

The French regulations applicable to nuclear activities are not the product of a general framework law, but have evolved gradually, to keep pace with changes in the nuclear activities themselves. Many of the texts governing these activities are therefore based on legislation of a general nature, particularly the Environment Code, which codifies law 76-629 of 10 July 1976 concerning nature protection, law 92-3 of 3 January 1992 on water and law 96-1236 of 30 December 1996 on air and the rational use of energy, the Public Health Code and the Labour Code.

The legislative provisions applicable to radiation protection and nuclear safety can be found on the one hand in chapter III of section III of book III of the first part of the Public Health Code, the provisions of which were mainly taken from ordinance 2001-270 of 28 March 2001 concerning the transposition of community directives in the field of protection against ionising radiation and, on the other, in law 61-842 of 2 August 1961 concerning the reduction of atmospheric pollution and offensive odours.

Radiation protection and nuclear safety regulations are increasingly derived from rules adopted at an international level, whether community regulations and directives, such as Council directive 96/29/Euratom dated 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, or international conventions such as the Convention on Nuclear Safety signed in Vienna on 20 September 1994 or the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, signed in Vienna on 5 September 1997.

Finally, the legal framework for nuclear activities also stems from a variety of international norms, standards and recommendations. The following in particular should be mentioned:

- the recommendations of the ICRP (International Commission on Radiological Protection), in particular the ICRP 60 currently under revision;
- the standards of the International Atomic Energy Agency (IAEA) dealing with nuclear safety and radiation protection, particularly the International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources (Safety Series no. 115);
- the work of the Western European Nuclear Regulators' Association (WENRA).

Parts 1 and 2 of this chapter in turn present the current regulatory picture in the fields of radiation protection and nuclear safety and the work in progress.

1 THE REGULATION OF RADIATION PROTECTION

Since publication of Council directive 96/29/Euratom dated 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation and Council directive 97/43/Euratom dated 30 June of 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, a complete update has been undertaken of the legislative and regulatory provisions concerning radiation protection contained in the Public Health Code and the Labour Code.

Updating of the legislative part was completed with publication of the above-mentioned ordinance of 28 March 2001 and law 2004-806 of 9 August 2004 concerning public health policy, with the introduction of new articles concerning radiation protection inspections.

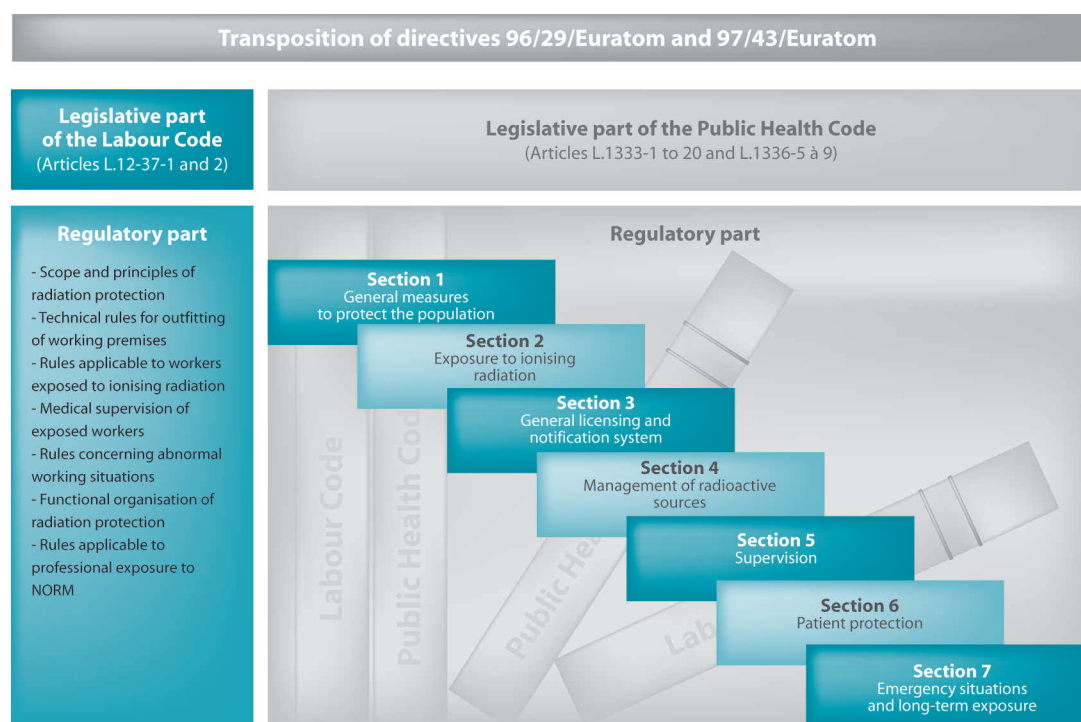
Updating of the regulatory part is currently being completed. The following were published in turn:

