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## 1 CHECKING THAT THE LICENSEE ASSUMES ITS RESPONSIBILITIES

### 1 | 1 Checking compliance with the requirements of the regulations: a fundamental role

Regulation of nuclear activities is ASN's fundamental role. This regulation consists in checking that any party responsible for a nuclear activity assumes full responsibility for it and complies with the requirements of the regulations with regard to nuclear safety and radiation protection. It makes a contribution to assessing the performance of a licensee and enables the stakes associated with a nuclear activity to be estimated.

### 1 | 2 The principles underpinning the regulatory role

ASN aims to ensure that the principle of responsibility of the licensee for safety and radiation protection is respected.

ASN includes the concept of proportionality when determining its actions, so that the scope and extent of the inspection is commensurate with the health and environmental safety issues.

Regulation by ASN is part of a multi-level approach and is carried out with the support of the Institute for Radiation Protection and Nuclear Safety (IRSN):

- before the licensee performs an activity requiring licensing, through a review and analysis of files, documents and information provided by the licensee to back up its actions. This regulation aims to ensure that the information supplied is both relevant and sufficient;
- during operation, by means of visits, inspections on all or part of the installation, checks on documents, field checks during work involving high stakes, such as scheduled nuclear reactor outages, and the analysis of significant events. This regulation comprises sampling and the analysis of justifications provided by the licensee with regard to the performance of its activities.

To consolidate the effectiveness and quality of its actions, ASN is adopting an approach involving continuous improvement of its regulatory practices. It analyses operating experience feedback from more than thirty years of nuclear safety inspections, from observation of practices in the small-scale nuclear sector over the past five years, and from observation of the inspection methods used by the main foreign regulatory authorities.

### 1 | 3 Regulating nuclear activities: a vast area

Pursuant to Article 4 of the TSN Act, ASN regulates compliance with the general rules and particular requirements of nuclear safety and radiation protection, applicable to:

- licensees of basic nuclear installations (BNIs);
- those in charge of the construction and operation of pressure vessels in BNIs;
- those in charge of radioactive material transport;
- those in charge of activities entailing a risk of exposure of individuals and workers to ionising radiations;
- those in charge of implementing ionising radiation exposure surveillance measures;
- the organisations and laboratories it approves, to enable them to take part in nuclear safety and radiation protection checks and surveillance.

In this chapter, these entities are called the “licensees”.

Although historically based on verifying the technical conformity of installations and activities with regulations or standards, regulation today also covers a broader field incorporating human and organisational factors. It takes account of individual and collective behaviour and attitudes, management, organisation and procedures, relying on a variety of sources: significant events, inspections, relations with the stakeholders (personnel, licensees, contractors, trade unions, occupational physicians, inspection services, approved organisations, and so on).

#### 1 | 3 | 1 Regulating nuclear safety in BNIs and radioactive material transport

IAEA defined the following principles in its safety fundamentals for nuclear installations (Safety Series No. 110):

- responsibility for safety must lie with the licensee organisation;
- the regulatory body must be effectively independent of the organisation in charge of promoting or using nuclear energy. It must have responsibility for licensing, inspection, and formal notices, 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 provisions of the TSN Act mean that ASN is the regulatory body meeting these criteria.

##### a) Regulating nuclear safety

Nuclear safety covers all technical and organisational measures taken at all stages in the life of nuclear installations

(design, creation, commissioning, operation, final shut-down, decommissioning) to guarantee normal operation, prevent or mitigate the effects of accidents in order to protect the workers, the population and the environment against the effects of ionising radiations. It also comprises technical measures to optimise management of waste and radioactive discharges.

BNI safety is guaranteed by a series of strong, leaktight barriers, for which the safety case must demonstrate the effectiveness in normal and accident conditions. There are generally 3 of them. For power reactors, there is the fuel cladding, the reactor coolant system boundary, the reactor building containment and possibly the secondary containment.

The safety of radioactive material transport (TMR)<sup>1</sup> is guaranteed by three main factors:

- first and foremost, the engineered robustness of the packages;
- transport reliability and certain specially equipped vehicles;
- an effective emergency response in the event of an accident.

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 safety or the monitoring and limitation of the doses received by the individuals working in the installations, and the waste management, effluents discharge control and environmental protection procedures.

### *b) Regulating pressure vessels*

Numerous systems in nuclear installations contain or carry pressurised fluids. They are therefore subject to pressure vessel regulations (see chapter 3, point 2|2|1).

The June 2006 Act states that ASN “monitors compliance with the general rules and special prescriptions as regards nuclear safety and radiation protection to which are subject [...] the manufacture and use of pressurised equipment specially designed for these installations”. ASN is responsible for checking implementation of the regulations concerning nuclear pressure vessels containing radioactive products in BNIs, while for other pressure vessels, this is the responsibility of the General Directorate for the Prevention of Risks (DGPR) at the Ministry for Ecology, Energy, Sustainable Development and Spatial Planning. However, so that BNI licensees only have to

deal with a single point of contact, ASN in practice checks that the regulations are implemented for all BNI pressure vessels.

Of the BNI pressure vessels regulated by ASN, the main primary and secondary systems of EDF’s PWRs are particularly important. Since under normal conditions they operate at high temperature and pressure, their in-service behaviour is one of the keys to nuclear power plant safety (see chapter 12, point 1|1|3). ASN regulation of these systems is consequently particularly thorough.

Pressure vessel operation is regulated. This regulation in particular applies to the in-service surveillance programmes, non-destructive testing, maintenance work, disposition of nonconformities affecting the systems and periodic post-maintenance testing of the systems. The principal PWR files currently being dealt with are discussed below in chapter 12.

## **1 | 3 | 2 Regulating working conditions in nuclear power plants**

In nuclear power plants, the regulation of nuclear safety, radiation protection and the conventional safety inspection aspects sometimes covers common topics, such as worksite organisation or the conditions in which subcontractors are called in. The legislator therefore assigned conventional safety inspector duties to engineers or technicians specifically designated for this purpose by ASN from among its staff (Article R. 8111-11 of the Labour Code).

There is nothing new in having the conventional safety inspection duties in nuclear power plants carried out by a technical inspectorate separate from the ordinary labour inspectorate. This role previously lay with the officers designated by the DRIREs, who could also intervene in facilities or works which were regulated by the Ministry responsible for energy, such as dams or electricity transmission lines. Only the staff designated by decision of the ASN Chairman can now perform these duties in nuclear power plants. They operate under the authority of the minister responsible for labour.

On top of the “traditional” issues aimed at improving health and safety at work and improving the conditions of work by contractors, there are now a number of new topics, such as the growth in dismantling operations or the need for greater understanding of organisational and human factors in risk management.

1. Transport comprises all operations and conditions associated with radioactive material movements, such as packaging design, manufacture, maintenance and repair, as well as the preparation, shipment, loading, carriage, including transit storage, unloading and reception at the final destination of radioactive material consignments and packages.

Owing to this change, ASN carried out a review of the principles of a long-term organisation which should clarify the methods for controlling and supporting a network of officers responsible for inspection, the qualification criteria of these officers, how their skills are acquired and sustained, the relations to be maintained with the other safety stakeholders and an evaluation of the human resources required to carry out these duties.

The review conducted in 2007 identified six key issues linked to the conventional safety inspection role in nuclear power plants:

1. exercise closer regulation of contractor working conditions and of EDF's surveillance of the activities subcontracted;
2. deal with the growing problems of dismantling/construction;
3. take full account of organisational and human factors;
4. encourage EDF to include the goal of security in addition to safety and radiation protection;
5. ensure effective and uniform application nationwide of the Labour Code and collective agreements;
6. ensure the credibility of ASN's expanded conventional safety inspection role.

ASN implemented changes to its organisation in order to clarify:

- the status of the ASN officers tasked with conventional safety inspection duties and their scope of intervention, in particular with regard to Convention 81 of the International Labour Organisation. According to this convention, “conventional safety inspection shall be placed under the supervision and control of a central authority. The inspection staff shall be composed of public officials whose status and conditions of service are such that they are assured of stability of employment and are independent of changes of government and of improper external influences”;
- the role and duties of the officers in charge of conventional safety inspection in the nuclear power plants;
- relations with the State's other departments concerned, including:
  - the labour unit, both centrally (General Directorate for Labour) and regionally with the DR/DDTEFP (Regional/Departmental Directorates for Labour, Employment and Professional Training) for definition of subjects with high stakes, scientific, technical and methodological support, the available powers in terms of appeal or coordination, contractor networking, etc.;
  - the regional health insurance funds (CRAM) for technical appraisal, recommendations, inquiries into health and safety conditions, etc.;
  - the professional organisation for prevention in the building and public works sectors (OPPBTP) to promote the prevention of work accidents and occupational diseases, as well as to improve working

conditions of building and public works contractors, in particular for dismantling and construction activities;

- the Directorate for Energy for statutory and social issues concerning companies and organisations involved in providing the public gas and electricity service.

Finally, in the other BNIs for which ASN does not exercise the conventional safety inspection role, exchanges with the ordinary labour inspectors constitute a valuable source of information about the state of labour relations, as part of a more general view of nuclear safety and radiation protection that takes greater account of the importance of human and organisational factors.

In 2008, ASN devoted particular efforts to clarifying the working methods of its officers performing conventional safety duties, in particular the interfaces with the Ministry for Labour and its regional offices. A joint working group was set up on this subject jointly by the General Directorate for Labour and ASN. One of its main aims is to update the DAGEMO circular of 23 November 2005.

