than individual resolutions having an impact on the environment.

ASN has decided to apply this widely. Consequently, all draft ASN regulations concerning BNIs, including those relating to nuclear pressure equipment, are considered as having an impact on the environment and are therefore subject to public participation. The same approach is applied for the ASN regulations relative to the transport of radioactive substances.

2. *See Article L. 121-15 of the Environment Code.*

CONSULTATIONS, WHAT THEY INVOLVE

The public participation procedure consists in posting the draft ASN regulation on the website for at least 21 days, in order to give people time to make their comments.

An indicative list of the scheduled consultations on draft ASN regulations and guides having an impact on the environment is updated every three months on *asn.fr*.

A synthesis of the remarks received, indicating how they were taken into account and a document setting out the reasons for the regulation are published on *asn.fr* at the latest on the date of publication of the regulation.

ASN's regulations relating to radiation protection are also submitted to public participation if they concern activities involving significant discharges into the environment, producing a significant quantity of waste, causing significant nuisance for the neighbourhood or representing a risk for the people living nearby and the surrounding environments in the event of an accident.

Lastly, although they are not of a statutory nature, ASN applies this same procedure to certain draft guides and draft opinions.

Eight consultations held in 2021 concerned draft ASN regulations.

2.3.2 Consultation of the public on draft ASN individual resolutions

The individual resolutions[3] concerning nuclear safety and radiation protection can form the subject of several public consultation procedures which are presented below.

The public inquiry

In application of the Environment Code, the BNI creation authorisation and decommissioning applications form the subject of a Public inquiry[4]. 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.

The TECV Act introduced a provision subjecting "*the measures proposed by the licensee during the periodic safety reviews after the 35th year of operation of a nuclear power reactor*" to a public inquiry. This is a special provision since the public inquiry does not focus on the continued operation of a nuclear power reactor as such, but on the adequacy of all the "measures proposed by the licensee" of which the end-purpose must aim to reduce the impacts of the facility on the environment with a view to its continued operation. Decree 2021-903 of 7 July 2021 lays down the requisite conditions for conducting this public inquiry, notably to encourage the effectiveness of public participation by enabling the public to have an appreciation of the safety improvements already made and those planned by the licensee for the continued operation of its facility (as an example, see "Notable events" in the introduction to this report).

Disclosure of drafts 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.

During 2021, 32 consultations concerned draft individual resolutions relating to BNIs and the transport of radioactive substances and 48 concerned small-scale nuclear activities.

2.3.3 Consultation of particular bodies

The BNI authorisation procedures also provide for consultation of the environmental authority, the regional authorities and their groupings concerned by the project, and the CLIs (see point 2.4.3). The CLIs also have the possibility of being heard by the ASN Commission before it issues its opinion on the draft authorisation decree submitted to ASN by the Minister responsible for nuclear safety.

The CLI is consulted on the draft ASN requirements concerning water intakes, effluent discharges into the surrounding environment and the prevention or mitigation of detrimental effects of the installation for the public and the environment. The Prefect forwards, for information, the draft requirements and the presentation report to the Departmental Council for the Environment and for Health and Technological Risks (Coderst). It can also ask this Council for its opinion on the draft requirements.

2.3.4 Consultation: for ever wider and more varied participation of the various audiences

ASN ensures that these consultations allow the public and the associations concerned to contribute, in particular by verifying the quality of the licensee's files and by trying to develop the CLI's resources so that they can express an opinion on these files.

Digital technologies and citizen participation practices are bringing ASN to change the public consultation framework to ensure effective participation of the public in the decision-making process.

2.4 The actors in the area of information

2.4.1 High Committee for Transparency and Information on Nuclear Security

The High Committee for Transparency and Information on Nuclear Security (HCTISN), created by the TSN Act, is a body that informs, discusses and debates on nuclear activities, their safety and their impact on human health and the environment. It can also deal with any issue concerning the accessibility of nuclear security information and propose any measures such as to guarantee or improve transparency.

The HCTISN develops opinions and makes them public. It organises four plenary meetings per year, at which major topical subjects are presented and discussed: all the presentations can be consulted 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.

3. *Resolution that applies to a licensee for a given installation.*
4. *In application of the provisions of Article L.593-8 or L. 593-28 of the Environment Code.*

THE FUNCTIONAL FRAMEWORK OF THE LOCAL INFORMATION COMMITTEES AND THE SITE MONITORING COMMITTEES

The CLIs, whose creation is incumbent upon the President of the Departmental Council, comprise various categories of members: representatives of *département* General Councils, of the municipal councils or of the deliberative assemblies of the groups of communities and the Regional Councils concerned, members of Parliament elected in the *département*, representatives of environmental protection associations or of economic interests and representatives of employee trade union and medical profession union organisations, and qualified personalities. The representatives of State services, including ASN, and of the licensee have an automatic right to participate in the work of a CLI in an advisory capacity. The TECV Act provides for the participation of foreign members in the CLIs of border *départements*. The CLIs are chaired by the President of the Departmental Council or by an elected official from the *département* designated by the President for this purpose. They receive the information they need to fulfil their functions from the licensee, from ASN and from other State services. They may request expert assessments or have measurements taken on the installation's discharges into the environment. All BNI sites have a CLI, except for the Ionisos facility in Dagneux in the Ain *département*.

The CLIs are funded by the regional authorities, and by ASN which devotes about €1.25 million per year to the financial support of the CLIs and their national federation, Anccli. Within the framework of its reflections on the financing of the oversight of nuclear safety and radiation protection, ASN regularly suggests to the Government the application of the provision of the TSN Act of 13 June 2006, to add to the budget of the CLIs with association status (there are about ten of them) with a matching contribution of funds drawn from the BNI Tax.

With regard to former nuclear sites, research laboratories and waste treatment sites, Site Monitoring Commissions (CSS) are gradually replacing the Local Information and Monitoring Committees (CLIS) in application of the Decree of 7 February 2012(*). Providing frameworks for discussion and information concerning the actions of the licensees of the targeted installations, they promote the informing of the public. They are, for example, kept informed of the incidents and accidents affecting the installations –and even of installation creation, extension or modification projects.

ASN is invited to the meetings of the monitoring committees for defence sites and former mining sites.

(*) Issued in application of Article L. 125-2-1 of the Environment Code.

In 2019, with the assistance of ASN, IRSN, EDF and the National Association of Local Information Committees and Commissions (Anccli), the HCTISN set up the consultation on the continued operation of the 900 MWe reactors. At the end of 2020, all the consultation actors presented the way in which they had taken account of the public and other audiences' contributions and expectations gathered in 2019. All the documents relating to this consultation can be consulted on the website *concertation.suretenucleaire.fr*.

2.4.2 Institute of Radiation Protection and Nuclear Safety

The Institute of Radiation Protection and Nuclear Safety (IRSN) implements a policy of information and communication that is consistent with the objectives agreement signed with the Government.

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 of concern that prompt questions on the part of the public or the public actors, ASN and IRSN ensure that their statements are properly coordinated in order to guarantee coherent, clear and consistent information.

Alongside this, each year IRSN makes public the results of its research and development programs, with the exception of those concerning national Defence.

In the context of a referral from ASN and with ASN consent, IRSN can request the participation of informed audiences, neighbourhood residents, or even the public at large. IRSN in this case provides them with information that is complete and understandable, and in return notes their subjects of concern and their questions in order to integrate them in the expert assessment work carried out for ASN.

2.4.3 Local Information or Monitoring Committees

The CLIs have a general mandate of monitoring, informing and consultation with regard to nuclear safety and radiation protection. They analyse the impacts on people and the environment of the nuclear activities of the facilities on the sites around which the CLIs have been set up[5].

ASN considers that the smooth functioning of the CLIs contributes to safety and it maintains a meaningful dialogue with them. It is attentive to ensuring that the CLIs are as fully informed as possible, including by attending their public meetings. In partnership with Anccli, ASN fosters the networking of the CLI special advisors and gives the CLIs the necessary tools and assistance for them to provide reliable information to "layman" audiences. ASN assisted the CLIs at their request: on technical issues through its inspectors, and on questions of dissemination of information through its communication supervisors. The ASN-IRSN exhibition is regularly made available to the CLIs.

The ASN inspectors can also give the CLI representatives the opportunity to take part in inspections[6]. 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

5. *The operating framework for the CLIs is defined by Articles L. 125-17 to L. 125-33 of the Environment Code and by Decree 2008-251 of 12 March 2008 relative to the CLIs for the BNIs, and by Decree 2019-190 of 14 March 2019 codifying the provisions applicable to BNIs, to the transport of radioactive substances and to transparency in the nuclear field.*
6. *In the current situation, only the ASN inspectors and the experts accompanying them have an enforceable right of access to the licensee's facilities. This means that the consent of the licensee is necessary for observers from CLIs to participate in inspections.*

Round table at the 33rd CLI conference, with the Chairmen of ASN and Anccli

CLIs through its group of scientific experts. In 2021, it responded to several requests, for example on the subject of monitoring the tritium in the River Loire (Val de Loire CLI) and soil pollution (Chinon CLI). Some CLIs call upon external service providers to advise them concerning technical files on which they wish to take a stance.

The CLIs and informing the various audiences
The CLIs organise plenary meetings and set up specialist commissions. The TECV Act obliges each CLI to hold at least one public meeting per year. ASN promotes exchanges of good practices in order to make these public meetings moments of worthwhile discussion and opportunities to contribute to having a well-informed population.

The majority of the CLIs have a website or have pages on the website of the local authority that supports them; some twenty CLIs publish a newsletter (sometimes as inserts in the news bulletin of a local authority).

As in 2020, the CLI conference in 2021 was revisited so that it could be held remotely. It brought together 200 participants *via* a digital platform.

The programme included two round tables on the challenges of decommissioning and representation of the nuclear risk.

2.4.4 National Association of Local Information Committees and Commissions

Article L. 125-32 of the Environment Code provides for the setting up of an association of CLIs (see point 2.4.3), and the Decree of 12 March 2008 details the mandate of this federation. Anccli brings together the 34 French CLIs and the 34 committees put in place for the defence-related installations. The Anccli has a scientific committee and has set up five thematic advisory groups (“Radioactive materials and waste”, “Post-accident –territories”, “Safety”, “Decommissioning” and “Health”). It is also heavily involved in the discussion and interchange bodies set up by its partners (HCTISN, ASN, IRSN, etc.).

Partnership with ASN
Anccli interchanges with ASN very regularly and participates in several of its permanent or occasional working groups. Anccli fosters the enhancing of the technical competence of CLI members by organising thematic seminars with IRSN in the context of its expert assessment work carried out for ASN. Anccli, with ASN and IRSN, maintains a technical dialogue on the high-stake issues and takes part in the public consultations on nuclear questions. Each year, ASN organises the national conference of CLIs (see above) in cooperation with Anccli.

The activity of Anccli
Anccli runs the network of CLIs that it represents. By ensuring a regular watch and issuing clarifications and information that can be readily understood by the general public, Anccli helps give the CLIs the means to fulfil their duties of informing the various audiences. Attentive to the concerns of the CLIs and in relation with diverse sources of expertise, Anccli conducts national reflections on nuclear safety issues and widely passes on the results of this work (Anccli positions) to the national and European bodies and to local elected officials and CLI audiences.

06
International relations

06

INTERNATIONAL RELATIONS

Through a range of bilateral, European and multilateral cooperation frameworks, in which it participates, the French Nuclear Safety Authority (ASN) aims to promote the adoption of ambitious international baseline requirements. Within these frameworks, ASN also ensures that the French positions and doctrines are made known and that best practices are adopted internationally to achieve progress in nuclear safety and radiation protection in France and worldwide.

As part of its actions, and within its area of competence, ASN proposes France's positions on international negotiations to the Government and represents France in international and community entities in this field.

1 // ASN's objectives regarding international relations

The international arena is a strategic challenge to which ASN devotes particular attention and resources. ASN's actions in this field aim for continuous improvement in safety, based on changing knowledge and sharing of practices, in particular in terms of regulation and oversight. This action also aims to ensure ambitious harmonisation of international requirements regarding nuclear safety and radiation protection.

ASN's objectives internationally are thus organised around four main points:
- to promote the creation of ambitious international baseline requirements;
- to make the French and European positions and regulations known to its counterparts;
- to encourage international work on the priority technical issues identified by ASN;
- to benefit from the best international practices to achieve progress in nuclear safety and radiation protection in France.

To achieve these goals, ASN maintains close bilateral relations with numerous countries. It also takes part in numerous multilateral exchanges within bodies and organisations with a variety of statuses, whether at European level, notably with the European Nuclear Safety Regulators Group (ENSREG) and the Western European Nuclear Regulators Association (WENRA) or, more broadly, at an international level, notably with the International Atomic Energy Agency (IAEA) and the Nuclear Energy Agency (NEA) of the Organisation for Economic Cooperation and Development (OECD).

Through its bilateral relations, ASN's goal is direct exchanges with its counterparts on topical subjects or on particular points regarding regulations or oversight. These exchanges are an opportunity for ASN to share its experience and compare its positions and practices in order to progress. They also cast an outside light on position statements, technical questions or societal acceptability, thereby enriching the national debates and consolidating decisions and resolutions. They also enable ASN to be directly informed of the nuclear safety and radiation protection situation at its counterparts. 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. Within European associative or community circles, ASN's aim is to share its vision of the priority safety issues, to compare its analyses and to conduct discussions on practices in use at its counterparts, in order to help establish and maintain a high level of stringency in nuclear safety and radiation protection at the European level, which can be based on harmonised baseline requirements and doctrines established together.

The final ASN goal is for nuclear safety and radiation protection best practices and regulations to be shared 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 therefore works within three main cooperative frameworks. It aims to ensure that a constant and balanced presence is maintained within each one, considering that each one is specific and that the complementarity between them contributes to the target of harmonisation and continuous improvement of nuclear safety.

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 primary law in the field, allowing the harmonised development of provisions allowing a strict regime of oversight for nuclear safety and security and radiation protection. The European Union (UE) Court of Justice, considering that the fields of nuclear safety and radiation protection form an inseparable whole, recognised the principle of the existence of community competence in the field of safety, as in the field of management of radioactive waste and spent fuel.

ASN experts participate in the work of the EURATOM Treaty committees and working groups:
- group of experts specified in Article 31 (Basic Radiation Protection Standards);
- group of experts specified in Article 35 (verification and monitoring of radioactivity in the environment);
- group of experts specified in Article 36 (information concerning the monitoring of radioactivity in the environment);
- group of experts specified in Article 37 (notifications relative to radioactive effluent discharges).

The Article 31 group of experts met three times remotely in 2021: twice in June and once in November. It familiarised itself with the work of the European Commission, drew up its programme of work and issued an opinion on the report from the EU's Joint Research Centre entitled "*Technical assessment of nuclear energy with respect to the 'do no significant harm' criteria of Regulation (EU) 2020/852 ('Taxonomy Regulation')*".

An "*Advances/Innovations in individual dosimetry*" scientific seminar was also organised in November 2021 to review innovations in the field of dosimetry.

The Article 37 group of experts met twice remotely in 2021 (February and June) to deal with questions regarding the planned construction of two EPR reactors on the Sizewell site in the United Kingdom, and the extension of the Paks Nuclear Power Plant (NPP) in Hungary.

In addition, in accordance with Article 35 of the EURATOM Treaty, representatives from the European Commission went to the Orano site in Malvesi from 14 to 16 December 2021, for a verification visit on the steps taken by France to monitor environmental radioactivity around this nuclear site.

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 the entire UE (derived from the baseline safety requirements produced by WENRA), establishes an European peer review system for safety topics and requires periodic safety reviews every 10 years. It also reinforces provisions concerning education and training.

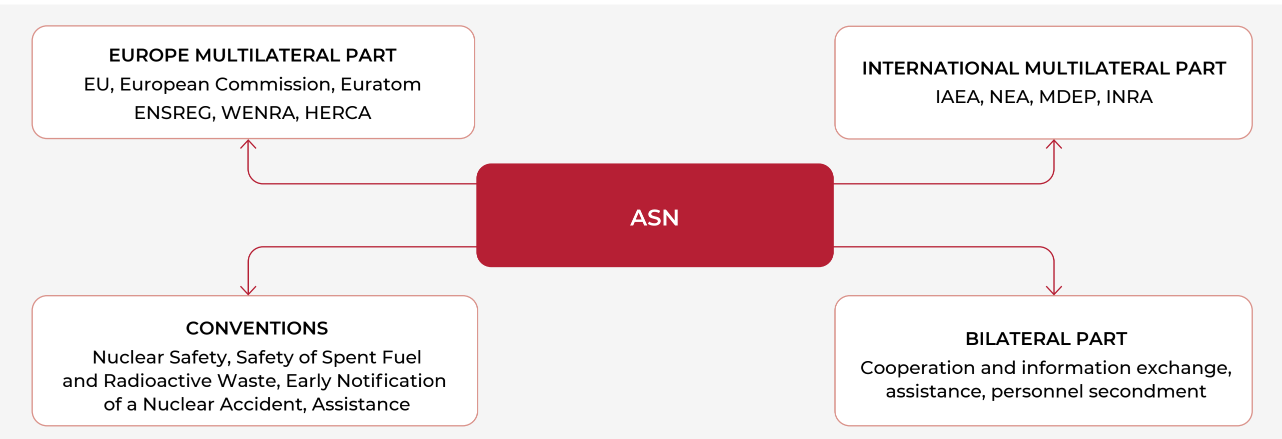
This Directive and its amendment are transposed into French law.

It should however be noted that European legislation does not yet enshrine in law the institutional independence of the safety regulators.

2.3 The European Euratom Directive on the Management of Spent Fuel and Radioactive Waste

On 19 July 2011, the Council of the EU adopted a Directive establishing a community framework for the responsible and safe management of spent fuel and radioactive waste (Directive 2011/70/Euratom). The adoption of this Directive contributes to reinforcing safety within the EU, by making the Member States more accountable for the management of their spent fuels and their radioactive waste.

ASN ACTION ON THE INTERNATIONAL STAGE



This Directive is legally binding and covers all the aspects of spent fuel and radioactive waste management, from production through to long-term disposal.

It reiterates the prime responsibility of the producers and the ultimate responsibility of each Member State to ensure the management of the waste produced on its territory, making sure that the necessary measures are taken to guarantee a high level of safety and to protect workers and the general public against the dangers of ionising radiation.

It clearly defines the obligations regarding the safe management of spent fuel and radioactive waste and requires that each Member State adopt a legal framework for safety issues, making provision for the creation of:
- a competent regulatory authority with a status that guarantees its independence from the waste producers;
- authorisation procedures involving authorisation applications examined on the basis of the safety cases required from the licensees.

The Directive regulates the drafting of the 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 UE. The Energy Transition for Green Growth Act (TECV Act) and the Ordinance of 10 February 2016 ensured that the provisions of the Directive were transposed into French law.

2.4 The Euratom European Directive on Radiation Protection Basic Standards

Directive 2013/59/Euratom of 5 December 2013 on Radiation Protection Basic Standards applies to the justification, optimisation and limitation of doses, regulatory control, preparedness for emergency situations, training and other related fields (for example the radon risk, Naturally Occurring Radioactive Materials and Construction Materials –NORM). The modifications made in 2016 and 2018 to the Defence, Environment, Public Health and Labour Codes, allowed its transposition into French law.

2.5 The European Nuclear Safety Regulators Group (ENSREG)

The ENSREG was created in 2008 and brings together experts delegated by the Member States of the EU, with the aim of supporting the European Commission in its legislative initiatives in the field of nuclear safety and radiation protection.

ENSREG helped bring about a political consensus in the drafting of European Directives on nuclear safety and the management of spent fuel and waste. ENSREG also took part in the process to revise the Nuclear Safety Directive, following on from the assessment and analysis of the Fukushima Daiichi NPP accident.

The activities of ENSREG are underpinned by three working groups, devoted to installations safety and international cooperation (WG1), the safe management of radioactive wastes and spent fuels (WG2) and transparency in the nuclear field (WG3) respectively. ASN contributes to the work done by each of them.

In accordance with the Safety Directive of 2014, ENSREG organises European thematic peer reviews. The first of these exercises concerned the management of ageing of the nuclear reactors. Each of the participating countries first of all drafted a national report, which was then examined in 2018 by experts appointed by the Member States. This examination led to the drafting of a report on the generic results and a report on the specific results per country. On this basis, the national action plans from the countries were submitted in September 2019. Updates were published in 2021. On this occasion, France published its closing report. The national report, the national action plan and the closing report for France are available on *asn.fr*, in both French and English.

In 2020, the Member States began their work on the second thematic peer review concerning the protection of nuclear facilities against fire risks. In 2021, the work continued, notably with the drafting of the terms of reference for the peer review and the technical specifications providing the countries with guidelines for their self-assessment presented in the national reports.

2.6 The European Community Urgent Radiological Information Exchange system (ECURIE)

ECURIE is one of the rapid action systems set up by the European Commission, which has an information exchange network for receiving and triggering an alert, and thus for rapidly circulating information within the UE in the event of a radioactive emergency or major nuclear accident.

This system was put into place in 1987 by a Decision of the Council of the EU of 14 December 1987, notably in the wake of the Chernobyl (Ukraine) accident in 1986. This Decision came into force on 21 March 1988 and was ratified by all the Member States of the UE and a certain number of third-party countries, such as Switzerland and Turkey.

2.7 The Western European Nuclear Regulators' Association (WENRA)

WENRA was created in 1999 at the initiative of ASN and has been chaired since November 2019 by Olivier Gupta, the ASN Director General. Its members are the heads of the safety regulators of the European countries with electricity generating reactors. Other European countries, or major non-European countries with power generating reactors, take part in WENRA's activities as either observers or associate members.

WENRA's actions are based on experience sharing by safety regulators with a view to developing a common approach and harmonised safety rules for reactors, waste management facilities and research reactors.

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).

For each technical topic, each of these groups defined "safety reference levels" based on the most recent safety standards, mainly from IAEA, and the most stringent nuclear safety approaches implemented within the EU.

Concrete implementation of the strategy defined by WENRA for the period 2019-2023 is ongoing. In 2021, WENRA held two plenary meetings, the first remotely in April and the second –a "hybrid" arrangement– in Montrouge in October.

WENRA plenary meeting at ASN – 14 October 2021

During these meetings the following decisions were taken:
- approval of the WGRR programme of work for the period 2021-2025;
- creation of a working group under ASN supervision devoted to the drafting or the technical specification for the second thematic peer review (see above) and validation of the principles adopted regarding the graded approach and the implementation of the reference levels produced by WENRA for performance of this exercise;
- granting of observer status to the American Nuclear Regulatory Commission (NRC), and of associate member status to its Canadian counterpart (Canadian Nuclear Safety Commission –CNSC);
- creation of a working group tasked with exploring the means, opportunities and difficulties linked to the possible expansion of the association to include other countries;
- confirmation of the applicability of the safety objectives defined by WENRA in 2010 for new reactors to Small Modular Reactors (SMRs), and of the need that these objectives constitute a minimum to be achieved for this type of reactor, considering their expected safety improvements.

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 informal 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 57 authorities from 32 European countries, including the 27 members of the EU, Iceland, Norway, the United Kingdom, Serbia and Switzerland. ASN is responsible for the technical secretariat.

Six expert groups are currently working on the following themes:
- practices and sources in the industrial and research fields;
- medical applications of ionising radiation;
- preparedness for and management of emergency situations;
- veterinary applications;
- natural radiation sources;
- education and training.

In 2021, the association held plenary meetings, remotely in June, and using a “hybrid” arrangement in Prague in December. The major decisions taken include:
- the change in the Chair of the association, now entrusted to the Swedish nuclear safety regulator (*Strålsäkerhetsmyndigheten* –SSM), and the Vice-Chairs, entrusted to the Luxembourg Ministry for Health and to ASN;
- approval of the new HERCA strategy, which was defined with a significant contribution from ASN, with its main focus being reinforced cooperation between the radiation protection competent authorities;
- HERCA’s aim to participate actively in the project to overhaul the recommendations of the International Commission on Radiological Protection (ICRP) as a special partner.

HERCA also plans to organise several seminars, notably concerning the implementation of national radon risk management plans or the deployment of radiation protection experts and officers as required by the European Directive on Radiation Protection Basic Standards.

2.9 The European Commission’s assistance programmes

Between 2007 and 2021, the actions of the UE with regard to assistance and cooperation for third-party countries in the field of nuclear safety have continued under the Instrument for Nuclear Safety Cooperation (INSC). In 2021, ASN took part in a project.

A new European Instrument concerning assistance and cooperation in the field of Nuclear Safety (EINS) was approved by the European Parliament on 27 May 2021. The EINS will replace the previous instrument. Between the date of approval and 31 December 2027, a budget envelope of €300 million is planned.

The goals of the new EINS instrument concern:
- the promotion and implementation of the strictest nuclear safety and radiation protection standards in nuclear facilities and for radiological practices in third-party countries;
- the implementation of frameworks and methods for application of effective checks on nuclear materials in third-party countries;
- the drafting and implementation of responsible strategies for the ultimate disposal of spent fuel, for waste management, for delicensing of facilities and for clean-out of former nuclear sites.

These instruments are supplemented by other international technical assistance programmes that respond to resolutions taken by the G8 or by IAEA to improve nuclear safety in third-party countries and which are financed by contributions from donor States and from the EU.

3 // The multilateral framework for ASN's international relations

At the multilateral level, cooperation takes place notably within the framework of the IAEA, a United Nations agency founded in 1957, and the NEA, created in 1958. These two agencies are the two most important intergovernmental organisations in the field of nuclear safety and radiation protection.

3.1 The International Atomic Energy Agency (IAEA)

The IAEA is a United Nations organisation based in Vienna and comprises 173 Member States. The IAEA's activities are focused on two main areas: one of them concerns the control of nuclear materials and non-proliferation and the other concerns all activities related to the peaceful uses of nuclear energy. In this latter field, two IAEA departments are tasked with developing and promoting nuclear energy on the one hand, and the safety and security of nuclear facilities and activities, on the other.

Following on from the action plan approved by the IAEA Board of Governors in September 2011 and with the aim of reinforcing safety worldwide by learning the lessons from the Fukushima Daiichi NPP accident, the IAEA is in particular focusing its work on the following fields: safety standards and peer review missions.

Safety Standards

The IAEA Safety Standards describe the safety principles and practices that the vast majority of Member States uses as the basis for their national regulations. This activity is supervised by the IAEA's Commission on Safety Standards (CSS), set up in 1996. The CSS comprises 24 highest level representatives from the safety regulators, appointed for a term of 4 years. 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. In 2021, the IAEA made significant efforts to shorten the time taken to publish its standards. Prioritisation of the safety standards to be revised or produced over the period 2022-2027 is currently ongoing. Work is also being done to identify any adaptations to the body of standards required, in order to take account of the issues related to SMRs.

Peer review missions

The IAEA proposes peer review missions in the field of safety to the Member States. These services consist of expert missions organised by the IAEA in countries which ask for them. Each team of auditors consists of experts from other Member States and from the IAEA. These audits are produced on the basis of the IAEA's baseline safety standards. Several types of audit are proposed, notably the Integrated Regulatory Review Service (IRRS) missions devoted to the national regulatory framework for nuclear safety and the working of the safety regulator, the Operational Safety Review Team (Osart) missions, devoted to the safety of NPPs in operation and, finally, the ARTEMIS missions, devoted to national radioactive waste and spent fuel management programmes. The audit results are written up in a report transmitted to the requesting country and may comprise various levels of recommendations and also recognise good practices. It is up to the requesting country to take account of the recommendations issued by the experts. A follow-up mission, the purpose of which is to verify the progress made in taking account of the recommendations, is held between 18 months and 4 years after the initial mission, depending on the type of audit. ASN's situation regarding these missions is presented below.

IRRS missions

The IRRS missions are devoted to analysing all aspects of the framework governing nuclear safety and the activity of a safety regulator. ASN is in favour of holding these peer reviews on a regular basis, and incorporates their results into its continuous improvement approach. It should be noted that, pursuant to the provisions of the 2009/71/Euratom Directive amended in 2014, the Member States of the EU are already subject to periodic and mandatory peer reviews of their general nuclear safety and radiation protection oversight organisation.

Owing to the global health situation, very few IRRS missions could be held in 2020 and those in which ASN should have taken part were postponed.

ASN also informed the IAEA of its desire to host an IRRS mission in France concerning the full range of its activities in the first half of 2024.

Osart missions

In France, the performance of Osart missions devoted to the safety of NPP operation, is requested from the IAEA by ASN, in coordination with the licensee of the NPPs, EDF.

Three Osart missions were held in France in 2021, in the Paluel, Belleville-sur-Loire and Flamanville (follows-up mission) NPPs respectively.

The regional training and assistance missions

ASN responds to requests from the IAEA secretariat, in particular to take part in regional radiation protection training and in assistance missions. The beneficiaries are often countries of the French-speaking community.

In addition and still under the supervision of the IAEA, ASN is also involved in the Regulatory Cooperation Forum (RCF). This forum, created in 2010, aims to establish contacts between the safety regulators of countries adopting nuclear energy for the first time and the safety regulators of the leading nuclear countries, in order to identify their needs and coordinate the support to be provided, while ensuring that the fundamental principles of nuclear safety are met (independence of the regulator, appropriate legal and regulatory framework, and so on).

In 2021, in addition to a detailed review of the situation of the safety authorities in Bangladesh, Belarus, Ghana, Morocco and Poland, the RCF reinforced its cooperation with the EU (EINS) and with "regional" safety regulator forums.

Harmonisation of communication tools

ASN takes part in the INES consultative committee, a body comprising experts in the evaluation of the significance of radiation protection and nuclear safety events, tasked with advising the IAEA and the INES national representatives of the member countries on the use of the International Nuclear and Radiological Event Scale (INES) and its updates. In this respect it was closely involved in the work to revise the INES scale manual recently published by IAEA, the previous version of which was about ten years old. In addition to the updates to take account of advances in scientific knowledge, this revision also includes guidelines for communication in how to use the scale as well on how to apply it in a crisis.

Generally speaking, ASN is closely involved in the various actions carried out by the IAEA, providing significant support for certain initiatives, notably those which were developed following the Fukushima Daiichi NPP accident.

Management of nuclear and radiological emergency situations

ASN takes part in the IAEA's work to improve notification and information exchanges in radiological emergency situations.

On this subject, ASN takes part in the exercises organised by the IAEA to test the operational provisions of the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency, called "convention exercises" or "ConvEx exercises". These exercises, which are more specifically designed to enable all 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 2021, ASN took part in one ConvEx-3 type exercise (see chapter 4).

ASN also takes part in defining international assistance strategy, requirements and means and in developing the Response Assistance Network (RANET).

3.2 The Nuclear Energy Agency (NEA) of the OECD

Created in 1958, the NEA today comprises 38 member countries from among the most industrially developed states. Its main goal is to help the member countries to maintain and expand the scientific, technological and legal bases essential to the safe, environmentally-friendly and economical use of nuclear energy.

Within the NEA, ASN is more particularly involved in the work of the Committee on Nuclear Regulatory Activities (CNRA). It also takes part in the Committee on Radiological Protection and Public Health, the Radioactive Waste Management Committee, the Committee on Decommissioning of Nuclear installations and Legacy Management, as well as several working groups of the Committee on the Safety of Nuclear Installations.

The various NEA committees coordinate working groups of experts from the member countries. Within the CNRA, ASN contributes to the working groups on inspection practices, acquired operating experience, the regulation of new reactors, safety culture, codes and standards, as well as public communication by safety regulators.

3.3 The Multinational Design Evaluation Program (MDEP) for new reactor models

The MDEP is an association of safety regulators created in 2006 by ASN and the NRC. The MDEP aims to share experience and approaches in the regulatory evaluation of new reactor models, to contribute to harmonisation of safety standards and their implementation.

Programme members

With the inclusion of Argentina in 2017, the MDEP now comprises 16 national safety regulators: AERB (India), ARN (Argentina), ASN (France), CNSC (Canada), FANR (United Arab Emirates), HAEA (Hungary), NNR (South Africa), NNSA (China), NRA (Japan), NRC (United States), NSSC (South Korea), ONR (United Kingdom), *Rostechnadzor* (Russia), SSM (Sweden), STUK (Finland), NDK (Turkey).

Organisation

The broad outlines of the work done within the MDEP are defined by a strategy committee and implemented by a technical steering committee, which has been chaired by an ASN deputy Director General since 2014. The work is carried out by working groups for the main nuclear reactor designs currently under construction around the world: the Framatome EPR, the AP-1000 from the American Westinghouse, the Korean APR-1400, the Russian VVER and the Chinese HPR-1000 (Hualong). A transverse working group concerns the inspection of nuclear component suppliers, the Vendor Inspection Cooperation Working Group (VICWG).

Each of the groups dedicated to a particular reactor model brings together the safety regulators of the countries building or envisaging the construction of reactors of this type. The EPR group in which ASN participates also includes authorities from the United Kingdom, Finland, China, India and Sweden.

Activities in 2021 and closure of the programme

In 2021, seeing that work was coming to an end on several reactor models, the members of the programme and its technical secretariat, the NEA, organised the transition to a scaled-down MDEP programme as of 2022. Eight of the sixteen members, including ASN, withdrew from the MDEP in 2021. The continued international cooperation as of 2022 in the field of EPR reactor operations, will be between the safety regulators concerned, outside the MDEP, in an *ad hoc* administrative framework.

Moreover, in 2021, nuclear component supplier inspection activities were transferred to the NEA's CNRA committee.

3.4 The International Nuclear Regulators' Association (INRA)

INRA comprises the heads of the regulators of Canada, France, Germany, Japan, South Korea, Spain, Sweden, the United Kingdom and the United States. This association is a forum for regular and informal discussions concerning topical matters in these various countries and the positions adopted on common international issues. It meets twice a year in the country holding the Presidency, with each country acting as president for one year in turn.

Four meetings were held in 2021. The first three, which were held remotely, enabled the association's members to discuss national topical subjects, management and the safety consequences of the Covid-19 pandemic, safety culture and improving the efficiency of the regulators. At the September meeting, held in-person in the margins of the IAEA's General Conference, the situation on the Fukushima Daiichi site and innovation in the nuclear sector were extensively covered.

4 // International Conventions

ASN is the national point of contact and the Competent Authority for the two nuclear safety conventions which deal with NPPs (Convention on Nuclear Safety) and spent fuel and radioactive waste (Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management). ASN is also the Competent Authority for the two Conventions dedicated to the transboundary management of the possible consequences of accidents (the Convention on the Early Notification of a Nuclear Accident and the Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency).

4.1 The Convention on Nuclear Safety

The Convention on Nuclear Safety is one of the results of international discussions initiated in 1992 in order to contribute to maintaining a high level of nuclear safety worldwide.

The Convention sets a certain number of nuclear safety objectives and defines the measures which aim to achieve them. The Convention on Nuclear Safety was signed by France in 1994 and entered into force on 24 October 1996. At the end of 2021, it had 91 contracting parties.

The objectives of the Convention are to attain and maintain a high level of nuclear safety worldwide, to establish and maintain effective defences in nuclear facilities against potential radiological risks and to prevent accidents which could have radiological consequences and mitigate their consequences should they occur. The areas covered by the Convention have long been part of the French approach to nuclear safety.

In 2015, the contracting parties to the Convention, taking account of the lessons learned from the Fukushima-Daiichi NPP accident, adopted the Vienna Declaration on nuclear safety. This Declaration, which extensively incorporates the principles of the European Directive on the Safety of Nuclear Facilities, sets precise and ambitious nuclear safety objectives aiming to prevent nuclear accidents worldwide and to mitigate the radiological consequences if one were to occur.

The Convention makes provision for review meetings by the contracting parties every three years, to develop cooperation and the exchange of experience.

As Competent Authority, ASN coordinates French participation in this three-yearly peer review exercise, in close collaboration with the institutional and industrial partners concerned. This coordination work concerns the drafting of the national report, analysis of the reports from the other contracting parties and participation in the review meetings.

Owing to the Covid-19 pandemic, the review meeting could not be held in March 2020 and was postponed to 2023 in the form of a review meeting common to the 8th and 9th cycles.

4.2 The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management

The Joint Convention is the counterpart to the Convention on Nuclear Safety for the management of spent fuel and radioactive waste from civil nuclear activities. France signed it on 29 September 1997, and it entered into force on 18 June 2001.

There were 87 contracting parties to this Convention at the end of 2021. In the same way as the Convention on Nuclear Safety, it is based on a peer review mechanism comprising the submission of a national report by each contracting party every three years, which undergoes review by the other contracting parties, as well as a contracting parties peer review meeting.

The French report, the production of which is coordinated by ASN, was submitted to the AIEA in October 2020 and is available on *asn.fr*. In 2021, this work consisted in analysing foreign reports, in order to prepare for France's participation in the 7th review meeting of the Joint Convention.

Owing to the pandemic, the Joint Convention's 7th review meeting scheduled for May 2021, was postponed to the summer of 2022.

4.3 The Convention on Early Notification of a Nuclear Accident

The Convention on Early Notification of a Nuclear Accident entered into force on 27 October 1986, six months after the Chernobyl accident and had 131 contracting parties at the end of 2021.

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 Unified System for Information Exchange in Incidents and Emergencies (USIE), which is in use in ASN's emergency centre and is tested on the occasion of each exercise.

The Interministerial Directive of 30 May 2005 specifies the conditions of application of this text in France and mandates ASN as the Competent National Authority. It is therefore up to ASN to report the events without delay to the international institutions, to rapidly provide pertinent information about the situation, in particular to border countries, so that they can take the necessary population protection measures and, finally, to provide the ministers concerned with a copy of the notifications and the information transmitted or received.

4.4 The Convention on Assistance in the Event of a Nuclear Accident or Radiological Emergency

The Convention on Assistance in the event of a Nuclear Accident or Radiological Emergency entered into force on 26 February 1987 and had 124 contracting parties at the end of 2021.

Its aim is to facilitate cooperation between countries should one of them be affected by an accident having radiological consequences. This Convention has already been activated on several occasions as a result of irradiation accidents caused by abandoned radioactive sources. More specifically, France's specialised medical services have already provided treatment for the victims of such accidents.

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.

The pandemic did not spare bilateral exchanges in 2021. ASN and its counterparts nonetheless succeeded in maintaining active relations, optimising the use of remote meetings over the first part of the year, and "hybrid" or in-person meetings subsequently.

Even if the lessons learned from the health situation were a regular subject of discussion, many other topics were covered throughout the year by ASN and its counterparts, such as the reactors fourth periodic safety reviews, decommissioning, radioactive waste management, the precautionary culture, modular reactors, management of emergency situations and the transformation of the regulators.

5.1 Bilateral cooperation between ASN and its foreign counterparts

SOUTH AFRICA

On 18 November 2021 a remote technical meeting was held between ASN and its South African counterpart (National Nuclear Regulator –NNR) on extending reactor lifetimes. The NNR was particularly interested in the lessons learned from France's fourth periodic safety review of the 900 Megawatts electric (MWe) reactors, given the upcoming examination of the review file for the two reactors of the Koeberg NPP.

GERMANY

The Franco-German Commission (CFA/DFK) was created as an inter-governmental body and involves several competent authorities at both national and local levels. With regard to ASN, both the head office departments and the Strasbourg regional division are concerned. 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 2021, the Commission and its working groups held remote meetings **on 9 June, 24 September and 6 December**. The scaled-down plenary meeting of the commission was an opportunity to present developments in the situation of each of the two countries, such as the fourth periodic safety review of the 900 MWe reactors, the situation in the NPPs near the Franco-German border, or changes to the regulations. A Franco-German workshop on the topic of decommissioning was also held remotely **on 22 and 26 November**. This workshop, organised by Germany and also open to the French Institute for Radiation Protection and Nuclear Safety (IRSN), led to extensive discussions on Germany's experience of decommissioning and the role of the authorities in this field. The workshop was particularly well received by the French participants.

BELGIUM

ASN cooperates on all subjects within its field of competence with its Belgian counterpart, the *Agence Fédérale de Contrôle Nucléaire* (AFCN). This leads to cooperation both nationally and locally, with certain of the ASN regional divisions. The Franco-Belgian steering committee was unable to meet in 2021. Two technical meetings on NPP safety, waste management and decommissioning were however held remotely **on 17 and 18 March 2021**.

CANADA

On 29 January and 4 June 2021 remote technical meetings were held on the digital transformation and the use of artificial intelligence, during which ASN and its American (NRC) and Canadian (CNSC) counterparts shared their experience of the digital tools currently in use or under development.

On 5 February 2021 the annual ASN/CNSC bilateral meeting was held *via* video-conference. This meeting discussed current topics concerning regulations, inspection practices and inspector training, small modular reactor projects, safety culture and the planned personnel secondments between the two Authorities.

CHINA

In 2021, discussions with ASN's Chinese counterpart (National Nuclear Safety Administration –NNSA) concerned Operating Experience Feedback (OEF) from operation of the Taishan NPP. This plant, located in the Province of Guangdong in the South of China, houses the world's first two EPR reactors to have been commissioned.

Further to an ASN proposal, technical meetings were held remotely with the NNSA to examine to what extent the feedback from the operating situation of Taishan reactor 1 can be taken into account in the ongoing examination of the commissioning application for the Flamanville EPR. Other meetings are scheduled for early 2022.

SPAIN

On 18 October 2021 a meeting was held in Montrouge between the Chairmen of ASN and its Spanish counterpart (*Consejo de Seguridad Nuclear* –CSN) to identify the subjects for the next bilateral meeting scheduled for June 2022. The management of radioactive waste and spent fuel, cross-inspections on the regulation and oversight of nuclear reactors, transparency and public information were selected.

At the end of 2021, technical discussions concerning industrial radiography were also held between the CSN and ASN's Bordeaux regional division. The discussions notably concerned the regulatory requirements regarding the protection of ionising radiation sources against malicious acts and the inspection methods applicable to this topic. A video-conference technical meeting was held on 4 November 2021. It was followed by the arrival of a CSN inspector to observe the 25 November ASN inspection of the French subsidiary of a transboundary Spanish industrial radiography company. These exchanges will be continued in 2022.

UNITED STATES

From 8 to 11 March 2021, a video-conference was used to hold the 33rd edition of the Regulatory Information Conference (RIC), organised annually by ASN's American counterpart, the NRC. The ASN Director General presented ASN's digital transformation and, in particular, the artificial intelligence system it uses to support its inspection process.

On 30 June 2021 the 12th bilateral meeting between ASN and the NRC was held by video-conference. The discussions notably concerned national topical subjects and the respective regulations, materials degradation, design deviations on the Flamanville EPR reactor, extension of the lifetime of the American reactors, inspections concerning fraud and the processing of whistle-blower reports, and changing inspection practices in the wake of the pandemic. The ASN Director General, who is also President of WENRA, also gave an update on the activities of the association.

INDIA

The ASN Chairman met his counterpart from the Indian Atomic Energy Regulatory Board (AERB) in September, in the margins of the IAEA General Conference. This meeting was the opportunity to sign the extension of the cooperation agreement in place between the two countries for more than two decades, and to confirm the mutual desire to organise a bilateral in-person meeting in 2022.

IRELAND

Exchanges with Ireland resumed **on 1 July 2021** with a meeting between ASN and its Irish counterpart (Environmental Protection Agency –EPA) in charge of radiation protection. This meeting was an opportunity to discuss the topics of radon, management of emergency situations, the implementation of the European Directive on radiation protection basic standards in Ireland, the graded approach, and justification in the medical field in France.

JAPAN

For the first time since the beginning of the pandemic, the Chairmen of ASN and the Japanese Nuclear Regulation Authority (NRA) were able to meet in person **on 20 September**, in the margins of the IAEA General Conference. This meeting was notably an opportunity to define the priority topics to be discussed at the next high-level meeting, which should be held in Japan in 2022. These topics more particularly concern SMRs, risk culture and safety and radiation protection culture, along with the conditions for the continued operation of the electricity generating reactors.

At the same time, information exchanges continued throughout the year on topical subjects in the two countries, as well as on implementation of a specific agreement between the two authorities concerning sharing of experience between inspectors.

An ASN Commissioner is also taking part in the expert mission set up by the IAEA to audit the project for the discharge at sea of decontaminated water from the Fukushima Daiichi NPP.

LUXEMBOURG

The Franco-Luxembourg joint Commission on nuclear safety held its 19th meeting **on 2 February 2021** remotely. The Commission comprises the national and Prefect level competent authorities and the Ministries of Foreign Affairs. It discussed recent developments in the two countries in the fields of nuclear safety and radiation protection, including the 2020 results for the Cattenom NPP, latest news in the medical fields (graded approach and radiotherapy inspections), periodic safety reviews on the French nuclear reactors, and the preparation for and management of emergency situations.

NORWAY

By video-conference, a high-level meeting was held **on 28 May 2021** between ASN and its Norwegian counterpart (*Direktoratet for Strålevern og Atomtryggleik* –DSA). This meeting covered topical regulatory subjects, the radon problem, radiation protection and its justification principle in the medical field, French regulations concerning the management of nuclear medicine effluents and the management of emergency situations.

Signing of the extension of the cooperation agreement between the Indian safety regulator and ASN – September 2021

POLAND

A remote high-level bilateral meeting was held **on 10 June 2021** between the Polish safety regulator (*Państwowa Agencja Atomistyki* –PAA) and ASN. The meeting was an opportunity for discussions on topical subjects in the two countries, notably concerning the future Polish nuclear programme and the construction of the Flamanville EPR reactor. The meeting gave the two Authorities the opportunity to reaffirm their intention to continue their cooperation, notably for the future construction of electricity generating reactors in Poland.

RUSSIA

The high-level bilateral meeting by video-conference **on 26 May 2021** with the Russian safety regulator *Rostechnadzor*, was the opportunity for discussions on the latest regulatory developments in the two countries. An update was given on the high-level waste geological disposal projects and on the decommissioning of graphite reactors and the safety of SMRs. Finally, technical cooperation projects were discussed.

SWEDEN

The annual meeting between ASN and its Swedish counterpart (*Strålsäkerhetsmyndigheten* –SSM) was held virtually **on 19 November 2021**. The discussions primarily concerned waste management and decommissioning. Technical discussion meetings between experts are being scheduled for 2022. The two Authorities also held virtual meetings during technical discussions with the Orléans regional division.

SWITZERLAND

The Franco-Swiss commission was created as an inter-governmental body and involves several competent authorities at both national and local levels. This Commission met **on 13 and 14 January 2021**. With regard to ASN, this Commission involves both the head office departments and the Lyon and Strasbourg regional divisions. **On 6 and 7 December 2021**, the Franco-Swiss nuclear emergency expert group met remotely for technical discussions on nuclear emergency and post-accident management.

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 are essential for a national system of nuclear safety and radiation protection oversight. Nuclear safety oversight must be based on national competence and ASN consequently only provides support for the establishment of an adequate national framework, ensuring that the national safety regulator it advises retains full responsibility for its oversight of the nuclear facilities. It pays particular attention to countries acquiring technologies of which it has experience in France.

ASN considers that developing an appropriate safety infrastructure requires a minimum of fifteen years before a nuclear power reactor can begin to operate in good conditions. For these countries, the goal is to set up a legislative framework and an independent and competent safety regulator with the financial and human resources it needs to perform its duties and to develop skills in terms of safety, safety culture and oversight as well as in radiological emergency management. In 2021, ASN continued its mission under the EINS project it is coordinating, on behalf of the Turkish safety regulator (*Nükleer Düzenleme Kurumu* –NDK).

5.3 Personnel secondments between ASN and its foreign counterparts

Understanding the working and practices of foreign nuclear safety and radiation protection regulators enables pertinent lessons to be learned for the working of ASN and the training of its personnel. One of the means used to achieve this goal is personnel secondments, generally for a period of one to three years. This immersion in the activities and working of the counterpart safety regulator is a unique means of assimilating subjects of common interest. Between January 2018 and August 2021, an ASN staff member was thus seconded to the NRC for a period of three and a half years. In addition, since 1 January 2019, an ASN senior inspector has been seconded to the British regulator (ONR).

6 // Outlook

In an international context made difficult by the Covid-19 pandemic, ASN succeeded in 2021 in maintaining regular exchanges with most of its counterparts, within bilateral and multilateral bodies. In addition, the preparation of important work (safety conventions coordinated by the IAEA, thematic peer reviews under the 2014 safety Directive) took place with no major difficulty.

In 2022, and depending on how the health situation develops, ASN will make efforts to maintain these exchanges, in priority with countries with whom bilateral relations were made more difficult owing to the Covid-19 pandemic, such as South Africa, Korea, China, Finland or the United Kingdom.

2022 will be a year rich in international events. ASN will be extensively involved, notably through WENRA and ENSREG, in preparing the thematic peer review on the protection of nuclear facilities against fire risks, the specifications and conditions of which will have been finalised in the Spring of 2022. In addition, the joint convention review meeting, scheduled for early Summer, and the preparation of the nuclear safety convention review meeting scheduled for March 2023, will also be important international events extensively mobilising ASN.

ASN will continue to identify the subjects it continues to be priorities for discussions with its counterparts, be they strategic, technical or organisational, in order to share thoughts, experiences and best practices.

07

Medical uses of ionising radiations

07 MEDICAL USES OF IONISING RADIATION

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 for the population to ionising radiation (behind exposure to natural ionising radiation) and the leading source of artificial exposure (see chapter 1).
The exposure of patients to ionising radiation is distinguished from the exposure of workers, the public and the environment, for which there is no direct benefit. The principle of dose limitation does not apply to patients due to the need to adapt the delivered dose to the diagnostic or therapeutic end-purpose. The principles of justification and optimisation are fundamental, even if the radiation protection risks differ according to the medical uses. In radiotherapy (external-beam or brachytherapy) and Internal Targeted Radiotherapy (ITR), the major risk is linked to the administered dose and, if applicable, the high dose rates used. There are specific risks linked to the use of sealed radionuclide sources (in brachytherapy, with high-activity sources) and unsealed sources (in nuclear medicine), which bring the risks associated with waste and effluent management.
The fast expansion of Fluoroscopy-Guided Interventional Procedures/Practices (FGIPs) carried out using increasingly sophisticated devices can lead to significant exposure of the patient and the personnel in the immediate vicinity.
Lastly, Computed Tomography (CT) examinations, although they do not present a major risk in terms of delivered dose or dose rate, contribute significantly to population exposure resulting from medical diagnostic procedures due to their frequency of use, underlining the importance of justification for each procedure using ionising radiation.

1 // Radiation protection and medical uses of ionising radiation

1.1 The different activity categories

Medical nuclear activities can be divided into nuclear activities for diagnostic purposes such as computed tomography, conventional radiology, dental radiology and diagnostic nuclear medicine, interventional practices using ionising radiation (FGIPs), which bring together different techniques used primarily for invasive medical or surgical procedures for diagnostic, preventive or therapeutic purposes, and activities for therapeutic purposes, most of which are dedicated to cancer treatment, such as external-beam radiotherapy, brachytherapy and Internal Targeted Radiotherapy (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 (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 2020 by French Institute for Radiation Protection and Nuclear Safety (IRSN), the medical and veterinary sectors account for the majority of the people monitored: 59%, *i.e.* 228,585 persons were subject to dosimetric monitoring of their exposure. The average annual individual dose is 0.25 millisievert (mSv). This dose, which was stable from 2017 to 2019, decreased in 2020 (-17%). This drop can be linked, at least partly, to the Covid-19 pandemic. The analysis of the breakdown of the persons according to their level of exposure shows that the very large majority of workers (86% all sectors combined) received no dose above the detection threshold. A review spanning the 1998-2020 period nevertheless reveals that medical and veterinary activities account for the majority of cases of exceeding the regulatory limit.

The largest proportion (47%) of exposed medical personnel is involved in radiology activities (radiodiagnosis and interventional radiology), with an average annual individual dose of 0.19 mSv. Nuclear medicine represents 3% of the personnel but with a significantly higher average annual individual whole body dose, estimated at 0.74 mSv.

The medical and veterinary activity sectors account for the majority of exposures of the extremities, with nearly 61% of the workers subject to this monitoring. Thus, 16,675 personnel members (7.3%) were subject to dosimetry of the extremities, with an average dose at the extremities of 14.7 mSv. The activities most frequently concerned are: nuclear medicine, which today is the main contributor with 66% of the total dose registered, and interventional activities, whose contribution to the total dose

1. *Internal Targeted Radiotherapy (ITR) aims to administer a RadioPharmaceutical Drug (RPD) emitting ionising radiation which will deliver a high dose to a target organ for curative or palliative purposes.*

is still underestimated, particularly due to insufficient use of extremity dosimeters in the operating theatre.

Lastly, nearly 87% of the personnel monitored for exposure to the lens of the eye work in the medical and veterinary sectors, and represent 3,840 workers with an average individual dose of 1.80 mSv. 69% of the personnel monitored for lens of the eye dosimetry come from the FGIP sector (2,640 workers in 2020).

1.2.2 Exposure of patients

In medical applications for diagnostic purposes, optimisation of exposure to ionising radiation allows delivery of the minimum dose that produces the relevant diagnostic information or allows performance of the planned interventional procedure. With therapeutic applications, the highest dose possible must be delivered in order to destroy the targeted tumoral cells while preserving the surrounding healthy tissue as best possible. As the principle of limitation does not apply to patients, the principles of justification and optimisation (see point 1.3) must be applied all the more rigorously.

In medical imaging, the principles of optimisation and justification (avoiding unnecessary examinations, or those whose result can be obtained using non-irradiating techniques that give an equivalent diagnostic level when available) are at the centre of the action plans for controlling doses delivered to patients. These action plans were developed by ASN in 2011 and 2018 in collaboration with the services of the Ministry of Solidarity and Health and the health professionals (see chapter 1, point 3.3).

The optimisation principle, defined by Article L. 1333-2 of the Public Health Code (see chapter 2), known as the ALARA (As Low As Reasonably Achievable) principle, has led to the introduction, in the area of medical imaging using ionising radiation, of the concept of "Diagnostic Reference Levels" (DRL). These DRLs, which must not be considered to be "dose limits" or "optimum doses", are established for standard examinations and typical patients. DRLs are therefore dosimetric indicators of the quality of practices, intended to identify the examinations on which optimisation efforts must be focused in priority. They should not be exceeded in standard procedures without justification. ASN resolution 2019-DC-0667 of 18 April 2019 sets the DRL values and requires heads of radiology and nuclear medicine departments to carry out (or have others carry out) periodic dosimetric evaluations and to send the results to IRSN. The data collected by IRSN are analysed with a view to updating the DRLs.

The last "ExPRI" study, which analyses exposure of the French population to ionising radiation due to medical imaging examinations, was published by IRSN in late 2020. It presents the data for 2017, which are compared with those of 2012 to show how they have evolved. These analyses are carried out using diagnostic imaging procedures drawn from a representative sample of beneficiaries of the French health insurance system, by method of imaging (conventional, interventional and dental radiology, CT scans and nuclear medicine), by explored anatomical region, by age and by sex. On the whole the analyses reveal stability of exposure on average (see chapter 1, point 3.3).

1.2.3 Exposure of the public

The impact of medical applications of ionising radiation is likely to concern:
- members of the public who are close to facilities that emit ionising radiation;
- sewage network and wastewater treatment plant personnel who could be exposed to effluents or wastes produced by nuclear medicine departments;
- people involved in comforting a patient.

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 the sewage networks and wastewater treatment plants (IRSN studies, 2005 and 2014). In 2015, IRSN developed an aid baptised CIDRRE (French acronym for "Calculation of the impact of radioactive discharges into wastewater networks"), which enables nuclear medicine departments and research laboratories to estimate, with reasonably penalising assumptions, conservative dose values for the sewage system workers based on the activities administered by the departments.

In the case of an examination performed on a pregnant woman, the embryo or foetus exposed *in utero* is considered like a member of the public for which dose limits for the public are applicable. Pregnant women unaware of their pregnancy represent one third of the Significant Radiation Protection Events (ESRs) reported annually to ASN, that is to say about 200 cases per year (see point 2.7). The doses delivered to the uterus by imaging examinations are usually less than 100 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%)[2].

In nuclear medicine, a radionuclide source is administered to the patient, who can then emit ionising radiation and expose the persons around them. To control this type of exposure, the regulations have introduced the notion of "dose constraints". To verify compliance with these dose constraints, equivalent ambient dose rate measurements can be taken before discharging a patient who has received a nuclear medicine treatment or examination. In clinical practice, nuclear medicine departments make the discharging of patients having received a high activity (therapeutic application) conditional on an equivalent dose rate of about 20 microsieverts per hour (µSv/h) at a distance of 1 m (recommendations of the Advisory Group for Radiation Protection in Medical Applications –Oct. 2017). It is usually necessary to hospitalise the patient in a radiation-proof room while waiting for the activity to decay

1.2.4 The environmental impact

In nuclear medicine, the radioactive sources administered to the patients will undergo physical decay (period of time stemming from the physical-chemical properties of the sources) but also biological elimination (resulting from the biological metabolism, as with any medication). Patients having received an injection eliminate part of the administered radioactivity, mainly *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 (PGED) detailing the collection, management and disposal

2. ICRP Publication 84. Ann. ICRP 30. ICRP Supporting Guidance 2. Ann. ICRP 31. ICRP Publication 90. Ann. ICRP 33. ICRP Publication 103. Ann. ICRP 37, ICRP Publication 105. Ann. ICRP 37.

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. The environmental gamma radiation does not reveal any exposure exceeding the background radiation. Radioactivity measurements in major rivers or wastewater treatment plants of large towns occasionally reveal the presence of artificial radionuclides used in nuclear medicine (iodine-131, for example). However, no trace of these radionuclides has been detected in water intended for human consumption (see chapter 1).

1.3 Regulations

1.3.1 General regulations

Protection of the personnel working in facilities that use ionising radiation for medical purposes is governed by the provisions of the Labour Code (Articles R. 4451-1 to R. 4451-135).

In order to protect the public and the workers, the facilities that use medical devices emitting ionising radiation must also satisfy the technical rules defined in the ASN resolutions (see technical rules described in point 2).

The monitoring of sources (radioactive sources including RadioPharmaceutical Drugs (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) which concern the acquisition, distribution, import, export, sale, transfer and recovery and disposal of the sources. More specifically, the sources must be declared, registered or licensed if they are not exempted, they must be inventoried, recovered when expired/disused, and be subject to financial guarantees of recovery.

1.3.2 Medical devices and radiopharmaceuticals

The radionuclides used in nuclear medicine can be classified in two categories:
- the RPDs, subject to obtaining a Marketing Authorisation (MA), issued by either the French Health Products Safety Agency (ANSM) or the European Medicines Agency (EMA);
- medical devices, which are required to obtain the “CE” marking (for example, implantable medical devices, such as microspheres marked with yttrium-90).

Pending the obtaining of an MA, and to allow early access to medicines for patients suffering from serious or rare diseases, derogation processes have proliferated in France of the last twenty years. In order to simplify and harmonise these different processes, a reform of the access to medicines by derogation was implemented on 1 July 2021 (Decree 2021-869 of 30 June 2021). This reform, which aims to “*allow even faster access to these medicines for patients at a therapeutic dead-end*”, replaces the six authorisation systems by two conditions of access, namely compassionate access and early access.

Medical Devices (MD) emitting ionising radiation (electrical devices and particle accelerators) used in nuclear-based medical activities must meet the essential requirements defined in the Public Health Code (Articles 5211-12 to R 5211-24). The “CE” marking, which certifies conformity with these essential requirements, is mandatory. Further to technological developments, the Order of 15 March 2010 laying down the essential requirements applicable to medical devices has been modified to reinforce the provisions concerning the display of the dose during imaging procedures. Moreover, the new European regulation EU 2017/745 entered into application on 26 May 2021 and its implementation extends until 27 May 2025 (date limit for putting on the market or commissioning MDs under the old regulation). This new European regulation reinforces patient safety, through a better clinical assessment of the MDs, and transparency, thanks to the European database on medical devices –Euramed), also accessible to the general public, which helps to improve collaboration between the competent European authorities. To facilitate early access of patients to innovative and useful technologies which do not yet have the “CE” marking, the French National Authority for Health (HAS) has instituted an “innovation pass”, conditional on the deployment of a clinical study to confirm the substantial health benefit of the new technology.

The clinical assessments conducted for putting onto the market MDs, RPDs or derogation processes allowing patients to receive an innovative treatment are determining factors in the application of the justification principle (see point 1.3.4).

On 8 July 2019, in order to plan ahead for the radiation protection risks associated with the introduction of new techniques and emerging practices using ionising radiation, ASN created “Canpri”, a Committe for analysing new techniques and practices using ionising radiation. Chaired by ASN and comprising 16 experts and representatives of French health institutions, Canpri’s aim is to identify new techniques and practices in the medical field, analyse their radiation protection risks and to produce recommendations and conclusions with regard to patient and worker radiation protection. Its first work, still in progress, focuses on intraoperative radiotherapy, the gyroscopic radiosurgery platform Zap-X (which obtained the “CE” marking in January 2021) and new radionuclides in nuclear medicine.

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 people, patients and the environment. Licensing serves to regulate the activities presenting the greatest risks, for which ASN checks, when examining the application file, that these risks have effectively been identified by the applicant and that the barriers intended to mitigate their effects are appropriate. Registration also involves the examination of submitted documents, but in limited number.

Thus, since 1 July 2021, the ASN on-line services portal allows heads of nuclear activities to register their activities. The list of medical activities subject to registration has been defined on the basis of the radiation protection risks by ASN resolution 2021-DC-0704 of 4 February 2021. This system is applicable to computed tomography and to FGIPs, activities with radiation protection risks. Conventional radiology and dental radiology will continue to come under the notification system. The licensing system is maintained for external-beam radiotherapy, brachytherapy and diagnostic and therapeutic nuclear medicine.

1.3.4 The particularities of patient radiation protection

Justification and optimisation – The protection of patients undergoing medical imaging examinations or therapeutic procedures using ionising radiation is regulated by specific provisions of the Public Health Code (Art. R. 1333-45 to R. 1333-80). The principles of justification of the procedures and optimisation of the delivered doses constitute the cornerstone of this regulation. The principle of dose limitation does not apply to patients due to the need to adapt the delivered dose to the diagnostic or therapeutic end-purpose for each patient. ASN ensures that this regulatory framework is updated through specific provisions with regard to optimisation, quality assurance, training and qualification as described below.

The required qualifications – The use of ionising radiation on the human body is restricted to physicians and dental surgeons having the necessary skills to perform these procedures (Article R. 1333-68 of the Public Health Code). ASN updated and specified the necessary qualifications in October 2020. This aim of the updating is to adapt the regulatory provisions to the developments in the techniques and conditions of practise. ASN resolution 2020-DC-0694 of 8 October 2020, approved by Order

TABLE 1 **Classification of nuclear-based medical activities according to the radiation protection risks**

ACTIVITIES	PATIENTS	PROFESSIONALS	PUBLIC AND ENVIRONMENT
External-beam radiotherapy	3	1	1
Brachytherapy	2	2	2
Internal targeted radiotherapy	3	2	3
Fluoroscopy-guided interventional practices	2 to 3 depending on the procedures	2 to 3 depending on the procedures	1
Diagnostic nuclear medicine	1 to 2 depending on the procedures	2 to 3 depending on the procedures	2
Computed tomography	2	1	1
Fluoroscopy-guided procedures on remotely-controlled table in radiology department	1	1	1
Conventional radiology	1	1	1
Dental radiology	1	1	1

1: no risk or low risk – 2: moderate risk – 3: high risk

PATIENT RADIATION PROTECTION: THE JUSTIFICATION PRINCIPLE

As the first principle of radiation protection enshrined in the Public Health Code, justification aims to ensure that the patient derives benefit from the examination or treatment received, as compared with the risks inherent to exposure to ionising radiation and in view of the alternative techniques that do not involve exposure to ionising radiation. It ties in with the medical notion of relevance, which means endeavouring to perform "the right procedure for the right patient at the right time", taking into account the benefit-risk trade-off. The clinical assessments conducted for putting onto the market medical devices, RPDs or derogation processes enabling patients to have early access to an innovative treatment are determining factors in the application of the justification principle (see point 1.3.2).

Application of the principle of justification is materialised by the publication of guides defining the medical indications justifying the procedures involving exposure to ionising radiation in the various applications (radiology, nuclear medicine, radiotherapy). To this end, the Minister responsible for health or the organisation he/she designate (the HAS) draws up, in collaboration with the health professionals, and distributes a guide defining the medical indications justifying the procedures involving exposure to ionising radiation, especially those used the most frequently (Article R. 1333-47 of the Public Health Code). These guides have to be updated periodically according to the changes in techniques and practices and are distributed to the practitioners requesting and performing the procedures. In view of the radiation protection risks, the updating of these guides, particularly in radiotherapy, is a priority for ASN.

The individual justification of the procedure for each patient is based on consideration these professional guides.

Justification is the joint responsibility of the "referring" physician and the "performing" physician. In application of Article R. 1333-52 of the Public Health Code, prior to referral for and performance of a procedure, the physician or dental surgeon checks that it is justified by referring to the guide or the documents mentioned in Article R. 1333-47. In the event of disagreement between the referring physician and the performing physician, the decision lies with the latter.

In imaging, the *Guide to good use of medical imaging examinations* produced by the French Society of Radiology (SFR) and the French Society of Nuclear Medicine and Molecular Imaging le (SFMN) was updated in 2021 and transformed into a website baptised ADERIM (Aid to Referral for Radiology and Medical Imaging Examinations), intended primarily for general practitioners. Its serves to guide the referring physician in choosing the most appropriate examination for exploring the pathology concerned. It features an indication recommendation (indicated, not indicated, or even counter-indicated), the level of proof of the recommendation and the level of exposure to ionising radiation resulting from the examination. Its aim is to reduce the exposure of patients by eliminating unjustified imaging examinations and by giving preference if necessary to the use of non-irradiating techniques when available.

In external-beam radiotherapy and brachytherapy, the *Guide to recommendations for the practise of external-beam radiotherapy and brachytherapy* (Recorad) produced by the French Society for Radiation Oncology (SFRO), was revised in February 2022. It presents recommendations aiming to optimise, harmonise and render uniform the practises.

of 5 July 2021, entered into effect in July 2021. It repeals the resolution of 23 August 2011 (2021-DC-0238) and updates the qualifications required for physicians and dental surgeons who perform procedures using ionising radiation for medical purposes or research involving humans, and for the physicians appointed to coordinate a medical nuclear activity or who apply for a license or registration as a natural person.

The quality assurance obligations – To control the doses delivered to patients and thereby contribute to improved treatment safety, the obligations of heads of nuclear activities with regard to quality assurance for all medical activities involving ionising radiation are now governed by two ASN resolutions:
- resolution 2019-DC-0660 of 15 January 2019 in medical imaging, that is to say in nuclear medicine for diagnostic purposes, in dental and conventional radiography, in computed tomography and for FGIPs;
- resolution 2021-DC-0708 of 6 April 2021 for therapeutic procedures, that is to say external-beam radiotherapy, including contact therapy and intraoperative radiotherapy, brachytherapy, nuclear medicine for therapeutic purposes (ITR) and radiosurgery.

These resolutions oblige the head of the nuclear activity, with requirements proportionate to the radiation protection risks, to formalise the processes, procedures and work instructions associated with the operational implementation of the two general principles of radiation protection, namely justification for the procedures and dose optimisation, and those concerning the lessons learned from the events, the training of professionals and, for therapeutic procedures, the prospective risk analysis. ASN resolution 2021-DC-0708 of 6 April 2021, which entered into effect on 17 August 2021, repeals resolution 2008-DC-0103 of 1 July 2008 relative to quality assurance obligations in radiotherapy. It updates and steps up the quality assurance requirements, particularly in the event of an organisational or technical change or the outsourcing of services.

Training in patient radiation protection – The obligations for continuous training in patient radiation protection are set in Articles L. 1333-19, R. 1333-68 and R. 1333-69 of the Public Health Code. The system as a whole was revised in ASN resolution 2017-DC-0585 of 8 January 2015 amended, further to discussions with all the National Professional Councils (CNP) concerned in order to clarify and reinforce the teaching objectives concerning justification, to integrate new players and to foster links with the other continuous training instruments. Since this resolution entered into application, some twenty professional guides have been produced by the learned societies, validated by ASN and put on line. To monitor the practical implementation of this new framework, a qualitative and quantitative assessment was initiated at the end of 2021, involving all the players. An inventory of the training offerings will be 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, a specific assessment shall be conducted on the number and content of the training course offerings in these two areas. This assessment will focus 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. This work will be presented in 2022 to the committee that monitors the national plan for controlling imaging doses.

1.4 The risks and oversight priorities

In order to establish its oversight priorities, ASN has classified the nuclear-based medical activities according to the risks for the patients, the personnel, the public and the environment. This classification takes particular account of the doses delivered or administered to the patients, individually or collectively, the fitting out of the premises and the conditions of use of sources of ionising radiation by the medical professionals, the production of waste and effluents contaminated by radionuclides, the source security risks (high activity sealed sources), lessons learned from significant events reported to ASN and the radiation protection situation in the institutions exercising these activities.

On the basis of this classification (see point 1.3.3, Table 1), ASN considers that its oversight must focus in priority on external-beam radiotherapy, brachytherapy, nuclear medicine and FGIPs. The inspection frequencies have been adapted and enable all the radiation-risk activities to be inspected over a period of 3 to 5 years, depending on the sectors. As from 2018, ASN defined a list of systematic inspection points concerning the radiation protection of workers, patients and the public, the management of sources, waste and effluents, and the security of sources. These inspections, associated with indicators, enable regional and national assessments to be carried out and the developments to be measured over time.

Some indicators are common to all the inspected activities, such as the organisation of worker radiation protection and of medical physics, and training in radiation protection of workers and patients. Others are specific to a given activity, such as the management of waste and effluents in nuclear medicine or the security of sources in brachytherapy. These indicators serve in particular as the basis for assessing the radiation protection situation in the medical sector (see point 2). These systematic checks are complemented by investigations on specific themes defined in an annual or multi-annual framework and adapted to the particular situations encountered in the inspections.

The main themes chosen in 2021 were:
- in radiotherapy and brachytherapy: risk management, management of skills and training, mastery of the equipment and the security of high-activity sealed sources;
- in nuclear medicine: the experience feedback process for reported internal or external events (ESRs);
- in FGIPs: implementation of the optimisation approach.

For the routine inspections, ASN has defined an inspection frequency per inspected nuclear activity (Table 2) based on a graded approach to the radiation protection risks. These frequencies are increased when vulnerabilities that could have an impact on radiation protection are identified (difficulties linked to human resources, technical or organisational changes, quality management or insufficient control of risks –lateness in formalising practises, absence of risk assessments, lack of risk culture–, particular risks associated with certain techniques, etc.). This can lead ASN to place certain centres under tightened surveillance, when significant persistent malfunctions have been found, and to inspect them at least annually.

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TABLE 2 **Frequency of inspections per area of nuclear-based medical activity**

NUCLEAR-BASED MEDICAL ACTIVITY	ROUTINE FREQUENCY
External-beam radiotherapy	Every 4 years
Brachytherapy	Every 4 years
Diagnostic nuclear medicine	Every 5 years
Therapeutic nuclear medicine on out-patient basis (*e.g.* iodine <800 megabecquerels (MBq), synoviortheses, etc.)	Every 4 years
Therapeutic nuclear medicine with complex therapies using iodine >800 MBq, of lutetium-177, yttrium-90 and hospitalisation	Every 3 years
Fluoroscopy-guided interventional practices	Every 5 years
Computed tomography (emergencies or paediatrics)	Sampling: about twenty facilities per year

1.5 Significant radiation protection events

It is mandatory to report ESRs to ASN in application of the Public Health Code (Articles L. 1333-13, 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, 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 reports on line. This portal is integrated in the "one-stop vigilance portal" managed by the Ministry of Solidarities and Health. Depending on the type of event reported, the notification is sent automatically to ASN (regional division), to the Regional Health Agency (ARS) for all events concerning the patient, while events relating to medical devices vigilance or drug safety monitoring (RPDs) are sent to the ANSM.

ASN Guide No. 11 specifies the procedures for reporting significant radiation protection events. ASN Guide No. 16 applies specifically to the reporting of ESRs concerning patients that occur in the field of radiotherapy (external-beam radiotherapy and brachytherapy). A specific scale, the ASN-SFRO scale has been developed in collaboration with the French Society for Radiation Oncology (SFRO) to inform the public about radiation protection events affecting patients undergoing radiotherapy procedures (see chapter 3). In addition to the confirmed consequences, it enables the potential effects of the event and number of patients exposed to be taken into consideration.

Moreover, the incident notices are published on *asn.fr*.

To encourage the sharing of the lessons learned from experience feedback from the medical professionals, ASN has published the newsletter *Patient safety –Paving the way for progress* since March 2011, *Experience feedback from ESR* sheets and circular letters addressed to the heads of nuclear activities. Produced by multidisciplinary working groups coordinated by ASN, the newsletter offers a thematic presentation of the good practices of medical departments and the recommendations developed by the learned societies of the discipline concerned and the health and radiation protection institutions. The "Experience feedback" sheet, for its part, draws attention to a specific ESR reported to ASN to prevent it from occurring in another centre.

2 // Nuclear-based medical activities

2.1 External-beam radiotherapy

Radiotherapy, along with surgery and chemotherapy, is one of the key techniques employed to treat cancerous tumours. Radiotherapy uses ionising radiation to destroy malignant cells (and non-malignant cells in a small number of cases). The ionising radiation necessary for the treatments is produced by an electric generator or emitted by radionuclides in sealed sources. We distinguish external-beam radiotherapy, where the source of radiation (particle accelerator or a radioactive source such as Gamma knife®) is external to the patient, from brachytherapy, where the source is placed as close as possible to the cancerous lesion.

The radiation sessions are always preceded by the preparation of a treatment plan which serves to set the conditions for achieving a high dose in the target volume while preserving the surrounding healthy tissues. The treatment plan defines the dose to deliver, the target volume(s) to treat, the volumes at risk to be protected, the ballistics of the radiation beams and the predicted dose distribution (dosimetry). Preparation of the treatment plan requires close cooperation between the radiation oncologist, the medical physicist and, if necessary, the dosimetrists.

The main radiation protection risk is linked to the dose delivered to the patient; the change of treatment techniques with the development of hypofractionated radiotherapy (see point 2.1.1), which consists in delivering higher doses during a given session, makes it all the more crucial to control delivery of the dose.

This is why ASN's oversight focuses on both the ability of the centres to control delivery of the dose to the patient and to learn lessons from the malfunctions that could occur. Implementation of the treatment quality and safety management system, skills management, mastery of the equipment, ESR recording and follow-up are the focal points of the ASN inspections. As technical, organisational and human changes have been identified as potential risk-generating situations, particular attention is also given to change management during the inspections.

2.1.1 Presentation 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) published in September 2016 and 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. This technique consists in irradiating a target volume by continuous irradiation rotating around the patient.

Helical radiotherapy, or tomotherapy enables radiation treatment to be delivered by combining the continuous rotation of an electron accelerator with the longitudinal movement of the patient during the treatment. The possibility of modulating radiation intensity allows equally well the irradiation of large complex-shaped volumes as of highly-localised lesions, if necessary in mutually independent anatomical regions. The system requires the acquisition of images under the treatment conditions of each session for comparison with reference computed tomography images in order to reposition the patient.

Stereotactic radiotherapy is a treatment method that aims at delivering high-dose radiation to intra- or extracranial lesions with millimetric accuracy through multiple mini-beams which converge at the centre of the target. The total dose is delivered either in a single session or in a hypofractionated manner, depending on the disease being treated. The term radiosurgery is used to designate treatments carried out in a single session. This technique demands great precision in defining the target volume to irradiate, following the shape of the tumour as closely as possible, and uses specific identification techniques in order to locate the lesions with millimetric accuracy.

This therapeutic technique chiefly uses three specific types of equipment, such as:

- Gamma Knife® which uses more than 190 cobalt-60 sources. It acts like a veritable scalpel over an extremely precise and delimited zone (five units in service);
- robotic stereotactic radiotherapy; CyberKnife® is a miniaturised linear accelerator mounted on a robotic arm;
- multi-purpose linear accelerators equipped with additional collimation means (mini-collimators, localisers) that can produce mini-beams.

Since 2018, the combination of **a linear accelerator for radiotherapy coupled with an MRI scanner** has been developing.

Contact therapy or contact radiotherapy is an external-beam radiotherapy technique. The treatments are delivered by an X-ray generator using low-energy beams which are particularly suited to the treatment of skin cancers because the delivered dose decreases rapidly with depth.

Intraoperative radiotherapy combines surgery and radiotherapy, with the radiation dose being delivered in the operating theatre to the tumour bed during surgical intervention. This technique is used primarily for treating small cancers of the breast. In April 2016, the HAS published the results of the assessment of this practice and concluded that the conditions necessary to propose coverage by the state health insurance scheme were not satisfied at the time. It considers that the clinical and medico-economic studies must be continued in order to have clinical data over the longer term. The development of this technique, which has been implemented for four years, is limited and its assessment is continuing.

New **intraoperative electron radiotherapy devices**, with the "CE" marking, have been put on the market. They allow optimal irradiation of the tumour while preserving the surrounding healthy tissues to the maximum possible extent. Intraoperative electron radiotherapy was presented at the Canpri meeting of April 2021 and is currently under discussion.

Hadron therapy is a treatment technique based on the use of beams of charged particles (protons and carbon nuclei), which can deliver the dose in a highly localised manner during treatments, thereby drastically reducing the volume of healthy tissue irradiated. According to its advocates, hadron therapy with carbon nuclei is more suited to the treatment of the most radiation-resistant tumours and could result in several hundred additional cancer cases being cured each year.

2.1.2 Technical rules applicable to external-beam radiotherapy installations

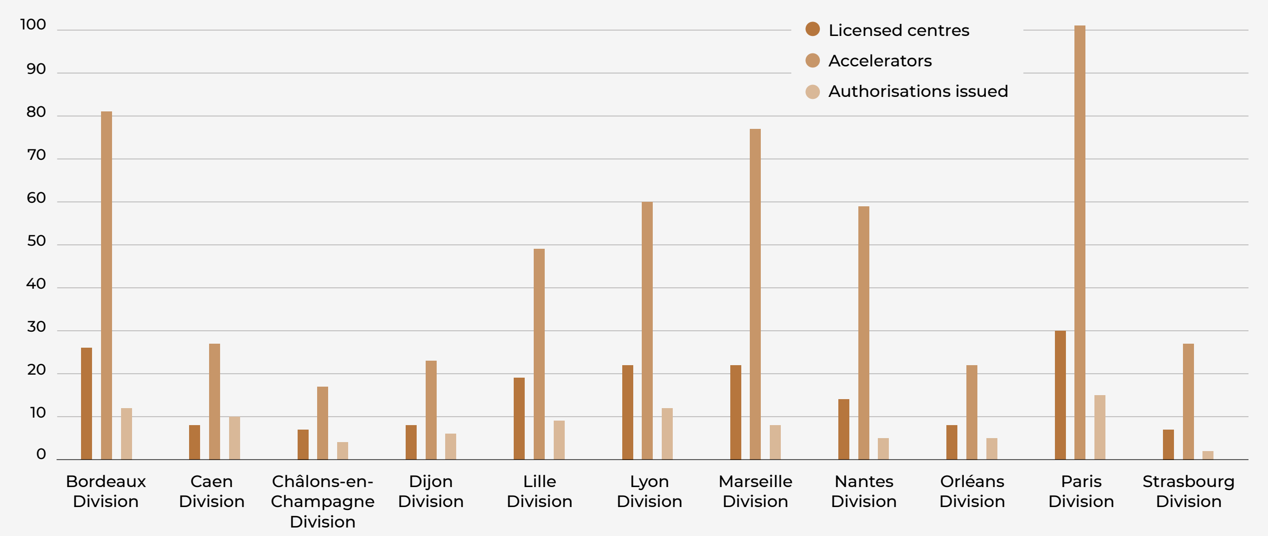
On account of the high dose rate when delivering the dose to the patient, the devices must be installed in rooms specially designed to guarantee radiation protection of the staff, turning them into veritable bunkers in which the wall thickness can vary from 1 to 2.5 metres of ordinary concrete). A radiotherapy 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 were reviewed in 2019. A specific study must be carried out for each installation by the machine supplier, together with the medical physicist and the Radiation Protection Expert-Officer (RPE-O). 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 and below the treatment room. This study must be included in the file submitted to ASN to support the application for a license to use a radiotherapy installation.

In addition, a set of safety systems informs the operator of the machine operating status (exposure in progress or not) and switches off the beam in an emergency or if the door to the irradiation room is opened.

The bunker with shielding baffle remains the design reference insofar as it reduces the shielding required at the ventilation duct and electrical duct inlets and provides greater security in the event of failure of the door motorisation system or if anyone gets accidentally locked inside. However, if the space available to the licensee is limited, which compromises the installation of the accelerator, a smaller shielding baffle, or even none at all, can be envisaged under certain restrictive conditions. The gyroscopic platform Zap-X, a new medical device intended for intracranial irradiations of the "radio surgery" type, which obtained the "CE" marking in January 2021, presents the innovative characteristic of being self-shielded. This device is currently under discussion within Canpri.

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 2021**



2.1.3 Radiation protection situation in external-beam radiotherapy

The installed base of external-beam radiotherapy facilities in 2021 comprises 543 particle accelerators installed in 171 radiotherapy centres subject to ASN licensing (see Graph 1). More than 200,000 patients(3) are treated each year, which represents nearly 4.2 million radiation sessions. The French radiotherapy observatory (French National Cancer Institute –INCa), lists 891 radiation oncologists in 2020. ASN issued 84 licenses in 2021. The majority of cases concerned the updating of an existing license.

The safety of radiotherapy treatments has been a priority area of ASN oversight since 2007 on account of the high doses delivered to the patient. The inspection programme for the 2020-2023 period places the emphasis on the ability of the centres to deploy a risk management approach. Skills management, the implementation of new techniques or practices and the mastery of the equipment are also examined in depth, depending on the centres.

ASN has continued its graded approach to inspection:
- by reducing, in the light of the progress made in the control of treatment safety, the average frequency of inspection, which since 2016 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.

As in 2020, ASN adapted its oversight actions on account of the Covid-19 pandemic. It continued to give priority to the more critical inspections, but some were carried out remotely or postponed, while taking care to observe the four-yearly frequency. ASN thus carried out 43 inspections in 2021, covering 25% of the national total. Of the 43 inspections performed, 7 were conducted entirely remotely.

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 risks for the medical staff are limited due to the protection provided by the facility.