- decree 2001-1154 of 5 December 2001 concerning mandatory maintenance and quality control of medical devices;
- decree 2002-460 of 4 April 2002 concerning the protection of individuals against the dangers arising from ionising radiation;

- decree 2003-270 of 24 March 2003 concerning the protection of persons exposed to ionising radiation for medical and medico-legal purposes;
- decree 2003-295 of 31 March 2003 concerning intervention in a radiological emergency and in the event of long-term exposure;
- decree 2003-296 of 31 March 2003 concerning worker protection against the hazards of ionising radiation.

The decrees of 4 April 2002, 24 March 2003 and 2003-295 of 31 March, mentioned above, are codified in chapter III “Ionising Radiation” of part III of book III of the new regulatory part of the Public Health Code (art. R.1333-1 to R.1333-92). Decree 2003-296 of 31 March 2003 is codified in section 8 “Prevention of the risk of exposure to ionising radiation” in chapter I of part III of book II of the second part of the Labour Code.

The following overall architecture was adopted for updating of this legislative and regulatory framework:



Structure of the legislative and regulatory radiation protection framework

Section 7 “Emergency situations and long-term exposure” of chapter III of part III of book III of the Public Health Code was supplemented by decree 2005-1179 of 13 September 2005 concerning radiological emergency situations, in order to complete transposition of Council directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency.

Effective implementation of the new regulatory provisions remains dependent on the publication of numerous orders: 25 were published between July 2003 and December 2005, and 7 are still to be published in 2006. However, transposition of the above-mentioned directives 96/29/Euratom, 97/43/Euratom and 89/618/Euratom is considered to be complete. Completion of transposition of these three directives in 2005 was accompanied by work to update the provisions of chapter III “Ionising radiation” of part III of book III of the Public Health Code, with the following goals:

- to transpose Council directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources;
- to introduce administrative simplification measures, particularly with regard to the ionising radiation source licensing and notification procedures, incorporating the experience acquired in application of the new regulations;
- to supplement requirements concerning supervision of radiation protection;
- to provide clarifications and additional data in the wording of a number of provisions already in force.

A draft decree, subject to extensive discussion with the various parties concerned, as well as the general public (consultation on the ASN's website in September 2005), was produced and notified for information to the European Commission (under the terms of article 33 of the Euratom treaty). Its publication is scheduled for the second half of 2006.



Stamp bearing the picture of H. Becquerel, commemorating the discovery of radioactivity in 1896

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The legislative bases of radiation protection

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The Public Health Code

The principles of radiation protection

The new chapter III "Ionising Radiation" of part III of book III of the legislative part of the Public Health Code aims to cover all "nuclear activities", that is all activities involving a risk of human exposure to ionising radiation, emanating either from an artificial source, whether a substance or a device, or from a natural source when the natural radionuclides are or have been treated owing to their fissile or fertile radioactive properties. It also includes "interventions" aimed at preventing or mitigating a radiological hazard following an accident, due to environmental contamination.