### 1 | 3 | 3 Regulating activities involving a risk of exposure to ionising radiations (referred to as small-scale nuclear activities)

The international fundamental standards for protection against ionising radiations and the safety of radioactive sources issued by the IAEA define the general functions of the regulatory body.

In France, ASN performs this role of regulatory body, through its duty of drafting and monitoring technical regulations in the field of radiation protection (see chapter 3, point 1).

The scope of ASN radiation protection regulation covers the use of ionising radiations in all activities. This duty is exercised jointly with other inspectorates, such as the conventional safety inspectorate, the inspectorate for installations classified on environmental protection grounds, the departments of the ministry responsible for health and the French Health Products Safety Agency (AFSSAPS).

As required by the IAEA basic safety standard, ASN regulation takes the form of review of files, pre-commissioning visits, inspections and finally discussions with professional organisations (trade unions, professional orders, learned societies, etc.). This action directly concerns either the users of ionising radiations, or organisations approved to carry out technical inspections on these users. These actions are summarised in the following table:

Table 1: Methods of ASN regulation of the various radiation protection players

	Review/authorisation	Inspection	Openness and cooperation
Users of ionising radiations	Files produced in accordance with the procedures laid down in the Public Health Code (Articles R. 1333-1 to R. 1333-54).  Review of the file and visit prior to commissioning.  Leads to registration of the declaration or to issue of an authorisation.	Radiation protection inspectorate (Article L. 1333-17 of the Public Health Code).	Jointly with the professional organisations, drafting of a guide of good practices for users of ionising radiations.
Organisations approved for radiation protection inspections	Application file for approval to perform the inspections specified in Article R. 1333-95 of the Public Health Code and Articles R. 4452-12 to R. 4452-17 of the Labour Code.  Review of the file and audit of the organisation.  Leads to issue of approval. (10 approvals issued in 2008, 49 organisations approved as at 31.12.2008).	Second level inspection through: – audits, – in-depth inspections at head office and in the branches of the organisations, – unannounced field inspections.	Jointly with the professional organisations, drafting of guides of good practices for performance of radiation protection inspections.

## 2 REGULATION THAT IS PROPORTIONATE TO THE ISSUES INVOLVED IN THE ACTIVITIES

The licensee remains the key player in the regulation of its activities. ASN organises its regulatory work in a way that is proportionate to the stakes involved in the activities. The performance of certain inspections by organisations and laboratories offering the necessary guarantees and validated by ASN approval, contributes to this action.

### 2 | 1 Deploying the principle of licensee responsibility

The licensee is responsible for the activities it performs. The regulation carried out by ASN in no way relieves it of the duty to supervise and check its own activities.

#### 2 | 1 | 1 Operations subject to enhanced internal supervision by the licensee

With regard to certain operations that are sensitive from the nuclear safety and radiation protection viewpoints, ASN wanted the licensees to apply a system of reinforced and systematic internal checks, called the “internal authorisations system”, offering sufficient guarantees of quality,

independence and transparency. This system could be applied to operations which do not compromise the safety cases adopted for BNI operation or decommissioning. The decision on whether or not to carry out the operations concerned must be formally authorised by the qualified members of the licensee’s staff.

The “internal authorisations” system implemented at EDF and CEA in recent years now falls within the scope of Article 27 of decree 2007-1557 of 2 November 2007 concerning basic nuclear installations and the regulation of the nuclear safety aspects of radioactive material transport. Before it is implemented, this system must be approved by an ASN decision, in accordance with ASN decision 2008-DC-106 of 11 July 2008 concerning the implementation of the internal authorisations system in basic nuclear installations (see chapter 3, point 2 | 2 | 3).

ASN checks correct application of the “internal authorisations system” by various means: inspections, review of the periodic reports forwarded by the licensees, cross-checking of the files, etc. It can at all times either terminate or temporarily suspend an “internal authorisations

system” if it considers it to be unsatisfactorily implemented, in which case the corresponding operations must be referred to ASN for prior authorisation.

## 2 | 1 | 2 Internal regulation of radiation protection by the users of ionising radiations

The aim of internal regulation of radiation protection is to ensure regular assessment of the radiological safety of the installations using sources of ionising radiations. This regulation is performed under the responsibility of the licensees. It may be carried out by the person with competence for radiation protection (PCR), appointed and mandated by the employer, or be entrusted to IRSN or to organisations approved by ASN. It does not replace either the periodic checks required by the regulations, or the inspections conducted by ASN. It for example concerns the performance of the protection systems, monitoring of the ambient atmosphere in regulated zones, or checks on medical appliances before they enter service or after modification.

## 2 | 2 Expanding regulation through the approval of organisations and laboratories

Paragraph 2 of Article 4 of the TSN Act states that ASN issues the required approvals to the organisations taking part in the inspection and surveillance of nuclear safety or radiation protection. Depending on the health or safety stakes involved in a nuclear activity or installation category, ASN may call on the services of approved organisations for all or part of its regulatory work. The purpose of these approvals is to be able to perform surveillance on a larger number of entities than would be possible through the ASN staffing resources alone.

ASN thus approves organisations for carrying out technical inspections required by the regulations in the fields within its scope of competence. The organisations approved in this way thus carry out:

- radiation protection checks;
- measurement of radon activity concentration in premises open to the public;
- evaluations of nuclear pressure vessel conformity and inspection of operational equipment.

The checks carried out by these organisations contribute to ASN’s overview of all nuclear activities.

In order to approve those organisations which apply, 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 maximum benefit is gained from the approval issued, in particular through regular exchanges with the organisations it has approved and the mandatory transmission of an annual report, in order to:

- exploit operating feedback;
- improve the approval process;
- improve intervention conditions.

ASN also approves laboratories to conduct analyses requiring a high level of measurement quality if the results are to be of any use. It thus approves laboratories:

- for monitoring of environmental radioactivity (see chapter 5);
- for worker dosimetry (see chapter 1).

The list of approvals issued by ASN is kept up to date on its website (*“bulletin officiel de l’ASN/agrément d’organismes”* section (ASN official bulletin/organisation approvals).

In 2008, ASN issued:

- 10 new or renewed approvals for organisations responsible for radiation protection inspections;
- 3 approvals for organisations dealing with nuclear pressure vessels;
- 39 approvals for measurement of the activity concentration of radon (33 level N1 and 6 level N2 approvals).

In 2008, concerning the measurement of environmental radioactivity, it also issued:

- two decisions approving environmental radioactivity measurement laboratories:
  - ASN decision 2008-DC-0120 of 16 December 2008 approving environmental radioactivity measurement laboratories;
  - Decision DEP-0009-2008-PRESIDENT of 28 January 2008 giving ASN approval of environmental radioactivity measurement laboratories;
- three decisions refusing approval of environmental radioactivity measurement laboratories belonging to EDF:
  - ASN decision 2008-DC-0123 of 16 December 2008 refusing approval for tritium activity measurements in water and air;
  - ASN decision 2008-DC-0122 of 16 December 2008 refusing approval for water total beta activity index measurements;
  - ASN decision 2008-DC-0121 of 16 December refusing approval for aerosol on filter total beta activity index measurements.

ASN sends the General Directorate for Health an opinion on the approval of the laboratories analysing radioactivity in water intended for human consumption.

It sends the ministers responsible for nuclear safety and/or transport an opinion on approval of the organisations responsible for:

- training the drivers of vehicles transporting radioactive materials (class 7 dangerous goods);
- organising safety adviser examinations for transport of dangerous goods by road, rail or navigable waterway;
- certifying the conformity of packagings designed to contain 0.1 kg or more of uranium hexafluoride (initial and periodic checks);
- issuing type approval for tank-containers and mobile tanker units intended for transport of class 7 dangerous goods by road;
- initial and periodic checks on tankers intended for the transport of dangerous goods.

## 2 | 3 Defining the stakes

In order to consider both the health and environment issues and licensee nuclear safety and radiation

protection performance, as well as the large number of activities it regulates, ASN periodically identifies those activities and topics with high stakes so that it can regulate them directly.

In order to identify these activities and topics, ASN relies on current scientific and technical knowledge and uses the information collected by both itself and IRSN: results of inspections, frequency and nature of incidents, major modifications made to installations, review of files, feedback of data concerning the dose received by workers, information resulting from checks by approved organisations. It can revise its priorities in the light of significant events occurring in France or around the world, as was the case with the succession of radiotherapy incidents and accidents. These events led to ASN carrying out inspections in all radiotherapy centres in France in 2007 and then in 2008.