The results of the inspections carried out in 2021 reveal no major problems in this sector:
- the effective designation of Radiation Protection Advisors (RPA) was confirmed in the majority of the centres inspected;
- the radiation protection technical controls were carried out in about 90% of the centres inspected and were satisfactory.

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 2008-DC-0103 of 1 July 2008. This resolution has been repealed and replaced by ASN resolution 2021-DC-0708 of 6 April 2021, applicable since 17 August 2021. Since 2016, in the course of its inspections ASN verifies the adequacy of the human resources, and in particular the presence of the medical physicist and the internal organisation procedures for tracking and analysing adverse events –or malfunctions– recorded by the radiotherapy centres.

A medical physicist is effectively present during the treatments in 100% of the inspected centres. All the centres have a medical physics organisation plan, but the quality of the plans varies from one centre to another.

The detection of adverse events, their reporting (internally or to ASN) and their recording are deemed satisfactory on the whole. Furthermore, distinct progress is seen in the analysis of these adverse events, the defining of corrective actions and capitalising on them: they are satisfactory in 74% of the inspections, compared with 66% in 2020 (see Graph 2). This confirms a trend towards improvement.

The improvement in practices through experience feedback and assessment of the effectiveness of the corrective actions were deemed satisfactory in only 30% of the centres inspected

3. In 2019, 205,585 people with cancer were treated by radiotherapy in 4,284,242 sessions (source: INCa Observatory).

compared with 38% in 2020 (see Graph 2). In order to be effective, these approaches must bring together representatives of all the professionals involved in the delivery of treatments. The lack of availability of personnel, especially medical, limits their effectiveness.

In order for there to be real continuous improvement in treatment quality and safety, it is necessary to regularly assess the corrective actions put in place, to involve all the personnel and to use the lessons learned to review the prospective risk analysis, which is mandatory pursuant to the abovementioned ASN resolution 2021-DC-0708 of 6 April 2021. In effect, the only way of testing the long-term robustness of the measures taken is to assess the corrective actions. The addition of check points, for example, can constitute a "false security" if they cannot be implemented by the professionals for various reasons. Moreover, the analysis of events can reveal that the safety barriers in place have not been effective, like those for ascertaining that the treatment has been delivered to the correct side, which should lead to a review of the prospective risk analysis and a team reflection to find more effective protection measures.

The ability of a centre to deploy a risk management procedure was again subject to specific investigations in 2021. These investigations reveal that:

- Although the requirements for quality and safety management in radiotherapy departments are satisfied in the majority of cases, there are still disparities between centres. Thus, the prospective risk analysis –which is mandatory– is only complete or updated in half the inspected centres, mainly due to lack of training or resources, or to a change in the operational quality manager. This incompleteness concerns, for example, the residual unassessed risks after applying corrective actions, or the lack of integration of experience feedback (from other centres, for example, disseminated through the ASN publications –Patient safety newsletters and experience feedback sheets).
- More generally, further to the inspections carried out since 2016, ASN considers that the risk management procedure is only implemented satisfactorily in half of the inspected centres. These are the centres in which management has defined a policy with shared, assessable and assessed operational objectives, has communicated on the results of this policy and allocated the necessary resources, in particular, to the operational quality manager.

ASN notes that the impact of a 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 lessons learned from the inspections carried out in 2021 effectively show that, when a new technique is deployed, the centres have an adequate command of change management in 74% of the cases and the installation of new equipment in 66% of the cases. ASN nevertheless notes that deployment of these procedures is progressing, since the figures for 2020 and 2019 were 58% and 40% respectively for the deployment of a new technique, and 69% and 25% respectively for the installation of new equipment.

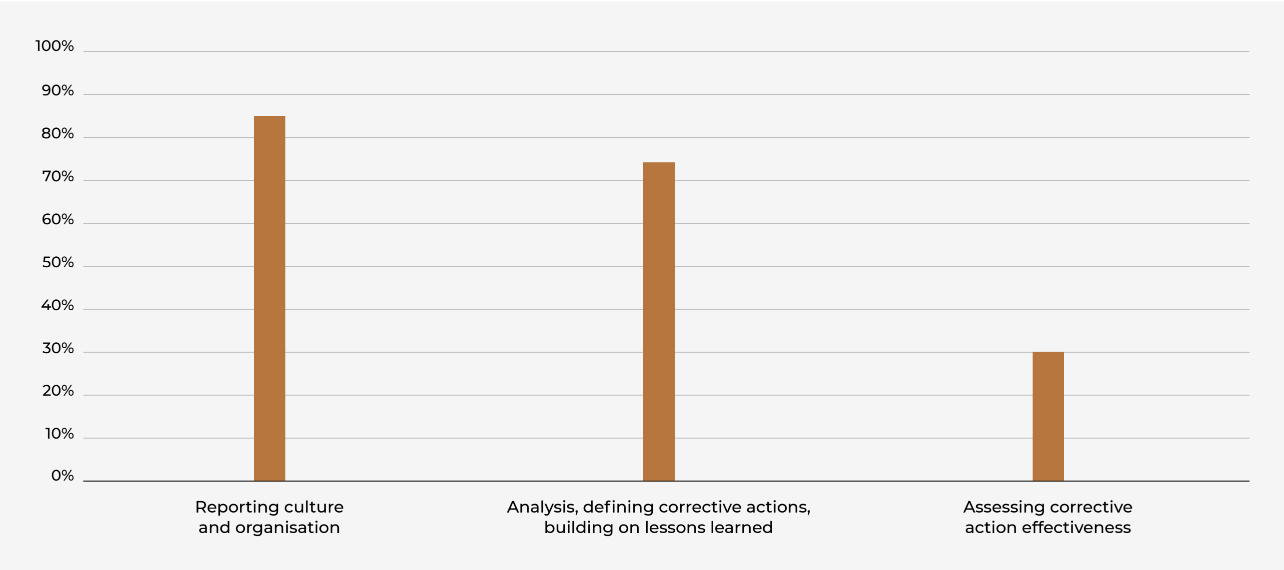
In view of the difficulties found during inspections or when examining ESRs, ASN asked IRSN in 2018 to draw up recommendations to help the radiotherapy centres embrace equipment and/or technical changes. In October 2021, in partnership with the radiotherapy professionals, IRSN published a *Guide to embracing technical or equipment changes in radiotherapy*.

2.1.3.3 Significant events in external-beam radiotherapy

In 2021, 97 ESRs were reported in radiotherapy under criterion 2.1 (exposure of patients for therapeutic purposes). Among these events, 55 were rated level-1 on the ASN-SFRO scale, *i.e.* 57% of the total, and four were rated level 2. The four level-2 events concern one wrong-side error, one patient identification error and two excess doses, one of which was due to a calibration error.

Most of the events reported in 2021 concern patient radiation protection, and the majority of them are not expected to have any clinical consequences.

GRAPH 2 **Percentage of conformity of the facilities concerning the management of events giving rise to corrective actions in 2021**



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CALIBRATION: A CRITICAL STEP IN THE RADIOTHERAPY PROCESS

On 23 April 2021, the Sainte-Catherine Cancer Institute – Avignon-Provence, situated in Avignon, reported a significant event that occurred in its radiotherapy department, which induced ionising radiation overdoses in several hundred patients.

The reported event resulted from errors made when calibrating the photon beams of one of the accelerators in the institute's radiotherapy department.

The consequence of these errors, which were discovered ten months after the incorrect calibration operation, was overdosing during the external-beam radiotherapy sessions performed using this accelerator. A total of 749 patients were concerned by at least one treatment session on this accelerator, including 99 who received a delivered dose that was between 5 and 6.8% higher than the prescribed dose.

ASN conducted an inspection of the radiotherapy department in June 2021. In view of the conclusions of this inspection and of the ESR, ASN has decided to re-inspect this centre in the first quarter of 2022.

This event concerning several patients was rated level 2+ on the ASN-SFRO scale of radiotherapy events, graded from 0 to 7 in increasing order of severity.

A REVIEW OVER 10 YEARS OF ESRs RATED LEVEL 2 ON THE ASN-SFRO SCALE

Since 2008, the ESRs affecting patients during a radiotherapy procedure are rated on the ASN-SFRO scale developed by ASN in collaboration with the SFRO. This scale, dedicated to informing the public, comprises 8 levels: deviations from 0 to 1, incidents from 2 to 3 and accidents from 4 to 7. The severity of the effects is assessed by referring to the international clinical classification used by practitioners (Common Terminology Criteria for Adverse Events –CTCAE grades).

A retrospective study spanning 10 years (from 2008 to 2018) was carried out on the follow-up of patients affected by an ESR rated level 2. The data relative to 57 ESRs and 112 patients were collected and analysed by the multidisciplinary working group that produced the ASN bulletin (GT REX).

The results of this study show that 30% of the patients have been lost to follow-up and the median follow-up time is less than 2 years, illustrating the fact that follow-up must be improved to ensure better patient care management.

Thus, in this bulletin, the GT-REX working group reiterates the regulatory obligation to report an ESR and the moral obligation, further to the ESR, to ensure the long-term follow-up of the patients, beyond the requirements of the INCa (approval criterion No. 18 setting the follow-up time at 5 years). Lastly, the working group issues recommendations concerning the organisation and systematisation of the patient follow-up file. These recommendations concern the creation of a follow-up register and the obligatory items to include in the patient's file.

As in the preceding years, these events always highlight organisational weaknesses concerning:
- the management of the movement of patients' medical files;
- the validation steps, which are insufficiently explicit;
- the keeping of patients' files in a manner that provides an overall view and gives access to the necessary information at the right time.

Variations in practices within a given centre, frequent task interruptions, a high and uncontrolled workload affecting the length of working hours, or the deployment of a new technique or practice, all constitute situations that disrupt work activities and weaken the safety measures defined in the quality management system. It is therefore essential to assess these measures regularly and to draw lessons from the malfunctions that occur.

In 2021, ASN published a *Patient safety newsletter* assessing of 10 years of use of the ASN-SFRO scale for ESRs rated level 2.

SUMMARY

The inspections carried out in 2021 in nearly a quarter of the radiotherapy departments, and of which the majority were able to be conducted on site despite the constraints associated with the Covid-19 pandemic, confirm that the safety fundamentals are in place: organisation of medical physics, equipment verifications, training in the radiation protection of patients, deployment of quality assurance procedures, recording and analysis of events and production of prospective risk analyses. Nevertheless, the assessment of corrective action effectiveness is struggling to achieve widespread adoption and the prospective risks analyses still remain relatively incomplete and insufficiently updated prior to an organisational or technical change or following experience feedback from events. Although the inspections frequencies have been reduced in response to the progress made by the radiotherapy centres, the departments presenting vulnerabilities or specific issues continued to be subject to tighter monitoring in 2021. The occurrence of events such as wrong-side or patient identification errors reveals persistent organisational weaknesses and the need to regularly assess practices. The lessons learned from events also illustrate the fact that the calibration of medical devices is a critical step for treatment safety.

2.2 Brachytherapy

Brachytherapy can be used to treat cancerous tumours either specifically or as a complement to another treatment technique.

This technique consists in placing 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, which differ more specifically in the dose rate applied (details below) according to the indications.

As with radiotherapy, the radiation protection risks are linked to the intensity of the dose delivered to the patient and, if applicable, the high dose rates and the mastery of the equipment. Furthermore, as high-activity sources are involved, the management of emergency situations in the event of source jamming, as illustrated by the feedback from events reported to ASN, and the security of the sources, constitute specific risks of brachytherapy. That is why the ASN checks focus on the management of source security in addition to those on external-beam radiotherapy.

2.2.1 Presentation of the techniques

The radiation protection risks in brachytherapy, apart from the problem of managing sealed sources, depend on the dose rate associated with the technique, the method of delivering the radiation to the tumour (permanent or temporary implantation, or temporary application). The use where necessary of source afterloaders means that the medical personnel do not have to handle the sources and allows the patient to be treated without irradiating the personnel or interrupting the treatment when the sources are stored in the afterloader. On the other hand, it is necessary to make provision for accident situations associated with malfunctioning of the source afterloader and the high dose-rate delivered by the sources used.

Low Dose-Rate (LDR) brachytherapy is carried out 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).

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 duration of the planned treatment, hence the name pulsed dose-rate brachytherapy.

High Dose-Rate (HDR) brachytherapy is carried out using high-activity (about 370 GBq) sealed sources of iridium-192 or cobalt-60. The dose rates are higher than 12 Gy/h. The treatment is performed using an afterloader containing the source, and the treatments are delivered on an out-patient basis in one or more sessions lasting a few minutes, spread over several days.

2.2.2 Technical rules applicable to brachytherapy facilities

The rules for radioactive source management in brachytherapy are comparable to those defined for all sealed sources, regardless of their use (see point 1.3.1).

In cases where permanent implant techniques are used (LDR), the applications are carried out in the operating theatre with ultrasonography monitoring, and do not require hospitalisation in a room with radiation protection. The PDR technique, which uses source after loaders (usually 18.5 GBq of iridium-192), necessitates hospitalisation of the patient for several days in a room with radiological protection appropriate for the maximum activity of the radioactive source used. Lastly, with the HDR sources, as the maximum activity used in the source afterloaders is high (370 GBq of iridium-192 or 91 GBq of cobalt-60), the irradiations can only be carried out in a room with a configuration comparable to that of an external-beam radiotherapy room in terms of collective protection because of the high dose level used.

2.2.3 Radiation protection situation in brachytherapy

ASN has licensed 59 brachytherapy centres, 50 of which use the HDR technique. ASN issued 19 licenses in 2021. The majority of these cases concerned the updating of an existing license (see Graph 3).

The brachytherapy activity is stable. The INCa observatory has recorded 500 to 600 LDR treatments per year using iodine-125 seeds, 650 to 800 PDR treatments per year for gynaecological cancers, and about 3,000 HDR treatments per year.

In the same way as for external-beam radiotherapy, the safety of brachytherapy treatments has been a priority area of ASN oversight since 2007, because of the intensity of the doses delivered and, where applicable, the high dose rates. As brachytherapy is carried out within the radiotherapy departments, the inspection programme for the 2020-2023 period is identical to that for external-beam radiotherapy, with a four-yearly frequency and checks similar to those applied in external-beam radiotherapy (see point 2.1.3.2). On account of the use of high activity sources, specific checks focus on medical staff training, such as knowledge of the action to take in the event of an emergency (source jamming), and the security of these sources (organisation in place for source management, appropriate measures to prevent unauthorised access to the sources, source inventory, protection against malicious acts and management of sensitive information).

16 inspections were carried out in 2021, representing slightly over a quarter of the licensed departments, and four of them were conducted remotely due to the Covid-19 pandemic.

2.2.3.1 Management of sources

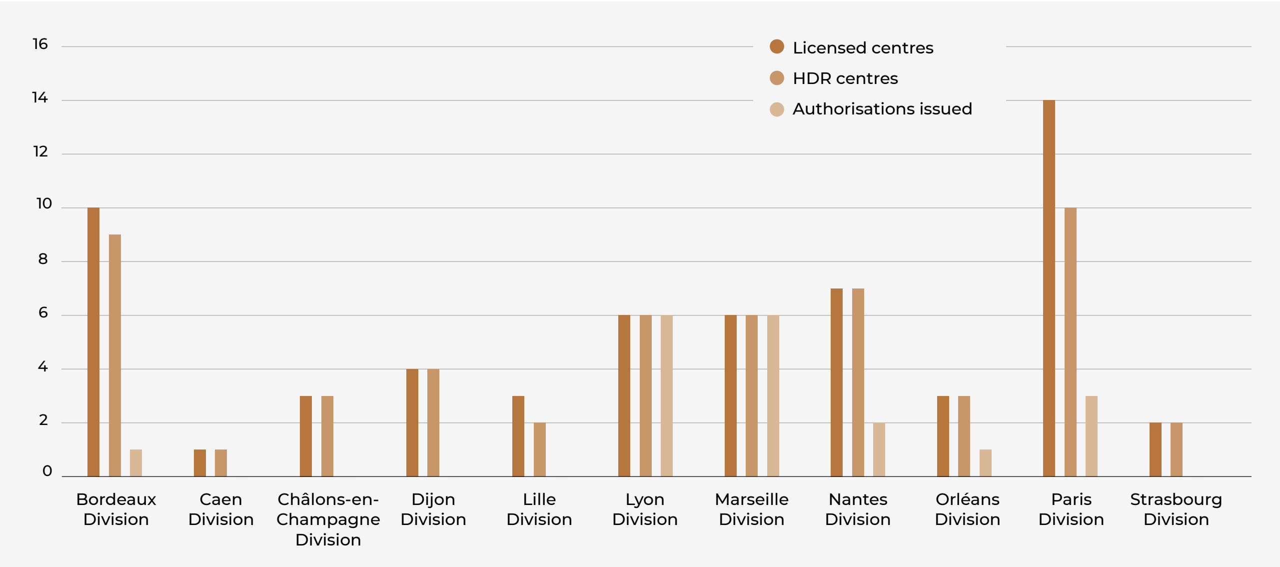
The brachytherapy sources are well managed. All the centres inspected record the tracking of source movements, transmit the source inventory to IRSN and store the sources waiting to be loaded or collected in a suitable place.

The Order of 29 November 2019 sets the obligations concerning the protection of ionising radiation sources and batches of radioactive sources of categories A, B, C and D against malicious acts The requirements concerning the protection barriers and their resistance time for category A, B and C sources shall be enforceable as from 1 July 2022.

The organisational measures in place in 2021 enable the category of each source or batch of sources to be identified in all the inspected centres and in half the centres the personnel have been issued with the necessary authorisations to access the high-activity sealed sources. Furthermore, 66% of the inspected centres have put in place appropriate measures to prevent unauthorised access to these sources.

ASN notes that the new requirements relative to protecting access to high-activity sources are being progressively deployed.

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 2021**



DISCONNECTION OF AN APPLICATOR SOURCE TRANSFER TUBE

On 5 August 2021, the Antoine Lacassagne Centre (Nice) reported an incident that occurred in its brachytherapy department to ASN.

In January 2021, during the second HDR brachytherapy session, the medical staff detected a malfunction. It was reportedly linked to disconnection of the source transfer tube and the applicator. The source was reportedly ejected from the afterloader without reaching the target organ and remained in contact with the patient outside the treatment areas for several minutes, where a dose of between 150 and 200 grays (Gy) was reportedly administered. During a follow-up consultation of the patient in June 2021, the centre observed the presence of a lesion outside the treatment zone which could result from radiation necrosis (also called radionecrosis). The sequence of events was re-analysed and an ESR was reported to ASN.

ASN conducted two inspections of the centre's brachytherapy department, one on 10 August 2021, the other with the ARS on 2 September 2021. These inspections revealed several breaches of the regulations: no internal reporting of the incident, lack of internal communication on the malfunction, failure to report the ESR within 48 hours, staff shortages, inadequately formalised procedures, etc.

This phenomenon of disconnection of the source transfer tube from the applicator, also identified as a malfunction of the medical device, was reported to the ANSM by the centre as a medical devices vigilance report.

ASN moreover asked IRSN perform an expert assessment of the centre's dosimetric reconstruction, which confirmed that the level of exposure of the skin is compatible with the onset of radiation necrosis.

In view of the unintentional exposure of the patient having led to the onset of radiation necrosis, ASN rated the event level 3 on the ASN-SFRO scale.

2.2.3.2 Emergency situations and management of malfunctions

Malfunctions of brachytherapy devices which can result in jams or incorrect positioning of the source can lead to overexposure –sometimes serious– of staff or patients (see point 2.2.3.5). 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 2021 by the brachytherapy departments were considered satisfactory. Out of the 16 inspected centres possessing high-activity sources, 11 have put in place enhanced training in emergency situations and have organised situational exercises, particularly for managing situations linked to source jamming. ASN considers that these efforts must be continued in order to reinforce the radiation protection training of medical professionals where high-activity sources are held.

2.2.3.4 Radiation protection of patients

As with external-beam radiotherapy, the radiation protection of brachytherapy patients is assessed from the inspections concerning the implementation of the treatment quality and safety management system.

The presence of medical physicists in sufficient numbers for the activity was observed in all the centres inspected. A medical physics organisation plan is also available in all the centres inspected.

The treatment quality and safety management system

The qualitative result of the inspections carried out in 2021 has shown that the majority of brachytherapy departments inspected have deployed the quality management system, with the support of the external-beam radiotherapy departments.

Maintenance and quality controls – The majority of the centres have an inventory of the medical devices and a register for recording maintenance operations and quality controls. In the absence of regulatory baseline requirements for the quality controls of brachytherapy devices, the quality controls implemented are based on the recommendations of the manufacturers or medical professionals.

Maintenance of the afterloaders (for the 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.

2.2.3.5 Significant events in brachytherapy

In 2021, 8 ESRs were reported in brachytherapy under criterion 2.1 (exposure of patients for therapeutic purposes), including one rated level 3 on the ASN-SFRO scale concerning unintentional exposure of a female patient during an HDR brachytherapy treatment.

In addition, one event is linked to the loss of seeds of iodine-125 during treatment preparation, which led to an atypical exposure of the workers without exceeding dose limits.

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 the informing of the patient, the sources and emergency situations.

SUMMARY

ASN did not note any failure to comply with the radiation protection rules regarding treatment safety in brachytherapy in the centres inspected. The radiation protection of medical staff and the management of high-activity sealed sources are considered satisfactory. The training drive for medical professionals where high-activity sources are held must be maintained, and increased in some centres. ASN notes that the new requirements relative to safeguarding access to high-activity sources are being progressively deployed, in particular regarding measures to prevent unauthorised access to these sources. The reported events highlight the importance of a having an active events recording system in order to identify malfunctions as early as possible, to assess the risks in degraded situations (staff shortages), to formalise and record device quality controls.

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 expansion of new radionuclides and vectors, nuclear medicine has considerably developed over the last few years, for diagnostic and therapeutic purposes alike.

Nuclear medicine forms part of ASN's inspection priorities. The main radiation protection risks are linked in particular to the use of unsealed sources, which generate radioactive waste and effluents, and can lead to contaminations. Nuclear medicine is moreover the main contributor to doses at the extremities of professionals in the nuclear sector (see point 1.2.1) During inspections, particular attention is focused on management of the sources, waste and effluents, occupational radiation protection, control of drug dispensing, through quality assurance obligations and the experience feedback process.

2.3.1 Presentation 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 using a specific radioactive substance called a RadioPharmaceutical Drug (RPD) which is administered to a patient. The nature of the RPD used depends on the organ or function to be studied. The RPD conventionally consists of a radionuclide which can be used directly (in this case the radionuclide constitutes the RPD) or be attached to a vector (molecule, hormone, antibody, etc.). In the latter case, it is the specific attachment of the vector that determines the studied function. Table 3 presents some of the principal radionuclides used in various explorations.

It is by detecting the ionising radiation emitted from the radionuclide by using a specific detector that the RPD can be located in the organism and images of the functioning of the explored tissues or organs can be obtained. The majority of detection devices allow tomographic acquisitions and cross-sectional imaging and a three-dimensional reconstruction of the organs. The imaging techniques depend on the type of radionuclide used: Single Photon Emission Computed Tomography (SPECT), sometimes called "gamma-camera", uses radionuclides emitting gamma radiation, while Positron Emission Tomography (PET) uses radionuclides emitting positrons.

In order to make it easier to merge functional and morphological images, hybrid appliances have been developed. They combine PET cameras or gamma cameras with a CT scanner (PET-CT or SPECT-CT).

According to a survey conducted by ASN in 2018 on the installed base of SPECT and "Cadmium-Zinc-Telluride" (CZT) semiconductor cameras in 2017, the inventory comprised:
- 423 SPECT cameras, of which 70% are coupled to a computed tomography (CT) scanner, accounting for 924,000 procedures per year;
- 51 CZT semiconductor cameras, of which 7 are coupled to a CT scanner, accounting for 125,000 procedures per year.

The installed base of PET cameras comprised:
- 158 PET cameras, all coupled to a CT scanner, accounting for 486,000 procedures per year;
- 4 PET cameras coupled to an MRI scanner, performing some 2,000 procedures per year.

***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. At the end of 2019, about fifty *in vitro* diagnostic laboratories were licensed by ASN.

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

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

dynamic in recent years, primarily in the field of oncology therapy with the emergence of new vectors and radionuclides.

ITR treatments can be administered either by mouth (*e.g.* capsule of iodine-131) or by systemic route (intravenous injection or *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.

45 nuclear medicine departments have a combined total of 164 ITR rooms for therapeutic purposes (see Graph 4).

Medical dispensaries

When a medical dispensary is authorised in a health care centre, the room in the nuclear medicine department in which RPDs are prepared, called the "nuclear pharmacy" or "radiopharmacy", is part of the medical dispensary. In 2019, there were 128 nuclear pharmacies in the nuclear medicine departments in public health care institutions and non-profit private health care institutions, such as the cancer centres. The radiopharmacist is primarily responsible for managing the RPD circuit (procurement, possession, preparation, control, dispensing and traceability) and the quality of preparation.

The equipment

In addition to the cameras installed in the nuclear medicine departments, about 400 radiation-proof enclosures are installed in the departments to permit safe handling of unsealed sources.

There are also nearly 110 automated or semi-automated de-vices for preparing RPDs marked with fluorine-18 and about 60 automated injection devices.

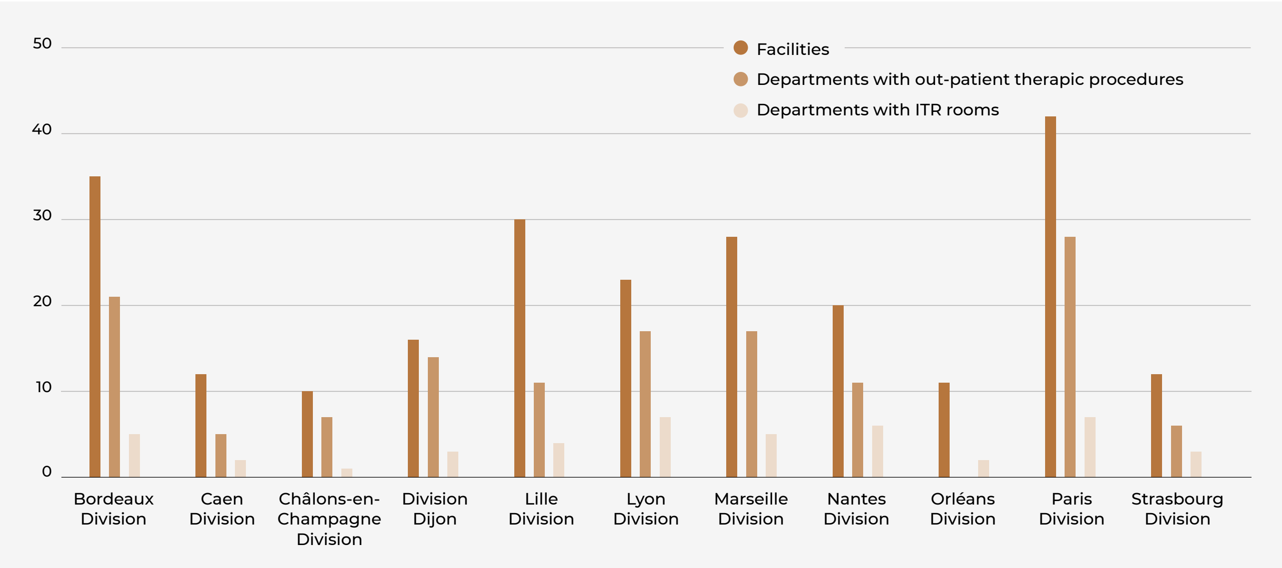
2.3.2 Technical rules applicable to nuclear medicine facilities

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

GRAPH 4 **Breakdown by ASN regional division of the nuclear medicine facilities, the number of departments with out-patient therapies and departments with hospitalisation rooms dedicated to internal targeted radiotherapy in 2021**



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 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. The IRSN recommendations are expected in 2022.

2.3.3 The radiation protection situation in nuclear medicine

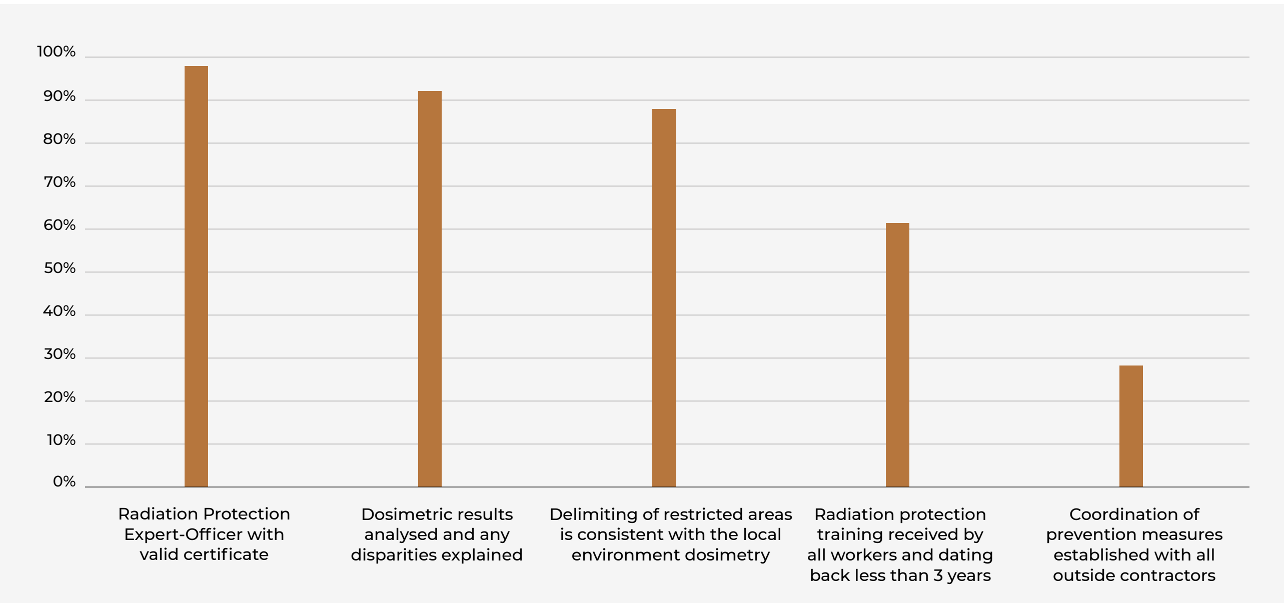
The nuclear medicine facilities base in 2021 comprises 239 licensed nuclear medicine departments, of which 45 practice high-activity ITR requiring hospitalisation in an ITR room, 137 practice moderate-activity ITR on an out-patient basis, and 57 only carry out diagnostic examinations.

To have a situation assessment for France as a whole, ASN conducted a survey with all the nuclear medicine departments in 2018. The results of this survey gave a total of about 1,537,000 annual procedures in France in 2017, including some 900,000 scintigraphy or SPECT procedures, 125,000 procedures using semiconductor camera detection and about 500,000 PET procedures.

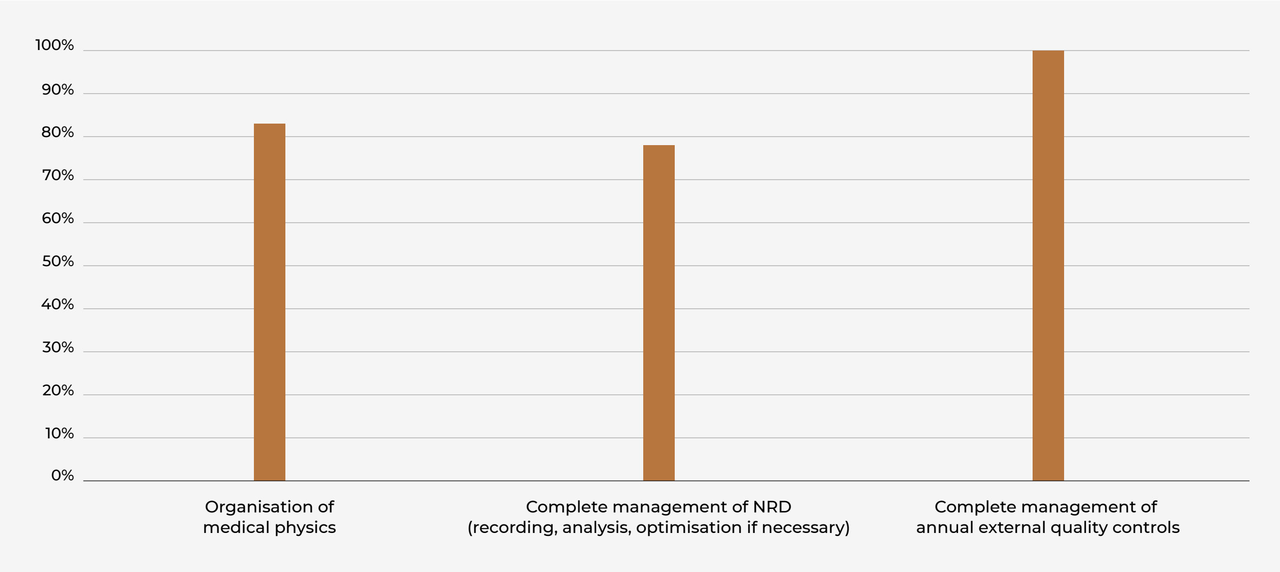
134 nuclear medicine licenses were delivered during 2021, most of which concerned changes of cameras or license extensions to allow the use of new radionuclides.

ASN inspections in nuclear medicine are scheduled applying a graded approach that takes into account the breakdown of the types of procedures performed in the departments, with risks that differ depending on whether they concern diagnostic or therapeutic procedures. In this context, the inspection frequency is five-yearly for departments that only perform diagnostic examinations, four-yearly for departments performing diagnostic examinations and out-patient therapeutic procedures (delivery of iodine with activities below 800 MBq, synoviortheses, etc.) and three-yearly for the departments performing complex therapies using iodine with delivered activities exceeding 800 MBq, lutetium-177, yttrium-90 (with hospitalisation in a room that may or may not be radiation-proof). Consequently, about a quarter of the French nuclear medicine base is inspected each year, that is to say about 15 of the 45 departments performing complex therapies, 34 of the 137 departments performing diagnostic examinations and out-patient therapies, and 11 of the 57 departments only performing examinations for diagnostic purposes.

GRAPH 5 **Conformity of the inspected facilities with regard to radiation protection of medical professionals in 2021**



GRAPH 6 **Conformity of the inspected facilities with regard to radiation protection of patients in 2021**



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 2021, 79 nuclear medicine departments were inspected, representing 33% of the facilities. Despite continuation of the epidemic, inspections that were unable to be done in 2020 were carried out in 2021. Just one inspection was carried out remotely, under the adaptation of inspection methods to the pandemic situation.

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 results concerning radiation protection of professionals (see Graph 5) show that the radiation protection measures implemented by nuclear medicine departments are generally satisfactory with regard to the appointing of a Radiation Protection Expert-Officer (RPE-O) dedicated to this activity (valid certificate issued by the employer in all the inspected departments), the analysis of the dosimetric results of the medical staff, and the consistency between the delimiting of restricted areas and the results of the working environment verifications.

Two lines for improvement have nevertheless been identified: the updating of personnel training in occupational radiation protection (all the medical professionals concerned have been trained within the last three years in only 61% of the departments,) and coordination with outside contractors, for which less than one third of the nuclear medicine departments (28%) have established a prevention plan with all the intervening outside contractors.

Alongside this, the radiation protection technical controls have been carried out over the last two years at the regulatory frequency for all the sources and devices and for the radioactivity measuring and detection devices, in 93% of the 79 departments inspected. Only four of the 21 departments concerned by nonconformities had not corrected them on the day of the inspection.

2.3.3.2 Radiation protection of nuclear medicine patients

Since ASN resolution 2019-DC-0667 of 18 April 2019 on Diagnostic Reference Levels (DRLs)[4] came into effect, ASN has been assessing the new requirements concerning the quality of recording of doses, their analysis and the optimisation put in place where necessary. The inspections carried out were satisfactory in 78% of the departments. However, 22% of the departments had not optimised their practices even though this was necessary (exposure levels significantly higher than the DRLs)

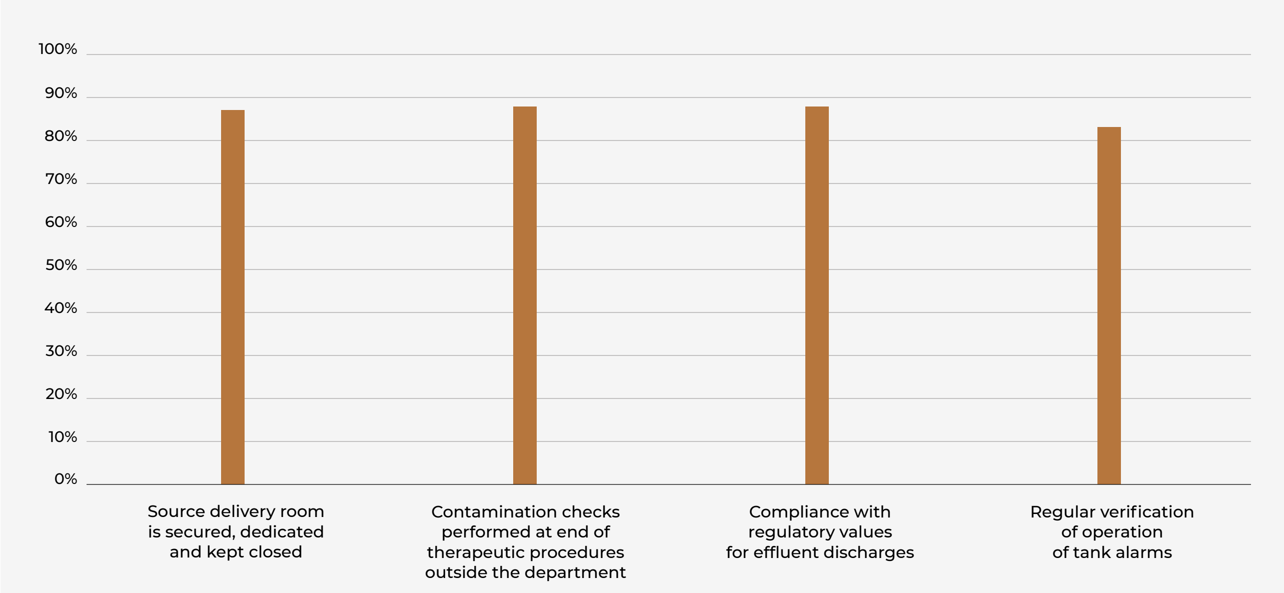
The external quality controls of the last two years have moreover been carried out on all the medical devices at the required regulatory frequency and the nonconformities discovered have been remedied in all the inspected departments.

The organisation put in place to integrate medical physicists and specify their duties and time of presence on site is fully defined in 83% of the inspected departments (see Graph 6). On the other hand, in 15% of the cases the Medical Physics Organisation Plan (POPM) was incomplete, and in one department the medical physics organisation described in the POPM was deemed inadequate in view of the risks associated with the activity (insufficient medical physics resources to fulfil tasks such as recording and analysing the doses for the CT scanner).

Along with this, further to the publication of two ASN resolutions, 2019-DC-0660 and 2021-DC-0708 laying down the quality assurance obligations for medical imaging and therapeutic procedures respectively, ASN observes commitment and significant investment on the part of the medicine departments in the deployment of quality management systems and notes a good events reporting culture in the majority of the inspected departments.

4. Order of 23 May 2019 approving ASN resolution 2019-DC-0667 of 18 April 2019 concerning the methods for evaluating ionising radiation doses delivered to patients during a radiology procedure, fluoroscopy-guided interventional or nuclear medicine practices, and the updating of the corresponding diagnostic reference levels.

GRAPH 7 Conformity of the inspected facilities with regard to protection of the public and the environment in 2021



2.3.3.3 Protection of the general public and the environment

Compliance with the requirements concerning protection of the general public and the environment was checked in all the inspected centres. Thus, 87% of the departments have a dedicated and protected deliveries area that complies with the requirements of ASN resolution 2014-DC-0463 of 23 October 2014. In 88% of the departments the activity concentration of the effluents discharged after decay complies with the regulatory limits (10 becquerels per litre –Bq/L– for contaminated effluents after storage, or 100 Bq/L for effluents from the rooms of patients treated with iodine-131) (see Graph 7). In 10% of the cases, documentation tracking (registers) needs to be improved. The storage tank leak detectors in the retention trays are checked at the required frequency and the verifications are duly formalised in 83% of the departments. In 13% of the cases, the frequencies defined in the Effluents and Waste Management Plan (PGED) are not observed and verification traceability is poor. Only two inspected departments (3%) did not check the leak detectors.

2.3.3.4 Significant events reported in nuclear medicine

Out of the 79 departments inspected, 74% have a system for recording adverse events. These latter departments analysed the events and reported them to ASN when necessary. However, 21% of the inspected departments had not reported their ESRs to ASN, primarily due to the personnel's lack of awareness of events reporting.

After a drop in the number of ESRs reported for two years in succession, a total of 186 ESRs were reported in 2021, a figure comparable with that of 2018.

As in the preceding years, most of the reported events (>70%) concerned patients who had undergone a nuclear medicine procedure. The majority of the reported events have no expected clinical consequences, in view of the activities injected (see Graph 8).

Significant events concerning patients (133 ESRs, or >70% of the reported ESRs)

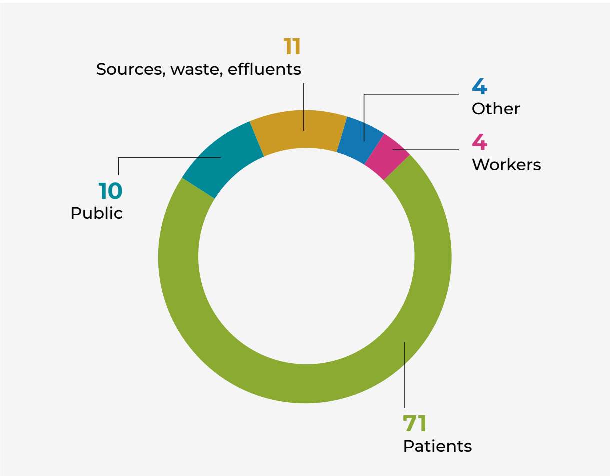
The large majority of the ESRs concerning nuclear medicine patients are due to an identity monitoring problem, that is to say the administration of an RPD to the wrong patient, and result from organisational and human malfunctions, usually in heavy workload situations. Although most of the departments have put in place events recording systems in application of ASN resolution 2019-DC-0660, the experience feedback procedures need to be improved in the large majority of the departments, particularly to further the analyses and to assess the robustness of the corrective actions. In addition to the identity monitoring problems, errors in the preparation of RPDs or in prescriptions, proportionally fewer in the latter case, are also reported.

In 2021, five events that occurred during a therapeutic procedure were reported: one identity monitoring error resulting from confusion between two patients treated by iodine-131 capsule (one patient received a dose lower than the prescribed dose but consistent with their pathology), two targeting errors with yttrium-90 microspheres leading to exposure of organs at risk, one case of skin contamination with lutetium-177 at the seat of catheter insertion (failure to clean the point of injection) and one case of extravasation with no consequences.

Significant events concerning nuclear medicine professionals (7 ESRs, *i.e.* <4% of the reported ESRs)

Seven events concerning nuclear medicine professionals were reported in 2021. They result from external contaminations,

GRAPH 8 Breakdown (in %) of ESRs in 2021



external exposure further to surface contaminations (at an automatic injector and a radiation-proof enclosure), an over–exposure of three workers who spent time in an area that should have been classified as restricted (room next to an RPD delivery air lock), an overexposure of workers during an intervention to cope with tank overflows and an unintentional exposure of workers and the public due to a delivery error. No exceeding of regulatory values was reported in 2021.

Significant events concerning the public (18 ESRs, *i.e.* <10% of the reported ESRs)

All the events concerning members of the public in nuclear medicine, with one exception, concerned the exposure of the foetus in women unaware of their pregnancy. The doses received had no consequences for the child to be born (source: ICRP, 2007). A *Patient safety* newsletter published in 2021 was devoted to this type of event (see point 2.7). The last ESR that concerned a member of the public was the exposure of a parent who, contrary to the procedure, remained in the examination room during X-ray emission of their child's CT scan.

Significant events concerning radioactive sources, waste and effluents (20 ESRs, *i.e.* 11% of the reported ESRs)

These ESR are mostly related to source losses/discoveries, the dispersion of radionuclides (resulting from overflows of radioactive effluent tanks), deliveries that do not comply with the licenses and unauthorised discharges of effluents into the environment (emptying of tanks, etc.).

SUMMARY

The inspections conducted in nuclear medicine reveal that radiation protection is duly taken into account in the large majority of the departments. Nevertheless, improvements must be made in effluent management in order to control discharges into the sewage networks, and in formalising the coordination of prevention measures with outside contractors (for maintenance, upkeep of the premises, the intervention of private practitioners, etc.) and the training of professionals. ASN notes a significant investment on the part of the nuclear medicine departments in the deployment of quality management systems and underlines the good adverse events reporting culture in the majority of departments inspected in 2021. The reported events nevertheless underline the need to regularly assess the drug administration process in order to control it, particularly in therapeutic procedures due to the potentially serious consequences of a drug administration error.

2.4 Fluoroscopy-guided interventional practices

Fluoroscopy-Guided Interventional Practices (FGIPs) group all the imaging techniques using ionising radiation to perform invasive medical or surgical procedures for diagnostic, preventive and/or therapeutic purposes, and surgical and medical procedures using ionising radiation for the purpose of guidance or verification.

They can be carried out in imaging departments dedicated to interventional imaging or in the operating theatre. If the fixed-facilty interventional radiology rooms have been designed and fitted out taking into account the use of ionising radiation, this cannot be said for all operating theatres, which are gradually undergoing compliance work. Moreover, these practices are growing rapidly and being used for diversified indications, concerning more and more surgeons and physicians from different disciplines who, although they are not specialists in ionising radiation, are becoming the practitioners of procedures involving ionising radiation. Furthermore, the devices used are increasingly sophisticated. On account of the new exposures involved, as much for the patients as for the professionals, who can be obliged to work close to the radiation, the FGIPs and operating theatres in particular –due to a less developed radiation protection culture– form part of ASN's national inspection priorities.

2.4.1 Presentation of the techniques

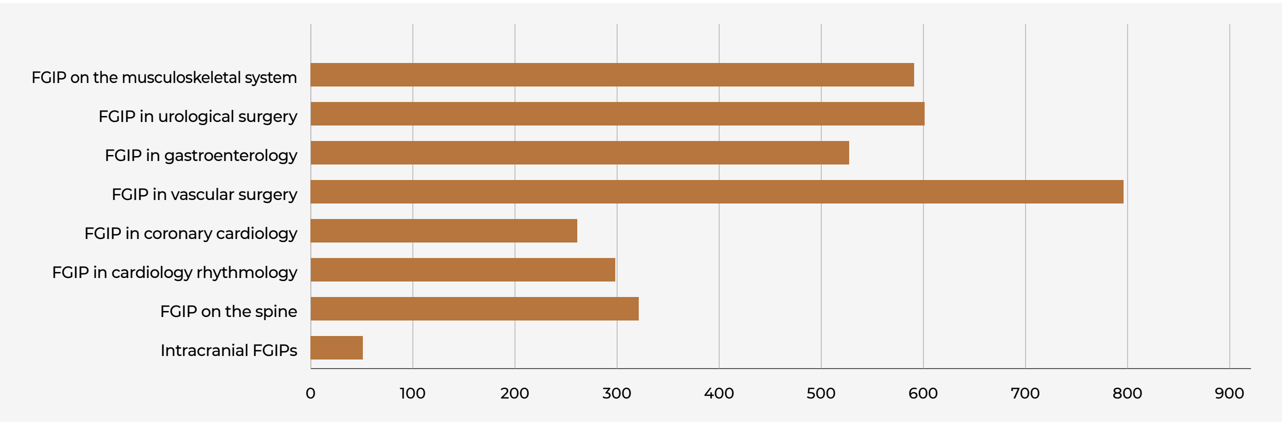
The health care centres

According to the codes of the common classification of medical procedures and the activity data reported by the health care centres to the Agency for Information on Hospital Care (AIHC), 905 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. The distribution of the number of centres by category of FGIP is shown in Graph 9.

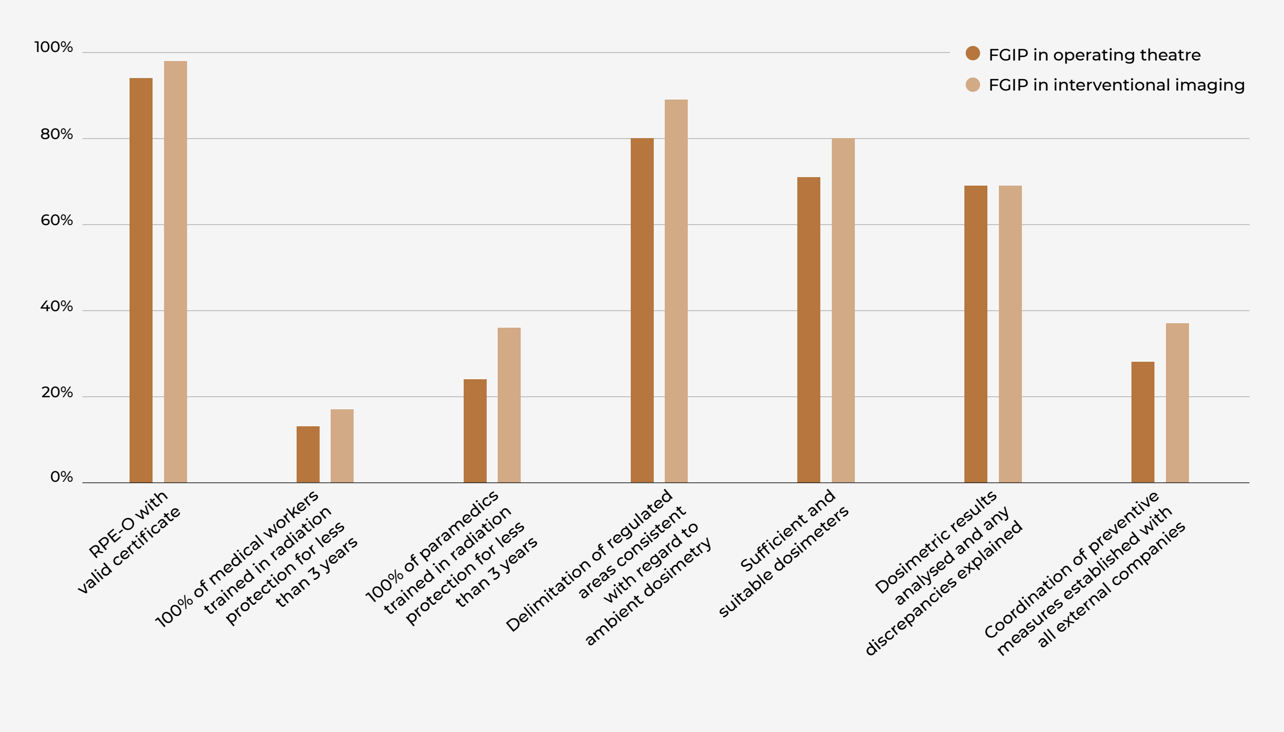
The equipment

The equipment items used in FGIPs are either fixed C-arm de–vices 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.

GRAPH 9 **Breakdown of the number of centres by category of fluoroscopy-guided interventional practices in 2021**



GRAPH 10 **Percentage conformity of the FGIP facilities inspected on the theme of radiation protection of medical professionals in 2021**



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 high-resolution spatial images. Practitioners can also use the subtraction method to obtain images, after injecting a contrast agent.

Operating theatres are being equipped with ever-more efficient and sophisticated medical devices. These are mobile CT scanners or fixed C-arms in "hybrid" rooms which combine the characteristics of a conventional surgical room with those of an interventional imaging room; this combination enables the surgeon to perform "mini-invasive" surgery with 2D and 3D imaging. Fixed CT scanners coupled to fixed C-arms are also beginning to be installed in health care centres. If used without specific dose-reduction technology, these devices can expose the patient and the medical staff –who most often work in the immediate vicinity of the patient– to higher dose levels than during other interventional practices. In these conditions, given the exposure risks for both the operator and the patient, practices must be optimised to reduce doses and ensure the radiation protection of operators and patients alike.

In 2021, the ASN regional divisions issued 335 FGIP notification acknowledgements, fewer than in 2020 due to the introduction of the new registration system, put in place since 1 July 2021. The need for better knowledge of the FGIPs implemented in the centres and the need to check the facilities for conformity with the applicable fitting out rules before they enter service, has led ASN, in a graded approach to the radiation protection risks, to subject these activities to this new system, which corresponds to a simplified authorisation.

2.4.2 Technical rules for fitting out 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 –the operating theatre in this case– to assess the risk in order to take appropriate radiation protection measures on entering or when inside the room. With regard to signalling systems, they are obligatory at the point of access to the operating rooms and inside the rooms when a device is present and to signal the emission of radiation. It is important to point out that many medical and non-medical staff members intervene in the operating theatre. Simple and practicable instructions must be favoured in a context of multiple risks and a complex environment. The signalling systems moreover count among the most effective prevention measures, as does the wearing of appropriate personal protective equipment and dosimeters by each operator, from the moment a restricted area is delimited due to the risk of exposure to ionising radiation.

2.4.3 Radiation protection situation in fluoroscopy-guided interventional practices

For several years now, ESRs have been regularly reported to ASN in the area of FGIPs. Although these events represent just a small proportion of all the medical events reported to ASN, the doses administered are high (for a diagnostic activity) 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).

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 (extremities, lens of the eye) and medical monitoring of the personnel, the provision of personal protective equipment. Concerning patients, particular attention is paid to the optimisation of doses delivered to the patient (putting in place DRLs and dose analysis), personnel training in patient radiation protection and the use of the medical devices.

As FGIPs are numerous, varied, and performed in many different departments (neuroradiology, interventional cardiology, interventional radiology and operating theatres) within a given centre, the inspection programme is established so that all the departments performing radiation-risk procedures are inspected every 5 years.

Inspection prioritisation is based on the number of procedures performed within a centre, the nature of these procedures, on which depend the radiation protection risks for the patients and professionals, the state of the facilities (conformity with the facility fitting-out rules), the radiation protection culture of the teams and current situation factors (ESRs, vulnerabilities identified in the previously inspected centres). Some 200 inspections are carried out each year.

In 2021, the operating theatre complexes of the university hospital centres and the largest hospital centres, and the departments licensed by the ARS (licensed for treatments in cardiac rhythmology, interventional cardiology and neuroradiology) were prioritised. Two hundred and ten centres were thus inspected, representing a total of 260 departments performing FGIPs. 55% of the inspections in 2021 were carried out in operating theatre departments. To adapt to the departments' organisational constraints on account of the Covid-19 pandemic, ASN inspected 17 centres entirely remotely and 38 in a mixed format with a remote inspection followed by a short on-site visit.

Characteristics of the inspected departments

The breakdown of the 260 departments having undergone an inspection in 2021 is as follows:

- The 117 interventional imaging departments inspected comprise 40 coronary angiography departments, 34 cardiac rhythmology departments, 34 interventional vascular and osteoarticular radiology departments and, lastly, 9 neuroradiology departments. 77 had at least one fixed C-arm, 12 had mobile C-arms, 9 had fixed CT scanners and 1 had a mobile CT scanner.
- Among the 143 operating theatre departments inspected in 2021, 123 had at least one mobile C-arm, 7 had fixed C-arms, 2 had a mobile CT scanner and 1 a fixed CT scanner.

Sixty-eighty per cent of the interventional imaging departments inspected have fixed C-arms, whereas in the operating theatres the physicians mainly use mobile C-arms (86%) to guide their surgical procedures.

Slightly over 50% of the departments inspected in 2021 have rooms that meet the requirements of ASN resolution 2017-DC-0591 of 13 June 2017 laying down the technical fitting-out rules and have established a conformity report. The situation is progressing in pace with the renovations or fitting-out of new rooms. Conducting compliance work in the oldest operating theatre rooms still poses problems, notably regarding the technical solutions for meeting the lighted signalling requirements in restricted areas. The conformity of interventional radiology departments is better than that of operating theatres (73 versus 53 respectively), and is mainly attributable to the more stringent technical constraints for the latter, with more complex work environments.

2.4.3.1 Radiation protection of medical professionals

In interventional imaging departments and in operating theatres

The radiation protection of the professionals is deemed highly satisfactory as regards the appointment of an RPE-O (about 97% of the inspected departments) and the implementation of radiological zoning in the facilities (85% of the inspected departments). For the remaining 3%, there is either no internal RPE-O or the external RPE-O is not present during the FGIPs as required by ASN resolution 2009-DC-0147 of 16 July 2009 (see Graph 10).

The lack of training of the medical professionals in occupational radiation protection is a recurrent finding in inspections, as much for the operating theatres as for the interventional imaging departments. Thus, for the operating theatre departments, only 13% of them have 100% of their medical personnel duly trained, and 24% of them have 100% of their paramedical personnel trained; the figures for the interventional imaging departments are 17% and 36% respectively. If we take 85% of the personnel trained as the indicator, the percentage of departments having trained their medical and paramedical personnel is respectively 24% and 32% for the operating theatres and 32% and 53% for the imaging departments. These figures are lower than those for 2020, very probably due to the health context, which led to the postponement of training courses and the noncompliance with the regulatory training frequencies noted in 2021.

Yet this training is essential to get a full grasp of the radiation protection risks and identify the risk situations, in order to be capable of implementing the prevention measure to ensure personnel safety, such as positioning of the equipment limiting exposures levels, the putting in place or wearing of collective and personal protective equipment respectively, the wearing of dosimetry devices, etc.

Lastly, the coordination of prevention measures with the outside contractors working in the interventional imaging departments and in the operating theatres is better in 2021, with 31% of the centres having formalised these coordination measures in a prevention plan signed with all the outside contractors, compared with 20% in 2020 for the centres that were inspected. This coordination is particularly insufficient in the case of private practitioners in the centres where they exercise their activity.

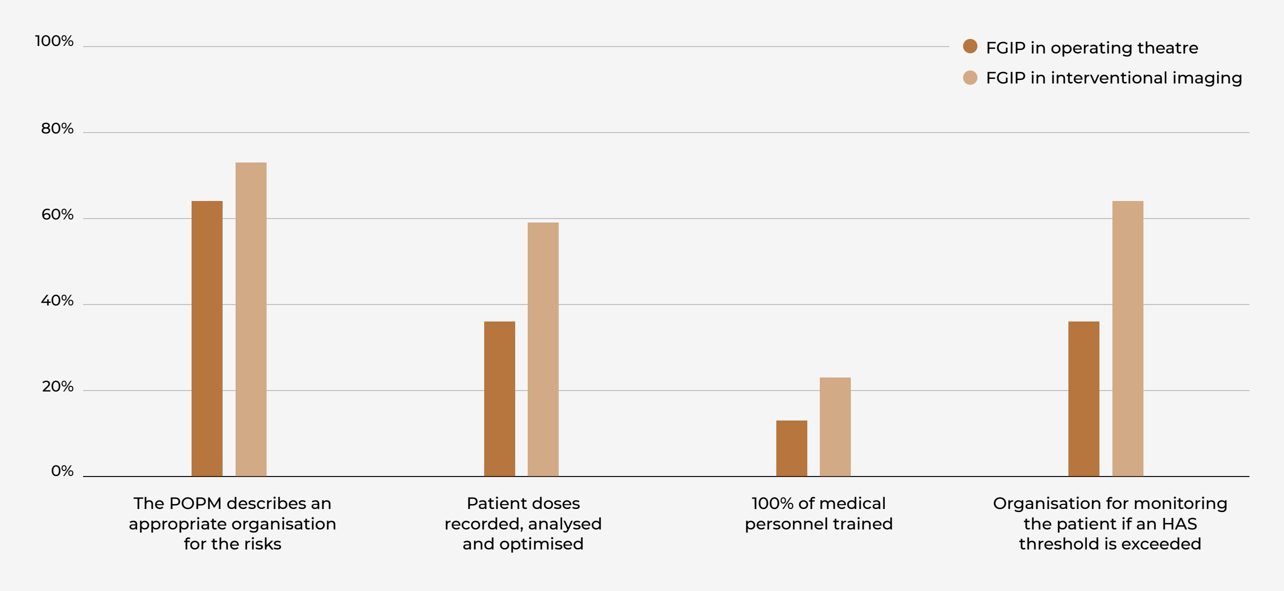
Spotlight on the operating theatres

In 71% of the inspected sites, the operating theatre professionals have dosimetric monitoring devices that are appropriate for worker exposure and in sufficient quantity, a less satisfactory situation than in 2020 (76% of the inspected sites).

The lack of appropriate dosimetric monitoring for certain fluoroscopy-guided procedures, particularly at the extremities, and the absence of medical monitoring of the practitioners, make it difficult to assess the radiation protection situation of these professionals in the operating theatres.

There are still organisational difficulties for the RPE-Os, who do not always have sufficient means to perform their duties in full. Furthermore, the time allocated to their duties is not always appropriate, particularly in some centres which rely on the RPE-O to ensure patient radiation protection. ASN notes that the RPE-Os analyse the dosimetric results in order to detect incorrect practices and remedy them. In operating theatres in the private sector, dosimetric monitoring, medical monitoring and, where applicable, employee monitoring, represent a recurrent difficulty.

GRAPH 11 **Percentage conformity of the FGIP facilities inspected on the theme of radiation protection of patients in 2021**



Radiation protection technical verifications

The external radiation protection technical verifications of were carried out at the required frequency in only 40% of the interventional imaging departments and 40% of the operating theatres, very much less than in 2020, when the figures for these radiation protection verifications were 79% and 69% respectively. When nonconformities had been identified, they had been corrected or were in the course of being corrected on the date of inspection in 53% of the cases. On account of the pandemic, a large number of departments were unable to perform the regulatory verifications in 2020, creating a backlog which explains the noncompliance with the verification frequency in 2021.

2.4.3.2 Radiation protection of patients

The findings from the inspections of 2021 reveal better integration of patient radiation protection (see Graph 11).

ASN thus observe that 73% of the departments performing FGIPs, compared with 60% in 2020, call upon a medical physicist and have a POPM describing the organisation in place for the involvement of a medical physicist, and defining their duties and times of presence on site according to the centre's activities.

In effect, close collaboration between operators and the medical physicist, with regular presence of the physicist in the departments, would allow better use of the equipment with the setting up of protocols adapted to the procedures performed, recording of the delivered doses and evaluation in the light of locally defined dosimetric reference levels. When medical centres use outside contractors for medical physics services, it is found that the optimisation approach is less well embraced. These findings have been noted in particular in the operating theatres, where the optimisation approach is rarely put in place, a situation that must be remedied.

In interventional imaging departments and in operating theatres

The observed shortcomings concern firstly the training of medical professionals in patient radiation protection (all the personnel are up to date in their training in 23% of the interventional imaging departments and 13% of operating theatres), and secondly, application of the principle of procedure optimisation in the setting of device parameters and the protocols used.

ASN observes that the recording, analysis and optimisation of doses are more widely deployed in the interventional imaging departments (59%) than in the operating theatres (36%). Likewise, patient monitoring in the event of exceeding the skin exposure threshold defined by the HAS[5], is formalised more often in interventional imaging departments (64%), which are more concerned by procedures leading to such levels of exposure, than in operating theatres (36%).

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. The patient dose archiving and analysis systems currently being deployed facilitate the development of local reference levels and alert levels per machine and per type of procedure. These systems are an asset for tracking the doses previously received by the patient and for patient monitoring, and they contribute to the principle of optimisation of the dose delivered to the patient.

The External (third-party) Quality Controls (EQC) of the medical devices are generally carried out at the right frequency and on the day of the inspection any previously detected nonconformities had been or were being corrected, equally well in the operating theatres as in the interventional imaging departments.

2.4.3.3 Significant events relating to fluoroscopy-guided interventional practices

An events recording system is in place for FGIPs in more than 76% of the sites inspected. 22 significant events were reported in this area in 2021 (14 of which concern the operating theatre):
- 10 events concerned overexposure of patients, some having led to tissue effects (one case of radiodermatitis);
- 9 concerned exposure of medical professionals;
- 3 concerned pregnant women exposed during a fluoroscopy-guided interventional examination; these women were unaware of their pregnancy at the time of exposure.

5. *Improving patient monitoring in interventional radiology and fluoroscopy-guided procedures– reducing the risk of deterministic effects of 21 May 2014.*

Five ESRs concern medical devices vigilance reports.

For the ESRs concerning FGIP patients, most of the overexposures are due to long and complex procedures (in interventional neuroradiology and in cardiology). Two events relate to deficiencies in communication between maintenance operators and the interventional cardiology departments. In the first case, changes of setting carried out during the EQCs were not communicated to the physicist, even though they had a dosimetric impact; as the medical device concerned was not connected to a Dose Archiving and Communication System (DACS), the changes were only discovered when the EQC report was received. In the second case, poor coordination between the different medical teams involved and insufficient knowledge of the medical device functionalities caused the event, which occurred during a long, complex and rarely performed procedure.

As for the ESRs concerning FGIP professionals, all of which occurred in the operating theatre, the reported overexposures result from accidental exposures without exceeding regulatory limits. Insufficient training of the professionals, some of whom did not regularly wear their dosimeter, and the absence of collective protective equipment were evidenced.

All the ESRs concerning the public involved accidental exposure of the foetus of pregnant women unaware of their pregnancy, who underwent a therapeutic procedure in the pelvic region. Feedback specific to this type of event was provided in one of the *Patient safety* newsletters in 2021 (see point 2.7).

SUMMARY

In the area of FGIPS, ASN still observes lateness in bringing premises into conformity with the technical design rules, especially in the operating theatres, and points out that this fitting-out work is fundamental for the prevention of professional risks. Deviations from regulations are still noted frequently in inspections, as much in radiation protection of the professionals as of the patients, with unsatisfactory situations regarding training in the radiation protection of workers and patients, prevention measures during concomitant activities, particularly with private practitioners. Nonconformities associated with noncompliance with the radiation protection technical verification frequencies were observed in 2021, as the departments were unable to carry them out in 2020 due to the pandemic. Although the use of medical physicists and formalising of the POPMs appears to be gaining ground, progress must be made in the implementation of the optimisation procedure, particularly in the operating theatres where doses are still insufficiently analysed. The reporting culture, however, is spreading, with the putting in place of events recording systems. The reporting of ESRs underlines that the maintenance operations, which can have consequences on the delivered doses, must be correctly supervised and that the training or practitioners in the use of the medical devices is crucial for control of the doses. Extensive work to raise the awareness of all the medical, paramedical and administrative professionals in the centres is still necessary to give them a clearer perception of the risks, especially for operating theatre staff. The recommendations for improving radiation protection in the operating theatres, issued in 2020, are still applicable in this respect.

2.5 Medical and dental radiodiagnosis

2.5.1 Overview of the equipment

Medical diagnostic radiology is based on the principle of differential attenuation of X-rays by 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, radiography of the thorax, chest-abdomen-pelvis CT scan, etc.).

The request for a radiological examination by the physician must be part of a diagnostic strategy taking account of the patient's known medical history, the question posed, the expected benefit for the patient, the examination exposure level and the dose history and the possibilities offered by other non-irradiating investigative techniques. A guide intended for general practitioners (*Guide to good medical imaging examination practices*) indicates the most appropriate examinations to request according to the clinical situations.

If the dose delivered does not in itself represent a radiation protection health risk, it is the large number of examinations carried out among the population that contributes significantly to the collective dose of medical origin.

2.5.1.1 Medical radiodiagnosis

Conventional radiology

Conventional radiology (producing radiographic images, 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 tree (arteriography) or venous tree (venography) 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 function at low voltage and offers high definition and high contrast, is at present approved by the HAS for breast cancer screening. ASN participates in a working group coordinated by the HAS which is assessing the position of tomosynthesis mammography in the breast cancer screening strategy.

The use of these devices is subject to quality controls defined by the ANSM. The planar imaging (2D) quality controls are defined by the ANSM resolution of 15 January 2020 which entered into effect on 15 January 2021. ASN was consulted in this context and gave a favourable opinion on the draft resolution relative to the internal and external quality controls of digital mammography facilities.

This resolution is currently being updated. The future resolution will update the checks performed on 2D mammography units and will introduce EQCs for the tomosynthesis devices.

Computed tomography
Computed tomography (CT) scanners use a beam of X-rays emitted by a tube which moves in a spiral around the body of the patient (helical CT scanner). These scanners produce a three-dimensional reconstruction of the organs with very much better image quality than that of conventional radiology devices. The number of rows of detectors (multidetector-row CT scanner, also known as a multislice or volumetry CT scanner) has been increased in recent machines, enabling thinner slices to be produced. An examination can comprise several helical image acquisitions of a specific anatomical region (with or without injection of a contrasting agent) or of different anatomical regions.

This technique can, like MRI, be associated with functional imaging provided by nuclear medicine in order to obtain fusion images combining functional information with structural information.

The technologies developed over the last few years have made examinations easier and faster to perform, and have led to an increase in exploration possibilities (example of dynamic volume acquisitions) and in the indications[(6)]. 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 re-construction. Computed tomography can thus provide consistent image quality at reduced doses. The devices can also be equipped with dose-reduction tools.

Teleradiology
Teleradiology provides the possibility of guiding the performance and interpreting the results of radiology examinations carried out in another location. The interchanges must be carried out in strict application of the regulations (relating to radiation protection and the quality of image production and transfer in particular) and professional ethics.

Essentially two interchange methods are used:
- Telediagnosis, which enables a doctor on the scene (*e.g.* an emergency doctor), who is not a radiologist, to perform the radiological examination and then send the results to a radiologist in order to obtain an interpretation of the images. If necessary the radiologist can guide the radiological operator during the examination and imaging process. In this case, the doctor on the scene is considered to be the doctor performing the procedure and assumes responsibility for it.
- Tele-expertise, which is an exchange of opinions between two radiologists, where one asks the other –the “expert radiologist” (teleradiologist)– for a remote confirmation or contradiction of a diagnosis, to determine a therapeutic orientation or to guide a remote examination. The data transmissions are protected and preserve medical secrecy and image quality.

Teleradiology involves many responsibilities which must be specified in the agreement binding the practitioner performing the procedure to the teleradiologist. The teleradiology procedure is a medical procedure in its own right, like all other imaging procedures, and cannot be reduced to a simple remote interpretation of images. Teleradiology therefore fits into the general health care organisation governed by the Public Health Code and obeys the rules of professional ethics in effect.

The Teleradiology Charter published by the French professional council of radiology (G4) was re-updated in 2020. It details the organisation of the two parts of teleradiology (telediagnosis and tele-expertise). In addition, a guide to good practices concerning the quality and safety of teleimaging procedures was published in May 2019 by the HAS. In this guide the HAS makes important clarifications concerning the proper use of “medical imaging examinations with remote interpretation”. It has the particularity of also addressing nuclear telemedicine, deployed with the aim of providing uniform coverage of the country. This guide does not consider mammography, which cannot be done by teleradiology because it necessitates clinical examination of the patient, including palpation.

2.5.1.2 Dental radiodiagnosis

Intra-oral radiography
Intra-oral radiography generators, which are usually mounted on an articulated arm, are used to take localised planar images of the teeth (the radiological detector is placed in the patient’s mouth). They operate with low voltage and current and a very short exposure time, of about a few hundredths of a second. This technique is usually associated with a digital system for processing and filing the radiographic image.

Panoramic dental radiography
Panoramic radiography (orthopantomography) gives a single picture showing both jaws in full, by rotating the radiation generating tube around the patient’s head for a few seconds.

Cone-beam computed tomography
Cone-beam computed tomography (3D) is developing very rapidly in all areas of dental radiology, due to the exceptional quality of the images produced (spatial resolution of about 100 microns). The trade-off for this better diagnostic performance is that these devices deliver significantly higher doses than in conventional dental radiology. They must be used in accordance with the recommendations given by the HAS in 2009, the conclusions of which indicate that it should only be proposed in certain duly selected clinical indications and reiterate that whatever the case, the fundamental principles of justification and optimisation must be applied.

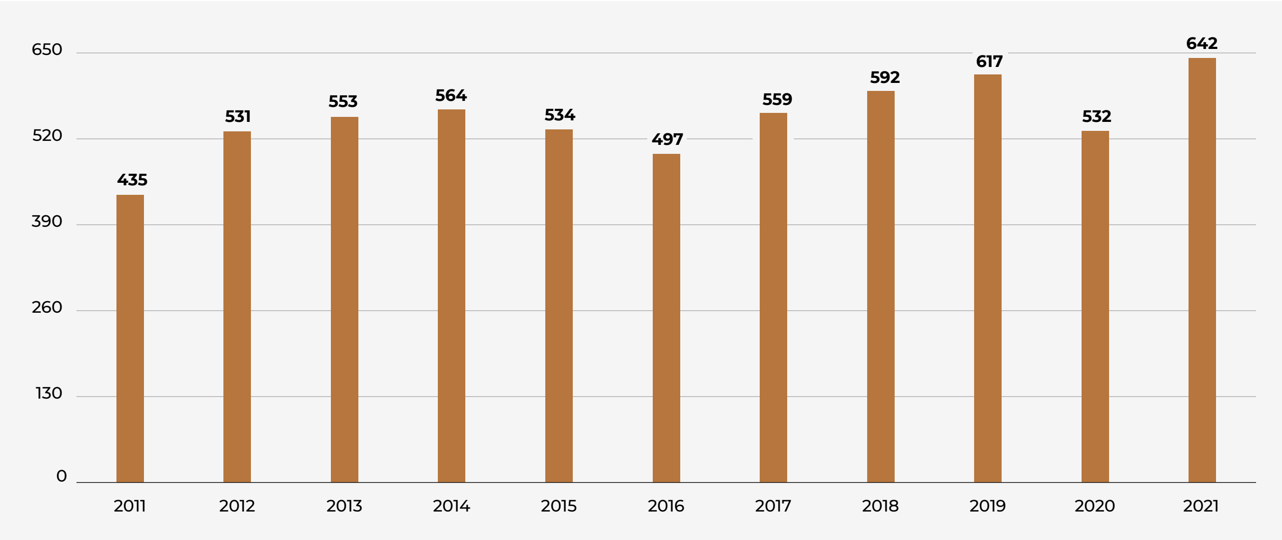
2.5.2 Technical fitting out rules for medical and dental radiodiagnosis facilities

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.

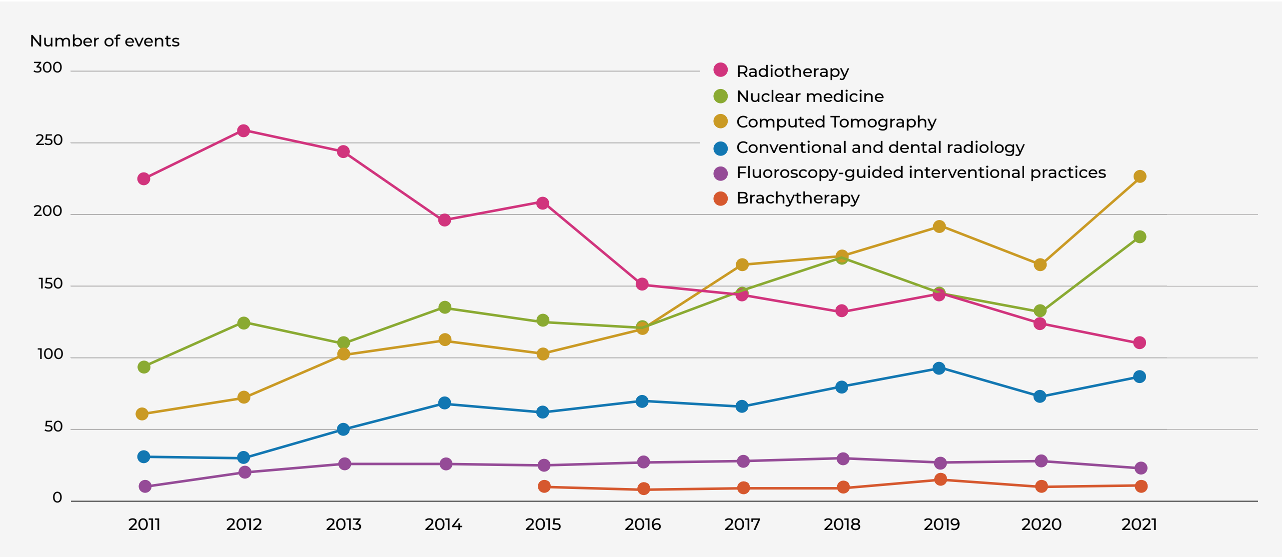
Mobile facilities, but which are often used in the same given room, such as the X-ray generators used in operating theatres, are to be considered as fixed facilities.

6. 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.

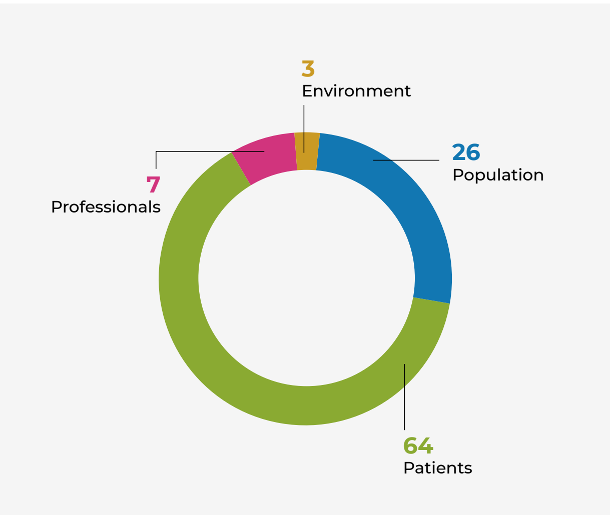
GRAPH 12 **Evolution of number of annual ESR reports from 2011 to 2021**



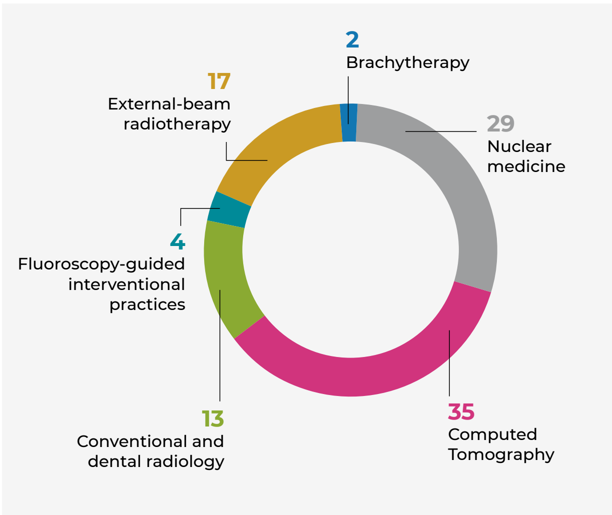
GRAPH 13 **ESRs by activity category during the 2011-2021 period**



GRAPH 14 **Breakdown (in %) of ESRs by area of exposure in 2021**



GRAPH 15 **Breakdown (in %) of ESRs by activity category concerned in 2021**



Radiological facilities must be fitted out in accordance with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017. This resolution applies to all medical radiology facilities, including computed tomography and dental radiology. It does not however apply to X-ray generators that are used exclusively for bedside radiography and excluding any use in fluoroscopy mode. A technical report demonstrating conformity of the facility with the requirements of the ASN resolution must be drawn up by the person or entity responsible for the nuclear activity.

Portable X-ray generating devices

ASN and the Dental Radiation Protection Commission (CRD) published an information notice in May 2016 reiterating the rules associated with the possession and utilisation of portable X-ray generating devices. "*The performance of radiological examinations outside a room fitted out for that purpose must remain the exception and be justified by vital medical needs, limited to intraoperative examinations or for patients who cannot be moved. Routine radiology practice in a dental surgery equipped with a compliant facility shall not be carried out using mobile or portable devices*".

This position is consolidated by that adopted by the Heads of the European Radiological protection Competent Authorities – HERCA), for which the use of such devices should be reserved for invalid patients, for the forensic medicine sector and for military personnel in the field of action (*Position statement on use of handheld portable dental X-ray equipment* –HERCA, June 2014).

2.5.3 Radiation protection situation: spotlight on the CT scanner

More than 900 facilities possess nearly 1,250 CT scanners. Since 1 July 2021, CT scanners come under the registration system (see point 1.3.3).

In France, medical applications represent the primary source of artificial exposure of the public to ionising radiation, chiefly due to CT examinations (see chapter 1). Imaging examinations have proven their benefits for both diagnosis and treatment. The issue at stake however is to avoid examinations that are not really necessary or that offer no real benefit for the patients and the results of which could be obtained by other available, non-irradiating techniques. In order to control the increase in doses observed over these last few years, two successive dose control plans (see chapter 1) have been developed in recent years. Issued in this context, ASN resolution 2019-DC-660 of 15 January 2019 relative to quality assurance in medical imaging contributes to the control of doses by requiring operational implementation of the justification and optimisation principles. Each year, ASN conducts about twenty inspections in computed tomography, adopting a graded approach by targeting the Accident & Emergency (A&E) departments (most often shared with the radiology department) and the paediatric CT scanners because of the vulnerability of the population concerned. Numerous ESRs occur in CT examinations in the A&E departments and are caused by poor communication or organisation between the A&E staff and radiology. The inspections conducted by ASN focus in particular on the verification of proper application of the requirements defined by ASN resolution 2019-DC-0660 of 15 January 2019 relative to quality assurance in medical imaging, especially the justification of the examinations and optimisation of the procedures. The majority of the inspected departments moreover have recourse to teleradiology to ensure Out-Of-Hours (OOH) service. The activity carried out in this context also enters into the checks performed in inspections. In 2021, ASN carried out 21 inspections in the area of computed tomography.

On the whole, the organisation for the examination of patients at risk (vulnerable patients, children, pregnant women, etc.) is formalised and duly followed (66% of centres) and more than half of the inspected CT scanners have a Dose Archiving and Communication System (DACS). Furthermore, the various stages in the verification of the examination requests (reception, prior analysis, validation, substitution, procedure cancellation) are well formalised (70% of centres). The medical staff however are insufficiently trained in patient radiation protection (50% of centres) and their qualification at the work station is insufficiently carried out and formalised (30% of centres).

2.5.4 Significant events reported in medical and dental radiodiagnosis

313 ESRs were reported in medical and dental radiodiagnosis:
- 85 in conventional radiology, of which 45 concerned women unaware of their pregnancy;
- 226 in computed tomography, of which 98 concerned women unaware of their pregnancy;
- two in dental radiology.