The general principles of radiation protection (justification, optimisation, limitation), established internationally (ICRP) and incorporated in the above-mentioned directive 96/29/Euratom, are enshrined in the Public Health Code (article L. 1333-1). They constitute guidelines for the regulatory action for which the ASN is responsible.

1°) The principle of justification - "A nuclear activity or intervention may only be undertaken or carried out if its health, social, economic, or scientific benefits in relation to the risks inherent in the human exposure to ionising radiation which it is likely to entail so justify."

Depending on the type of activity, decision-making power with regard to justification lies with different levels of authority: it lies with the government for issues of general interest, such as whether or not to resort to nuclear energy; it is delegated by the Minister for Health to the ASN in the case of sources used for medical, industrial and research purposes; it is the competence of AFSSAPS when authorising use of a new irradiating medical device and is the responsibility of the doctors when prescribing and carrying out diagnostic or therapeutic procedures.

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 would not seem to outweigh the risk.

This prohibition is either generic (for example: ban on the intentional addition of radioactive substances in consumer goods), or the licence required with regard to radiation protection will be refused or will not be renewed. For existing activities, justification may be reassessed if current know-how and technology so warrants.

2°) The principle of optimisation - "Human exposure to ionising radiation as a result of a nuclear activity or medical procedure must be kept as low as reasonably achievable, given the current technological, economic and social factors and, as applicable, the medical purpose involved."

This principle, referred to by the acronym ALARA (as low as reasonably achievable), for example leads to a reduction in the discharge licences of the quantities of radionuclides present in radioactive effluent from nuclear installations, to mandatory monitoring of exposure at the workstation in order to reduce it to the strict minimum necessary, or to supervision to ensure that medical exposure resulting from diagnostic procedures remains close to the predetermined reference levels.

3°) The principle of limitation - "Exposure of an individual to ionising radiation resulting from a nuclear activity may not raise the sum of the doses received beyond the limits set by the regulations, unless this person is being exposed for medical or biomedical research purposes."

The exposure of the general population or of workers as a result of nuclear activities is subject to strict limits. These limits comprise significant safety margins to prevent the appearance of deterministic effects. They are also far below the doses at which probabilistic effects (cancers) have begun to be observed (100 to 200 mSv). Exceeding these limits is considered to be unacceptable and in France, can lead to administrative or legal sanctions.

In the case of medical exposure, no strict dose limit is established in that this voluntary exposure is justified by the anticipated health benefits to the person exposed.

The notification and licensing system

The new legislative base introduced into the Public Health Code means that decrees passed after advice of the Council of State can be used to lay down general rules concerning the conditions for prohibition, licensing and notification of use of ionising radiation (art. L.1333-2 and 4), as well as rules for artificial or natural radionuclides management (art. L.1333-6 to L.1333-9). These licences and notifications concern all applications of ionising radiation generated by radionuclides or by electrical X-ray generators, whether for medical, industrial or research purposes. Some may however benefit from exemptions.

Exposure to TENORM

The transposition of above-mentioned directive 96/29/Euratom also led to new provisions being defined to assess and reduce exposure to naturally-occurring ionising radiation (NORM), in particular exposure to radon, when human activities contribute to enhancing this exposure (article L.1333-10 of the Public Health Code).

Inspection of radiation protection

In 2004, new provisions were introduced, creating the new radiation protection inspectorate (art. L.1333-17 to L.1333-19), oversight of which is entrusted to the ASN. An implementing decree setting the procedures for designating, qualifying and swearing-in the radiation protection inspectors is currently being finalised. The radiation protection inspectors, designated by the ministers for Health and Labour, on proposals from the DGSNR, will mainly be chosen from among ASN staff, but also from among inspectors of installations classified on environmental protection grounds working in the DRIRES. The administrative and judicial police powers of the radiation protection inspectors were also defined (art. L.1337-1-1).

Finally, a new system of legal sanctions accompanies these provisions (articles L. 1337-5 to L. 1337-9).