In 2008, the particularly significant aspects were as follows:

Table 2: Significant activities in 2008

Field	Significant aspects
Basic nuclear installations including: <ul style="list-style-type: none"> <li>– Nuclear power plants</li> <li>– Research reactors</li> <li>– Laboratories and plants</li> <li>– Installations undergoing decommissioning</li> </ul>	<ul style="list-style-type: none"> <li>– Reactor outage</li> <li>– Organisational and human factors</li> <li>– Operation of the installation</li> <li>– Condition of barriers</li> <li>– Condition of systems</li> <li>– Prevention and management of risks, emergency situations</li> <li>– Radiation protection</li> <li>– Environment and transport</li> </ul>
Small-scale nuclear activities	<ul style="list-style-type: none"> <li>– Industrial radiography activities</li> <li>– External radiotherapy</li> <li>– Interventional medical radiology</li> <li>– Brachytherapy</li> <li>– Suppliers of ionising radiation sources</li> <li>– Nuclear medicine units performing therapeutic and/or in vivo diagnostic procedures</li> <li>– Holders of unsealed source licences</li> <li>– Industrial or research irradiation installations or particle accelerators</li> <li>– Implementation of high activity sealed sources</li> <li>– Tomography installations</li> </ul>
Radioactive material transport	<ul style="list-style-type: none"> <li>– Compliance with quality assurance requirements for radioactive material transport</li> <li>– Safety adviser duties</li> </ul>



### 3 DEPLOYING THE MOST EFFICIENT INSPECTION MEANS

The licensee is required to provide ASN with the information it needs to perform its regulation. The volume and quality of this data should enable the technical demonstrations presented by the licensee to be analysed and the inspections to be targeted. It should also allow identification and monitoring of the key events marking the operation of a nuclear activity. The actions specific to inspection of radioactive material transport are described in detail in chapter 11.

#### 3 | 1 | 1 Assessing the supporting documents submitted by the licensee

Reviewing the supporting documents produced by the licensees and the technical meetings organised with them are one of the forms of inspection carried out by ASN.

Review of this data may lead ASN to accept or on the contrary reject the licensee's proposals, to ask for additional information or studies or to ask for work to bring the relevant items into conformity. ASN's requirements are expressed in the form of a decision.

The purpose of the documents supplied by the licensee is to demonstrate compliance with the objectives set by the general regulations, as well as those that it has set for itself. ASN is required to check the completeness of the documents and the quality of the demonstration.

Whenever it deems necessary, ASN seeks the advice of technical support organisations, primarily IRSN. The safety review implies cooperation by numerous specialists, as well as efficient coordination, in order to identify the essential points relating to safety, radiation protection and protection of the environment.

The IRSN assessment relies on research and development programmes and studies focused on risk prevention and improving our knowledge of accidents. It is also based on in-depth technical exchanges with the licensee teams responsible for designing and operating the plants.

For major issues, ASN requests the opinion of the competent Advisory Committee of Experts, to which IRSN presents its analyses. For other matters, safety analyses give rise to IRSN opinions transmitted 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.

#### 3 | 1 | 1 Analysing the information supplied by the licensee

At the design and construction stage, ASN checks the safety cases describing and justifying basic design data, equipment design calculations, utilisation and test procedures, and quality organisation provisions made by the prime contractor and its suppliers. ASN also checks the manufacture of pressurised water reactor main primary system (CPP) and main secondary system (CSP) equipment. In accordance with the same principles, it checks the packages intended for the transport of radioactive materials.

Once the nuclear installation has entered service, after being authorised by ASN, all modifications made by the licensee and liable to affect public health and safety or the protection of the environment, are submitted to ASN. In addition to these submissions, made necessary by changes to the installations or how they operate, the licensee must, pursuant to the TSN Act, carry out periodic safety reviews in order to update the evaluation of the installation in the light of changing techniques and regulations and on the basis of operating feedback. The conclusions of these reviews are submitted to ASN, which can issue new provisions in order to strengthen the safety requirements.

#### *Other data submitted by BNI licensees*

The licensee submits routine activity reports and summary reports on water intake, liquid and gaseous discharges and the waste produced.

Similarly, there is a considerable volume of data on specific topics, such as, for example, the plant's seismic behaviour, fire protection, PWR fuel management strategies, relations with subcontractors, and so on.

#### 3 | 1 | 2 Ensuring vigilance during particularly significant interventions: nuclear power plant scheduled outages

The nuclear power plants operated in France are periodically shut down in order to:

- replace the spent fuel;
- carry out checks and maintenance on the parts of the installation which are not accessible during operation.

These shutdowns are referred to as “reactor outages”. ASN approves the outage programme forwarded by EDF and decides on whether or not the installations can subsequently be restarted.

From preparation of the outage to implementation of the post-outage steps, ASN oversees the safety measures adopted by the licensee.

Given the importance for safety of the maintenance work done during the outage and the risks involved in certain outage situations, ASN requires detailed information from the licensee. This information mainly concerns the work programme involved (see chapter 12) and any anomalies observed during the outage. The ASN regional divisions regulate the outage process, step by step. During the “site” inspections, the inspectors will carry out spot checks on the conditions in which the work in progress on the various sites is conducted, whether for repair or for modification of the installations, in-service monitoring of equipment, or periodic equipment testing.

As part of its policy of transparency, ASN places the reactor outage information notices on-line on its website. In these information notices, it gives the context of the outage, the main worksites involved, the supervision and monitoring actions it carried out and the main events that occurred during the outage.

These information notices are published once ASN has authorised the licensee to restart the reactor concerned.

### 3 | 1 | 3 Review of the procedures laid down by the Public Health Code

It is up to ASN to review applications for the use of ionising radiations for medicine, dentistry, human biology and biomedical research, as well as for any other nuclear activity. 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 inadequacies detected during these inspections.

In addition to the internal inspections carried out under the responsibility of the establishments and the periodic checks required by the regulations, ASN carries out its own verifications. In this respect it directly carries out checks during the procedures for issue (pre-commissioning inspections) or renewal (periodic inspections) of the authorisations to possess and use radiation sources granted on the basis of Article R. 1333-23 of the Public Health Code. The authorisation notifications can only be issued if the requests submitted by ASN following the checks have been taken into account. These checks are in particular designed to compare the data contained in the files with the actual physical reality (sources inventory, check on the conditions of production, distribution and utilisation of

the sources and the appliances containing them). They also enable ASN to ask the establishments to improve their in-house provisions for source management and radiation protection.

## 3 | 2 Inspection of installations and activities

### 3 | 2 | 1 Inspection objectives and principles

The inspection carried out by ASN is based on the following principles:

1. It aims to detect any drift indicative of a possible deterioration in installation safety or the protection of individuals and any non-compliance with the legislative and regulatory requirements the licensee is bound to apply;
2. the inspection is proportionate to the level of risk presented by the installation or activity;
3. the inspection is neither systematic nor exhaustive, is based on sampling and focuses on subjects for which the stakes are highest.

### 3 | 2 | 2 Inspection resources

To ensure greater efficiency, ASN's action is organised on the following basis:

- inspections, according to a predetermined frequency, of the nuclear activities and topics of particular health and environmental significance;
- inspections on a representative sample of licensees in other nuclear activities;
- systematic technical inspections of all installations by approved organisations.

ASN focuses its inspection resources on activities and topics for which the stakes are particularly high. For the other activities, ASN relies in particular on the organisations it has approved. However, to avoid ignoring activities of lesser significance, it does devote a part of its inspection programme to them (targeted action). In 2008, inspection programmes were carried out on medical radiology practices and companies detecting lead in paint. This type of action maintains an ASN presence among those in charge, evaluates application of the regulations in a particular sector and helps raise awareness within the profession. A summary of these inspections is sent out to the professional trade union organisation concerned.

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 relevant activities (work, transport operation). 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.

The inspections are generally carried out by two inspectors, possibly with the support of an IRSN representative specialising in the installation visited or the technical topic of the inspection. ASN uses various types of inspections:

- standard inspections;
- reinforced inspections, on topics involving particular technical difficulties and directed by senior inspectors (see chapter 2);
- in-depth inspections, which take place over several days and mobilise about ten or so inspectors. Their aim is to carry out an in-depth examination;
- inspections with sampling and measurements. These are designed to check discharges by means of samples that are independent of those taken by the licensee;
- reactive 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 decommissioning phase.

These inspections give rise to factual records, made available to the licensee. They concern:

- anomalies in the installation or points warranting additional justifications;
- deviations between the situation observed during the inspection and the regulatory texts or documents produced by the licensee pursuant to the regulations.

To achieve its goals:

*a) ASN employs inspectors chosen for their professional experience and for their legal and technical expertise.*

The inspectors carry out their inspection duties under the authority of the ASN Director General. They are sworn-in and bound by professional secrecy. They are designated once they have acquired the necessary competence through their professional experience, tutoring and appropriate training. To ensure constant progress, ASN:

- in the same way as the main foreign nuclear regulatory bodies, has defined a system for qualification of its inspectors. This is based on recognition of their technical expertise. This system is today managed by decrees and was identified as a good practice by IAEA's IRRS review;
- adopted a number of foreign experiences identified through inspector exchanges between nuclear regulatory bodies. These exchanges are organised either for a particular inspection or for a longer period, via a secondment of up to 3 years. For example, after confirming the benefits to be gained, ASN adopted the in-depth inspections described in point 3|2|3. On the other hand, it did not opt for the system of inspectors resident on the nuclear sites: ASN considers that its inspectors must work in a structure that is large enough to allow experience to be shared and must take part in inspections of different licensees and installations, in order to gain a broader picture of this field of activity. This also helps to avoid a blurring of responsibilities;
- encourages an open-minded attitude on the part of its inspectors to other regulatory practices. ASN encourages



ASN inspectors accompanied by a representative of the Gravelines CLI (Nord département) during an inspection of the power plant – October 2007



Inspector carrying out a dosimetric inspection in Nantes university hospital (Loire-Atlantique *département*)

its departments to take on inspectors from other regulatory bodies (inspectorate for installations classified on environmental protection grounds, AFSSAPS, technical services of the Ministry for Health, etc.). It also proposes organising joint inspections with these bodies concerning the activities falling within its scope of expertise. In order to identify other methods for risk management by the licensees, the ASN inspectors may also observe inspections on specialised subjects in installations which do not fall within their field of expertise.