The ESRs primarily concern women unaware of their pregnancy (143), failings in the patient management process (identity monitoring error, protocol errors, etc.) and situations of inappropriate exposure of professionals (12). Checks by the medical staff for possible pregnancy in patients must be further increased. A specific *Patient safety* newsletter was produced and published in September 2021 to improve the organisational measures to reduce the number of events of this type (see point 2.7).

In addition, an "Experience feedback" sheet was put on line in 2021 further to an ESR reported in 2020 concerning the overexposure of a cohort of 32 patients, including 10 children, in a health care centre which had just installed a new CT scanner using spectral technology for its A&E department. The aim is to share the corrective actions put in place by the centre in order to render safe the use of a new CT scanner that employs a new technology, through proper identification of the different steps and formalising them, particularly in the quality assurance system, to prevent the recurrence of this type of event.

SUMMARY

ASN's oversight in the area of computed tomography focuses essentially on observance of the principle of justification to avoid delivering unnecessary doses to patients. In this respect, during the inspections it conducted in 2021, ASN still finds a lack of traceability of justification of the examinations and of the difficulties medical professionals encounter in applying the principle. The lack of training of the referring practitioners, the lack of use of the *Guide to good medical imaging practices*, and the lack of justification protocols for the most common procedures partly explain the fact that the justification principle is not always applied. Furthermore, the lack of availability of other diagnostic methods (MRI, ultrasonography) and of health professionals limits the replacement of irradiating procedures by non-irradiating procedures. Alongside this, ASN notes that the examination protocols are optimised, the quality controls of the medical devices are carried out at the required regulatory frequency and that the medical physics resources are appropriate for the tasks to perform.

2.6 Blood product irradiators

2.6.1 Presentation of the techniques

The irradiation of blood products is used to prevent post-transfusion reactions in blood-transfusion patients. The blood bag is irradiated with a dose of about 20 to 25 grays.

Since 2009, source irradiators have been gradually replaced by X-ray generators, for which notification to ASN has been required since 2015. In 2019, the inventory stood at 29 irradiator devices equipped with X-ray generators.

2.6.2 Technical rules applicable to facilities

A blood product irradiator must be installed in a dedicated room designed to provide physical protection (against fire, flooding, break-in, etc.). Access to the device, which must have a lockable control console, is limited to the persons authorised to use it.

The fitting out of premises accommodating irradiators equipped with X-ray generators must comply with the provisions of ASN resolution 2017-DC-0591 of 13 June 2017.

2.7 Significant radiation protection events

The number of ESRs reported to ASN in 2021 (642) has increased compared with the preceding years, and especially with respect to 2020 (a low year with 532 ESRs for all the activities combined, with the Covid-19 pandemic very probably being one of the explanatory factors). ASN reiterates the importance of reporting ESRs in order to define shared experience feedback and improve radiation protection.

Graphs 12 and 13 illustrate how the number of ESRs has evolved by activity category since 2011. Graphs 14 and 15 illustrate the breakdown of the number of ESRs in 2021 by area of exposure (environmental impact, exposure of the general public, exposure of patients, exposure of professionals) and by category of activity.

In view of the events reported to ASN in 2021, the most significant findings concerning patient radiation protection are, in radiotherapy, wrong-side errors, identity monitoring errors and calibration errors (four ESRs rated level 2 on the ASN-SFRO scale, see box); in brachytherapy, the unidentified disconnection of an applicator source transfer tube (one ESR rated level 3 on the ASN-SFRO during an HDR brachytherapy treatment, see box); in diagnostic nuclear medicine, identification errors, that is to say administration of an RPD to the wrong patient as a result of organisational and human malfunctions, usually in the context of heavy workloads; in therapeutic nuclear medicine, one identity monitoring error with no consequences (underdosing) and two leaks of yttrium-90 microspheres towards areas that should not have been exposed. Lastly, most of the ESRs concerning FGIP patients are due to long and complex procedures (in interventional neuroradiology and cardiology). Two other events having led to overexposures relate to deficiencies in communication between maintenance operators and the interventional cardiology departments.

Pregnant women unaware of their pregnancy represent one third of the ESRs reported annually to ASN, *i.e.* about 200 cases per year. In order to share feedback on these situations, a *Patient safety* newsletter published in 2021 was devoted to this subject –which essentially concerns diagnostic examinations– in order to increase the vigilance of the medical teams and raise awareness in women of reproductive age to limit the occurrence of such exposures.

PATIENT SAFETY NEWSLETTER "IONISING RADIATION: LIMITING EXPOSURES OF WOMEN UNAWARE OF THEIR PREGNANCY"

The exposure to ionising radiation of pregnant women who were unaware of their pregnancy is the main cause of ESRs reported to ASN in computed tomography and conventional radiology. This represents nearly 200 cases per year, or one third of the 600 ESRs reported annually to ASN.

With nearly one million pregnancies per year in France (total number of pregnancies, including births and pregnancy terminations), the issue concerns all health professionals, whether referring patients or performing diagnostic or therapeutic procedures, because they are all liable to treat female patients of reproductive age.

The Multidisciplinary Working Group, through this newsletter, calls for the teams to step up their vigilance to avoid delivering doses to the embryo or foetus. If a woman is known to be pregnant, only the radiological examinations necessary for her health are to be carried out. All the professionals (secretary, radiologist, physicist, general practitioner, mid-wife, radiologist or other specialist) must share the same concern to raise patient awareness and to investigate possible pregnancies.

3 // Synthesis and prospects

Although the year 2021 was also marked by the Covid-19 pandemic, the disturbances in the health care system did not lead ASN to cut back its inspection programme. More specifically, the inspection frequencies defined according to the risks entailed by the various nuclear activities in the medical sector were duly respected. Twenty percent of the inspections were conducted remotely, either entirely or in part.

On the basis of the inspections carried out in 2021, ASN considers that, despite the impact of the Covid-19 pandemic on the functioning of the health services, the radiation protection situation in the medical field is comparable with that of the 2019 and 2020, reflecting the fact that the departments have been able to adapt and maintain a good standard of radiation protection. Thus, no major deficiency was detected in the areas of radiation protection of medical professionals, patients, the public or the environment. Nevertheless, due to the pandemic, lateness in performing the radiation protection technical verifications for the FGIPs has been observed, leading to noncompliance with the regulatory frequencies. In addition to this, the coordination of prevention measures when third-party interventions are involved, particularly those of private practitioners, must be reinforced in nuclear medicine and FGIPs. Lastly, raising awareness in operating theatre personnel –users who are not ionising radiation specialists, such as surgeons– remains necessary for a better perception of the risks and embracing of radiation protection measures in this sector where, moreover, the work to bring the premises into conformity is progressing too slowly. The events reported to ASN highlight that the formalising of practices, the explanation of validations, the supervision of maintenance services and the reporting of adverse events are essential to enhance the safety of practices.

In 2022, ASN will continue its inspections in radiotherapy, nuclear medicine, FGIPs and computed tomography, in line with the inspections carried out in 2021, paying particular attention to the vulnerabilities identified in 2021 (frequency of radiation protection verifications, coordination of prevention measures during third-party interventions, notably those of private practitioners, training in the radiation protection of workers and patients and in the use of the equipment, bringing operating theatres into conformity with the fitting-out rules in effect) and the updating of the new quality assurance obligations for therapeutic nuclear activities which came into effect in July 2021 (ASN resolution 2021-DC-0708 of 6 April 2021).

With regard to its regulatory role, in 2022 ASN will continue revising resolution 2008-DC-0095 of 29 January 2008 setting out the technical rules for the elimination of effluents and waste contaminated by radionuclides, along with its contribution to the regulatory work conducted by the Minister responsible for health concerning the duties of medical physicists, the organisation of medical physics and the deployment of clinical audits. ASN will also start the updating of resolution 2010-DC-0192 of 22 July 2010 relative to the detailed content of the information that must be included in first-time license or license-renewal applications.

Lastly, the fast development of new radionuclides and vectors in nuclear medicine, of new, ever-more efficient and sophisticated medical devices, of new practices and clinical indications in the various medical nuclear activity sectors, remains a major concern for ASN. Working in collaboration with the various institutional actors of the health sector, the learned societies, and assisted by its groups of experts and the Canpri in particular, ASN will work to identify the radiation protection risks, to promote and facilitate –in an innovation-driven context– safe operating frameworks, paying particular attention to the generic justification of these new techniques in order to assess the radiation protection benefits for patients.

08

Sources of ionising radiation and their industrial, veterinary and research applications

08 SOURCES OF IONISING RADIATION AND THEIR INDUSTRIAL, VETERINARY AND RESEARCH APPLICATIONS

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 practices/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”.

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

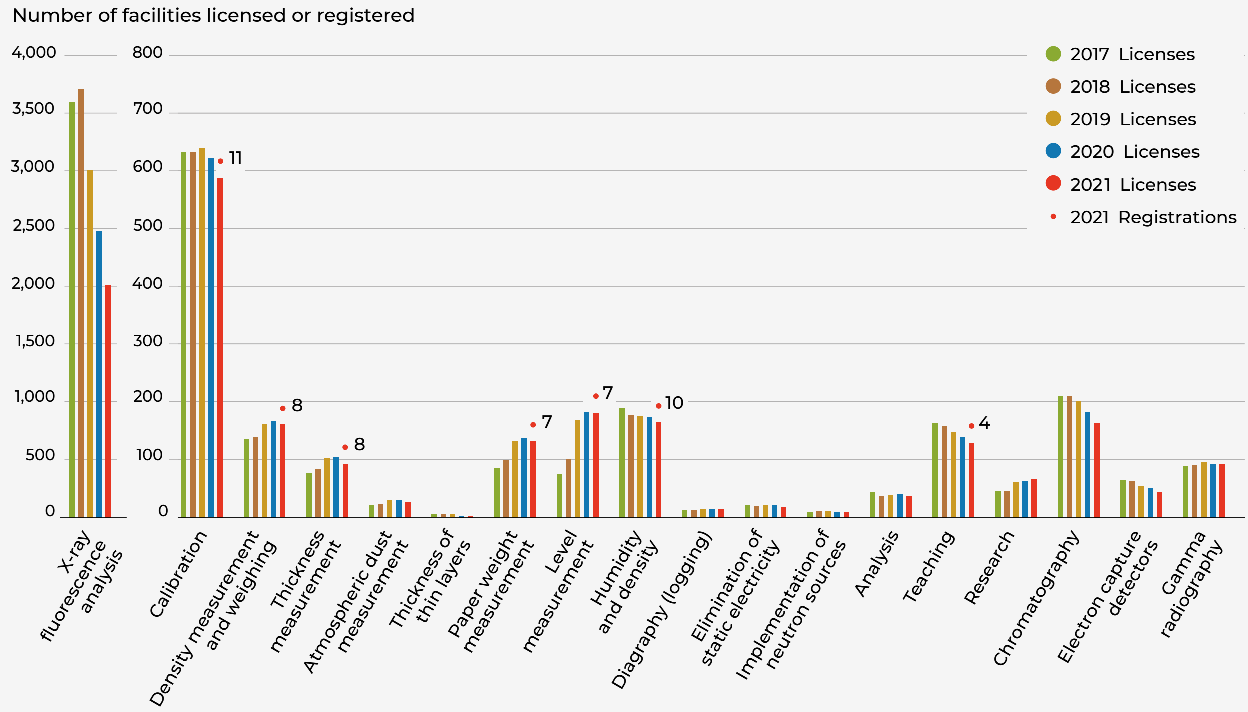
The operating principle of these physical parameter verification devices is the attenuation of the signal emitted: the difference between the emitted signal and the received signal can be used to assess the desired information.

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).

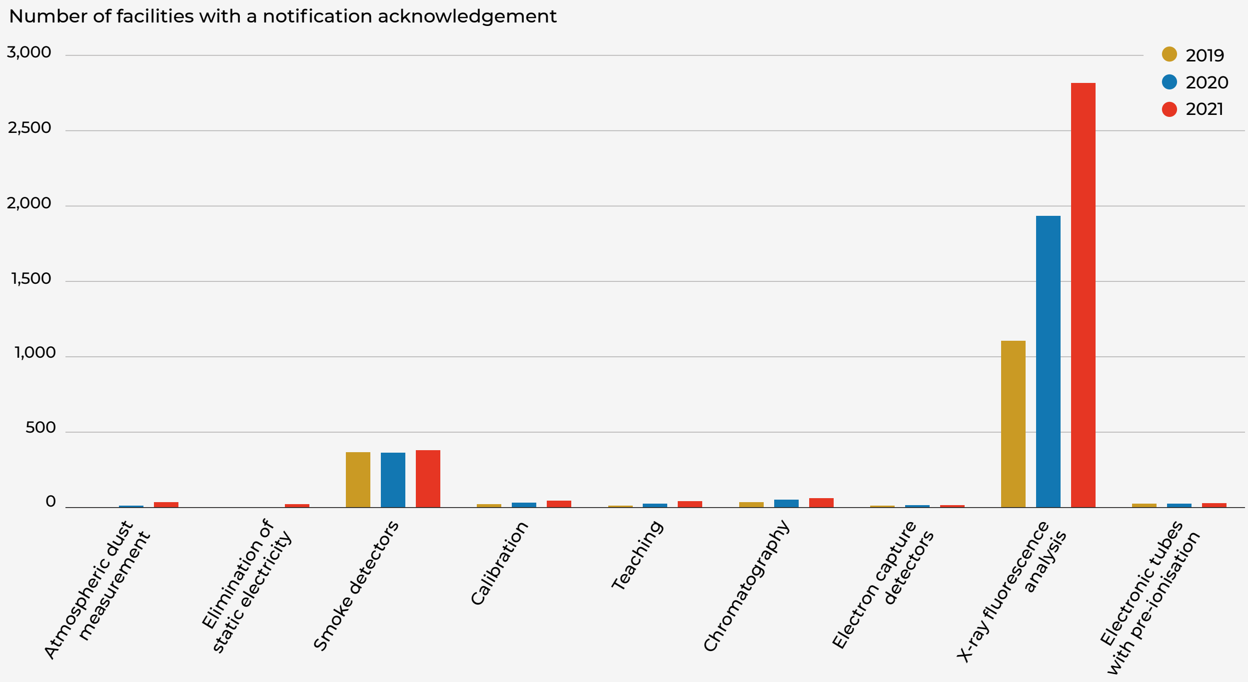
The sources are used for the following purposes:
- Atmospheric dust measurement: the air is permanently filtered through a tape placed between the source and detector and running at a controlled speed. The intensity of radiation received by the detector depends on the amount of dust on the filter, which enables this amount to be determined. The most frequently used sources are carbon-14 (with an activity of 3.5 megabecquerels –MBq) or promethium-147 (with an activity of 9 MBq). These measurements are used for air quality monitoring by verifying the dust content of discharges from plants.
- Paper weight measurement: a beam of beta radiation passes through the paper and hits a detector situated opposite. The signal attenuation on this detector indicates the density of the paper, and therefore its weight per unit area. The sources used are generally krypton-85 or promethium-147, with activities of 3 GBq at the most.
- Liquid level measurement: a gamma radiation beam passes through the container holding the liquid. It is received by a detector positioned 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, depending on the case, americium-241 (with an activity of 1.7 GBq) or caesium-137 –barium-137m (with an activity of 37 MBq);
- Density measurement and weighing: the principle is the same as for the above two measurements. The sources used are generally americium-241 (with an activity of 2 GBq), caesium-137 –barium-137m (with an activity of 100 MBq) or cobalt-60 (with an activity of 30 GBq).
- Soil density and humidity measurement (gammadensimetry), particularly in agriculture and public works. These devices function with a source of caesium-137 and a pair of americium-beryllium sources.
- Diagraphy (logging), which enables the geological properties of the subsoil to be examined by inserting a measurement probe containing a source of cobalt-60, caesium-137, americium-241 or californium-252. Some sources used are high-activity sealed sources.

USE OF SEALED RADIOACTIVE SOURCES BY END-PURPOSE

GRAPH 1A **Breakdown of licenses or registrations for sealed radioactive sources**



GRAPH 1B **Breakdown of notifications for sealed radioactive sources**



1.1.2 Neutron activation

Neutron activation consists in irradiating a sample with a flux of neutrons to activate the atoms in the sample. The number and the energy of the gamma photons emitted by the sample in response to the neutrons received are analysed. The information collected is used to determine the concentration of atoms in the analysed material.

This technology is used in archaeology to characterise ancient objects, in geochemistry for mining prospecting and in industry (study of the composition of semiconductors, analysis of raw mixes in cement works).

Given the activation of the analysed material, this requires particular vigilance with regard to the nature of the objects analysed. Articles R. 1333-2 and R. 1333-3 of the Public Health

Code prohibit the use of materials and waste originating from a nuclear activity for the manufacture of consumer goods and construction products if they are, or could be, contaminated by radionuclides, including by activation. Waivers may however be granted in a very limited number of cases (see point 2.2.1).

1.1.3 Other common applications

Sealed radioactive sources can also be used for:
- industrial irradiation, particularly for sterilization (see point 3.2.1);
- gamma radiography, which is a non-destructive inspection method (see point 3.3.1);
- eliminating static electricity;
- calibrating radioactivity measurement devices (radiation metrology);
- practical teaching work concerning radioactivity phenomena;
- detection by electron capture. This technique uses sources of nickel-63 in gaseous phase chromatographs and can be used to detect and dose various chemical elements;
- ion mobility spectrometry used in devices that are often portable and used to detect explosives, drugs or toxic products;
- detection by X-ray fluorescence. This technique is used in particular for detecting lead in paint. The portable devices used today contain sources of cadmium-109 (half-life 464 days) or cobalt-57 (half-life of 270 days). The activity of these sources can range from 400 MBq to 1,500 MBq. This technique, which uses a large number of radioactive sources nationwide (nearly 4,000 sources), is the result of a legislative system designed to prevent lead poisoning in children by requiring a check on the lead concentration in paints used in residential buildings constructed before 1 January 1949 for any sale, new rental contract, or work significantly affecting the coatings in the common parts of the building.

Graphs 1A and 1B 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 and the following diagrams for each activity;
- the breakdown between the licensing, registration and notification system (radioactive sources and electrical devices emitting ionising radiation) for a given application is not yet stabilised, because the changes of administrative system concerning the nuclear activities subject to notification since 1 January 2019, will extend through to 31 December 2023 (see point 2.4.2) and until 1 July 2026 (see point 2.4.3) for those subject to registration since 1 July 2021.

1.2 Uses of unsealed radioactive sources

The main radionuclides used in the form of unsealed sources in non-medical applications are phosphorus-32 or 33, carbon-14, sulphur-35, chromium-51, iodine-125 and tritium. They are used, in particular, in research and in the pharmaceutical sector. They constitute a powerful investigative tool in cellular and molecular biology. Using radioactive tracers incorporated into molecules is common practice in biological research. There are also a number of industrial uses, for example as tracers or for calibration or teaching purposes. Unsealed sources are used as tracers for measuring wear, detecting leaks or friction spots, building hydrodynamic models and in hydrology.

As at 31 December 2021, 710 facilities were authorised to use unsealed radioactive sources (to which can be added 15 facilities covered by the registration system).

Graph 2 specifies the number of facilities authorised to use unsealed radioactive sources, according to the various listed applications, in the last five years.

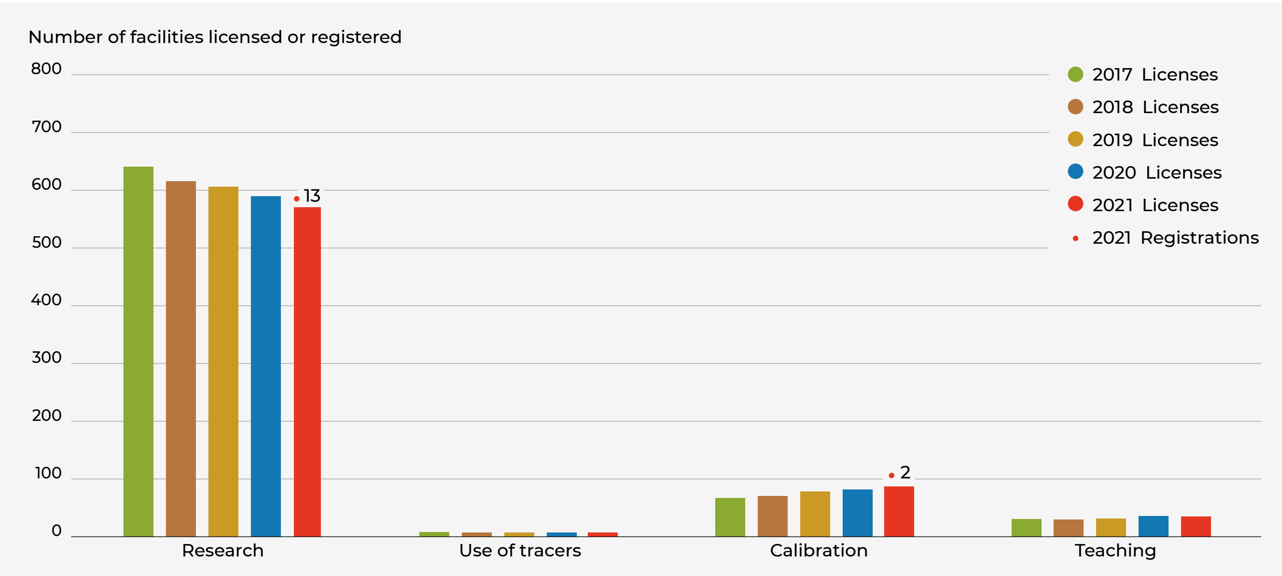
1.3 Uses of electrical devices emitting ionising radiation

1.3.1 Main industrial applications

In industry, electrical devices emitting ionising radiation are used mainly in non-destructive testing, where they replace devices containing radioactive sources.

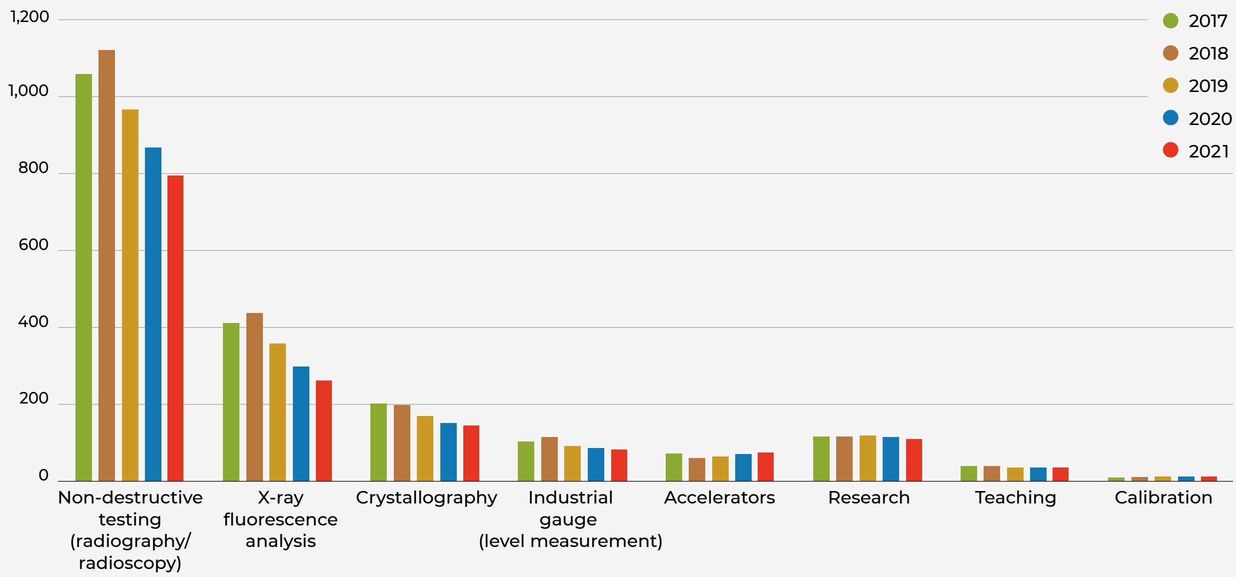
Graphs 3A and 3B show the number of facilities using electrical devices generating ionising radiation in the listed applications under the licensing, registration or notification systems respectively. They illustrate the diversity of these applications and their development over the last five years. This development is closely

GRAPH 2 Use of unsealed radioactive sources by end-purpose

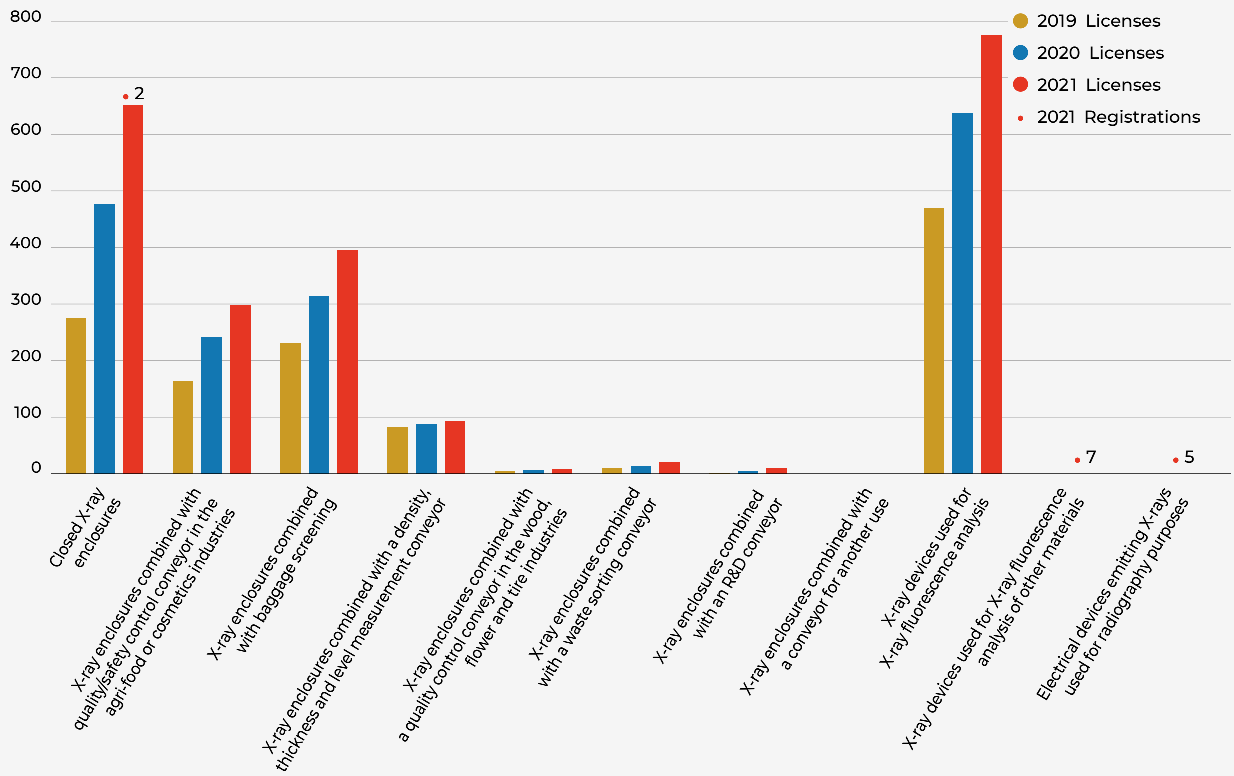


USE OF ELECTRICAL DEVICES GENERATING IONISING RADIATION BY END-PURPOSE (VETERINARY SECTOR EXCLUDED)

GRAPH 3A **Breakdown of licenses for electrical devices emitting ionising radiation**



GRAPH 3B **Breakdown of notifications or registrations of electrical devices emitting ionising radiation**



related to the regulatory changes which have gradually created a new system of licensing or notification, and more recently registration (see point 2.4.3), concerning the use of these devices. At present, measures to bring the professionals concerned into compliance are very widely engaged in many activity sectors.

The electrical devices emitting ionising radiation are chiefly X-ray generators. They are used in industry for non-destructive structural analyses (analysis techniques such as tomography, diffractometry, also called X-ray crystallography, etc.), checking the quality of weld beads or inspecting materials for fatigue (in aeronautics, in particular).

These devices, which work using the principle of X-ray attenuation, are also used as industrial gauges (measurement of drum filling, thickness measurement, etc.), inspection of goods containers or luggage, as well as the detection of foreign bodies in foodstuffs.

The increase in the number of types of device available on the market can be explained more particularly by the fact that when possible, they replace devices containing radioactive sources. The advantages of this technology with regard to radiation protection are linked in particular to the total absence of ionising radiation when the equipment is not in use. Their utilisation does nevertheless lead to worker exposure levels that are comparable with those resulting from the use of devices containing radioactive sources.

Baggage inspection

Ionising radiation is used constantly in security screening checks, whether for the systematic verification of baggage or to determine the content of suspect packages. The smallest and most widely used devices are installed at the inspection and screening checkpoints in airports, in museums, at the entrance to certain buildings, etc.

The devices with the largest inspection tunnel areas are used for screening large baggage items and hold baggage in airports, as well as for air freight inspections. These devices are supplemented by tomographs, which give a series of series of cross-sectional images of the object being examined.

The irradiation zone inside these appliances is sometimes 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 use of X-ray scanners on people during security checks is prohibited 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 built by experimenters themselves with parts obtained from various suppliers (goniometer, sample holder, tube, detector, high-voltage generator, control console, etc.)

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 2021, the profession counted 19,530 veterinary surgeons, some 13,300 non-veterinarian employees (counted in full-time equivalents) and 6,644 veterinary facilities. Veterinary surgeons use diagnostic radiology devices for purposes similar to those used in human medicine. Veterinary diagnostic radiology activities essentially concern pets.

- some 5,250 veterinary facilities in France have at least one diagnostic radiology device;
- around 70 Computed Tomography (CT) scanners are used in veterinary applications;
- other practices drawn from the medical sector are also implemented in specialised centres: scintigraphy, brachytherapy, external-beam radiotherapy and interventional radiology.

The treatment of large animals (mainly horses) requires the use of more powerful devices installed in specially equipped premises (radiography of the pelvis, for example) and portable X-ray generators, used indoors –whether in dedicated premises or not– or outdoors.

In order to better ensure compliance with regulatory requirements, ASN introduced a notification system in 2009 for what were termed "pet-care activities" involving less serious radiation risks (see point 2.4.2). This simplification has led to regularisation of the administrative situation of a growing number of veterinary facilities (see Graph 4).

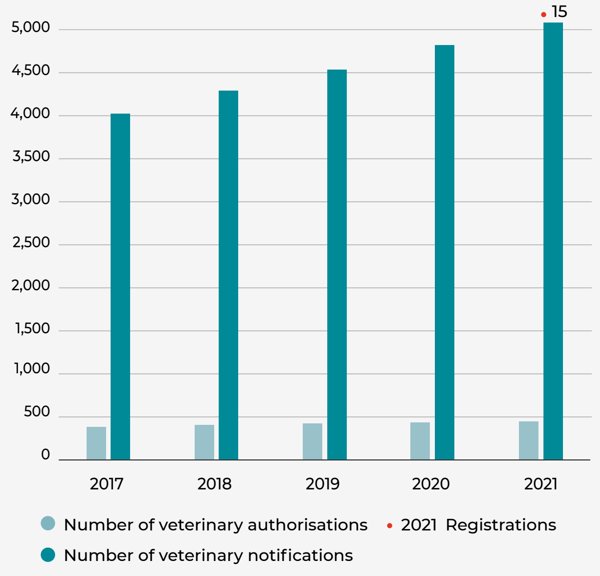
To continue this adaptation of the regulatory requirements to the radiation exposure risks, as from July 2021 all activities using electrical devices emitting ionising radiation for veterinary diagnostic radiology come under the registration system (see point 2.4.3), with the exception of pet-care activities which remain eligible for the notification system. Consequently, only a few high-risk activities (brachytherapy, external-beam radiotherapy and interventional radiology) stemming from the medical sector will still be subject to licensing.

The devices used in the veterinary sector are sometimes derived from the medical sector. However, the profession is increasingly adopting new devices specially developed to meet its own specific needs.

With regard to veterinary clinics, the administrative situation has been continuously improving for a number of years now. At the end of 2021, ASN counted 5,500 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).

GRAPH 4 Use of electrical devices generating ionising radiation for veterinary activities



During its various oversight actions (carried out as and when required or during thematic campaigns) covering all veterinary activities involving ionising radiation, ASN has seen the results of the efforts the veterinary bodies have made in the last few years to comply with the regulations and has noted good field practices in the inspected veterinary facilities, including in particular:
- the presence of in-house Radiation Protection Expert-Officers (RPE-Os) in the majority 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 extensive 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 regularly takes part in meetings with the profession's national bodies (more particularly the veterinary radiation protection commission) jointly with the General Directorate for Labour (DGT).

1.3.3 The other uses of electrical devices emitting ionising radiation

This category covers all the electrical devices emitting ionising radiation other than those mentioned above and which are not concerned by the licensing, registration or notification exemption criteria set out in Article R. 1333-106 of the Public Health Code.

This category includes, for example, devices generating ionising radiation but not used for this property, namely ion implanters, electron-beam welding equipment, klystrons, certain lasers, certain electrical devices such as high-voltage fuse tests.

Lastly, some applications use particle accelerators (see point 3.3.1).

2 // Regulation of industrial, research and veterinary activities

2.1 The Authorities regulating the sources of ionising radiation

ASN is the authority that grants the licenses, issues the registration decisions and receives the notifications, depending on regulatory regime applicable to the nuclear activity concerned.

However, to simplify administrative procedures for licensees already licensed under another system, the Public Health Code makes specific provisions. This concerns more specifically:
- The radioactive sources held, manufactured and/or used in installations licensed under the Mining Code (Article L. 162-1) or, for unsealed radioactive sources, those held, manufactured and/or used in Installations Classified for Protection of the Environment (ICPEs) which come under Articles L. 511-1 to L. 517-2 of the Environment Code, and have a licensing system. The Prefect is responsible for including, in the licenses he delivers, radiation protection requirements for the nuclear activities carried out on the site.
- The installations and activities relating to national defence, for which Defence Nuclear Safety Authority (ASND) is responsible for regulating the radiation protection aspects.
- The installations licensed under the legal system governing BNIs. ASN regulates the radioactive sources and electrical devices emitting ionising radiation necessary for the operation of these installations under this system. Holding and using other sources within the bounds of the BNI remain subject to licensing pursuant to Article R. 1333-118 of the Public Health Code.

These provisions do not exempt the licensee from complying with the requirements of the Public Health Code, and in particular those relative to source acquisition and transfer; they do not apply to the distribution, importing and exporting of radioactive sources, which remain subject to ASN licensing under the Public Health Code.

Since the publication of Decree 2014-996 of 2 September 2014 amending the nomenclature of the ICPEs, some facilities previously licensed by Prefectoral Order under the Environment Code for the possession and use of sealed radioactive sources are now regulated by ASN, under the Public Health Code. The requirements applicable to these installations are now those of the Public Health Code. The provision of Article 4 of the abovementioned Decree, which provided that the license or notification issued under the former section 1715 continued to be deemed a license or notification under the Public Health Code, on condition that no change was made to the nuclear activity, for a maximum period of five years, that is to say until 4 September 2019 at the latest, has now ended. These facilities must therefore have a license or a notification acknowledgement issued under the Public Health Code.

Only the facilities possessing unsealed radioactive substances in quantities exceeding 1 tonne (t) or managing radioactive waste in quantities exceeding 10 cubic metres (m^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.

It 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 (Order of 18 November 2011 from the Ministers responsible for health and construction, ASN opinion 2011-AV-0105 of 11 January 2011 and ASN opinion 2011-AV-0124 of 7 July 2011). In 2017, this waiver was renewed for ten years for two cement works, the third cement works mentioned in the initial Order of 2011 having closed (Order of 19 April 2017 of the Ministers responsible for health and construction respectively, ASN opinion 2017-AV-0292 of 7 March 2017). In 2019, another waiver was granted for a third cement works (Order of the Ministers responsible for health and ecological transition of 4 December 2019, ASN opinion 2019-AV-0333 of 1 August 2019). The opinion of ASN was requested in 2020 for a project concerning a waiver for the use of a neutron analysis device in a cement works of the CALCIA group; it is currently being reviewed on the basis of the additional elements requested of the licensee.

It was also applied in 2014 for light bulbs containing very small quantities of radioactive substances (krypton-85 or thorium-232), serving mainly for applications requiring very high intensity lighting such as public places, work places, or for certain vehicles (Order of 12 December 2014 of the Ministers responsible for health and construction, ASN opinion 2014-AV-0211 of 18 September 2014). The waiver was renewed in 2019 (Order of 25 May 2020 of the Ministers responsible for ecological and solidarity-based transition, for solidarity, health, and the economy and finance (ASN opinion 2019-AV-0340 of 26 September 2019).

A waiver was moreover granted in 2019 to the Tunnel Euralpin Lyon-Turin for the use of neutron analysis devices (Order of the Ministers responsible for health and ecological 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 justification principle 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 have been 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 10 years;
- supervising the maintenance or removal operations, which necessitate certain precautions with regard to worker radiation protection;
- preventing any uncontrolled removals and organising the collection operations in order to avoid detectors being directed to an inappropriate disposal route, or even simply being abandoned;
- monitoring the pool of detectors.

In this context, as at 31 December 2021, ASN had issued 379 acknowledgements of notification and 11 national licenses (issued to industrial groups with a total of 125 agencies) for ICSD removal activities. Among these 11 licenses, eight authorise maintenance operations on fire safety systems and five authorise ICSD dismantling operations, thereby materialising a disposal route for all 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 2105, in collaboration with ASN, a computerised system enabling the professionals working in this sector (maintenance technicians, installers and removal companies) to file annual activity reports on line. The transmitted information is nevertheless not exhaustive enough to allow a conclusive assessment.

Although the removal operations have progressed over the last few years, not all the 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 problem of removal of these ICSDs, notably the Ministry of Ecological Transition, in order to study the various possible regulatory options. This has not resulted in a new regulatory instrument, but this does not call into question the removal and dismantling operations governed by the notifications, registrations or licenses issued by ASN, which enables the drive to remove the ICSDs to continue.

ASN maintains close relations with Qualdion, an association created in 2011 which labels the companies that comply with the regulations relative to radiation protection and fire safety. The list of Qualdion-labelled companies is available on the Internet. ASN participates with the association in communication campaigns targeting the holders of ionic detectors and the professionals (Expoprotection trade fair, Mayors' trade fair, etc.).

Surge suppressors

Surge suppressors (sometimes called lightning arresters), not to be confused with lightning conductors, are small objects with a very low level of radioactivity used to protect telephone lines against voltage surges in the event of lightning strike. These are sealed devices, often made of glass or ceramic, enclosing a small volume of air containing radionuclides to pre-ionise the air and facilitate electrical sparkover. The use of surge suppressors has been gradually abandoned since the end of the 1970s, but the number remaining to be removed, collected and disposed of is still very high (several million units). When installed, these devices represent no risk of exposure for individuals. However, there can be a risk of exposure and/or contamination, albeit very low, if these objects are handled without precautions or if they are damaged. ASN issued a reminder to the company Orange (formerly *France Télécom*), which has begun an experimental process to identify, remove, sort and dispose of surge suppressors in the Auvergne region and has proposed a national removal and disposal plan. This plan was presented to ASN, and led in September 2015 to the issuing of a license governing the removal of all surge suppressors containing radionuclides present on the Orange network in France and their interim storage on identified sites. This license was renewed in 2021. The search for a disposal route is in progress in collaboration with the French National Agency for Radioactive Waste Management (Andra). The removal and disposal plan is being gradually implemented and should be completed in 2024. Lastly, *Réseau de Transport d'Électricité* (RTE), the French power transmission utility, filed an application for a license in late 2021 to remove the surge arresters installed on its network.

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 expects 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.

Andra estimates that some 40,000 radioactive lightning conductors were installed in France. Nearly 11,000 have already been removed and recovered by Andra. The current rate of removal is about 275 per year.

2.3 The regulatory changes

2.3.1 Tightening the regulation of electrical devices emitting ionising radiation

ASN considers that the regulatory oversight of suppliers of electrical devices emitting ionising radiation is still insufficient, when the placing of devices on the market is so vitally important for the optimisation of the future radiation exposure of users. The work carried out by ASN in this area, which at present is directed towards the use of these devices, particularly in enclosures, has led to the publication of ASN resolution 2017-DC-0591 of 13 June 2017 setting the minimum technical design rules applicable to facilities that use X-rays.

This resolution came into effect on 1 October 2017. It replaces ASN resolution 2013-DC-0349 of 4 June 2013 without creating additional requirements for already compliant facilities. It concerns facilities in the industrial and scientific (research) sectors, such as industrial X-ray radiography in bunkers and veterinary radiology. It takes account of experience feedback and sets the radiation protection goals by adopting a graded approach to the risks.

ASN considers that these provisions, which are directed exclusively at the use these devices, must be supplemented by provisions concerning their actual design.

This is because, for electrical devices used for non-medical purposes, there is no equivalent of the "CE" marking that is mandatory for medical devices, certifying conformity with several European standards that cover various aspects, including radiation protection. Furthermore, experience feedback shows that a large number of devices do not have a certificate of conformity to the standards applicable in France. These standards have been mandatory for many years now, but some of their requirements have become partly obsolete or inapplicable due to the lack of recent revisions.

On the basis of the work done in collaboration with the Electrical Certification and Testing Entity (LCIE), the Alternative energies and Atomic Energy Commission (CEA) and IRSN, draft texts have been produced with the aim of defining minimum radiation protection requirements for the design of these devices; an informal technical consultation of the stakeholders (suppliers, French and foreign manufacturers and the principal users) was conducted in 2015. The various contributions are currently being analysed with the assistance of IRSN and the reference players (CEA and LCIE). The conclusions of this work will be taken into account to adapt the regulatory framework and subject the supply of electrical devices emitting ionising radiation to licensing, in the same way as for radioactive sources. In 2021, ASN continued its work to characterise the advantages, drawbacks and the feasibility of various options for regulating, on the basis of appropriate technical baselines, the design of industrial radiology devices. Discussions with the General Directorate for Labour (DGT) will be continued.

2.3.2 Implementation of oversight of the protection of ionising radiation sources against malicious act

Although the safety and radiation protection measures provided for by the regulations guarantee a certain degree of protection of ionising radiation sources against the risk of malicious acts, they cannot be considered sufficient. Reinforcing the oversight of protection against malicious acts targeting sealed radioactive sources has therefore been encouraged by the International Atomic Energy Agency (IAEA), which published a Code of Conduct on the Safety and Security of Radioactive Sources, approved in 2003, supplemented in 2012 by two implementation guides in the Nuclear Security Series relative to the security of radioactive sources and the security of radioactive material transport. As of 2004, France confirmed to the IAEA that it was working on the application of the guidelines set out in this Code.

The organisation adopted for the oversight of protection against malicious acts

Measures implemented to ensure radiation protection, safety, and protection against malicious acts have many interfaces. Generally speaking, ASN's counterparts in other countries are responsible for oversight in these three areas (see Table 2 in chapter 2).

In France, the protection against malicious acts concerning nuclear materials, particularly those used in certain facilities termed "of vital importance" because they are essential for the functioning of the country, is coordinated by a Service under the authority of the Defence and Security High Official (the SHFDS) 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 SHFDS of the Ministry responsible for energy in facilities whose security is already under its control;
- to the Ministry of Defence in the locations placed under its authority;
- to ASN for the other facilities where nuclear activities take place.

The process necessary to set up this oversight, initiated by the Government in 2008 with the assistance of ASN, resulted in Ordinance 2016-128 of 10 February 2016 and then Decree 2018-434 of 4 June 2018 introducing various provisions concerning nuclear activities. These texts, which amend the Public Health Code, divide up the oversight duties in the various installations as indicated above, by including protection against malicious acts in the risks that must be taken into account by those responsible for nuclear activities and by the regulatory bodies when reviewing the licensing applications.

The sources and installations concerned

Oversight of source protection against malicious acts concerns all sources of ionising radiation, that is to say all the devices that could cause exposure to radiation. The majority of the regulatory requirements are however taken to increase the security of the sources presenting the greatest radiological risks: this concerns radioactive sources of categories A, B and C as defined in the Public Health Code, which stems directly from that of the IAEA. The protection requirements are proportionate to the intrinsic dangerousness of the sources. The graded approach therefore implies stricter obligations for the sources (or batches of sources) in category A than in category C. Sealed sources that are not in categories A, B or C and whose activity exceeds the exemption threshold are classified in category D.

Some 250 facilities in the civil sector in France hold around 5,300 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.

Regulatory work

The Decree modifying the regulatory part of the Public Health Code taken in application of Ordinance 2016-128 of 10 February 2016 (Decree 2018-434 introducing various provisions with regard to nuclear activities) was published on 4 June 2018. It contains several provisions concerning the protection of sources against malicious acts, and more specifically:
- the classification of ionising radiation sources and aggregation (batching) of radioactive sources into category A, B, C or D (Article R. 1333-14 of the Public Health Code);
- the prompt notification to various administrative authorities, and the regionally competent law enforcement agencies, of any actual or attempted malicious act or loss concerning a source of ionising radiation or a batch of radioactive sources of category A, B or C (R. 1333-22);
- the sending of documents that could facilitate malicious acts by separate, specially identified mail (R. 1333-130);
- the nominative and written authorisations to be delivered to the persons having access to ionising radiation sources or batches of radioactive sources in category A, B or C, transporting them, or having access to information concerning their protection against malicious acts (R. 1333-148).

Subsequently, the Ministerial Order setting the organisational and technical requirements to protect sources of ionising radiation (or batches of radioactive sources) against malicious acts was signed on 29 November 2019 and published in the *Official Journal of the French Republic* on 11 December 2019. It entered into force on 1 January 2020 for the sites not licensed on its date of publication (nor being examined on that same date).

For already licensed sites, entry into force takes place in two stages which were postponed due to the Covid-19 pandemic. The first was set for 1 January 2021 and concerned the organisational and human provisions; the second, set for 1 July 2022, will chiefly concern the systems providing physical protection against malicious acts. These two dates were therefore pushed back six months by the Order of 24 June 20120, on which ASN issued an opinion (opinion 2020-AV-0353 of 11 June 2020).

The Order of 29 November 2019 amended also applies to the transport of category A, B and C sources, whether individually or in batches.

The main requirements of this Order aim, by adopting a graded approach based on categories A, B, C (and D for two items), to have the licensee put in place physical barriers and equipment, along with a policy and an internal organisation to protect sources against malicious acts. These technical and organisational arrangements 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.
- regularly raise awareness, inform and train the personnel on the subject;
- periodically check the effectiveness of the equipment and organise exercises.

For obvious reasons of restricting access to sensitive information, some of the provisions of this Order, detailed in its appendices, were not published in the *Official Journal*. ASN therefore, within its area of competence, sent the relevant appendices by personalised letter to each of the nuclear activity licensees concerned.

ASN had also planned to raise awareness on the publishing of the Order by actions in the regions at professional events or by holding *ad hoc* meetings with professionals concerned. Due to the Covid-19 pandemic, this initiative was suspended after just one event. It was able to be resumed throughout year 2021, and finally two-thirds of the regions have organised such workshops.

Alongside the preparation of the Order, and to facilitate its practical implementation, a working group has started preparing a joint ASN/SHFDS (Service of the Defence and Security High Official of the Ministry of Ecological Transition) guide for nuclear activity licensees and for the ASN and SHFDS inspectors. This guide should facilitate common understanding of the requirements of the Order by the professionals and inspectors alike.

It will present recommendations for the implementation of these requirements and include numerous examples. As it details certain elements of the appendices to the Order, its circulation will be limited. In the second half of 2020, ASN conducted a targeted consultation of professionals on this draft guide. The comments received were taken into account and the ultimate discussions with the SHFDS of the Ministry of Ecological Transition should enable it to be adopted and distributed in 2022.

In addition, assessment of the resistance of the windows and doors that were installed when less importance was given to protecting sources against theft is a subject that will be fully relevant in mid-2022 when the appendices of the Order of 29 November 2019 become applicable. On the basis of work performed by IRSN, an assessment grid has been drawn up and distributed. This document will enable all the professionals concerned to adopt a common methodology.

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.

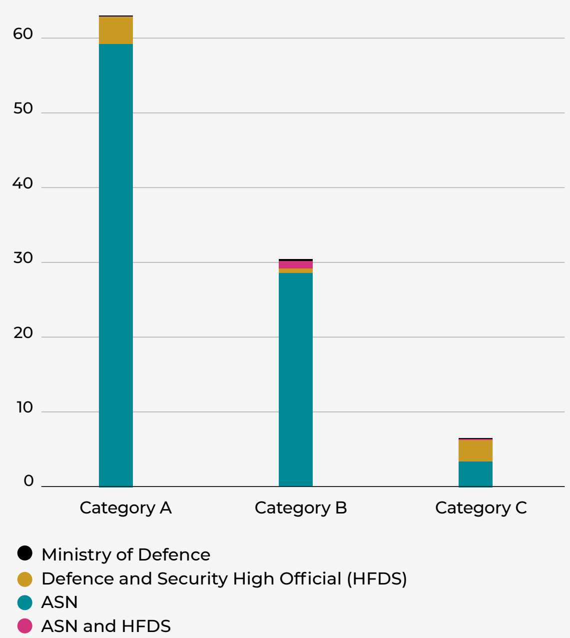
Assessment of the expected benefit of a nuclear activity and the corresponding health drawbacks may lead to prohibition of an activity for which the benefit does not seem to outweigh the risk. Either generic prohibition is declared, or the license required for radiation protection purposes is not issued or is not extended. For the existing activities, the elements supporting implementation of the justification principle are recorded in

CATEGORISATION OF RADIOACTIVE SOURCES

Radioactive sources have been classified by the IAEA since 2011 on the basis of predetermined exposure scenarios, in five categories from 1 to 5, according to their ability to create early harmful effects on human health if they are not managed safely and securely. Category 1 sources are considered extremely dangerous while those in category 5 are considered very unlikely to be dangerous. Sources in categories 1 to 3 are considered dangerous for humans to varying degrees.

This categorisation is based solely on the capacity of the sources to produce deterministic effects in certain exposure scenarios and must not under any circumstances be considered as proof that there is no danger in exposure to a category 4 or 5 source, as such exposure could cause stochastic effects in the longer term. The principles of justification and optimisation must therefore be respected in all cases. This IAEA work has been taken up in an Appendix to the Public Health Code amended by Decree 2018-434 establishing various provisions in the nuclear field. Nevertheless, the IAEA categories 4 and 5 have been grouped together in category D of this Code.

GRAPH 5 **Breakdown of high-activity sealed sources according to their category and their oversight authority for protection against malicious acts**



The sources in category A of the Public Health Code (PHC) correspond to the IAEA category 1 sources.

The PCH category B sources correspond to:
- the IAEA category 2 sources, and
- the IAEA category 3 sources contained in a mobile or portable device.

The PHC category C sources correspond to the IAEA category 3 sources not contained in a mobile or portable device.

writing by the person responsible for the nuclear activity, and are updated every five years and whenever there is a significant change in available knowledge or techniques.

Optimisation is a notion that must be considered in the technical and economic context, and it requires a high level of involvement of the professionals. ASN considers in particular that the suppliers of devices are at the core of the optimisation approach (see point 4). They are effectively responsible for putting the devices on the market and must therefore design them such that the exposure of the future users is minimised. ASN also checks application of the principle of optimisation when examining the license applications, when conducting its inspections, and when analysing reported significant events.

2.4.2 Applicable licensing and notification systems

Applications relating to the possession and utilisation of ionising radiation are examined by the ASN regional divisions, while those concerning the manufacture and supply of sources or devices containing sources are examined at the ASN head office by the Department of Transport and Sources (DTS). The entry into effect on 1 July 2018 of Decree 2018 434 of 4 June 2018, introducing various provisions in the nuclear field, has introduced a third administrative system lying between the notification system and the licensing system: this is a simplified authorisation system called the "registration system". ASN has prepared a classification system to allocate the various categories of nuclear activities to one of these three systems, whose implementation began on 1 January 2019 with the entry into effect of the ASN resolution extending the notification system to additional nuclear activities which until then were subject to licensing, and continued on 1 July 2021 with the entry into effect of the resolution concerning the registration system.

The licensing system

Small-scale nuclear activities stand out by their considerable diversity and the large number of licensees involved. The licensing system is designed to regulate the nuclear activities involving the greatest radiation protection implications, for which ASN checks, when examining the license application, that the applicant has identified the risks and that the measures intended to limit their effects have been studied and planned for. To support this process, licensing application forms adapted to each activity are available on *asn.fr*.

These forms are designed for the licensing applications to be formulated by the representative of a legal person, although it is possible for a physical person to apply for a license. These forms 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.

The notification system

As part of the overhaul of the classification of nuclear activities into the three administrative systems introduced by the above-mentioned Decree of 4 June 2018, ASN decided to implement a more graded approach, proportionate to the risks.

Its initial work focused on the notification system. Notification is a simple procedure which does not require the submission of any supporting documents. It is particularly suited to the nuclear activities that present the lowest risks for people and the environment. Since April 2018, those responsible for a nuclear activity in the industrial, research or veterinary sectors that comes under the notification system, can carry out the notification procedure *via* the ASN "on-line services" portal.

Through ASN resolution 2018-DC-0649 of 18 October 2018 approved on 21 November 2018, ASN has extended the list of activities subject to notification. The notification system extension should concern about 6,000 companies or individuals which were previously subject to the licensing system. However, the exact number of cases will not be quantifiable until after five years (31 December 2023). This is because, in accordance with the principle of grandfathering, the licenses issued before

INTERNATIONAL THINK TANK ON ALTERNATIVE TECHNOLOGIES

Radioactive sources present radiation exposure and safety risks for their users, the general public and the environment, which must be taken into consideration in the reflection phase preceding the deployment of a nuclear activity. Consequently, in France, when technologies presenting lower risks than a nuclear activity are available under technically and economically acceptable conditions, they must be implemented instead of the nuclear activity initially envisaged: this is the principle of justification.

On this basis, as of 2014 and subsequently at the Nuclear Security Summit in Washington in April 2016, France was the initiator of an international initiative now supported by 31 countries and by Interpol. The aim is to support research into and the development of technologies that do not use high-activity sealed radioactive sources and to promote the use of these technologies.

In this context, since April 2015 ASN has, along with the National Nuclear Security Administration (United States), initiated an informal think tank involving several countries working on the subject of replacing high-activity radioactive sources by alternative technologies. The aim of this group, which meets once a year, is to foster greater awareness of the benefits of such alternatives and to share experience feedback from each country in this respect. At the group meetings ASN has presented, for example, the operations conducted by the French blood transfusion agency to replace –in application of the principle of justification– its irradiators that use radioactive sources by electric irradiators emitting X-rays. ASN has also enabled the French Confederation for Non-Destructive Testing to present the progress of its work to replace gamma radiography by other non-destructive testing technologies.

In December 2018, during the International Conference on Nuclear Security organised by the IAEA, the subject of alternative technologies was addressed by several presentations and two panel sessions, and the relevance of this think tank was underlined.

The think tank meetings continued in 2019 and 2021, with a break in 2020 on account of the Covid-19 pandemic. Other foreign licensees shared their experience, particularly in the use of electrical irradiators emitting X-rays for research activities. 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.

THE PROTECTION OF RADIOACTIVE SOURCES AGAINST CYBERCRIME

The aim of the regulations concerning the protection of sources against malicious acts put in place since 2016 is to ensure that this problem is given greater consideration in the organisation, functioning and the protection systems adopted by companies.

This also concerns the **security of sensitive information relating to the protection of sources and the information systems** in which this information is processed and stored.

This is moreover reflected in the increasing press coverage of computer attacks (cyberattacks) targeting French and foreign companies, hospitals or public services.

In early 2021, a company licensed by ASN was the subject of such an attack. Documents relating to the protection of the site were stolen, thereby rendering the company potentially vulnerable and obliging it to reconsider some of its safety systems. The alert was given rapidly, which enabled the necessary steps to be taken (filing of a complaint, hiring of a specialised lawyer and the services of several digital investigation companies) with the aim of putting in place the necessary corrective actions and reinforcing digital security, such as:

- changing all the passwords with the application of tightened rules;
- looking for signs of compromise;
- updating of all the applications used;
- new segmentation of accesses;
- revision of the surveillance procedures for accounts, networks and firewalls.

The operational and economic impact of such an attack is not negligible, whether on account of the time devoted to the technical and legal procedures, the need to adapt the technical or organisational systems for protection against malicious acts, the difficulty in identifying the sensitive information to protect in priority, or operation in degraded mode until normal operation can be restored.

ASN was attentive to the measures taken by the company that suffered the cyberattack to restore a level corresponding to that required by the amended Order of 19 November 2019. A circular letter was also sent out to all companies licensed to possess or use category A, B or C radioactive sources. Urging them to be vigilant in this respect, this letter indicates more specifically that the ANSSI[1] makes available on its website several elements (computer graphics, guides, etc.) relative to cyberattacks and measures for reducing the probability of such acts occurring or mitigating their consequences, and a Computer Hygiene Guide in particular.

ASN points out that digital documents containing "sensitive information" must systematically be ciphered.

1. *French National Agency of Information Systems Security.*

1 January 2019 act as notification acknowledgements until the license reaches term, on condition that in the interim there is no change in the nuclear activity. This means that a number of nuclear activities, though now subject to notification, are still regulated by a license.

2.4.3 The new registration system (simplified authorisation)

The new registration system came into effect on 1 July 2021, after approval on 4 March 2021 of ASN resolution 2021-DC-0703 of 4 February 2021. This resolution governs nuclear activities in industry, research and veterinary applications, as nuclear activities for medical purposes that come under this system are governed by another resolution (see chapter 7). This system applies to certain sources of ionising radiation, whether in the form of sealed or unsealed radioactive sources, and X-ray generators, where the risks and drawbacks of possessing or using them can be prevented by complying with the specific general requirements set by the resolution. The resolution therefore defines, apart from the nuclear activities concerned, the content of the simplified authorisation application and the conditions for exercising (specific general requirements) the nuclear activity with which the licensees must comply.

Its entry into effect marks the second stage –following that of extension of the notification system– of effective implementation of the reform of small-scale nuclear activity regulation, aiming to better materialise a graded approach to the risks. The resolution effectively implies significant alleviations in the administrative procedures compared with those for nuclear activities subject to licensing, such as: a simplified application (both in the information and the substantiation documents to provide), ten-year registration validity by default (and even unlimited validity by default for certain nuclear activities), the possibility of applying for registration *via* the on-line registration service which will be available on *asn.fr*, review and assessment by ASN within six months, with silence after six months being considered as acceptance of registration of the applicant nuclear activity.

Entry into effect of the registration system should ultimately concern between 1,200 and 2,000 licensees in industry, research and veterinary applications, hitherto subject to the licensing system. However, as is the case with the notification system, the number will not be able to be accurately quantified until a five-year period has expired (1 July 2026). This is because, in accordance with the principle of grandfathering, the licenses issued before 1 July 2021 will act as registration until the license reaches term, on condition that in the interim there is no change in the nuclear activity.

2.4.4 Statistics for the year 2021

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 2021, 100 radioactive source supply license applications or license renewal applications were examined by ASN, and 33 inspections were carried out (all ionising radiation sources combined).

Users

The case of radioactive sources

In 2021, ASN examined and notified 19 new licences, 250 license renewals or updates, 82 license cancellations, and issued for the first time 51 registration decisions. ASN also issued 956 notification acknowledgements for sealed radioactive sources. Graph 6 shows the regulatory acts issued by ASN for radioactive sources in 2021 and, where applicable, their development over the last five years. The entry into effect of ASN resolution 2018-DC-0649 of 18 October 2018 (see point 2.4.2) is the main reason for the very large drop in the number of licenses issued in favour of the issuance of notification acknowledgements, and illustrates the concrete application of the graded approach to risk control. This drop will become greater in the coming years as the new registration system (see point 2.4.3.) applicable since 1 July 2021 gradually increases in scale.

ADMINISTRATIVE TRACKING OF RADIOACTIVE SOURCES

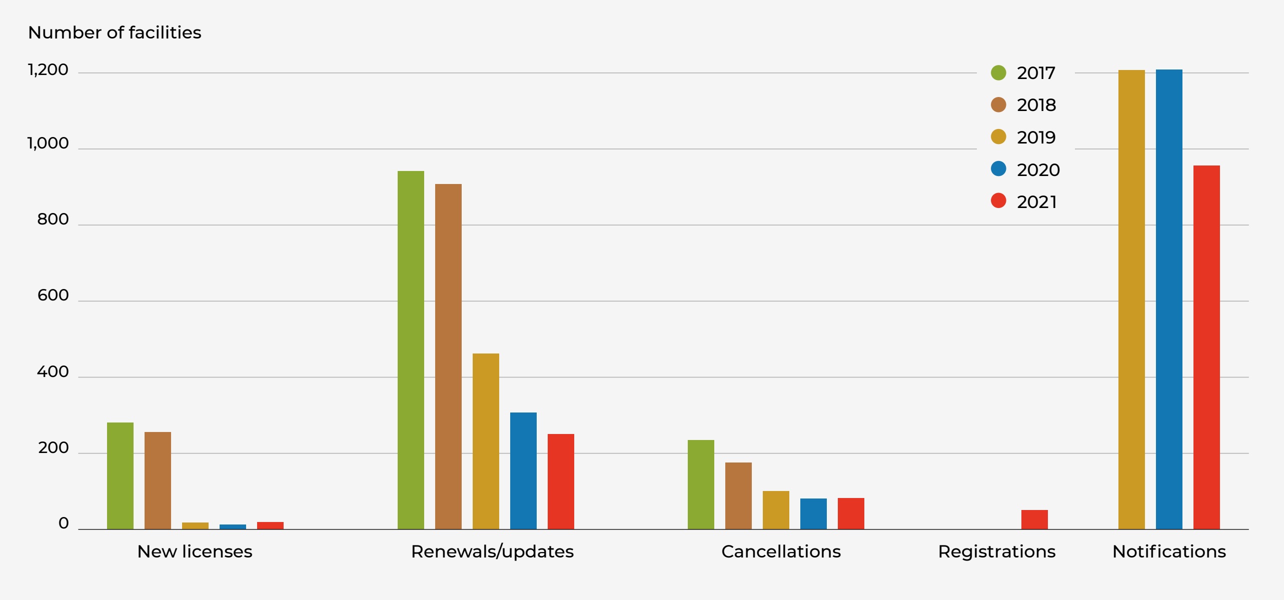
Articles R. 1333-154, 156 and 157 of the Public Health Code provide for the prior registration by the French Institute of Radiation Protection and Nuclear Safety (IRSN) of transfers of radioactive sources and Article R. 1333-158 for administrative tracking of these sources.

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.

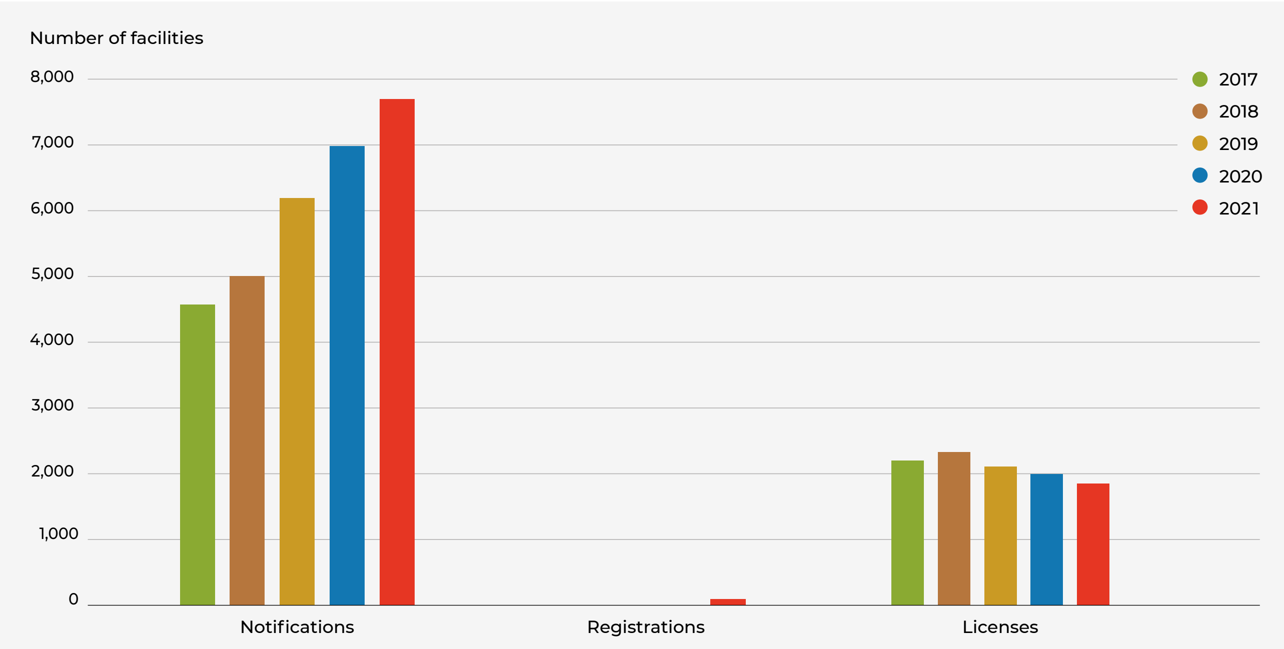
This resolution, applicable as of 1 January 2016, takes into account the existing mode of functioning and supplements it as follows by:

- 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" licenses, registrations and notifications for radioactive sources issued each year



GRAPH 7 "User" licenses, registrations and notifications for electrical generators of ionising radiation in effect over the last five years



Once the license, registration or notification acknowledgement is obtained, the holder can procure sources. To do this, it collects 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 or notification acknowledgement issued to the user and the license of its supplier. If the order is correct, the transfer is then recorded by IRSN, which notifies the interested parties that delivery can take place. In the event of difficulty, the transfer is not validated and IRSN refers the case to ASN (see box page 246).

Cases of ionising radiation generators
ASN has been responsible for the oversight of these devices since 2002, devices for which numerous administrative compliance actions are still required. In 2021, it granted 43 new licenses, 141 license renewals or updates and issued, for the first time, 41 registration decisions for the use of devices emitting X-rays. ASN also delivered 718 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.

In all, 1,848 licenses, 41 registrations and 7,698 notification acknowledgements have been issued since 2002 for electrical devices emitting ionising radiation. Graph 7 illustrates the trend for 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

3.1.1 The devices used

Gamma radiography
Gamma radiography is a non-destructive inspection method used for detecting homogeneity defects in materials such as weld beads. It involves obtaining a radiographic image on silver-based or digital media using the gamma rays emitted by a radioactive source and passing through the object to inspect.

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.

Gamma radiography devices 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 device, the dose rates can reach several grays per hour at one metre from the device, depending on the radionuclide and its activity level.

As a result of the activity of the sources and the movement of the sources outside the storage container when the device is being used, gamma radiography can entail significant risks for the operators in the event of incorrect use, failure to comply with radiation protection rules, or operating incidents. Furthermore, these gamma radiography activities are often carried out on work sites under difficult conditions (working at night, or in places that are exposed to the elements, or in cramped spaces). This is therefore an activity with serious radiation protection implications that figures among ASN's inspection priorities.

Industrial X-ray radiography
Industrial X-ray radiography is used for checking the quality of weld beads or for the fatigue inspection of materials.

It is carried out using fixed devices or worksite devices employing directional or panoramic beams which substitute for gamma radiography devices if the conditions of use so permit.

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 Assessment of radiation protection in industrial radiography activities

Industrial radiology activities are high-risk activities which have been an inspection priority for ASN for several years now.

In 2021, ASN conducted 151 inspections in this area, a number that is stable with respect to the two preceding years. Among these inspections, 74 were unannounced inspections on worksites which also include night work. As in 2020, the conduct of some inspections was adapted so that they could partially be carried out remotely.

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 licensees concerned generally use this system for the worksite notifications. This being said, the reliability of the information provided is still variable. The points to improve include:
- the updating of schedules when they are changed;
- 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).

From its inspection findings, ASN considers that, on the whole, the risks are properly taken into account –albeit with disparities between companies– with the exception of the cordoning off of work zones at temporary worksites.

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 (a single noncompliance observed) and worker dose monitoring (less than 10% noncompliance observed). Furthermore, the inspectors noted that the frequency of maintenance of gamma radiography devices on the whole complies with regulations (no noncompliance found for projectors, 10% noncompliance found for accessories). Similarly, 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.

The inspectors also noted that the efforts made by the companies to train newly-arrived classified workers had been maintained. Consequently, this information was duly dispensed to the new staff in more than 94% of the inspected facilities concerned in 2021. However, the periodic refreshing of this training and its content require further improvements.

Conversely, ASN still considers that the deviations observed in cordoning off the work zones on worksites (found in slightly more than one inspection in four) are a cause for concern. ASN underlines that the lack of preparation and cooperation between the ordering customers and the radiography contractors before starting temporary worksites (particularly the failure to draw up a precise prevention plan) is one of the causes of these deviations.

ASN points out that the work area must be cordoned off before the work begins and, in all events, before the radiography equipment is installed, that the cordoning off must be continuous and that it is essential to have warning lights in sufficient quantity. To ascertain that cordoning off ensures compliance with the regulatory dose rate values, it is vital to take at least one measurement and to record the result(s). Zoning and cordoning off effectively constitute the main safety barrier in worksite configurations, particularly to prevent unintended exposures. Consequently, ASN remains extremely vigilant regarding this point, which is systematically checked during worksite inspections; moreover, penal enforcement actions have already been proposed for serious breaches.

The recurrence of the deviations observed in the last few years in cordoning off the work zone induced ASN to address a circular letter to the profession as a whole in 2021, asking for tightened vigilance in this respect.

ASN moreover took advantage of the inspections of worksites using gamma radiography devices to conduct a verification campaign of the carriers' ADR class 7 certificates (certificate necessary for the carriage of these devices) and the CAMARIs (see above) of the operators on the worksite. At the end of the year, these documents were compared with the databases of the bodies that issued them. This verification campaign was part of the anti-fraud actions implemented by ASN for several years now to check the veracity of the documents presented by the licensees. No attempted falsification of documents was detected.

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 contractors 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. Furthermore, the inspections carried out in 2021 show that in a quarter of the cases the X-ray radiography lighted signalling systems were not properly installed or verified.

Lastly, the protection of ionising radiation sources against malicious acts (see box page 252) must be further improved. For example, the individual authorisations for access to sources were correctly drawn up in just over half the inspected sites, the policy for protection against malicious acts was established in less than half the inspected sites, and sensitive information was identified and controlled in less than a third of the inspected sites.

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.

Moreover, France has a good network of fixed industrial radiography facilities, thereby enabling 70% of the professionals to propose services in exposure bunkers (of which 97 can be used for gamma radiography). ASN considers that the risks of incidents and the workers' occupational exposure are generally well controlled by the licensees when radiography is performed in a bunker complying with the applicable regulations. Despite the availability of such facilities, ASN still observes too often that parts that undergo radiography on worksites, particularly those scheduled at night in workshops, could have been easily moved to a bunker. Apart from optimising doses for the workers, it would also eliminate the risk of having to temporarily shut down the workshop in the event of an incident preventing the radioactive source of the 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 facilities that have a bunker.

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, Haute-Normandie, 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 2021 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. These events were correctly diagnosed by the operators and the persons concerned did not undertake any inappropriate or prohibited operations. ASN draws that attention of companies having gamma radiography inspections carried out in their facilities to the consequences of the radioactive source getting jammed outside the gamma ray projector, and especially the setting up of an exclusion zone for the time necessary to definitively place the source in safe condition, which can often be several days.

3.2 Industrial irradiators

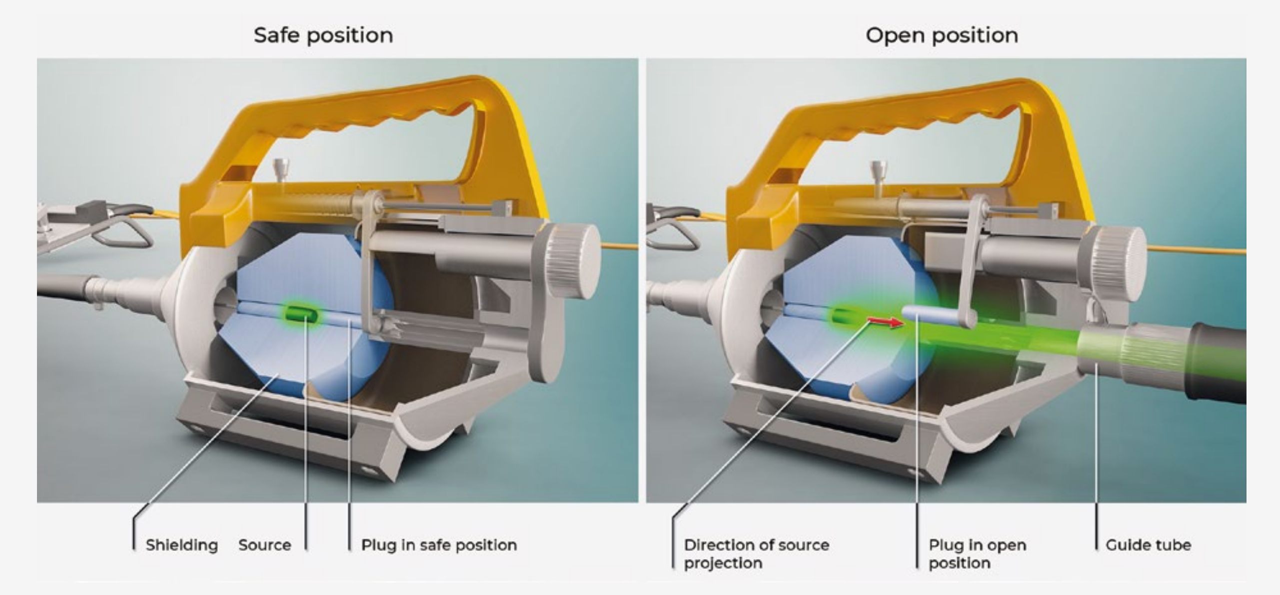
3.2.1 The devices used

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 installations are classified as BNIs (see chapter 12). In many sectors, X-ray generators are gradually replacing high-activity sealed sources for the irradiation of products (see point 1.3.1).

OPERATING SCHEMATIC OF A GAMMA RAY PROJECTOR



SELENIUM-75 GAMMA RADIOGRAPHY

The use of selenium-75 in gamma radiography has been authorised in France since 2006. Implemented in the same devices as those functioning with iridium-192, selenium-75 offers significant radiation protection advantages in gamma radiography. This is because the equivalent dose rates are about 55 millisieverts (mSv) per hour and per TBq one metre from the source, as opposed to 130 millisieverts per hour per terabecquerel (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, less than 20% of portable devices are equipped with a selenium-75 source. The deployment of selenium-75 has remained stationary in the last few years due to a shortage of supplies resulting from difficulties encountered by the source manufacturer. As a new supply route has been established, ASN still encourages the use of selenium-75.

3.2.2 The radiation protection situation

BNIs excluded, ASN carried out 21 inspections from 2018 to 2021 (of which 9 were in 2021) 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 renewal of verifications are satisfactory, as no significant deviations from the regulations have been observed. The risk is well controlled, in particular thanks to the satisfactory verification, upkeep and maintenance of the facilities in accordance with the provisions described in the licensing applications.

Nevertheless, in one in four inspections ASN found that the verification of the safety systems needed to be improved. Furthermore, the findings related to the protection of ionising radiation sources against malicious acts carried out in the industrial sector (see page 253) are on the whole valid for this irradiation activity. ASN thus observed in 2021 that the individual authorisations for access to sources were only drawn up correctly in one in two of the inspected sites, as is the case for the policy of protection against malicious acts.

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 68 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.

1. *To which can be added six licenses to use an accelerator, either under worksite conditions, or for the shared use of a device of which possession is regulated by the other party's license.*

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 gigabecquerels (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 situation must nevertheless not be taken for granted and continued vigilance is required. ASN keeps a watchful eye on accidents occurring abroad which have sometimes had serious effects. Over the last ten years, examples brought to ASN's attention confirming the risks to which operators can be exposed as a result of inappropriate actions, include:

- In 2021 in the USA, an employee of a non-destructive testing company was exposed to a dose of 70 mSv (whole body) while carrying out gamma radiography exposures within a dedicated facility. The procedures in force at the time of this accident authorised the operator to be present inside the facility even when the source was in the irradiation position. An employee of another non-destructive testing company was exposed to a dose of 93 mSv (whole body) when manipulating a defective gamma radiography projector whose source was not in the safe position. These two events were rated level 2 on the INES scale.
- In 2021 in Serbia, an iridium-192 source became detached from the remote control cable during an outdoor non-destructive test. The two operators did not check that the source had returned to the safe position at the end of the inspection and did not notice its absence until they got back to their company base. The source was found the next day after the intervention of a specialised laboratory. The two operators were exposed to doses of 451 mSv and 960 mSv.
- In 2021 in Spain, an employee of a non-destructive testing company was exposed after entering a gamma radiography bunker when the iridium-192 source was not in the safe position (source jammed). The passive dosimeter of the first employee indicated a dose of about 70 mSv, and that of the second about 3 Sv. The event was rated level 2 on the INES scale.
- In 2020 in the United States, a radiographer and two assistant-radiographers performing non-destructive tests in an asphalt production unit were exposed to whole body doses of 636, 104 and 26 mSv respectively while attempting to reintroduce the source into the gamma ray projector after the guide tube had been crushed by a support which fell from a storage tank. The event was rated level 2 on the INES scale.
- In 2019 in Spain, an employee of a non-destructive testing company was exposed to about 200 mSv (whole body) by entering a gamma radiography bunker when the iridium-192 source was not in the safe position. The door-opening slaving system for prohibiting access to the bunker during the emission of ionising radiation, did not function due to the failure of the dose rate measuring system. The event was rated level 2 on the INES scale. A similar accident happened the same year in Germany: two employees were exposed to 100 and 30 mSv respectively (whole body) when they entered a gamma radiography bunker when the iridium-192 source was not in the safe position and the radiological environment had not been checked. The event was rated level 2 on the INES scale.
- In 2016 in Turkey, the operators had apparently not verified that the source had returned to the safe position after using a gamma ray projector. A 16-year old adolescent found the source the day after the inspection and took it home where several persons said they handled it. 20 people in all were reportedly exposed, with most severely exposed person reportedly receiving a dose of 1 gray (Gy). The event was rated level 2 on the INES scale.

The data from before 2016 can be consulted in the previous issues of this annual report. The issues are available at *asn.fr*, under the headings "ASN informs", "Publications", "ASN annual reports".

In the field of research, two synchrotron radiation production facilities can be mentioned in France: the European Synchrotron Radiation Facility (ESRF) in Grenoble, and the Optimised Source of Intermediate Energy Light of the Lure Laboratory (Soleil) synchrotron in Gif-sur-Yvette.

Particle accelerators have been used for several years now in France to fight fraud and large-scale international trafficking. This technology, which the operators consider effective, must however be used under certain specific conditions, in order to comply with the radiation protection rules applicable to workers and the public, in particular:

- a ban on activation of construction products, consumer goods and foodstuffs as specified by Article R. 1333-2 of the Public Health Code, by ensuring that the maximum energy of the particles emitted by the accelerators used excludes any risk of activation of the materials being verified;
- a ban on the use of ionising radiation on the human body for purposes other than medical;
- the setting up of procedures to ensure that the checks conducted on the goods or transport vehicles do not lead to accidental exposure of workers or other individuals. The use of ionising technologies to seek out illegal immigrants in transport vehicles is prohibited in France. During customs inspections of trucks using tomographic techniques, for example, the drivers must be kept away from the vehicle and other checks must be performed prior to irradiation to detect the presence of any illegal immigrants, in order to avoid unjustified exposure of people during the inspection.

3.3.2 The radiation protection situation

The use of particle accelerators presents significant radiation exposure risks for the workers; ASN is particularly attentive to these facilities and therefore inspects them regularly. In 2018, ASN put in place inspection indicators specific to particle accelerators, which now enable the radiation protection situation in this sector of activity to be better assessed on the national scale.

Between 2018 and 2021, 50 facilities equipped with these devices were inspected by ASN, 13 of them in 2021.

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.

LOSS OF CONTROL OF THE SOURCE IN GAMMA RADIOGRAPHY

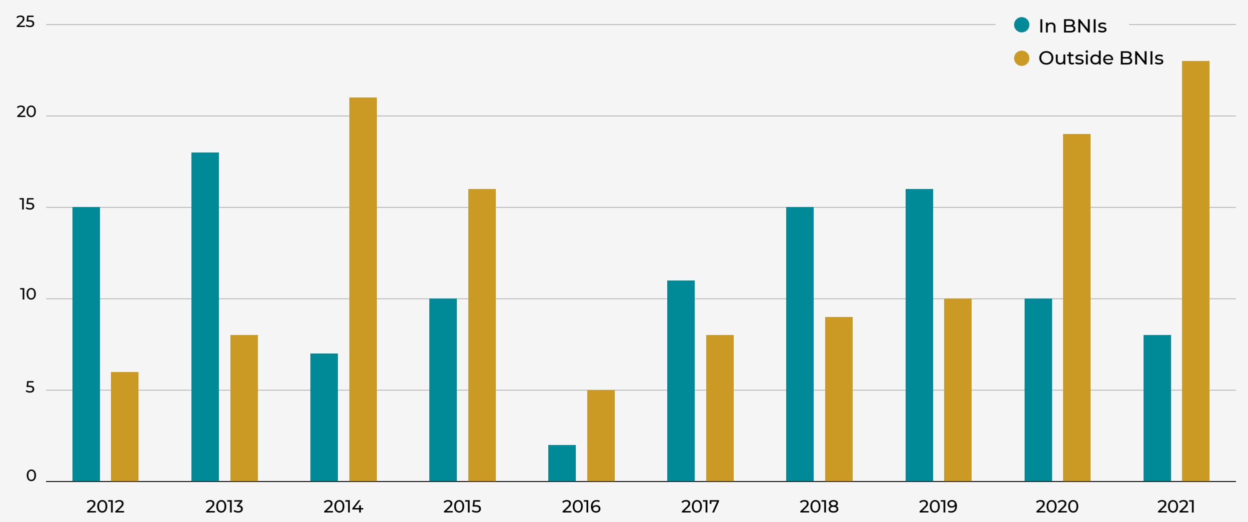
Gamma radiography is a non-destructive testing technique consisting in positioning a radioactive source close to the element to be inspected, in order to obtain a radiographic image which can subsequently be used to check the quality of the part.