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The Labour Code

The new provisions of the Labour Code (articles L. 230-7-1 and L. 230-7-2) introduce a legislative base specific to the protection of workers, whether or not salaried employees, with a view to transposition of Council directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas, and the above-mentioned Council directive 96/29/Euratom. They bring French legislation into line with directive 90/641/Euratom concerning non-salaried workers exposed to ionising radiation.

A link with the three radiation protection principles in the Public Health Code is established in the Labour Code, and the rules concerning worker protection are the subject of a specific decree (decree 2003-296 of 31 March 2003).

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Protection of individuals against the dangers of ionising radiation from nuclear activities

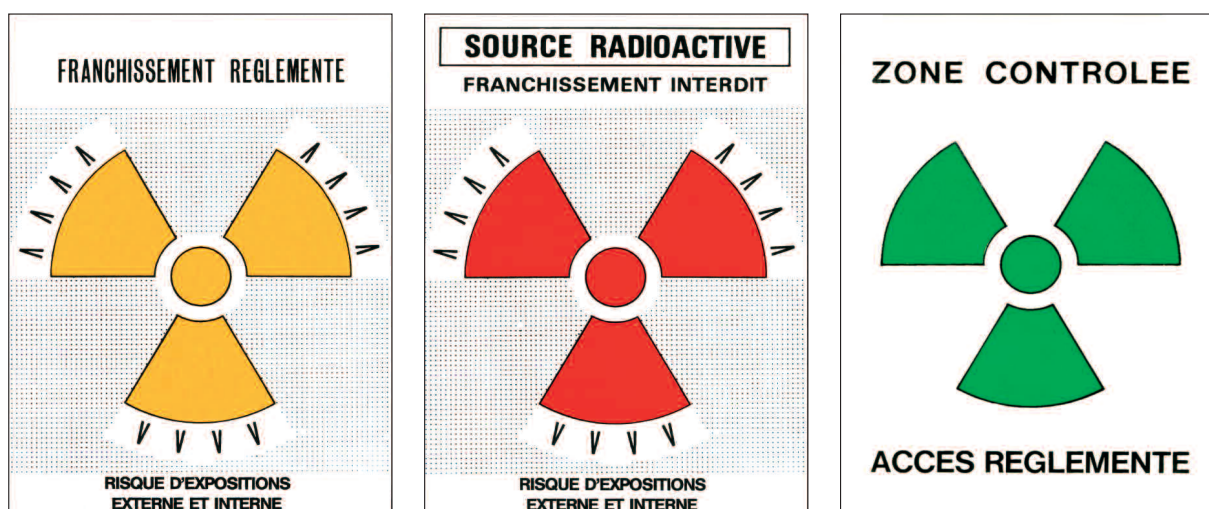
A table appended to this chapter gives the various levels and exposure limits set by the new regulations or the regulations currently under preparation.

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General protection of workers

The new articles R. 231-71 to R. 231-116 of the Labour Code, introduced by above-mentioned decree 2003-296 of 31 March 2003, create a single radiation protection system for all workers (whether or not salaried) likely to be exposed to ionising radiation during their professional activities. Of these requirements, the following should be mentioned:

- application of the optimisation principle to the equipment, processes and work organisation (art. R. 231-75), which will lead to clarification of where responsibilities lie and how information is circulated between the head of the facility, the employer, in particular when he or she is not the head of the facility, and the person with competence for radiation protection;
- the dose limits (art. R. 231-76) were reduced to 20 mSv for 12 consecutive months, barring waivers resulting from exceptional exposure levels justified in advance, or emergency occupational exposure levels;



Signs indicating areas in which radioactive work is in progress

-the dose limits for pregnant women (art. R. 231-77) or more accurately for the child to be born (1 mSv for the period from the declaration of pregnancy up until birth).

The publication of six implementing orders since March 2003 has provided the clarification necessary for these new measures to be put into practice.