- aims to ensure the uniformity of its practices. It encourages participation by its officers in inspections on different subjects, in different regions and sectors.

The ASN Chairman appoints the inspectors as defined by decree 2007-831 of 11 May 2007 which determines the procedures for appointing and approving nuclear safety inspectors (formerly known as BNI inspectors) and the

officers responsible for checking pressure vessels specifically designed for BNIs and by Articles R. 1333-100 to R. 1333-108 of the Public Health Code (radiation protection inspectors).

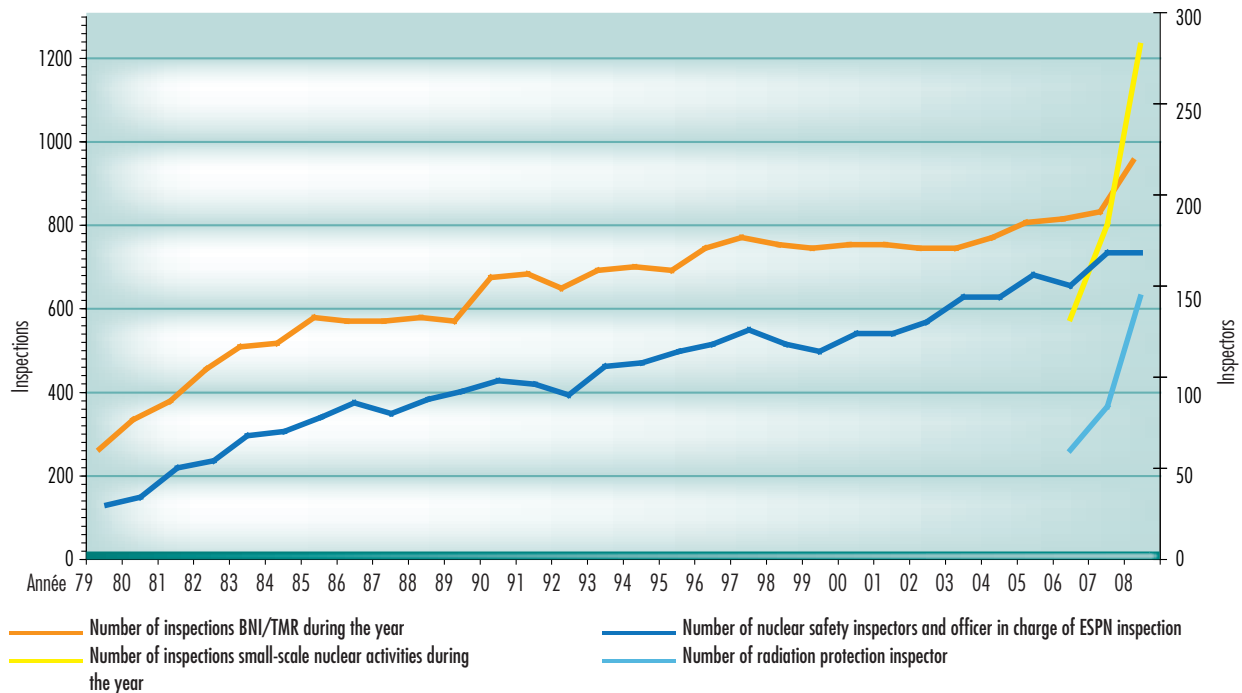
Table 3 presents the inspector staffing levels on 31 December 2008. Some officers are inspectors in several categories.

*b) To guarantee an adequate distribution of the inspection resources, proportionate to the nuclear safety, radiation protection and environmental protection impact of the various installations and activities, ASN each year drafts an inspections forecast schedule. It identifies the installations, activities and subjects targeted. This is not known beforehand to those in charge of nuclear activities.*

Table 3: breakdown of inspectors per type of inspection (on 31.12.2008)

Type of inspector	Departements	Divisions	Total
Nuclear safety (BNI) inspector and officer responsible for inspecting nuclear pressure vessels	81	88	169
Nuclear safety inspector (transport)	9	39	48
Radiation protection inspector	38	105	143
Conventional safety inspector (site)	0	12	12
Number of inspectors (all fields included)	106	139	245

Graph 1: changes in the number of ASN inspectors and inspections



c) ASN trains its inspectors and provides them with inspection guides and decision-making aids concerning any follow-up to infringements observed.

d) ASN performs qualitative and quantitative supervision of the inspection programme and the actions taken subsequent to the inspections. Reports are issued on compliance with the forecast schedule of inspections and enable the activities checked to be evaluated in terms of both the licensee and the sector or particular topic concerned.

e) ASN informs the public by placing the nuclear safety and radiotherapy centre inspection follow-up letters on its website, as well as through its publications. This subject is developed further in chapter 6.

f) ASN is setting up a system for constant improvement of its inspection process. It could be based on internal and external audits.

### 3 | 2 | 3 Inspection of BNIs and pressure vessels in 2008

In 2008, 796 inspections were conducted, 188 of which were unannounced. The breakdown according to the

various installation categories is described in the following graphs.

The ASN Nuclear Pressure Equipment Department (DEP) is responsible for monitoring application of nuclear pressure vessel regulations, including for PWR main primary and secondary systems.

Regulation of the design and manufacture of the main primary and secondary systems (CPP and CSP), as well as assessment of the conformity of the main components (level N1 defined in the order of 12 December 2005) are the direct duty of this department (see chapter 12). Assessment of the conformity of other nuclear pressure vessels is the role of organisations approved and regulated by ASN (see point 2 | 2).

Regulation of the operation of nuclear pressure vessels is the responsibility of ASN regional divisions, with the support of the DEP.

### 3 | 2 | 4 Inspection of radioactive material transport in 2008

The 81 inspections on transport activities in 2008 can be broken down according to topic as shown in graph 4.

### 3 | 2 | 5 ASN checks on radiation protection in 2008

ASN has organised its checks and inspections so that they are proportionate to the radiological issues involved in the use of ionising radiations, and consistent with the actions of the other inspection services. Of the 50,000 or so nuclear installations and activities concerned, ASN carried out 1075 inspections in 2008, including 717 in the medical field, 346 in the industrial or research field and 12 in other fields (TENORM, polluted soils, etc.). The breakdown according to the various categories of activity is described in graph 5.

### 3 | 2 | 6 ASN checks on approved organisations and laboratories in 2008

ASN carries out a second level of inspection on approved organisations and laboratories. In addition to reviewing

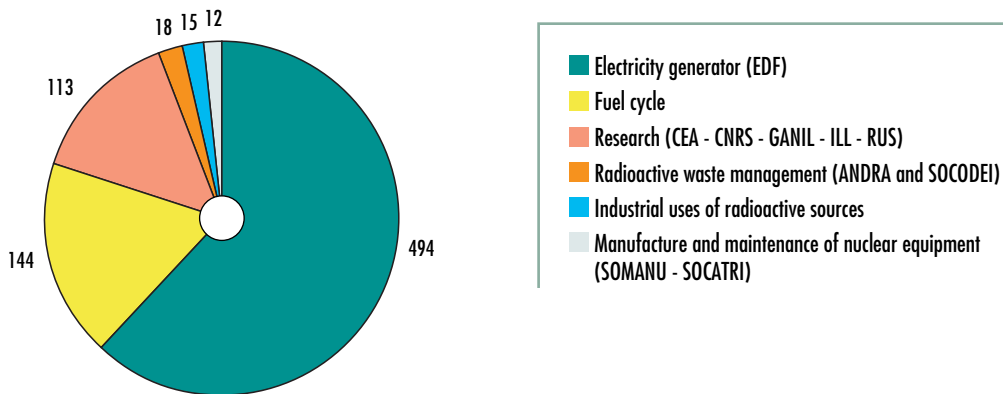
the application file and issuing the approval, this comprises surveillance such as the following:

- approval follow-up or renewal audits;
- checks to ensure that the organisation and operation of the entity concerned comply with the applicable requirements;
- supervisory checks, which may be unannounced, to ensure that the organisation's staff work in satisfactory conditions.

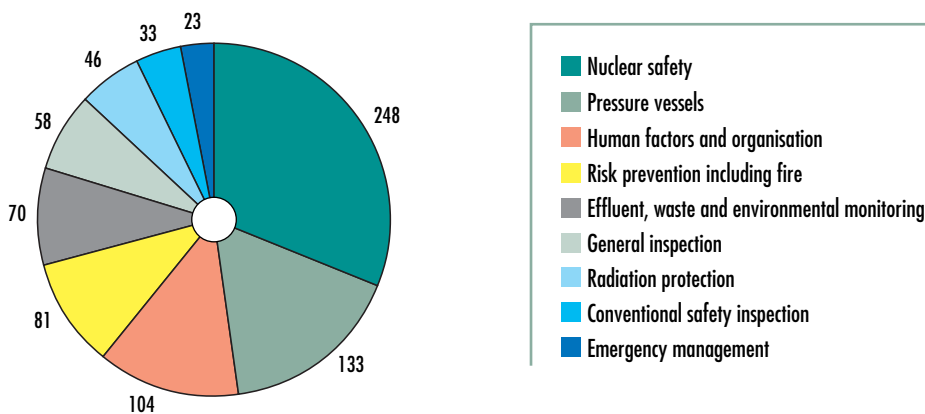
In 2008, the following inspections were carried out:

- organisations carrying out radiation protection technical checks: 132 including 68 unannounced supervisory checks;
- organisations evaluating nuclear pressure vessel conformity and inspecting operational equipment: 12 inspections.
- laboratories approved for environmental radioactivity measurements: 4 inspections.