Loss of control of the sources is one of the main causes of incidents in this area. 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. Jamming is often caused by foreign bodies in the tube or deterioration of the tube.
- The source-holder containing the radionuclide is no longer connected to the remote control cable. The cable joining the source and the remote control is not correctly connected and the source can no longer be moved.

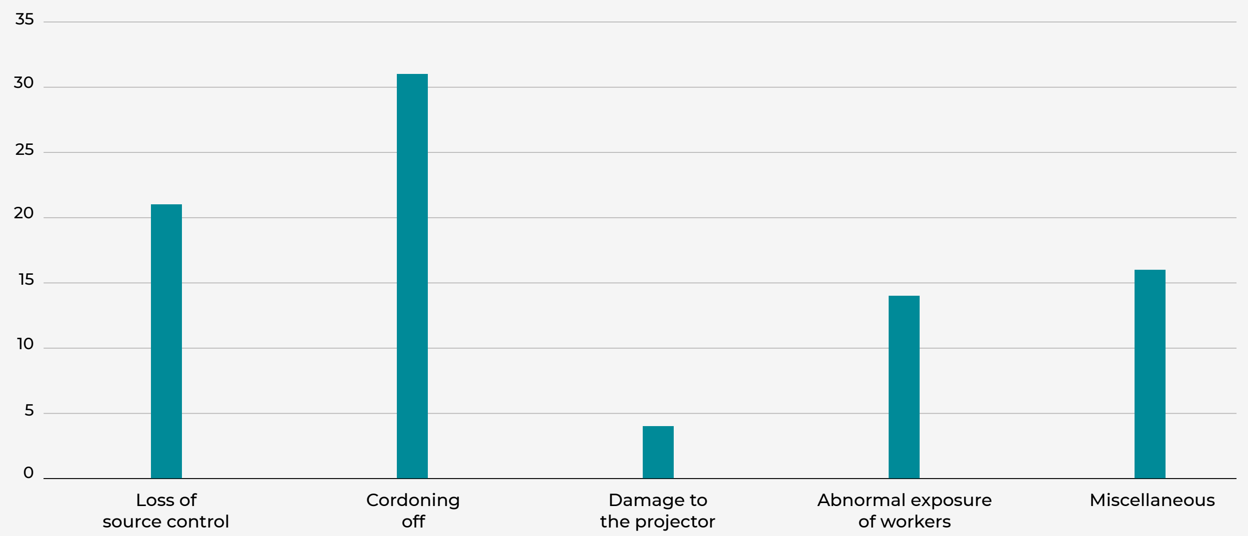
In France, gamma radiography projectors comply with technical specifications that are stricter than the international ISO standards. However, equipment failures can never be ruled out, especially in the event of poor upkeep of the equipment. In the last few years, incorrect manipulations have also been 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 contributing to industrial radiography events reported to ASN over the 2019-2021 period**



INSPECTIONS RELATING TO THE PROTECTION OF IONISING RADIATION SOURCES AGAINST MALICIOUS ACTS: KEY FINDINGS AND TRENDS

Since 2019, when ASN inspects facilities where sealed radioactive sources of category A, B or C, whether individually or in batches, are present; it checks compliance with the regulations relative to the protection of sources against malicious acts. The following indicators are systematically addressed and monitored nationally.

This monitoring was widened in 2021 due to the entry into force on 1 January 2021 of additional regulatory provisions. The number of industrial facilities inspected doubled (211 in all). The number of medical facilities inspected remained stable.

The trend[1] compares, when there is a significant number of responses, the cumulative result for the years 2019-2020 with respect to the values for 2021 and differentiates the industrial sectors (chiefly gamma radiography) and medical sectors. In effect, the Covid-19 pandemic reduced the number of inspections carried out by ASN, primarily in the medical facilities, where the drop was about 40% between 2019 and 2020, and likewise between 2020 and 2021. Consequently, the change trends no longer had any real meaning in this sector.

Classification of radioactive sources, whether individual or in batches

Three-quarters (75% [↑]) of the industrial facilities inspected in 2021 do not raise any comments in this respect; the other sites either carried out this classification only partially (19% [↓]), or not at all (6% [↓]).

In the medical sectors, over the three years nearly three-quarters (71%) of the facilities have carried out this classification. In almost one facility in five (18%) nothing has been done yet. The remaining facilities (13%) have established this classification incompletely or incorrectly.

The situation of the sites that have not yet carried out this classification is becoming delicate, insofar as this provision has been in effect for three and a half years and forms the basis of the measures for the physical protection of sources that will come into force in mid-2022.

Nominative authorisations

These are delivered by the nuclear activity licensee to allow access to these sources (or their batch), their carriage, or access to the information relating to the means or measures that protect them.

The percentage of industrial facilities with compliant situations in 2021 is improving since it accounts for almost half of them (48% [↑]).The provisions are partially observed in exactly one third of the cases [↑] but above all, there is a reduction in the number of industrial sites on which nothing has yet been done in this respect (18% [↓]).

In the medical sectors, the inspections as a whole reveal that less than one site in five (18%) manages this question properly. In view of the number of persons concerned and the diversity of the situations, it was predictable that it would be less well managed than in the industrial sector. It must nevertheless be pointed out that nearly half (48%) the centres have not yet addressed the question. For the remaining third (34%), further progress is required.

Measures taken to prevent unauthorised access to sources

This indicator will be abandoned and replaced in 2022 because the provisions entering into application on 1 July 2022 will be more precise and will allow a better evaluation of the situation. At present, based on a general assessment, these measures are deemed satisfactory in the industry (82% [≈]).

Considering the inspections in the medical sectors as a whole, the situation is less satisfactory, which finally does not seem abnormal because these are, as a matter of principle, open facilities, even if access to the sources must be restricted to patients, personnel and accompanying persons. 46% of the sites are considered satisfactory. 8% have taken no measures whatsoever to prevent access to the sources. For the remainder of the sites (46%), it is found that the situation needs to be improved.

Inventories of sources held by the inspected sites

Here it is a question of ensuring that the SIGIS inventory is identical to that which must be kept up to date internally and that no expired/disused sources are present on the site. The consistency between the inventories has further improved this year (85% [↑]) in the industrial sector. In the medical sectors, the inspections as a whole reveal a similar situation (82%).

Policy of protection against malicious acts

This new indicator serves to assess the commitment of company senior management to the protection of sources against malicious acts. It covers the existence of a general commitment statement on this subject and its dissemination to the personnel. In the industrial sector, this policy is found to be correctly formalised in writing and known to the personnel in somewhat less than half the sites (41%). In about a third of the sites (30%), no policy has been drawn up. In the remaining large quarter (29%), this policy must be improved, disseminated more widely or made better known.

In the medical sector, more than half (58%) the sites have a general policy statement that raises no comments, but one third (33%) do not have one. The remainder represents policies that need to be clarified or made better known to the personnel.

Identification and control of sensitive information

The vulnerability of information concerning protection of sources against malicious acts is a new indicator that is properly managed in just one industrial company in three (34%) but, in nearly half the cases (43%) there are no written provisions. For the remainder, either the protection of electronic documents needs to be better integrated in the provisions, or the planned procedures are poorly applied.

In the medical sector, although a third (33%) of the facilities have a document addressing this issue, half of them (50%) have no procedure whatsoever.

1. The change in trends between 2019-2020 and 2021 is indicated by the symbols [↑] (increase), [↓] (decrease) and [≈] (stability).

INITIATING TRUSTWORTHINESS CHECKS

The Public Health Code stipulates that the person responsible for the nuclear activities shall issue individual authorisations to the people who need access to the sources or to the information protecting them against malicious acts. To do this, the person may request the opinion of the Command Specialised in Nuclear Security (CoSSeN). This service, which has national competence, is part of the Ministry responsible for energy and the Ministry of the Interior; it is attached to the Director General of the National Gendarmerie.

The CoSSeN's opinion is based on an administrative review intended to check that the behaviour of the persons concerned is not, or has not become, incompatible with the functions or duties exercised. This trustworthiness check is based on the review of police databases and, if the persons are mentioned in the said databases, additional verifications. The persons concerned must be informed of this trustworthiness check. The conditions of investigation are governed by the Interior Security Code.

This Code also provides the possibility of conducting such trustworthiness checks on the person responsible for a nuclear activity, if the activity requires a license. Performing such checks meets one of the principles of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources.

ASN considers that is would be illogical for a person responsible for a nuclear activity to be able to ask the CoSSeN to perform a trustworthiness check on a member of their staff or their subcontractors' staff without themselves undergoing such a check insofar as they supervise the conditions of exercise of the nuclear activity. At the end of 2020, ASN initiated an experiment in this respect on persons responsible for nuclear activities who are either suppliers of category A, B or C sealed radioactive sources or users of such sources in the Auvergne-Rhône-Alpes region. The preparation of this experiment included numerous interchanges with the CoSSeN.

Thanks to this experiment, the procedures applicable by all the ASN entities concerned were definitively laid down, and improvements were made to the form used to collect information to be forwarded to the CoSSeN to initiate the check. At the end of 2021, all the trustworthiness checks were being initiated for the existing licenses. As from 2023, these trustworthiness checks will only be carried out again for license renewal applications. License modification applications will not be concerned by this procedure, except when the requested change concerns the nuclear activity licensee. First-time license applications are now systematically subject to a trustworthiness check.

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 functioning of the audio signal associated with the patrol procedure, which aims to confirm that nobody is in the room before authorising the emission of ionising radiation.
- the availability of radioactivity measurement devices in sufficient quantities for the operators who access these rooms and keeping these devices fit for duty.

Lastly, with regard to experience feedback, no Significant Radiation Protection Event (ESR) was reported to ASN in 2021, 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 2021, ASN counted 630 licenses and about ten 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. Added to these factors, since 2019, is the transfer of certain nuclear activities from the licensing system to the notification system (see point 2.4.2). This decrease is continuing with the entry into effect in mid-2021 (see point 2.4.3) of the new registration system, which targets in particular the holding/utilisation of unsealed sources, hitherto governed by the licensing system. The complete transitions of research laboratories from the licensing system to the registration system will continue over the coming years, particularly for the laboratories that reduce the quantities of radionuclides handled. These facilities and laboratories use mainly unsealed sources for medical and biomedical research, molecular biology, the agrifood business, the sciences of matter and materials, etc. They can also be suppliers of unsealed sources. They also use sealed sources for performing gas-phase chromatography, liquid scintillation counting or in irradiators. X-ray generators are also used for X-ray fluorescence or X-ray diffraction spectrum analysis. Particle accelerators are used for research into matter or for the production of radionuclides.

3.4.2 The radiation protection situation

In 2021, ASN carried out 67 inspections in this sector[(2)] (compared with 52 inspections per year on average over the 2019-2021 period). This rise with respect to 2020 (42 inspections) is the consequence of postponing until 2021 the inspections which could not take place in 2020 on account of the Covid-19 pandemic. Broadly speaking, the actions undertaken over the last few years have brought improvements in the implementation of radiation protection within research laboratories thanks to a growing overall awareness of the radiation exposure risks.

Among the areas of progress observed in 2021, ASN underlines the strong involvement of the RPAs, due in particular to the allocation of dedicated means and their interaction with the research teams, thereby allowing better integration of radiation protection. Conversely, the conditions of storage and removal of waste and effluents remain the main difficulties encountered by the research units. This worrying situation is particularly

2. Among these inspections, 14 focused exclusively on the use of sealed radioactive sources or X-ray emitting devices.

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.

pronounced in universities which have historically stored their expired/disused sealed radioactive sources and their waste contaminated by radionuclides, sometimes over very long periods of time rather than disposing of them regularly, which today poses two main problems:
- in view of their diversity, the radioactive waste and expired/disused radioactive sources cannot be further managed without first being precisely identified and characterised;
- this retrieval, to which must be added prior characterisation where applicable, represents a significant financial cost which has often been neither foreseen nor budgeted for.

The technical, economic and regulatory difficulties concerning the disposal of legacy sealed sources therefore persist, despite entry into effect on 1 July 2015 of Decree 2015-231 of 27 February 2015 relative to the management of disused sealed radioactive sources. In effect, this text, which aims to facilitate the disposal of sealed sources, gives source holders the possibility of seeking alternative disposal routes with source suppliers or Andra without making it obligatory to return the source to its original supplier.

ASN has moreover identified areas for progress, which will remain points requiring particular attention in the next inspections, especially the performance and traceability of the checks before final disposal of the waste, as traceability is still incomplete, if not –as in many cases– absent. The inspections in 2021 have revealed a lack of rigour in complying with the license conditions, particularly those concerning the use of the rooms, or license updating if there is a change in practices. Lastly, a few deviations are noted due to failure to fully apply the periodic verifications programme (verifications that are incomplete or lacking). Entry into effect of the Order of 23 October 2020 concerning the radiation protection verifications of equipment and workplaces gives the RPA's more responsibilities in this area. Particular attention shall be paid to this point in the next inspections.

As in 2020, 2021 saw continued improvement in the systematic setting up of systems for recording and analysing adverse events and ESR's. In effect, virtually all the inspected facilities had an events recording system.

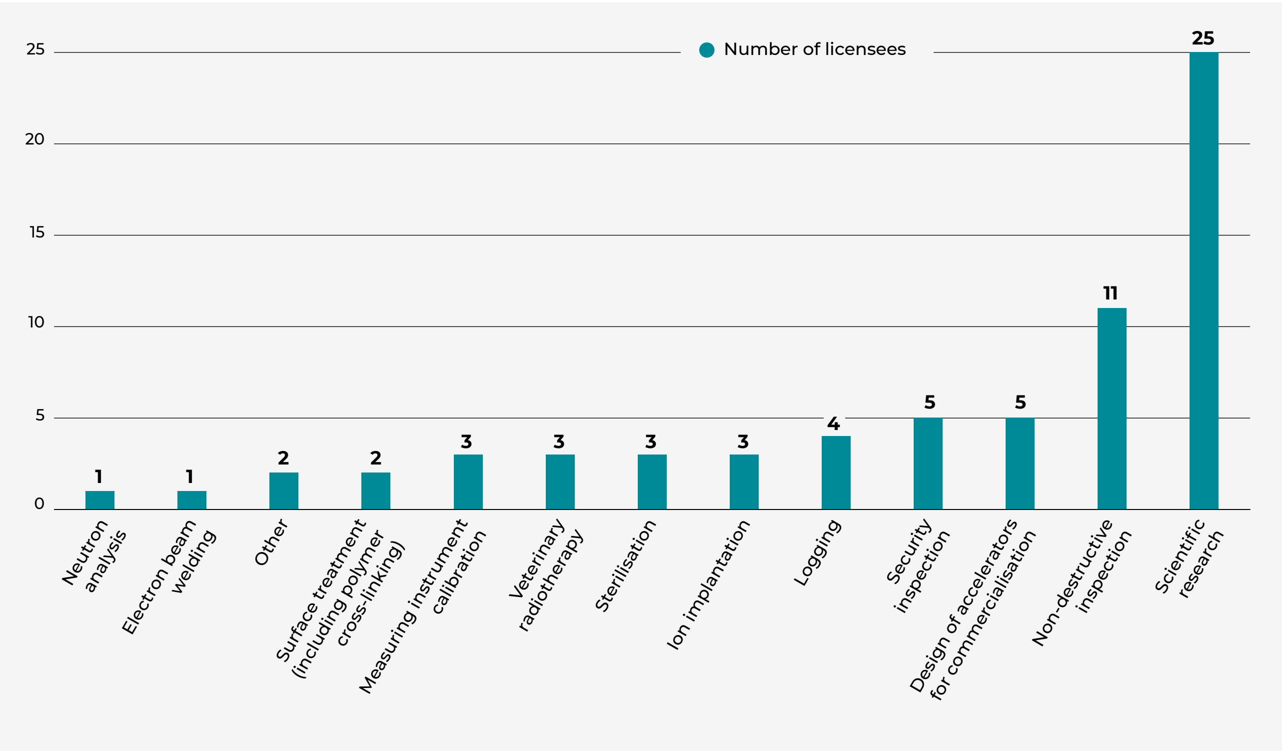
In 2021, ASN recorded 35 ESRs concerning research activities (see Graph 12).

The reported ESRs are essentially of three types:
- discovery of sources (63 %);
- slight contamination of workers or the work environment during the handling of sources (26%);
- transfer of waste to an inappropriate disposal route (6%).

The discoveries of sources can be explained in particular by poor overall traceability: this often results from the failure to take action to dispose of them when laboratories cease their activity, or from irregular and incomplete keeping of source inventories.

Whereas cases of contamination of workers or the environment were virtually inexistent in 2020 due to the reduction or even the stoppage of manipulations because of the Covid-19 pandemic this type of event constitutes a quarter of the ESR's in 2021. These contaminations are often due to equipment deficiencies, which are discovered during the in-house verifications; however, the doses received by the workers remain below the regulatory limits.

GRAPH 10 **Breakdown of particle accelerators by end-purpose in 2021**



Indeed, only one event of this type was rated level 1 on the INES scale. This was a case of atmospheric contamination in a laboratory which led to internal and external contamination of a worker. A reactive follow-up inspection of this laboratory is planned in 2022.

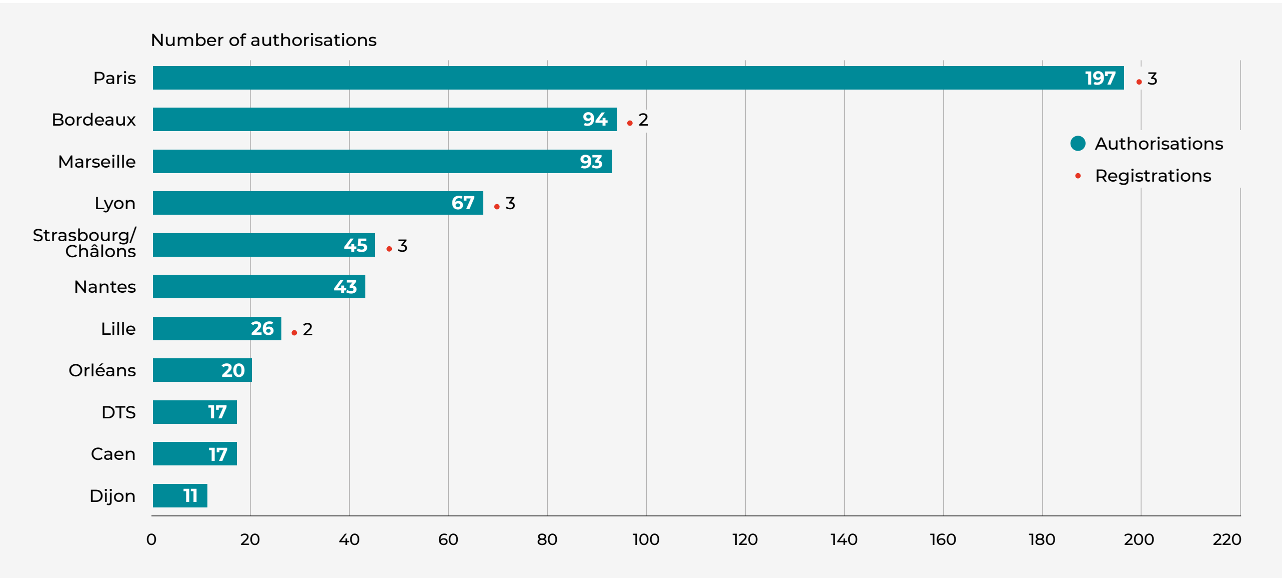
Lastly, the directing of waste to the wrong disposal routes often concerns material contaminated by unsealed sources and poorly characterised before removal.

ASN is also continuing its collaboration with the General Inspectorate of the National Education and Research Administration, which has competence for labour inspection in the public research sector. An agreement signed in 2014 provides for mutual information sharing to improve the effectiveness and complementarity of the inspections. An annual meeting is held to assess the functioning of this collaboration.

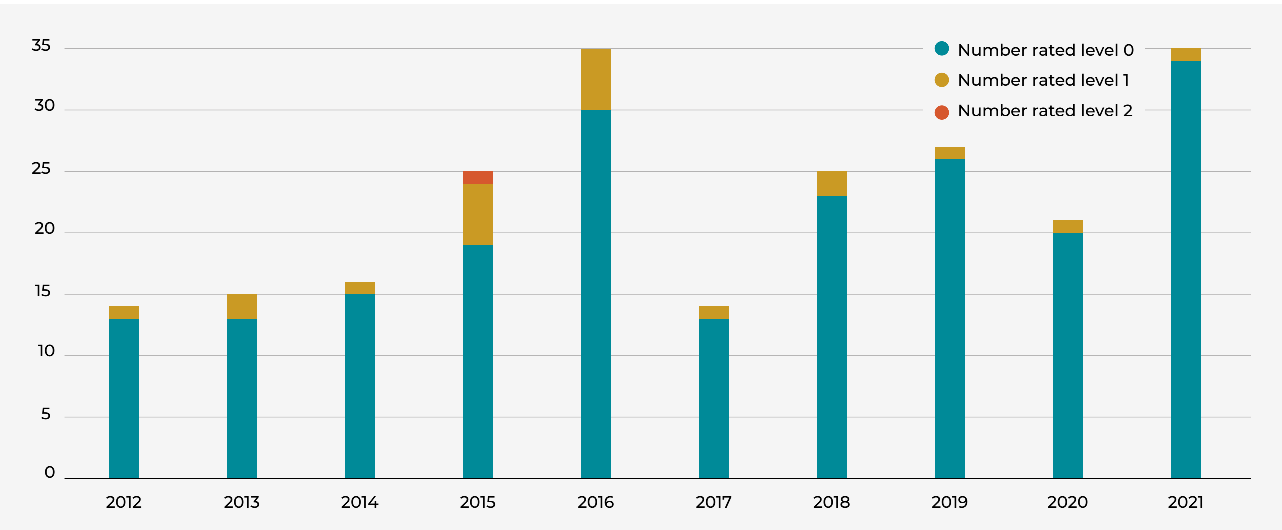
RESEARCH ACTIVITIES

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.

GRAPH 11 **Distribution over the French territory, according to the competent ASN entity, of licensed or registered facilities using sources of ionising radiation in the research sector in 2021**



GRAPH 12 **Trends in the number of events reported to ASN in the research sector**



4 // Manufacturers and distributors of radioactive sources and their oversight by ASN

4.1 The issues and implications

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 slightly over 150 suppliers with safety significant business, including 35 low and medium-energy cyclotrons which are currently licensed under the Public Health Code in France.

4.2 Cyclotrons

Functioning

As at 31 December 2021, 4 cyclotrons were "on standby" and 31 were in operation, including 1 in the test phase. Among the 30 devices in nominal operation, 16 are used exclusively for the daily production of radiopharmaceuticals, 7 are used for research purposes and 7 for both production and research.

The commissioning of 4 cyclotrons is planned for 2022 and 2023, with two of them expected to start functioning for research purposes in 2022.

The assessment of radiation protection in facilities using cyclotrons

ASN has been exercising its oversight in this area since early 2010. Each new facility or any major modification of an existing facility undergoes an extensive examination by ASN. The main radiation protection issues concerning these facilities must be considered as of the design stage. Application of the relevant standards, in particular standard NF M 62105 "Industrial accelerators: installations", ISO 10648-2 "Containment enclosures" and ISO 17873 "Ventilation systems for nuclear installations", guar–antees safe utilisation of the equipment and brings a significant reduction in risks.

Facilities that have a cyclotron used to produce radionuclides and products containing radionuclides are subject to gaseous effluent discharge limits specified in their license. The discharge levels depend on the frequency and types of production involved.

Systems for filtering and trapping the gaseous effluents are installed in the production enclosures and in the facilities' ventilation systems in order to minimise the activity discharged at the stack outlet. Some licensees have also installed –as close as possible to the shielded enclosures– systems for collecting and storing the gases to let them decay before being discharged, bringing a substantial reduction in the activities discharged into the environment.

Consequently, the discharged activity levels and the short half-life of the radionuclides discharged in gaseous effluents mean there is no significant impact on the public or the environment.

ASN, jointly with IRSN, continued a study they began in 2016 on the gaseous discharges into the environment from these facilities. The conclusions of the first step, which involved both IRSN and the licensees, served to establish in 2018 general principles on managing gaseous effluent discharges, the key points of which will be taken up in a draft regulatory text. Alongside this, new assessments of the impacts of discharges from the facilities situated near residential areas have been carried out, using for some facilities modelling tools that are better suited to near-field studies. To complement this, IRSN acquired a computing tool in 2020 that provides a more accurate estimate of the radiological impacts by better modelling the dispersion of discharges in the immediate vicinity of the site and can perform, if necessary, counter-assessments of the studies provided by the licensees.

Lastly, on 23 September 2021, ASN and IRSN held a meeting to present to the licensees of the 31 cyclotrons in operation, in metropolitan France and overseas, the new guidelines for developing the impact assessment to be included in a license application. 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 will be widely disseminated to the profession in 2022.

ASN performs about ten inspections at facilities of this type each year. Eight sites were inspected in 2021, including one currently being set up. 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, in addition to the aspects relating to radiation protection, the management of abnormal events, monitoring and maintenance of the production equipment, inspection of the surveillance and control systems as well as the gaseous discharge results and the management of waste and liquid effluents. The seven inspected facilities in operation have a satisfactory radiation protection organisation (at least one RPA and one person holding the CAMARI qualification), and a good grasp of the regulations, as much from the viewpoint of worker protection as for the verification of equipment and compliance with the provisions applicable to source, waste and effluent management. One inspected facility, however, exceeded the authorised limit for atmospheric discharges, resulting in it being served a formal compliance notice.

Lastly, national action plans are put into place by the licensees of two major French radiopharmaceutical production groups and are monitored by ASN to ensure continuous improvement of radiation protection and safety in these facilities.

Six ESRs were reported by the cyclotron licensees in 2021. None of these events led to significant exposure of workers or the public.

Two ESRs concerned the delivery of a higher activity than the maximum authorised for the customer, chiefly linked to inconsistencies in the computing aid. Two other ESRs concerned the contamination (with no radiological consequences) of an operator's hand when disconnecting a capillary tube from a flask and the handling of activity levels exceeding those effectively authorised.

Lastly, two facilities reported exceeding of their annual limit for discharges of radioactive gaseous effluents. One of the incidents occurred in a one-off manner during the tests phases prior to putting the cyclotron into routine operation, while the other concerned a fluorine-18 production site where the discharge filtration system was faulty for several months and exceeding the annual limit was not detected immediately. In both cases measures were taken to bring the discharges back within the authorised limits.

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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 of the particles and their acceleration at each revolution.

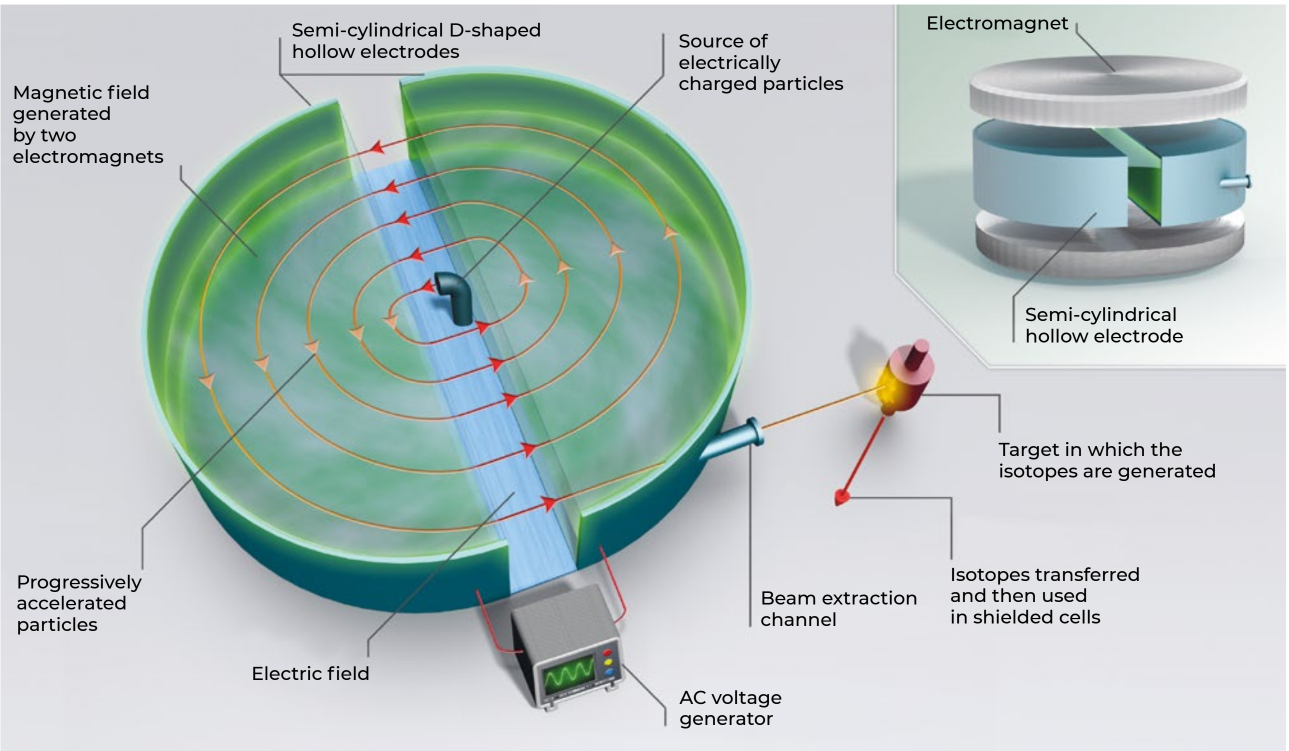
The accelerated particles strike a target which is activated and produces radionuclides.

Low and medium energy cyclotrons are primarily used in research and in the pharmaceutical industry to produce positron emitting isotopes, such as fluorine-18 or carbon-11. The radionuclides are then combined with molecules of varying complexity to form radiopharmaceuticals used in medical imaging. The best known of them is ^{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.

The approximate levels of activities involved for the fluorine-18 usually found in pharmaceutical facilities vary from 30 to 500 GBq per production batch. The positron emitting radionuclides produced for research purposes involve activities that are usually limited to a few tens of gigabecquerels.

SIMPLIFIED DIAGRAM OF THE OPERATION OF A CYCLOTRON

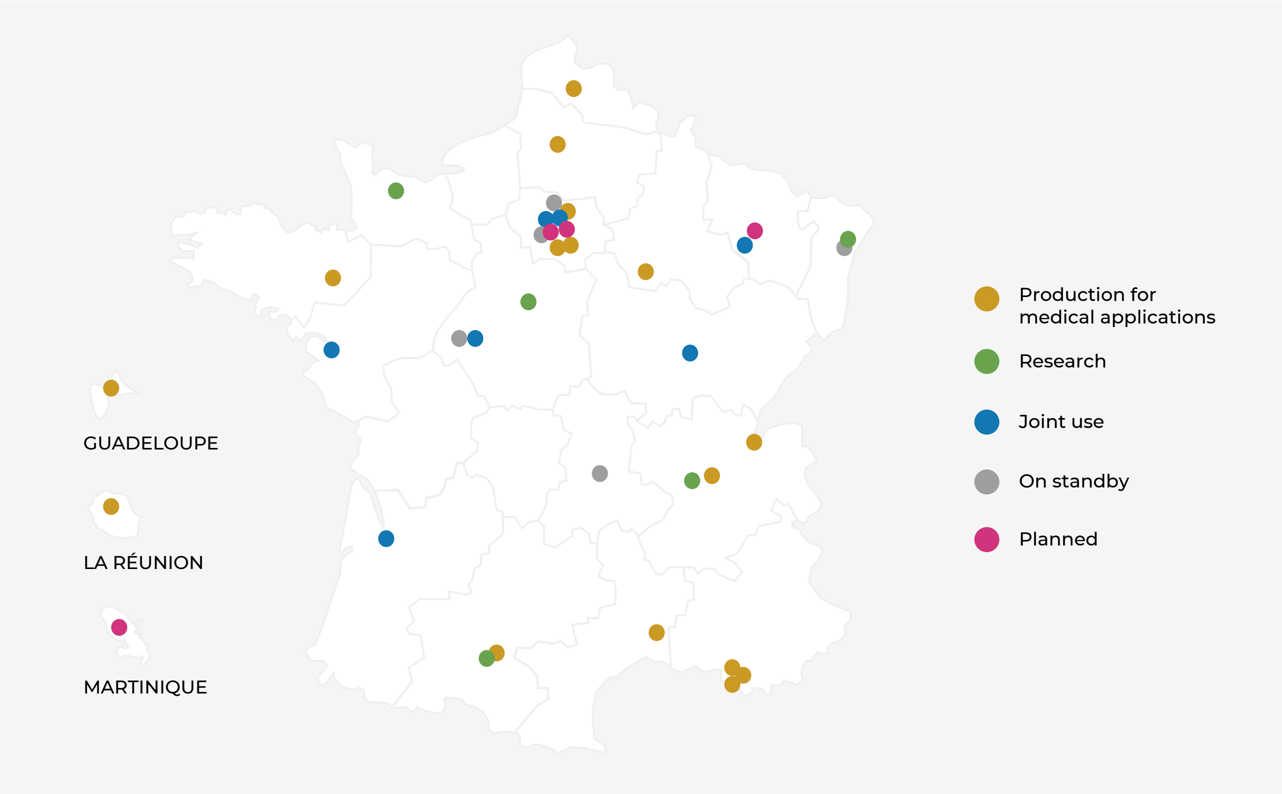


The impact of these events on the people living near the sites remained limited and very far below the regulatory annual dose limit for the public (1 mSv).

These two events led to an incident notice published on the ASN website and were rated level 1 on the INES scale. The site on which discharge limits were exceeded over several months was moreover given formal notice to restore a compliant situation.

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 regulatory text on the technical design and operating rules applicable to companies producing radionuclides using a cyclotron. This draft text was made available for consultation by the stakeholders in 2016. A revised version was produced in 2018, taking account of the observations received and including additional chapters on the control and monitoring of gaseous effluent discharges. This second version of this draft underwent a new consultation by the stakeholders in 2019. Preparation of this draft text will continue in 2022, taking into account the discussions held with the DGT in 2019 and information provided by IRSN in 2020 in order to establish a single regulatory baseline for the entire sector of activity concerned. The main conclusions of this regulatory work are already being used in the examination of license applications in order to include appropriate individual license conditions.

LOCATION OF CYCLOTRONS IN FRANCE



4.3 The other suppliers of sources

Evaluation of radiation protection

Suppliers of radioactive sources, cyclotrons excluded, propose technical solutions for the industrial, medical and research sectors. Suppliers may be manufacturers of "bare" sources or of devices containing sealed radioactive sources, manufacturers of unsealed sources, or distributors who import sources from other countries. Whatever the case, ASN examines the license application files for the sources these suppliers wish to distribute in France.

In 2021, cyclotrons excluded, 25 inspections were carried out (of which 7 were done remotely[3] at manufacturers/suppliers of sealed or unsealed sources, at companies involved in the dismantling and reconditioning of ICSDs, companies recovering lightning conductors and companies manufacturing and installing X-ray generators (although these devices are not yet subject to a distribution license, their utilisation is regulated, including the commissioning and maintenance operations carried out by the companies that sell them). As a complement to what was done until now, 5 of the 25 inspections focused on priority themes other than the supply of sources (protection of sources against malicious acts, maintenance of electrical devices emitting ionising radiation, radiological cleanliness of the sites ceasing their activity, removal of lightning conductors and dismantling of ICSDs). Lastly, two of these inspections concerned foreign companies distributing ionising radiation sources in France.

These inspections have covered about a quarter of the suppliers with safety-significant business, checking specific inspection indicators more particularly linked to the suppliers' responsibilities in the tracking and recovery of disused sealed radioactive sources from the users, in order to dispose of them appropriately, taking into account the radiation risks they present for people and the environment.

ASN considers the radiation protection situation associated with the radionuclide distribution activity to be satisfactory on the whole. The large majority of licensees meet the main requirements and assume their responsibilities adequately (verifications prior to supply, technical verifications of the supplied sources, setting up the source recovery streams, transmission of information to IRSN). These inspections also served to inform source suppliers of new changes in the regulations, particularly those concerning the protection of the radioactive sources they hold, either for their own use of for future supply to customers, against malicious acts.

However, these inspections and the analyses of significant events reports have also revealed points requiring particular attention, including:

- Defining the conditions of source recovery between suppliers and their customers before making the deliveries. This is because the conditions of future recovery of the delivered sources (ten years counting from the date of the first recording figuring on the supply form) are often imprecisely communicated to the customer, which reduces the fluidity of the recovery operations.
- The systematic verifications prior to delivery. 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 a license (or a notification) authorising holding of the source concerned and verification of the fact that the delivery of a source in itself, considering the other sources already delivered by the supplier, will not result in the customer's license limits being exceeded.

3. *The remote inspections were conducted on suppliers who did not hold physical stocks of sources.*

5 // Conclusion and outlook

Implementation of the new regulatory framework applicable to nuclear activities

In 2021, reinforcing of the graded approach to oversight, based on a classification of the different categories of nuclear activities involving sources of ionising radiation continued, with the entry into effect of resolutions relative to the registration system. For the actual entry into effect of this new system, ASN has developed an on-line registration service on its website, allowing application files to be submitted on line, and widely disseminated information to the professionals.

Alongside this, to finalise the overhaul of the systems of the Public Health Code as a whole, ASN will in 2022 start updating the resolutions concerning the content of the application for nuclear activities subject to the licensing system; this update will include, if necessary, the part relating to the supply of devices emitting X-rays. In addition, it will continue its actions to speed up the removal of ICSDs after December 2021.

Lastly, ASN will work in collaboration with the DGT 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).

Oversight of the protection of radioactive sources against malicious acts

ASN has been designated as the authority to oversee the provisions to protect the radioactive sources against malicious acts in the majority of facilities. Publication of the abovementioned Decree brought into effect the first provisions in this respect in mid-2018: those responsible for nuclear activities must more specifically give individual authorisations for access to the most hazardous sources, including for their transport, and for access to sensitive information.

These initial provisions to protect sources against malicious acts have been reinforced with the entry into effect on 1 January 2021 of part of the amended Order of 29 November 2019 which requires company functioning and organization to be adapted to these specific risks.

Although these are new regulatory provisions, it is above all and additional risk (just like the cyber security associated with it, from the moment it concerns information necessary for the protection of sources) to be managed and integrated in the corporate culture particularly through measures to raise awareness and inform the personnel.

In this respect, the senior management of the companies concerned must henceforth determine and formalise a policy of protection against malicious acts implemented by the nuclear activity licensee. The necessary resources, authority and skills must also be delegated to the licensee.

On 1 July 2022, the entire Order will enter into force and the technical systems to ensure the physical protection of the sources will have to be in place. This concerns activities within facilities, on worksites (utilisation, possession) and road transport alike.

Since 2019, the ASN inspections address the protection of sources against malicious acts with greater emphasis. Inspections devoted entirely to this question began in 2021, will be more numerous in 2022 and should reach "cruising speed" as of 2023, the first full year during which the entire amended Order of 29 November 2019 will be applicable.

When examining the nuclear activity licensing applications, ASN ensures that the necessary provisions have been put in place. The required content of the application files has therefore also evolved in recent years to include protection of radioactive sources.

ASN has moreover continued the actions initiated to train its personnel in this new duty and has made in-house aids available (inspection guide, license application examination matrices, question-and-answer sheets).

In addition to the information that can be provided during inspections, regional workshops were organised to present the Order. A guide written jointly by ASN and the Defence and Security High Official of the Ministry responsible for energy (Ministry of Ecological Transition) presenting recommendations for implementing the requirements regarding the protection of sources against malicious acts is currently being prepared. Lastly, to take account of the last three years of feedback from the examination of the license applications, from the inspections and more broadly from the numerous discussions with the professionals, an update of some of the provisions of the Order is already being considered.

09

Transport of radioactive substances

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TRANSPORT OF RADIOACTIVE SUBSTANCES

The transport of radioactive substances is a specific sector of dangerous goods transport characterised by the risks associated with radioactivity. The regulation and oversight of the safety of radioactive substance transports cover a wide range of activities in the industrial, medical and research sectors. This is based on stringent international regulations.

1 // Radioactive substances traffic

The regulations divide the dangerous goods liable to be transported into nine "classes" according to the nature of the corresponding risk (for example: explosive, toxic, flammable, etc. materials). Class 7 covers radioactive substances.

The transport of radioactive substances stands out owing to its considerable diversity. Packages of radioactive substances can weigh from a few hundred grams up to more than a hundred tons and the radiological activity of their content can range from a few thousand becquerels to billions of billions of becquerels for the packages of spent nuclear fuel. The safety implications are also extremely varied. The vast majority of packages have limited individual safety implications, but for a small percentage of them, the potential safety consequences are very high.

About 770,000 consignments of radioactive substances are transported each year in France. This represents about 980,000 packages of radioactive substances, or just a few percent of the total number of dangerous goods packages transported each year in France. The vast majority of shipments are made by road, but some also take place by rail, by sea and by air (see Table 1). These shipments concern three activity sectors: non-nuclear industry, medical sector and nuclear industry (see Graph 1).

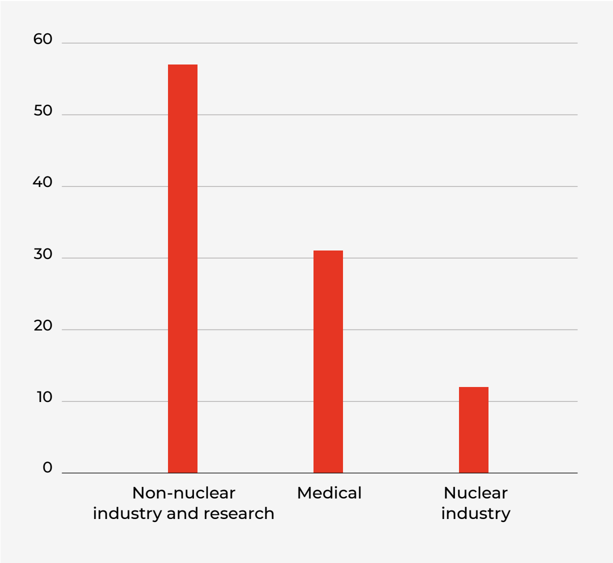
Most of the packages transported are intended for the non-nuclear industry, or for non-nuclear research: this mainly involves devices containing radioactive sources which are not used in a single location and which therefore need to be transported very frequently. For example, these could be devices for detecting lead in paint, used for real estate sale diagnostics, or gamma radiography devices used to detect defects in materials. Travel to and from the various worksites explains the very large number of shipments for the non-nuclear industry. The safety issues vary considerably: the radioactive source contained in lead detectors has very low radiological activity, while that contained in gamma radiography devices has a far higher activity.

About one third of the packages transported are used in the medical sector: this involves providing health care centres with radioactive sources, for example sealed sources used in radiotherapy, or radiopharmaceutical products, and removing the corresponding radioactive waste. The activity of radiopharmaceutical products decays rapidly (for example, the radioactive half-life of fluorine-18 is close to two hours). Consequently, these products have to be regularly transported to the nuclear medicine units, creating a large number of shipments, which have to be carried out correctly to ensure the continuity of the health care given. Most of these products have low activity levels, although a small proportion of them, such as the sources used in radiotherapy or the irradiated sources used to produce technetium (used in medical imaging) have significant safety implications.

Finally, 12% of the packages shipped in France are for the nuclear industry. This represents about 19,000 shipments annually, involving 114,000 packages. These shipments are required to ensure the working of the "fuel cycle", owing to the distribution of the various facilities and Nuclear Power Plants (NPPs) around the country (see map below). Depending on the step in the "cycle", the physicochemical form and radiological activity of the substances varies widely. The transport operations with very high safety implications are notably the shipments of uranium hexafluoride (UF_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 OXide) fuels;

GRAPH 1 **Proportion of packages transported per field of activity in %**



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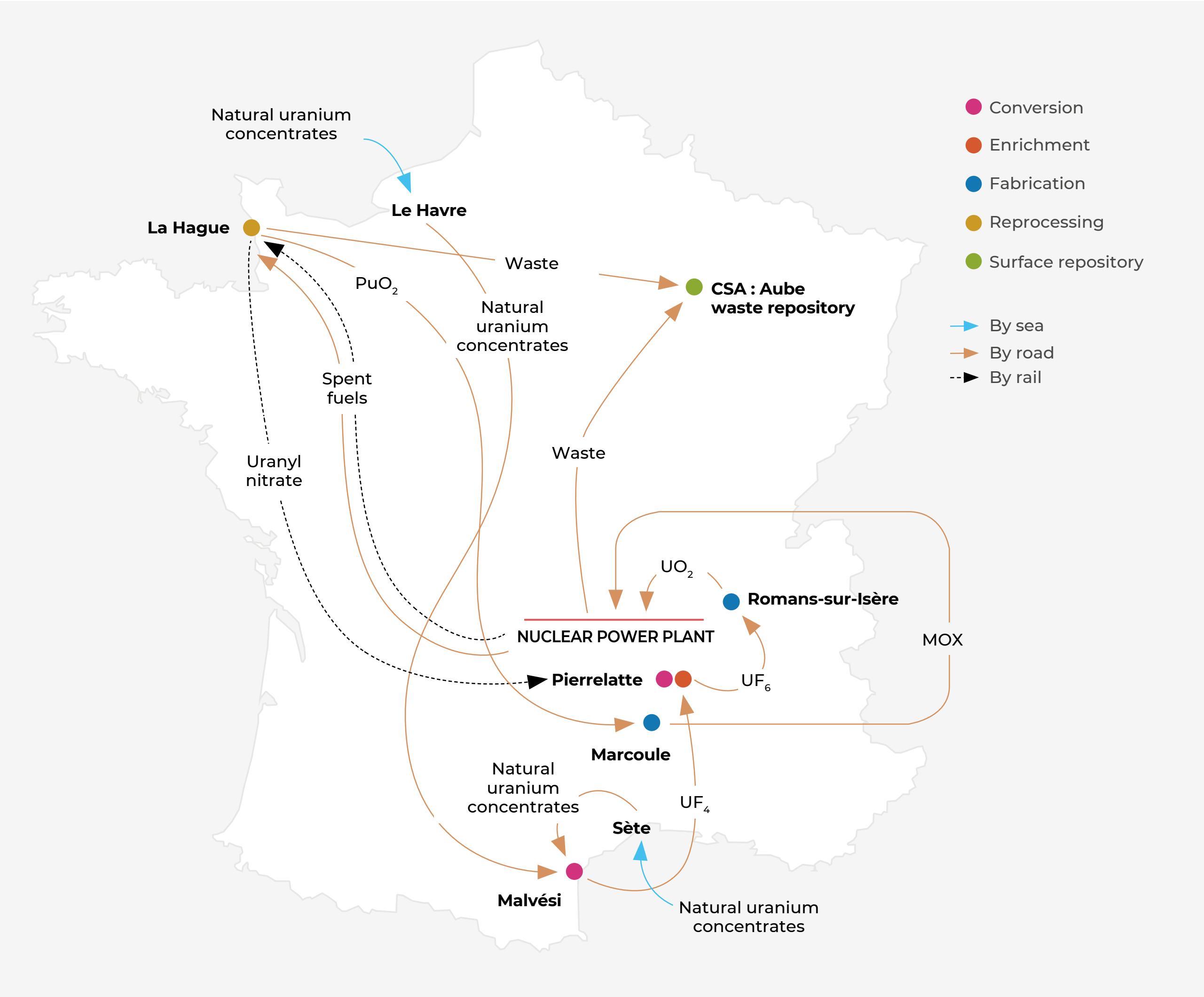
TRANSPORT OPERATIONS RELATING TO THE "FUEL CYCLE" IN FRANCE



- 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. It is based on information collected in 2011 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*").

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 minimise 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 packages

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%

01 02 03 04 05 06 07 08 09 10 11 12 13 14 AP

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 centimeters per hour –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 metre);
- compression equivalent to five times the weight of the package;
- penetration by dropping a standard bar onto the package from a height of 1 metre.

Additional tests are required if the content of the package is in liquid or gaseous form.

Industrial packages allow the transportation of material with a low specific activity, or objects with limited surface contamination. Uranium-bearing materials extracted from foreign uranium mines are, for example, carried in France in industrial drums with a capacity of 200 litres loaded into industrial packages. Three sub-categories of industrial packages exist according to the hazards presented by the content. Depending on their sub-category, the industrial packages are subjected to the same tests as type A packages, some of the tests or only the general provisions applicable to excepted packages.

As a result of the restrictions on the authorised contents, the consequences of the destruction of a type A package or an industrial package would remain manageable, provided that appropriate accident management measures are taken. The regulations do not therefore require that this type of package be able to withstand a severe accident.

Due to the limited safety implications, type A and industrial packages are not subject to ASN approval: the design of the packages and the performance of the tests are the responsibility of the manufacturer. These packages and their safety case files are subject to spot checks during the ASN inspections.

2.3.3 Type B packages and packages containing fissile substances

Type B packages are those used to transport the most radioactive substances, such as spent fuels or high-level vitrified nuclear waste. The packages containing fissile substances are industrial, A or B type packages, which are also designed to carry materials containing uranium-235 or plutonium and which can thus lead to the start of an uncontrolled nuclear chain reaction. These packages are essentially used by the nuclear industry. Gamma radiography devices also fall into the type B package category.

Given the high level of risk presented by these packages, the regulations require that they must be designed so that, including in the case of a severe transport accident, they maintain their ability to confine the radioactive substances and ensure radiological protection (for type B packages) as well as sub-criticality (for packages containing fissile materials). The accident conditions are simulated by the following tests:
- a 9m drop test onto an unyielding target. The fact that the target is unyielding means that all the energy from the drop is absorbed by the package, which is highly penalising. If a heavy package actually falls onto real ground, the ground will deform and thus absorb a part of the energy. A 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 kilometres per hour (km/h). However, this corresponds to a real impact at far greater speed, because in reality, the vehicle and obstacle would both absorb a part of the energy;
- a penetration test: the package is released from a height of 1 metre onto a metal spike. The aim is to simulate the package being damaged by perforating objects (for example, debris torn off a vehicle in the event of an accident);
- a fire test at 800°C for 30 minutes. This test simulates the fact that the vehicle can catch fire after an accident;
- an immersion test under 15 metres of water for 8 hours. This test is used to test the pressure-resistance of the package if it were to fall into water (river by the side of the road or port during offloading from a ship). Certain type B packages must also undergo a more severe immersion test, which consists in immersion under 200 metres of water for one hour.

NEW 2020 EDITION OF STANDARD ISO 7195

This standard:
- clarifies the specifications for the UF_6 transport cylinders to ensure compatibility between the various users;
- describes the design of the cylinders;
- details the manufacturing requirements for the procurement of new cylinders designed for the transport of 0.1 kilograms or more of UF_6;
- sets the manufacturing requirements for the procurement of new valves and new plugs;
- determines the requirements concerning the cylinders and valve covers in service.

This third edition supersedes the previous edition ISO 7195:2005. The main changes with respect to the previous edition concern:
- the general structure of the document, which has been reorganised for greater clarity and easier comparison with the equivalent American standard ANSI N14.1;
- withdrawal of the 48G cylinder model, replaced by the 30C cylinder;
- introduction of countersunk head plugs for the 30 and 48 inch cylinders, in addition to the hex-head plugs;
- for the 30B, 48X and 48Y cylinders, the possibility of using non-destructive inspections as an alternative to the hydrostatic checks during the periodic inspections, provided that additional inspections are carried out during manufacturing;
- the use of different tightness test methods;
- the ban on reusing valves and plugs previously removed from the cylinders.

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 shipped. 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 requirements for packages of UF_6. They must meet the requirements of standard ISO 7195 (see box previous page), which governs the design, manufacture and utilisation of packages. These packages are also subject to three tests:
- a free-fall test of between 0.3 and 1.2 metres (depending on the weight of the package) onto an unyielding target;
- a thermal test, with an 800°C fire for 30 minutes;
- a hydrostatic resistance test at 27.6 bar.

Packages containing enriched, and therefore fissile UF_6, are also subject to the requirements previously presented (see point 2.3.3).

The UF_6 is transported in 48Y or 30C type 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 1mSv. 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 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.

PREVENTION OF RISKS OF EXPOSURE TO IONISING RADIATION

The joint ASN and Ministry for Labour instruction DGT/ASN/2018/229 of 2 October 2018, concerning the prevention of risks of exposure to ionising radiation, broadened the scope of application of the notion of "zoning", which aims to limit worker and public exposure, to the transfer of radioactive substances within a facility, its annexes or worksites. Thus, the phases of package loading or unloading on a conveyance, modification of a shipment, transhipment or temporary parking within the perimeter of a facility or its annexes can lead to the creation of a "monitored" or "controlled" zone, depending on the characteristics of the packages carried.

In addition, specific actions are provided for in the Order of 23 October 2020 regarding measurements taken for the assessment of risks and checks on the effectiveness of the prevention means put into place for the protection of workers against the risks from ionising radiation. It notably requires that the periodic checks on vehicles used to carry radioactive substances are performed or supervised by the Radiation Protection Advisor. Whereas the first check is carried out before a vehicle is used for carriage of radioactive substances, to ensure the radiological cleanness of the vehicle, the subsequent checks are carried out to ensure that there is no contamination of the vehicle. These checks are conducted at a frequency defined by the employer, taking account of the frequency of shipments and the radiological issues, as well as after each transport operation for which a contamination risk has been identified. In any case, the time between two checks may not exceed three months.

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.*

CREATION OF A SYSTEM OF AUTHORISATION FOR SECURITY REASONS

Pursuant to Articles L. 1333-8 and R. 1333-146 of the Public Health Code, ASN intends to revise its resolution 2015-DC-0503 on the system of notification for companies transporting radioactive substances on French territory, so that the transport operations involving the most highly radioactive sources will be subject to authorisation owing to their security implications. Authorisation will therefore be required for the transport of sealed radioactive sources, or batches of category A, B or C sources, as defined in Appendix 13-7 to the Public Health Code.

The workers involved in the transport of radioactive substances are also subject to the provisions of the Labour Code concerning protection against ionising radiation.

On 29 March 2018, ASN published Guide No. 29 to help carriers meet their regulatory obligations relative to the radiation protection of workers and the general public. ASN has begun to update this Guide, to take account of the new provisions of the Labour Code and the Health Code, and their implementing texts, for example the Order of 23 October 2020 (see box in the previous page), resulting from Directive 2013/59/Euratom (known as the "BSS" Directive). In 2022, ASN will continue actions to inform professionals, and more specifically raising awareness on changes to the regulations.

2.4.2 Package and vehicle marking

So that the workers can be informed of the level of risk arising from each package and so that they can protect themselves effectively, the regulations require that the packages be labelled. There are three types of labels, corresponding to different dose rate levels in contact and at 1m from the package. The personnel working in proximity to the packages are thus visually informed of those which lead to the highest dose rates, and can thus limit the time they spend close to them and can put them as far away as possible (for example, by loading them towards the rear of the vehicle).

The packages containing fissile materials must also display a special label. This is to ensure that these packages are kept apart to prevent the triggering of a nuclear chain reaction. The special label enables compliance with this prescription to be easily verified.

Finally, the markings on packages must comprise their type, the address of the consignor or consignee and an identification number. This enables delivery errors to be avoided and allows packages to be identified if lost.

The vehicles carrying packages of radioactive substances must also have specific markings. Like all vehicles carrying dangerous goods, they carry an orange-coloured plate at the front and back. They must also carry a placard with the radiation trefoil and the word "Radioactive". The purpose of these vehicle markings is to provide the emergency services with the necessary information in the event of an accident.

2.4.3 Responsibilities of the various transport players

The regulations define the responsibilities of the various parties involved during the lifetime of a package, from its design up to the actual shipment. These responsibilities entail special requirements. Therefore:

- the package model designer shall have designed and sized the packaging in accordance with the intended conditions of use and the regulations. It must obtain an ASN certificate (or in certain cases a certificate from a foreign authority) for type B or fissile packages containing UF_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;
- the transport may be organised by the forwarding agent. The forwarding agent is responsible, on behalf of the consignor or the consignee, for obtaining all the necessary authorisations and for sending the various notifications required by the regulations. The forwarding agent also selects the conveyance, the carrier and the itinerary, in compliance with the regulatory requirements;
- the loader is responsible for loading the package onto the vehicle and for stowing it in accordance with the consignor's specific instructions and the rules of good professional practice;
- the carrier and, more particularly, the driver, is responsible for carriage of the shipment to its destination. Their duties include checking the good condition of the vehicle, the presence of the on-board equipment (extinguishers, driver's personal protection equipment, etc.), compliance with the dose rate limits around the vehicle and the display of the orange plates and placards;
- the consignee is under the obligation not to postpone acceptance of the goods, without imperative reason and, after unloading, to verify that the requirements concerning them have been satisfied. It must more specifically perform dose rate measurements on the package after receipt in order to detect any problems that may have occurred during shipment;
- the package owner must set up a maintenance system in conformity with that described in the safety case and the approval certificate in order to guarantee that the elements important for safety are maintained in good condition.

All the transport players must set up a quality management system, which consists of a range of provisions for meeting 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.

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 territory shall declare these transport activities to the ASN, using the ASN on-line services portal(3), before carrying them out. This on-line service has also been available in English since mid-2019.

3. *teleservices.asn.fr*

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 2021, 1,418 notifications were sent to ASN.

2.5 Preparedness for management of emergency situations

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.

The driver may be unable to give the alert, if injured or killed in the accident. In this case, detection of the radioactive nature of the consignment would be the entire responsibility of the first responder emergency services. The orange-coloured plates and the trefoil symbols on the vehicles thus indicate the presence of dangerous goods: the emergency services are then instructed to automatically evacuate an area around the vehicle, usually with a radius of 100 metres, and to notify the radioactive nature of the load to the Office of the Prefect, which will then alert ASN.

Management of the accident is coordinated by the Prefect, who oversees the response operations. Until such time as the national experts are in a position to provide him or her with advice, the Prefect relies on the emergency plan adopted to deal with these situations. Once its national emergency centre has been activated, ASN is able to offer the Prefect assistance by providing technical advice on the more specific measures to be taken. The Institute for Radiation Protection and Nuclear Safety (IRSN) assists ASN in this role, by assessing the condition of the damaged package and anticipating how the situation could develop. Furthermore, the ASN regional division dispatches a staff member to the Prefect to facilitate liaison with the national Emergency Centre.

At the same time, human and material resources would be sent out to the scene of the accident as rapidly as possible (radioactivity measuring instruments, medical means, package recovery means, etc.). The fire service teams specialising in the radioactive risk (the Mobile Radiological Intervention Units –CMIR) would be called on, along with IRSN's mobile units, or even those of certain nuclear licensees (such as the Alternative Energies and Atomic Energy Commission– CEA, or EDF), which could be requisitioned by the Prefect if needed, even if the shipment in question does not concern these licensees.

As with other types of emergency, communication is an important factor in the event of a transport accident so that the population can be informed of the situation and be given instructions on what to do.

In order to prepare the public authorities for the eventuality of an accident involving a shipment of radioactive substances, exercises are held to test the entire response organisation that would be put into place.

ASN will continue in 2022 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 (MARN), ASN produced a document to help direct the actions of the emergency services. It contains general information about radioactivity, general recommendations for the emergency services so that their response can take account of the specific nature of radioactive substance transports, plus sheets organised per type of substance, providing more detailed information and advice for the emergency response coordinator during phase 2.

2.6 Regulations governing the transport operations within the perimeter of nuclear facilities

Dangerous goods transport operations can take place on the private roads of nuclear sites, in what are referred to as "on-site transport operations". Such operations are not subject to the regulations governing the transport of dangerous goods, which only apply on public roads. However, these operations present the same risks and detrimental effects as dangerous goods transports on the public highway. The safety of these operations must thus be overseen with the same rigour as for any other risk or detrimental effect present with the perimeter of BNIs.

This is why the on-site transport of dangerous goods is subject to the requirements of the Order of 7 February 2012 setting out the general rules applicable to BNIs. This Order requires that on-site transport operations be incorporated into the baseline safety requirements for BNIs.

The Environment Code, supplemented by ASN resolution 2017-DC-0616 of 30 November 2017, defines the on-site transport operations for which authorisation must be requested from ASN. In addition, in 2017, ASN published Guide No. 34 providing the licensees with recommendations for implementing the regulatory requirements concerning on-site transport operations.

Finally, in 2020, ASN extended the on-line notification and on-line transmission functions to deal with requests for noteworthy changes to on-site transports as set out in Articles R. 593-59 and R. 593-56 of the Environment Code.

3 // Roles and responsibilities in regulating the transport of radioactive substances

3.1 Regulation of nuclear safety and radiation protection

In France, ASN has been responsible for regulating the safety and the radiation protection of transports of radioactive substance for civil uses since 1997, while the Defence Nuclear Safety Authority (ASND) fulfils this role for transports relating to national defence. Within its field of competence, ASN is responsible, in terms of safety and radiation protection, for the regulation and oversight of all steps in the life of a package: design, manufacture, maintenance, shipment, actual carriage, receipt and so on.

3.2 Protection against malicious acts

The prevention of malicious acts consists in preventing sabotage, losses, disappearance, theft and misappropriation of nuclear materials (as defined in Article R*.1411-11-19 of the Defence Code) that could be used to manufacture weapons. The Defence and Security High Official (HFDS), under the Minister responsible for energy, is the Regulatory Authority responsible for preventing malicious acts targeting nuclear materials.

In the field of transport security, the IRSN Transport Operations Section (EOT) is responsible for managing and processing applications for approval of nuclear material shipments, for supervising these shipments and for notifying the authorities of any alerts concerning them. This security duty is defined by the Order of 18 August 2010 relative to the protection and regulation of nuclear materials during transport. Thus, prior to any transport operation, the Defence Code obliges the carriers to obtain a transport authorisation. The EOT reviews the corresponding application files. This review consists in checking the conformity of the intended provisions with the requirements defined by the Defence Code and the abovementioned Order of 18 August 2010.

ASN has initiated the process to update its resolution 2015-DC-0503 of 12 March 2015 relative to the notification system for companies transporting radioactive substances on French soil. This update aims to introduce an authorisation system for the transport of the most radioactive sources, in the light of their security implications.

In 2019, ASN held a public consultation on the orientations it was planning to adopt for this update. ASN will complete this update, primarily focusing on 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.

3.3 Regulation of the transport of dangerous goods

Regulation of the transport of dangerous goods is the responsibility of the Dangerous Materials Transport Commission (MTMD) of the Ministry responsible for the environment. This entity is tasked with measures relative to the safe transport of dangerous goods other than class 7 (radioactive) by road, rail and inland waterways. It has a consultative body (standing sub-committee in charge of dangerous goods transport, within the High Council for the Prevention of Technological Risks), that is consulted for its opinion on any draft regulations relative to the transport of dangerous goods by rail, road or inland waterway. Inspections are carried out by land transport inspectors attached to the Regional Directorates for the Environment, Planning and Housing (Dreals).

For the regulation of dangerous goods to be as consistent as possible, ASN collaborates regularly with the administrations concerned.

ASN regularly takes part in the training of the General Directorate for Civil Aviation (DGAC) inspectors responsible for the inspection of air transport of dangerous goods in order to present them with the specificities of class 7 and to share experience feedback from ASN's inspections on these subjects.

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 kilogramme of UF_6 must be covered by an ASN approval certificate in order to be transported. The designers of the package models who request approval from ASN must support their application with a safety case demonstrating the compliance of their package with all the regulatory requirements. Before deciding whether or not to issue an approval certificate, ASN reviews these safety cases, drawing on the expertise of IRSN, in order to ensure that the safety cases are pertinent and conclusive. If necessary, the approval certificate is issued with requests in order to improve the safety case.

In some cases the IRSN appraisal is supplemented by a meeting of the ASN Advisory Committee for Transports (GPT). The opinions of the Advisory Committee are always published on *asn.fr*. The approval certificate specifies the conditions for the manufacture, utilisation and maintenance of the transport package. It is issued for a package model, independently of the actual shipment itself, for which no prior ASN opinion is generally required. This shipment may however be subject to safety checks (physical protection of the materials against malicious acts under the supervision of the HFDS of the Ministry for the Environment).

These approval certificates are usually issued for a period of five years. If a package is unable to meet all the regulatory requirements, the regulations nonetheless allow for its transport by means of a shipment under special arrangement. The consignor must then define compensatory measures to ensure a level of safety equivalent to that which would have been obtained had the regulatory requirements been met. For example, if it cannot be completely demonstrated that a package is able to withstand the 9m drop, a compensatory measure may be to reduce the speed of the vehicle, have it escorted and choose a route avoiding such a drop height. The probability of a serious accident, and thus of a violent shock on the package, is thus considerably reduced. A shipment under special arrangement is only possible with the approval of the competent authority, which then issues approval for shipment under special arrangement, stipulating the compensatory measures to be applied.

In the case of certificates issued abroad, the international regulations provide for their recognition by ASN. In certain cases, this recognition is automatic and the foreign certificate is directly valid in France. In other cases, the foreign certificate is only valid if endorsed by ASN, which then issues a new certificate.

In 2021, 42 approval applications were submitted to ASN by various companies.

ASN issued 42 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.

In 2019, the Robatel Industries company began the development of a new packaging, called R85, designed for the road or rail transport of irradiated and contaminated control rod cluster guide tubes from French NPPs. Before shipment, the package may be stored for several years. In mid-2020, ASN issued a favourable opinion on the safety options for this new package model, in the light of the new provisions of the 2018 edition of IAEA's SSR-6 regulations. In 2022, the GPT will review the safety of the new package model.

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 2021, ASN carried out 108 inspections in the field of radioactive substances transport (all sectors considered). The follow-up letters to these inspections are available on *asn.fr*.

4.2.1 Regulation of package manufacturing

The manufacture of transport packaging is subject to the regulations applicable to the transport of radioactive substances. The manufacturer is responsible for producing packagings in accordance with the specifications of the safety case, demonstrating regulatory compliance of the corresponding package model. To do this, it must implement a quality management system covering all the operations from procurement of parts and raw materials up to final inspections. Furthermore, the manufacturer must be able to prove to ASN that it complies with the regulatory provisions and, in particular, that the as-built packagings are compliant with the specifications of the safety case.

The inspections carried out by ASN in this field aim to ensure that the manufacturer satisfactorily fulfils its responsibilities.

In 2021, ASN carried out three inspections on the manufacturing of various packagings for which ASN had issued an approval certificate, at various steps in the manufacturing process: welding, final assembly, manufacturing completion checks, assembly of internals (to immobilise the contents), etc.

During these inspections, ASN reviews the quality management procedures implemented for the manufacture of a packaging on the basis of the design data and verifies their effective implementation. ASN ensures that the inspections performed and any manufacturing deviations are traceable. It also visits the manufacturing shops to check the package components storage conditions, the calibration of the inspection instruments and compliance with the technical procedures at the various manufacturing steps (welding, assembly, etc.).

ASN checks the monitoring of package manufacturing by the lead contractor and may intervene directly on the sites of any subcontractors, who may sometimes be located abroad.

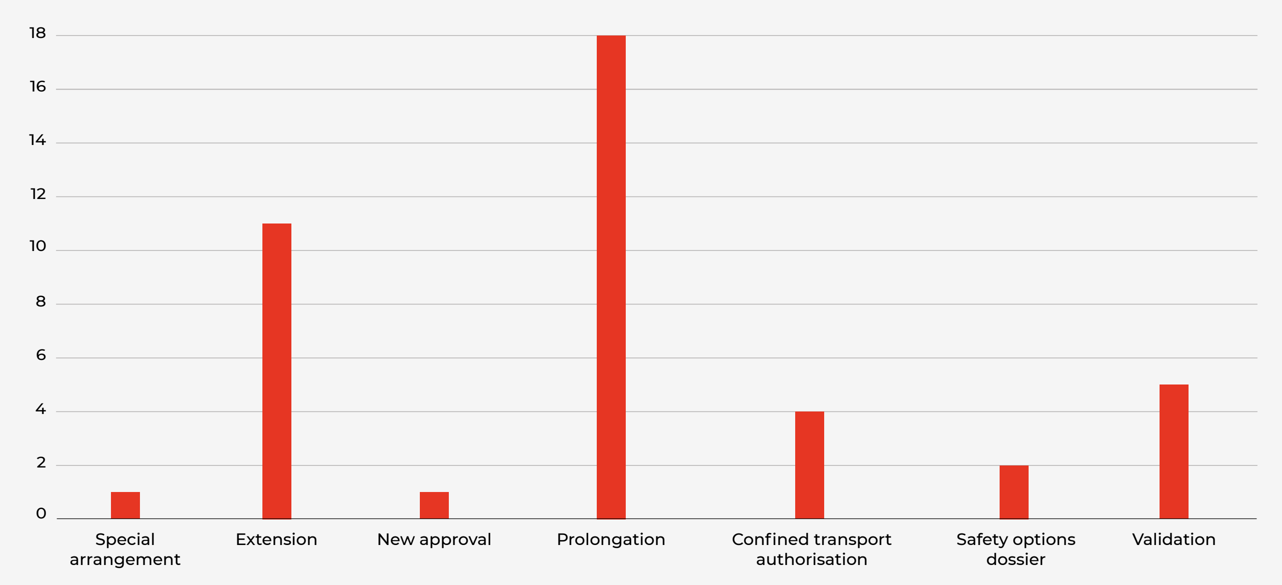
ASN may also inspect the manufacture of the specimens used for the drop tests and fire tests required by the regulations. The objectives are the same as for the series production model because the specimens must be representative and comply with the maximum requirements indicated in the mock-up manufacturing file, which will determine the minimum characteristics of the actual packaging to be manufactured.

In 2022, ASN intends to continue spot-check inspections of transport packaging manufacturing. This is because the irregularities detected at the Framatome Le Creusot plant, which notably affected certain transport packagings, confirmed the importance of inspecting the packaging manufacturing and maintenance operations.

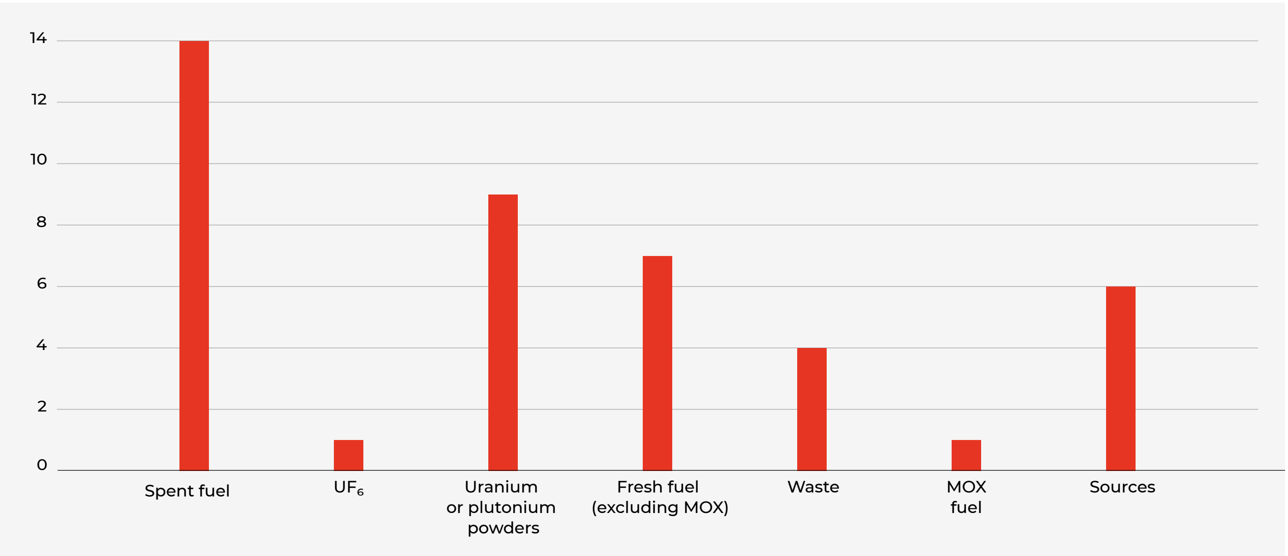
TABLE 3 **Administrations responsible for regulating the mode of transport and the packages**

MODE OF TRANSPORT	REGULATION OF MODE OF TRANSPORT	PACKAGE REGULATION
By sea	Directorate General for Infrastructures, Transports and the Sea (DGITM) at the Ministry for the Environment. In particular, the DGITM is responsible for regulating compliance with the prescriptions applicable to ships and contained in the International Code for the Safe Carriage of irradiated nuclear fuel, plutonium and high-level radioactive wastes on board ships ("Irradiated Nuclear Fuel" Code).	The DGITM has competence for regulation of dangerous goods packages in general and is in close collaboration with ASN for radioactive substances packages.
By road, rail and inland waterways	General Directorate for Energy and Climate (DGEC) of the Ministry for the Environment.	The General Directorate for the Prevention of Risks (DGPR) is responsible for regulation of packages of dangerous goods in general and, in close collaboration with ASN, of packages of radioactive substances.
By air	General Directorate for Civil Aviation (DGAC) at the Ministry for the Environment.	The DGAC has competence for regulation of dangerous goods packages in general and is in close collaboration with ASN for radioactive substances packages.

GRAPH 2 **Breakdown of number of approvals according to type, issued in 2021**



GRAPH 3 **Breakdown of number of approvals according to content transported, issued in 2021**



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, updated in 2016, proposes a structure and a minimum content for the safety cases demonstrating that packages which are not subject to approval do comply with all the applicable requirements, along with the minimum content of a declaration of conformity of a package design with the regulations.

ASN thus noted improvements in the content of the certificate of conformity and the safety case drawn up by the relevant players, more specifically for the industrial package models. The representativeness of the tests performed and the associated safety case remain the focal points during the ASN inspections, in particular for type A packages.

Furthermore, ASN still finds shortcomings in the demonstration by some of the players (designers, manufacturers, distributors, owners, consignors, companies performing the regulatory drop tests, package maintenance, etc.) of package conformity with the regulations. The areas for improvement concern the following points in particular:

- the description of the authorised contents per type of packaging;
- the demonstration that there is no loss or dispersion of the radioactive content under normal conditions of transport;
- compliance with the regulatory requirements regarding radiation protection, more specifically the demonstration, as of the design stage, that it would be impossible to exceed the dose rate limits with the maximum authorised content.

4.2.4 Monitoring the shipment and transportation of packages

The scope of ASN inspections includes all regulatory requirements binding on each of the transport players, that is compliance with the requirements of the approval certificate or declaration of conformity, training of the personnel involved, implementation of a radiological protection programme, satisfactory stowage of packages, dose rate and contamination measurements, documentary conformity, implementation of a quality assurance programme, etc.

More particularly with respect to transports concerning small-scale nuclear activities, the ASN inspections confirm significant disparities from one carrier to another. The differences most frequently identified concern the quality assurance programme, actual compliance with the procedures put into place and radiation protection of the workers.

Knowledge of the regulations applicable to the transport of radioactive substances seems to be sub-standard in the medical sector in particular, where the procedures adopted by some hospitals or nuclear medicine units for package shipment and reception need to be tightened. Their quality management system has not yet been formally set out and deployed, more specifically with regard to the responsibilities of each member of staff involved in receiving and dispatching packages.

More generally, in transport operations for small-scale nuclear activities, the radiological protection programmes and the safety protocols have not yet been systematically defined. ASN also found that checks on vehicles and packages prior to shipment need to be improved. The inspections concerning the transport of gamma ray projectors regularly reveal inappropriate stowage or tie-down.

In the BNI sector, ASN considers that the consignors must improve how they demonstrate that the content actually loaded into the packaging complies with the specifications of the approval certificates and the corresponding safety cases, including if this demonstration is provided by a third-party. In this latter case, the consignor's responsibilities then require that it verify that this demonstration is appropriate, and that it monitor the third-party company in accordance with the usual methods of a quality assurance system.

As BNI licensees are increasingly using contractors to prepare and ship packages of radioactive substances, ASN is paying particularly close attention to the organisation put into place to monitor these contractors.

Finally, with regard to on-site transports within NPPs, ASN considers that the licensees must remain vigilant to the application of package stowage rules.

4.2.5 Oversight of preparedness for emergency situations management

In order to reinforce the preparedness of the transport operators (mainly consignors and carriers) for emergency situations management, ASN published Guide No. 17 in December 2014 on the content of accident and incident management plans concerning the transport of radioactive substances. This Guide recommends the production of plans to prepare for emergency situations management and stipulates their minimum contents.

4.2.6 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 it can ensure that the detection system, the analysis approach and the integration of Operating Experience Feedback (OEF) are effective. This also provides ASN with an overview of events so that the sharing of 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 (see box page 276).

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, which was entirely revised in 2017, is available on *asn.fr*. After notification, a detailed report of the event must be sent to ASN within two months.

Events notified in 2021

In 2021, in the field of radioactive substances transport, ASN was notified of 80 Significant Events for Transport safety (EST) rated "level 0" on the International Nuclear and Radiological Event Scale (INES) and four events rated "level 1". A slight rise in the number of "level 0" events is observed by comparison with 2020, whereas the number of "level 1" events remains stable. Graph 4 shows the variations in the number of significant events notified since 2004.

In addition, ASN was notified of 52 Events Relevant for Transport safety (EIT), a figure that was significantly up on the previous years. Given that they have no actual or potential consequences, these events are not rated on the INES scale. There is thus no obligation to notify ASN, but the latter does encourage periodic information so that it has an overview of the EITs and can detect any recurrence or trends which could be indicative of an issue.

In 2020, for the first time, two Significant Events for On-site Transport (see point 2.6) rated "level 0" on the INES scale, were reported. This figure rose to three in 2021.

The increase in the reported Events Relevant for Transport safety (EIT) and Significant Events for On-site Transport (EST) indicates an improvement in the culture of safety and reporting to ASN.

Sectors concerned by these events

Most of the significant events (EST) notified concern the nuclear industry. Only just over 10% are related to transports for the non-nuclear industry. By comparison with 2020, the number of transport events involving pharmaceutical products fell considerably and only represents barely 7% of the significant events (as against 21% in 2020). As for the events rated "level 1" on the INES scale, they concerned loss of a source during a journey back to the office by a real estate diagnostic technician, non-compliance with a package transport approval certificate, the poor design of a vent plug, and the under-estimation of the quantity of radioactive substances in a tanker.

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.

INSPECTION ON THE TOPIC OF CRITICALITY

A inspection was carried out at the Cattenom NPP on 8 June 2021. The topic was maintaining sub-criticality when using the TN 13/2 package for transport on the public highway and the aim was to conduct spot checks on compliance with the regulatory requirements applicable to the transport of radioactive substances. The TN 13/2 package model is designed to transport uranium oxide based spent fuel assemblies. It is notably approved by ASN as a type B(M) package for the transport of fissile material.

The inspectors more particularly examined the manufacturing files for a packaging shipped by the NPP, and its internal arrangements. They then looked at the maintenance operations carried out on this packaging, and the loading of the fuel assemblies into the packaging, notably in order to verify the packaging cavity drainage and drying operations. During the inspection, both on the site and via audioconference with certain players, the inspectors were able to hold discussions with representatives from Orano Nuclear Packages and Services (Orano NPS), the designer and manufacturer of the TN 13/2 package model, representatives from the package consignor –the Cattenom NPP– and representatives from EDF's head office support departments.

The transport regulations notably state that the consignor must hand over to the carrier a shipment that complies with the regulatory requirements and that it only use approved packagings suitable for transport and carrying the regulation markings. If the consignor calls on the services of other contractors (loaders, packers), it must take appropriate measures to guarantee that the shipment meets the requirements of the transport regulations. The inspection was thus carried out on the package dispatch site.

The ASN inspectors were accompanied by two experts from the IRSN office in charge of criticality studies, as well as an expert from the IRSN office in charge of transports.

The inspection showed that the transport operation inspected, with significant safety implications in terms of maintaining sub-criticality, was on the whole carried out in accordance with the safety case produced for the TN 13/2 package model, on the basis of which ASN had issued the approval of compliance with international transport regulations. However, the inspectors consider that EDF and its subcontractor Orano NPS must, during maintenance operations, ensure that the packaging continues to comply with the package model to which it refers, notably with regard to the parameters that are important for demonstrating that sub-criticality would be maintained during shipments, notably concerning the dimensions and nature of materials.

INSPECTION OF A RAIL SHIPMENT

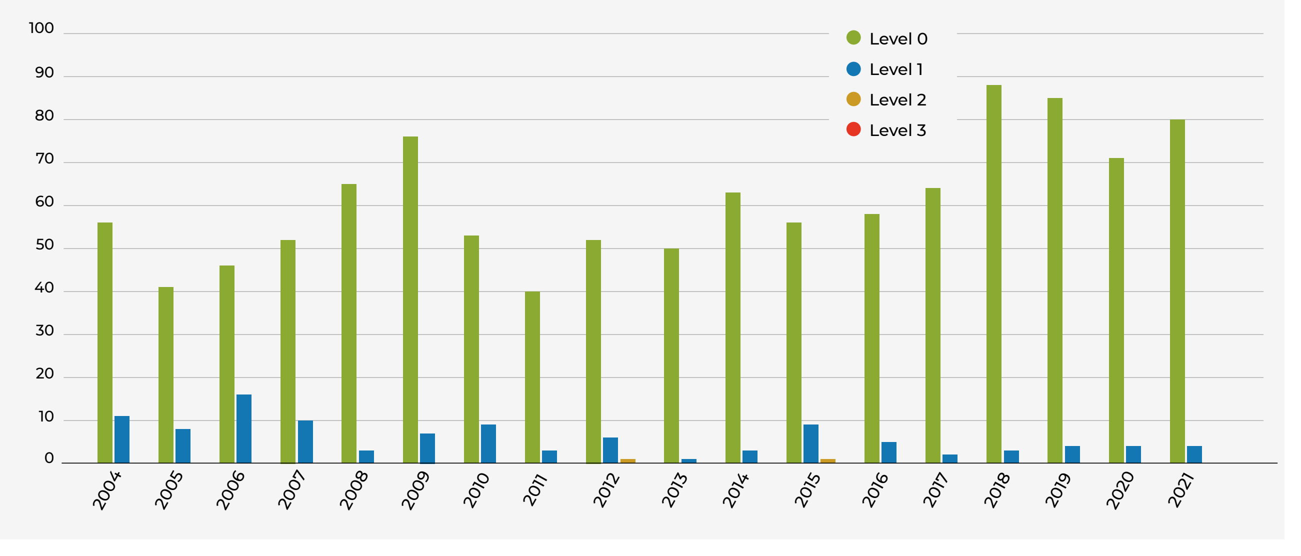
On 27 October 2021, ASN inspectors checked the operations involved in the transport of a spent fuel wagon to Woippy station (*département* 57). When it arrived in the station, this wagon was detached from the locomotive and joined to a new train before leaving again. IRSN carried out dose rate measurements on contact and at two metres from the wagon, along with radiological contamination measurements.