Zoning

New stipulations concerning the definition of controlled areas, monitored zones and specially regulated zones are yet to be published (planned for 2006), in order to take account of the new dose limits. The monitored zone is required to cover potential exposure of workers in excess of 1 mSv per year, and the controlled area is required to cover exposure likely to exceed 6 mSv per year. This order will also give the necessary additional information for defining signalling rules and health and safety rules within these zones.

The person with competence for radiation protection (PCR)

The duties of the person with competence for radiation protection (PCR) were extended to marking out the areas in which radiation work is being carried out, to studying the exposed workstations and to taking measures such as to reduce exposure (optimisation). For the performance of these duties, the PCR will have access to passive dosimetry and operational dosimetry data (art. R. 231-106). The instructor must be certified by an organisation accredited by the COFRAC.

The new order of 26 October 2005 concerning training of the person with competence for radiation protection and certification of the instructor, which abrogated the previous order of 29 December 2003, now makes a distinction between three sectors of activity:

- a) the “medical” sector, comprising nuclear and radiological activities intended for preventive and curative medicine - including medico-legal examinations - dentistry, medical biology and biomedical research, as well as veterinary medicine;
- b) the “BNI - ICPE” sector, covering establishments containing one or more basic nuclear installations and those which comprise an installation subject to licensing as a classified facility, with the exception of the nuclear activities in the medical sector defined above;
- c) the “industry and research” sector, covering the nuclear activities defined in article R. 231-73 of the Labour Code, with the exception of the activities in the “medical” and “BNI - ICPE” sectors defined above.

Training comprises a theory module - common to all the options - and a practical module specific to each sector, comprising two options (“sealed sources and electric generators of ionising radiation” and “unsealed sources”). The duration and content of the PCR training programme therefore differ according to the activity sector in which the person is to work and the type of sources used.

Dosimetry

The new modalities for accreditation of organisations responsible for worker dosimetry have also been published (order of 6 December 2003); the new modalities for worker medical supervision and transmission of information on individual dosimetry were published in the order of 30 December 2004.

Radiation protection supervision

Technical supervision of sources and devices emitting ionising radiation, protection and alarm devices and measuring instruments, as well as ambient environment checks, can be entrusted to IRSN, to the department with competence for radiation protection or to organisations approved under application of article R. 1333-44 of the Public Health Code. The supervision procedures were published in the order of 26 October 2005.

In application of articles R. 231-84 of the Labour Code and R. 1333-44 of the Public Health Code, this order defines the type and frequency of radiation protection technical supervision inspections. These concern sources and devices emitting ionising radiation, the ambient environment, measuring instruments and protection and alarm devices, management of sources and of any waste and effluent produced. This supervision is partly carried out as part of the operator's in-house inspection processes and partly by outside organisations (the outside checks must be performed by the IRSN or an organisation approved under article R. 1333-44 of the Public Health Code). The approval procedures for these organisations were defined in the order of 9 January 2004. ASN is now responsible for examining accreditation applications submitted by the organisations. A new list of approved organisations was published by orders dated 17 March and 18 July 2005.

Radon in the working environment (see point 1/4/1 below)

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General protection of the population

Apart from the special radiation protection measures included in individual nuclear activity licences for the benefit of the population as a whole and the workers, a number of general measures included in the Public Health Code help to protect the public against the dangers of ionising radiation.

The intentional addition of natural or artificial radionuclides in all consumer goods and construction materials is prohibited (art. R. 1333-2 of the Public Health Code). Waivers may however be granted by the Minister for Health after receiving the opinion of the French High Public Health Council, except with respect to foodstuffs and materials placed in contact with them, cosmetic products, toys and personal ornaments. This new range of prohibitions does not concern the radionuclides naturally present in the initial components or in the additives used to prepare foodstuffs (for example potassium 40 in milk) or for the manufacture of materials used in the production of consumer goods or construction materials.