Graph 2: breakdown of BNI inspections performed in 2008 per type of licensee



Graph 3: breakdown of BNI inspections performed in 2008 per topic



3 | 2 | 7 Checks on exposure to radon and NORM in 2008

ASN also regulates radiation protection in premises where exposure of individuals to NORM can be enhanced owing to the underlying geological context (radon in premises open to the public) or the characteristics of the materials used in industrial processes (non-nuclear industries).

a) Checking exposure to radon

Since August 2004, the activity concentration of radon in places open to the public has to be measured, in accordance with the order of 22 July 2004, by organisations approved by ASN. The measurement campaigns must take

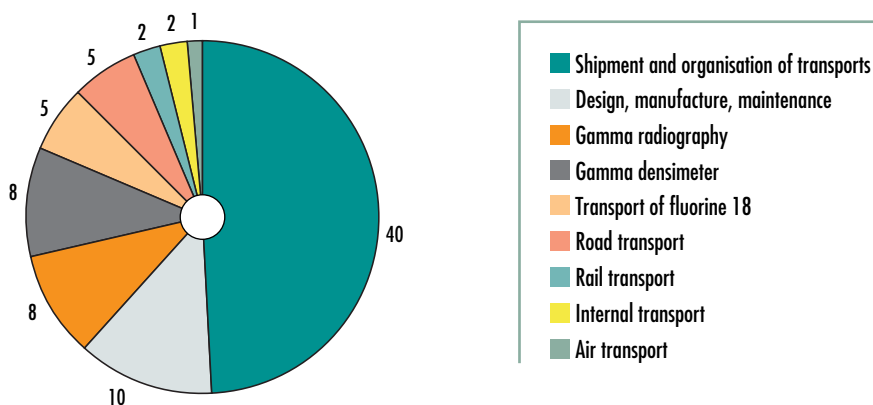
place between 15 September of year N and 30 April of the following year.

For the 2008-2009 measurement campaign, the number of approved organisations is given in table 4.

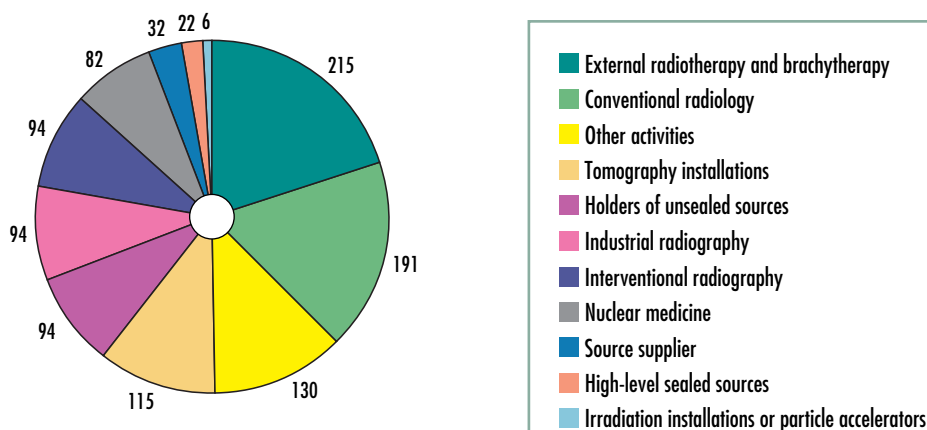
Based on the information transmitted by the approved organisations, initial results can be presented for the 1204 establishments that underwent screening during the 2007-2008 campaign:

- in 952 establishments, or about 79%, a radon activity level of less than 400 Bq/m<sup>3</sup> was measured;
- in 174 establishments, or about 15%, a radon activity level of between 400 and 1000 Bq/m<sup>3</sup> was measured;

Graph 4: breakdown of radioactive material transport inspections in 2008 per topic



Graph 5: breakdown, per activity category, of the visits or inspections carried out in 2008 in the small-scale nuclear sector



– in 78 establishments, or about 6%, a radon activity level in excess of 1000 Bq/m<sup>3</sup> was measured.

The Departmental Health and Social Action Directorates (DDASS) in the 31 priority *départements*<sup>2</sup> (see chapter 3), together with ASN (circular of 20 December 2004 concerning management of the radon risk in premises open to the public) are responsible for monitoring establishments in which radon concentrations higher than 400 Bq/m<sup>3</sup> were measured.

### b) Checking exposure to NORM in non-nuclear industries.

The order of 25 May 2005, published the list of professional activities (industries, spas and drinking water treatment plants) requiring regulation of human exposure to Naturally Occurring Radioactive Materials (NORM), owing to the fact that the materials used contain natural radionuclides and are likely to generate doses that are significant from the radiation protection standpoint.

Checks on implementation of these new requirements over the period 2007-2008 confirmed that certain industries were more particularly concerned by the issue of technologically enhanced naturally occurring radiation. These include installations for zircon production and for processing of titanium ore and rare earths, to which the worker radiation protection regulations apply in accordance with Articles R.4457-13 and R.4457-14 of the Labour Code.

The inspection and evaluation actions taken in collaboration with the conventional safety inspectorate and the inspectorate for installations classified on environmental protection grounds will continue over the period 2008 – 2009. These actions will complete the results obtained and will improve understanding of the issues in these industrial sectors, as well as in spas and groundwater extraction installations.

### c) Checks on natural radioactivity in water intended for human consumption

Since 1 January 2005 (order of 12 May 2004), checks on natural radioactivity in water intended for human

consumption are an integral part of the health monitoring carried out by the DDASS. The checks take account of the recommendations issued by ASN (DGS circular of 13 June 2008) and the results concerning the radiological quality of this water are jointly analysed by the Ministry for Health and ASN. A summary of these results is presented in chapter 1.

## 3|3 Learning the lessons from significant events

### 3|3|1 Anomaly detection and analysis

#### a) History

Following the Three Mile Island accident, the BNI licensees were obliged to adopt an anomaly notification system. This system is part of the defence in depth approach and was incorporated into the international conventions ratified by France (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; Article 19vi of the Nuclear Safety Convention of 20 September 1994). The licensee is required to implement a reliable system for detecting possible anomalies, such as equipment failures or errors in application of operating rules. This system should lead to early detection of any abnormal operation. These anomalies must be notified to ASN.

Based on twenty years of experience, ASN felt that it would be useful to transpose this approach to radiation protection and protection of the environment. ASN thus drafted two guides defining the principles and obligations on the licensees with regard to notification of incidents and accidents:

- the 21 October 2005 guide contains the requirements applicable to BNI licensees and to carriers. It concerns significant events affecting BNI safety, radioactive material transport (TMR) safety, radiation protection and protection of the environment;
- the ASN/DEU/03 guide of 15 June 2007 is intended for those in charge of nuclear activities as defined in L. 1333-1 of the Public Health Code and the heads of

Table 4: number of organisations approved to measure radon in premises open to the public

	Approval until 15 September 2009	Approval until 15 September 2010	Approval until 15 September 2011
Level 1 (screening)	34	11	20
Level 2 (additional investigations)	2	2	4

2. Administrative region headed by a *Préfet*.



the facilities in which ionising radiations are used (medical, industrial and research activities using ionising radiations). It has been experimentally implemented since 1 June 2007, in order to familiarise the professionals with this approach and take account of any problems they could encounter, while enabling them to meet their legal obligations straight away.

These guides can be consulted on the ASN website, [www.asn.fr](http://www.asn.fr).

### b) What is a significant event?

Detection of events (deviations, anomalies, incidents, etc.) by those in charge of the activities using ionising radiations, and implementation of corrective measures highlighted by this analysis, play a fundamental role in accident prevention. To give an idea of what this entails, the nuclear licensees detect and analyse 100 to 300 anomalies a year for each EDF reactor and about 50 a year for a research laboratory.

Rating the anomalies should enable priority to be given to addressing the most important ones. For this purpose, ASN has defined a category of anomalies called “significant events”. These are events that are sufficiently important in terms of safety or radiation protection to justify rapid notification of ASN, followed by a subsequent and more complete report. Significant events must be notified to it, as specified in the TSN Act (Article 54), the Public Health Code (Articles L. 1333-3 and R. 1333-109 to R. 1333-111) and the Labour Code (Article R. 4455-7). The criteria for notification to the public authorities of events considered to be “significant” take account of the following:

- the actual or potential consequences for workers, the public, patients or the environment, of events that could occur and affect nuclear safety or radiation protection;
- the main technical, human or organisational causes that could lead to the occurrence of such an event.

This notification process is part of the continuous safety improvement approach. It requires the active participation of all licensees (users of ionising radiations, carriers, etc.) in the detection and analysis of deviations. It enables the authorities:

- to ensure that the individual in charge of the activity has carried out a pertinent analysis of the event and taken appropriate measures to correct the situation and prevent it happening again;
- to analyse the event in the light of the experience available to other parties in charge of similar activities.

The purpose of this system is not to identify or penalise any individual person or party (see point 4).