During this examination, the IRSN experts recorded no radiological contamination of the wagon. The dose equivalent rates were below the regulation thresholds.

The placards on the wagon, which notably contain information needed to identify the dangerous goods concerned, were compliant with the regulations.

The Transport Safety Advisor (CST) and the Fret SNCF dangerous goods transport expert present at the inspection, both held the required training certificates. The inspectors also checked the training of the two drivers involved in the transfer, as well as the track agent who joined the wagon to the train. The inspectors found that the training monitoring required by the RID was not operational and that the training of the personnel concerned was not up to date, including with regard to radiation protection. The inspectors consider that, although the safety of class 7 dangerous goods transport operations is on the whole satisfactory, a number of improvements must be made to the quality management system by the carrier Fret SNCF.

GRAPH 4 **Trend in the number of significant events affecting the transport of radioactive substances reported between 2004 and 2021**



Causes of events

The recurring causes of EST notified in 2021, which were slightly less numerous than in previous years, include:
- the presence of surface contamination spots exceeding the regulation limits, detected on conveyances which have been used to transport spent fuel packages, or packagings, or containers. The impact of these events on radiation protection is limited for the public, because the contamination spots detected were inaccessible to them;
- nonconformities affecting a package: these mainly concern container damage (perforation or structural deformation) or labelling faults (error or omission). These events had no actual consequences for safety or radiation protection;
- stowage or tie-down errors concerning equipment and tools, whether or not contaminated, transported in containers.

The EIT reported to ASN are primarily deviations relating to incorrect labelling of packages and non-structural deformation of containers.

With regard to the significant on-site transport events, these concern non-compliance with a package transport authorisation and the detection of contamination on the transport system carrier vehicle.

4.3 Participation in drawing up the regulations applicable to the transport of radioactive substances

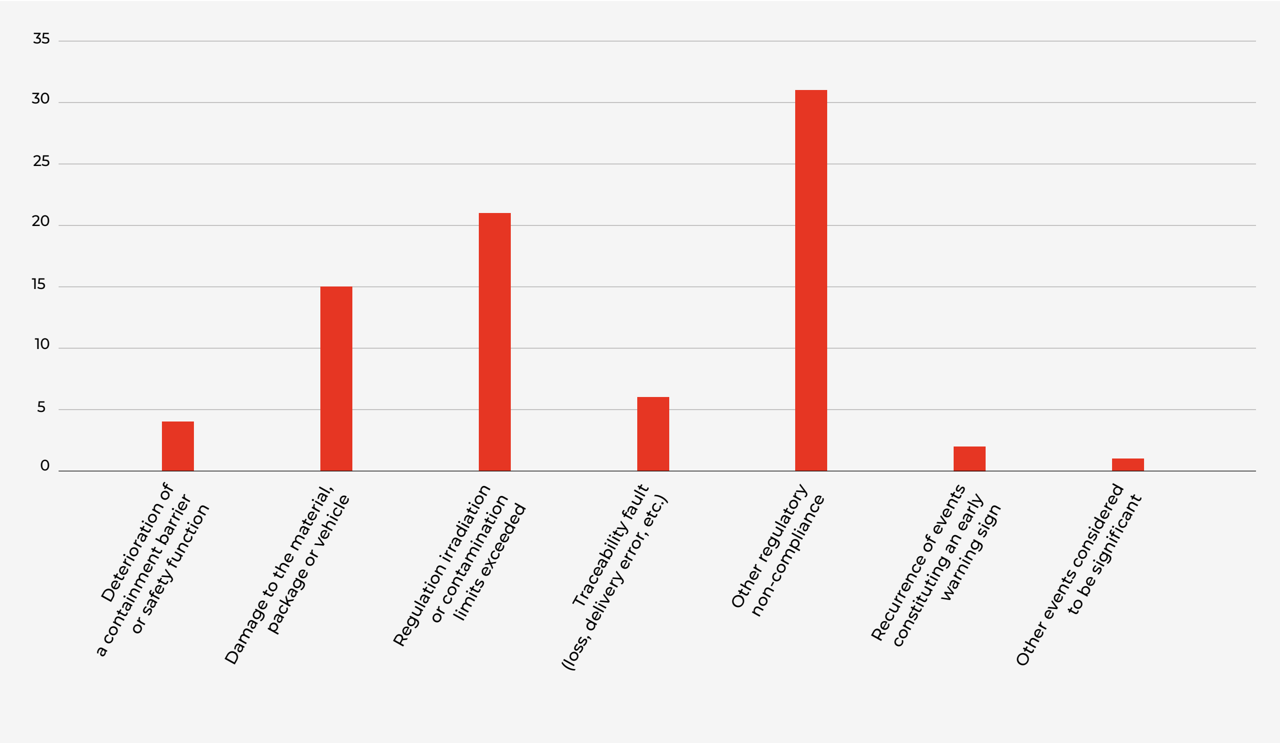
4.3.1 Participation in the work of the International Atomic Energy Agency

ASN represents France on the IAEA's Transport Safety Standards Committee (TRANSSC), which brings together experts from all countries and reviews the IAEA Safety Standards constituting the basis of regulations concerning the transport of radioactive substances. With a view to constant improvement of the safety level, ASN notably played an active part in drafting the 2018 edition of this document, SSR-6, a French translation of which has been available since mid-2019. The publication of the IAEA guide for application of the radioactive materials transport regulation (SSG-26) is expected in 2022.

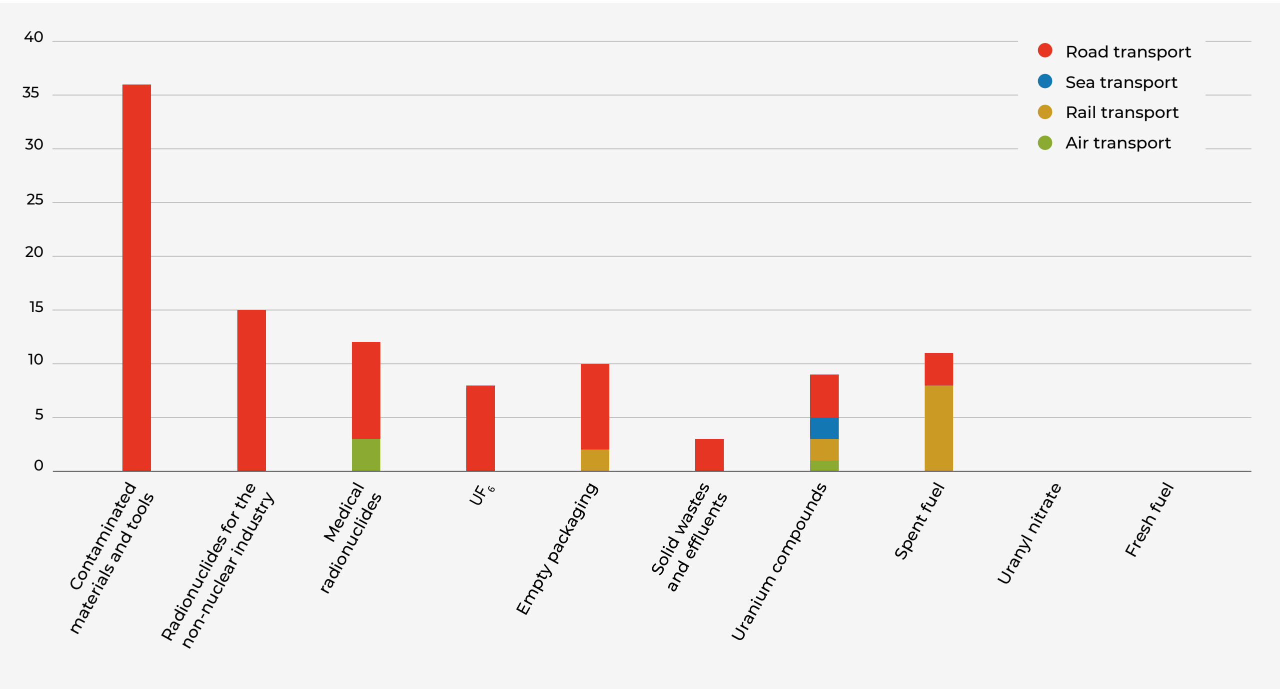
4.3.2 Participation in drafting of national regulations

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

GRAPH 5 **Breakdown of significant events notified in 2021 by notification criterion**



GRAPH 6 **Breakdown of notified transport events by content and mode of transport in 2021**



materials in sea ports. ASN therefore sits on the High Council for the Prevention of Technological Risks, which is required to issue an opinion on any draft regulation for the transport of dangerous goods by rail, road and inland waterway. ASN is also consulted by the Ministry responsible for transport when a modification of the three Orders mentioned above can have an impact on the transport of radioactive substances.

4.4 Contributing to public information

Ordinance 2012-6 of 5 January 2012, modifying Books I and V of the Environment Code, extends the obligations for public information to the persons responsible for nuclear activities. Article L. 125-10 of the Environment Code sets the thresholds beyond which the person responsible for transport must

INTERNATIONAL CROSS-INSPECTION OF RIVER TRANSPORT OF THE UPPER PARTS OF THE USED STEAM GENERATORS FROM THE FESSENHEIM NPP

These six items were taken by road, then river and sea, to the Cyclife plant in Sweden, for reprocessing and recycling. They crossed France, Germany, the Netherlands and Belgium, before arriving in Sweden.

Before the upper parts of the Steam Generators (SGs) left France, three ASN inspectors, one inspector from the Belgian Authority, one inspector from the Swiss Authority and two inspectors from the Dutch Authority inspected their transhipment to a barge in the port of Neuf-Brisach, on 24 and 25 November 2021, prior to river transport along the Rhine. The German inspectors were unable to join the inspection owing to the health measures in force in their country. Two members of the HFDS department of the Ministry for Ecological Transition were present as observers, as part of the HFDS mandate regarding protection against malicious acts.

In particular, the inspectors checked that the packages complied with the dose rate limits required by the surface contaminated objects radioactive materials transport regulations (SCO-I).

The upper parts of the SGs are concerned by these regulations owing to their low level of surface contamination.

The inspectors checked that the cabin of the crane operator loading the upper parts of the SGs on the barge was not exposed to radiation from the packages. They also boarded the barge and its push tug to examine the on-board documents, the measures taken to ensure the radiological monitoring of the personnel on-board and the conformity of the navigation systems with the river transport regulations. They checked that the personnel had in fact been trained in the safety and radiation protection of transports and their knowledge of the required response to any incident.

The inspection team found no deviations from the regulations and considered that the safety of the river transport was satisfactory. This was the first time radioactive substances had been transported by river in France, Belgium and the Netherlands.

EVENTS RELATED TO THE TRANSPORT OF ORE FROM THIRD-PARTY COUNTRIES

Recurring deviations have been observed in “fuel cycle” natural uranium ore transports from mines in Central Asia, Africa and Australia: on their arrival in France, contamination spots exceeding the regulation limits and damaged drums are discovered. ASN has observed a slight improvement in the situation over the past four years, but continues to work to improve the transport conditions of these packages, together with the transport stakeholders and the ordering parties.

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

The European Association of Competent Authorities on the Transport of Radioactive Material (EACA) was created in December 2008. Its purpose is to promote the harmonisation of practices in the regulation of the safety of transport of radioactive substances, and to encourage exchanges and experience feedback between the various Authorities. France, which initiated the creation of this association, plays an active part in its work, including by presenting its views on the regulatory changes that may be needed, in particular on the occasion of the association’s annual meeting.

4.5.2 Bilateral relations with ASN’s foreign counterparts

ASN devotes considerable efforts to maintaining close ties with the competent authorities of the countries concerned by the numerous shipments to and from France. Prominent among these are Germany, Belgium, the United Kingdom and Switzerland.

Germany

In 2016, the French and German Authorities decided to meet regularly to discuss a range of technical subjects. ASN also participates in the Franco-German technical committees concerning the programme for returning German spent nuclear fuel reprocessing waste.

Belgium

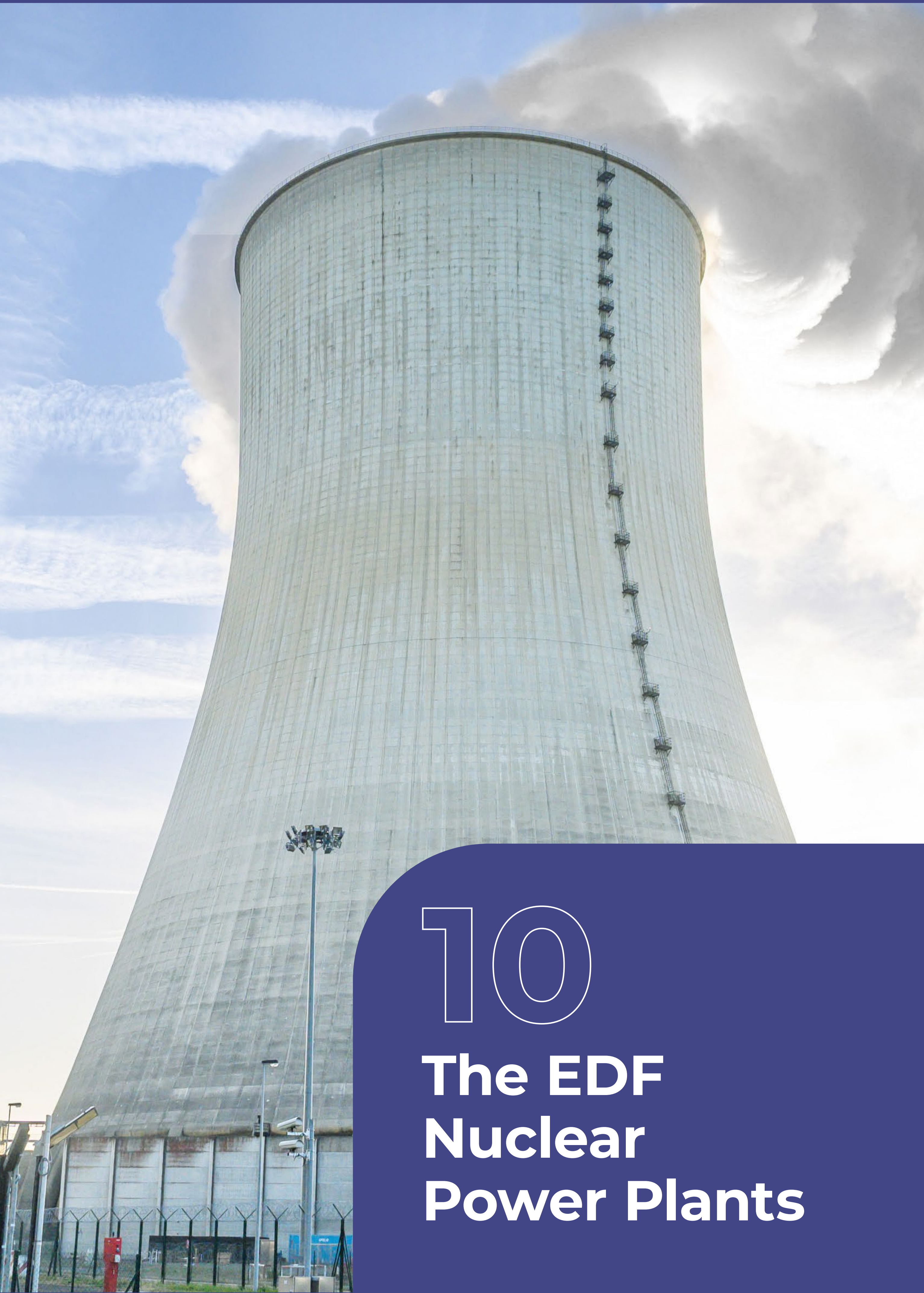
For the production of nuclear electrical power in Belgium, French-designed packagings are sometimes used for "fuel cycle" shipments. In order to harmonise practices and achieve progress in the safety of these shipments, ASN and the competent Belgian Authority (Belgian Federal Nuclear Regulating Agency –AFCN) regularly exchange know-how and experience. The exchanges more particularly concern the review of safety cases for French package models for which approval is validated in Belgium, and inspection practices in each country.

United Kingdom

ASN and the British regulator (Office for Nuclear Regulation –ONR) share many subjects of interest, notably with regard to validation of English approvals by ASN and *vice-versa*. Bilateral contacts are therefore held regularly to ensure good communication between these two Authorities.

Switzerland

In 2012, ASN began bilateral exchanges on transports with the Swiss Federal Nuclear Safety Inspectorate (IFSN –called *Eidgenössisches Nuklearsicherheitsinspektorat* (ENSI) in German). Since then, ASN and IFSN have met annually in order to discuss the packaging model safety cases and the checks on the requirements associated with the correct utilisation of these transport packages.



10

The EDF Nuclear Power Plants

10

THE EDF NUCLEAR POWER PLANTS

The electricity generating reactors are at the heart of the nuclear industry in France. Many other installations described in other chapters of this report produce the fuel intended for the Nuclear Power Plants (NPPs) or reprocess it, dispose of the waste from the NPPs or 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 thus requires a high degree of reactivity and rigour on the part of EDF when analysing the generic nature of these flaws and their consequences for the protection of people and the environment, as well as when processing them.

ASN exercises 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). To monitor the safety of the reactors in operation, under construction or being planned, ASN mobilises nearly 200 staff on a daily basis in the Nuclear Power Plant Department (DCN), the Nuclear Pressure Equipment Department (DEP) and its regional divisions, and can draw on nearly 200 experts from the Institute for Radiation Protection and Nuclear Safety (IRSN).

ASN develops an integrated approach to the oversight of the facilities. It intervenes at all stages in the life of the NPP reactors, from design up to decommissioning and delicensing. Through its expanded scope of intervention it examines the fields of nuclear safety, environmental protection, radiation protection, occupational safety and the application of labour laws, at all stages. For each of these fields, it monitors all aspects, whether technical, organisational, or human. This approach requires that it take account of the interactions between these fields and that it define its monitoring actions accordingly. The resulting integrated overview enables ASN to fine-tune its assessment of the state of nuclear safety, radiation protection, environmental protection and worker protection within the NPPs.

1 // General information about Nuclear Power Plants

1.1 General presentation of a Pressurised Water Reactor

By transferring heat from a hot source to a heat sink, an electricity generating thermal power plant produces mechanical energy that it converts into electricity. Conventional thermal power plants use the heat given off by the combustion of fossil fuels (fuel oil, coal, gas). NPPs use that given off by the fission of uranium or plutonium atoms. The heat produced in a Pressurised Water Reactor (PWR) leads to the creation of steam, which does not come into contact with the nuclear fuel. The steam is then expanded in a turbine which drives a generator producing a 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.

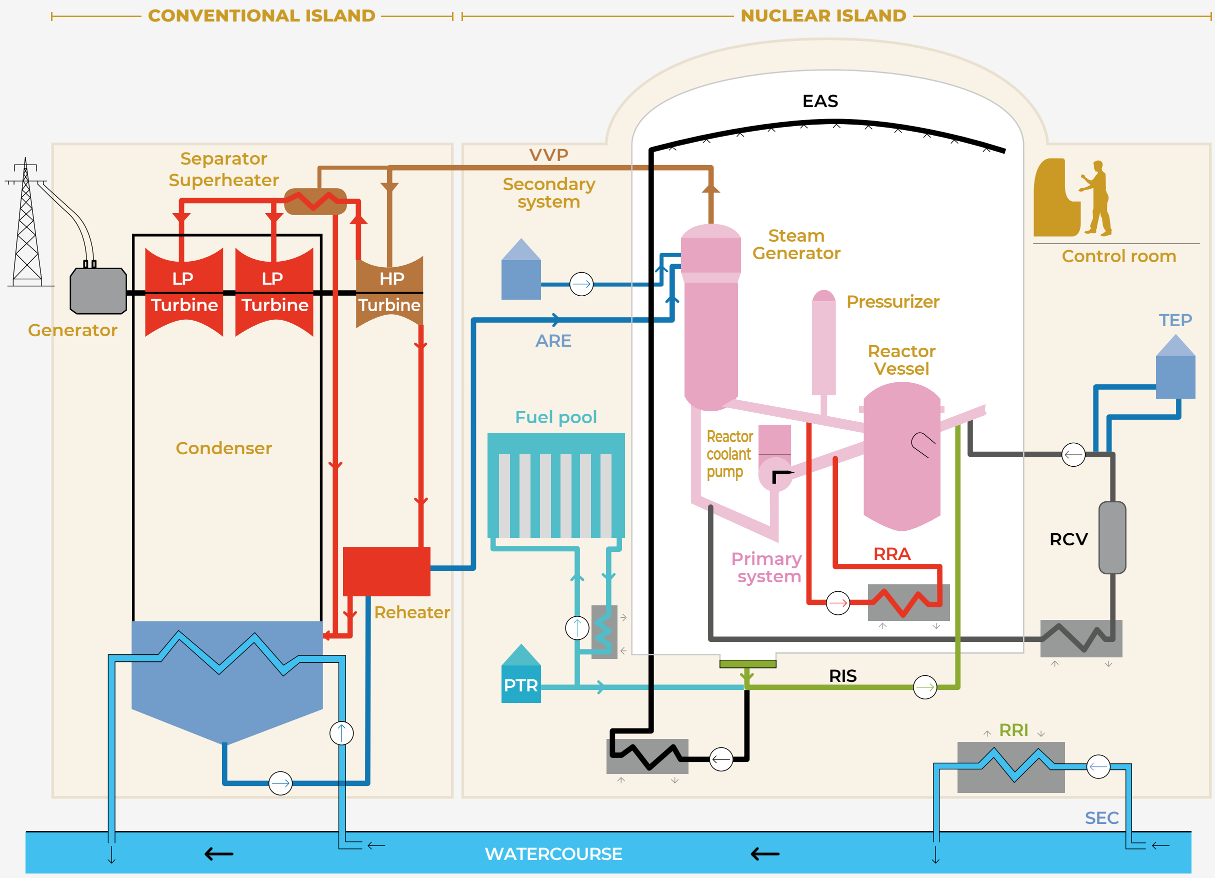
Each reactor comprises a nuclear island, a conventional island, water intake and discharge structures and possibly a cooling tower.

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 and Control (I&C) and reactor protection systems. These elements are also associated with systems providing support functions: monitoring and processing of primary effluents, water supply, ventilation and air-conditioning, back-up electricity supply (diesel electricity generating sets).

The nuclear island also comprises systems for the evacuation of steam to the conventional island, as well as the Building housing the fresh and spent fuel storage and cooling pool (BK). When mixed with boric acid, the water in this pool helps absorb the neutrons emitted by the nuclei of the fissile elements in the spent fuel, to avoid sustaining nuclear fission, to cool the spent fuel and to provide the workers with radiological protection.

The conventional island notably comprises the turbine, the generator and the condenser. Some components of these items take part in reactor safety. The secondary system is partly in the nuclear island and partly in the conventional island.

PRESSURISED WATER REACTOR OPERATING PRINCIPLE



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 (ESWS)
TEP: Boron Recycle System
LP or HP Turbine: Low-Pressure or High-Pressure Turbine
VVP: Main Steam Systems
: Pump

1.2 Safety principles

The design of the nuclear reactors is based on safety principles aimed at ensuring the safety functions:

- control of core reactivity, that is control of the nuclear chain reactions;
- removal of the thermal power produced by the radioactive substances and nuclear reactions;
- containment of radioactive substances. The aim is to prevent the dispersal of radioactive substances into the environment and to protect people and the environment from ionising radiation.

The design of nuclear facilities is based on the principle of "Defence-in-Depth", which leads to the implementation of successive defence levels (intrinsic characteristics, material provisions and procedures), intended to prevent incidents and accidents, and then, if the preventive measures fail, to mitigate their consequences.

Radioactive substances are contained by three successive 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 4.5% by mass. These fuels are fabricated in several French and foreign plants, by Framatome and Westinghouse;
- fuels consisting of a mixture of depleted MOX. MOX fuel is produced by Orano's Melox plant. The maximum authorised plutonium content is currently set at 9.08% (average per fuel assembly) giving an energy performance equivalent to UO_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 (DAC) authorise the use of plutonium fuel. EDF is currently preparing to introduce MOX fuel into a few 1,300 MWe reactors.

1.4 The primary system and the secondary systems

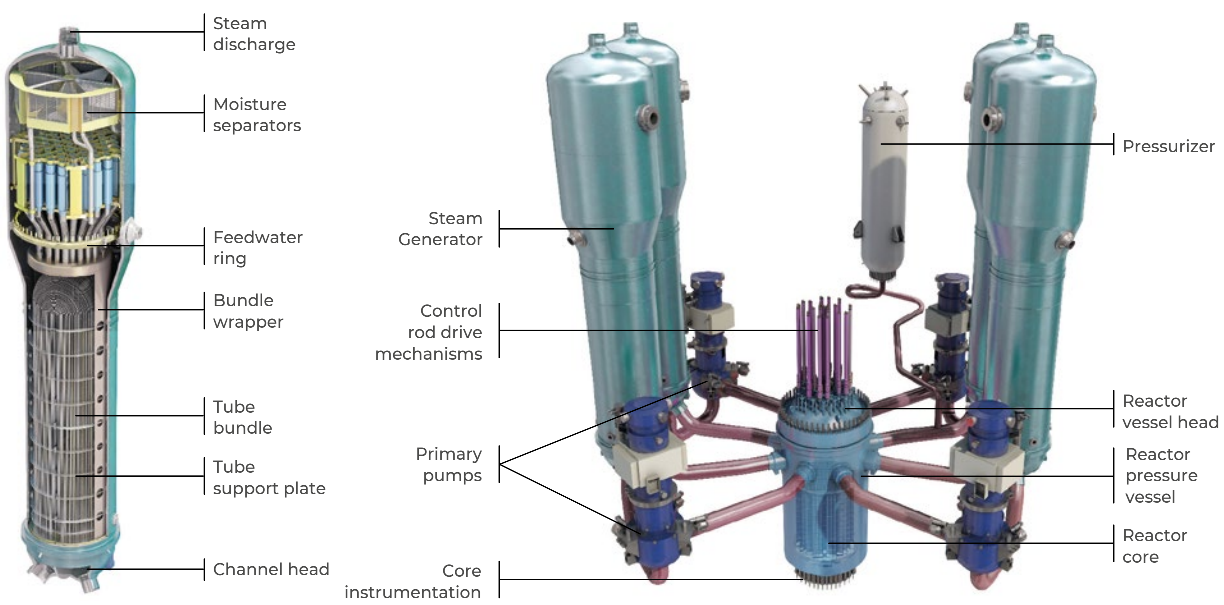
The primary system and the secondary systems transport the energy given off by the core in the form of heat to a turbine generator set which produces electricity.

The reactor coolant (primary) system comprises cooling loops, of which there are three for a 900 MWe reactor and four for the 1,300 MWe, 1,450 MWe or 1,650 MWe Evolutionary Power Reactor (EPR) type reactors. The role of the reactor coolant system is to extract the heat given off by the core by means of circulating pressurised "primary water" or "reactor coolant". Each loop, connected to the reactor vessel containing the core, comprises a circulating pump, called the "reactor coolant pump" and a SG. The reactor coolant, heated to more than 300°C, is maintained at a pressure of 155 bar by the pressuriser, to prevent boiling. The primary system is entirely situated within the containment.

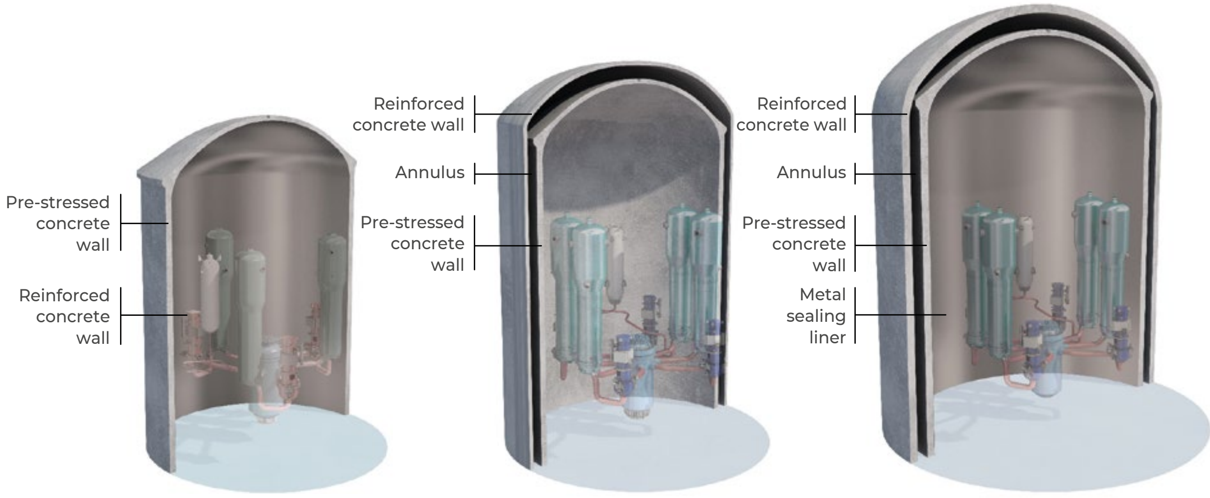
The primary system coolant transfers its heat to the water of the secondary systems in the SGs. The SGs are heat exchangers which contain from 3,500 to 6,000 tubes, depending on the model, through which the primary reactor coolant water circulates. These tubes are immersed in the secondary system water, which thus boils without coming into contact with the reactor coolant.

Each secondary system consists primarily of a closed loop through which water passes, in the form of liquid in one part and in the form of steam in the other. The steam produced in the SGs is partially expanded in a high-pressure turbine and then passes through moisture separator-reheaters before entering the low-pressure turbines for final expansion, from which it passes to the condenser. Once condensed, the water is then sent to the SGs by the extraction pumps, followed by the feedwater pumps after passing through the reheaters.

A STEAM GENERATOR AND A MAIN PRIMARY SYSTEM FOR A 1,300 MWE REACTOR



REACTOR CONTAINMENTS



Containment of 900 MWe reactors

Containment of 1,300 / 1,450 MWe reactors

Containment of 1,650 MWe reactors (EPR)

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 (TAR) –closed or semi-closed circuit.

The cooling systems are environments favourable to the development of pathogenic micro-organisms. Replacing brass by titanium or stainless steel in the construction of riverside reactor condensers, in order to reduce metal discharges into the natural environment, requires the use of disinfectants, mainly by means of biocidal treatment. The copper contained in brass has bactericidal properties that titanium and stainless steels do not. TAR can contribute to the atmospheric dispersal of legionella bacteria, whose proliferation can be prevented by stricter maintenance of the works (descaling, implementation of biocidal treatment, etc.) and monitoring.

1.6 The containment

The PWR containment performs two functions:
- the containment of radioactive substances liable to be dispersed in the event of an accident; to do this, the containments were designed to withstand the temperatures and pressures that would result from a primary or secondary system rupture and to ensure satisfactory leaktightness in these conditions;
- reactor protection against external hazards.

There are three containment model designs:
- Those of the 900 MWe reactors comprise a single pre-stressed concrete wall (concrete comprising steel tendons tensioned to compress the structure in order to increase its tensile strength). This wall provides mechanical pressure resistance and ensures the integrity of the structure in the event of an external hazard. Tightness is provided by a metal liner covering the entire internal face of the concrete wall.
- Those of the 1,300 and 1,450 MWe reactors are made of two walls: the inner prestressed concrete wall and the outer re-inforced concrete wall. Leaktightness is provided by the inner wall and by a Ventilation System (EDE) which, between the two walls, collects and filters residual leaks from the inner wall before discharge. Resistance to external hazards is primarily provided by the outer wall;
- That of the Flamanville EPR consists of two concrete walls and a metal liner covering the entire internal face of the inner wall.

1.7 The main auxiliary and safeguard systems

In normal operating conditions, at power, or in reactor outage states, the auxiliary systems control nuclear reactions, remove heat from the primary system and residual heat from the fuel and provide containment of radioactive substances. They mainly comprise the reactor's Chemical and Volumetric Control System (RCV) and the reactor's Residual heat Removal System (RRA).

The role of the safeguard systems is to control and limit the consequences of incidents and accidents. This chiefly concerns the following systems:
- the Safety Injection System (SIS), the role of which is to inject water into the primary system in the event of it leaking;
- the reactor building Containment Spray System (EAS), the role of which is to reduce the temperature and thus the pressure in the containment, in the event of a major primary system leak;
- the SGs Auxiliary feedwater System (ASG), which supplies water to the SGs if the normal feedwater system is lost, thus enabling heat to be removed from the primary system. This system is also used in normal operation during reactor outage or restart phases. After the Fukushima Daiichi NPP accident, the decision was taken to install a diversified water source, called the "ultimate water source", which can be used in extreme situations to supply the SGs with water, when the water reserves in the ASG system are empty and the various resupply solutions are no longer available.

1.8 The other systems important for safety

The other main systems important for safety and required for reactor operation are:
- the Component Cooling System (RRI) which cools a certain number of nuclear equipment items. This system functions in a closed loop between the auxiliary and safeguard systems on the one hand, and the systems carrying water from the river or sea (heatsink) on the other;
- the Essential Service water System (SEC) which cools the RRI system with water from the river or sea (heatsink). This is a backup system comprising two redundant lines. In certain situations, each of its lines is capable of removing heat from the reactor to the heatsink;
- the Reactor Cavity and Spent Fuel Pit Cooling and Treatment System (PTR), which in particular removes residual heat from the fuel elements stored in the fuel building pool. The design of the ultimate water source installed in the wake of the Fukushima Daiichi NPP accident, can also –in an extreme situation– inject water into the fuel building pool, if the PTR system and the water make-up systems are lost;
- the ventilation systems, which ensure containment of radioactive materials by creating negative pressure in the rooms and by filtering discharges;
- the fire-fighting water systems;
- the I&C system, which processes the information received from all the sensors in the NPP. It uses transmission networks and sends orders to the actuators from the control room, through the programmable logic controllers or operator actions. Its main role with regard to reactor safety is to monitor reactivity, control the removal of residual heat to the heatsink and take part in the containment of radioactive substances;
- the electrical systems, which comprise sources and electricity distribution. The French NPPs have two external electrical sources: the step-down transformer and the auxiliary transformer. These two external sources are supplemented by two internal electrical sources: the backup diesel generators. In the event of total loss of these external and internal sources, each reactor has another electricity generating set comprising a turbine generator and each NPP has an ultimate backup source, the nature of which varies according to the plant in question. Finally, following the Fukushima Daiichi NPP accident, these resources were supplemented by an "ultimate back-up" Diesel Generator Set (DUS) for each reactor.

2 // Oversight of nuclear safety of the reactors in operation

2.1 Fuel

2.1.1 Fuel and its management in the reactor

The leaktightness of the cladding of the fuel rods, tens of thousands of which are present in each core and which constitute the first containment barrier, receives particularly close attention.

In normal operation, leaktightness is monitored by EDF through permanent measurement of the activity of the radionuclides contained in the primary system. Any significant increase in this activity is a sign of a loss of leaktightness in the fuel assemblies. If the activity of the primary system exceeds a predetermined threshold, the General Operating Rules (RGEs) require shutdown of the reactor before the end of its normal cycle.

At each outage, EDF is required to search for and identify the assemblies containing leaking rods: reloading of fuel assemblies containing leaking rods is not authorised. EDF conducts examinations of leaking rods, in order to determine the origin of the failures and prevent them from reoccurring. The preventive and corrective measures may concern the design of the rods and assemblies, their manufacture or the reactor operating conditions.

The conditions of fuel assembly handling, of core loading and unloading, as well as prevention of the presence of foreign objects in the systems and pools are also covered by operating specifications, in order to prevent the risks of fuel rods leaking.

2.1.2 Assessment of the condition of the fuel and its management in the reactor

EDF's management of the integrity of the first barrier, that is the fuel rod cladding, was on the whole satisfactory for all the NPPs.

ASN notes progress in implementation of the approach to prevent the risk of foreign objects entering the primary system, which could then damage the first containment barrier. This progress however differs from one site to another.

In 2021, cladding defects were found on seven reactors. This number is similar to the previous year. ASN will remain attentive to the investigations carried out by EDF on the fuel assemblies concerned, in order to determine the origin of these defects and identify the necessary corrective measures.

As in 2020, few events were reported during fuel handling operations.

With regard to the fabrication of fuel pellets, the MOX anomalies encountered in 2017 and 2019 (random presence of large-sized plutonium enriched islands in certain fuel pellets) notably led EDF to implement compensatory measures in the loading plans.

CORROSION OF FUEL ASSEMBLIES WITH "M5" CLADDING

In February 2021, when unloading fuel from the Chooz B NPP reactor 2, EDF detected traces of white corrosion on several fuel assemblies. This corrosion caused the spalling of several fuel rod claddings, but they were not perforated.

EDF subsequently observed the same corrosion phenomenon on other reactors. This only concerns fuel assemblies fabricated by Framatome with cladding made of "M5" alloy.

The analyses carried out revealed several parameters liable to explain this phenomenon, notably the iron content of the cladding and the operating power of the reactor.

EDF has revised its iron content requirements for the M5 material. Pending the deployment of this modification on all its reactors, EDF can continue to use fuel assemblies with a low iron content, provided that it can be shown that they will not undergo spalling during irradiation and that proportional compensatory measures are taken (power reduction, special core or reactor operating procedures). This strategy led EDF to exclude from the core several fuel assemblies for which the iron content in the M5 alloy was too low.

The analyses aiming for improved characterisation of the phenomenon will continue in 2022.

In addition, the detection of a rising neutron flux phenomenon at the bottom and top of the fissile column of MOX fuel assemblies led ASN in 2018 to ask the licensee to adopt compensatory measures in 2018, pending the deployment of changes to the design of these assemblies. These particular operating measures have been in place since 2020, pending complete replacement of the MOX fuel assemblies present in the reactors by modified assemblies. The MOX assemblies loaded into the core since 2021 are equipped with a new shim designed to attenuate the rising flux phenomenon at the bottom of the fissile column. EDF will propose an optimised design in 2022, which will be deployed in full in 2025. EDF is also working on a modification for the top of the fissile column of rods.

In 2021, the production difficulties encountered at the Melox plant led EDF to use numerous specific refuelling loads in its reactors. In 2021, ASN notably authorised three or four consecutive reloads with no new MOX type fuel assemblies.

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 also take account of their importance for the safety of the installation. The manufacturer defines and applies the rules enabling it to demonstrate compliance with these requirements.

As of 2015, the industrial firms, EDF and Framatome in particular, took fundamental measures to change their rules and bring them into line with the regulatory requirements. Most of these actions were carried out within the framework of the French Association for Nuclear Steam Supply System Design (NSSS), Construction and Monitoring Rules (AFCEN), which involves the majority of the profession. This approach was repeated for the years 2019 to 2022, so that the profession continues to make progress on certain topics and in order to learn the lessons from the initial applications of the guidelines and methods created and the deviations observed during manufacturing.

The Framatome Le Creusot plant gradually resumed operations in 2021, with the manufacture of several shells intended for the SG replacement programme.

During the investigations carried out by Framatome following the discovery in 2019 of a deviation concerning the use of post-weld heat treatment, the manufacturer found a new problem in 2021 linked to high residual stresses generated during the cooling of this stress-relieving heat treatments (see box above).

2.2.2 Assessment of the design and manufacturing of Nuclear Pressure Equipment

ASN assesses the regulatory compliance of the NPEs most important for safety, referred to as "level N1", corresponding to the reactor pressure vessel, the SGs, the pressuriser, the reactor coolant pumps, the piping, notably that of the Main Primary (MPS) and Secondary (MSS) Systems, as well as the safety valves.

This conformity assessment concerns the equipment intended for the new nuclear facilities (more than 200 equipment items are concerned on the Flamanville EPR reactor) and the spare equipment intended for nuclear facilities already in service (notably the replacement SGs). ASN can be assisted in this task by organisations that it approves. These latter can be mandated by ASN with performance of some of the inspections on the "level N1" equipment and are tasked with assessing the regulatory compliance of the NPEs less important for safety, said to be "level N2 or N3". The oversight by ASN and the approved organisations is carried out at the different stages of the design and manufacture of the NPEs. It takes the form of an examination of the technical documentation of each equipment item and inspections in the workshops of the manufacturers, as well as at their suppliers and subcontractors. Four inspection organisations or bodies are currently approved by ASN to assess NPEs compliance: Apave SA, *Bureau Veritas Exploitation*, Vinçotte International and the inspection body of the EDF users.

In 2021, with regard to NPEs design and manufacture, the approved organisations carried out about 3,100 inspections on the NPEs intended for the Flamanville EPR and about 4,700 inspections on the replacement NPE intended for the NPP reactors in operation. These inspections are performed under ASN supervision.

ASN notes the steps taken by industry to deal with the problems identified in its findings, as well as the appropriate nature of AFCEN's publications. ASN asked that AFCEN's 2019-2022 programme address the management of deviations and OEF acquired with regard to welding.

With the involvement of the approved organisations and IRSN, ASN examined the programme of work implemented by Framatome to characterise the impact of the residual stresses generated during stress-relieving heat treatment. Provisions regarding the in-service monitoring of the equipment could be needed to ensure that the level of equipment safety is maintained. ASN also asked the other manufacturers to evaluate this impact and is examining the steps they are taking.

Framatome continued its quality improvement actions at its three plants. This entails an approach to closely monitor the most sensitive industrial processes affected by significant deviations. Through its inspections, ASN assesses the results of these actions. It thus underlines the quality and pertinence of the steps taken, which should lead to improved production quality. ASN in particular maintained its involvement in monitoring the steps defined to ensure that a long-term, robust and efficient organisation tailored to the safety issues is maintained within the Framatome Creusot plant.

The manufacturer Westinghouse continued to apply its improvement plan in its SG manufacturing plant in Italy, with regard to the internal monitoring quality system. The conditions for lifting of reinforced monitoring were defined but were not met in 2021.

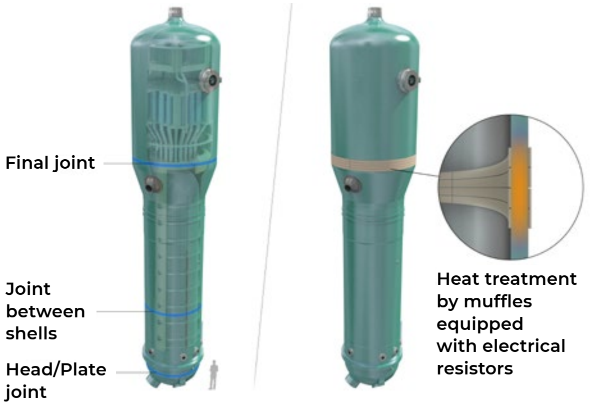
The approved organisations, the manufacturers and the licensees are developing an organisation and the corresponding resources within their own structures, in order to prevent and detect the risk of fraud. Even though progress has been observed, the technical measures implemented still need to be improved, as in 2020. The processing of the irregularities reported at the end of 2018 by the supplier of special alloys and steels, Aubert & Duval, is also continuing. The investigations carried out have not yet identified any consequences for the safety of the facilities.

2.2.3 Pressure Equipment operation

The reactor Main Primary and Secondary Systems (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

DEVIATION IN FRAMATOME'S USE OF POST-WELD HEAT TREATMENT PROCESSES DURING THE MANUFACTURE OF NUCLEAR PRESSURE EQUIPMENT



Assembling components by welding creates mechanical stresses in the welded areas. To reduce these stresses, the manufacturer applies a Post-Weld Heat Treatment (PWHT), which consists in heating the material for several hours to a temperature of several hundred degrees. This heating can be carried out on the complete part in a furnace if the size of the part so permits, or locally by using heating devices such as electrical heating elements. The treatment temperature and duration must be controlled, in order to remove the stresses resulting from the welding without altering the mechanical properties of the material.

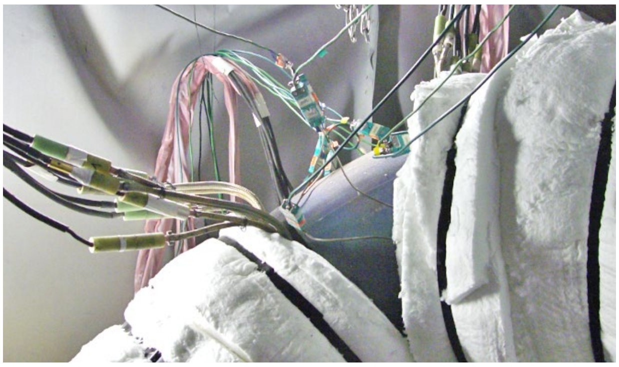
In 2019, the manufacturer Framatome brought to light the fact that certain processes used in its Saint-Marcel plant, or in the NPPs for SG assembly, had led to insufficient control of the temperatures around the circumferences of the treated welds.

This deviation concerns 177 of the 192 SGs installed in EDF's reactors in operation. EDF justified the continued integrity of the equipment concerned, by drawing on the results of tests performed on representative mock-ups, on material test coupons and on numerical temperature prediction models.

The equipment currently being manufactured is also concerned by this deviation. This involves 22 SGs intended for reactors in operation, as well as the SGs, pressuriser and secondary system lines for the Flamanville EPR reactor. Framatome is defining the appropriate treatment strategies for each of the equipment items concerned. These include repair studies, test mock-ups and digital simulation studies to assess the impact of the deviations on the required mechanical properties when repairs cannot be carried out.

In 2021, during the additional investigations it was carrying out, Framatome brought to light residual stresses of an unexpected level, generated during the implementation of these heat treatments, even if performed correctly. For the equipment in service, Framatome deployed a characterisation programme which, on the basis of experimental measurements and digital simulation, was able to assess the level of these stresses and their impact on the mechanical strength of the equipment. ASN is examining the specific justifications provided by EDF for the welds concerned by the deviation. For all the heat treated welds, ASN also asked EDF to conduct an analysis of the potential risks.

ASN is also examining the justifications provided by Framatome for the equipment currently being manufactured. It also questioned other manufacturers of large equipment (Westinghouse and MHI), so that they could examine whether the post-weld heat treatment processes they use also generate similar effects.



of operation of the MPS and the MSS of nuclear PWRs. These systems are thus the subject of monitoring and periodic maintenance by EDF.

These systems are subject to periodic re-qualification every ten years, which comprises a complete inspection of the systems involving non-destructive examinations, pressurised hydrotesting and verification of the good condition and good operation of the over-pressure protection accessories.

The licensee is required to keep and update the regulatory reference files required by the above-mentioned Order of 10 November 1999 with regard to MPS and MSS monitoring. These files consist of design, manufacture, overpressure protection files, materials files, in-service observations and, as applicable, deviations processing files. The licensee is required to update these files as often as necessary and on the occasion of the periodic requalifications. Owing to the standardised nature of the French NPP reactors, EDF can perform a generic update of these files.

The safety implications of some of the components of the primary or secondary systems are detailed below.

The reactor pressure vessels

The reactor pressure vessel is an essential component of a PWR and contains the reactor core and its instrumentation.

In normal operating conditions, the vessel is entirely filled with water, at a pressure of 155 bar and a temperature of 300°C. It is made of ferritic steel, with a stainless steel inner liner.

Regular inspection of the condition of the vessel is essential for two reasons:
- The vessel is a component for which replacement is not envisaged, owing to both technical feasibility and cost.
- Monitoring contributes to the break preclusion approach adopted for this equipment. This approach is based on particularly stringent design, manufacturing and in-service inspection provisions in order to guarantee its strength throughout the life of the reactor, including in the event of an accident.

During operation, the vessel's metal slowly becomes brittle, under the effect of the neutrons from the fission reactions in the core. This embrittlement more particularly makes the vessel more susceptible to thermal shocks under pressure, or to sudden

STRESS CORROSION DETECTED ON THE PIPES OF SEVERAL REACTORS

During the ultrasounds inspections carried out during the second ten-yearly outage on the Civaux NPP reactor 1, indications(1) were found on the welds of the elbows on the line connecting the safety injection system to the reactor's Main Primary System.

EDF decided to shut down Civaux NPP reactor 2 so that these inspections of the areas could be carried out ahead of schedule, as the previous inspections dated from 2012. The results of these inspections confirmed the presence of indications similar to those of reactor 1.

The parts of the pipes concerned on reactor 1 were cut for metallurgical analysis in the laboratory and revealed the presence of cracking resulting from a stress corrosion phenomenon.

Given the unexpected origin of the cracks found, EDF decided to shut down the reactors of a design similar to that of the Chooz NPP, in order to conduct further inspections in addition to those performed in 2019 and 2020 during their ten-yearly outage. These examinations revealed indications. Indications were also detected during the third ten-yearly outage of Penly reactor 1.

At the beginning of 2022, EDF continued its investigations in order to characterise the factors that caused this phenomenon and identify the reactors and the areas potentially concerned.

With the technical support of IRSN, ASN is closely following these investigations and the resulting conclusions.

For the latest information on the subject: *asn.fr*, headings "*L'ASN informe*", "*Actualités*".

1. An indication is a signal (typically an echo for ultrasonic inspections) revealing the possible presence of a defect in the material being inspected.

pressure rises when cold. This susceptibility is also aggravated by the presence of technological flaws, which is the case for some vessels with manufacturing defects under their stainless steel liner.

Cast elbow assemblies

The MPS of a reactor comprises several austenitic-ferritic stainless steel cast elbow assemblies. The ferritic phase experiences ageing under the effect of temperature. Certain alloy elements present in the material aggravate this ageing sensitivity, notably on the 900 MWe reactors and the first 1,300 MWe reactors. The result is a deterioration of certain mechanical properties, such as toughness and resistance to ductile tearing.

The elbows also comprise flaws inherent in the static casting manufacturing method. The effects of thermal ageing lessen the properties of this cast steel and reduce 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 stress corrosion. This particular phenomenon occurs in the presence of significant mechanical stresses. It can lead to the appearance of cracks, as observed on certain SG tubes in the early 1980s or, more recently in 2011, on a vessel bottom head penetration in Gravelines NPP reactor 1 and in 2016 on a vessel bottom head penetration in Cattenom NPP reactor 3. These cracks led the licensee to repair the zones concerned or isolate the part of the system concerned.

At the request of ASN, EDF adopted an overall approach to monitoring and maintenance for the zones concerned. Several zones of the MPS 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 the licensee, is submitted to ASN, which checks that the performance and frequency of the checks carried out by EDF 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 the fouling described above, 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 require a license for the discharge of some of the products used.

Some chemical cleaning processes are still being tested to confirm that the chemical products utilised are harmless.

Since the 1990s, EDF has been running a programme to replace the SGs with the most severely degraded tube bundles.

The SG replacement campaign for 26 reactors with non-heat treated Inconel 600 alloy tube bundles has been completed. It is continuing with replacement of SGs on the 26 reactors in which the tube bundle is made of heat treated Inconel 600.

2.2.4 Assessment of Pressure Equipment in operation

The reactor pressure vessels

ASN issues reports following the inspections made during each ten-yearly outage on the primary systems, the reactor pressure vessels in particular, which undergo numerous checks and a hydro-test during these outages.

As part of the preparation for the fourth periodic safety reviews of the 900 MWe reactors (see point 2.9.3 and "Notable Events" in the introduction to this report), EDF sent ASN a dossier in 2017 substantiating the in-service strength of these reactors up until their fifth periodic safety review. The generic approach adopted by EDF consists in conservatively considering the mechanical properties of the vessel experiencing the worst-case irradiation embrittlement for the 900 MWe reactors. EDF carried out fast fracture resistance studies taking account of the changes in the properties of the materials and will carry out inspections to check there are no prejudicial defects in the steel during the ten-yearly outage of each reactor.

This generic approach was submitted to the Advisory Committee for Nuclear Pressure Equipment (GPESPN) for its opinion on 20 November 2018, 15 October 2019 and 8 September 2020. The examination concerned the defects analysed, the estimated irradiation ageing of the metal of the vessel, the thermo-mechanical analyses and the studies assessing the margin with respect to fast fracture of the vessels, the classification of small primary break transients and justification of the level of residual stresses in the circumferential welds of the core shells.

The studies carried out and the additional information provided at the request of GPESPN lead to a favourable conclusion regarding the ability of the reactor pressure vessels to function for a further ten years, subject to the result of the examinations performed on the occasion of the fourth ten-yearly outages of the reactors concerned.

Cast elbow assemblies

The dossier produced by EDF was examined by ASN with production of an opinion from the GPESPN on 23 May 2019. Following this analysis, ASN sent EDF requests for additional substantiation of the predicted behaviour of the aged material, identification of the flaws present in the cast elbow assemblies, analysis of the fast fracture margins and in-service monitoring of these components.

In 2020, EDF provided substantiating documents for certain types of elbow assemblies and the replacement strategy envisaged for others. The situation of certain elbow assemblies it would be hard to replace has led to technical developments in the fields of non-destructive testing and thermal regeneration.

Nickel-based alloy zones

In 2018, EDF updated its analysis of the nickel-based alloy zones by reviewing the design, evaluating the risk of initiation of stress corrosion, analysing national and international OEF, reviewing mechanical analyses and safety studies, listing available repair and inspection procedures, and updating its maintenance strategy.

This dossier was examined jointly by ASN and IRSN and then presented to the GPESPN during its session of 26 November 2020.

The update work carried out by EDF is satisfactory. However, EDF must provide greater guarantees regarding the ability of the non-destructive examinations to detect any damage early on, in particular for the vessel bottom head penetrations.

The Steam Generators

For ASN, the situation of the second containment barrier remained a point for particular attention in 2021. The significant fouling levels observed in certain SGs, liable to impair their operating reliability, has led to scheduling of a preventive cleaning programme in 2022 and in the subsequent years. Maintenance, in order to guarantee a satisfactory level of cleaness, has been insufficient and must be a priority. The monitoring strategy for the secondary part of the SGs deployed by EDF was revised in mid-2020 to better prevent these situations.

THE PRINCIPLES OF THE REACTOR VESSELS IN-SERVICE STRENGTH DEMONSTRATION

The regulations in force require in particular that the licensee:
- identify the operating situations with an impact on the vessel;
- take measures to understand the effect of ageing on the properties of the materials;
- deploy resources to enable it to ensure sufficiently early detection of defects prejudicial to the integrity of the structure;
- eliminate all cracks detected or, if this is impossible, provide appropriate specific justification for retaining such a type of defect as-is.

ASN notes that the SG replacement operations were able to resume after a year with no work of this type. This work will continue at the rate of one intervention per year in the coming years.

The regular perforation of SG tubes, which is the subject of a multi-year tube inspection and plugging strategy by EDF, and the detection of a boiler effect in a "thimble" tube of an SG on Nogent-sur-Seine reactor 1 –repaired in 2021– illustrate the risk of further deterioration associated with the ageing of the installations and confirms the need to adapt the level of in-service monitoring and forward planning for development of repair processes.

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 BNIs.

Other equipment takes part in the containment function, such as the points of access to the interior of the containment (airlocks and equipment hatch), the circuit depressurising the annulus between the double-wall containments or the control room ventilation system. Since 2016, EDF has also been carrying out an action plan with the aim of guaranteeing that the flowrates in the ventilation systems meet the safety requirements both for the containment and for thermal conditioning of the installations, in the light of the changes made to the reactors since they were built. The action plan is being deployed, reactor by reactor, on all the ventilation systems concerned, and includes an inventory of the condition of the equipment and ducts. As necessary, EDF carries out repairs and improvements and adjusts the ventilation flow rates.

2.3.2 Assessment of the containments

Overall management of the containment function

ASN observes occasional but recurring unavailabilities affecting certain equipment participating in the containment function. These unavailabilities, already identified in 2020, were the subject of discussions with EDF, which will continue in 2022 in order to verify the pertinence of the measures envisaged by EDF to mitigate these unavailabilities.

In 2021, ASN ran a dedicated inspection campaign on the action plan for the ventilation systems. ASN found that it is correctly implemented on the reactors and that the corresponding safety requirements are met. In 2022, EDF will run a programme to ensure the sustainability of the settings needed for correct operation of the ventilation systems determined by this action plan. ASN will examine 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 2009 as part of their third ten-yearly outages did not bring to light any generic problems liable to compromise their operation.

The containment of Bugey NPP reactor 5 did however need to be repaired, following damage to the tightness of its metal liner at the lower part of the reactor building, observed in 2015. EDF subsequently implemented specific monitoring of this containment. The tightness of this containment also received particular attention during the fourth ten-yearly outage of this reactor in 2021. The results of the pressure test on this containment performed in 2021 were satisfactory.

The results of the pressure tests performed as part of the fourth ten-yearly outages has so far also proven to be satisfactory.

Double-wall containments

The tests on the double-wall containments performed during the first ten-yearly outages of the 1,300 MWe reactors detected a rise in the leak rate from the inner wall of some of them, under the combined effect of concrete deformation and a loss of prestressing of certain tendons that was greater than anticipated at the design stage.

EDF then initiated major work consisting in locally applying a resin sealing coating to the interior and exterior surfaces of the inner wall of the containments of the most severely affected 1,300 MWe reactors, as well as to the 1,450 MWe reactors. For all the reactors on which it was carried out, this work enabled the leak rate criteria to be met during the containment pressure tests.

ASN remains vigilant with regard to changes in the leaktightness of these containments and to maintaining the long-term effectiveness of the coatings.

2.4 Risk prevention and management

2.4.1 The General Operating Rules

The General Operating Rules (RGEs) cover the operation of nuclear power generating reactors. These are drafted by the licensee and are the operational implementation of the hypotheses and conclusions of the safety assessments constituting the nuclear safety case. They set the limits and conditions for operation of the installation.

Depending on their significance, RGE modifications that could affect safety require either submission of an authorisation application to ASN or notification to ASN before they are implemented.

Normal operation

Operating Technical Specifications

The Operating Technical Specifications (STEs), which are part of the RGEs, define the normal operating conditions based on the facility's design and sizing hypotheses and identify the systems needed to maintain the safety functions, in particular the integrity of the radioactive substances containment barriers and the monitoring of these functions in the event of an incident or accident. They also stipulate the action to be taken in the event of temporary failure of a required system or if a limit is exceeded, situations which constitute "degraded mode" operation.

EDF regularly updates the STEs to incorporate the lessons learned from their application and the modifications made to the reactors. The licensee can also modify them temporarily if need be, for example to carry out an operation in conditions that differ from those initially considered in the nuclear safety case. The licensee must then demonstrate the relevance of this temporary modification and define adequate compensatory measures to control the associated risks.

Periodic tests

The Protection Important Component (PIC) of persons and the environment undergo qualification to guarantee their ability to perform their assigned functions in the situations where they are needed. They must be tested in order to verify the long-term validity of their qualification. The periodic test rules for equipment important for safety are incorporated into the RGEs. They set the nature of the technical checks to be performed, their frequency and the criteria for determining the satisfactory nature of these checks.

Core physics tests

The purpose of core physics tests is, on the one hand, to confirm that the core in operation is compliant with the design baseline requirements and the safety case and, on the other, to calibrate the automatic control and protection systems. These tests, prescribed in the RGEs, are performed periodically.

The physics tests at restart are comparable to requalification tests following reloading of the core. The physics tests during a cycle and a cycle extension guarantee the availability and representativeness of the instrumentation as well as the characteristics of the core in operation.

Operating rules in the event of an incident or accident

Operation in the event of an incident or accident

The RGEs also deal with the reactor operating procedures in an incident or accident situation. They specify the operations to be performed by the shift crew when the reactor experiences an incident or accident situation; these operations aim to restore the reactor to normal operation or, for accident situations, to mitigate the consequences. The control teams are regularly trained in the use of these procedures.

EDF is updating these procedures to take account of experience feedback from incidents and accidents, to correct the anomalies detected during their application or to take account of modifications made to the facilities, in particular those resulting from the periodic safety reviews.

Operation in a severe accident situation

Following an incident or accident, if the safety functions (control of reactivity, cooling and containment) are not guaranteed owing to a series of failures, the situation is liable to develop into a severe accident with severe fuel damage. When faced with such unlikely situations, the installation control strategies place emphasis on preserving the integrity of the containment in order to minimise releases into the environment. The implementation of these strategies mobilises the expertise of the local and national emergency teams. These teams draw on the On-site Emergency Plan (PUI) plus the severe accident intervention guide and the emergency teams action guides in particular.

2.4.2 Assessment of reactor operations

ASN checks the content of the RGEs during their examination prior to implementation, and monitors application of the RGEs during inspections.

Normal operation

During NPP inspections, ASN verifies that the licensee complies with the STEs and, if applicable, the compensatory measures associated with any temporary modifications. It also checks the consistency between the modifications made to the facilities and those made to the documents used by the reactor control teams, such as operational control instructions and alarm sheets. It also ensures that the procedures used to configure the systems or lock out equipment do actually take account of the requirements arising from the STEs. Finally, it is attentive to the good understanding and good application of these various documents by the control teams and the correct management of sensitive activities, which are often the cause of anomalies.

Failures to comply with the STE constitute significant events which are to be reported to ASN. ASN analyses the origin and consequences of these events and, during its inspections, checks that measures have been taken by the licensee to correct the deviations and prevent them from happening again.

In 2021, ASN observes that the quality of monitoring in the control room remained at a satisfactory level, as in 2020, even if certain deviations this year are still the result of shortcomings in this monitoring. The number of system configuration deviations also remained at a level equivalent to that of last year.

However, in 2021, the situations in which the reactor was operated outside the planned limits were far more numerous than in 2020 and returned to the level observed in 2019. Industrial activity in 2021, which was denser than in 2020 (reduced owing to the health crisis) no doubt partially explains this trend, but steps must be taken to limit these deviations and more broadly improve operating rigour in the facilities.

The Covid-19 pandemic disrupted the training of the control teams in 2020 and 2021. ASN considers that the consequences of these disruptions on safety performance need to be analysed. In 2022, it will carry out an inspection campaign specifically on this topic.

ASN checks that the periodic tests on equipment important for safety enable its correct operation and its level of performance to be checked. It carries out this verification when RGE modification authorisation applications are submitted. During inspections, it also verifies that these periodic tests are carried out in accordance with the test programmes stipulated in the RGEs.

In 2021, the periodic tests were the cause of several significant events, owing to incorrect changes to test rules, inconsistency between the test rules and the rest of the RGEs, or inappropriate implementation of the test rules in the operating documents. With regard to OEF from these events, EDF is adapting its organisations to ensure better sharing of information between the various actors responsible for defining, programming and carrying out tests.

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 2021 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. Following these inspections, ASN considered that management of control situations by the control teams in the event of an incident or accident was satisfactory.

In 2021, ASN also found that the EDF national engineering teams had done considerable work to correct errors and inaccuracies in the operating documents to deal with an incident or accident and which had been detected in recent years. ASN will be attentive to ensuring that the new process to correct deviations implemented by EDF will allow them to be rapidly dealt with, so that the deviations do not remain in the operating documents for long periods of time.

Emergency organisation

When the situation in the facility deteriorates or additional means are needed to manage the situation, the incident or accident operating procedures provide for activation of the PUI, which leads to deployment of an emergency organisation.

In 2021, EDF activated its PUI for a transformer fire in the non-nuclear part of the Paluel NPP. The situation did not entail radioactive releases and did not require any population protection measures.

In 2021, ASN carried out inspections on the EDF emergency organisation and resources. These inspections as a whole demonstrated that the NPPs have assimilated the principles of organisation, preparation and management of emergency situations to the extent that they can take the required action in the event of an emergency. ASN also underlines the professionalism and considerable motivation of the on-call personnel mobilised. However, following a change in the alert system, EDF must continue with its training efforts to guarantee that the crisis personnel assimilate the alert systems and it must make progress regarding the time taken to mobilise all the stakeholders. Finally, the through life support for a certain number of resources stored and deployable in an emergency situation must also be reinforced.

2.4.3 Maintenance of the facilities

Preventive maintenance is an essential line of defence in maintaining the conformity of a facility with its baseline safety requirements.

In order to improve the reliability of the equipment important for safety but also industrial performance, EDF is optimising its maintenance activities, drawing on practices used in conventional industry and by the licensees of NPPs in other countries. In 2008, EDF decided to deploy a new maintenance methodology, called "AP913", developed by the American nuclear licensees and built around two main points: organisational changes to enhance monitoring of the reliability of the equipment and systems and implementation of a new type of preventive maintenance programmes.

The AP913 implementation diagnostic performed by EDF in mid-2016 revealed difficulties with implementing performance monitoring and with increasing the maintenance tasks generated by the AP913 maintenance programmes. In 2017, EDF thus defined strategic guidelines for maintenance and reliability. It specified the roles of the various departments and professions related to the performance of maintenance, by reaffirming that the maintenance departments are responsible for the project ownership of the equipment they maintain, in particular in a context of continued operation of the reactors beyond 40 years. EDF also adopted function reviews to obtain an integrated view of the equipment and systems participating in each function, as well as a new phase of its project to control the volume of maintenance.

Moreover, in response to the ASN request made in 2019, EDF submitted an authorisation application at the end of 2021 to add a new chapter to the RGEs, devoted to maintenance.

2.4.4 Assessment of maintenance

Maintenance is an important topic, regularly checked by ASN during its inspections in the NPPs.

The organisation within the NPPs for significant maintenance work was relatively satisfactory in 2021. However, ASN still

REACTOR OUTAGES

The nuclear power reactors must be periodically shut down for replacement of the fuel depleted during the electricity production cycle. One third or one quarter of the fuel is thus renewed at each outage.

These outages means that certain parts of the installations which are not accessible during the production phase then become temporarily accessible. They are thus put to good use by EDF to carry out checks, tests and maintenance, as well as to perform works on the facility.

These refuelling outages can be of several types:
- Refuelling Outage and Maintenance Outage: these outages, which last a few weeks, are devoted to replacing a part of the fuel and to carrying out a verification and maintenance programme, which is more extensive during a maintenance outage than during a refuelling outage.
- Ten-yearly outage: this is an outage involving a programme of in-depth verification and maintenance. This type of outage, which lasts several months and takes place every ten years, enables the licensee to carry out large-scale operations such as the complete inspection and hydraulic testing of the reactor coolant system, hydrotesting of the containment or incorporation of design changes resulting from the periodic safety reviews.

These outages are scheduled and prepared by the licensee several months in advance. ASN checks the steps taken by the licensee to ensure the safety of the facility, environmental protection and radiation protection of the workers during the outage, as well as the safety of the reactor for the next production cycle.

In the light of the provisions of its resolution 2014-DC-0444 of 15 July 2014 concerning shutdowns and restarts of pressurised water reactors, the monitoring performed by ASN primarily concerns:
- during the outage preparation phase, the content of the outage programme drawn up by the licensee. As necessary, ASN may ask for additions to this programme;
- during the outage, through regular briefings and inspections, the implementation of the programme and the handling of any unforeseen circumstances;
- at the end of the outage, on the condition of the reactor and its suitability for restart. It is after this inspection that ASN will either approve reactor restart, or not;
- after reactor restart, the results of all the tests performed during the outage and in the restart phase.

Since 2020, ASN has reduced the volume of its documentary examinations for reactor outages and has increased its field inspections. These new oversight methods enable ASN's resources to be targeted on the activities with the highest risks and this oversight to be made more efficient.

regularly finds points for improvement, such as addressing various hazards or preparing for activities. The procurement of non-conforming spare parts once again in 2021 led to faults in the management of the activities. Incorrectly applied national EDF documents or incorrect operational documents are also the cause of inappropriate maintenance operations or maintenance quality defects. Finally, ASN observed that the requalification tests are not always able to detect equipment defects following maintenance or modification work.

Despite an improvement observed in 2019 and 2020 in the technical oversight of the work and contractor monitoring, particularly through the use of computer tools recently deployed in the NPPs, there were still numerous significant events arising from maintenance non-quality, undetected by monitoring or by the first level analyses.

In the context of the continued operation of the reactors, the "major overhaul" programme and all the modifications made as a result of the lessons learned from the accident at the Fukushima Daiichi NPP, 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.

In 2021, through its inspections, ASN found that the various sites did on the whole deploy the maintenance policy changes initiated by EDF as of 2016.

2.4.5 Protection against internal and external hazards

Fire risks

A fire can lead to failure of the equipment needed to control the fundamental safety functions. Steps must thus be taken to protect the sensitive parts of the facility against fire.

In the same way as the other BNIs, NPPs are covered by ASN resolution 2014-DC-0417 of 28 January 2014, relating to the rules applicable to BNIs for controlling fire risks.

The way the fire risk is taken into account in the NPPs is based on the principle of "Defence-in-Depth" built around three levels, that is the design of the facilities, fire prevention and firefighting.

Design rules aim to prevent a fire from spreading and mitigate its consequences; they are based primarily on "fire sectorisation". This involves dividing the facility into sectors and containment areas designed to keep the fire within a given perimeter bounded by items (doors, walls and fire dampers) offering a specified fire resistance duration. The main purpose is to prevent a fire spreading to two redundant equipment items performing a fundamental safety function.

Prevention primarily consists in:
- ensuring that the nature and quantity of combustible material in the premises remains below the hypotheses adopted for fire sectorisation;
- identifying and analysing the fire risks, in order to take steps such as to avoid them. More specifically, for all the work liable to generate a fire, a "fire permit" must be issued and protective measures taken.

Finally, the detection of an outbreak of fire and fire-fighting measures should enable a fire to be brought under control and then extinguished within a time compatible with the fire resistance duration of the sectorisation elements.

Explosion risks

An explosion can damage the items essential for maintaining safety or lead to rupture of the containment and the dispersal of radioactive materials into the facility, or even into the environment. Steps must thus be taken by the licensee to protect the sensitive parts of the facility against explosions.

Internal flooding risks

An internal flood, that is originating inside the facility, can lead to failure of the equipment needed to control the fundamental safety functions. Flooding may in particular be caused by an earthquake. Steps are therefore taken to prevent internal flooding (maintenance of piping carrying water, etc.), or mitigate its consequences (presence of floor drains and water extraction pumps, installation of sills or leaktight doors to prevent the flood from spreading, etc.).

External flooding risks

Following the partial flooding of the Blayais NPP in December 1999, the licensees, under the supervision of ASN, reassessed the safety of their facilities in the face of this risk, in conditions that were more severe than before, and made numerous safety improvements, according to a schedule defined according to the risks. In accordance with the ASN requirements, EDF completed the required work on all its NPPs.

At the same time, to ensure more exhaustive and more robust integration of the flooding risk, as of the facilities design stage, ASN published Guide No. 13 in 2013 concerning BNI protection against external flooding.

Following the stress tests performed in the wake of the Fukushima Daiichi NPP accident, ASN considered that with regard to flooding protection, the requirements resulting from the complete reassessment carried out following the flooding of the Blayais NPP in 1999 would be able to provide the NPPs with a high level of protection against the external flooding risk. However, ASN issued several resolutions in June 2012 asking the licensees:

- to reinforce NPP protection against certain hazards, such as intense rainfall and earthquake-induced flooding;
- to define and implement a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations and, in particular, in the case of flooding beyond the design-basis safety requirements.

Seismic risks

Although seismic activity in France is moderate or slight, EDF's inclusion of this risk in the safety case for its nuclear power reactors is the subject of constant attention on the part of ASN, given the potential consequences for the safety of the facilities. Seismic protection measures are designed into the facilities. They are periodically re-examined in the light of changing knowledge and changes to the regulations, on the occasion of the periodic safety reviews.

Basic Safety Rule (RFS) 2001-01 of 31 May 2001 defines the methodology used to determine the seismic risk for surface BNIs (except for radioactive waste long-term disposal facilities).

This RFS is supplemented by ASN Guide 2/01 of May 2006 which defines acceptable calculation methods for a study of the seismic behaviour of nuclear buildings and particular structures, such as embankments, tunnels and underground pipes, supports or tanks.

The design of the buildings and the equipment important for safety in the NPPs must thus enable them to withstand earthquakes of an intensity greater than the strongest earthquakes that have occurred in the region. EDF's NPPs must thus be able to withstand seismic levels incorporating the local geological features specific to each one.

As part of the periodic safety reviews, the seismic reassessment consists in verifying the adequacy of the seismic design of the facility, taking account of changing knowledge about seismic activity in the region of the site or about the methods for assessing the seismic behaviour of elements of the facility. The lessons learned from international experience feedback are also analysed and integrated into this framework.

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 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.

Following the Fukushima Daiichi NPP accident, ASN asked EDF to define and implement a "hardened safety core" of material and organisational measures to control the fundamental safety functions in extreme situations comparable, in the French context, to that which occurred in Japan on 11 March 2011. This "hardened safety core" shall notably be designed to withstand an earthquake of an exceptional level, exceeding those adopted in the design or periodic safety review of the installations.

In order to define this exceptional level earthquake, ASN asked EDF to supplement the deterministic approach to defining the seismic hazard with a probabilistic approach, in order to take account of international best practices.

Heatwave and drought risks

During the heat waves in recent decades, some of the watercourses used to cool NPPs experienced a reduction in their flow rate and significant warming. Significant temperature rises were also observed in certain NPP premises housing heat-sensitive equipment.

EDF took account of this OEF and initiated reassessments of the operation of its facilities in air and water temperature conditions more severe than those initially included in the design. In parallel with development of these "extreme heat" baseline safety requirements, EDF initiated the deployment of a number of priority modifications (such as the increase in the capacity of certain heat exchangers) and implemented operating practices optimising the cooling capacity of the equipment and improving the resistance of equipment susceptible to high temperatures.

For the periodic safety review of its reactors, EDF has initiated a modifications programme on its facilities designed to provide protection against heat wave situations. The capacity of certain cooling systems for equipment required for the nuclear safety case will in particular be improved.

EDF has also initiated a climatic monitoring programme to anticipate climate changes which could compromise the temperature hypotheses adopted in its baseline requirements.

ASN asked EDF to take account of the OEF from the heatwave events of 2015, 2016 and 2019, and their effects on the facilities.

Other hazards

The safety case for the EDF NPPs also takes account of other hazards such as high winds, snow, tornados, lightning, cold air temperatures, man-made hazards (transport of dangerous goods, industrial facilities, airplane crashes, etc.), and hazards affecting the heatsink.

2.4.6 Assessment of the risk prevention measures relating to hazards

ASN checks that risks linked to hazards in the NPPs are taken into account, notably based on the reassessment of the design of the installations during the periodic safety reviews, analysis of the licensee's baseline safety requirements, examination of significant events and the inspections performed on the sites. The steps taken to mitigate the risks linked to hazards are regularly inspected by ASN.

The Fukushima Daiichi NPP accident led EDF to reinforce its organisation for the management of risks relating to extreme hazards. More specifically, networks of coordinators were set up for all the NPPs to oversee the implementation of the actions defined to deal with these hazards. Annual reviews are also held to improve this organisation.

Fire risks

Fire risks are significant. ASN thus reminded EDF in 2016 that, for the purposes of the fourth periodic safety review of the 900 MWe reactors, it expected a well-structured and robust safety case based on a "Defence-in-Depth" approach. ASN examined the justification methods produced by EDF, along with the corresponding modifications, and obtained the opinion of the Advisory Committee for Nuclear Reactors (GPR) in 2019. This examination shows that the changes proposed by EDF represented considerable improvements to the safety case (for example, sectorisation resistance studies, taking account of the effect of smoke). In addition, the new methods adopted identified sectorisation aspects for which correct working is particularly important. For example, the fire doors which are required to be closed were identified and will be subject to specific monitoring.

On the sites, ASN observes no significant change concerning management of the fire risks, with a number of outbreaks of fire for the year 2021 comparable to that found in 2020, and an appreciably higher number of significant fire-related events.

In 2021, ASN ran an enhanced inspections campaign concerning management of fire risks in seven NPPs and asked for corrective measures to remedy the findings made following these inspections, in particular:
- the management of equipment stores and warehouses, which represent considerable calorific potential, must be improved. EDF must in particular demonstrate that fire sectorisation is sufficient, in the light of these stores, keep exhaustive inventories and guarantee compliance with the conditions specified for these activities;
- the management of sectorisation must also be improved in certain NPPs: ASN sometimes notes that inspections are incomplete, inaccurate information is communicated to the control teams and anomalies are not detected or processed.

ASN has observed a number of improvements in the monitoring of fire permits related to the deployment of a new computer application. Fire detection management, equipment maintenance and personnel training are in general satisfactory and, since the end of 2021, ASN notes that the alarm verification officers in all the NPPs have been working in pairs. In 2021, 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.

ASN thus considers that the efforts made by the NPPs to take corrective measures, notably the deployment of tools and action plans, must continue and the personnel must receive greater support in this respect and be given the means needed to perform the required actions.

Finally, following an ASN request in 2019, EDF in 2021 presented ASN with its guidelines to improve its firefighting organisation, notably by reinforcing the capacity of its response resources to deal with an established fire. In 2022, EDF will define the deployment plan for its new organisation for all the NPPs.

Explosion risks

ASN checks the explosion risk prevention and monitoring measures, paying particular attention to ensuring that it is taken into account in EDF's baseline safety requirements and organisation. ASN also ensures compliance with the "EXplosive ATmospheres" (ATEX) regulations to ensure worker protection.

The management of explosion risks is not yet satisfactory for all the nuclear reactors. Certain maintenance and inspection work required by EDF's internal doctrine is not always carried out satisfactorily. Furthermore, ASN observes that the integration of OEF, the processing of certain deviations and the deployment of certain modifications are sometimes postponed and this is not always justified given the potential safety consequences. During inspections, ASN is particularly vigilant to the inspections and corrective measures taken by EDF to guarantee the compatibility of the electrical equipment with use in rooms where an explosive atmosphere is liable to form.

ASN notes the efforts made by EDF to reduce these deviations through the implementation of reinforced monitoring and the deployment of action plans leading to equipment replacement. Furthermore, in 2021, EDF worked on updating documents concerning protection against explosions, required by the regulations concerning the risks involved in the formation of ATEX and conducted conformity audits on the equipment concerned. EDF also changed its personnel training programme regarding explosion risks and incorporated it into the regularly held exercises on the explosion topic. ASN considers that EDF must continue to pay particular attention to this subject and ensure that the explosion risk prevention approach is implemented with all necessary rigour on all the sites.

Internal flooding risks

Considerable efforts are required on most sites to improve control of the internal flooding risk, in particular with respect to:
- the maintenance of the necessary equipment (piping, floor drains, etc.);
- the risk assessments during maintenance operations and in the event of detection of a malfunction of a necessary equipment item;
- the compliance with the corrective action deadlines identified by the annual reviews;
- the training of the coordinators and awareness-raising among the EDF and contractor personnel.

In 2019, ASN thus sent requests to EDF asking it to supplement the approach adopted for improved control of the internal flooding risk, to ensure the correct operation of the floor drains, to reinforce maintenance of the piping liable to lead to internal flooding and to ensure improved management of their ageing. In response to these requests, EDF implemented improvement measures.

In addition, EDF has initiated 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.

THE DEFINED REQUIREMENTS

The Order of 7 February 2012 stipulates that a defined requirement is a "requirement assigned to an item of Protection Important Component (of persons and the environment), so that, with the expected characteristics, it can perform the function stipulated in the safety case, or to an activity important for protection (of persons and the environment) so that it meets its objectives with respect to this safety case".

For the equipment, these requirements may in particular concern:
- the characteristics of the materials used;
- the manufacturing, assembly, erection and repair processes;
- the physical parameters and criteria characteristic of the performance of the equipment.

For the activities, these requirements may in particular concern:
- the skills needed to perform the activity;
- any qualifications necessary;
- checks and hold points;
- the equipment and hardware needed to enable the activity to be carried out in accordance with the regulatory or even contractual requirements, such as to guarantee compliance with the safety case.

PROCESSING OF DEVIATIONS

A deviation is a non-compliance with a defined requirement or a requirement set by the licensee's integrated management system. A deviation may thus affect a structure, a system or a component of the facility. It may also concern compliance with an operating document or the working of an organisation.

The regulations require that the licensee identify all deviations affecting its facilities and process them. The activities related to the processing of deviations are activities important for the protection of persons and the environment. They are thus subject to oversight and monitoring requirements, the implementation of which is regularly checked by ASN.

Finally, for the fourth periodic safety review of the 900 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 (Ardèche *département*). Following this earthquake, 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. According to EDF, the Le Teil earthquake has no impact on the seismic level adopted for protection of the Tricastin site, but that of Cruas-Meysse should be re-evaluated. This re-evaluation requires additional field investigations and should be completed in 2022. Pending the results of these investigations, EDF defined a new, temporary design-basis spectrum. This spectrum will be used to initiate the seismic re-evaluation studies associated with the fourth periodic safety review of this site. ASN will issue a position statement on this subject in 2022.

REINFORCED OVERSIGHT OF SUPPLIERS OF EQUIPMENT IMPORTANT FOR NUCLEAR SAFETY

In 2021, ASN reinforced its oversight of the EDF procurement chain for equipment important for safety intended for NPPs. In 2021, ASN therefore carried out 42 inspections, most of them in manufacturing plants.

During these inspections, ASN examined compliance with the regulatory requirements during manufacturing operations, the ability of the suppliers to manufacture equipment meeting the safety requirements and how the risk of fraud is addressed. During these inspections, ASN also checked EDF's monitoring of its suppliers and their subcontractors.

ASN in particular took part in multinational inspections with its foreign counterparts under the Multinational Design Evaluation Programme (MDEP) in Framatome's Saint-Marcel plant (Saône-et-Loire *département*), Flowserve's Raleigh plant (United States) and the Fairbanks plant in Beloit (United States).

Risks linked to extreme temperatures

The inspections concerning the risks associated with extreme temperatures show that EDF's organisation must be improved on the majority of sites. On several sites, ASN more particularly found a lack of forward planning in preparing the facility for the summer or winter configuration, which led to corrective action requests.

In recent summers, at ASN's request, EDF ran operating tests on the emergency diesel generator sets during a period of high temperatures. The purpose of these tests is to confirm the qualification demonstration of this equipment.

Lightning risks

The inspections relating to lightning risks reveal the need on all sites to set up reinforced organisation and oversight to improve the integration of the regulatory requirements associated with the management of this hazard. Corrective measures have been requested.