Furthermore, the use of materials or waste from a nuclear activity is also in principle prohibited, when they are contaminated or likely to have been contaminated by radionuclides as a result of this activity.

The annual effective dose limit (article R. 1333-8 of the Public Health Code) received by a member of the public as a result of nuclear activities, is set at 1mSv; the equivalent dose limits for the lens of the eye and the skin are set at 15mSv/year and 50mSv/year respectively (average value for any 1cm surface of skin). The calculation method for the effective and equivalent dose rates and the methods used to estimate the dosimetric impact on a population are defined by ministerial order of 1 September 2003.

A national network for collection of environmental radioactivity measurements is currently being set up (art. R. 1333-11 of the Public Health Code) and the data collected will help estimate the doses received by the population. This network collates the results of the various environmental impact assessments required by the regulations, and those of analyses performed by the various government departments and its public institutions, by local authorities and by associations who so request. These results will be made available to the public. Management of this monitoring network has been entrusted to the IRSN, with guidelines being defined by the ASN (order of 27 June 2005 organising



Sun lotion advertisement

the national network for environmental radioactivity measurements and setting the procedures for laboratory accreditation).

So that the quality of the measurements taken can be guaranteed, the laboratories in this network must meet approval criteria, which in particular include intercomparison tests.

Management of waste and effluent from BNIs and ICPEs is subject to the provisions of the special arrangements concerning these installations (see point 2 of this chapter). For management of waste and effluent from other facilities, including hospitals (art R. 1333-12 of the Public Health Code), general rules will be specified by an interministerial order (not yet published). These waste and effluent must be eliminated of in duly authorised facilities, unless there are special provisions for on-site organisation and monitoring of their radioactive decay (this concerns radionuclides with a radioactive half-life of less than 100 days).

Although above-mentioned directive 96/29/Euratom so allows, French regulations have not adopted the notion of discharge threshold, in other words the generic level of radioactivity below which the effluent and waste from a nuclear activity can be disposed of without supervision. In practice, waste and effluent disposal is monitored on a case by case basis when the activities which generate them are subject to licensing (as is the case of BNIs and installations classified on environmental protection grounds). The regulations also do not include the notion of “trivial dose”, in other words the dose below which no radiation protection action is felt to be necessary. This notion appears however in above-mentioned directive 96/29/Euratom (10 µSv/year).

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The licensing and notification procedures for sources of ionising radiation

The new system of licensing or notification, which covers all sources of ionising radiation, is now described in full in section 3 of chapter III of part III of book III of the Public Health Code. All medical, industrial and research applications are concerned by these measures. This more specifically concerns the manufacture, possession, distribution - including import and export, and use of radionuclides or products and devices containing them. The use of X-ray equipment is subject to notification for medical radio-diagnostic (except for very large systems) or to licensing in all other cases.

It should be noted that the licensing system applies irrespectively to companies or facilities which have radionuclides on-site, as well as to those which trade in them without directly possessing them. This is in conformity with directive 96/29/Euratom which explicitly mentions both import and export. From the public health and safety viewpoint, this obligation is essential to close monitoring of source movements and to prevent accidents as a result of stray sources.

It should be remembered that, in accordance with article L. 1333-4 of the Public Health Code, licences for industries subject to the Mining Code, for BNIs and for ICPEs, replace the radiation protection licence. However, this exception does not concern ionising radiation applications for medical purposes or for biomedical research.

The modalities for submitting licensing or registration applications were specified in the order of 14 May 2004.

a) the medical, biomedical research and medico-legal fields

For medical and biomedical research applications, the licensing system contains no exemptions:

- the licences required for the manufacture of radionuclides, or products and devices containing them, as well as for their distribution, import or export, are issued by the French Health Products Safety Agency (AFSSAPS);

- the licences required for the use of radionuclides, products or devices containing them, are issued at a national level by the ASN;

- X-ray generators, which hitherto were subject to technical approval by OPRI, are now subject to notification to the Prefect if they are of low-intensity (radiology or dental surgery), while a system of licences issued by the ASN applies to sophisticated equipment (scanners).