## 3 | 3 | 2 Implementation of the approach

### a) Event notification

In the event of an incident or accident, whether or not nuclear, with a real or potential risk of significant consequences for the safety of the installation or transport or, as a result of significant exposure to ionising radiations, liable to constitute a risk to individuals, property or the environment, the TSN Act requires that the BNI licensee or individual in charge of a radioactive material transport immediately notify ASN and the State’s representative in the *département* in which the incident or accident occurred and, as applicable, the State’s maritime representative.

As specified in the Public Health Code, the individual required to notify the significant event is the individual in charge of the nuclear activity.

According to the provisions of the Labour Code, the party declaring a significant event affecting a worker is the head of the facility. When the head of a facility carrying out a nuclear activity calls in an external contractor or non-salaried worker, the significant events concerning salaried or non-salaried workers are notified in accordance with the prevention plans and the agreements concluded pursuant to Article R. 4451-8 of the Labour Code.

### b) ASN analysis of the notification

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. This information is extremely valuable for ASN and its technical

Significant event notification guides on the ASN website

support organisation, IRSN, in particular for the periodic safety reviews conducted on basic nuclear installations.

ASN ensures that the licensee has carried out a pertinent analysis of the event and taken appropriate steps to remedy the situation, prevent it happening again and ensure that operating experience feedback is sent out to the licensees.

The ASN regional divisions are responsible for immediate analysis of significant events in order to check that immediate corrective steps have been taken and, if necessary, prepare for the necessary public information. ASN coordinates the actions of the regional divisions in this field and every year provides training for the staff concerned.

Examination of a significant event covers compliance with the rules in force concerning detection and declaration of significant events, the immediate technical steps taken by the licensee to keep the installation in or bring it to a safe condition and finally, the pertinence of the significant event reports provided by the licensee.

ASN and its technical support body, IRSN, carry out a subsequent examination of the operating feedback from the events. The data supplied by the regional divisions and analysis of significant event reports, together with periodic records sent in by the licensees, form the basis of ASN operating experience feedback structures. This operating experience feedback can lead to requests for improvement of the condition of the installations and the organisation adopted by the licensee, as well as for changes to the regulations.

Operating experience feedback encompasses events occurring both in France and abroad, whenever relevant to enhancing nuclear safety or radiation protection.

### 3 | 3 | 3 Public information

Independently of this process, the public must be informed of those events with consequences that so warrant (see chapter 6).

### 3 | 3 | 4 Statistical summary of events in 2008

The following graphs describe in detail the significant events notified to ASN in 2008, differentiating between the various notification criteria for each domain:

- nuclear safety, radiation protection and environment for BNIs;

- TMR, all activities included;
- non-BNI radiation protection.

Apart from the technical analysis specific to each criterion, it can be seen that half of the events notified are due to non-compliance with requirements or rules.

## 3 | 4 Raising awareness

Compliance with the regulations can also be obtained through education. Regulation is thus supplemented by awareness 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 who will be implementing this approach by issuing good practice and professional information guides. These initiatives are mentioned in chapter 9.

Raising awareness also involves joint action with other administrations and organisations who carry out supervisory duties on the same installations, but with different prerogatives, such as the conventional safety inspectorate, inspection of medical appliances by the AFSSAPS or health inspection as entrusted to the technical divisions of the Ministry for Health.

This approach is illustrated by the joint creation by ASN and the French Oncology Radiotherapy Society (SFRO) of a common scale for rating radiation protection events affecting patients undergoing radiotherapy treatment.

Finally, jointly with the General Directorate for Labour (DGT), ASN initiated coordination of conventional safety inspections and radiation protection inspections. This will in particular include local and national exchanges of information, joint inspections and cross-training exercises.

## 3 | 5 Conducting a technical inquiry in the event of an incident or accident concerning a nuclear activity

Before it was modified by the TSN Act, the Act of 3 January 2002<sup>3</sup> made it possible to conduct a technical inquiry following an event at sea, a terrestrial transport accident or an air accident, in order to prevent future events, accidents or incidents. This inquiry consists in collecting and analysing all useful information, without

3. Act 2002-03 of 3 January 2002 on the safety of transport infrastructures and systems, technical investigations and underground storage of natural gas, hydrocarbons and chemical products.

prejudice to the judicial inquiry, in order to determine the circumstances and the identified or possible causes of the event, if necessary drawing up the necessary recommendations. A specialist organisation is designated to carry out the inquiry, although it can call on outside individuals or even convene a board of inquiry.

Pursuant to this Act, a number of bodies with national competence were set up: the “Maritime events investigation bureau” (BEA-mer), the “terrestrial transport accident investigation bureau” (BEA TT), the “air transport accident investigation bureau” and the “air defence accident investigation bureau” (the investigation and analysis bureau for civil aviation safety (BEA “air”) already existed before this Act).

In giving ASN, an independent administrative authority, the roles of regulating nuclear safety and radiation protection and public information in these areas, the TSN Act (5° of Article 4) expanded the scope of application of the Act of 3 January 2002 to incidents or accidents concerning a nuclear activity and gave ASN the prerogatives accorded to the investigation bureaux for other accidents. This expansion covers incidents and accidents associated with both basic nuclear installations and radioactive material transport as well as with those which can occur during activities entailing a risk of human exposure to ionising radiations, in particular activities carried out for medical purposes.

Insofar as ASN previously carried out incident and accident investigations as part of its regulatory duties, the

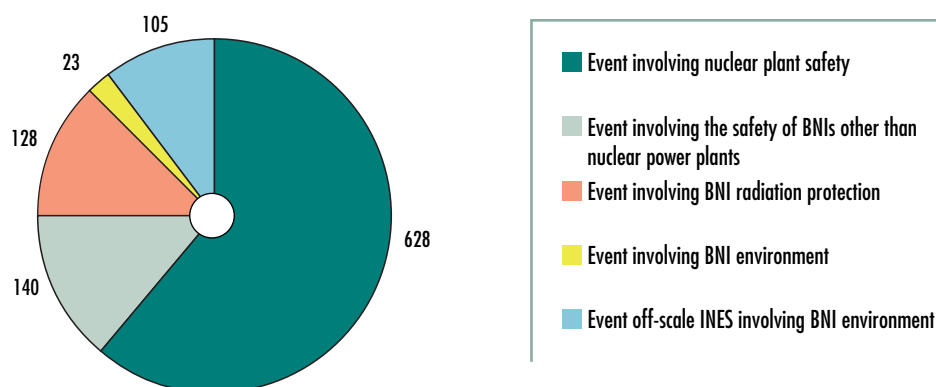
main innovation of the TSN Act in this respect is to give ASN the right to conduct inquiries and access the necessary information in the event of a judicial inquiry.

However, unlike the investigation bureaux mentioned above, whose sole purpose is to conduct inquiries, disseminate information gleaned from operating experience feedback and conduct research into accidents and their causes, ASN’s main role is regulation. This entails certain particularities in how the investigators and ASN work together.

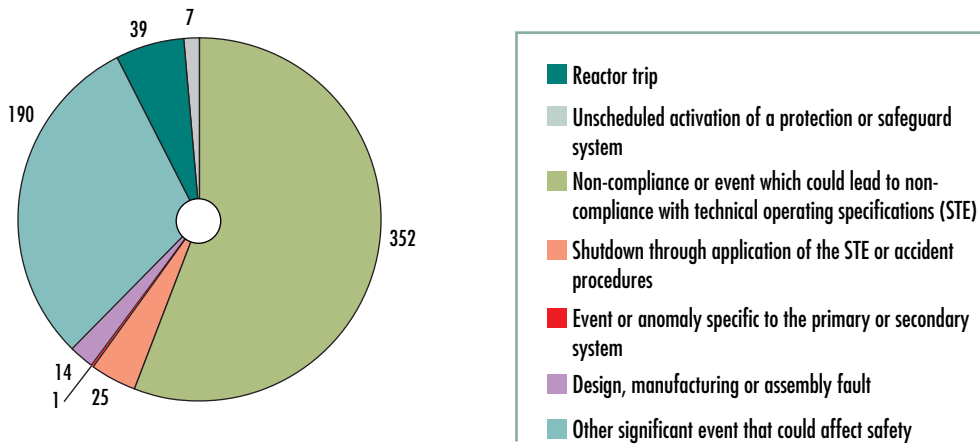
This primarily concerns three aspects:

- the objectives of the BEAs and the boards of inquiry they can set up are one and the same. For inquiries into a nuclear activity, it is necessary to differentiate between the role of the inquiry, whose aim is to determine the circumstances and causes of the event, and that of ASN, whose goal is to regulate and supervise nuclear safety and radiation protection in order to protect workers, patients, the public and the environment from the risks related to nuclear activities. It is for this purpose that ASN will use the recommendations issued by the board of inquiry;
- the BEA officers whose duty is to take part in the inquiries, receive permanent commissions as technical investigators. ASN’s staff primarily carry out a regulatory duty and can be commissioned on a case by case basis;
- the investigators must offer guarantees of independence and impartiality. This requirement applies to ASN’s staff given that they might have taken part in regulating the activity covered by the inquiry.