ASN still observes shortcomings in the lightning risk management approach, notably in the dedicated risk assessments, which regularly contain incorrect information regarding the state of the installations. ASN also observes significant delays in the performance of the work identified in the technical studies. Moreover, the deadlines for performance of the periodic checks on the lightning protection systems by the competent inspection organisations are not always met. These points were the subject of requests for corrective action. EDF has defined a programme of work to improve the situation.

2.4.7 Monitoring facilities compliance with the 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 compliance of the facilities with the requirements resulting from this safety case.

The identification and processing of deviations

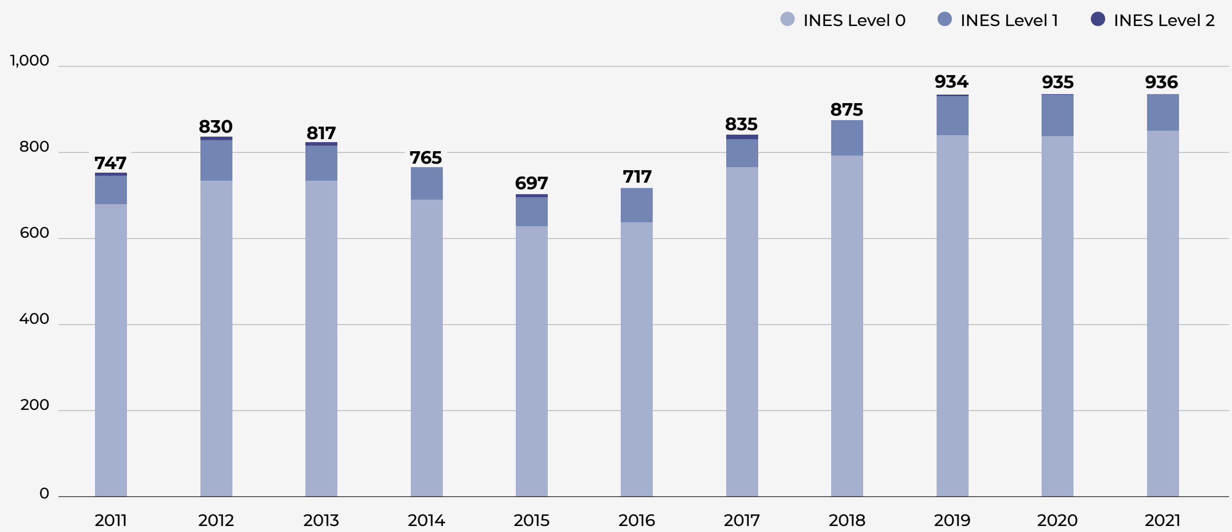
The checks initiated by EDF within the framework of its operating baseline requirements and the additional verifications requested by ASN, on the basis more particularly of OEF, can lead to the detection of deviations from the defined requirements, which must then be processed. These deviations can have a variety of origins: design problems, construction errors, insufficient expertise in maintenance work, deterioration through ageing, organisational shortcomings, etc.

The steps taken to detect and correct deviations, specified in the Order of 7 February 2012, play an essential role in maintaining the level of safety of the facilities.

"Real-time" checks

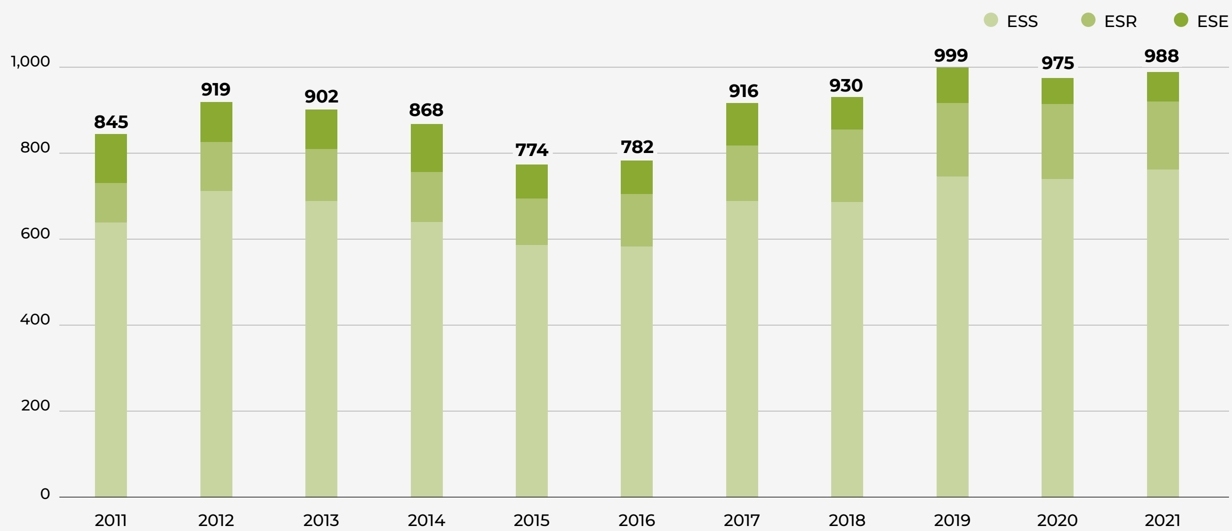
Carrying out periodic test and preventive maintenance programmes on the equipment and systems contributes to identifying deviations. Routine visits in the field and technical inspection and verification of activities considered to be important for the protection of persons and the environment are also effective means of detecting deviations.

GRAPH 1 **Trend in the number of significant events rated on the INES scale in the EDF Nuclear Power Plants between 2011 and 2021**



This Graph includes data from the Fessenheim NPP until 2020.

GRAPH 2 **Trend in the number of significant events by domain in the EDF Nuclear Power Plants between 2011 and 2021**



This Graph includes data from the Fessenheim NPP until 2020.

Verifications during reactor outages
EDF takes advantage of nuclear reactor outages to carry out maintenance work and inspections which cannot be performed when the reactor is generating electricity. These operations more particularly correct deviations already known, but can also lead to the detection of new ones. Before each reactor restart, ASN asks EDF to list any deviations not yet remedied, to take appropriate compensatory measures and to demonstrate the acceptability of these anomalies with respect to the protection of persons and the environment for the coming production cycle.

Ten-yearly verifications: conformity checks
EDF carries out periodic safety reviews of the nuclear reactors every ten years, in accordance with the regulations (see point 2.9.2). EDF then carries out an in-depth review of the actual state of the facilities by comparison with the applicable safety requirements, more particularly on the basis of the in-service monitoring hitherto carried out, and lists any deviations. These verifications can be supplemented by a programme of additional investigations, the aim of which is to check the parts of the facility which are not covered by a preventive maintenance programme.

The additional verifications in response to ASN requests
In addition to the steps taken by EDF with regard to its operating baseline requirements, additional checks are carried out at the request of ASN, whether, for example, with regard to OEF about events which have occurred on other facilities, after inspections, or after examination of the provisions proposed by the licensee within the context of the periodic safety reviews.

Information of ASN and the public
When a deviation is detected, and in the same way as any BNI licensee, EDF is required to assess the impacts on nuclear safety, radiation protection and protection of the environment. If necessary, EDF then sends ASN a significant event notification report. In addition, when the most noteworthy significant events occur, EDF informs the public by publishing notices on the website of the NPPs concerned, or in its external newsletter. For its part, ASN informs the public on *asn.fr* of significant events of level 1 or higher on the International Nuclear and Radiological Event Scale (INES).

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 nonconformities and presents the approach expected of the licensee in accordance with the principle of proportionality. This is based more specifically on an assessment of the potential or actual consequences of any deviation identified and on the licensee's ability to guarantee the safety of the reactor in the event of an accident, by taking appropriate compensatory measures. The Guide also recalls the principle of the correction of compliance deviations as soon as possible and in any case defines the maximum times allowed.

2.4.8 Assessment of facilities compliance with the applicable requirements

In the past, ASN has found that the organisational measures taken to deal with deviations were unsatisfactory and that the time taken to characterise, check and process the deviations did not always comply with the requirements of the Order of 7 February 2012. In 2019, EDF therefore revised its internal baseline requirements for management of deviations, in order to improve how they are processed and provide ASN with reactive information proportional to the safety implications. In 2021, ASN observed a notable improvement in the situation. The efforts made by EDF must be continued over the coming years.

Significant events concerning several reactors were once again reported in 2021 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 2022 and will in this respect continue its inspections of the condition of equipment and systems.

Finally, ASN observes that certain systems linked to the "support", "reactivity control" and "cooling" safety functions are subject to recurring unscheduled unavailability. This is notably the case with the reactor component cooling systems, post-accident monitoring, reactor nuclear power measurement and rod cluster control. These unavailabilities, already identified in 2020, were the subject of discussions with EDF, which will be continued in 2022, in order to verify the pertinence of the steps taken by EDF.

Notification of significant events by EDF
Pursuant to the rules for the notification of significant events (see chapter 3, point 3.3), ASN received 762 Significant Safety Events (ESS) reports from EDF in 2021, along with 158 Significant Radiation Protection Events (ESR) reports and 68 Significant Environmental Protection Events (ESE) reports. In 2021, the number of significant events is slightly up on the previous year, in particular the ESS (746 in 2019, 740 in 2020). It should also be noted that for the first time in 2021, the events reported by the Fessenheim site were not included in these results.

Graph 1 shows the trend since 2011 in the number of significant events reported by EDF and rated on the INES scale.

Graph 2 shows the trend since 2011 in the number of significant events according to the notification field: ESS, ESR and ESE. Events not rated on the INES scale are also taken into account.

Significant events affecting several nuclear reactors are grouped under the term generic "significants events". In 2021, 31 events of this type were reported in the field of nuclear safety.

2.5 Prevention and management of environmental and health impacts

2.5.1 Discharges and waste management

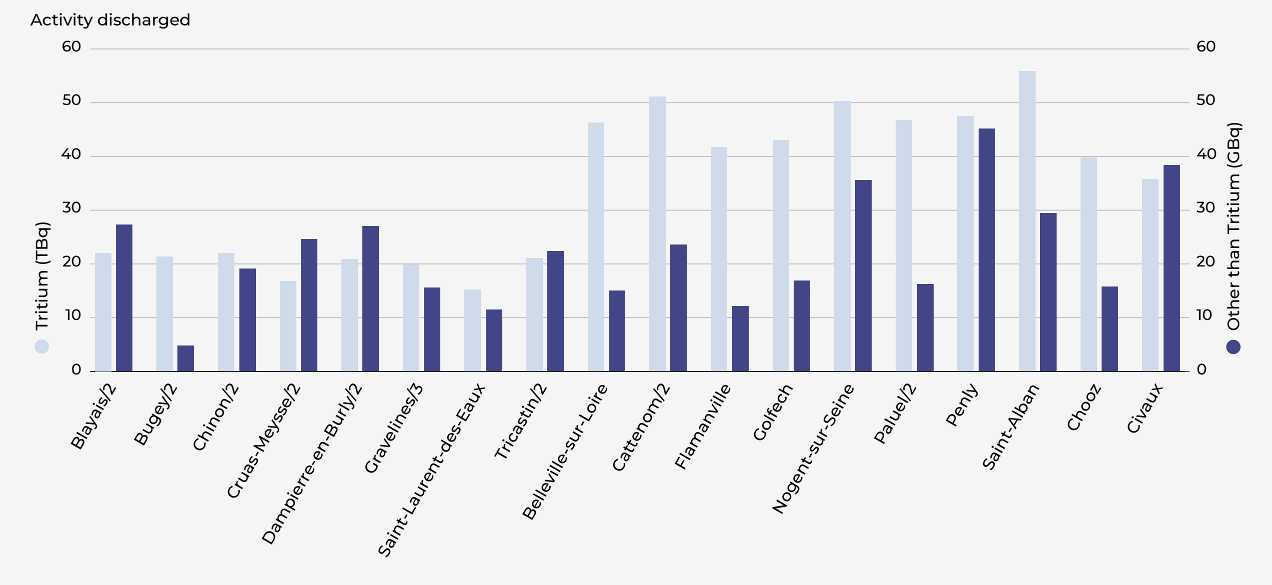
Limiting water intake and environmental discharges
NPPs discharge liquid and gaseous effluents. These effluents, which can be radioactive or chemical, are created by the actual operation of the reactor, primarily the operations designed to ensure the radiochemical quality of the MPS, the chemical conditioning of the systems, in order to contribute to their good condition, the production of demineralised water to supply certain systems, biocidal treatments and effluents from the site's wastewater treatment plant.

For each site, ASN sets the limit values for water intake and discharge of effluents on the basis of the best available technologies in technically and economically acceptable conditions, taking into consideration the characteristics of the installation, its location and the local environmental conditions.

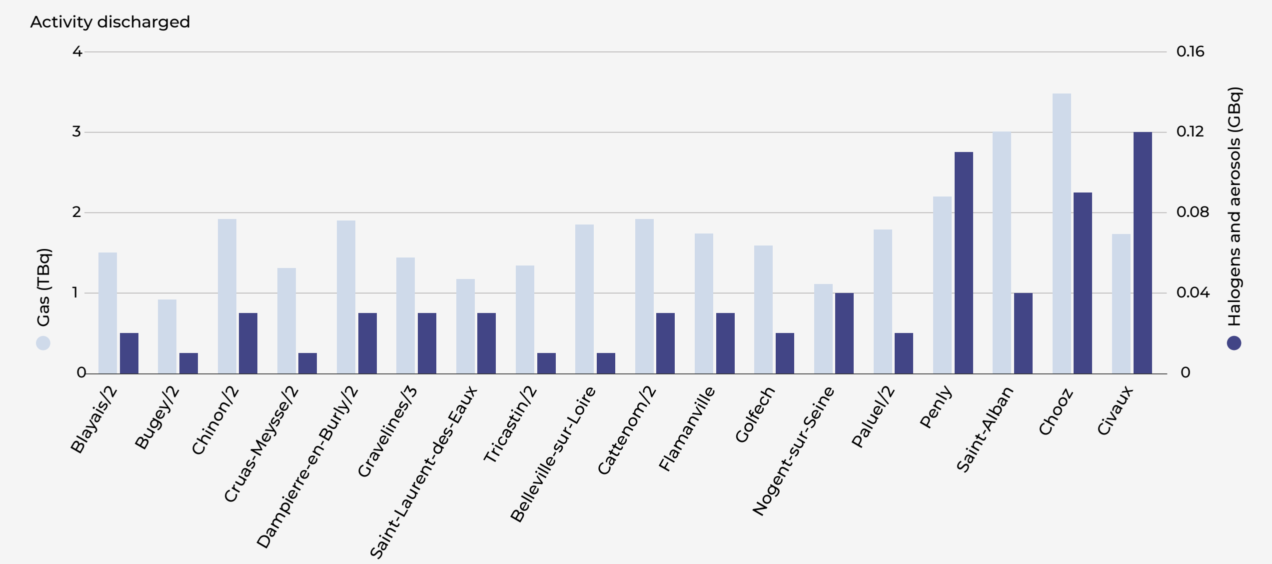
ASN also sets the rules concerning the management of detrimental effects and the impact on health and the environment of the PWRs. These requirements are notably applicable to the management and monitoring of water intake and effluent discharge, to environmental monitoring and to information of the public and the authorities (see chapter 3, point 4.1).

In setting these requirements, ASN uses OEF from all the reactors as the basis, while also taking account of operational changes (change in conditioning of systems, anti-scaling treatment, biocidal treatment, etc.) and changes to the general regulations.

GRAPH 3 **Liquid radioactive discharges for the NPPs in 2021 (per pair of reactors)**



GRAPH 4 **Gaseous radioactive discharges for the NPPs in 2021 (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.

Finally, every year, the NPP licensees send ASN an annual environmental report which notably contains a summary of the intakes from and discharges into the environment, any impacts they may have, and any significant events which have occurred.

The impact of thermal discharges from the NPPs

NPPs discharge hot effluents into watercourses or the sea, either directly, from those NPPs operating with "once-through" cooling, or after cooling of these effluents in cooling towers, enabling some of the heat to be dissipated to the atmosphere. Thermal discharges from NPPs lead to a temperature rise between the points upstream and downstream of the discharge which, depending on the reactors, can range from a few tenths of a degree to several degrees. These thermal discharges are regulated by ASN resolutions.

Since 2006, provisions have been incorporated into the ASN resolutions for advance definition of the operations of NPPs in exceptional climatic conditions leading to significant warming of the watercourse. These special provisions are however only applicable if the security of the electricity grid is at stake.

Waste management

In compliance with the provisions of the Environment Code, EDF carries out waste sorting at source, differentiating in particular between waste from nuclear zones and other waste. For each installation, EDF produces a summary of the management of this waste, in particular presenting a description of the operations which are the cause of production of the waste, the characteristics 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.

2.5.2 Prevention of soil pollution and health impacts

Prevention of pollution resulting from accidental spillage of dangerous substances

As with numerous industrial activities, the operation of an NPP involves the handling and storage of dangerous chemical substances. The management of these substances and the prevention of pollution, which are the responsibility of the licensee, are regulated by the Order of 7 February 2012 and ASN resolution 2013-DC-0360 of 16 July 2013 and must also comply with the requirements of the European texts. The licensee has obligations regarding the operational management of these substances and the identification of the corresponding potential hazards. It must also be able to take the necessary steps in the event of any incident or accident situations which would lead to pollution.

The licensee must thus for instance precisely identify the location of each dangerous substance on its site, along with the corresponding quantities. Drums and tanks must be labelled in compliance with the European "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.

Prevention of the health impacts caused by the growth of legionella and amoeba in certain cooling systems of the NPP secondary systems

The cooling systems of nuclear reactors equipped with a cooling tower are environments favourable to the development of legionella and other amoeba (see point 1.4). EDF monitors the legionella and amoeba concentrations and takes preventive measures and, if necessary, remedial measures in accordance with the provisions of ASN resolution 2016-DC-0578 of 6 December 2016 on the prevention of risks resulting from the dispersion of pathogenic micro-organisms (legionella and amoeba) by the cooling installations of the system.

For most of these reactors, preventive and remedial measures to limit the development of legionella and amoeba are based on the injection of a biocidal product (monochloramine) into the cooling system.

2.5.3 Assessment of control of detrimental effects and impact on the environment

ASN monitors the organisational and material provisions adopted by EDF to manage the dangerous substances present in its facilities and to deal with any pollution.

In 2021, ASN carried out a campaign of inspections on the organisation of 11 NPPs and their ability to confine dangerous substances in an accidental spillage scenario. These inspections, which were primarily based on field checks, consisted of an unannounced situational exercise that was identical for all the NPPs. Most of the NPPs inspected have an organisation and means enabling them to confine a large volume of pollution. These inspections were also able to identify the corrective measures to be implemented rapidly in each facility. EDF must also continue with the extensive work it has undertaken to reinforce the confinement capacity on certain sites.

ASN also ran a campaign of inspections on the NPPs emitting the most sulphur hexafluoride (SF_6), a gas with a significant greenhouse effect. This gas is used in the NPPs as an electrical insulator in electricity distribution equipment. During this inspection campaign, ASN verified that EDF had implemented an action plan to deal with sources of leaks. The organisation and the correction plan put in place by the NPPs, based on prevention, detection and reactive repair resources, are satisfactory. ASN considers that EDF must remain fully mobilised to implement this action plan.

In 2021, as in previous years, ASN observed that discharges are well managed on most of the sites. However, certain events indicate occasional weaknesses.

Finally, with regard to waste management, the inspections carried out by ASN reveal that operational management of waste needs to be further improved. During its inspections, ASN also found missing signage, non-compliance with operating baseline requirements, notably on the outside areas, and waste storage in unauthorised zones.

2.6 The contribution of man and the safety organisations

The contribution of people and organisations to the safety of NPPs is a decisive factor in all steps of the plant lifecycle (design, construction, commissioning, operation, decommissioning).

2.6.1 The operation of organisations

The Integrated Management System

The Order of 7 February 2012 stipulates that the licensee must have the technical skills needed to manage the activities involved in operation. Of these, the processing of significant events requires an in-depth analysis of the organisational and human causes in addition to the technical causes.

Furthermore, this order requires that the licensee define and implement an Integrated Management System (IMS) to ensure that the requirements concerning the protection of interests are systematically considered in any decision concerning the facility. This IMS must specify the steps taken with regard to organisation and to resources of all kinds, in particular those adopted to control the activities important for the protection of persons and the environment.

Management of subcontracted activities

Maintenance and modification activities on French reactors are to a large extent subcontracted by EDF to outside contractors. EDF justifies the use of subcontracting by the need to call on specific or rare expertise, as well as the highly seasonal nature of reactor outages and thus the need to absorb workload peaks.

EDF's decision to resort to subcontracting must not compromise the technical skills it must retain in-house, in order to carry out its responsibility as licensee with regard to the protection of persons and the environment and to be able to effectively monitor the quality of the work performed by the subcontractors. Poorly managed subcontracting is liable to lead to poor quality work and have a negative impact on the safety of the facility and the radiation protection of the workers involved.

EDF takes the necessary steps to control the risks associated with the subcontracted activities and regularly updates them. EDF has thus reinforced the preparation of reactor outages, more particularly to guarantee the availability of human and material resources.

2.6.2 Assessment of the operation of the organisations and control of activities

ASN focuses on the conditions which are favourable or prejudicial to the contribution to NPP safety by the operators and worker groups. It defines the Organisational and Human Factors (OHF) as being all the aspects of working situations and the organisation which will have an influence on the work done by the operators.

ASN oversight of the working of the organisations set up by EDF aims to check the IMS implementation procedures. More specifically, ASN ensures that the design or modification approaches implemented by the engineering centres at the moment of the design of a new facility or modification of an existing one take account of the needs of the users and organisations that will be operating it.

More broadly, ASN monitors the organisation put into place by EDF to manage the resources needed to perform these activities.

The comments expressed during the inspections observed are the subject of requests for corrective action.

The overall organisation

EDF is able to satisfactorily adapt its organisations along with certain professional practices in order to deal with the consequences of the Covid-19 pandemic. The main difficulties identified concerned postponed training programmes.

In 2021, ASN continued its campaign of "explanatory" interviews, which it had started in 2020, so that its personnel could talk about their experiences and their day-to-day working conditions. Through these discussions, ASN noted that the personnel were on the whole satisfied with their working conditions, but –in particular for the operation and maintenance professions– it noted recurring operational difficulties, more especially the activities preparation phases (modification of schedules exacerbating the time pressure, problems with logistics and availability of tools and spare parts, inappropriate or overly voluminous operational documentation). The result of these difficulties was the deterioration in the preparation of activities (insufficient quality in the risk assessments and integration of OEF, lack of familiarisation with the documentation) with a direct impact on the quality of the activities in the control room or in the field.

Skills management

Despite the difficulties related to the Covid-19 pandemic and with making up the delays in certain training programmes (control operators, safety engineers), the organisation implemented by the sites to manage skills, qualifications and training remained on the whole satisfactory.

The robust implementation and assimilation of the discipline baseline requirements on the sites (baseline requirements identifying the duties of each discipline and the corresponding training path) was confirmed in 2021, as was the good working by the specific training programming and follow-up entities (common training service, training committees at several levels of the organisation).

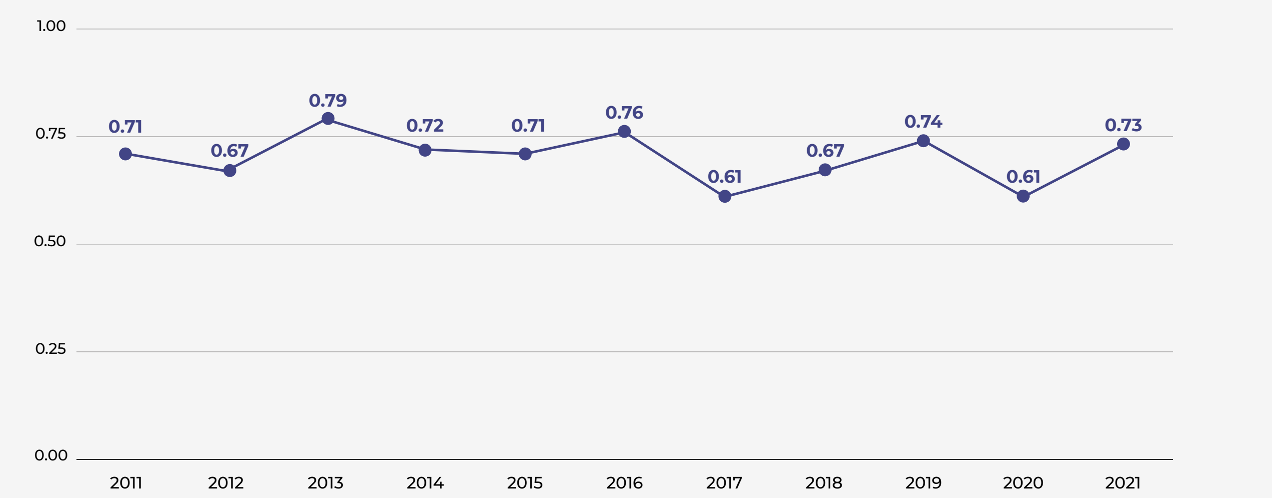
Even if the overall results with regard to skills are on the whole positive, ASN regularly found weaknesses in 2021 in the field of skills, notably with regard to the operation of the facilities. Certain shortcomings have been persistent for several years (process control, familiarity with equipment and hardware modifications) on a vast majority of the sites. Weak points, notably related to alignment and lock-out activities, are even tending to get worse.

Monitoring 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.

Monitoring of subcontracted activities was on the whole satisfactory in 2021, notably thanks to the correct deployment of the tool designed to help with production of monitoring programmes and performance of monitoring actions. However, the inspections are still showing weaknesses on certain sites (monitoring overly focused on quality assurance and safety rules and not enough on technical proficiency and the specific nature of the activities, inappropriate or only partially implemented monitoring plans). These difficulties mean that monitoring is not always an effective line of defence against potential failures by the contractors.

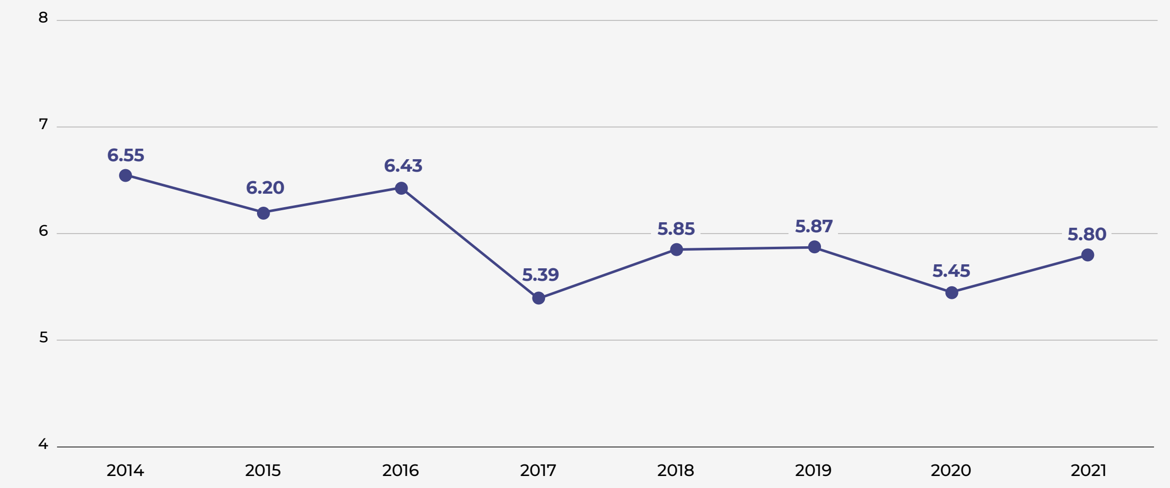
GRAPH 5 **Mean collective dose per reactor (Man.Sv/reactor)**



This Graph includes data from the Fessenheim NPP until 2020.

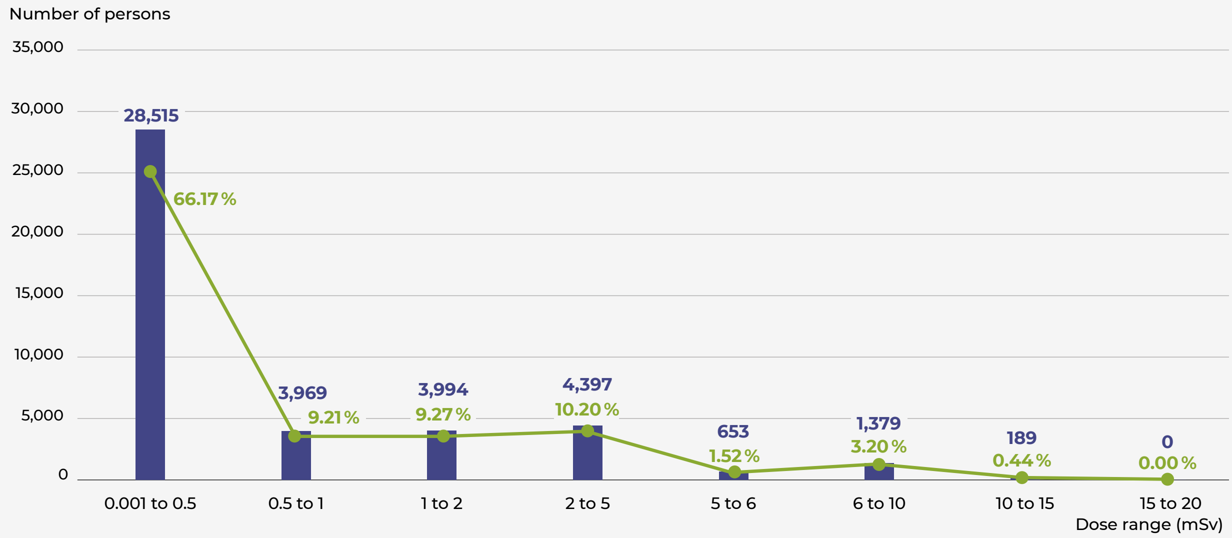
Source: EDF.

GRAPH 6 **Collective dose for one hour of work in a controlled area (in µSv)**



Source: EDF.

GRAPH 7 **Number and percentage of workers per dose range (in mSv) for 2021**



Source: EDF.

Management of operational documentation

ASN considers that the operational documentation is still not fully adequate in 2021. This has been a recurring fundamental problem for several years now. In 2021, the inspections again found numerous events for which the root causes included documentary problems. The weak points identified vary in nature (documentation not concise enough, not explicit, incomplete or non-existent) and have consequences for a wide range of activities, including control activities (periodic tests, lock-outs and administrative closures, alignment) and maintenance work (technical inspections, maintenance work on equipment, requalifications, local control actions).

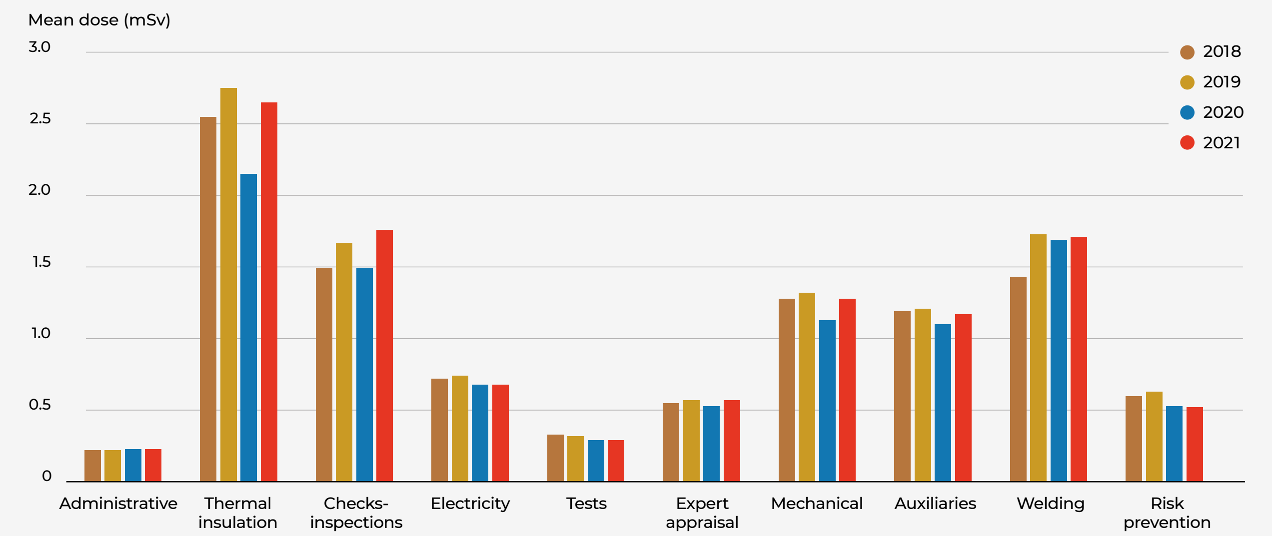
These weak points are to a large extent related to organisational malfunctions in the documentation creation and update process and they potentially compromise the documentary support line of defence.

The Operating Experience Feedback process

All the NPPs have implemented a formal organisation and dedicated tools to oversee and coordinate internal and external Operating Experience Feedback (OEF). The inspections targeted on OEF management underlined the overall engagement by the management of the NPPs on this subject. All those persons encountered, including outside contractors, showed a good level of involvement in the process. Weak points however persist on certain key aspects of this process, such as the incorporation of OEF into the activities preparation phases, or the transmission of difficulties encountered in the field (the quality of the debriefings fluctuates considerably from one discipline to another).

ASN also finds that the annual process reviews conducted by the sites are extremely pertinent, with the actors involved well able to identify weaknesses in OEF management. However, the monitoring of corrective measures resulting from the various

GRAPH 8 **Trend in mean individual dosimetry according to the categories of trades of the workers in the NPPs**



This Graph includes data from the Fessenheim NPP until 2020.

Source : EDF.

EXTERNAL CONTAMINATION OF A WORKER IN THE CRUAS-MEYSSE NPP

On 24 August 2021, during the check conducted at the exit from the controlled area in Cruas-Meysse NPP reactor 2, contamination was detected on a worker. The medical service immediately took charge of the employee and located the radioactive particle causing the contamination at the nape of the neck. The particle was removed.

Despite the investigations carried out along the route followed by the worker, the areas or points of contamination that could have caused this contamination could not be determined.

Consequently, EDF conducted an evaluation of the received dose considering that the particle was present from the moment the worker entered the reactor building until the particle was removed. This evaluation gives a dose at the nape of the worker's neck exceeding the regulation limit set for the equivalent dose to the skin (500 mSv for a skin surface area of 1 cm²).

ASN carried out an inspection on the site on 31 August 2021. The inspectors checked that EDF had taken all necessary steps for adequate management of the event and analysis of its causes.

Owing to the regulatory occupational exposure limit being exceeded, this event was rated 2 on the INES scale (ratings from 0 to 7 in ascending order of severity). The previous Significant Radiation protection Event (ESR) of level 2 reported by an EDF NPP dates back to 2015.

diagnostics related to the identified weak points and their recurrence needs to be improved.

The ASN reviews of the event reports received in 2021 revealed no particular weakness regarding the competence of the teams in charge of the in-depth analysis of significant events. The quality and availability of the human resources assigned to the analyses are satisfactory on all the sites, whether in terms of numbers or of competence. The involvement of OHF skills in the analysis phase is satisfactory on the majority of the sites.

2.7 Personnel radiation protection

2.7.1 Exposure of personnel to ionising radiation

Exposure to ionising radiation in a nuclear power reactor comes primarily from the activation of corrosion products in the primary system and fission products in the fuel. All types of radiation are present (neutrons, α, β and γ), with a risk of internal and external exposure. In practice, more than 90% of the doses received come from external exposure to β and γ radiation. Exposure is primarily linked to maintenance operations during reactor outages.

The average collective dosimetry on all the reactors (Graph 5), and the average dose received by the workers for one hour of work in a controlled area (Graph 6) rose in 2021 by comparison with 2020, which had been marked by several reactor outage postponements. These values reach a level comparable to that of 2019, before the Covid-19 pandemic.

The doses received by the workers are broken down as illustrated above in Graphs 7 and 8.

Graph 8 shows the breakdown of the workers according to whole body external dosimetry. As in 2020, the dosimetry for 75% of the exposed workers was less than 1 mSv (millisievert) in 2021, which corresponds to the annual regulation limit for the public. The annual regulation limit for whole body external dosimetry (20 mSv) was exceeded on no occasion in 2021.

Graph 8 shows the trend in whole body average individual dosimetry according to the categories of disciplines of the workers in the NPPs. As in previous years, the most exposed worker categories are personnel in charge of heat insulation, welding, monitoring, mechanical work and ancillary systems. The doses recorded by the most exposed workers are up by comparison with 2020.

Significant contamination events

The number of significant contamination events concerning workers in the NPPs fell in 2021: four events were reported in 2021, as against eight in 2020 and seven in 2019. Of these events, three led to exposure greater than one quarter the annual regulation limit per square centimetre of skin and were rated level 1 on the INES scale. The fourth event concerned exposure greater than the regulation limit for skin and was rated level 2 on the INES scale (see box).

The workers concerned by these events were given care and the radioactive particles responsible for their contamination were removed, in accordance with the procedure applied by EDF.

2.7.2 Assessment of personnel radiation protection

ASN monitors compliance with the regulations relative to the protection of workers liable to be exposed to ionising radiation in NPPs. In this respect, ASN is attentive to all the workers on the sites, both EDF personnel and those of contractors.

This monitoring is performed during inspections once or twice a year and per NPP, specifically on the topic of radiation protection, and during reactor outages as well as following significant events, or more occasionally in the EDF head office departments and engineering centres. It is also carried out during examination of the worker radiation protection files (significant event reports, design, maintenance or modification files, documents implementing the regulations and produced by EDF, etc.).

During inspections carried out in 2021, ASN found improvements in how radiation protection is addressed on several NPPs. Progress is more particularly to be noted with regard to the dose optimisation approach. Improvements were also made in management of access to and demarcation of red controlled areas, a sensitive process with regard to the high dose equivalent rates liable to be received there (higher than 100 mSv/h).

Nonetheless, during inspections carried out on worksites in controlled areas, the ASN inspectors repeatedly found that radiological monitoring equipment was missing and containment means did not conform to the rules in force and they made corrective action requests. Deviations from radiation protection rules, in particular with regard to compliance with contamination checks on exiting controlled or contaminated areas, continue to be observed. EDF must continue to take measures to remedy these deviations. The situation remains a concern in certain NPPs, for which ASN will have to maintain its vigilance.

Given the worker significant contamination events which occurred in 2021 and the deviations observed in the field, ASN will in 2022 be continuing its checks on the prevention of the dissemination of radioactive contamination, as well as on procedures for treating contamination victims, in order to verify that the time taken to provide treatment actually enables the workers exposure time to be reduced.

2.8 Labour Law in the Nuclear Power Plants

2.8.1 Oversight of Labour Law in the Nuclear Power Plants

ASN is responsible for labour inspectorate duties in the 18 NPPs, the EPR reactor under construction at Flamanville and 11 other installations, most of which are reactors undergoing decommissioning. 800 to 2,000 people work in each NPP. About 24,000 EDF employees and 23,000 employees from outside contractors are thus assigned to these nuclear sites.

The role of the labour inspectorate is to ensure that the Labour Code as a whole is applied by the employers, whether EDF or its contractors.

The labour inspectorate, which takes part in the integrated vision of oversight sought by ASN, carries out its monitoring work in conjunction with the other activities to monitor and oversee the safety of facilities and radiation protection.

Oversight of occupational health and safety regulations

Throughout the year 2021, the ASN labour inspectors were called on by the employers, the staff, and the EDF or contractor personnel representatives, regarding the protection measures to be implemented in the workplaces and the conditions for the continuity of their activities on the sites. The labour inspectorate provided considerable support, by supplying information and explanations regarding the Government measures to deal with the Covid-19 pandemic to the employers and the health, safety and working conditions commissions of the social and economic committees.

At the same time, action continued concerning the worksites entailing a risk linked to the presence of asbestos, the conformity of the work equipment and, more specifically lifting gear, fire and explosion risks and improved aeration and ventilation conditions in the workplaces.

Finally, the labour inspectors systematically initiate an inquiry in the event of a severe accident or severe near-accident.

2.8.2 Assessment of health and safety, professional relations and quality of employment in the Nuclear Power Plants

Certain occupational risk situations, such as the risks linked to working equipment and more particularly to lifting gear, explosion and fire risks and electrical risks, are still subjects of concern and must be further improved.

This year, particular focus was placed on checks on the electrical installations that EDF is required to carry out in accordance with the Labour Code, with the performance of inspections on this topic in all the NPPs. The various inspections carried out by the labour inspectors brought to light weaknesses in the organisation on the sites for the correct performance of electrical checks or for coordination of these checks between the various EDF entities.

The labour inspectorate also still occasionally observes situations in which the risk linked to accidental exposure to any asbestos present is not considered prior to the work.

In 2022, progress is still required in the management of joint contractor working (quality of prevention plans, in particular), the use of subcontracting and foreign staff secondment situations.

In the second half of 2021, ASN observed a deterioration in the occupational health and safety situation, against the backdrop of a considerable industrial workload. This deterioration led to a rising number of accidents, including numerous “high safety potential” or “near accident” events, the consequences of which could have been significant. The main causes identified were problems with the assessment of risks related to the activities, inappropriate individual behaviours with respect to the basic safety rules and a lack of proficiency in the lock-out of electrical equipment.

The labour inspectors issued reminders on compliance with the maximum working hours and the fact that waivers could only be granted for good reason and then only relatively exceptionally.

Steps were taken in 2021 regarding the monitoring of notifications and the conditions for the secondment of staff from foreign companies. Several inquiries into the transfer of labour contracts were also carried out when the contractors on the sites were changed.

In 2021, three administrative enforcement sanctions were initiated by the labour inspectors and sent to the Regional Directorates for the Economy, Employment, Labour and Solidarity, who have the power to pronounce sanctions in this area:
- two enforcement procedures for non-compliance with the maximum working hours and the absence of a reliable system for counting working hours;
- one enforcement procedure for foreign worker secondment violations.

2.9 Continued operation of the Nuclear Power Plants

2.9.1 The age of the Nuclear Power Plants

The NPPs currently in service in France were built over a relatively short period of time: 45 nuclear power reactors representing nearly 50,000 MWe, or three-quarters of the power output by all the French nuclear power reactors, were commissioned between 1980 and 1990, and seven reactors, representing 10,000 MWe, between 1991 and 2000. In December 2021, the average age of the 56 reactors in operation, calculated from the dates of first divergence, can be broken down as follows:
- 39 years for the 32 nuclear power reactors of 900 MWe;
- 34 years for the 20 nuclear power reactors of 1,300 MWe;
- 24 years for the 4 nuclear power reactors of 1,450 MWe.

2.9.2 The periodic safety review

The principle of the periodic safety review

Every 10 years, EDF must carry out a periodic safety review of its installations. The periodic safety reviews of nuclear power reactors comprise the following two parts:
- A check on the condition and conformity of the facility: this step aims to assess the situation of the facility 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 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 facilities 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

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 AGEING OF NUCLEAR POWER PLANTS EQUIPMENT

As in any industrial installation, the equipment in NPPs experiences ageing. This ageing is the result of physical phenomena (corrosion of metals, hardening of polymers, hardening of certain steels under the effect of irradiation or temperature, swelling of certain concretes, etc.) which can degrade their characteristics according to their age or their operating conditions. This degradation obliges the licensee to repair or replace the equipment or to limit the lifetime of non-replaceable equipment, such as the reactor pressure vessel (see point 2.2.3).

The ageing management process implemented by EDF is based on three main points: anticipating the effects of ageing as of the design stage, monitoring the actual condition of the facility and repairing or replacing equipment degraded by the effects of ageing. Before being installed, equipment important for safety more particularly undergoes a qualification processes to ensure its ability to perform its functions in conditions corresponding to the situations in which it will be needed, accident situations in particular.

The management of equipment ageing, and of the risk of obsolescence –which refers to difficulties linked to guaranteeing the procurement of spares over time– are essential to maintaining a satisfactory level of safety. They also contribute to reactor conformity being maintained over time.

For the continued operation of the 900 MWe reactors beyond their fourth periodic safety review, management of ageing was given particularly close attention by ASN. The provisions implemented or planned by EDF to ensure the management of ageing and obsolescence are satisfactory. However, ASN asked that, without delaying their decommissioning, the final shutdown of the Fessenheim NPP reactors should be used as an opportunity to check the absence of any unexpected degradation or ageing phenomena, in particular on those parts of the installation that are hard to access.

review. EDF more particularly carries out a large part of the checks and modifications related to the periodic safety reviews during the ten-yearly inspections of its reactors. In accordance with the provisions of Article L. 593-19 of the Environment Code, following this periodic safety review, the licensee sends ASN a periodic safety review concluding report. In this report, the licensee states its position on the conformity of its facility and details the modifications made to remedy deviations observed or to improve the safety of the facility and, as necessary, specifies the additional improvements that it will be making.

ASN analysis

ASN examines the periodic safety reviews in several stages. It first of all issues a position statement on the objectives of the review and the guidelines of the generic verification programmes on the state of the facility and the safety reassessment proposed by EDF, after obtaining the opinion of the Advisory Committees of Experts (GPE).

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 GPE. This position statement closes the generic phase of the periodic safety review, common to all the reactors.

This generic assessment does not take account of any specific individual aspects and ASN gives a ruling on the suitability for continued operation of each nuclear power reactor, notably on the basis of the results of the conformity checks and the assessment made in the periodic safety review concluding report for the reactor submitted by EDF. Following examination of the periodic safety review concluding report for each reactor, ASN communicates its analysis to the Ministry responsible for nuclear safety. It can issue new requirements governing its continued operation.

The Energy Transition for Green Growth Act 2015-992 of 17 August 2015 supplemented the framework applicable to the periodic safety reviews on nuclear power reactors. It more specifically requires ASN authorisation, following a public inquiry, of the provisions proposed by the licensee during the periodic safety reviews beyond the 35th year of operation of a nuclear power reactor. Five years after submitting the periodic safety review report, the licensee also submits an interim report on the condition of these equipment items, in the light of which ASN may supplement its prescriptions.

2.9.3 Ongoing periodic safety reviews in the Nuclear Power Plants

The 900 MWe reactors

The third periodic safety review

In July 2009, ASN issued a position statement on the generic aspects of continued operation of the 900 MWe reactors beyond their third periodic safety review. ASN did not identify any generic elements compromising EDF's ability to ensure the safety of the 900 MWe reactors up until the next periodic safety review. It considers that the new baseline safety requirements presented in the generic safety report for the 900 MWe reactors and the modifications to the installation envisaged by EDF are such as to maintain and improve the overall level of safety of its nuclear power reactors.

In 2021, EDF completed the third ten-yearly outages and submitted the periodic safety review concluding reports for all its 900 MWe reactors.

The fourth periodic safety review (**see "Notable events" in the introduction to this report**)

A high-stakes review

EDF's 32 reactors of 900 MWe in operation were commissioned between 1978 and 1987. The first ones have reached the milestone of their fourth periodic safety review.

This fourth periodic safety review comprises particular challenges:

- Some items of equipment are reaching their design-basis lifetime. The studies concerning the conformity of the installations and the management of equipment ageing therefore need to be reviewed to take account of the degradation mechanisms actually observed and the maintenance and replacement strategies implemented by EDF.
- The safety reassessment of these reactors and the resulting improvements must be carried out in the light of the safety objectives of the new-generation reactors, such as the EPR, the design of which meets significantly reinforced safety requirements.

The modifications associated with this periodic safety review will incorporate those linked to deployment of the "hardened safety core" (see box next page).

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.

IMPLEMENTATION OF A "HARDENED SAFETY CORE" OF MATERIAL AND ORGANISATIONAL MEASURES FOR THE MANAGEMENT OF EXTREME SITUATIONS

The steps taken further to the lessons learned from the Fukushima Daiichi NPP accident, in particular the DUS and ultimate water sources, are supplemented during the periodic safety reviews by implementation of a "hardened safety core" of material and organisational provisions. In the event of an extreme situation, the purpose of this "hardened safety core" is:

- to prevent an accident with fuel melt, or limit its progression;
- to limit large-scale radioactive releases;
- to enable the licensee to carry out its emergency management duties.

The most important measures are:

- the addition of a new makeup pump to the primary system;
- the addition of a new means of injecting borated water into the primary system when it is at high pressure;
- the completion of connection by fixed backup water supply systems for the SGs and ultimate water make-up for the fuel storage pool;
- the addition of an extra fuel pool cooling system, partly reliant on mobile means;
- the installation of an ultimate containment cooling system, partly reliant on mobile means, to prevent opening of the filtered vent on this containment in the event of a severe accident;
- the adoption of measures to stabilise the corium on the basemat, in the event of an accident with core melt and reactor vessel melt-through;
- the installation of an ultimate instrumentation and control system and the necessary instrumentation.

Since 2019, these provisions have been deployed during the fourth periodic safety reviews of the 900 MWe reactors. More particularly, the containment ultimate cooling system, the system designed to stabilise the corium on the basemat, in the event of an accident with core melt, and the additional fuel pool cooling system, are installed as of the fourth ten-yearly outages.

After examining the objectives proposed by EDF, with the support of IRSN, and following consultation of its Advisory Committees, ASN released a position statement on these objectives and issued additional requests in April 2016. EDF supplemented its programme of work and in 2018 presented ASN with the measures it envisages taking in response to these requests.

In 2020, with the support of IRSN, ASN finalised its examination of the generic studies linked to this review. At the beginning of 2021, ASN issued a position statement on the conditions for continued operation of the reactors.

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 2021, EDF had carried out or initiated seven of these ten-yearly outages. These outages are a major step in the fourth periodic safety reviews. During these outages, EDF carries out the required inspections and deploys most of the safety improvements associated with the review.

Involving the public at each step

For the purposes of this periodic safety review, ASN has been involving the public since 2016 in the drafting of its position statement regarding the objectives proposed by EDF. This approach continued in 2018, under the aegis of the High Committee for Transparency and Information on Nuclear Safety (HCTISN), in the form of a consultation on the measures planned by EDF to meet these objectives. At the end of 2020, ASN also consulted the public on its draft resolution specifying the conditions for continued operation of these reactors. Pursuant to the law, a public inquiry will then be held, reactor by reactor, after submission of the periodic safety review concluding report for each reactor.

ASN will thus issue a position statement on the continued operation of Tricastin NPP reactor 1 after this public inquiry is held in 2022.

The 1,300 MWe reactors

The third periodic safety review

At the beginning of 2015, ASN issued a position statement on the generic aspects of the continued operation of the 1,300 MWe reactors beyond 30 years of operation. On this occasion, ASN underlined the importance of the modifications made by EDF following their third periodic safety review. Within the framework of this review, EDF is notably deploying material and operational modifications in order to mitigate the consequences of an SG tube break accident, to prevent the occurrence of severe accidents with early loss of containment, and to reduce the risk of uncovering the fuel assemblies present in the spent fuel pool. With regard to hazards, EDF is modifying its installations in order to guarantee operation of the equipment needed for the safety of these reactors in the event of a heatwave, to protect the equipment important for safety against projectiles created by strong winds and to prevent the risks of explosion further to an earthquake.

To help conclude the generic phase of this review, ASN issued additional requests in 2021 applicable to all the 1,300 MWe reactors, with the aim of reinforcing their safety.

In 2021, Belleville-sur-Loire NPP reactor 1 and Cattenom NPP reactor 3 underwent their third ten-yearly outage. The third ten-yearly outages for the other 1,300 MWe reactors will run until 2024.

The fourth periodic safety review

In July 2017, EDF presented a file giving the orientations envisaged for the generic phase of the fourth periodic safety review of the 1,300 MWe reactors. In 2019, ASN issued a position statement on these orientations, after involvement of the public and consultation of the GPR on 22 May 2019. ASN considers that the general objectives set by EDF for this review are acceptable in principle. They notably aim to do away with population protection measures for design-basis accidents, and –for severe accidents– to tend more towards population protection measures that are limited in both scope and duration. With regard to the safety of the spent fuel pool, ASN asked EDF to set an objective of no uncovering of the assemblies and to eventually return the installation to and permanently maintain it in a state without pool water boiling.

In 2021, ASN continued with the expert assessments for the generic phase of this periodic safety review. They more specifically concerned the methods to be used during this review for the study of certain accidents and the assessment of the robustness of the installations to hazards. EDF has also started the studies needed to update the regulation reference files for the main primary and secondary systems; this update is particular in that the design hypotheses were initially produced for 40 years of operation.

EDF will begin the first ten-yearly outage associated with this periodic safety review at the end of 2025.

The 1,450 MWe reactors

The second periodic safety review

In 2011, EDF transmitted the envisaged guidelines for the generic study programme for the second periodic safety review of the 1,450 MWe reactors, notably concerning the prevention of core melt and mitigation of the consequences of severe accidents.

ASN issued a position statement in February 2015 regarding the orientations of this second periodic safety review. It in particular asked EDF to look for measures to mitigate the radiological consequences of design-basis accidents and measures with a strong impact in terms of preventing and mitigating the consequences of severe accidents.

The examination of the generic phase of this periodic safety review was completed in 2021 and ASN aims to issue a position statement on this generic phase in 2022.

Chooz NPP reactors B1 and B2 carried out their second ten-yearly outages in 2019 and 2020. The ten-yearly outage for Civaux NPP reactor 1 was started in 2021. That for reactor 2 is scheduled for 2022.

3 // Oversight of the safety of the Flamanville EPR reactor

The EPR is a PWR using a design that has evolved from that of the reactors currently in operation in France. It meets reinforced safety objectives: reduction in the number of significant events, limitation of discharges, reduced volume and activity of waste, reduced individual and collective doses received by the workers (in normal operation and incident situations), reduced overall frequency of core melt, taking account of all types of failures and hazards and reduced radiological consequences of any accidents.

In May 2006, EDF submitted a creation authorisation application to the Ministers responsible for nuclear safety and for radiation protection, for an EPR type reactor with a power of 1,650 MWe on the Flamanville site, which was already home to two 1,300 MWe reactors.

The Government authorised its creation through Decree 2007-534 of 10 April 2007, after a favourable opinion issued by ASN following the examination process. This Decree was modified in 2017 and in 2020, to extend the time allowed for commissioning of the reactor.

After the issue of this Creation Authorisation Decree and the building permit, construction of the Flamanville EPR reactor began in September 2007. The first concrete was poured for the nuclear island buildings in December 2007.

EDF plans to load fuel and start up the reactor by mid-2023. This schedule takes account of the time needed on the one hand to repair certain MPS welds and, on the other, for the end of the assembly and testing operations.

3.1 Examination of the authorisation applications

Examination of the commissioning authorisation application

In March 2015, EDF sent ASN its commissioning authorisation application for the installation, including the safety analysis report, the RGEs, a study of the facility's waste management, the PUI, the decommissioning plan and an update of the facility's impact assessment. Following a preliminary examination, ASN considered that all the documents required by the regulations were officially present, but it decided that additional justifications were needed if ASN was to be able to reach a final decision on the commissioning authorisation application. ASN began the technical examination of the subjects for which most of the information was available, although it did submit some requests on certain points.

In June 2017, ASN received updated versions of the commissioning authorisation files and in 2018 made requests for additional information, notably concerning the RGEs.

ASN obtained the opinion of the GPR on 4 and 5 July 2018 concerning the safety analysis report for the Flamanville EPR reactor. This meeting was devoted in particular to the action taken following the previous GPR sessions devoted to this reactor since 2015. The Advisory Committee considered that the reactor's safety case is on the whole satisfactory and points out that some additional information is still required concerning how the fire risk is addressed and the behaviour of the fuel rods which have experienced a boiling crisis. The GPR also considered that the design and dimensioning of the back-up systems and auxiliary safety systems are on the whole satisfactory and observed that additional information was still required concerning the breaks liable to affect the fuel storage pool cooling system. In 2019 and 2020, in the light of this opinion and the conclusions of its technical examinations, ASN submitted requests for supplements to the safety case that are needed for it to make a final decision on the commissioning authorisation application.

In June 2021, EDF sent ASN a new commissioning authorisation application. This application replaces the initial application of March 2015 and contains a complete update of the file appended to the initial application, incorporating certain additions requested and the conclusions of the examinations conducted since 2015.

Partial commissioning authorisation for arrival of the fuel

On 8 October 2020, ASN authorised partial commissioning of the installation for arrival of the fuel on the site. This authorisation enabled EDF to receive fuel assemblies and store them in the fuel storage pool, for use in the first fuelling of the reactor. This partial commissioning is one of the steps prior to commissioning of the Flamanville EPR reactor, but in no way prejudges this commissioning, which is the subject of a separate examination.

3.2 Construction, start-up tests and preparation for operation

ASN is faced with numerous challenges concerning oversight of the construction, start-up tests and preparation for operation of the Flamanville EPR reactor. These are:

- checking the quality of equipment manufacturing and installation construction, in order to be able to issue a position statement on the ability of the installation to meet the defined requirements;
- ensuring that the start-up tests programme is satisfactory, that the tests are correctly performed and that the required results are obtained;
- ensuring that the various stakeholders learn the lessons from the construction phase and the performance of the start-up tests, including the upstream phases (selection and monitoring of contractors, construction, procurement, etc.) which will

enable the as-built installation to comply with the safety case for the duration of the project;
- ensuring that the licensee takes the necessary steps so that the teams in charge of operating the installation after commissioning are well-prepared.

To do this, ASN has set binding requirements regarding the design, construction and start-up tests for the Flamanville EPR reactor and for operation of the two Flamanville 1 and 2 reactors close to the construction site.

As this is a nuclear power reactor, ASN is also responsible for labour inspection on the construction site. Lastly, ASN ensures oversight of the manufacture of the NPE that will be part of the primary and secondary systems of the nuclear steam supply system.

In 2021, EDF continued with work to complete the installation, to make modifications to certain equipment and to draw up the various documents needed for operation. EDF also continued to analyse and remedy deviations, notably those affecting the MSS welds (see box below) as well as three MPS nozzles. EDF implemented a programme of additional inspections as part of the quality review requested by ASN owing to significant shortcomings in the monitoring of its contractors. EDF also deployed its equipment conservation and maintenance strategy and drew up the equipment requalification test programme in preparation for commissioning of the reactor.

3.3 Assessment of design, construction, start-up tests and preparation for operation of the Flamanville EPR reactor

The examinations in progress

ASN considers that the design of the Flamanville EPR reactor should be able to achieve the ambitious safety objectives set for the third generation reactors. It should also lead to a significant reduction in the probability of core melt and radioactive releases in the event of an accident, by comparison with the second generation reactors. The EPR reactor design in particular includes systems for managing severe accidents and is able to withstand extreme external hazards. This design only required very minor changes to take account of the lessons learned from the accident at the Fukushima Daiichi NPP.

In 2021, EDF continued with the examinations linked to the commissioning authorisation application. ASN notably obtained the opinion of the Environmental Authority. A number of important technical subjects are still being examined. This is in particular the case with the design of the primary system safety valves, I&C upgrades, the performance of the containment internal water tank filtration system, the RGEs that will be applicable as of commissioning and incorporation of the lessons learned from the commissioning of the first EPR reactors abroad, in particular the various anomalies found on the cores of the EPR reactors in Taishan (China), including the fuel clad perforations observed in 2021.

NPE conformity assessment

The NPE of the Flamanville reactor includes that making up the main primary and secondary systems presented in point 2.2 (reactor pressure vessel, SG, pressuriser, reactor coolant pumps, piping, safety valves) but also that constituting other parts of the NSSS.

During the course of 2021, ASN continued to assess the conformity of the NPE design of the main primary and secondary systems and, as in 2020, in particular checked the preparation for and performance of the repairs to the main steam lines subject to the break preclusion requirements.

ASN also continued the analysis of the deviations which affected the post-weld heat treatment of the connection welds on the SGs and pressuriser components carried out in Framatome's Saint-Marcel plant, as well as on the MSS lines carried out on the Flamanville site. EDF and Framatome plan repair operations whenever possible or, failing which, justification that the conformity of the equipment is not compromised.

In 2021, ASN also continued to assess the conformity of the main primary lines with the break preclusion requirements.

WELDS ON LINES OF THE MAIN SECONDARY SYSTEMS OF THE FLAMANVILLE EPR REACTOR

Implementation of the orbital TIG process –weld on the main secondary system

Major repairs are required on the welds on the lines of the MSS of the Flamanville EPR reactor. The majority of these welds are located on the main steam lines, and are subject to a "break preclusion" approach: they thus require mechanical properties and a level of manufacturing quality that are particularly high.

Eight of these welds are located in the annulus between the two containment walls of the reactor building. The difficult access conditions required the development of special intervention means and the qualification of specific welding, inspection and heat treatment processes. After examining these intervention means and the qualification of the processes in 2020, ASN inspected the production of these eight welds in 2021.

Most of the other welds on the main steam lines which are to be repaired, of which there are about 50, are located in an environment with no access difficulties. In 2021, ASN continued to assess the conditions for their repair and to monitor the weld repair operations. EDF was attentive to ensuring that the number of repairs made at the same time is compatible with the organisation of worksite surveillance. This work should continue until the summer of 2022.

At the same time, EDF analysed the quality of other welds, in particular those on the SG feedwater lines. This work led EDF to decide to repair ten or so additional welds. ASN will issue a position statement on the scope of the welds to be repaired once it has received all the justifications from EDF.

With regard to the deviation affecting three primary system nozzles, EDF proposed installing a retaining collar around each nozzle concerned. In the event of rupture of the nozzle set-in weld, this collar would limit the size of the resulting break. The consequences of this break would then be covered by the reactor's existing safety studies. ASN considers that the solution proposed by EDF is in principle acceptable. ASN will issue a final ruling on this modification once EDF has provided the required data concerning the demonstration of the effectiveness of the arrangement, the design, manufacturing and operating requirements applicable to the collars and the quality of the set-in welds around which these collars would be installed.

Oversight of construction, start-up tests and preparation for operation

Oversight of construction also regularly brought to light construction quality flaws, which required corrective action and led EDF to conduct additional checks, which are the subject of discussions with ASN within the context of the quality review. In 2021, ASN checked the production of the additional inspections programme and its implementation, through periodic meetings and two on-site inspections. In 2022, EDF should be issuing the results of these actions and draw up the corresponding conclusions.

ASN considers that EDF's equipment conservation strategy is satisfactory, provided that EDF carries out additional maintenance to prevent ageing of the equipment and sets up an equipment inspection programme at the end of the conservation phase, to check the effectiveness of the steps taken and detect any latent defects.

In 2019, EDF had carried out most of the installation start-up tests. In June 2020, EDF sent ASN a first version of the results of these tests. These results are updated as and when the remaining tests are performed. ASN has begun examination of this document, in order to verify that the as-built installation complies with the hypotheses contained in the safety case. This examination will continue in 2022. In addition, during its inspections, ASN ensures that EDF has taken sufficient measures to guarantee that the work carried out after the start-up tests does not compromise the results obtained during these tests.

In 2021, ASN carried out 14 inspections on the Flamanville site and two inspections in the engineering departments. ASN also carried out labour inspections. The conclusions of these inspections are presented in the Regional Overview in the introduction to this report.

4 // Oversight of the reactor projects

The EPR 2 reactor

EDF is developing a new reactor, called "EPR 2". It aims to incorporate the lessons learned from the design, construction and commissioning of the EPR reactors and from operation of existing reactors. As with the EPR reactors, this project aims to meet the general safety objectives for third-generation reactors. In addition, the design of this reactor aims to incorporate all the lessons learned from the Fukushima Daiichi NPP accident. 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, then called "EPR NM", with the support of IRSN, taking account of the recommendations of Guide No. 22 on PWR design. On 16 July 2019, ASN then published its opinion on the proposed safety options. ASN considers that the general safety objectives, the safety baseline requirements and the main design options are on the whole satisfactory. ASN's opinion identifies the subjects to be considered in greater depth prior to submitting a reactor creation authorisation application. Additional justifications were in particular needed on the break preclusion approach for the main primary and secondary piping, the approach for dealing with hazards, fire and explosion in particular, and the design choices for certain safety systems. The justifications required were specified by ASN in a letter sent to EDF in July 2021.

Further to ASN's opinion, EDF changed its break preclusion approach for the main primary and secondary systems piping. EDF intends to make a number of design, manufacturing and organisational changes to enhance safety. These changes will more particularly concern the choice of materials and manufacturing and inspection techniques. Furthermore, even though EDF applies a break preclusion approach, it also intends to add certain devices to mitigate the consequences of any break, such as separating walls, whip-restraint devices and steam evacuation vents.

ASN considers that, given the additional measures, using a break preclusion approach for the main lines of the primary and secondary systems of the EPR 2 reactor project is acceptable. This position statement, issued in September 2021, supplements ASN's 2019 opinion on the safety options for this reactor project. Examination of the break preclusion baseline requirements will continue in 2022.

In April 2021, ASN also issued a position statement on the additional information provided by EDF regarding a military aircraft crash. ASN considers that the EDF approach would be able to achieve sufficient safety objectives for the EPR 2 reactor, identical to those of the Flamanville EPR reactor.

In February 2021, EDF sent ASN a preliminary version of the safety analysis report for advance examination, were a construction programme for new reactors actually to be launched. A file examination programme was drawn up jointly with IRSN.

Finally, Framatome submitted reactor vessel and SG conformity assessment requests to ASN for these two reactors. Procurement of the first components is scheduled for 2022 on the Le Creusot site.

Small Modular Reactors

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

The characteristics of the SMRs, in particular their low power and compactness, contribute to their safety. ASN considers that the designers should take advantage of these characteristics to propose reactors aiming for more ambitious safety objectives than the existing high-power reactors.

A French SMR project, called "Nuward", sponsored by a consortium involving EDF, Technicatome, the Alternative Energies and Atomic Energy Commission (CEA) and Naval Group is currently at the preliminary design stage. ASN has initiated technical discussions with the Nuward project, which intends to submit a DOS at the end of 2022.

ASN is also participating in international SMR working groups. Within this framework, it is holding discussions with its foreign counterparts in order to promote the definition of ambitious international baseline requirements, share its practices and benefit from OEF from its counterparts.

11

“Nuclear fuel cycle” installations

11

"NUCLEAR FUEL CYCLE" INSTALLATIONS

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 were closed in 2000, so the "fuel cycle" concerns the fabrication of the fuel and then its reprocessing once it has been used in the nuclear reactors.

The licensees of the fuel cycle plants are part of the Orano or EDF (Framatome) groups: Orano operates Melox 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 this context, ASN periodically asks EDF to submit a "Cycle Impact" file prepared jointly with the "fuel cycle" stakeholders and presenting the consequences –for each step of the "fuel cycle"– of EDF's strategy for using the different types of fuel in its reactors, various energy mix scenarios envisaged by the multi-year energy plan, as well as operating contingencies in the plants contributing to the "fuel cycle".

In 2021, malfunctions at certain steps of the "fuel cycle" worsened. It is important for the licensees to significantly reinforce their forward planning and take the steps necessary to deal with the risk of situations that could block the "cycle" and thus the production of nuclear electricity.

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 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.

After a period of use of about three to four years, the spent fuel assemblies are removed from the reactor and cooled in a pool, firstly on the site of the plant in which they were used, and then in the Orano recycling plant at La Hague.

In this plant, the uranium and plutonium from the spent fuels are separated from the fission products and other transuranic elements[1]. The uranium and plutonium are conditioned and then stored for subsequent re-use. However, at present, the uranium obtained from this reprocessing is no longer used to produce fresh fuels. EDF announced its intention to resume its use in 2023, after re-enrichment of the reprocessed uranium in Russia.

The plutonium resulting from the reprocessing of uranium oxide fuels is used in the Orano plant in Marcoule, called "Melox", to fabricate MOX fuel (mixture of uranium and plutonium oxides), which is used in certain 900 Megawatts electric (MWe) nuclear power reactors in France. The MOX nuclear fuels are not currently reprocessed after being used in the reactors. Pending reprocessing or disposal, the spent MOX fuels are stored at the La Hague plant.

The main material flows for the fuel cycle are presented in Table 1.

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.

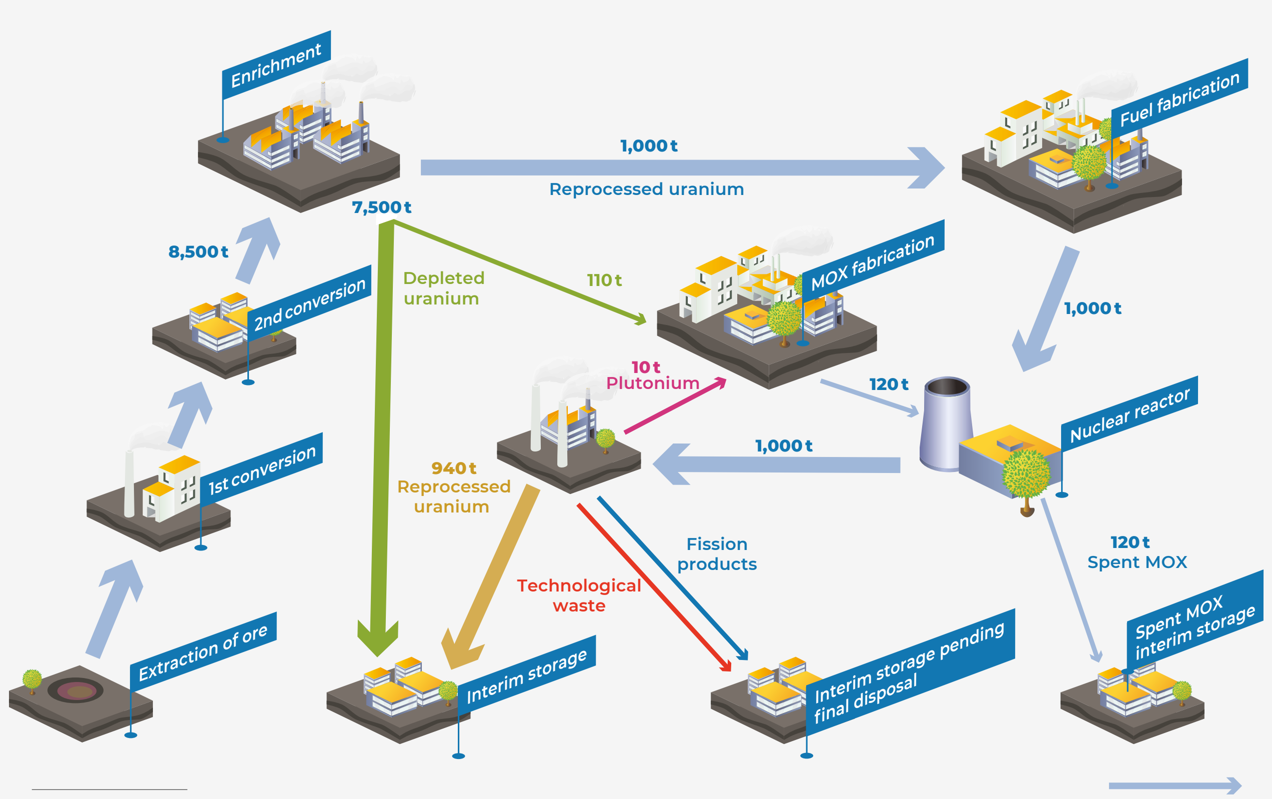
1. *Transuranic elements are chemical elements heavier than uranium (atomic number 92). The main ones are neptunium (93), plutonium (94), americium (95), curium (96). In a reactor, they are derived from uranium during secondary reactions other than fission.*

TABLE 1 **"Fuel cycle" industry movements in 2021**

	PRODUCT PROCESSED			PRODUCT OBTAINED		PRODUCT SHIPPED	
INSTALLATION	ORIGIN	PRODUCT PROCESSED	TONNAGE	PRODUCT OBTAINED	TONNAGE	DESTINATION	TONNAGE
Orano Tricastin Conversion	ICPE (*) Malvési	UF_4	11,259	UF_6	12,758	Orano storage areas Tricastin	12,758
Orano Tricastin TU5 Unit	Orano La Hague	Uranyl nitrate	3,660	U_3O_8	1,089	Orano storage areas Tricastin	1,089
Orano Tricastin W plant	Orano Tricastin GB II	UF_6 depleted	8,167	U_3O_8	6,506	Orano storage areas Tricastin	6,506
Orano Tricastin GB II	Orano Tricastin Conversion	UF_6	10,208	UF_6 depleted	8,644	Orano Tricastin Plant W	8,644
				UF_6 enriched	1,393	Fuel fabrication plants	1,393
Framatome Romans	Orano Tricastin GB II	UF_6 enriched	564	Fuel assemblies	750	EDF	710
	Urenco (Netherlands, Germany and United Kingdom)		142			Taishan (China)	42
	Tenex (Russia)		21			Göesgen (Switzerland)	2
	ANF Lingen (Germany)	Uranium based UO_2 rods	13	UO_2 and U_3O_8 powder	3	Framatome Richland (United States)	5
						CEA	4
Orano Melox Marcoule	Framatome Lingen (Germany)	UO_2 depleted	54	MOX fuel elements	51	EDF	38
	WSE Vasteras (Sweden)		6				
	Orano La Hague	PuO_2	5			Kansai (Japon)	7
Orano La Hague	Fuels reprocessed in the La Hague plant						
	EDF and other licensees	UOX and MOX	1,021	Uranyl nitrate	997	Orano Tricastin	865
	Reactor BR2 Mol (Belgium)	RTR	0.01	PuO_2	12	Melox Marcoule	6
	Fuels stored in the La Hague plant pools						
	EDF and other licensees	Irradiated fuel elements	10,088	–	–	–	–

(*) Installation Classified for Protection of the Environment.

"FUEL CYCLE" DIAGRAM



The tonnages shown in the diagram correspond to rated operation which has not been observed in recent years.

Flows expressed in tonnes/year

1.1 The "fuel cycle" front-end

Before fuels are fabricated for use in the reactors, the uranium ore must undergo a number of chemical transformations, from the preparation of the "yellow cake" through to conversion into UF_6, the form in which it is enriched. These operations take place primarily on the Orano sites of Malvési, in the Aude *département*, and Tricastin in the Drôme and Vaucluse *départements* (also known as the Pierrelatte site).

On the Tricastin site, Orano operates:

- the TU5 facility (BNI 155) for conversion of uranyl nitrate $UO_2(NO_3)_2$ produced by reprocessing spent fuel at La Hague into uranium sesquioxide (U_3O_8);
- the W plant (ICPE within the perimeter of BNI 155) for converting depleted UF_6 into U_3O_8;
- the former Comurhex facility (BNI 105) for converting uranium tetrafluoride (UF_4) into UF_6, which contains the Philippe Coste plant;
- the Georges Besse II UF_6 ultra-centrifuge enrichment plant (BNI 168);
- the Atlas analysis laboratory (BNI 176);
- areas for the storage of uranium and thorium in various forms (BNIs 93, 178 and 179);
- the IARU facility (BNI 138 –formerly Socatri) which manages waste from the Tricastin site and carries out nuclear equipment maintenance and decommissioning;
- a Defence Basic Nuclear Installation (DBNI) which more particularly operates the radioactive substances storage areas, virtually all of which are for civil uses.

The TU5 facility and the Orano W plant –BNI 155

BNI 155, called "TU5", can handle up to 2,000 tonnes of uranium per year, enabling it to reprocess all the 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 able to guarantee safer uranium storage conditions than in liquid or gaseous form). Once converted, the reprocessed uranium is placed in storage on the Tricastin site.

The Orano uranium conversion plants –BNI 105

BNI 105, which notably transformed reprocessed uranyl nitrate into UF_4 or U_3O_8, is being decommissioned (see chapter 13).

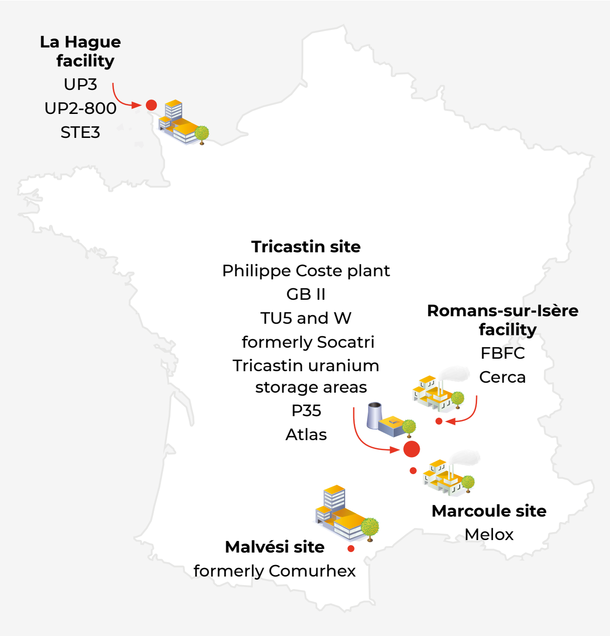
The Philippe Coste plant is located inside its perimeter and is devoted to the fluorination of UF_4 into UF_6, to allow its subsequent enrichment in the Georges Besse II plant (GB II). It has a production capacity of about 14,000 tonnes of UF_6 from the UF_4 coming from the Orano facility in Malvési. It has ICPE status subject to authorisation with institutional controls ("Seveso" class installation) and is monitored by ASN accordingly.

The Georges Besse II ultra-centrifuge enrichment plant –BNI 168

BNI 168, called Georges Besse II (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 U-235 isotope and a depleted stream. GB II comprises two enrichment units (South and North units) and a support unit, the REC II.

Enrichment of the uranium resulting from reprocessing, which would require prior authorisation from ASN, is not currently implemented in this plant.

THE "FUEL CYCLE" FACILITIES IN SERVICE



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 meets the most recent safety requirements and was commissioned in 2017.

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 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 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.

1.3 The "fuel cycle" back-end –reprocessing

The Orano reprocessing plants in operation at La Hague

The La Hague plants, intended for reprocessing of spent fuel assemblies from nuclear reactors, are operated by Orano.

The various facilities of the UP3-A (BNI 116) and UP2-800 (BNI 117) plants and of the STE3 (BNI 118) Effluent Treatment Station were commissioned from 1986 (reception and storage of spent fuel assemblies) to 2002 (R4 plutonium reprocessing facility), with most of the process facilities entering service in 1989-1990.

The Decrees of 10 January 2003 set the individual reprocessing capacity of each of the two plants at 1,000 tonnes per year (t/year), in terms of the quantities of uranium and plutonium contained in the fuel assemblies before burn-up (in the reactor), and limit the total capacity of the two plants to 1,700 t/year. The limits and conditions for discharges and water intake by the site are defined by two ASN resolutions of 22 December 2015 (resolution 2015-DC-0535 and resolution 2015-DC-0536), currently undergoing revision.

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 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 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 removed from the dissolver, rinsed in acid and then water, and transferred to a compacting and packaging unit.

The nitric acid solution comprising the dissolved radioactive substances is then processed, in order to extract the uranium and plutonium and leave the fission products and other transuranic elements.

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

After purification and concentration, the plutonium is precipitated by oxalic acid, dried, calcined 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 assembly 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 generally recycled. After verification and, in accordance with the discharge limits, certain radionuclides, such as iodine and tritium, are sent to the marine outfall pipe. The other effluents are routed to on-site packaging units (solid glass or bitumen matrix).

The solid waste is packaged 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 14) or stored on the Orano site at La Hague, pending a final disposal solution (in particular the CSD-V and CSD-C). 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 System", was approved by the Order of the Minister responsible for energy of 2 October 2008.

1.4 "Fuel cycle" consistency in terms of nuclear safety and radiation protection

The "nuclear fuel cycle" comprises the fabrication of the nuclear fuel used in the nuclear power plant reactors, its storage and its reprocessing after irradiation. Several licensees are involved in the cycle: Orano, Framatome, EDF and the French National Agency for Radioactive Waste Management (Andra).

ASN monitors the overall consistency of the industrial choices made with regard to fuel management and which could have consequences for safety. In this context, ASN periodically asks EDF to submit a "Cycle Impact" file prepared jointly with the "cycle" stakeholders and presenting the consequences –for each step of the "fuel cycle"– of EDF's strategy for use of the different types of fuel in its reactors.

ASN delivered its opinion of the "2016 Cycle Impact" file on 18 October 2018, the main conclusions of which are as follows.

ASN 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. This for example entails ensuring that –given the incompressible development times for industrial projects– the need for the creation of new spent fuel storage facilities or for new transport packaging designs are addressed sufficiently early.

ASN also asked the industrial players to study the consequences, in terms of safety and radiation protection, of the implementation of the Multi-year Energy Plan (MEP) on the "nuclear fuel cycle" and its coherence, at each of its revisions. Following the MEP update published in April 2020, new energy mix scenarios were defined in July 2020 and, together with Framatome, Orano and Andra, EDF updated its management prospects for the "fuel cycle" in December 2020, in accordance with these energy mix scenarios. Saturation of spent fuel storage capacity could occur in 2030, or even 2029. In 2020, EDF also announced the postponement of the commissioning of its centralised storage pool project, now scheduled for 2034, which means that countermeasures are needed, in order to deal with the delay in this project: densification of the storage pools at La Hague, dry storage of spent fuels and greater use of MOX fuel in the reactors.

1.5 Outlook: planned facilities

New uranium storage facility project on the Tricastin site
In November 2017, Orano submitted a creation authorisation application for new buildings to store uranium-bearing materials resulting from fuel reprocessing. In 2018, ASN informed the Minister responsible for nuclear safety that the content of the creation authorisation application was sufficient for its examination

DURING THE COURSE OF 2021, WORSENING OF THE PROBLEMS CONCERNING CERTAIN STEPS IN THE "FUEL CYCLE"

The year 2021 revealed a worsening of the problems concerning certain steps in the "fuel cycle":
- The Melox plant is still experiencing difficulties in producing MOX fuel of the required quality and quantity for the EDF fleet of reactors. These difficulties are leading to the production of a large quantity of radioactive materials containing plutonium qualified as "MOX scrap", which is then stored in the La Hague plant, either in powder form, or in the form of fuel assemblies.
- An action plan has been implemented by Orano since 2019 to overcome the production difficulties at Melox. However, Orano indicates that the prospects for improvement and its MOX production forecasts are primarily based on the use of a "wet process" uranium powder, which should be produced as of 2023 in the new unit called the "New Wet Process" (NVH) in Orano's Malvési plant, currently under construction.
- In the short term, problems at the Melox plant are also leading to faster than anticipated saturation of the storage capacity for plutonium-bearing materials, which requires the creation of new plutonium-bearing materials storage areas at La Hague. If storage capacity is not increased, reprocessing would have to be scaled down, which would then speed up congestion in the spent fuels storage pools. The authorisation application submitted by Orano for the creation of new plutonium-bearing materials storage areas at La Hague is currently being examined.
- A fission products evaporator-concentrator at La Hague was preventively shut down in September 2021 as it had reached a level of corrosion that precluded its continued operation. The shutdown of this evaporator, combined with an unscheduled maintenance shutdown of another evaporator in the same plant, led to a UP3-A plant outage of almost three months.