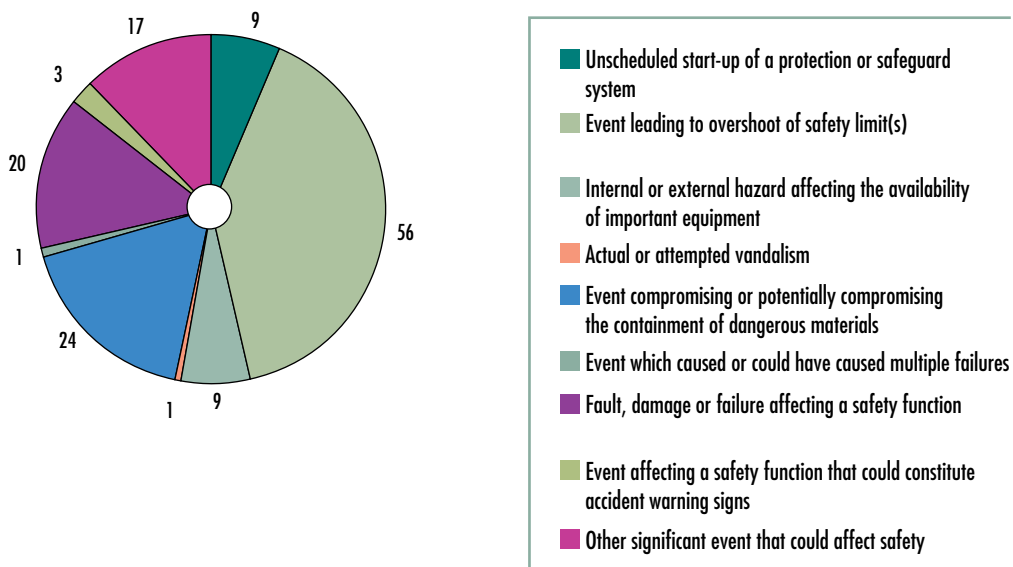
Graph 6: breakdown per type of event for BNIs



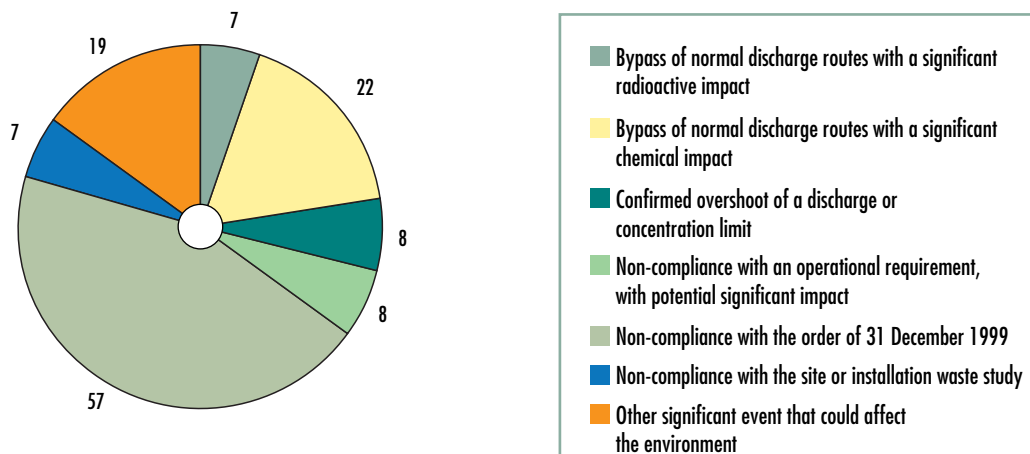
Graph 7: safety related events for nuclear power plants



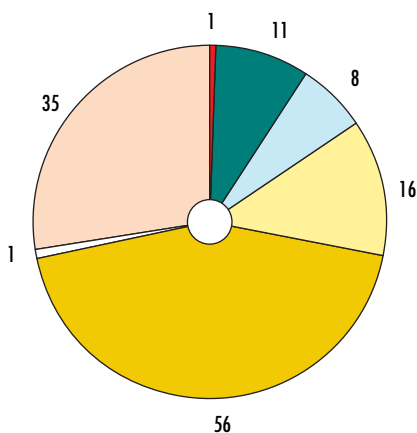
Graph 8: safety related events for BNIs other than nuclear power plants



Graph 9: significant environmental events in 2008 (BNI including "off-scale")

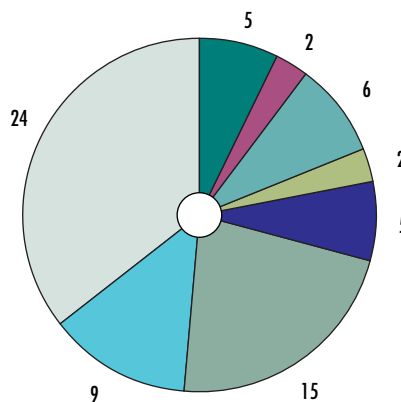


Graph 10: events involving radiation protection in BNIs



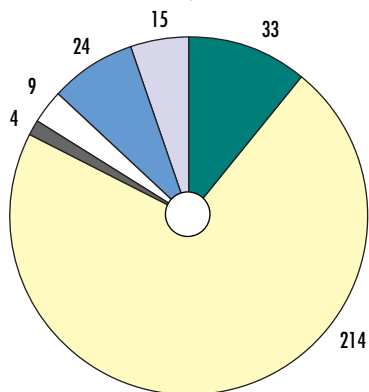
- Overshoot of one quarter of the annual dose limit or event that could lead to this situation
- Any significant deviation concerning radiological cleanness
- Operation involving a radiological risk performed without analysis or ignoring the analysis
- Abnormal situation affecting a source with activity higher than the exemption threshold
- Incorrect signage or non-compliance with zone access conditions
- Uncompensated failure in radiological monitoring systems
- Other significant events that could affect radiation protection

Graph 11: radioactive material transport events



- Loss or theft of a package or radioactive material during transport
- Shipment of a package even through the consignee is not ready for delivery
- Hazard that affected or could affect the safety of transport
- Fault, damage or failure affecting a safety function
- Events which affected at least one barrier with actual or potential consequences
- Non-compliance with radioactive material transport regulations
- Non-compliance with one of the radiation intensity or contamination limits
- Other significant events that could affect transport

Graph 12: events involving radiation protection (other than BNI and radioactive material transport)



- Concerning one or more workers
- Concerning one or more patients (therapeutic application)
- Concerning one or more patients (diagnostic application)
- Concerning the public
- Loss, theft of sources or radioactive materials
- Other significant event involving radiation protection

The Act of 3 January 2002 specifies the purpose of the inquiry, defines the organisation responsible for it, lays down the principles of the independence of the organisation or individuals and of protection of medical secrecy. It determines the links with the Public Prosecutor and the judicial procedure and defines the penalties. It restates the right of access to the site on which the event occurred, of preservation of clues and the release of information in the event of a risk. Finally, it clarifies how the safety recommendations and the inquiry report are to be publicised.

Decree 2007-1572 of 6 November 2007 on technical inquiries into accidents or incidents concerning a nuclear activity, specifies the procedure to be followed for accidents or incidents concerning a nuclear activity. It is based on the practices established for the other accident investigation bureaux and takes account of the specific characteristics of ASN, particularly its independence, its ability to impose requirements if necessary and the co-existence of its investigative and other duties. ASN issued opinion 2007-AV-0021 on 26 March 2007 with regard to this draft decree.

## 4 IDENTIFYING AND PENALISING INFRINGEMENTS

### 4 | 1 Ensuring that licensee penalty decisions are proportionate, fair and consistent

In certain situations in which the licensee fails to conform to the regulations or legislation, or when it is important that appropriate action be taken by it to remedy the most important risks immediately, ASN may impose the penalties provided for by law. The principles of ASN's penalty policy are based on:

1. penalties that are impartial, justified and appropriate to the level of risk presented by the situation concerned. Their scale is proportionate to the health and environmental consequences of the infringement detected and also takes account of intrinsic factors relating to the behaviour of the party at fault and external factors relating to the context of the infringement;
2. administrative action initiated on proposals of the inspectors and decided on by ASN in order to remedy risk situations and non-compliance with the legislative and regulatory requirements as observed during its inspections.

When it detects an infringement during its checks, ASN must ensure that its decisions concerning both enforcement (action obligation) and penalties are fair and consistent. ASN has a range of tools at its disposal, in particular:

- a verbal warning by the inspector to the licensee;
- the official letter from the ASN departments to the licensee;
- formal notice from the ASN Commission to the licensee to regularise the administrative situation or meet certain conditions placed on the licensee of an installation or on the individual responsible for transport, within a specified time-frame;
- administrative penalties applied after formal notice.

In parallel with ASN's administrative action, reports can be drafted by the inspector and sent by ASN to the Public

Prosecutor's Office, for a decision on any legal action to be taken.

Of the recommendations made by the IRRS review, two concerned the need for ASN to provide its inspectors with tools enabling them to determine the scale of the problems observed and deal with minor infringements, in order to implement a level of penalties that is appropriate with regard to safety on the one hand and radiation protection on the other. ASN therefore drew up procedures and decision-making tools regarding the position to be adopted by the inspectors when an infringement is identified. These documents cannot cover the full complexity of the actual situation, but they provide a structured framework for reaching an impartial decision proportionate to the infringement observed, that is applied consistently by all inspectors and is in line with the policy defined by ASN. More indirectly, they also constitute a learning aid for the less experienced inspectors and contribute to the transparency of ASN's decisions, by explaining a decision, in particular to the licensees.

The decision to issue demands is based on the observed risk for individuals or the environment and takes account of factors specific to the licensee (history, behaviour, repeated nature of the problem), contextual factors and the nature of the infringements observed (regulations, standards, "rules of good practice", etc.).

### 4 | 2 Tailoring the response to the stakes: a proportionate approach

#### 4 | 2 | 1 For BNIs

When ASN regulatory actions reveal failures to comply with safety requirements, penalties can be imposed on the

licensees concerned, in some cases, after service of formal notices. Penalties in such cases may consist in prohibiting restart or suspending operation of a nuclear installation until the corrective measures have been taken (see point 1 | 4).

If any such failures are observed, the TSN Act makes provision for:

- a scale of administrative penalties applied after formal notice and defined in Articles 41 to 44 of the Act:
  - deposit with a public accountant of a sum corresponding to the cost of the work to be performed;
  - automatic performance of the work at the expense of the licensee (any sums deposited beforehand can be used to pay for this work);
  - suspension of operation of the installation or of performance of an operation until the licensee conforms;

If the licensee has any observations concerning these penalties it shall present them to the ASN Commission.

The Act also makes provision for interim measures to safeguard public health and safety or protection of 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.

Penal sanctions ranging from a fine of 7,500 euros to three years imprisonment and a fine of 150,000 euros depending on the nature of the violation. They are defined in Articles 48 to 51 of the Act. They may apply to corporate bodies, in which case the amount of the fine can be up to 1,500,000 euros.

Decree 2007-1557 of 2 November 2007 concerning basic nuclear installations and the supervision of the transport of radioactive materials with respect to nuclear safety, also makes provision for class 5 infringements as detailed in its article 56.

For example, during the course of its checks on the construction of the EPR reactor, ASN identified several anomalies in 2008 relating to civil engineering operations. ASN therefore asked EDF:

- to suspend the pouring of concrete for structures important in terms of safety;
- to analyse the problems observed and the corrective measures. It asked it more particularly to improve the thoroughness of the technical inspections carried out by the contractors working on the site, the surveillance

carried out by EDF itself and the management of any deviations detected.

In 2008, ASN served EDF with formal notice to comply with the requirements of Article 16 of the order of 31 December 1999 in the Cruas-Meyssse nuclear power plant (BNI 111 and 112) (ASN Decision 2008-DC-0119 of 13 November 2008).

Following the 7 July 2008 incident in the SOCATRI plant in Bollène, ASN issued three decisions requiring that this company take emergency measures to guarantee public health and safety or protection of the environment pursuant to IX of Article 29 of the TSN Act:

- ASN decision 2008-DC-0104 of 11 July 2008 requiring that emergency measures be taken by the *Société Auxiliaire du Tricastin* (SOCATRI) for BNI 138 in the commune<sup>4</sup> of Bollène (Vaucluse), designed to safeguard the installation;
- ASN decision 2008-DC-0105 of 11 July 2008 requiring that emergency measures be taken by the *Société Auxiliaire du Tricastin* (SOCATRI) for BNI 138 in the commune of Bollène (Vaucluse), concerning the implementation of an enhanced surveillance plan;
- ASN decision 2008-DC-0107 of 22 July 2008 requiring that emergency measures be taken by the *Société Auxiliaire du Tricastin* (SOCATRI) for BNI 138 in the commune of Bollène (Vaucluse), concerning the implementation of an enhanced surveillance plan.

In parallel with these administrative actions, ASN in 2008 sent the Public Prosecutor's Office two reports concerning breaches by BNI licensees of the requirements of the TSN Act and its implementing texts.

## 4 | 2 | 2 For small-scale nuclear activities, approved organisations and laboratories

The Public Health Code makes provision for administrative and penal sanctions in the event of breach of the radiation protection requirements.

Administrative decision-making powers lie with ASN and can entail:

- revocation of licence (after formal notice);
- interim suspension of an activity (whether licensed or notified) if urgent measures are required to safeguard human health.
- revocation or suspension of any approvals it has issued.

The formal notice prior to revocation of licence (based on Article L.1333-5 of the Public Health Code) concerns

4. Smallest administrative subdivision administered by a mayor and a municipal council.

implementation of all the requirements of the “ionising radiations” chapter of the legislative part of the Public Health Code (Articles L.1333-1 to L.1333-20), regulatory requirements and the stipulations of the licence. Temporary or final revocation of the licence by ASN must be fully explained in a decision within one month following serving of formal notice.

The formal notices prior to penal sanctions (based on Article L.1337-6 of the Public Health Code) are served by ASN. They concern the provisions of Articles L.1333-2, L.1333-8 (surveillance of exposure, protection and information of individuals), L.1333-10 (surveillance of exposure to TENORM and of premises open to the public) and L.1333-20 (decrees implementing certain legislative provisions).

Infringements are written up in reports by the radiation protection inspectors and transmitted to the Public Prosecutor’s Office, which decides on what subsequent action is to be taken. The parts of the Public Health Code providing for penal sanctions are detailed in Articles L.1337-5 to L.1337-9 and range from a fine of 3,750 euros to one year of imprisonment and a fine of 15,000 euros.

In 2008, ASN issued decisions refusing approval of 17 EDF laboratories for measurement of environmental radioactivity (see point 2 | 2).

ASN also sent the Public Prosecutor’s Office four reports detailing radiation protection violations by parties responsible for small-scale nuclear activities.

## 4 | 2 | 3 For Labour law

In the performance of their duties in nuclear power plants, the ASN’s conventional safety inspectors have at their disposal all the inspection, decision-making and enforcement resources of ordinary inspectors. Observation, formal notice, official report, injunction (to obtain immediate cessation of the risks) or even shutdown of the site, offer a range of enforcement and constraining measures for the conventional safety inspector that is broader than that available to a nuclear safety inspector or a radiation protection inspector.

The conventional safety inspector has special decision-making powers enabling him to check the employer’s disciplinary capability, to protect the general interest from an economic standpoint and to act as arbitrator, if necessary by delegation from the DDTEFP. He is also tasked with examining approval applications by the occupational health departments, jointly with the occupational physicians.

The conventional safety inspector is in contact with many parties from different EDF entities. Management of these internal interfaces is an integral part of his duties. The inspector is first of all in contact with the plant senior management, the risk prevention departments and the occupational health departments. He is in direct contact with the members of the health, safety and working conditions committees (CHSCT) and the trade union representatives. The members of the CHSCT are a vital means of transmitting information for the conventional safety inspector, in the light of their knowledge of the facility, the operating procedures, working conditions and accidents that occur in the installation. The members of the CHSCT are informed of the inspector’s visits and of his observations during the inspections.

The inspector is notified of the ordinary meetings of the CHSCT (one every quarter) and the inter-company working conditions and safety committee (CIESCT) meetings held on the power plant sites, and can attend them. He takes part in extraordinary meetings held following a work accident, and in issuing an alert in the event of serious and imminent danger.

The mandatory posting of the contact details of the inspector with competence for each nuclear power plant leads to him being frequently contacted both by EDF personnel and by the personnel of the contractors working in the nuclear power plants. The main subjects concern performance of their employment contract (working times, rest periods, travel, leave, etc.), but also notification of degraded working conditions.

The conventional safety inspector is in contact with the occupational health departments. He may be required to validate (or invalidate) a decision by the occupational physician. Close relations with the occupational physician may enable him to gain a relatively clear picture of the “health” of the facility, in particular with regard to organisational and human factors.

Relations on the site can also concern EDF entities from outside the plant, which have their own staff consultation and medical supervision structures. The entities most concerned are the National Electricity Generation Equipment Centre (CNEPE) which is in charge of carrying out and supervising major non-nuclear works, the Engineering Centre for Operating Plants (CIPN) for major operations on the nuclear island (in particular steam generator replacement), the Engineering Centre for Decommissioning and Related Environmental Issues (CIDEN) for all work relating to the decommissioning of retired nuclear power plants, and which on some sites has a separate structure, the workforce of which will rise as the decommissioning phases progress.



### 4 | 3 Information about ASN's inspections

As part of the process to coordinate government departments, ASN informs the other departments concerned of its inspection programme, the follow-up to these inspections, the penalties imposed on the licensees and any significant events that could be of interest to them.

To ensure that its inspection work is transparent, ASN informs the public (both general and specialised) by placing the following on its website:

- nuclear safety and radiotherapy centre inspection follow-up letters;
- approval authorisations or rejections;
- incident notifications;
- the results of reactor outages;
- its publications on specific subjects (*Contrôle* magazine, etc.).

The conditions in which this information is made public must protect medical secrecy, industrial secrecy, national defence interests and individual freedoms. ASN makes every effort to avoid publishing any nominative information (patients, employers, employees, etc.).

## 5 OUTLOOK

Inspection is one of ASN's fundamental duties. For 2009, it has scheduled more than 1900 inspections on BNIs, radioactive material transport, activities using ionising radiations, organisations and laboratories it has approved and activities involving pressure vessels.

In 2009, ASN will be pursuing its inspection of radiotherapy centres and will continue to assert its presence in the regulation of activities entailing a risk of exposure of individuals and workers to ionising radiations.

With regard to nuclear safety, particular attention will be focused on the explosion risk in nuclear power generating plants.

In 2009, ASN intends to reinforce its arsenal of compulsory measures and use the tools at its disposal in all the fields under its responsibility.

Finally, to enhance the effectiveness of the inspections carried out by the Government departments in areas of shared competence, the various ASN components (divisions and departments) will continue to hold regular meetings with their counterparts in other Government administrations and departments (Ministry for Health, inspectorate for installations classified on environmental protection grounds, AFSSAPS, etc.) to exchange information about the inspection programmes and the results of these inspections.