These disruptions of the cycle back-end plants confirm the need identified by ASN in its opinion of 18 October 2018 for countermeasures, assuming that commissioning of the EDF centralised storage pool would occur after saturation of French spent fuel storage capacity. In September 2021, ASN called Orano to a hearing on these subjects. On this occasion, ASN asked Orano to reinforce its forward planning approach, notably by taking account of pessimistic scenarios regarding the Melox plant's return to nominal operation, in order to define arrangements and storage solutions offering a high level of safety.

to take place. A public inquiry was held on this subject at the end of 2020. The project received an authorisation decree in 2022.

"New concentration of fission products" 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 2020, concerning the process of three of these evaporators (NCPF T2). The authorisations for connection of this new equipment to the existing units will be the subject of other resolutions and authorisations in the course of 2022.

Construction of new storage capacity for waste packages

To anticipate the saturation of storage capacity for CSD-V (units R7, T7 and E/EV/SE), construction work on new storage facilities, known as the "glass storage extension on the La Hague site" (E/EV/LH) began in 2007. These facilities are being built module by module, with the construction of identical units called "pits". Pits 50 and 60 are under construction to increase storage capacity.

An extension to the CSD-C storage facility was also authorised by the Decree of 27 November 2020; ASN had issued a favourable opinion regarding this draft text on 8 September 2020. Construction is under way and the introduction of radioactive substances into this extension for the first time will require authorisation from ASN.

The special fuels reprocessing unit project

In order to be able to receive and reprocess special fuels irradiated in the Phénix reactor or in other research reactors, Orano submitted the safety options file in 2016 for a new special fuels reprocessing unit. This unit would comprise new shearing and dissolving equipment. In March 2017, ASN informed the licensee that the safety options for this new unit were on the whole satisfactory. Orano however encountered technical difficulties in developing the process, which led to a significant change in the initial design options. In the light of this, ASN granted Orano more time to submit the authorisation application for this unit. The licensee transmitted new safety options for this project in January 2020. ASN released its observations on this file on 9 December 2020.

EDF centralised storage pool project

During the public debate held in 2019, prior to the fifth edition of the National Radioactive Materials and Waste Management Plan (PNGMDR), EDF reaffirmed that the strategy to increase the spent fuel storage capacity is based on the construction of a new centralised storage pool. This new facility should allow storage of spent fuels for which reprocessing or disposal can only be envisaged in the long-term future. The envisaged operating life for this storage facility is about a century. In 2017, EDF transmitted a safety options file for this project. In July 2019, ASN issued its opinion on the safety options presented by EDF for such a facility and considers that the general safety objectives and the design options adopted are satisfactory.

In 2020, EDF indicated a delay in this storage pool project, which would be located on the La Hague site, but would not be commissioned before 2034. In 2021, EDF referred this project to the National Commission for Public Debate (CNDP) and a prior public inquiry under the aegis of the CNDP was organised by EDF from 22 November 2021 to 15 February 2022.

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 and use dry storage of spent fuels.

With regard to the increased density in the La Hague pools, Orano submitted a safety options file in November 2020. In order to promote technical discussions around this subject, 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 in February 2022. In its letter of 14 February, ASN considers that the safety options presented by the licensee are on the whole satisfactory. Observations and additional information were requested and are to be transmitted as part of the noteworthy modification authorisation application the licensee intends to submit in mid-2022. ASN also recalls that the increased density in the La Hague pools cannot be a lasting solution for saturation of fuel storage capacity and that this countermeasure cannot take the place of a new storage facility compliant with the most recent safety standards. With regard to dry storage of spent fuels, Orano sent ASN a safety options file in November 2021 and it will be added to in the coming months.

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 (in the ceramic plants which use heating processes), as well as the dissemination of radioactive substances (in powder or crystallised form) and exposure to ionising radiation (when they use reprocessed substances).
- The spent fuel reprocessing facilities mainly entail risks of dissemination of radioactive substances (the substances used are mainly liquids and powders), of criticality (the fissile substances employed change geometrical shape) and exposure to ionising radiation (the fuels contain highly irradiating substances).

Their common point is that they never seek to create chain reactions (prevention of the criticality risk) and that they use dangerous substances in industrial quantities. Conventional industrial risks are therefore particularly present. Certain plants, Orano at Tricastin and La Hague or Framatome at Romans-sur-Isère, are in this respect subject to the Seveso Directive.

ASN endeavours to apply oversight that is proportionate to the potential risks of each facility, classified by ASN in one of three categories defined on the basis of the scale of the risks and detrimental effects it represents. 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 nature, the environment and public health and safety. ASN monitors the working of the organisations put into place by the licensees mainly through inspections, more specifically those devoted to safety management. In this respect, Orano submitted applications for a change of licensee concerning all its BNIs, in February 2020. The purpose of this project, called "PEARL" –authorised by Decrees of 15 December 2021– is to separate the group's activities into three separate subsidiaries dealing with the "cycle" front-end, the "cycle" back-end and decommissioning. ASN's examination of this application showed that it led to a change in organisation in the Orano group BNIs undergoing decommissioning, liable to compromise the principle set out in the Environment Code, whereby operational responsibility for a BNI lies with its nuclear licensee. Orano thus submitted a request for a waiver to this principle in December 2020. This request was examined by ASN, which will issue a position statement in 2022.

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. The first reviews concerned BNIs 151 (Melox) and 138 (IARU, formerly Socatri) and identified numerous points on which these facilities could be reinforced. Most of this work has today been completed.

The examination of these periodic safety reviews confirmed that the subjects to be examined by the licensee during the periodic safety reviews, along with the required methodologies, should be defined during what is referred to as the orientation phase. In addition, probabilistic analyses must be added to the safety cases for all the BNIs. The periodic safety review of the UP2-800 plant (BNI 117) is nearing completion, with finalisation of the examination of the improvement proposals concerning the NPH unit, scheduled for early 2022. For the UP3-A plant (BNI 116), Orano transmitted its review concluding report at the end of 2020 and it will be examined by the Advisory Committee for plants during the course of several meetings scheduled between 2023 and 2025. Finally, ASN will issue a position statement shortly on the continued operation of STE3 (BNI 118).

The periodic safety review of FBFC (BNI 98) comprises safety improvements to the facility, notably with regard to controlling fire risks, controlling criticality and reinforced civil engineering. However, it demonstrated the need for improved incorporation of the hazards linked to dangerous substances into the safety case of the "fuel cycle" facilities, while ensuring a level of stringency at least equivalent to that of Seveso classified upper-tier facilities. In 2020, ASN therefore issued a binding requirement in its resolution associated with this periodic safety review, for updating of the safety case with regard to the risks resulting from dangerous substances.

In October 2021, following the examination of the review concluding report for TU5 (BNI 155), ASN validated continued operation of BNI 155.

The periodic safety reviews show the importance of an *in situ* verification of the conformity of the Protection Important Component (PIC) that is as exhaustive as possible, or as representative as possible of the PIC that are not accessible. They also illustrate the need for a robust approach to the control of the ageing of "fuel cycle" facilities. It may be complex to develop these approaches because most of the fuel cycle facilities are unique.

In the context of the faster-than-anticipated corrosion of the fission products evaporators-concentrators and other equipment in the La Hague plant, the management of ageing is a priority issue for ASN with regard to the "cycle" back-end facilities, which are the subject of dedicated inspections and increased vigilance in the examination of the ongoing periodic safety reviews.

12

Nuclear research and miscellaneous industrial facilities

12 NUCLEAR RESEARCH AND MISCELLANEOUS INDUSTRIAL FACILITIES

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 International Thermonuclear Experimental Reactor (ITER) organisation and the National Large Heavy Ion Accelerator –Ganil) or by industrial firms (for instance CIS bio international, Steris and Ionisos, which operate facilities producing radiopharmaceuticals, or industrial irradiators).

1 // Research facilities, laboratories and other facilities in France

1.1 Research reactors

The purpose of research reactors is to contribute to scientific and technological research and to improve the operation of the Nuclear Power Plants (NPPs). Some of these facilities also produce radionuclides[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 neutron beam 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 Laue-Langevin Institute (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 Orphée reactor (BNI 101), operated by CEA in Saclay (rated power limited to 14 MWth), was finally shut down at the end of 2019.

"Test" reactors

"Test" reactors are pool type. They are designed to study accident situations. They are able to reproduce certain accidents postulated in the safety case of nuclear power reactors in a controlled manner and on a small scale, and gain a clearer understanding of the evolution of physical parameters during accidents.

In France, there is one "test" reactor in service: the Cabri reactor (BNI 24) operated by CEA in Cadarache. The reactor, whose power is limited to 25 MWth, can produce the neutron flux needed for the experiments. The safety issues are similar to those of the other reactors: controlling the reactivity of the driver core, cooling to remove heat and containment of the radioactive substances in the fuel rods making up the core.

Modifications were made to the facility so that it could run new research programmes to study the behaviour of high burn-up fraction fuel during reactivity insertion accident situations. Reactor divergence in its new configuration was authorised in 2015. On 30 January 2018, after major renovation work, ASN authorised the first active experimental test of the facility's pressurised water loop.

Irradiation reactors

The irradiation reactors are pool type. They are used to study the physical phenomena linked to the irradiation of materials and fuels, as well as their behaviour. As the neutron fluxes obtained by these facilities are more powerful than those in a Pressurised Water Reactor (PWR) type nuclear power reactor, the experiments enable ageing studies to be performed on the materials and components subjected to a high neutron flux. After irradiation, the samples undergo destructive examination, notably in the research laboratories, in order to characterise the effects of irradiation. They are thus an important tool for the qualification of materials subjected to a neutron flux.

These research reactors are also significant sources for the production of certain radionuclides for medical uses.

The power of these reactors varies from a few tens to a hundred Megawatts thermal. These reactors operate in cycles of about 20 to 30 days.

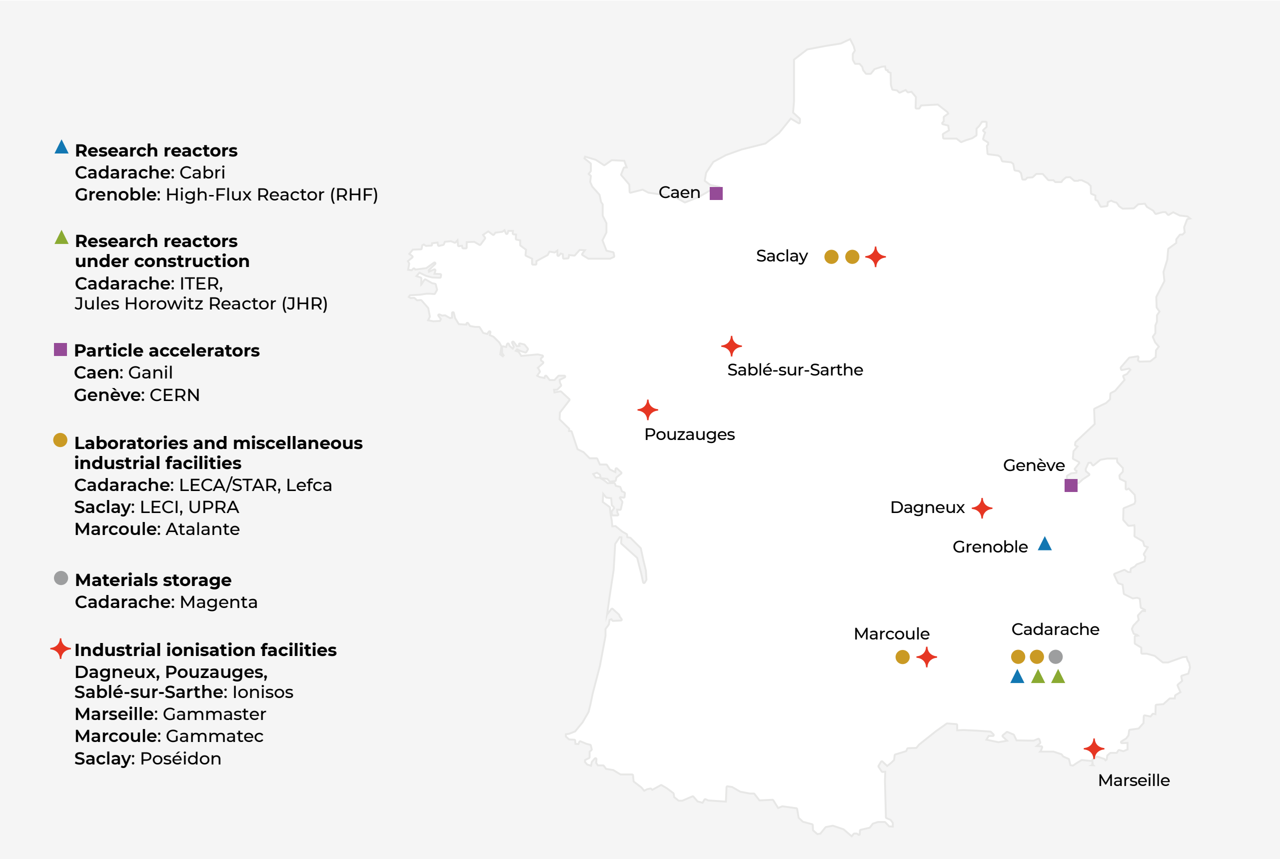
In France, no technological irradiation reactors are still in service: the Osiris reactor (BNI 40), in Saclay, was permanently shut down in 2015. The Jules Horowitz reactor (RJH –BNI 172), which is to replace it, is currently under construction in Cadarache.

Fusion reactors

Unlike the research reactors previously described and which use nuclear fission reactions, some research facilities aim to produce nuclear fusion reactions.

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



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 thermonuclear fusion by magnetic confinement of a deuterium-tritium plasma, during long-duration experiments with significant power (500 MW for 400 s).

The main risk and detrimental effect control challenges for this type of facility notably include control of the containment of radioactive materials (tritium in particular), the risks of exposure to ionising radiation (significant activation of materials under intense neutron flux) and the removal of the residual heat from the reactor compartments (in particular during maintenance work).

In the wake of the Fukushima Daiichi NPP accident, ASN initiated a "stress tests" approach for the nuclear facilities. The approach consists in assessing the safety margins in the facilities with regard to their ability to withstand a loss of electrical power, or cooling, and extreme natural hazards.

In the light of the conclusions of the stress tests on the ITER installation, appropriate organisational and material provisions, called the "hardened safety core" were implemented.

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, the "fuel cycle" 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 also essential factors in controlling 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.

In 2015, following the Fukushima Daiichi NPP accident, ASN ordered the implementation of new emergency management means, more particularly the construction or reinforcement of the “hardened safety core” emergency centres able to withstand extreme climatic conditions.

It finds that these projects are behind schedule on all the CEA centres, for various reasons, and that the initial deadlines were not met. For the Marcoule centre, ASN is still waiting for additional data on the strength of the existing emergency management buildings (containment, accessibility, operability, habitability, etc.).

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.

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 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.

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. The CERN does not operate just one particle accelerator to study the structure of matter, but an entire chain of devices (sometimes called injectors). This chain currently comprises several linear and circular accelerators. Owing to its cross-border location, the CERN is subject to particular verifications by the French and Swiss Authorities.

1.2.3 Industrial ionisation installations

Industrial ionisation facilities, called “irradiators”, use the gamma rays emitted by sealed sources of cobalt-60 to irradiate targets in the irradiation cells. These irradiation cells are designed with particularly thick walls and windows, to protect the operators against the ionising radiation. The sealed sources are either 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);
- the Steris group, which operates the Gammaster (BNI 147) and Gammatec (BNI 170) facilities in Marseille and Marcoule;
- the CEA, which operates the Poséidon irradiator (BNI 77) on the Saclay site.

1.3 Materials storage facilities

The materials storage facilities operated by CEA are primarily devoted to the conservation of non-irradiated (or slightly irradiated) uranium and plutonium-bearing fissile materials from other CEA facilities. This activity enables the laboratories (Atalante, Lefca, etc.) to be supplied according to the needs of the experiments being conducted. More recently, they have become a temporary storage solution for the fissile materials which were present in facilities that are now shutdown, such as the research reactors (Éole, Minerve, Osiris, Masurca, etc.).

Principles and safety issues

The main challenges inherent in these facilities are to prevent the dispersal of radioactive substances and to control the chain reaction (criticality).

The safety of these facilities is based on a series of static physical barriers (walls and doors of rooms and buildings) to prevent the dispersal of radioactive substances. When operations are carried out on these substances, static confinement is also provided by the equipment (glovebox, shielded cell) in which these operations are performed. This static confinement is supplemented by dynamic confinement consisting, on the one hand, of a cascade of negative pressure environments between the rooms where there is a risk of radioactive substance dissemination and, on the other, filtration of the gaseous releases into the environment. The chain reaction is controlled by strict instructions regarding the handling, storage and monitoring of the materials being stored.

Dedicated storage facilities

The Magenta facility (BNI 169), commissioned in 2011 and operated by CEA on its Cadarache site, is dedicated to the storage of non-irradiated fissile material and the non-destructive characterisation of the nuclear materials received. It is notably replacing the Central Fissile Material Warehouse (MCMF –BNI 53), which was finally shut down at the end of 2017.

Materials storage areas in BNIs

Other radioactive material storage areas, located within a BNI, are authorised to store radioactive materials on the site, but in quantities far lower than those stored in Magenta. This is, for example, the case with BNI 55, called “STAR”, which stores spent fuels, following reprocessing and/or conditioning.

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 and thus focused on those with the highest risks, in terms of the inspections and the examinations carried out 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.

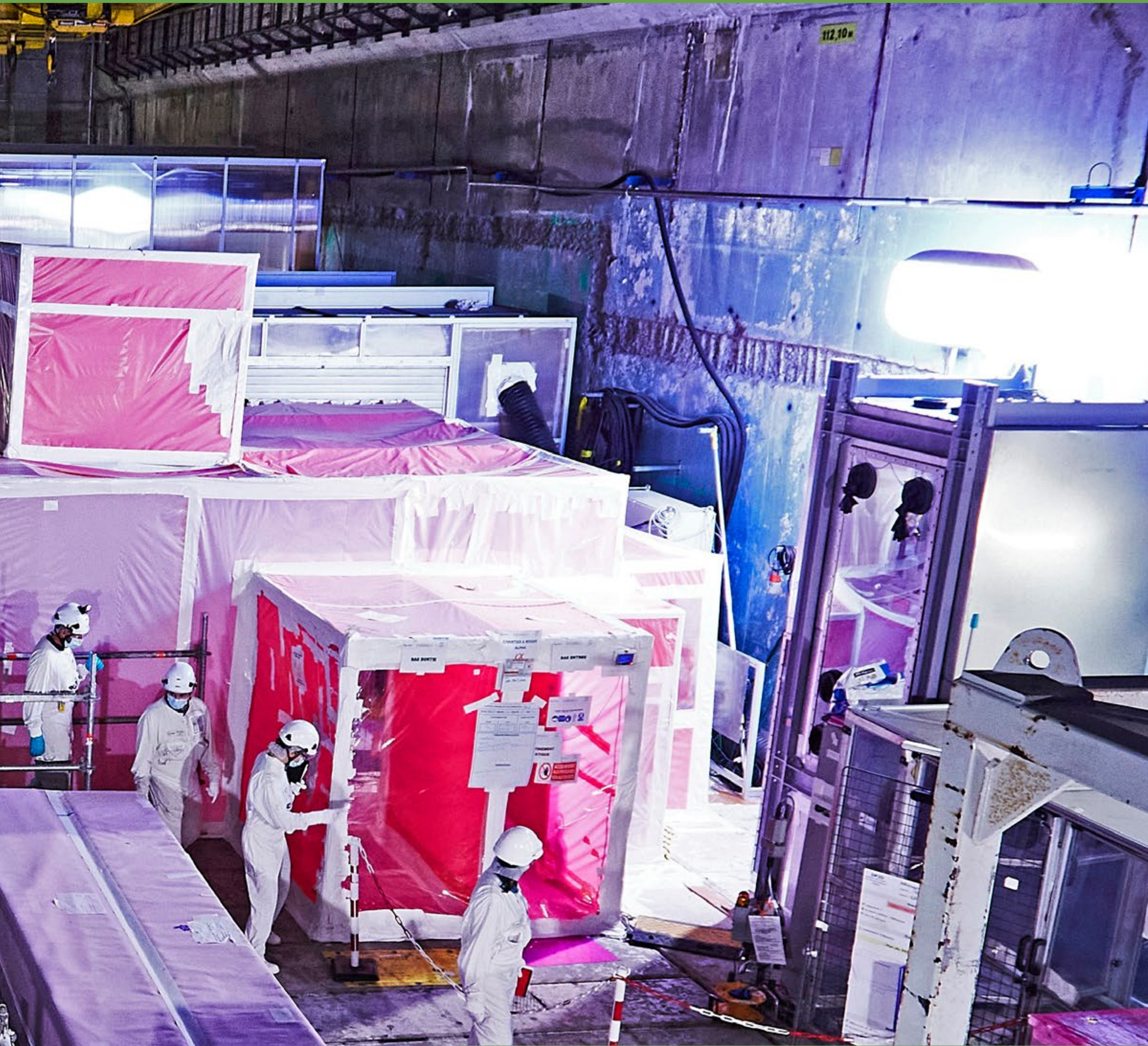
2.2 The periodic safety reviews

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 facilities require particular attention due to the risks they present, while for others presenting a lower level of risk, the extent of the inspections and examinations is adapted accordingly. The technical examination of all the reports will therefore take several years, owing to the specific nature of each of the facilities concerned.

For example, on 1 November 2017, CEA transmitted 16 periodic safety review reports to ASN. CEA then informed ASN that it wished to even out the workload involved in these reviews, in terms of its organisation and its resources, by bringing forward the submission of the periodic safety review reports for certain facilities in the coming decade. ASN is in favour of this approach.

In 2021, ASN continued with on-site inspections specifically devoted to the periodic safety review of the facilities in order to complete its examinations. It finds that CEA has now better assimilated the problems relating to the review, thanks to the implementation on each site of a transverse organisation specifically devoted to this process.



13

Decommissioning of Basic Nuclear Installations

13 DECOMMISSIONING OF BASIC NUCLEAR INSTALLATIONS

The term decommissioning covers all the technical and administrative activities carried out after the final shutdown of a nuclear installation, on completion of which the installation can be delicensed, that is to say it can be removed from the list of Basic Nuclear Installations (BNIs). These activities include removal of the radioactive materials and waste still present in the installation and disassembly of the equipment, components and facilities used during operation, and the clean-up of the premises, remediation of the soils, and possibly the destruction of civil engineering structures.

The aim of the decommissioning and Post Operational Clean Out (POCO) operations is to achieve a predetermined final state that prevents the risks or drawbacks the site can present for the protected interests.

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 often long and costly, which produce massive amounts of waste, and which must be optimally planned for –especially given that the regulatory framework require them to be carried out in the shortest time frame possible. 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 2021 in France, 35 nuclear installations of all types (power and research reactors, laboratories, fuel reprocessing plants, waste treatment facilities, etc.) were either shut down or undergoing decommissioning, which represents more than a quarter of the BNIs in operation.

1 // Technical and legal framework for decommissioning

1.1 Decommissioning challenges

Accomplishing the decommissioning operations –which are often long and costly– within the set time frames is a challenge for the licensees in terms of project management, skills maintenance and coordination of the various operations which involve numerous specialist companies. Despite this, the choice of immediate dismantling in France obliges the licensees to carry out their decommissioning operations in the shortest time frame possible under economically acceptable conditions (see point 1.2).

Decommissioning is characterised by a succession of operations which tend to gradually reduce the quantity of radioactive substances present in the facility, therefore the risk levels evolve. The work carried out, sometimes in close contact with the radioactive substances, nevertheless presents significant radiation exposure risks for the workers. Other risks increase, such as the risks of dispersion of radioactive substances into the environment or certain conventional risks, such as the risks of falling loads when handling large components on worksites situated at height, fires or burns during hot work in the presence of combustible materials, anoxia when working in confined areas, instability of partially dismantled structures, or chemical risks during decontamination operations.

One of the major challenges in the decommissioning of an installation is linked to the very large volumes of waste produced compared with the operational waste. The scale and the difficulty of the work must be assessed as early as possible in the life of the installation (as of the design stage for new facilities), in order to ensure completely safe decommissioning in as short a time frame as possible.

Correct performance of the decommissioning operations is also dependent on the availability of the decommissioning "support" facilities (waste storage, processing and conditioning facilities, effluent treatment facilities) and of appropriate management routes for all the types of waste likely to be produced. When the final waste disposal outlets are likely not to be available at the time the decommissioning waste is produced, the licensees must, with due caution, organise the facilities necessary for the safe interim storage of this waste pending opening of the corresponding disposal route. This point is the subject of provisions in the Decree of 23 February 2017 establishing the provisions of the French National Radioactive Material and Waste Management Plan (PNGMDR) 2016-2018 (see chapter 14).

ASN also believes that management of the waste resulting from decommissioning operations is crucial for the smooth running of the decommissioning programmes (availability of disposal routes, management of waste streams). This subject is addressed with particular attention during the assessment of the decommissioning and waste management strategies established by the Alternative Energies and Atomic Energy Commission (CEA), EDF and Orano (see point 4).

Decommissioning of CEA's old installations and Orano's first-generation plants (especially the plants that played a role in the French deterrence policy, such as the gaseous diffusion plants of the Pierrelatte Defence Basic Nuclear Installation –DBNI) at Tricastin and the UP1 plant of the Marcoule DBNI is going to produce extremely large quantities of very-low level (VLL) waste. This massive production of waste in the decades to come, which was not anticipated and which is incompatible with the current capacities of Cires[1], was addressed by a PNGMDR working group resulting in several lines of reflection, including the creation of a new centralised repository, the possible recycling of some metal waste or on-site disposal solutions. ASN issued a position statement in 2020 on the studies submitted by the licensees on this subject (see chapter 14).

1.2 The ASN decommissioning doctrine

At the international scale, many factors can influence the choice of one decommissioning strategy rather than another: national regulations, social and economic factors, financing of the operations, availability of waste disposal routes, decommissioning techniques and qualified personnel, knowledge of the operating history, exposure of the personnel and the public to ionising radiation resulting from the decommissioning operations, etc. Consequently, practices and regulations differ from one country to another.

1.2.1 Immediate dismantling

The principle of decommissioning "in the shortest time frame possible under economically acceptable conditions" figures in the regulations applicable to BNIs (Order of 7 February 2012 setting the general rules relative to BNIs). This principle, which ASN has affirmed since 2009 as regards BNI decommissioning and delicensing, has been enshrined in legislation by Act 2015-992 of 17 August 2015 relative to Energy Transition for Green Growth. This approach aims to avoid placing the technical and financial burden of decommissioning on future generations. It also provides the benefit of retaining the knowledge and skills of the personnel present during operation of the installation, which are vital during the first decommissioning operations.

The aim of the strategy adopted in France is that:
- the licensee prepares the decommissioning of its installation as of the design stage;
- the licensee anticipates decommissioning and sends ASN the decommissioning application file before it stops operating the installation;
- the licensee has financial resources to finance decommissioning, covering its anticipated expenses by dedicated assets;
- the decommissioning operations are carried out "in as short a time frame as possible" after shutting down the installation, a time frame which can nevertheless vary from a few years to a few decades.

The decommissioning plan, which describes the operations the licensee intends implementing to decommission its facility, aims in particular to prepare and plan ahead for decommissioning as best possible. Since 2007, this document has been required as from commissioning of the facility, and is then updated regularly during its lifetime. It capitalises on the operating experience feedback by identifying any impacts on the future decommissioning operations, and must enable the licensee to justify the chosen decommissioning strategy on the basis of technical and economic criteria.

1.2.2 Cleaning up and achieving the final state

The decommissioning and clean-up operations of a nuclear facility must lead to the gradual removal of the radioactive or hazardous substances from the structures and soils, with a view to delicensing the facility with its subsequent withdrawal from the list of BNI. The radioactive substances can result from activation or deposition phenomena caused by the activities of the BNI. 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. Clean-up corresponds to the operations to reduce or eliminate radioactivity or any other hazardous substances remaining in the structures or soils alike.

ASN asks the licensees to deploy clean-up practices that integrate the best available scientific and technical knowledge under economically acceptable conditions. The complete clean-up scenario must always be envisaged as the reference scenario. This scenario, which leads to unconditional release of the buildings and sites, effectively enables the protection of people and the environment to be guaranteed over time with no reservations.

In the event of identified technical, economic or financial difficulties, the licensee can submit one or more appropriate clean-up scenarios compatible with the site's futures usages (confirmed, planned or 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 clean-up operations constitute a technical and economic optimum. In such cases ASN examines the scenarios proposed by the licensee and ensures that the clean-up will be taken as far as reasonably possible.

Whatever the case, ASN considers that the clean-up strategy implemented by the licensee must lead to a final state of the BNI and its site that is compatible with administrative delicensing.

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[2]). 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).

By way of example, the International Atomic Energy Agency (IAEA) recommends, for the unconditional release of a site polluted by radioactive substances, achieving a final state corresponding to a level of exposure leading to an effective annual dose of 10 microsieverts (μSv) –*i.e.* one hundredth of the annual maximum dose of 1 millisievert (mSv) for the public. It recommends moreover, to have an effective annual dose of less than 300 μSv, the implementation of usage restrictions in application of the principles of radiation protection (limitation, optimisation and justification of the received dose). Whatever the case, once the site has been delicensed, the induced radiological exposure must not exceed the statutory value of 1 mSv over one year for all the usage scenarios.

This ASN position specifies its doctrine, which is laid down in the guides relative to the structure clean-up operations (Guide No. 14, available at *asn.fr*), and the management of polluted soils in nuclear installations (Guide No. 24, available at *asn.fr*). The provisions of these guides have already been implemented on numerous installations with varied characteristics, such as research reactors, laboratories, fuel manufacturing plants, etc.

1. *Cires: French acronym standing for "Industrial centre for grouping, storage and disposal". Located in Morvilliers (Aube* département*) and renamed Cires in October 2012, it was originally commissioned in 2003 under the name CSTFA, standing for "Very-low level waste disposal facility".*
2. *ALARA – As Low As Reasonably Achievable.*

PHASES IN THE LIFE OF A BASIC NUCLEAR INSTALLATION

END OF OPERATION

Shutdown notification → Transmission of the decommissioning file

2 years maximum

At least two years before the planned shutdown date, the licensee must inform the Minister responsible for nuclear safety and ASN of its intention to definitively shut down its facility.

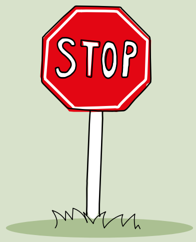
This notification is made available to the public.

The licensee must submit the decommissioning file to the Minister 2 years at the most after the shutdown notification.

This file sets out the decommissioning operations projected by the licensee and the measures it will take to limit the impacts on people and the environment.

DECOMMISSIONING PREPARATION PHASE

→ Final shutdown



As from the final shutdown date, the licensee is no longer authorised to operate its facility.

The licensee 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).

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. This decree sets out, among other things, the main decommissioning steps, the planned decommissioning end date and the final state to be achieved. As part of its oversight duties, ASN monitors the implementation of the decommissioning operations as directed by the decommissioning decree.

In order to avoid fragmentation of the decommissioning projects and improve their overall consistency, the decommissioning file must explicitly describe all the planned operations, from final shutdown to attainment of the targeted final state and, for each step, describe the nature and scale of the risks presented by the facility as well as the means of managing them. The licensee must demonstrate in its decommissioning file that the decommissioning operations will be carried out in as short a time frame as possible. This file undergoes a public inquiry, during which the local residents, local authorities and Local Information Committees (CLIs) are called upon to respond. Furthermore, the decommissioning files representing the most significant risks are examined by the Advisory Committee for Decommissioning (GPDEM), set up in 2018.

Given that installation decommissioning operations are often very long, the decommissioning decree can stipulate that some steps will be subject to prior approval by ASN on the basis of specific safety analysis files.

The 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

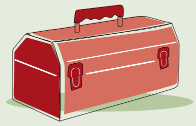
DECOMMISSIONING

Decommissioning decree

On the basis of the decommissioning file submitted by the licensee, the Minister issues a decree prescribing the decommissioning operations that will be carried out on the facility, 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 the clean-out and remediation of structures and soils.

DELICENSING

Delicensing resolution

Delicensing consist in withdrawing a facility from the list of BNIs, which implies that the facility from this point 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 be introduced if it has not been possible to remove all the pollution.

The duty of ASN stops here

preparatory phase permits, for example, the removal of a portion of the radioactive and chemical substances (including the fuel of a nuclear reactor) as well as preparing for the decommissioning operations (readying of premises, preparation of worksites, training of teams, etc.). It is also during this preparatory phase that the installation characterisation operations can be carried out (radiological mappings, analysis of the operating history), which are vital for establishing the targeted clean-up scenarios.

The Environment Code requires –as is the case for all other BNIs– that the safety of a facility undergoing decommissioning be reviewed periodically and at least every 10 years. ASN's objective with these periodic safety reviews is to ascertain that the installation complies with the provisions of its decommissioning decree and the associated safety and radiation protection requirements through to its delicensing by applying the principles of defence in depth specific to nuclear safety, with an approach that is proportionate to the risks. This is because, if the decommissioning operations result in a weakening, or even the disappearance of the existing physical barriers, the licensee must, depending on the residual safety and radiation exposure risks, maintain appropriate lines of defence necessary for the protection of workers and the environment (setting up of air locks, nuclear ventilation, radiation monitors, etc.).

On completion of decommissioning, a nuclear facility can be delicensed by an ASN resolution approved by the Minister responsible for nuclear safety. It is then removed from the list of BNIs and is no longer subject to the BNI regulatory framework. As part of its delicensing application, the licensee must provide a file containing a description of the state of the site after decommissioning (analysis of the state of the soils, remaining buildings or facilities, etc.) and demonstrating that the planned final state has been reached. Depending on the final state reached, ASN may require the implementation of active institutional controls as a condition of delicensing. These may set a number of restrictions on the use of the site and buildings (use limited to industrial applications for example) or precautionary measures (radiological measurements to be taken in the event of undermining[3], etc.). Some twenty facilities, most of them old research reactors, have been decommissioned and delicensed to date without being attached to a BNI or an Installation Classified for Protection of the Environment (ICPE).

As at 31 December 2021, ASN was examining 19 decommissioning files for definitively shut down facilities whose decommissioning has not yet been prescribed or whose decommissioning conditions have been substantially changed. It is also examining two delicensing files for facilities whose decommissioning operations have been completed.

1.4 The financing of decommissioning and radioactive waste management

Articles L. 594-1 to L. 594-10 and D. 594-1 to D. 594-18 of the Environment Code define the system for ring-fencing funds to cover the costs of decommissioning nuclear facilities and managing the spent fuel and radioactive waste. This system is clarified by the Order of 21 March 2007 relative to securing the funding of the nuclear costs.

It aims to secure the funding for nuclear costs applying the "Polluter-pays" principle. It is therefore up to the nuclear licensees to take charge of this financing by setting up a dedicated portfolio of assets capable of covering the expected costs. These costs must be evaluated conservatively, taking the various uncertainties into account. The licensees are thus obliged to submit triennial reports on these costs along with annual update notices to the Government. Provisioning is ensured 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 inappropriate. 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 2021, 35 nuclear facilities in France are definitively shut down or undergoing decommissioning, that is to say about a quarter of the BNIs (see map page 334). These facilities are varied (nuclear power reactors, research reactors, "fuel cycle" facilities, support facilities, etc.) and the decommissioning challenges can differ greatly from one facility to the next. These risks are nevertheless all linked to the large quantity of waste to be managed during decommissioning and to the need to work very close to contaminated or activated zones. The risks for safety and radiation protection are all the higher if the facilities contain legacy waste; this is the case, in particular, with the Orano former spent fuel reprocessing plants and the CEA's old storage facilities.

2.1 Nuclear power reactors

2.1.1 Pressurised water nuclear power reactors

The decommissioning of Pressurised Water Reactors (PWRs) benefits from experience feedback from numerous projects across the world and the design of these reactors facilitates their decommissioning compared with other reactor technologies. The decommissioning of this type of installation presents no major technical challenges and its feasibility is guaranteed. Nevertheless, whatever the service life of the reactors in operation, EDF will be confronted with the simultaneous decommissioning of several PWRs in the coming years, and will therefore have to organise itself to industrialise the decommissioning process, in order to meet the requirement to decommission each installation in the shortest time possible.

The first PWR decommissioning work site in France is the Chooz A reactor (BNI 163). This is a small model compared with the nuclear power reactors in operation. It presents some specific technical difficulties due to its construction inside a cavern. This makes some operations more complex, such as the removal of large components like the steam generators. Decommissioning of the Chooz A reactor vessel has been in progress since 2014 and should continue within the prescribed time frames.

The Fessenheim Nuclear Power Plant (NPP) was definitively shut down in 2020. Its two reactors will be the first 900 Megawatts electric (MWe) reactors to be decommissioned in France. Decommissioning of the Fessenheim reactors will thus provide EDF with considerable experience feedback for its other PWRs.

2.1.2 Nuclear power reactors other than PWRs

The nuclear power reactors that are not PWRs are all industrial prototypes. These comprise the first-generation Gas-Cooled Reactors (GCRs), the EL4-D heavy water reactor on the Brennilis site, and the sodium-cooled fast breeder reactors Phénix and Superphénix. The decommissioning of these reactors is characterised by the lack of prior experience at national (France) or international level. 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 thermal powers of these reactors is relatively high (all greater than 250 Megawatts thermal –MWth), their decommissioning requires the use of remotely operated means in certain highly irradiating zones (reactor core).

The GCRs have the particularity of being extremely massive and large-sized reactors, necessitating innovative cutting and access techniques under highly irradiating conditions. The decommissioning of these reactors will oblige EDF to manage significant volumes of waste. The final disposal route for some of this waste is currently being determined, such as the graphite bricks, representing some 15,000 tonnes of waste that will be produced, for which disposal appropriate for low-level long-lived nuclear waste (LLW-LL) is envisaged.

Decommissioning of the prototype heavy water reactor (EL4-D) has been slowed down, firstly due to the lack of prior experience in the decommissioning techniques to use, and secondly due to difficulties concerning Iceda, the Conditioning and Storage Facility for Activated Waste (see the Regional Overview in the introduction to this report), which must take in some of this decommissioning waste.

3. Undermining means the intentional excavation of a plot of land by soil extraction to conduct works (for example, digging the foundations of a construction).

The 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 –BNI 49) at Saclay, the Chemical Purification Laboratory (LPC –BNI 54) at Cadarache, the Irradiated Materials Plant (AMI –BNI 94) at Chinon and the "Procédé" laboratory (BNI 165) at Fontenay-aux-Roses. These laboratories, which began operating in the 1960s, were dedicated to research to support the development of the nuclear power industry in France.

These very old facilities are all confronted with the issue of managing the "legacy" waste, stored on site at a time when the waste management routes had not been put in place, such as intermediate level, long-lived waste (ILW-LL) and waste without a disposal route (such as asbestos, mercury, etc.). 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, making the decommissioning operations long and difficult. 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

Nine experimental reactors are in final shutdown status at the end of 2021: Rapsodie (sodium-cooled fast neutron reactor), Masurca, Éole and Minerve (critical mock-ups), Phébus (experimental reactor), Osiris and Orphée ("pool" type reactors), Ulysse and Isis (training reactors). 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.

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. 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 decommissioning experience feedback for the research reactors, given the decommissioning of numerous similar installations in France (Siloé, Siloette, Mélusine, Harmonie, Triton[4], the Strasbourg University Reactor –RUS) and abroad. Their dismantling time frames usually span about ten years. Most of these reactors have been demolished and the waste disposed of *via* conventional routes after clean-up of the activated or contaminated zones.

2.3 The front-end "nuclear fuel cycle" facilities

Two front-end "nuclear fuel cycle" facilities are undergoing decommissioning. They are situated on the Tricastin site, one specialising in uranium enrichment by gaseous diffusion (BNI 93), the other in uranium conversion (BNI 105).

The only radioactive materials used in these plants were uranium-bearing substances. One of the particularities of these facilities therefore lies in the presence of radioactive contamination associated with the presence of "alpha" particle-emitting uranium isotopes. The radiation exposure risks are therefore largely linked to the risk of internal exposure.

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 (uranium, chlorine trifluoride and hydrogen fluoride, for example), and 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

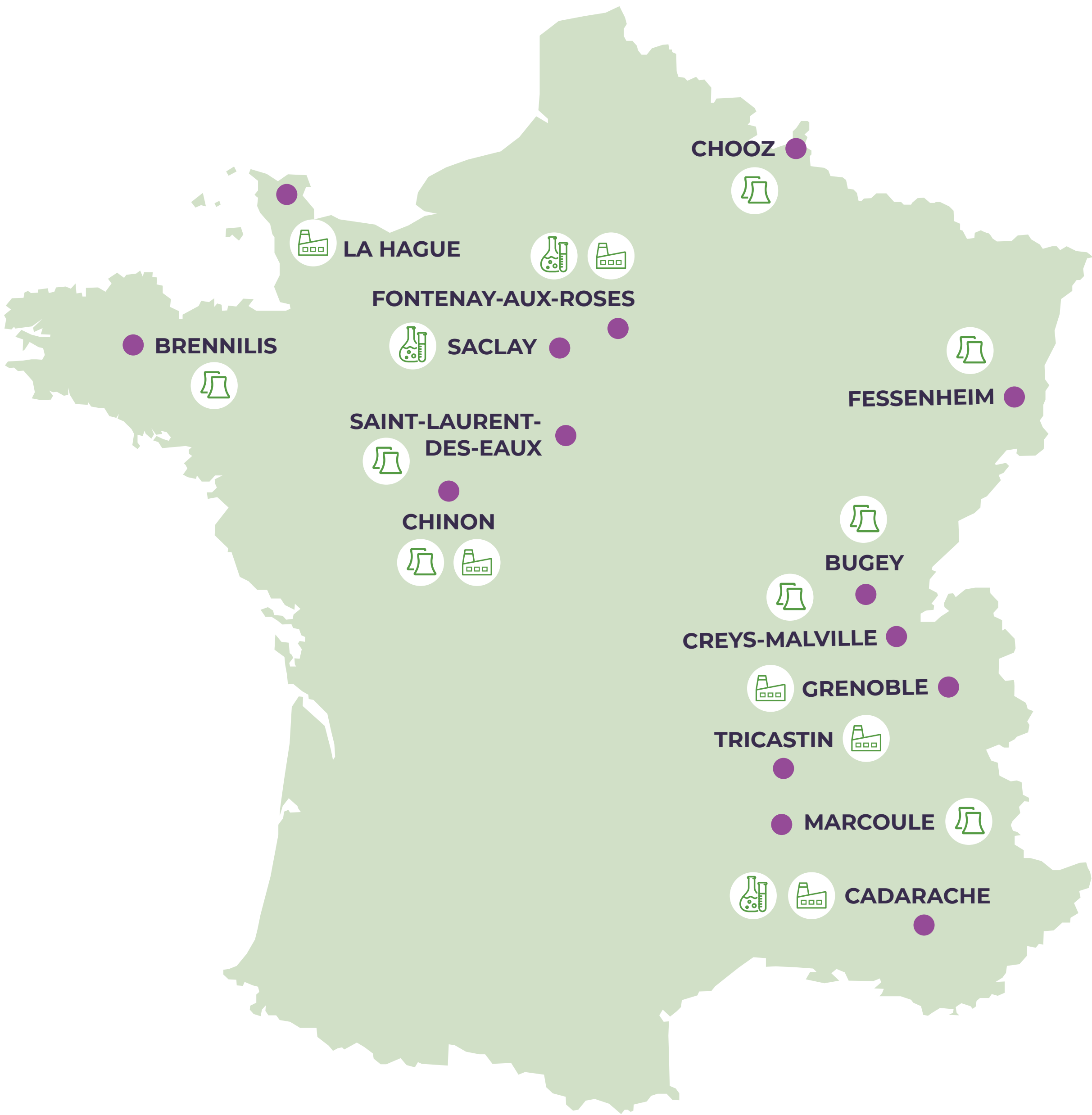
The back-end facilities of the "nuclear fuel cycle" are the spent fuel storage pools, the spent fuel reprocessing plants and the facilities for storing waste from the treatment process. These facilities are operated by Orano and situated on the La Hague site.

The first processing facility at La Hague was commissioned in 1966, initially for reprocessing the fuel from the first-generation GCRs This facility called "UP2-400" (BNI 33) standing for "Production Unit No. 2-400 tonnes", was definitively shut down on 1 January 2004 along with its support facilities: namely the effluent treatment station STE2 and the spent fuel reprocessing facility AT1 (BNI 38), the radioactive source fabrication facility ELAN IIB (BNI 47) and the "High Activity Oxide" facility (HAO), built for reprocessing the fuels from the "light water" reactors (BNI 80).

Unlike the direct on-line packaging of the waste generated by the UP2-800 and UP3-A plants in operation, most of the waste generated by the first reprocessing plant was stored without treatment or packaging. Decommissioning is therefore carried out concomitantly with the legacy Waste Retrieval and Packaging (WRP) operations. 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 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.

4. *Triton was one of the first very compact and very flexible pool type research reactors called "MTR" (Material Test Reactor). Triton (6.5 MWth) was installed in Fontenay-aux-Roses in 1959.*

35 NUCLEAR FACILITIES DEFINITIVELY SHUT DOWN OR IN THE PROCESS OF DECOMMISSIONING AS AT 31 DECEMBER 2021



TYPE OF FACILITIES

Reactor	Plant	Research laboratory and reactor

BRENNILIS

REACTOR — EDF

BNI 162 • EL4-D
- Commissioned: 1967
- Decommissioning in progress

BUGEY

REACTOR — EDF

BNI 45 • Bugey 1
- Commissioned: 1972
- Decommissioning in progress

CADARACHE

RESEARCH REACTORS — CEA

BNI 25 • Rapsodie
- Commissioned: 1967
- Decommissioning in progress

BNI 39 • Masurca
- Commissioned: 1966
- Final shutdown

BNI 42 • ÉOLE
- Commissioned: 1965
- Final shutdown

BNI 92 • Phébus
- Commissioned: 1978
- Final shutdown

BNI 95 • Minerve
- Commissioned: 1977
- Final shutdown

MANUFACTURE, TRANSFORMATION OR STORAGE OF RADIOACTIVE SUBSTANCES

BNI 32 • Plutonium technology facility –ATPu
- Commissioned: 1962
- Decommissioning in progress

BNI 52 • Enriched uranium processing facility –ATUe
- Commissioned: 1963
- Decommissioning in progress

BNI 37-B • Effluent Treatment Station –STE
- Commissioned: 2015[2]
- Final shutdown

BNI 53 • Central Fissile Material Warehouse –MCMF
- Commissioned: 1966
- Final shutdown

BNI 54 • Chemical Purification Laboratory – LPC
- Commissioned: 1966
- Decommissioning in progress

CHINON

UTILISATION OF RADIOACTIVE SUBSTANCES — CEA

BNI 94 • Irradiated Material Facility –AMI
- Commissioned: 1964
- Decommissioning in progress

REACTORS

BNI 133 – BNI 153 – BNI 161 • Chinon A1D – A2D – A3D
- Commissioned: 1963 – 1965 – 1966
- A1D and 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[1]
- Decommissioning in progress

EFFLUENT TREATMENT AND WASTE STORAGE FACILITY

BNI 166 • Support
- Commissioned: 2006[1]
- Decommissioning in progress

GRENOBLE

TRANSFORMATION OF RADIOACTIVE SUBSTANCES — CEA

BNI 36 • Effluent and Solid Waste Treatment Station –STED
- Commissioned: 1964
- Decommissioning in progress

BNI 79 • High-level waste storage unit
- Commissioned: 1972
- Decommissioning in progress

La Hague

TRANSFORMATION OF RADIOACTIVE SUBSTANCES — *Orano Recyclage*

BNI 33 • Spent fuel reprocessing plant –UP2-400
- Commissioned: 1964
- Decommissioning in progress

BNI 38 • Effluent and Solid Waste Treatment Station –STE2
- Commissioned: 1964
- Decommissioning in progress

BNI 47 • ELAN IIB facility
- Commissioned: 1970
- Decommissioning in progress

BNI 80 • Oxide High Activity facility –HAO
- Commissioned: 1974
- Decommissioning in progress

MARCOULE

REACTOR — CEA

BNI 71 • Phénix
- Commissioned: 1973
- Decommissioning in progress

SACLAY

RESEARCH REACTORS — CEA

BNI 18 • Ulysse
- Commissioned: 1961
- Decommissioning in progress

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

SAINT-LAURENT-DES-EAUX

REACTORS — EDF

BNI 46 • Saint-Laurent A1 – A2
- Commissioned: 1969 and 1971
- Decommissioning in progress

TRICASTIN

TRANSFORMATION OF RADIOACTIVE SUBSTANCES — *Orano Chimie Enrichissement*

BNI 105 • Comurhex uranium hexafluoride preparation plant
- Commissioned: 1978
- Decommissioning in progress

BNI 93 • Georges Besse plant for separating uranium isotopes by gaseous diffusion
- Commissioned: 1979
- Decommissioning in progress

(1) This date results from the joining of former BNIs commissioned in 1966 and 1968.

(2) This date results from the separation of BNI 37 (commissioned in 1964) into two BNIs: 37-A and 37-B.

OBSERVATORY OF WASTE RETRIEVAL AND PACKAGING PROJECTS

The number and scale of the Waste Retrieval and Packaging (WRP) projects that the licensees must carry out alongside the decommissioning operations has led them to prioritise those presenting the greatest safety risks. Considered as priorities, these projects concern the old facilities on the Orano La Hague site and the CEA sites (Cadarache, Fontenay-aux-Roses and Saclay). These are complex and costly operations that necessitate the deployment of specific means and can span several years, or even several decades. The priority projects most often concern intermediate-level long-lived waste (ILW-LL), for which new WRP processes must be defined. The following table presents a synthesis of the main safety risks on these priority projects and the difficulties encountered in their implementation, along with the associated time frames.

CEA Cadarache

	Operation and description	Challenge	Difficulties encountered	Time frame[1]	ASN observations
BNI 56	**Retrieval and packaging** of all the intermediate level bulk waste present in the pits ("*vrac MI*" [bulk IL] project)	**Safety of the pits containing waste with respect to a seismic hazard**	• Construction of a new building and putting into service an entirely automated retrieval process requiring substantial prior operations • Defining the definitive packaging process	**Not available**	Preliminary investigations of the pits containing the waste are in progress. ASN's examination of the decommissioning file for this project, which is at the detailed design study stage, is in progress[2].

CEA Saclay

	Operation and description	Challenge	Difficulties encountered	Time frame[1]	ASN observations
BNI 72	**Retrieval and packaging** of drums containing a mixture of waste and fragments of fuel (EPOC process)	**Safety of the storage areas with respect to containment and a seismic hazard**	• Construction of retrieval equipment • Adaptation of the retrieval equipment, whatever the envisaged state of the waste	**2029 (entry into service of the EPOC processes)**	The process sizing studies are completed; the next stage is the construction of the equipment. Entry into service was initially planned for 2023. This deadline was pushed back to 2029 due to numerous technical and organisational difficulties.
	Removal of the stored content from the pool and emptying of the **pool**		Availability of waste removal and packaging routes	**31/12/2024**	The removal operations are in progress. Given the numerous technical and organisational difficulties, the initial deadlines have been pushed back by several years.
	40 wells zone: removal of irradiating waste			**31/12/2030**	
	Removal of stored content from **blocks 108 and 116**			**30/06/2023**	
	Removal of ion exchange resins and sources from **building 116**		Availability of the single transport packaging for sources, which is shared between several facilities	**31/12/2022 for resins and from 2023 to 2025 for the sources**	

CEA Fontenay-aux-Roses

	Operation and description	Challenge	Difficulties encountered	Time frame[1]	ASN observations
BNI 166	**Retrieval of waste stored** in the pits of building 58	**Retrieval of waste to allow decommissioning of the facilities situated in a highly urbanised area**	• Construction of the new measuring and packaging equipment • Availability of waste disposal routes	**01/07/2018**	ASN is currently examining a modification request for the decrees authorising decommissioning of BNIs 165 and 166. In view of the numerous technical and organisational difficulties, particularly the lack of knowledge of the initial state of the shielded cells containing legacy waste, the end-of-retrieval deadline will be pushed back by several decades.
BNI 165	**Packaging of the ILW-LL waste** in PETRUS drums and characterisation of the waste from the decommissioning of the PETRUS unit		Construction of the new waste transfer and packaging enclosure (ETCB)	**01/07/2017**	

Orano La Hague

	Operation and description	Challenge	Difficulties encountered	Time frame[1]	ASN observations
BNI 38	**Silo 130**: End of retrieval of the solid natural uranium graphite-gas (UNGG) waste (ILW-LL) from the GCRs	**Short-term safety of the silo with respect to containment or a seismic hazard**	Maintaining satisfactory conditions of long-term storage of packages from the retrieval operations	31/12/2022	Retrieval began in February 2020 and ramping up to an industrial pace is planned during 2022. The end-of-retrieval deadline will therefore be pushed back.
	Silo 130: End of retrieval of active effluents and sludge		Characterisation of the waste contained in the silos	31/12/2022	The retrieval scenario has been determined. The studies to confirm its feasibility are continuing. This operation takes place on completion of retrieval of the solid UNGG waste (ILW-LL), therefore the end-of-retrieval deadline will be pushed back.
	Silo 130: End of packaging of the solid UNGG waste (ILW-LL)	**Packaging within time frames compatible with commissioning of the deep geological repository**	Defining the definitive packaging process	31/12/2025	Packaging in definitive packages acceptable in a deep geological repository is pushed back by several decades[2].
	SRP[3]: Start of retrieval of the sludge stored in the silos of the Effluents and Solid Waste Treatment Station (STE2)	**Safety of the silos with respect to containment and a seismic hazard**	Defining the sludge encapsulation matrix, development then putting into service the sludge treatment process	01/01/2020	The new sludge retrieval and management strategy is being revised in 2022. The technical discussions with Orano on the preferred technical solution are continuing. The time frames for the start and end of retrieval will therefore be pushed back significantly.
	SRP[3]: End of retrieval of the sludge stored in the STE2 silos			31/12/2025	
	SRP[3]: End of packaging of the sludge from the STE2 silos	**Packaging within time frames compatible with commissioning of the deep geological repository**	Defining the definitive packaging process	31/12/2030	The packaging in definitive packages acceptable in a deep geological repository will be pushed back by several decades[2].
BNI 33	**End of packaging of PF UMo[4]** solutions contained in three storage tanks	**High level liquid waste to be transformed into stable solid waste**		31/12/2020	Operations completed in July 2020.
BNI 80	**HAO Silo:** Start of retrieval of the solid ILW-LL waste and the active effluents	**Safety of the silo with respect to containment, a seismic hazard or resistance to an aircraft crash**	-	30/06/2022	In view of the difficulties associated with operation and maintenance of the planned process, the retrieval scenario was updated in 2021. ASN is examining the application for authorisation to put the equipment into active service. The first tests with radioactive substances are planned in the coming years. The time frame for start of retrieval will therefore be pushed back by a few years.
	HAO Silo: End of packaging of the waste from the HAO silo	**Packaging within time frames compatible with commissioning of the deep geological repository**	Compatibility of the packages with the safety case of a deep geological repository	31/12/2022	This operation takes place on completion of retrieval of the waste from the HAO Silo, therefore the end-of-packaging deadline will be pushed back.

(1) Time frame as presented in the last file subject to public inquiry or the time frame stipulated by ASN.
(2) Given the complexity of the operations, it will be necessary to modify Article L. 542-1-3 of the Environment Code.
(3) Retrieval and packaging of sludge from certain STE2 silos of BNI 38.
(4) Fission products from the reprocessing of uranium/molybdenum fuels used in the GCRs.

At present about ten projects of this type are underway in the former facilities. 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 does not comply with current best practices, have been shut down.

Old storage facilities were not initially designed to allow the removal of the waste, and in some cases they were seen as being the definitive waste disposal site. Examples include the Saint-Laurent-des-Eaux silos (BNI 74), the Orano plant silos in La Hague (silos 115 and 130 in BNI 38, the HAO silo in BNI 80), the pits and trenches of BNI 56 and the wells of BNI 72 and BNI 166. Retrieval of the waste from these facilities is complex and will span several decades. The waste must then be packaged and stored again in safe conditions. New packaging and storage facilities are thus projected or in the course of construction.

The Effluent Treatment Stations (STEs) for their part have been shut down due to their ageing or because the facilities producing the effluents treated in these STEs have stopped functioning. Examples include the Radioactive Effluent and Waste Treatment Station (STED) at Fontenay-aux-Roses, BNI 37-B at Cadarache, STE2 at the La Hague plant and the Brennilis' STE. The difficulties associated with the decommissioning of the STEs are closely dependent on their shutdown conditions, particularly the emptying and rinsing of their tanks.

The decommissioning of these support facilities raises many issues. Firstly, poor knowledge of the operating history and the state of the facility to be decommissioned (taking account of the corrosion of waste drums or pollution of soils resulting from significant events that occurred when in service, for example) necessitates prior characterisation of the old stored waste and of the sludge or deposits in the STE tanks. Secondly, the difficulty in accessing the waste for retrieval, which was not taken into consideration in the design (silos, trenches, concrete-lined pits, cramped premises, etc.), necessitating the costly construction of infrastructures in conformity with current safety requirements and leading to long retrieval times. A number of unforeseeable industrial setbacks are also encountered during these operations, leading to additional delays.

3 // ASN actions relating to facilities being decommissioned: a graded approach

3.1 The graded approach according to the risks of the facilities

ASN ensures the oversight of facilities undergoing decommissioning, as it does for facilities in operation. The BNI System also applies to definitively shut down facilities. ASN implements an approach that is proportional to the extent of the risks or drawbacks inherent in the facility.

The risks with facilities undergoing decommissioning differ from those for facilities in operation. For example, the risks of significant off-site discharges decrease as decommissioning progresses because the quantity of radioactive substances decreases. Consequently, the requirements relating to the control of risks and drawbacks are proportionate to the risks borne by the facilities. ASN thus considers that it is generally inappropriate to start significant reinforcement work on a facility undergoing decommissioning, on condition that the decommissioning operations reduce the sources of danger in the short term.

3.2 The periodic safety reviews of facilities undergoing decommissioning

Given the diversity of the facilities and the situations in question, each periodic safety review necessitates an appropriate examination method. Some facilities undergoing decommissioning warrant particular attention owing to the risks they present and may be reviewed by the GPDEM. For others presenting a lower level of risk, the extent of the inspections and examinations is adapted accordingly.

In 2021, ASN continued the examination of the safety review reports of some twenty facilities undergoing decommissioning that have been received since 2015. Inspections focusing on the periodic safety review were conducted in 2021 on four facilities undergoing decommissioning. These inspections are used to check the means implemented by the licensee to carry out its review, as well as compliance with the action plan resulting from its conclusions. They led to several requests for corrective action and additional information.

In 2021, ASN rendered public its conclusions on the safety review of the GCRs (BNIs 45, 46, 133, 153 and 161), of Superphénix (BNI 91), of Rapsodie (BNI 25), of the MCMF facility (BNI 53), of the Cadarache storage yard (BNI 56), of the ATUe's (BNI 52) and AMI Chinon (BNI 94).

3.3 Financing decommissioning: ASN's opinion on the triennial reports

The regulatory framework for ring-fencing the funds necessary for management of the long-term decommissioning and waste management expenses is presented in point 1.4.

On 13 August 2020, ASN published opinion CODEP-CLG-2020-040124 of 6 August 2020 relative to the examination of the three-yearly reports submitted in 2019 by the licensees, concerning the accounts closed at the end of 2018. The next triennial reports will be submitted in 2022.

ASN notes that the scope of evaluation of the expenses remains incomplete and omits certain high-stake financial operations. More specifically, the licensees are vague about the financing of the decommissioning preparation operations, and do not take into account in their cost assessment the characterisation and management of pollution of soils and structures, the complete clean-out and remediation operations, or the costs of works to maintain the facilities over their entire lifetime.

ASN also underlines that the assumptions adopted for evaluating the complete costs must be reassessed in order to show reasonable caution in the scheduling of the decommissioning projects and programmes, taking account of the risks related to the unavailability of storage, treatment and disposal facilities.

Furthermore, ASN considers that the projected costs at completion must be more detailed and more fully substantiated, particularly in the light of the observed state of progress of the projects, as falling behind in the decommissioning schedules can raise the costs at completion.

Lastly, ASN considers that the proposed assumptions for evaluating the management of radioactive material and wastes are not sufficiently conservative. They do not systematically include either the management of legacy waste locations or the uncertainties regarding the management of LLW-LL waste. Similarly, the licensees tend to overestimate the prospects of reusing certain materials and to underestimate the actions necessary for bituminised waste.

In 2021, ASN examined the update of these triennial reports and sent its observations to the Ministry responsible for the environment.

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, the progress of decommissioning operations is one of the major issues for the safety of shut down facilities. Yet ASN has noted that the majority of these operations are falling significantly behind schedule. Consequently, every 10 to 15 years, ASN asks the CEA, EDF and Orano to present their decommissioning and radioactive waste management strategies, thereby providing an overall view of the decommissioning projects and the management routes necessary for removal of the radioactive waste resulting from the decommissioning operations.

As far as decommissioning is concerned, the licensees must justify the priority operations, principally through safety analyses. This prioritisation provides a means of checking that even if some projects are substantially behind schedule the, the most significant resources will be devoted to operations with higher risk implications.

With regard to radioactive waste management, ASN checks the consistency of the planned actions with the regulatory framework and the guidelines of the PNGMDR. The assessment of the radioactive waste management strategies is presented in chapter 14.

4.1 Assessment of EDF's decommissioning strategy

The first decommissioning strategy file for the EDF reactors definitively shut down (Chinon A1, A2, A3, Saint-Laurent A1 and A2, Bugey 1, EL4-D, Chooz A and Superphénix) was transmitted in 2001 at the request of ASN. Immediate dismantling was adopted as the reference strategy. This strategy has been updated regularly, in order to adjust the decommissioning schedule or incorporate the complementary studies requested by ASN and elements concerning the future decommissioning of the reactor fleet in service.

For the six first-generation GCRs (Chinon A1-A2 and A3, Saint-Laurent A1 and A2 and Bugey 1), EDF informed ASN in March 2016 of a complete change in strategy calling into question the technique ("under water") used for the decommissioning of these reactors and the rate of decommissioning, leading to the decommissioning of all the GCRs being pushed back by several decades. ASN will rule on the decommissioning time frames put forward by EDF in the decommissioning files submitted at the end of 2022, which may also be revised if it turns out in the coming decades that this scenario can be optimised in view of acquired experience. This decommissioning strategy for the GCRs is governed by two ASN resolutions, 2020-DC-0686 and CODEP-CLG-2020-021253, published on 3 March 2020.

These resolutions establish the next steps necessary for the change in decommissioning strategy: submission of the decommissioning files corresponding to these new decommissioning techniques in late 2022, the defining of a robust waste management strategy, the decommissioning operations to be continued over the coming years, the commissioning of an industrial demonstrator in early 2022 and the information to be transmitted to ASN to monitor the effective implementation of the strategy.

ASN considers that it is justified for EDF to develop an industrial demonstrator before decommissioning the reactor pressure vessels, but decommissioning of the various reactors must nevertheless begin within reasonable time frames in view of the obligation for decommissioning to be carried out as rapidly as possible.

For the other shut down EDF facilities (notably Chooz A, AMI Chinon, EL4-D, Superphénix), decommissioning is under way and the requirement to ensure decommissioning in as short a time frame as possible is satisfied on the whole.

4.2 Assessment of Orano's decommissioning strategy

Decommissioning the old installations is a major challenge for Orano, which has to manage several large-scale decommissioning projects in the short, medium and long-term (UP2-400 facility at La Hague, Eurodif Production plant, individual facilities of the DBNI at Pierrelatte, etc.). Implementation of decommissioning is closely linked to the radioactive waste management strategy, given the quantity and the non-standard and hard to characterise nature of the waste produced during the prior operations phase and the new waste resulting from the decommissioning operations.

Furthermore, Orano must carry out special WRP operations in old waste storage facilities. The deadlines for completion have been stipulated by ASN, particularly for the La Hague site. Completion of these WRP operations governs the progress of decommissioning on the UP2-400 plant, as WRP is one of the first steps of its decommissioning. The WRP work is of particular importance given the inventory of radioactive substances present and the age of the facilities in which they are stored, which do not meet current safety standards. In addition, WRP projects are considerably complex owing to the interactions with the plants in operation on the site. Further to the difficulties observed in the examination of files relating to the WRP and decommissioning operations at the Orano La Hague site and failure to perform the operations within the prescribed deadlines, ASN and Orano agreed to set up regular monitoring in order to foresee and address any blocking situations and determine practical measures to put in place to accomplish the WRP and decommissioning operations in the shortest time frame possible.

In June 2016, at the request of ASN and the Defence Nuclear Safety Authority (ASND), Orano submitted its decommissioning and waste management strategy. The file also includes the application of this strategy on the La Hague and Tricastin sites. The Tricastin site accommodates one DBNI, hence the joint oversight of Orano by ASN and ASND (see "Notable Event" in the introduction to this report).

4.3 Assessment of the CEA's decommissioning strategy

Given the number and complexity of the operations to be carried out for all the nuclear facilities concerned, the CEA is giving priority to reducing the "dispersible inventory[5]", which is currently very high in certain facilities, particularly in some of the individual facilities of the Marcoule DBNI and in BNIs 56 and 72.

In their Position Statement Letter of 27 May 2019, ASN and the ASND considered that, given the resources allocated by the State and the large number of facilities undergoing decommissioning for which legacy waste retrieval and storage capacity will need to be built, it was acceptable for CEA to envisage staggering the decommissioning operations and that priority be given to the facilities with the greatest safety risks. The two Authorities have since observed changes in the WRP schedules presented by the CEA, particularly the pushing back of waste management deadlines, including for operations considered to be priorities. ASN, ASND and the CEA have agreed to set up regular monitoring of these operations, through progress indicators in particular.

As concerns facilities classified as lower priority, ASN and ASND have also noted significant push-backs of some of the decommissioning deadlines announced by the licensee since 2016. The two authorities will rule on the CEA's justifications for these schedule push-backs on reception of the facilities' decommissioning files.

5. *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.*

// Appendix

BNIs **List of Basic Nuclear Installations undergoing decommissioning or delicensed as at 31 December 2021**

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COM-MISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
IDE (Fontenay-aux-Roses)	(Former BNI 10)	Reactor (500 kWth)	1960	1981	1987: removed from list of BNIs	Decommissioned
Triton (Fontenay-aux-Roses)	(Former BNI 10)	Reactor (6.5 MWth)	1959	1982	1987: removed from list of BNIs and classified as ICPE	Decommissioned
ZOÉ (Fontenay-aux-Roses)	(Former BNI 11)	Reactor (250 kWth)	1948	1975	1978: removed from list of BNIs and classified as ICPE	Confined (museum)
Minerve (Fontenay-aux-Roses)	(Former BNI 12)	Reactor (0.1 kWth)	1959	1976	1977: removed from list of BNIs	Dismantled at Fontenay-aux-Roses and reassembled at Cadarache
EL2 (Saclay)	(Former BNI 13)	Reactor (2.8 MWth)	1952	1965	Removed from list of BNIs	Partially decom-missioned, remaining parts confined
EL3 (Saclay)	(Former BNI 14)	Reactor (18 MWth)	1957	1979	1988: removed from list of BNIs and classified as ICPE	Partially decom-missioned, remaining parts confined
Mélusine (Grenoble)	(Former BNI 19)	Reactor (8 MWth)	1958	1988	2011: removed from list of BNIs	Cleaned out
Siloé (Grenoble)	(Former BNI 20)	Reactor (35 MWth)	1963	2005	2015: removed from list of BNIs	Cleaned out – passive institutional controls(**)
Siloette (Grenoble)	(Former BNI 21)	Reactor (100 kWth)	1964	2002	2007: removed from list of BNIs	Cleaned out – passive institutional controls(**)
Peggy (Cadarache)	(Former BNI 23)	Reactor (1 kWth)	1961	1975	1976: removed from list of BNIs	Decommissioned
César (Cadarache)	(Former BNI 26)	Reactor (10 kWth)	1964	1974	1978: removed from list of BNIs	Decommissioned
Marius (Cadarache)	(Former BNI 27)	Reactor (0.4 kWth)	1960 at Marcoule, 1964 at Cadarache	1983	1987: removed from list of BNIs	Decommissioned
Former Le Bouchet plant (Vert-le-Petit)	(Former BNI 30)	Ore processing	1953	1970	Removed from list of BNIs	Decommissioned
Former ore processing plant (Gueugnon)	(Former BNI 31)	Ore processing	1965	1980	Removed from list of BNIs	Decommissioned
STED (Fontenay-aux-Roses)	(Former BNI 34)	Processing of solid and liquid waste	Before 1964	2006	2006: removed from list of BNIs	Integrated in BNI 166
STED (Cadarache)	(Former BNI 37)	Transformation of radioactive substances	1964	2015	2015: removed from list of BNIs	Integrated in BNIs 37-A and 37-B
Harmonie (Cadarache)	(Former BNI 41)	Reactor (1 kWth)	1965	1996	2009: removed from list of BNIs	Destruction of the ancillaries building
ALI (Saclay)	(Former BNI 43)	Accelerator	1958	1996	2006: removed from list of BNIs	Cleaned out – passive institutional controls(**)
Strasbourg University reactor	(Former BNI 44)	Reactor (100 kWth)	1967	1997	2012: removed from list of BNIs	Cleaned out – passive institutional controls(**)
Saturne (Saclay)	(Former BNI 48)	Accelerator	1966	1997	2005: removed from list of BNIs	Cleaned out – passive institutional controls(**)
Attila(*) (Fontenay-aux-Roses)	(Former BNI 57)	Reprocessing pilot	1968	1975	2006: removed from list of BNIs	Integrated in BNIs 165 and 166
LCPu (Fontenay-aux-Roses)	(Former BNI 57)	Plutonium chemistry laboratory	1966	1995	2006: removed from list of BNIs	Integrated in BNIs 165 and 166
BAT 19 (Fontenay-aux-Roses)	(Former BNI 58)	Plutonium chemistry laboratory	1968	1984	1984: removed from list of BNIs	Decommissioned
RM2 (Fontenay-aux-Roses)	(Former BNI 59)	Radio-metallurgy	1968	1982	2006: removed from list of BNIs	Integrated in BNIs 165 and 166
LCAC (Grenoble)	(Former BNI 60)	Fuels analysis	1975	1984	1997: removed from list of BNIs	Decommissioned
LAMA (Grenoble)	(Former BNI 61)	Laboratory	1968	2002	2017: removed from list of BNIs	Cleaned out
SICN (Veurey-Voroize)	(Former BNIs 65 and 90)	Fuel fabrication plant	1963	2000	2019: removed from list of BNIs	Buildings demolished, active institutional controls

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COM-MISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
STEDs (Fontenay-aux-Roses)	(Former BNI 73)	Radioactive waste decay storage	1971	2006	2006: removed from list of BNIs	Integrated in BNI 166
ARAC (Saclay)	(Former BNI 81)	Fabrication of fuel assemblies	1981	1995	1999: removed from list of BNIs	Cleaned out
LURE (Bures-sur-Yvette)	(Former BNI 106)	Particle accelerators	From 1956 to 1987	2008	2015: removed from list of BNIs	Cleaned out –active institutional controls(***)
IRCA (Cadarache)	(Former BNI 121)	Irradiator	1983	1996	2006: removed from list of BNIs	Cleaned out –passive institutional controls(**)
FBFC (Pierrelatte)	(Former BNI 131)	Fabrication of fuel	1990	1998	2003: removed from list of BNIs	Cleaned out –passive institutional controls(**)
Uranium warehouse (Miramas)	(Former BNI 134)	Uranium-bearing materials warehouse	1964	2004	2007: removed from list of BNIs	Cleaned out –passive institutional controls(**)
SNCS (Osmanville)	(Former BNI 152)	Ioniser	1983	1995	2002: removed from list of BNIs	Cleaned out –passive institutional controls(**)
Ulysse (Saclay)	18	Reactor (100 kWth)	1967	2007	2014: final shutdown and decommissioning decree	Decommissioning in progress
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	2013: final shutdown and partial decommissioning decree	Partial decommissioning in progress
STED and high-level waste storage unit (Grenoble)	36 and 79	Waste treatment and storage facility	1964/1972	2008	2008: final shutdown and decommissioning decree	Decommissioning in progress
STE (Cadarache)	37-B	Effluent treatment facility (non-permanent part of former BNI 37)	2015	2016		Preparation for decommissioning
STE2 (La Hague)	38	Effluent treatment station	1964	2004	2013: final shutdown and partial decommissioning decree	Decommissioning in progress
Masurca (Cadarache)	39	Reactor (5 kWth)	1966	2018		Preparation for decommissioning
Osiris-Isis (Saclay)	40	Reactor (70 MWth)	1966	2015		Preparation for decommissioning
ÉOLE (Cadarache)	42	Reactor (1 kWth)	1965	2017		Preparation for decommissioning
Bugey 1 (Saint-Vulbas)	45	Reactor (1,920 MWth)	1972	1994	2008: final shutdown and decommissioning decree	Decommissioning in progress
St-Laurent-des-Eaux A1 (St-Laurent-Nouan)	46	Reactor (1,662 MWth)	1969	1990	2010: decommissioning decree	Decommissioning in progress
St-Laurent-des-Eaux A2 (St-Laurent-Nouan)	46	Reactor (1,801 MWth)	1971	1992	2010: decommissioning decree	Decommissioning in progress
ÉLAN IIB (La Hague)	47	Manufacture of cesium-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

INSTALLATION LOCATION	BNI	TYPE OF INSTALLATION	COM-MISSIONED	FINAL SHUTDOWN	LAST REGULATORY ACTS	CURRENT STATUS
Phénix (Marcoule)	71	Reactor (536 MWth)	1973	2009	2016: decommissioning decree	Decommissioning in progress
Fessenheim NPP (Fessenheim)	75	Reactor (1,800 MWth)	1977	2020	2020: final shutdown	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	Partial decommissioning in progress
AMI (Chinon)	94	Utilisation of radioactive substances	1964	2015	2020: decommissioning decree	Decommissioning in progress
Minerve (Fontenay-aux-Roses)	95	Reactor (100 Wth)	1977	2017		Preparation for decommissioning
Orphée (Saclay)	101	Reactor (14 MWth)	1980	2019	2019: final shutdown	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 A2 D	Partially decommissioned, modified to storage BNI for waste left in place. Preparation for complete decommissioning
Chinon A3 D –former Chinon A3 (Avoine)	161 (Former BNI 7)	Reactor (1,360 MWth)	1966	1990	2010: decommissioning decree	Decommissioning in progress
EL4-D –former EL4 (Brennilis)	162 (Former BNI 28)	Reactor (250 MWth)	1966	1985	1996: decree ordering decommissioning and creation of the EL4-D storage BNI 2006: final shutdown and decommissioning decree 2007: decision of the *Conseil d'État* (State Council) cancelling the 2006 decree 2011: partial decommissioning decree	Partial decommissioning in progress. Preparation for complete decommissioning
Ardennes NPP –former Chooz A (Chooz)	163 (Former BNIs 1, 2, 3)	Reactor (1,040 MWth)	1967	1991	2007: final shutdown and decommissioning decree	Decommissioning in progress
Procédé (Fontenay-aux-Roses)	165	Grouping of former research installations (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

(*) Attila: reprocessing pilot located in a unit of BNI 57.
(**) Passive institutional controls.
(***) Active institutional controls.

14

Radioactive waste and contaminated sites and soils

14 RADIOACTIVE WASTE AND CONTAMINATED SITES AND SOILS

This chapter presents the role and actions of the French Nuclear Safety Authority (ASN), in the management of radioactive waste and the management of sites and soils contaminated by radioactive substances. It describes in particular the actions taken to define and set the broad guidelines for radioactive waste management.

According to Article L. 542-1-1 of the Environment Code, radioactive waste consists of radioactive substances for which no subsequent use is planned or envisaged or which have been re-qualified as such by the administrative authority in application of Article L. 542-13-2 of said code. The waste comes from nuclear activities involving artificial or natural radioactive substances, from the moment this radioactivity justifies the implementation of radiation protection controls.

On 21 February 2020, further to the conclusions of the public debate held in 2019, the Minister of Ecological Transition and the Chairman of ASN published a resolution setting out the guidelines of the 5th French Radioactive Material and Waste Management Plan (PNGMDR). In the second half of 2020 and early 2021, ASN also published its opinions, for each management route, on the studies submitted under the PNGMDR 2016-2018.

In 2021, ASN issued an opinion on the draft 2021-2025 plan developed by the General Directorate for Energy and the Climate (DGEC).

In 2019, ASN and the Defence Nuclear Safety Authority (ASND), issued a joint position statement on the decommissioning and waste management strategy of the Alternative Energies and Atomic Energy Commission (CEA), submitted in 2016. In 2020, ASN and ASND, in collaboration with the DGEC, initiated an approach to assess implementation of this strategy. In 2021, ASN continued, in collaboration with ASND, examining Orano's decommissioning and waste management strategy file. ASN's position concerning this strategy was formalised by a letter of 14 February 2022.

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. Whatever the case, it ensures that the waste resulting from contaminated site clean-up operations are directed to appropriate management routes.

1 // Radioactive waste

Pursuant to the provisions of the Environment Code, the producers of spent fuel and radioactive waste are responsible for these substances, without prejudice to the liability of those who hold these substances in their role as persons or entities responsible for nuclear activities. Radioactive waste must be managed in accordance with specific procedures. Waste producers must pursue the objective of minimising the volume and harmfulness of their waste, both before production by appropriate design and operation of the facilities, and after production by appropriate sorting, treatment and packaging.

The types of radioactive waste differ widely in their radioactivity (specific activity, nature of the radiation, half-life) and their form (scrap metal, rubble, oils, etc.).

Two main parameters can be used to assess the radiological risk that radioactive waste represents: firstly the activity, which contributes to the toxicity of the waste, and secondly the half-life of the radionuclides present in the waste which determines the required waste containment time A distinction is therefore made between very low, low, intermediate and high-level waste on the one hand and, on the other hand, very short-lived waste (whose activity level is halved in less than 100 days) resulting mainly from medical activities, short-lived waste (chiefly containing radionuclides whose activity level is halved in less than 31 years) and long-lived waste (which contains a large quantity of radionuclides whose activity level is halved in more than 31 years).

Each type of waste requires the implementation of an appropriate and safe management solution in order to control the risks it represents, particularly the radiological risk but also risks linked to their chemical composition.

1.1 Management of radioactive waste (with the exception of mining tailings and waste rock)

Defined in Article L. 542-1-1 of the Environment Code, the management of radioactive waste comprises all the activities associated with the handling, preliminary treatment, treatment, packaging, storage and disposal of radioactive waste, excluding off-site transportation.

ASN oversees the activities associated with the management of radioactive waste from BNIs or small-scale nuclear activities, other than those linked to national defence which are overseen by ASND and those relative to Installations Classified for Protection of the Environment (ICPEs), which are placed under the oversight of the Prefects.

TABLE 1 **Classification of radioactive waste**[1]

Activity	Level	VERY SHORT LIVED WASTE CONTAINING RADIONUCLIDES WITH A HALF-LIFE OF < 100 DAYS	SHORT LIVED WASTE IN WHICH THE RADIOACTIVITY COMES MAINLY FROM RADIONUCLIDES WITH A HALF-LIFE ≤ 31 YEARS	LONG LIVED WASTE CONTAINING MAINLY RADIONUCLIDES WITH A HALF-LIFE > 31 YEARS
0 Bq/g (*)	Very low-level (VLL)	**Management by radioactive decay on production site** then disposal *via* disposal routes dedicated to conventional waste	**Recycling or dedicated surface 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 gramme (Bq/g).
(**) There is no such thing as high-level, very short-lived.

1.1.1 Management of radioactive waste in Basic Nuclear Installations

Two economic sectors are the major contributors to the production of radioactive waste in BNIs.

First, the nuclear power sector, with the 19 Nuclear Power Plants (NPPs) operated by EDF, and the plants dedicated to the fabrication and reprocessing of nuclear fuel operated by Orano and Framatome. Operation of the NPPs generates spent fuel, part of which is reprocessed to separate the recyclable substances from the fission products or minor actinides which are waste. Radioactive waste is also produced during the operational and maintenance activities in the NPPs and the fuel reprocessing plants, like the structural waste, the hulls and end-pieces constituting the nuclear fuel cladding, and the technological waste, and the waste from the treatment of effluents such as the bituminised sludge. Furthermore, decommissioning of the facilities produces a large volume of radioactive waste.

Second, the research sector, which includes civil nuclear research, in particular the CEA's laboratory and reactor research activities, but also other research organisations. Radioactive waste is produced during the operation, maintenance and decommissioning of these facilities.

This radioactive waste is managed in accordance with specific provisions which take into account its radiological nature and are proportionate to the potential danger it represents.

1.1.2 Management of waste from small-scale nuclear activities governed by the Public Health Code

The issues and implications

The use of unsealed sources[2] in nuclear medicine, biomedical or industrial research creates solid and liquid waste: small laboratory items used to prepare sources, medical equipment used to administer injections for diagnostic or therapeutic purposes, etc. Radioactive liquid effluents also come from source preparation as well as from patients who eliminate the administered radioactivity by natural routes.

The diversity of waste from small-scale nuclear activities, the large number of establishments producing it and the radiation protection issues involved, have led the public authorities to regulate the management of the waste produced by these activities.

Management of disused sealed sources considered as waste

Sealed radioactive sources[3] are used for medical, industrial, research and veterinary applications (see chapters 7 and 8). Once they have been used, and if their suppliers do not envisage their reuse in any way, they are considered to be radioactive waste and must be managed as such.

The management of sealed sources considered as waste, and their disposal in particular, must take into consideration both their concentrated activity and their potential attractiveness in the event of human intrusion after loss of the memory of a disposal facility. These two factors therefore limit the types of sources that can be accepted in disposal facilities, especially surface facilities.

1.1.3 Management of waste containing natural radioactivity

Some professional activities using raw materials which naturally contain radionuclides, but which are not used for their radioactive properties, may lead to an increase in specific activity in the products, residues or waste they produce. The term "Naturally Occurring Radioactive Material" (NORM) is used when its activity exceeds the exemption thresholds figuring in Table 1 of Appendix 13-8 of the Public Health Code (for example, the treatment of rare earths, the production of phosphate fertilizers and phosphoric acid, the combustion of coal in thermal power plants, etc.). Consequently, NORM waste, for which there is no planned or envisaged use, is now considered as radioactive waste within the meaning of Article L. 542-1-1 of the Environment Code. Waste containing radioactive substances of natural origin but which do not exceed the abovementioned exemption thresholds is directed to conventional waste management routes.

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 the French National Agency for the Radioactive Waste Management (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 materials into the ambient environment, in normal use.*

NORM waste can be stored in two types of facility depending on its specific activity:

- in a waste disposal facility authorised by Prefectural Order, if the acceptance conditions stipulated in the Circular of 25 July 2006[4] relative to waste storage facilities, coming under sections 2760 of the ICPE classification are satisfied;
- in 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).

Four hazardous waste disposal facilities are authorised by Prefectural Order to receive waste containing NORMs.

Furthermore, following the entry into effect on 1 July 2018 of Decree 2018-434 of 4 June 2018 introducing various provisions with regard to nuclear activities, the provisions of the Labour Code relative to the protection of workers against ionising radiation also apply to professional activities involving materials that naturally contain radioactive substances, which include the NORMs.

1.2 The legal framework for radioactive waste management

Radioactive waste management falls within the general waste management framework defined in Book V, Part IV, Chapter I of the Environment Code and its implementing decrees. Particular provisions concerning radioactive waste were introduced first by Act 91-1381 of 30 December 1991 on research into the management of radioactive waste, and then by Planning Act 2006-739 of 28 June 2006 on sustainable management of radioactive materials and waste, called the "Waste Act", which gives a legislative framework to the management of all radioactive materials and waste. A large part of the provisions of these Acts are codified in Book V, Part IV, Chapter II of the Environment Code.

The Act of 28 June 2006 more specifically sets a calendar for research into high and intermediate-level, long-lived (HL and IL-LL) waste and a clear legal framework for ring-fencing the funds needed for decommissioning and for the management of radioactive waste. It also provides for the preparation of the PNGMDR, which aims to carry out a periodic assessment and define the prospects for the radioactive substance management policy. It also consolidates the missions of the French National Radioactive Waste Management Agency (Andra), notably by entrusting it with a public service mission for the management of waste from small-scale nuclear activities. Finally, it prohibits the disposal in France of foreign waste by providing for the adoption of rules specifying the conditions for the return of waste resulting from the reprocessing in France of spent fuel and waste from abroad. These rules provide for the returned reprocessed waste to be allocated according to the activity and mass of spent fuel introduced into France. However, subject to certain conditions, regulatory provisions introduced in 2017 and 2021 allow waiving of the conditions of allocation of the waste returned to the originating foreign countries by carrying out waste exchanges applying a system of equivalence. In 2021, recourse to a system of equivalence (by weight and radiological activity of the waste) was thus authorised by the Minister responsible for energy for the waste intended to be returned to Germany (Metall+ operation).

This framework was amended in 2016 with the publication of the Ordinance 2016-128 of 10 February 2016 introducing various provisions with regard to nuclear activities which made it possible to:

- transpose Council Directive 2011/70/Euratom of 19 July 2011 establishing a European community framework for the responsible and safe management of spent fuel and radioactive waste, while reasserting the prohibition on the disposal in France of radioactive waste from foreign countries and of radioactive waste resulting from the reprocessing of spent fuel and the treatment of radioactive waste from abroad, and detailing the conditions of application of this prohibition;
- define a procedure for the administrative authority to requalify materials as radioactive waste;
- reinforce the existing administrative and penal enforcement actions and provide for new enforcement actions in the event of failure to comply with the provisions applicable to the management of radioactive waste and spent fuel.

The conditions for creating a reversible deep geological repository for high-level and intermediate-level long-lived 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 or 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.

4. *Circular of 25 July 2006 relative to classified installations –Acceptance of technologically enhanced or concentrated natural radioactivity in the waste disposal centres.*
5. *French acronym standing for "Industrial centre for grouping, storage and disposal", name given in October 2012. It was originally commissioned in 2003 under the name CSTFA, standing for "Very low level waste disposal facility". Installation subject to licensing under the system of section 2797 of the ICPEs.*

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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 of the regulations must now be carried over to the environmental impact assessment and the BNI general operating rules. ASN will update the resolution of 21 April 2015 to include 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.

ASN resolution 2008-DC-0095 of 29 January 2008 lays out the technical rules applicable for the disposal of effluents and waste contaminated or potentially contaminated by radionuclides owing to a nuclear activity. ASN published a guide (Guide No. 18) to the application of this resolution in January 2012.

Management of disused sealed sources

Under the PNGMDR 2016-2018, Andra submitted a report in mid-2018 presenting a review of the situation regarding the acceptance of disused sealed sources considered as waste in the existing and planned disposal facilities.

Furthermore, Decree 2015-231 of 27 February 2015 enables holders of disused sealed sources to call upon not only the initial source supplier but also any licensed supplier or –as a last resort– Andra, to manage these sources. The holders are moreover no longer obliged to provide proof that they have contacted all the suppliers before turning to Andra. These provisions aimed to bring a reduction in the costs of collecting disused sources and provide a recovery route in all situations. ASN issued a position statement on 11 May 2021 on the management of disused sealed sources that could not be recycled. It considers that disused sealed sources which cannot be accepted in above-ground disposal facilities must be included in the inventories of projected disposal facilities, and that a complete inventory of the existing management routes must be established, indicating the responsibilities of the various actors. Moreover, ASN recommends that the notion of "last resort" mentioned in Decree 2015-231 must be specified.

Management by Andra of waste from small-scale nuclear activities

Article L. 542-12 of the Environment Code entrusts Andra with a public service mission for the management of waste produced by small-scale nuclear activities. Since 2012, Andra operates Cires, a facility situated in the municipalities of Morvilliers and La Chaise in the Aube *département*, designed for the collection and storage of waste from small producers that are not in the nuclear power sector. ASN considers that Andra's actions in this area are appropriate to fulfil its mission assigned under the above-mentioned Article L. 542-12 and that they must be continued.

Nevertheless, the tritiated solid waste must be managed with the waste from the 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.

6. *Formerly Article R. 1333-12.*

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.

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.

The last update was published in 2018. The Inventory presents information concerning the quantities, the nature and the location of radioactive material and waste by category and economic sector as at the end of 2016. A prospective exercise, more detailed than for the 2015 edition, was also conducted considering four contrasting scenarios for France's energy policy, such as envisaged in 2017. These scenarios were updated in 2021 and will be used for the next update of the National Inventory, planned to be published in 2023.

This Inventory constitutes an input database for preparing the PNGMDR. In its opinion of 8 October 2020, ASN considers it necessary to plan ahead for the consequences of possible changes in the energy policy concerning the management of radioactive material and waste, and specifies that these predictions must be based on various long-term hypotheses, consistent with the multi-year energy programme forecasts adopted by the Decree of 21 April 2020.

1.2.4 The National Radioactive Materials and Waste Management Plan

Article L. 542-1-2 of the Environment Code, amended by the abovementioned Ordinance 2016-128 of 10 February 2016, defines the objectives of the PNGMDR:
- draw up the inventory of the existing radioactive material and waste management methods and the chosen technical solutions;
- identify the foreseeable needs for storage or disposal facilities and specify their required capacities and the storage durations;
- set the general targets, the main deadlines and the schedules enabling these deadlines to be met while taking into account the priorities it defines;
- determine the objectives to be met for radioactive waste for which there is as yet no final management solution;
- organises research and studies into the management of radioactive materials and wastes, by setting deadlines for the implementation of new management modes, the creation of facilities or the modification of existing facilities.

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 will be prepared by the Ministry of Ecological Transition, based in particular on the work of

THE ROLE OF ASN IN WASTE MANAGEMENT

The public authorities, and ASN in particular, are attentive to the fact that there must be a management route for all waste and that each waste management step is carried out under safe conditions.

ASN thus considers that the development of management routes appropriate to each waste category is fundamental and that any delay in the search for long-term waste disposal solutions will increase the volume and size of the storage areas in the facilities and the inherent risks.

ASN takes care, particularly within the framework of the PNGMDR but also by inspecting the installations and regularly assessing the licensees' waste management strategy, to ensure that the system made up by all these routes is complete, safe and coherent. This approach must take into consideration all the issues of safety, radiation protection, minimising waste volume and toxicity, while ensuring satisfactory traceability of the operations performed.

Finally, ASN considers that this management approach must be conducted in a manner that is transparent for the public and involves all the stakeholders, in a framework that fosters the expression of different opinions.

The PNGMDR is drawn up by the Ministry of Ecological Transition. The Ministry has opted, in the light of the public debate of 2019, to rely on a pluralistic "Guidance Commission", chaired by an independent qualified person, in which ASN participates. Monitoring of the technical and operational implementation of the PNGMDR is still ensured by a pluralistic working group co-chaired by ASN and the DGEC, as described in chapter 2.

ASN also publishes on its website the PNGMDR, its synthesis, the minutes of the abovementioned working group's meetings, the studies required by the plan and the opinions it has issued on these studies.

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 assessed the studies submitted for the PNGMDR 2016-2018. For the preparation of the 5th PNGMDR, ASN has thus issued seven opinions on the radioactive material and waste management routes in which it sets out a number of recommendations. In addition, on 9 November 2021, ASN issued a favourable opinion for the draft PNGMDR 2021-2025, on condition that it is supplemented with a study of worst-case operating scenarios for the "fuel cycle", an assessment of the impact on the nuclear facilities of continuing the reprocessing of spent fuel beyond 2040 or not, the inclusion of measures relative to the safety of HL/ILW-LL waste management and the management of waste necessitating specific work, such as tritiated waste, and better assessing the recyclability of certain radioactive materials.

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 2020, Cires held 412,258 m^3 of VLL waste, which represents 63% of its authorised capacity. According to the National Inventory produced by Andra, the quantity of VLL waste resulting from decommissioning of the existing nuclear facilities will be about 2,200,000 m^3. According to current forecasts, the facility could be filled to maximum capacity around 2029. Andra is currently working on the Acaci project, which aims to increase the facility's authorised capacity to more than 900,000 m^3, without changing its ground surface area.

In its opinion 2020-AV-0356 of 30 June 2020 on the management of VLL waste, ASN calls for the continuation and extension of the work undertaken in the 2016-2018 edition of the PNGMDR with the aim of improving current management methods and developing complementary management solutions which remain to be devised and implemented.

ASN reaffirms that the foundations of VLL waste management must be based on the place of origin of the waste and guarantee its traceability from production through to disposal, with the exception of metallic VLL waste that is to be recycled, thanks to specific routes as stated in the abovementioned resolution of 21 February 2020.

The recycling of certain types of waste which will be produced in large volumes, along with the setting up of a specific oversight framework for a metal recycling facility, is encouraged, consistently with the waste management hierarchy defined in the Environment Code. ASN recommends in particular the operational implementation of a rubble recycling route for use by the disposal facilities, and continuation of the metals recycling facility project, with the setting up of a specific oversight framework for this facility. In 2021, the Government worked on setting up this regulatory framework. In its opinion 2021-AV-0380 of 11 May 2021, ASN expressed its views on the draft regulations.

In 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.

1.3.2 Low-level 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 are monitored for a period set by convention at 300 years. The facility safety analysis reports –which are updated periodically, including during the monitoring phase– must show that at the end of this phase, the residual activity contained in the waste will have reached a residual level such that human and environmental exposure levels are acceptable, even in the event of a significant loss of the containment properties of the facility. There are two facilities of this type in France, the Manche repository (CSM –BNI 66), which operated from 1969 until 1994 and is currently in the closure preparation phase, and the Aube repository (CSA –BNI 149) which is in operation (see "Regional overview" in the introduction to this report).

The quantity of LL/ILW-SL waste emplaced in the CSA repository totalled 363,000 m^3 at the end of 2021, which represents 36% of the facility's maximum authorised capacity. Added to this quantity is the waste emplaced in the Manche repository, which represents 527,225 m^3. The total quantity of LL/ILW-SL waste emplaced in the Andra facilities is therefore 890,225 m^3, to be compared with the quantity of 971,000 m^3 produced at the end of 2020. According to the data of the National Inventory drawn up by Andra, this waste will represent a maximum volume of 2,000,000 m^3 on completion of decommissioning of the existing facilities. According to the estimates made by Andra in 2016 at the time of the second periodic safety review of the CSA, this facility could reach its maximum filling capacity by 2060 instead of 2042 as initially forecast, this new estimate being based on better knowledge of the future waste and the waste delivery schedules.

1.3.3 Low-level long-lived waste

Low-level long-lived waste (LLW-LL) initially comprised two main categories: graphite waste resulting from the operation of the Gas-Cooled Reactor (GCR) NPPs, and radium-bearing waste, from the radium industry and its offshoots. Other types of waste have been added to this category such as certain bituminised wastes, substances containing radium, uranium and thorium with low specific activity, as well as certain disused sealed radioactive sources.

Furthermore, a fraction of the waste from the Orano Malvesi plant (Aude *département*) produced as from 1 January 2019 is now included in this waste category. The solid waste produced until 31 December 2018, on account of the large volumes it represents, is placed in a specific category of the national inventory called "RTCU" (French acronym standing for "Uranium Fuel Reprocessing Residues").

Putting in place a definitive management solution for this type of waste is one of the objectives defined by the Act of 28 June 2006. Finding such a management solution necessitates firstly having greater knowledge of LLW-LL waste and secondly conducting safety studies on the associated disposal solution. The successive editions of the PNGMDR have set out this objective. ASN also drafted a notice in 2008 giving general safety guidelines concerning the search for a site capable of accommodating LLW-LL. This notice defines the general guidelines to follow as from the phases of looking for a site and designing an LLW-LL waste disposal facility, in order to ensure its safety after closure.

The PNGMDR 2010-2012 opened up the possibility of separate disposal of graphite waste and radium-containing waste, and asked Andra to work on the two design options:
- reworked cover disposal in an outcropping geological layer by excavation followed by backfilling;
- intact cover disposal dug in an underground layer of clay at a greater depth.

The PNGMDR 2013-2015 required the various actors involved to carry out studies (characterisation and waste treatment possibilities, geological investigations on a site identified by Andra, design studies and preliminary safety analyses) so that in 2016 the State can specify guidelines for the management of LLW-LL waste. Thus, the holders of LLW-LL waste have progressed in the characterisation of their waste and in the processing possibilities, particularly with regard to graphite waste and some bituminised waste packages. More specifically, the radiological inventory for chlorine-36 and iodine-129 has undergone a significant downward reassessment.

As part of the PNGMDR, 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 Andra's interim report on the disposal project for LLW-LL waste 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 thus set up in Autumn 2018. The work of this group was synthesised in an IRSN report in December 2020, the recommendations of which were examined by an Advisory Committee of Experts in March 2021. On the basis of these recommendations, ASN began technical discussions with Andra and IRSN in 2021, focusing in particular on the assessment of the long-term dosimetric impact of the disposal project. This work will continue in 2022.

In 2011, Orano submitted (as part of the PNGMDR 2013-2015 preparatory work) a study concerning the long-term management of the waste already produced by the Malvési site and stored in the Écrin facility (BNI 175). Various envisaged disposal concepts are presented:
- above-ground disposal;
- near-surface (40 m), reworked cover disposal, in the former open-cast mine pit;
- near-surface (40 m) reworked cover disposal, in a new pit as yet to be built.

Given the nature of the waste and the configuration of the site, ASN indicated in its opinion 2012-AV-0166 of 4 October 2012 that it is not in favour of continuing the development of a surface disposal facility, as it considers that it does not meet the long-term safety requirements.

On 2 September 2019, ASN issued its opinion on the studies required by Article 7 of the Decree of 27 December 2013 relative to the implementation of a final management solution for the Malvési legacy waste in a near-surface repository. Orano's responses are currently being examined.

With the 5th edition of the PNGMDR 2021-2025 in view, ASN issued its opinion 2020-AV-0357 of 6 August 2020 which details the work focuses it recommends for the management of LLW-LL waste.

It more particularly urges continuation of the work undertaken under the PNGMDR 2016-2018, such as the consolidation of the inventories of the various families of LLW-LL waste and the periodic reassessment of storage needs, notably in order to allow the decommissioning of the nuclear facilities. As at 31 December 2019, the producers and holders of LLW-LL waste indicated that their storage capacities for this type of waste were sufficient for the next 30 years.

ASN considers that, on the basis of a multi-criteria analysis, Andra should submit the outlines of various technical and safety options for the near-surface disposal facilities for LLW-LL waste, comparing the health and environmental effects of the various options envisaged. All of the stakeholders concerned, in particular the representatives of the localities actually or liable to be concerned, must be involved more actively in defining the LLW-LL waste management solutions.

ASN also recommends setting time milestones for Andra's next design stages (preliminary design study and then safety options file), for a near-surface disposal project for LLW-LL waste in the Vendeuvre-Soulaines municipality federation, which will be incorporated into this general strategy.

In its opinion of 6 August 2020, ASN considers that the legacy RTCU waste, as a conservative measure, and the RTCU waste produced as from 1 January 2019 must, in application of Article 63 of the Order of 23 February 2017, be registered in the LLW-LL category. The waste must be better integrated in the current work on the LLW-LL waste management scenarios.

ASN recommends that the studies of a near-surface RTCU waste disposal facility, under reworked cover (either in the pit of the former open-cast mine, or in a new pit yet to be built), be continued, involving the representatives of the localities actually or liable to be concerned. The aim is to provide the technical and safety options for this facility at a level of maturity corresponding to a pre-feasibility study, before 30 June 2024.

The 5th edition of the PNGMDR is intended, during its implementation, to clarify the possible management scenarios for all LLW-LL waste and to analyse it applying several criteria in order to stabilise an overall management strategy. The main question is to define the scope of the waste that could be emplaced in the facility planned to be set up on the site of the municipal federation of Vendeuvre-Soulaines and to identify the additional needs for disposal sites, sites whose locations shall be sought under regulated conditions.

1.3.4 High-level and intermediate-level long-lived waste

Following on from the Act of 30 December 1991, the Act of 28 June 2006 provides for the research into the management of HLW and ILW-LL radioactive waste to be continued along three complementary lines: separation and transmutation of the long-lived radionuclides, interim storage and reversible deep geological disposal.

Separation/transmutation

The report of the Special Public Debates Commission of 25 November 2019 concerning the public debate prior to the 5th edition of the PNGMDR concludes in particular that "*there are two options, each one defended by a portion of the actors: deep geological disposal and interim sub-surface storage for a sufficient length of time to allow progress to be made in transmutation research in order to reduce the radioactivity of the waste*."

Separation/transmutation processes aim to isolate and then transform the long-lived radionuclides in radioactive waste into shorter-lived radionuclides or even stable elements. The transmutation of the minor actinides contained in the waste would have an impact on the size of the disposal facility, by reducing both the heating power, the harmfulness of the packages placed in it and the repository inventory. Despite this however, the impact of the disposal facility on the biosphere, which originates essentially from the mobility of the radionuclides contained in the fission and activation products, would not be significantly reduced.

In its opinion 2020-AV-0369 of 1 December 2020, ASN points out that the prospects of industrial- scale transmutation of the already packaged waste of the *Cigéo* reference inventory are not credible. It considers that, although transmutation studies should be continued, they should concern radioactive substances currently qualified as materials or the waste produced by a future fleet of reactors and that they should be carried out with a view to developing complete solutions, including the disposal of the waste resulting from transmutation and offering a high level of safety.

Lastly, at the end of 2021, ASN underlined the interest of the definition proposed by the CNE2 in its *Assessment Report No. 15* concerning the notion of alternatives to deep geological disposal, which in its opinion remains the reference solution for managing the most highly radioactive waste.

Storage

The second line of research and studies in the Act of 28 June 2006 concerns the storage of waste.

The long-term storage of high-level long-lived waste (HLW-LL), which was one of the lines of research provided for in the Act of 30 December 1991, has not been retained as a definitive management solution for this type of radioactive waste. Storage facilities are nevertheless indispensable pending commissioning of the deep geological disposal facility, to allow the cooling of certain types of waste and then to accompany the industrial operation of the disposal facility, which will develop in stages. Furthermore, if operations to remove emplaced packages were to be decided on in the context of the reversibility of the repository, storage facilities would be needed. Reception of the first radioactive waste packages for deep geological disposal is now planned for around 2040.

The Act of 28 June 2006 tasked Andra with coordinating the research and studies on the storage of HL and ILW-LL waste, which are therefore part of the approach of complementarity with the reversible repository. This law stipulated more specifically that the research and studies on storage should, by 2015 at the latest, allow new storage facilities to be created or existing facilities to be modified to meet the needs identified by the PNGMDR, particularly in terms of capacity and duration.

Progress in storage

In 2013, Andra submitted a report on the research and studies carried out. This report more particularly presented the established inventory of future storage needs, the exploration of the complementarity between storage and disposal, studies and research on engineering and on the phenomenological behaviour of the warehouses and a review of innovative technical options.

From 2013 to 2015, Andra conducted more in-depth studies 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 HL waste and situated in BNI 116. This extension comprises two pits: 30 and 40, commissioned in 2015 and 2017 respectively.

Within the framework of the PNGMDR 2013-2015, and after presenting the inventory of HLW and ILW-LL waste packages intended for *Cigéo* as at the end of 2013 and the status of the existing storage locations, the producers more specifically analysed the fundamental elements enabling waste package storage needs to be identified.

In its opinion 2020-AV-0369 of 1 December 2020 on the studies concerning the management of HL and ILW-LL radioactive waste, ASN noted that the dates at which the existing storage facility capacities reach saturation and the future storage needs for the next twenty years had on the whole been well identified by the waste producers. It did however indicate that the storage capacity estimates should be consolidated by all the producers by integrating margins to allow for any contingencies affecting the waste management routes concerned.

The work carried out under the PNGMDR 2016-2018

The studies required by the PNGMDR 2016-2018 focus on the analysis of the storage needs for HL and ILW-LL waste packages and take up the broad lines of the ASN opinion of 25 February 2016.

Article D. 542-79 of the Environment Code, introduced by the Decree of 23 February 2017 relative to the provisions of the PNGMDR 2016-2018, stipulates that the holders of spent fuel and HL and ILW-LL radioactive waste must keep up to date the availability status of the storage capacities for these substances by waste category and identify the future storage capacity needs for the next 20 years at least.

In accordance with Article 53 of the Order of 23 February 2017, the CEA, EDF and Orano have defined the future storage needs for all families of HL and ILW-LL waste, until 2040. The CEA, EDF and Orano have also studied, within this context, how sensitive the storage needs are to shifts in the *Cigéo* schedule.

In its opinion 2020-AV-0369 of 1 December 2020, ASN estimates in this respect that the dates of saturation of the existing storage capacities and the future storage needs until 2040 have on the whole been well identified by the producers.

Nevertheless, the storage capacity estimates must be consolidated by all the waste producers, integrating margins to cope with any contingencies affecting the waste management routes concerned and thereby be able to anticipate the needs for additional storage capacities and the corresponding licensing procedures.

Article 52 of the Order of 23 February 2017 requires Andra to substantiate the reasons that led it to reject the option of designing near-surface storage facilities. In response to this requirement, in 2018 Andra submitted a comparative study of the different types of storage it has studied.

In its opinion 2020-AV-0369 of 1 December 2020, ASN confirms that near-surface storage facilities have no decisive advantage in terms of nuclear safety and radiation protection over surface storage facilities.

The PNGMDR 2016-2018 sets out several guidelines for the design of HL and ILW-LL waste storage facilities (significant design margins, simple and modular architecture favouring passive systems, provisions for controlling the ambient storage conditions in normal, incident and accident situations, provisions for monitoring and surveillance and deviation management defined at the design stage, provisions for preserving the memory, etc.). ASN will be attentive to the integration of these recommendations in the new facilities that will be necessary pending commissioning of *Cigéo*.

Reversible deep geological disposal

Deep geological disposal is called out by Article L. 542-1-2 of the Environment Code, which stipulates that "*after storage, ultimate radioactive waste which, for nuclear safety or radiation protection reasons, cannot be disposed of on the surface or at shallow depth, shall be disposed of in a deep geological repository*".

The Act of 28 June 2006 assigns Andra the task of devising a project for a deep geological disposal facility which shall be a BNI, governed by the regulations specific to this type of installation, and as such shall be subject to ASN oversight.

The principle of this type of disposal

Deep geological disposal of radioactive waste consists in emplacing the radioactive waste in an underground facility specially designed for this purpose, complying with the principle of reversibility. The characteristics of the geological layer are intended to confine the radioactive substances contained in this waste. Such a disposal facility –unlike storage facilities– must be designed such that long-term safety is ensured passively, that is to say without depending on human actions (such as monitoring or maintenance activities) which require oversight, the durability of which cannot be guaranteed beyond a limited period of time. Lastly, the depth of the disposal structures must be such that they cannot be significantly affected by the expected external natural phenomena (erosion, climate change, earthquakes, etc.) or by human activities.

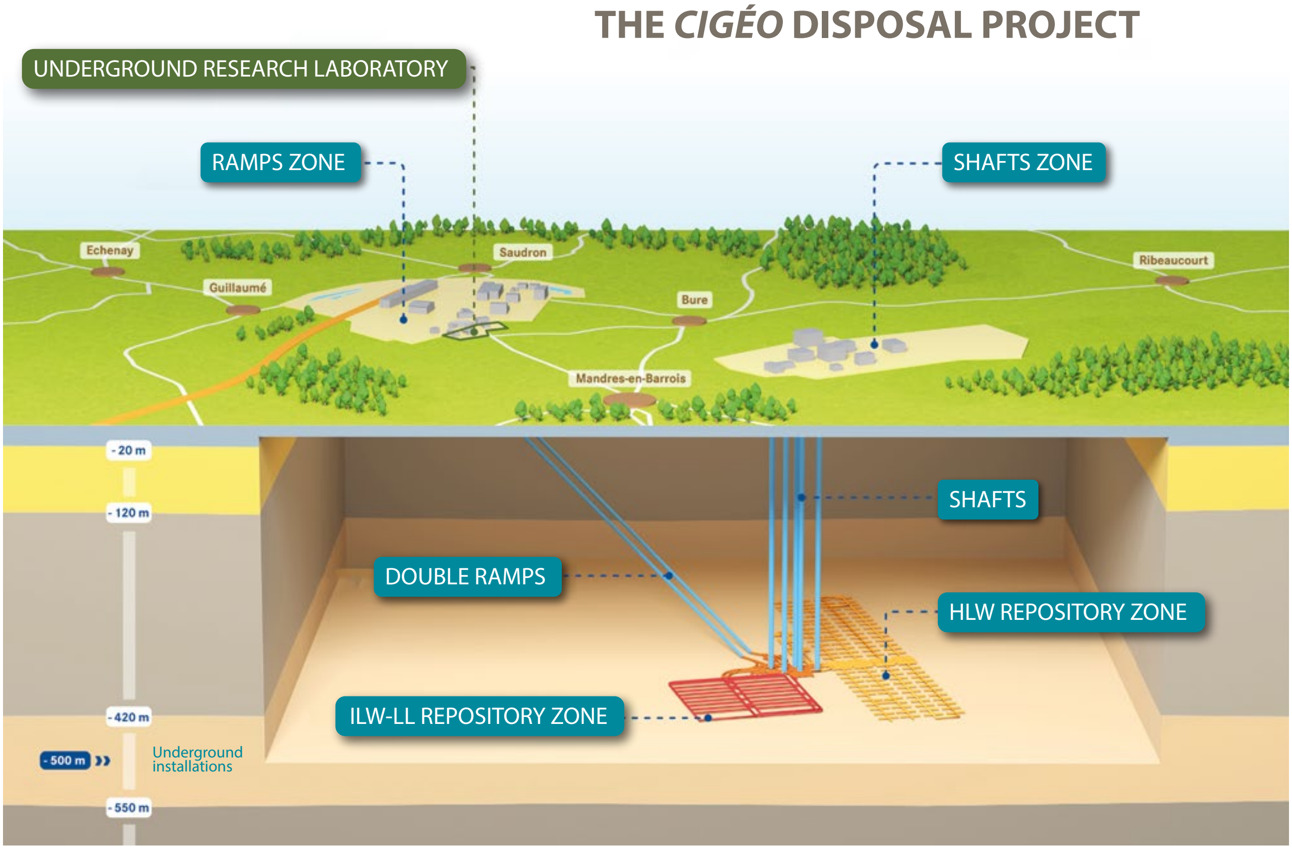
In 1991, ASN published Basic Safety Rule RFS III-2-f defining the objectives to be set in the design and works phases for final disposal of radioactive waste in deep geological formations, in order to ensure safety after the operational life of the repository. In 2008 it published an update of this document in the form of a safety Guide relative to radioactive waste disposal in deep geological formations (ASN Guide No. 1).

The conditions of creation of a reversible deep geological repository for HL and ILW-LL radioactive waste were specified by the Act of 25 July 2016, which defines the principle of reversibility, introduces the industrial pilot phase before complete commissioning of *Cigéo* and brings schedule adaptations concerning the deployment of *Cigéo*.

This Act defines reversibility as "*the ability, for successive generations, to either continue the construction and then the operation of successive sections of a disposal facility, or to reassess previous choices and change the management solutions. Reversibility is materialised by the progressive nature of the construction, the adaptability of the design and the operational flexibility of placing radioactive waste in a deep geological repository which can integrate technological progress and adapt to possible changes in waste inventory following a change in energy policy. It includes the possibility of retrieving waste packages from the repository under conditions and over a time frame that are consistent with the operating strategy and the 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,

SCHEMATIC DIAGRAM OF THE *CIGÉO* REPOSITORY SHOWING THE SURFACE AND UNDERGROUND FACILITIES



ASN had considered that the principle of reversibility implied a requirement for adaptability of the facility and retrievability of the packages during a period governed by law.

The Decree of 23 February 2017 relative to the provisions of the PNGMDR details certain principles applicable to *Cigéo*, and more particularly in Articles D. 542-88 to D. 542-96 of the Environment Code. Article D. 542-90 stipulates in particular that "*The inventory to be considered by the French National Agency for Radioactive Waste Management (Andra) for the studies and research conducted for the design of the repository provided for in Article L. 542-10-1 shall comprise a reference inventory and a reserve inventory. The reserve inventory shall take into account the uncertainties associated more specifically with putting in place new waste management routes or changes in energy policy. The repository shall be designed to accommodate the waste of the reference inventory. It shall also be designed by Andra, in consultation with the owners of the substances of the reserve inventory, to be capable of accommodating the substances figuring in that inventory, provided that changes in its design can be implemented if necessary during operation of the repository at an economically acceptable cost*".

Underground laboratory of Meuse/Haute-Marne

Studies on deep geological disposal necessitate research and experiments in an underground laboratory. Andra has been operating such an underground laboratory within the Bure municipality since 1999.

In the context of the studies on the deep geological disposal, ASN issues recommendations concerning the research and experiments conducted in the laboratory, and ascertains by random sampling during follow-up inspections that they are carried out using processes that guarantee the quality of the results.

Technical instructions

Pursuant to the Act of 30 December 1991, and then pursuant to the Act of 28 June 2006 and the PNGMDR, Andra has carried out studies and submitted reports on deep geological disposal. These reports have been examined by ASN –referring in particular to the Safety Guide of 2008– and it has issued an opinion on them.

ASN has thus more specifically examined the reports submitted by Andra in 2005 and 2009. It issued opinions on these reports on 1 February 2006 and 26 July 2011. Andra subsequently submitted various files to ASN presenting the progress of the studies and work carried out.

ASN issued a position statement:
- in 2013, on the documents produced between 2009 and 2013 –the year of the public debate, and on the intermediate design milestone at the outline stage presented by Andra in 2012;
- in 2014, on the safety components of the closure structures and the expected content of the safety options dossier 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* Safety Options Dossier (DOS).

The authorisation process

Examination of the creation authorisation application for a deep geological disposal facility will not start until formally requested by Andra and will be governed in particular by Book V, Title IX, Chapter III, Section 4 of the Environment Code and by Article L. 542-10-1 of the Environment Code, which is specific to deep geological disposal facilities.

The *Cigéo* Safety Options Dossier

The filing of a DOS marks the start of a regulatory process[7]. ASN received the DOS for *Cigéo* in April 2016. At the end of the technical examination phase, the ASN draft opinion underwent public consultation, which took place from 1 August to 15 September 2017. After analysing the resulting contributions, ASN issued its opinion on 11 January 2018. ASN also sent a follow-up letter giving recommendations on the safety options to prevent or limit the risks and asked Andra for additional studies and justifications (corrosion phenomena, low-pH concretes, representativeness of the hydrogeological model, surveillance strategy, etc.). The demands made in this letter take into account the suggestions and comments received through the public consultation.

The examination of the *Cigéo* DOS highlighted several issues relating to specific aspects (architecture, defining of hazards, post-accident management, etc.). Among these issues ASN pointed out that the management of bituminised waste required special attention.

The management of bituminised waste is moreover monitored under the PNGMDR, which demands several studies relative to the characterisation of these packages, their conditions of transport and the treatment possibilities (Articles 46, 47 and 48 of the Order of 23 February 2017).

In 2019, ASN made additional information requests[8] to the waste producers and to Andra further to the examination of the study submitted under Article 46. They focus more specifically on the effect of self-irradiation on the thermal behaviour of the bituminised waste packages, on the thermal reactivity of the bituminised coatings, on the long-term swelling considering the long-term behaviour of the *Cigéo* repository and on the design changes to control the risks associated with the disposal of packages of bituminised waste.

The Minister responsible for energy and ASN moreover wanted an independent multidisciplinary assessment drawing on international practices to be conducted on this issue. The conclusions of this assessment were presented to the working group tasked with monitoring the PNGMDR in September 2019. ASN considers in this respect in its opinion 2020-AV-0369 of 1 December 2020 that in view of the conclusions of the third-party review of the management of bituminised waste and the studies on the changes in design of the *Cigéo* ILW-LL waste disposal cells, which highlight new technical factors since the publication of the opinion of 11 January 2018, it is essential for the waste producers to conduct an ambitious programme to characterise the bituminised waste packages in order to demonstrate that all or part of these packages could be emplaced with a high level of safety in the projected *Cigéo* facility without prior treatment.

ASN considers moreover that the bituminised waste packages whose safety once emplaced in the disposal facility could not be demonstrated must undergo further investigations.

The CEA informed ASN of the launching in 2021 of a new "quadripartite" studies programme (grouping Andra and the three major licensees), aiming to enrich reflections on the methods of managing bituminised waste by contributing elements stemming from the research and development work. ASN welcomed this initiative and will follow the progress of this programme which will span five years.

From the Safety Options Dossier to the creation authorisation application

At present, Andra is continuing the *Cigéo* project design and preparing the requisite authorisation applications. Andra filed a Declaration of Public Utility (DUP) application in August 2020. The public inquiry relative to the DUP ran from 15 September to 23 October 2021. The reasoned opinion, the general conclusions and the inquiry commission report were published on 20 December 2021. Prior to this inquiry, ASN answered questions from the inquiry commissioners concerning certain technical aspects of the *Cigéo* project. Andra will acquire the status of nuclear licensee as soon as the creation authorisation application is filed. In 2021, ASN and IRSN discussed the matter of defining the in-service seismic hazard level with Andra, and started discussions with a view to preparing the examination of the creation authorisation application. Andra must also integrate the results of the bituminised waste review in its creation authorisation application file, particularly with regard to the architecture of the ILW-LL waste disposal cells.

In the public debate relative to the 5th edition of the PNGMDR, the question of *Cigéo* governance was identified as requiring closer examination, particularly with regard to the implementation of reversibility and the objectives of the industrial pilot phase. The Special Public Debate Committee (CPDP) concludes in particular that civil society must be involved in the governance of *Cigéo*, particularly during the industrial pilot phase. Furthermore, the CPDP considers that the public must also be involved in the steps that have an impact on the reversibility of the facility, particularly package retrievability.

The resolution of 21 February 2020 of the Minister of Ecological Transition and Solidarity and of the ASN Chairman further to the public debate provides in this respect that the PNGMDR will specify the conditions of reversibility of the facility, particularly regarding package retrievability, the decision-making milestones of the *Cigéo* project and the required method of governance in order to be able to review the choices made. It also specifies that the PNGMDR shall define the objectives and success criteria for the industrial pilot phase provided for in Article L. 542-10-1 of the Environment Code, the methods of informing the public between two successive updates of the operations master plan provided for in Article L. 542-10-1 of the Environment Code and the methods of involving the public in the decisive development steps of the *Cigéo* project. Provisions that meet the requirements set out in this opinion have been integrated in the draft PNGMDR 2021-2025.

The cost of the project

On 15 January 2016, in accordance with the procedure stipulated in Article L. 542-12 of the Environment Code and after consideration of ASN's opinion of February 2015 and the comments of the radioactive waste producers, the Minister responsible for energy issued an Order setting the reference cost of the *Cigéo* disposal project "*at €25 billion under the economic conditions prevailing on 31 December 2011, the year in which the cost evaluation work began*". This Order also specifies that the cost must be updated regularly and at least at the key stages of project development (creation authorisation, commissioning, end of "industrial pilot phase", periodic safety reviews).

7. *Article R. 593-14 of the Environment Code stipulates that* "any person planning to operate a BNI can, before initiating the creation authorisation procedure, ask ASN for an opinion on all or part of the options it has retained to ensure protection of the interests mentioned in Article L. 593-1. ASN, in an opinion issued and published in the conditions and forms determined by itself, specifies to what extent the safety options presented by the applicant are such as to prevent or limit the risks for the interests mentioned in Article L. 593.1 in view of the technical and economic conditions prevailing at the time. ASN may indicate 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".*

2 // Nuclear safety in waste management support facilities, role of ASN and waste management strategies of the major nuclear licensees

2.1 Nature of ASN oversight and actions

2.1.1 The graded approach

With regard to radioactive waste management, ASN's oversight aims at verifying on the one hand correct application of the waste management regulations on the production sites (for example with respect to waste zoning, packaging or the controls performed by the licensee), and on the other hand the safety of the facilities dedicated to radioactive waste management (waste treatment, packaging, storage and disposal facilities). This oversight is exercised in a manner proportionate to the nuclear safety issues associated with each waste management step and each facility. Thus, the e-waste management BNIs are classified in one of three categories, numbered from 1 to 3 in descending order of significance of the risks and adverse effects they present. This categorisation is taken into account in the preparation of the inspection schedule and helps to determine the level of expertise required for the examination of certain files submitted to ASN by the licensees.

The various facilities and ASN's assessment of their level of safety are presented in the introduction of this report.

2.1.2 Radioactive waste management support facilities

Treatment

Treatment is a fundamental step in the radioactive waste management process. This operation serves to separate the waste into different categories to facilitate its subsequent management and to significantly reduce the volume of waste.

The La Hague plants which process 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 the effluent advanced management and processing facility (Agate –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 being dispersed in the environment. The techniques used depend on the physical-chemical characteristic of the waste and their typology, which explains the large variety of packages used. These packages are subject to approvals by Andra if they are intended for existing disposal facilities, and to packaging agreements by ASN if they are intended to be directed towards disposal facilities still under study.

In some cases the packaging operations are carried out directly on the site of waste production, but they can also take place in dedicated facilities, like the La Hague plants, which package spent fuel hulls and end-pieces in "standard compacted waste containers" (CSD-C packages), and the fission products in stainless steel "standard vitrified waste containers" (CSD-V packages), and the effluent treatment stations such as the Stella station in BNI 35. The waste packages are sometimes packaged in the facilities in which they are to be stored, which will be the case for the ILW-SL waste packages in the Iceda facility, or directly in a disposal facility, such as Cires and CSA, which carry out these operations on a portion of the incoming packages.

Storage

Storage, as defined by Article L. 542-1-1 of the Environment Code, is a temporary management solution for radioactive waste. The waste is kept in storage for a limited period (which can extend to 50 years) pending its transfer to disposal, or in order to achieve a sufficient level of radioactive decay to enable it to be sent to conventional waste management routes in the particular case of very short-lived waste, which comes chiefly from the medical sector.

Some facilities (see below) are specifically dedicated to the storage of radioactive waste, such as Écrin, commissioned in 2018, and Cedra and Iceda, commissioned in 2020. This will also be the case with Diadem once this facility is commissioned around 2024. As for the CSD-C and CSD-V packages, they are stored directly in various facilities on the La Hague site pending commissioning of the deep geological repository for HL and ILW-LL waste planned for 2035.

Research and Development

Support facilities are used for research and development work to optimise radioactive waste management.

Among these, the Chicade facility (BNI 156) operated by the CEA on the Cadarache site conducts research and development work in low-level and intermediate-level objects and waste. This work primarily concerns aqueous waste treatment processes, decontamination processes, solid waste packaging methods and the expert assessment and inspection of waste packages.

2.1.3 Oversight of the packaging of waste packages

Regulations

The Order of 7 February 2012 defines the requirements associated with waste packaging. Producers of radioactive waste are instructed to package their waste taking into account the requirements associated with their subsequent management, and more particularly their acceptance at the disposal facilities.

ASN resolution 2017-DC-0587 of 23 March 2017 specifies the requirements regarding waste packaging for disposal and the conditions of acceptance of waste packages in the disposal BNIs.

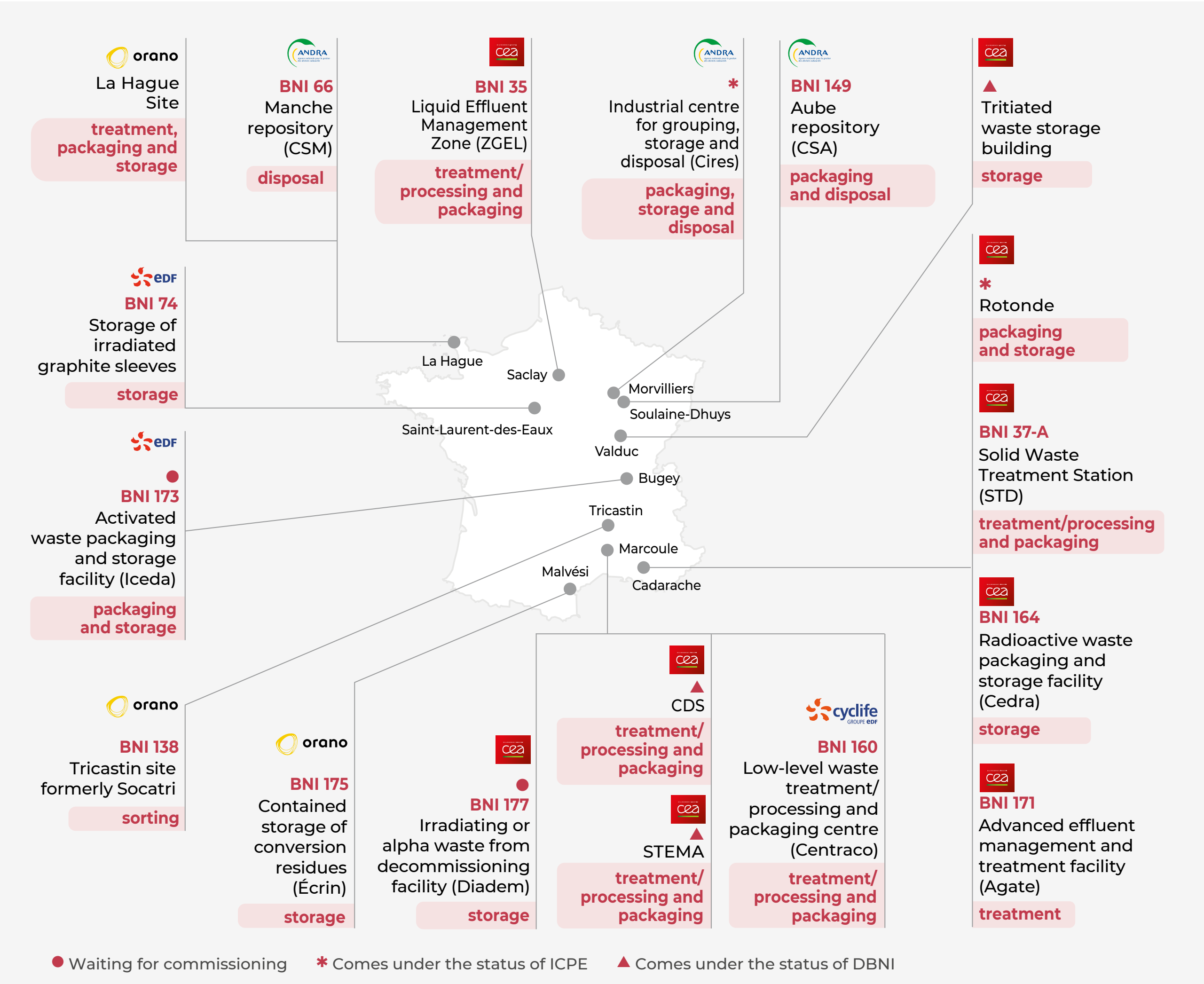
Production of waste packages intended for existing disposal facilities

The waste package producers prepare an approval application file based on the acceptance specifications of the disposal facility that is to receive the packages. Andra issues an approval formalising its agreement on the package manufacturing process and the quality of the packages. Andra verifies the conformity of the packages with the delivered approvals by means of audits and monitoring actions on the package producers' premises and on the packages received at its facilities.

Waste packages intended for projected disposal facilities

With regard to disposal facilities currently being studied, the waste acceptance specifications have of course not yet been defined. Andra therefore cannot issue approvals to govern the production of packages for LLW-LL, HLW-LL or ILW-LL waste.

THE MAIN SUPPORT FACILITIES FOR RADIOACTIVE WASTE MANAGEMENT



Under these conditions, the production of packages of these types of waste is subject to ASN approval on the basis of a file estab-lished by the waste producer called "packaging baseline requirements". This file must demonstrate that on the basis of existing knowledge and the currently identified requirements of the disposal facilities still under study, the packages display no unacceptable behaviour, and concerning, for example, the geometry and the maximum masses of the packages, waste that is prohibited or subject to restriction or the dose rate or radiological activity limits.

This provision also avoids delaying Waste Retrieval and Packaging (WRP) operations.

Within the framework of the PNGMDR 2016-2018, the waste producers were asked to study the acceptability of the waste packages intended for *Cigéo*. In its opinion 2020-AV-0369 of 1 December 2020, and in a letter of 23 July 2021, ASN made several observations relative to the methodology for producing these preliminary acceptance specifications for *Cigéo*, the chosen parameters and the envisaged modes of disposal. It considered in particular that the methodology for producing these preliminary acceptance specifications for *Cigéo* was satisfactory. It nevertheless noted that several parameters, qualitative in particular, should be consolidated, in order to facilitate their verification. Furthermore, as the producers' analysis of package acceptability could only be considered as partial, notably in view of the chosen mode of disposal, it will have to be carried out again on the basis of the next version of the preliminary acceptance specifications for *Cigéo*, which will be presented when the creation authorisation application for this facility is filed.

Checks and inspections

Alongside Andra's surveillance of approved packages, ASN checks the measures taken by the licensee to correctly implement the requirements of the authorisation and to master the packaging processes. For waste packages intended for disposal facilities still under study, ASN is particularly attentive to ensuring that the packages comply with the conditions of the issued packaging approvals.

ASN also ensures through inspections that Andra takes the necessary measures to verify the quality of the packages accepted in its disposal facilities. This is because ASN considers that Andra's role in the approvals issuing process and in monitoring the measures taken by the waste package producers is vital in guaranteeing package quality and compliance with the safety case of the waste repositories.

2.1.4 Developing recommendations for sustainable waste management

ASN issues opinions on the studies submitted under the PNGMDR. Between June 2020 and May 2021, ASN issued seven opinions on the radioactive material and waste management routes, for the preparation of the 5th PNGMDR. ASN also issued an opinion 2021-AV-0390 of 9 November 2021 on the draft 5th plan produced by the Ministry responsible for energy.

2.1.5 Developing the regulatory framework and issuing requirements to the licensees

ASN can issue regulations. Thus, the provisions of the Order of 7 February 2012 which concern the management of radioactive waste have been set out in the ASN resolutions mentioned earlier relative to waste management in BNIs and the packaging of waste. To give an example, the resolution of 23 March 2017 addresses the packaging of radioactive waste and the conditions of acceptance of the radioactive waste packages in the disposal BNIs. Its aim is to specify the safety requirements at the various stages of a management route. This resolution has been applicable since 1 July 2018. Moreover, to ensure a consistent approach to the management of waste in BNIs and DBNIs, ASN and ASND signed an agreement in January 2021 coordinating their actions in this area.

More broadly, ASN issues requirements relative to the management of waste coming from the BNIs.

ASN indicates certain waste management requirements in two guides: Guide No. 18 relative to the management of radioactive effluents and waste produced by a nuclear activity licensed under the Public Health Code, and Guide No. 23 relative to the BNI waste zoning plan (see points 1.2.1 and 1.2.2).

Lastly, ASN is consulted for its opinion on draft regulatory texts relative to radioactive waste management.

2.1.6 Evaluation of the nuclear financial costs

The regulatory framework designed to ring-fence the financing of nuclear facility decommissioning costs or, for radioactive waste disposal facilities, the final shutdown, maintenance and monitoring costs, in addition to the cost of managing spent fuel and radioactive waste, is described in chapter 13 (see point 1.4).

2.2 Periodic safety reviews of radioactive waste management facilities

BNI licensees, including for radioactive waste management facilities, carry out periodic safety reviews of their facilities in order to assess the situation of the facilities with respect to the rules applicable to them and to update the assessment of the risks or adverse effects, taking into account, more specifically, the state of the facility, the experience acquired during operation, and the development of knowledge and rules applicable to similar facilities. The diversity and frequently unique nature of each radioactive waste management facility lead ASN to adopt an examination procedure that is specific to each facility.

In this context, ASN is currently examining seven safety reviews of radioactive waste management facilities. They concern:
- two BNIs operated by the CEA: the treatment and packaging facility (BNI 35) on the Saclay site and the research and development facility Chicade (BNI 156) on the Cadarache site;
- one BNI operated by Orano: BNI 118, the waste treatment, packaging and waste package storage facility on the La Hague site;
- two BNIs operated by Andra: the Aube radioactive waste repository –CSA (BNI 149), and the Manche radioactive waste repository– CSM (BNI 66);
- one BNI operated by EDF: BNI 74 comprising the Saint-Laurent-des-Eaux storage silos;
- one BNI operated by Cyclife France: the Centraco facility for waste treatment by melting or incineration (BNI 160).

2.2.1 Periodic safety reviews of radioactive waste management support facilities

The periodic safety reviews of the oldest facilities such as BNIs 35, 74 and 118 present particular challenges. The Saint-Laurent-des-Eaux silos (BNI 74) present safety risks, particularly regarding their inventories. These safety reviews must address the control of the waste storage conditions, including legacy waste, the retrieval and packaging of this waste with a view to removal *via* the dedicated route and scheduled post-operational clean-out of the buildings. In relation with these challenges, the safety reviews must ensure that the impacts of discharges into the environment (soils, groundwater, or seawater in the case of BNI 118) are controlled.

For the most recent facilities, as is the case with Cedra and Chicade, the periodic safety reviews highlight more generic problems. The resistance of the buildings to internal and external hazards (earthquake, fire, lightning, flooding, aircraft crash) is one of the important aspects. ASN made its conclusions on the safety review of the Cedra storage facility known on 3 December 2021.

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 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, although they are at different stages of progress (the CSM review report was submitted in April 2019, whereas ASN is finalising the CSA report), 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.

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 cover which contributes to the final containment of the disposal concrete blocks. The durability of the CSM cover is, along with the preservation of the site memory for future generations, the predominant theme of the periodic safety review of a radioactive waste disposal facility.

Furthermore, 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 The CEA's waste management strategy and its assessment by ASN

Types of waste produced by the CEA

The CEA operates diverse types of facilities covering all the activities relating to the nuclear cycle: laboratories and plants associated with "fuel cycle" research, as well as experimental reactors.

The CEA also carries out numerous decommissioning operations.

Consequently, the types of waste produced by the CEA are varied and include more specifically:
- waste resulting from operation of the research facilities (protective garments, filters, metal parts and components, liquid waste, etc.);
- waste resulting from legacy waste retrieval and packaging operations (cement-, sodium-, magnesium- and mercury-bearing waste);

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- waste resulting from final shutdown and decommissioning of the facilities (graphite waste, rubble, contaminated soils, etc.).

The contamination spectrum of this waste is also wide with, in particular, the presence of alpha emitters in activities relating to fuel cycle research and beta-gamma emitters in operational waste from the experimental reactors.

The CEA has specific facilities for managing this waste (processing, packaging and storage). Some of them are shared between all the CEA centres, such as the liquid effluent treatment station in Marcoule or the solid waste treatment station in Cadarache.

The issues and implications

The main issues for the CEA with regard to radioactive waste management are:
- the renovation of existing facilities (BNI 37-A, for example) or commissioning of new facilities for the processing, packaging and storage of the effluents (Agate), 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 do not meet current safety requirements;
- the management of legacy waste retrieval and packaging projects.

ASN's examination of the CEA's waste management strategy

ASN's previous examination of the CEA's strategy, which was concluded in 2012, had shown that waste management had improved since the examination carried out in 1999. ASN nevertheless observed that certain aspects of the strategy could be consolidated, particularly with regard to the management of intermediate-level long-lived solid waste and low or intermediate-level liquid waste. Significant increases in the planned duration of the decommissioning operations declared by the CEA after the review conducted in 2012, as well as the quantity and the non-standard, poorly characterisable nature of certain substances or waste that will have to be removed or will be produced during the decommissioning operations, have led ASN, jointly with ASND, to ask the CEA to perform an overall review of its decommissioning and radioactive waste management strategy for the next 15 years. The CEA submitted the results of this work in December 2016. After examining this report, the two Authorities gave a joint opinion on this strategy in May 2019.

ASN and ASND consider that the CEA's facility decommissioning strategy and its updating of the waste and material management strategy are the result of an in-depth review and analysis. It appears acceptable for the CEA to envisage staggering the decommissioning operations in view of the resources allocated by the State and the large number of facilities undergoing decommissioning, for which waste retrieval and storage capacities will have to be built.

With regard to the material and waste management strategy, the two Authorities observe several vulnerabilities due in particular to the envisaged sharing of resources between centres, for the management of liquid radioactive effluents or solid radioactive waste for example, which means that for some operations, only a single facility will be available. The two Authorities also note uncertain-ties concerning the management of spent fuels or irradiated materials, which will have to be clarified.

ASN and ASND have therefore addressed several demands to the CEA with the aim of limiting these vulnerabilities, consolidating its strategy and detailing the operations schedule.

They demanded that the CEA make regular progress reports on the decommissioning and waste management projects, and ensure regular communication with the public, applying procedures appropriate to the nature of the facilities, civil or defence. ASN, ASND and the CEA have agreed to set up regular monitoring of these operations, through progress indicators in particular.

Monitoring implementation of the CEA waste management strategy

ASN has engaged regular interchanges with the DGEC, ASND and the CEA to reinforce progress monitoring on the priority projects. ASN has observed the difficulty the CEA has fully controlling the challenges associated with these projects, which must be carried out simultaneously and concern as much the management of the decommissioning operations as the operation of the waste management support facilities. ASN notes that the deadlines for a large number of priority projects have changed significantly since the file was submitted in 2016. It will therefore continue to be particularly attentive to the management and monitoring of these projects in 2022.

2.4 Orano's waste management strategy and its assessment by ASN

The spent fuel reprocessing plant at the La Hague site presents the main radioactive waste management issues for Orano. 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 mid-2016, Orano (formerly Areva) submitted to ASN and ASND a file presenting the decommissioning and waste management strategy for the group's installations in France and its practical application on the La Hague and Tricastin sites. This file was supplemented in 2017. Moreover, Orano submitted general and particular commitments for the La Hague and Tricastin sites in 2018. ASN has issued a position statement on this strategy (see "Notable events" in the introduction to this report). Furthermore, in order to verify Orano's ability to meet the deadlines indicated in its strategy, ASN has initiated an innovative procedure for inspecting the management of complex projects. In this context, in 2021 Orano proposed aids to facilitate ASN's monitoring of the progress of the major WRP projects on the La Hague site. The results are encouraging and ASN is going to continue this approach.

The issues and implications

The main issues relating to the management of waste produced by Orano concern in particular:
- The safety of the legacy waste storage facilities. On the La Hague site, the facilities dedicated to legacy waste retrieval, conditioning and storage have to be designed, built and then commissioned. These complex projects meet with technical difficulties which can make it necessary to adjust deadlines set by ASN (see chapter 13). In addition, the on-site storage capacities must be planned for with conservative margins in order to prevent them reaching saturation. The legacy waste stored on the Tricastin site necessitates a large amount of work to characterise it and find management solutions. The storage conditions in some of the Tricastin site facilities do not meet current safety requirements and must be improved.
- The defining of solutions for waste packaging, in particular the legacy waste. These solutions require the prior approval of ASN in accordance with Article 6.7 of the Order of 7 February 2012

(see point 2.2.2). Keeping control of the packaging deadlines is a particularly important aspect, which requires the development of characterisation programmes to demonstrate the feasibility of the chosen packaging processes and to identify sufficiently early the risks that could significantly affect the project. If necessary, when the feasibility of the defined packaging cannot be determined within times compatible with the prescribed deadlines, the licensee must plan for an alternative solution, including in particular interim storage areas allowing the retrieval and characterisation of the legacy waste as rapidly as possible. For information, Article L. 542-1-3 of the Environment Code requires that the ILW-LL waste produced before 2015 be packaged by the end of 2030 at the latest.

Within the framework of the WRP operations, Orano is examining packaging solutions that necessitate the development of new processes, particularly for the following ILW-LL waste:
- the radioactive sludge from the La Hague STE2 facility;
- the alpha-emitting technological waste which comes primarily from the La Hague and Melox plants (Gard *département*) and is not suitable for above-ground disposal.

For other types of ILW-LL waste resulting from the WRP operations, Orano is examining the possibility of adapting existing processes (compaction, cementation, vitrification). Some of the associated packaging baseline requirements are currently being examined by ASN.

2.5 EDF's waste management strategy and its assessment by ASN

The radioactive waste produced by EDF comes from several distinct activities. It mainly comprises waste from the operation of the NPPs, which consists of activated waste from the reactor cores, and waste from their operation and maintenance. Some legacy waste and waste resulting from ongoing decommissioning operations can be added to this. EDF is also the owner, for the share attributed to it, of HLW and ILW-LL waste resulting from spent fuel reprocessing in the Orano La Hague plan.

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. Lastly, the treatment of the spent Fuel Cluster Guide Tubes (TGG[9]) from the EDF fleet (about 2,000) could be carried out by Cyclife France in the Centraco facility. The various license applications relative to this project are currently being examined by ASN.

The issues and implications

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 graphite-moderated GCR fuels. This waste could be disposed of in a repository for LLW-LL waste (see point 1.3.4). It is stored primarily in semi-buried silos at Saint-Laurent-des-Eaux. Graphite waste is also present in the form of stacks in the GCRs currently being decommissioned. In the context of the PNGMDR 2016-2018, EDF conducted a study of the reliability of the activity predictions for this waste and submitted its conclusions in December 2019. This report is being examined by ASN.
- The changes linked to the "fuel cycle". EDF's fuel use policy (see chapter 10) has consequences for the fuel cycle installations (see chapter 11) and for the quantity and nature of the waste produced. ASN issued an opinion on the coherence of the "nuclear fuel cycle" in October 2018 (see chapter 11).

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 distributed among 17 disposal sites. These sites are ICPEs and their environmental impact is monitored.

Redevelopment of the uranium processing tailings disposal sites consisted notably in placing a solid cover over the tailings to provide a geochemical and radiological protective barrier to limit the risks of intrusion, erosion, dispersion of the stored products and the risks of external and internal exposure of the neighbouring populations.

The regulatory context

The uranium mines, their annexes and their conditions of closure are covered by the Mining Code. The disposal facilities for radioactive mining tailings are governed by section 1735 of the ICPE classification system. The mines and the mine tailings disposal sites are not subject to ASN oversight.

In the specific case of the former uranium mines, an action plan was defined by Circular 2009-132 of 22 July 2009 of the Minister responsible for the environment and the Chairman of ASN, along the following work lines:
- monitor the former mining sites;

9. The Fuel Cluster Guide Tubes (TGGs), currently stored in the pools of the NPPs, guide the control rod clusters inside the reactors These parts are significantly activated, especially in their bottom section. EDF considers the removed TGGs to be radioactive waste, to be processed via dedicated disposal or treatment routes.

- improve the understanding of the environmental and health impact of the former uranium mines and their monitoring;
- manage the mining waste rock (better identify the uses and reduce impacts if necessary);
- reinforce information and consultation.

PNGMDR: The long-term behaviour of the sites

The studies submitted for the PNGMDR since 2003 have enhanced knowledge of:

- the dosimetric impact of the mine tailing disposal areas on man and the environment, in particular through the comparison of data obtained from monitoring and the results of modelling;
- the evaluation of the long-term dosimetric impact of the waste rock stockpiles and waste rock in the public domain in relation to the results obtained in context of the Circular of 22 July 2009;
- the strategy chosen for the changes in the treatment of water collected from former mining sites;
- the relation between the discharged flows and the accumulation of marked sediments in the rivers and lakes;
- the methodology for assessing the long-term integrity of the embankments surrounding tailings disposal sites;
- transport of uranium from the waste rock piles to the environment;
- the mechanisms governing the mobility of uranium and radium within uranium-bearing mining tailings.

Further to ASN opinion 2016-AV-0255 of 9 February 2016, and in the context of the PNGMDR 2016-2018, Orano submitted 11 studies between January 2017 and February 2020 to supplement the studies submitted prior to this. Based on this, ASN issued an opinion on 4 February 2021 to review the situation on these subjects.

Consequently, ASN opinion 2021-AV-0374 of 4 February 2021 specifies the studies still to be carried out to meet the challenges associated with the former mining sites and reiterated above. These studies may lead to the performance of work such as removal of the mining tailings from public land, reinforcement of the structures encircling the disposal sites, and improving preservation of the memory. This opinion also recommends continuing the work of the two technical working groups concerning:

- Maintaining the functions of the structures encircling the uranium ore treatment residue disposal areas. The interim report was published on the ASN website. The work continued in 2021 and the final report on maintaining the functions of the structures encircling the uranium ore treatment residue disposal areas should be published in 2022. The subsequent publication of a methodological guide for assessing the stability of this type of structure could be envisaged.
- Management of the water from the former uranium mining sites. The interim report was published on the ASN website. In 2021, the dedicated technical working group continued development of the multi-criteria multi-player analysis methodology, and tested it on a site.

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). It is planned to launch the group in 2022.

The draft PNGMDR 2021-2025 provides for the continuation of these actions concerning the long-term environmental and health impact of the management of the former uranium mines. It will result in the defining of a detailed work programme in 2022. This programme will more specifically take into account the three new studies on the stability of the structures of the three sites situated in the Haute-Vienne *département* (Brugeaud, Lavaugrasse and Montmassacrot), submitted by Orano in October 2021, and the study on sediments submitted in January 2022.

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.

Article L.125-6 of the Environment Code provides for the State to create soil information sectors in the light of the information at its disposal. These sectors must comprise land areas in which the knowledge of soil contamination justifies –particularly in the case of change of use– carrying out soil analyses and taking contamination management measures to preserve safety, public health and the environment. Decree 2015-1353 of 26 October 2015 defines the conditions of application of these measures.

The Regional Directorates for the Environment, Land Planning and Housing (Dreals) coordinate the soil information sector development process under the authority of the Prefects. The ASN regional divisions contribute to the process by informing the Dreals of the sites they know to be contaminated by radioactive substances. The soil information sector development process is progressive and is not intended to be exhaustive. Ultimately these sites are to be registered in the urban planning documents.

Several inventories of contaminated sites are available to the public and are complementary: Andra's National Inventory, which is updated every three years and comprises the sites identified as contaminated by radioactive substances (the 2018 edition is available on *andra.fr*) and the databases of the Ministry responsible for the environment dedicated to contaminated sites and soils.

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 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 improve 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.

ASN considers moreover that the stakeholders and audiences concerned must be involved as early as possible in the process to rehabilitate a site contaminated by radioactive substances.

In application of the "polluter pays" principle written into the Environment Code, those responsible for the contamination finance the operations to rehabilitate the contaminated site and to remove the waste resulting from these operations. If the responsible entities default, Andra, on account of its public service remit and by public requisition, ensures the rehabilitation of radioactive contaminated sites.

In cases where contaminated sites and soils have no known responsible entity, the State finances their clean-up through a public subsidy provided for in Article L. 542-12-1 of the Environment Code. The French National Funding Commission for Radioactive Matters (CNAR) gives opinions on the utilisation of this subsidy, as much with respect to fund allocation priorities as to polluted site treatment strategies and the principles of assisted collection of waste.

Under Article D. 542-15 of the Environment Code, the CNAR comprises:
- "members by right": representatives of the Ministries responsible for the environment and energy, of Andra, the French Environment and Energy Management Agency (Ademe), IRSN, the CEA, ASN and the Association of Mayors of France;
- members mandated for four years by the Ministries responsible for energy, nuclear safety and radiation protection (the CNAR chair, two representatives of environmental associations and one representative of a public land management corporation).

By order of 21 March 2019, the mandated members have been appointed to the CNAR. The Commission met four times in 2021, focusing in particular on the files concerning the retrieval of radioactive objects held by private individuals, the management of contaminated sites and the management of soils from the remediation of legacy sites, such as the soils from the Bayard factory.

When contamination is caused by an installation that is subject to special policing (BNI, ICPE or nuclear activity governed by the Public Health Code), the sites are managed under the same oversight system. Otherwise, the Prefect oversees the measures taken regarding management of the contaminated site.

With regard to the management of radioactive contaminated sites coming under the ICPE system and the Public Health Code, when the responsible entity is solvent or defaulting, the Prefect uses the opinions of the classified installations inspectorate, of ASN and the Regional Health Agency (ARS) to validate the site rehabilitation project and supervises the implementation of the rehabilitation measures by Prefectural Order. ASN may thus be called upon by the services of the Prefect and the classified installation inspectors to give its opinion on the clean-out objectives of a site.

APPENDIX

Overview of Basic Nuclear Installations

as at 31 December 2021

To regulate all civil nuclear activities and installations in France, the French Nuclear Safety Authority (ASN) has set up a regional organisation comprising 11 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 Basic Nuclear Installation (BNI) regulation in the Bretagne (Brittany) and Île-de-France regions respectively. The Paris division oversees the overseas regions and the *département*[1] of Mayotte, while the Marseille division oversees radiation protection and radioactive substance transport in the Corse collectivity.

A Basic Nuclear Installation (BNI) is an installation which, due to its nature or the quantity or activity of the radioactive substances it contains, is subject to a specific regulatory system as defined by the Environment Code (Title IX of Book V). These installations must be authorised by decree issued following a public inquiry and an ASN opinion. Their design, construction, operation and decommissioning are all regulated.

The following are BNIs:
1. nuclear reactors;
2. large installations for the preparation, enrichment, fabrication, treatment or storage of nuclear fuels or 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 the possible future deep geological repositories for radioactive waste, which are all BNIs, Section 1 entitled “Nomenclature of Basic Nuclear Installations” of Chapter III of Title IX of Book V of the Environment Code sets the threshold for entry into the BNI System for each category.

For technical or legal reasons, the concept of a BNI can cover a number of different physical situations: for example in a Nuclear Power Plant (NPP), each reactor may be considered as a separate BNI, or a given BNI might in fact comprise two reactors. Similarly, a “fuel cycle” plant or a French Alternative Energies and Atomic Energy Commission (CEA) centre can comprise several BNIs. These different configurations do not alter the regulatory conditions in any way.

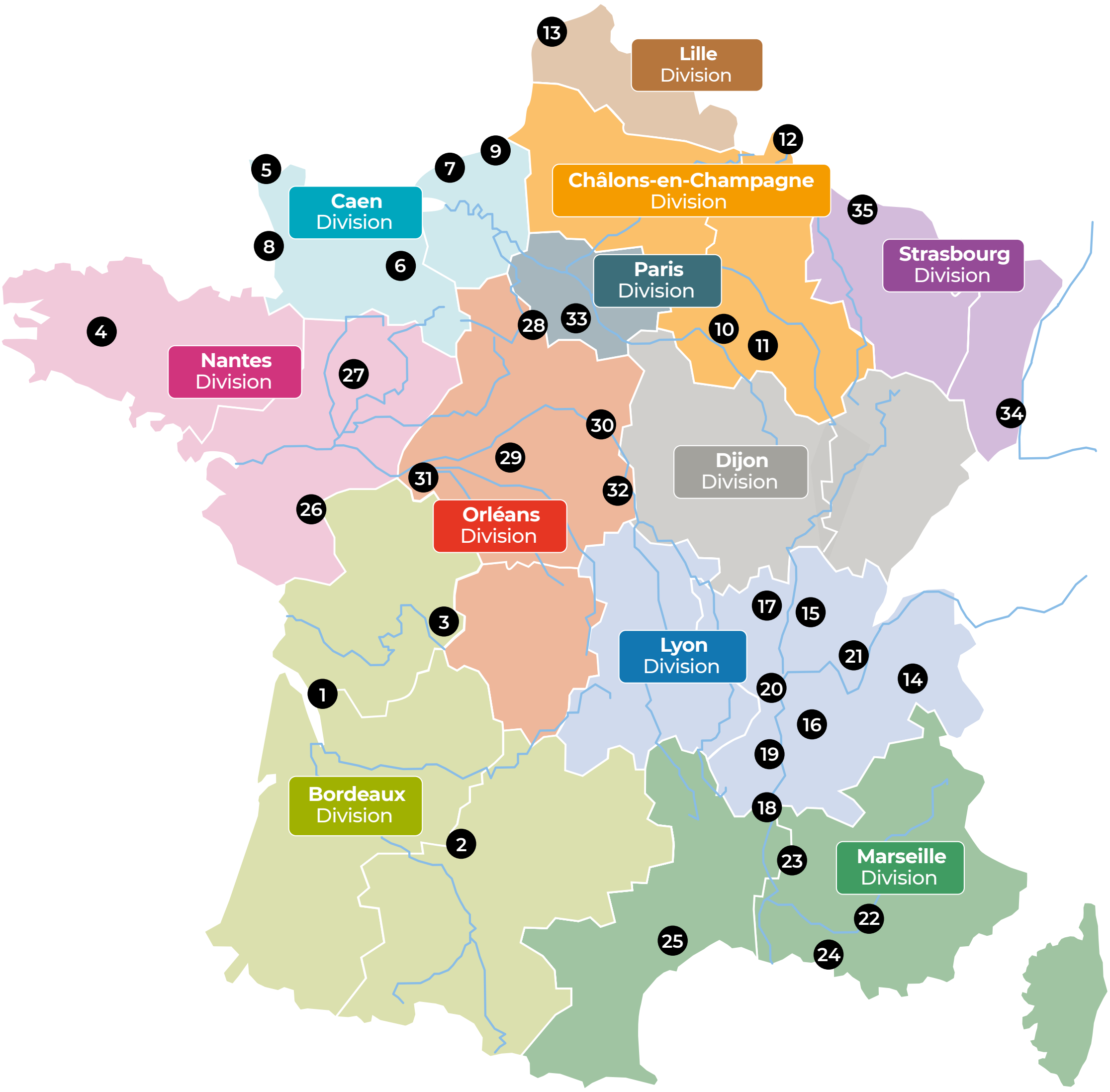
The following are subject to the BNI System:
- facilities under construction, provided that they are the subject of a Creation Authorisation Decree;
- facilities in operation;
- facilities shut down or undergoing decommissioning, until they are delicensed by ASN.

As at 31 December 2021, there were 123 BNIs (legal entities).

The notified BNIs are those which existed prior to the publication of Decree 63-1228 of 11 December 1963 concerning nuclear facilities and for which neither said Decree nor the Environment Code required authorisation but simply 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 facilities that figured in previous issues of the list, but which no longer constitute BNIs further to their delicensing (see chapter 13) or their licensing as new BNIs (for example, as a result of the combination of BNIs 63 and 98 into one only INB 63-U, numbers 63 and 98 have been removed from the list and number 63-U was created).

1. *Administrative region headed by a Prefect.*



Sites regulated by the ASN regional divisions

BORDEAUX

1. Blayais
2. Golfech
3. Civaux

CAEN

4. Brennilis
5. La Hague
6. Caen
7. Paluel
8. Flamanville
9. Penly

CHÂLONS-EN-CHAMPAGNE

10. Nogent-sur-Seine
11. Soulaines-Dhuys
12. Chooz

LILLE

13. Gravelines

LYON

14. Grenoble
15. Bugey
16. Romans-sur-Isère
17. Dagneux
18. Tricastin
19. Cruas-Meysse
20. Saint-Alban
21. Creys-Malville

MARSEILLE

22. Cadarache
23. Marcoule
24. Marseille
25. Malvési

NANTES

26. Pouzauges
27. Sablé-sur-Sarthe

ORLÉANS

28. Saclay
29. Saint-Laurent-des-Eaux
30. Dampierre-en-Burly
31. Chinon
32. Belleville-sur-Loire
33. Fontenay-aux-Roses

PARIS

The Orléans division is responsible for BNI regulation of the Île-de-France region.

STRASBOURG

34. Fessenheim
35. Cattenom

Types of installation

Nuclear Power Plant · Factory · Research installations · Disposal of Waste · Others

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
BORDEAUX DIVISION				
1 Blayais	BLAYAIS NUCLEAR POWER PLANT (reactors 1 and 2) 33820 Saint-Ciers-sur-Gironde (Gironde)	EDF	Reactors	86
1 Blayais	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-and-Garonne)	EDF	Reactor	135
2 Golfech	GOLFECH NUCLEAR POWER PLANT (reactor 2) 82400 Golfech (Tarn-and-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	EFFLUENT AND SOLID WASTE TREATMENT STATION (STE2) AND SPENT NUCLEAR FUELS REPROCESSING FACILITY (AT1) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	38
5 La Hague	ELAN IIB FACILITY 50100 Cherbourg (Manche)	Orano Recyclage	Transformation of radioactive substances	47
5 La Hague	MANCHE WASTE REPOSITORY (CSM) 50440 Digulleville (Manche)	Andra	Disposal of radioactive substances	66
5 La Hague	HIGH LEVEL OXIDE (HAO) FACILITY 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	80
5 La Hague	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP3 A) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	116
5 La Hague	REPROCESSING PLANT FOR SPENT FUEL ELEMENTS FROM LIGHT WATER REACTORS (UP2-800) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	117
5 La Hague	LIQUID EFFLUENT AND SOLID WASTE TREATMENT STATION (STE3) 50107 Cherbourg Cedex (Manche)	Orano Recyclage	Transformation of radioactive substances	118
6 Caen	NATIONAL LARGE 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 WASTE REPOSITORY (CSA) 10200 Bar-sur-Aube (Aube)	Andra	Radioactive waste surface repository	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	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
LILLE DIVISION				
13 Gravelines	GRAVELINES NUCLEAR POWER PLANTS (reactors 1 and 2) 59820 Gravelines (Nord)	EDF	Reactors	96
13 Gravelines	GRAVELINES NUCLEAR POWER PLANTS (reactors 3 and 4) 59820 Gravelines (Nord)	EDF	Reactors	97
13 Gravelines	GRAVELINES NUCLEAR POWER PLANTS (reactors 5 and 6) 59820 Gravelines (Nord)	EDF	Reactors	122
LYON DIVISION				
14 Grenoble	EFFLUENT AND SOLID WASTE TREATMENT STATION (STED) 38041 Grenoble Cedex (Isère)	CEA	Transformation of radioactive substances	36
14 Grenoble	HIGH FLUX REACTOR (RHF) 38041 Grenoble Cedex (Isère)	Institut Max Von Laue Paul Langevin (ILL)	Reactor	67
14 Grenoble	DECAY INTERIM STORAGE FACILITY (STD) 38041 Grenoble Cedex (Isère)	CEA	Storage of radioactive substances	79
15 Bugey	BUGEY NUCLEAR POWER PLANT (reactor 1) BP 60120 - 01150 Saint-Vulbas (Ain)	EDF	Reactor	45
15 Bugey	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 WAREHOUSE (MIR) BP 60120 - 01150 Saint-Vulbas (Ain)	EDF	Storage of new fuel	102
15 Bugey	ACTIVATED WASTE PACKAGING AND STORAGE INSTALLATION (ICEDA) 01150 Saint-Vulbas (Ain)	EDF	Packaging and interim storage of radioactive substances	173
16 Romans -sur-Isère	NUCLEAR FUELS FABRICATION UNIT 26104 Romans-sur-Isère Cedex (Drôme)	Framatome	Fabrication of fuels for NPPs	63-U
17 Dagneux	DAGNEUX IONISATION PLANT 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 URANIUM ISOTOPE SEPARATION BY GASEOUS DIFFUSION (EURODIF) 26702 Pierrelatte Cedex (Drôme and Vaucluse)	Orano Chimie-Enrichissement	Transformation of radioactive substances	93
18 Tricastin	URANIUM HEXAFLUORIDE PREPARATION PLANT (COMURHEX) 26130 Saint-Paul-Trois-Châteaux (Drôme)	Orano Chimie-Enrichissement	Transformation of radioactive substances	105
18 Tricastin	URANIUM CLEAN-UP AND RECOVERY FACILITY (IARU) 26130 Saint-Paul-Trois-Châteaux (Drôme and Vaucluse)	Orano Chimie-Enrichissement	Factory	138
18 Tricastin	TU5 AND W FACILITIES 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 CENTRIFUGAL SEPARATION OF URANIUM ISOTOPES (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 LABORATORY (ATLAS) 26700 Pierrelatte (Drôme)	Orano Chimie-Enrichissement	Laboratory for the utilisation of radioactive substances	176
18 Tricastin	TRICASTIN URANIUM-BEARING MATERIAL STORAGE YARD 26700 Pierrelatte (Drôme)	Orano Chimie-Enrichissement	Storage of radioactive substances	178
18 Tricastin	P35 26700 Pierrelatte (Drôme)	Orano Chimie-Enrichissement	Storage of radioactive substances	179
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	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
MARSEILLE DIVISION				
22 Cadarache	TEMPORARY DISPOSAL FACILITY (PEGASE) AND SPENT NUCLEAR FUEL DRY STORAGE INSTALLATION (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	Fabrication or transformation of radioactive substances	32
22 Cadarache	SOLID WASTE TREATMENT STATION (STD) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Transformation of radioactive substances	37-A
22 Cadarache	EFFLUENT TREATMENT STATION (STE) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Transformation of radioactive substances	37-B
22 Cadarache	MASURCA 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	39
22 Cadarache	ÉOLE 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	42
22 Cadarache	ENRICHED URANIUM PROCESSING FACILITY (ATUe) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Fabrication of radioactive substances	52
22 Cadarache	ENRICHED URANIUM AND PLUTONIUM WAREHOUSE (MCMF) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Storage 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 REPROCESSING, CLEAN-OUT AND REPACKAGING STATION (STAR) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Utilisation of radioactive substances	55
22 Cadarache	SOLID RADIOACTIVE WASTE STORAGE YARD 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Storage of radioactive substances	56
22 Cadarache	PHÉBUS 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	92
22 Cadarache	MINERVE 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	95
22 Cadarache	LABORATORY FOR RESEARCH AND EXPERIMENTAL FABRICATION OF ADVANCED NUCLEAR FUELS (LEFCA) 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	CEA	Fabrication 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	Packaging and interim storage of radioactive substances	164
22 Cadarache	MAGENTA 13115 Saint-Paul-lez Durance Cedex (Bouches-du-Rhône)	CEA	Reception and shipment of nuclear materials	169
22 Cadarache	EFFLUENT ADVANCED MANAGEMENT AND PROCESSING FACILITY (AGATE) 13115 Saint-Paul-lez Durance Cedex (Bouches-du-Rhône)	CEA	Packaging and interim storage of radioactive substances	171
22 Cadarache	JULES HOROWITZ REACTOR (RJH) 13115 Saint-Paul-lez Durance Cedex (Bouches-du-Rhône)	CEA	Reactor	172
22 Cadarache	ITER 13115 Saint-Paul-lez-Durance Cedex (Bouches-du-Rhône)	Organisation internationale ITER	Nuclear fusion reaction experiments with tritium and deuterium and deuterium plasmas	174
23 Marcoule	PHÉNIX 30205 Bagnols-sur-Cèze Cedex (Gard)	CEA	Reactor	71
23 Marcoule	ATALANTE 30200 Chusclan (Gard)	CEA	Research and development laboratory and study of actinides production	148
23 Marcoule	NUCLEAR FUELS FABRICATION PLANT (MELOX) BP 2 - 30200 Chusclan (Gard)	Orano Recyclage	Fabrication of radioactive substances	151
23 Marcoule	CENTRACO 30200 Codolet (Gard)	Cyclife France	Radioactive waste and effluent processing	160
23 Marcoule	GAMMATEC 30200 Chusclan (Gard)	Synergy Health Marseille	Ionisation treatment of materials, products and equipment, for industrial purposes and for research and development	170
23 Marcoule	DIADEM 30200 Chusclan (Gard)	CEA	Storage of solid radioactive waste	177
24 Marseille	GAMMASTER IONISATION PLANT M.I.N. 712 - 13323 Marseille Cedex 14 (Bouches-du-Rhône)	Synergy Health Marseille	Ionisation installation	147
25 Malvési	CONTAINED STORAGE OF CONVERSION RESIDUES (ÉCRIN) 11100 Narbonne (Aude)	Orano Chimie-Enrichissement	Storage of radioactive substances	175

SITE NAME	NAME AND LOCATION OF THE INSTALLATION	LICENSEE	TYPE OF INSTALLATION	BNI
NANTES DIVISION				
26 Pouzauges	POUZAUGES IONISATION PLANT Z.I. de Monlifant 85700 Pouzauges (Vendée)	Ionisos	Ionisation installation	146
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