X-ray installations used for medico-legal procedures are subject to a system of licensing or notification applicable to medical installations, whenever their operation involves exposing persons to ionising radiation.

Furthermore, to be able to carry out biomedical research, the “researcher” must obtain a premise licence (article L.1124-6 of the Public Health Code). The licence is issued by the Director General of AFSSAPS with regard to medical devices, drugs and cosmetics, or by the Minister for Health (General Directorate for Health) with regard to physiology, physiopathology, epidemiology and genetics research.

b) the industrial and non-medical research fields

The ASN is also responsible for issuing licences for industrial and non-medical research applications, on behalf of the Minister for Health. In these fields, this concerns:

- the import, export and distribution of radionuclides and products or devices containing them;
- the manufacture of radionuclides, products or devices containing them, the use of devices emitting X-rays or of radioactive sources, the use of accelerators other than electron microscopes and the irradiation of products of whatsoever nature, including foodstuffs, with the exception of activities which are licensed under the terms of the Mining Code, the BNI system or that applicable to ICPEs.

New criteria for licensing exemption incorporated in directive 96/29/Euratom (Appendix 1, table A) have been introduced into and appended to the Public Health Code (table A, appendix 13-8). Values for additional radionuclides were introduced in the order of 2 December 2003. These criteria replace those given in decree 66-450 of 20 June 1966 concerning the general principles of protection against ionising radiation. Exemption will be possible if one of the following conditions is met:

- the total quantity of radionuclides possessed is less than the exemption values in Bq;
- the radionuclide concentrations are less than the exemption values in Bq/kg.

For this latter criterion, the decree introduces an additional mass restriction criterion (the mass of material used must be less than 1 tonne). This reference criterion was used when preparing the scenarios used to define the exemption values. The transposition into French law is thus stricter than directive 96/29/Euratom which does not introduce this mass limit. Introduction of this restrictive criterion should avoid the risk of the radioactive material being diluted in order to fall below the exemption threshold.

The way this system of licences, issued according to the Public Health Code, interfaces with the system of classified installations was clarified by a circular from the Minister for Ecology and Sustainable Development on 19 January 2004.

c) technical supervision of radiation protection

Technical supervision of the radiation protection organisation, including supervision of the management of radioactive sources and any associated waste, is entrusted to approved organisations (R. 1333-44 of the Public Health Code). The type and frequency of the inspections were defined by the order of 26 October 2005, mentioned in point 1|2|1.

Radioactive source management rules

The general radioactive source management rules are contained in section 4 of chapter III of part III of book III of the Public Health Code. They were drafted on the basis of rules laid down by CIREA (Interministerial commission on artificial radioelements) and their supervision is now the responsibility of the ASN. However, CIREA's radioactive source inventory duties have been transferred to IRSN (article L1333-9 of the Public Health Code). These general rules are as follows:

- sources may only be transferred to or acquired from someone in possession of a licence;
- prior registration with IRSN is mandatory for the acquisition, distribution, import and export of radionuclides in the form of sealed or unsealed sources, or products or devices containing them. This prior registration is necessary so that monitoring of the sources and control by the customs services can be organised;
- traceability of radionuclides in the form of sealed or unsealed sources, or products or devices containing them, is required in each institution, and a quarterly record of deliveries must be sent to IRSN by the suppliers;
- any loss or theft of radioactive sources must be declared;
- validity of the formalities required for the import and export of radioactive sources, products or devices, defined by CIREA and the customs services, is renewed.

The system for disposal and recovery of sealed sources which have either expired or reached the end of their operational life, is taken from CIREA's special licensing conditions (decision of the 150th CIREA meeting of 23 October 1989):

- all users of sealed sources are required to recover sources that have expired, are damaged, or have reached the end of their operational life, at their own expense (except when a waiver is granted for decay in-situ);
- simply at the request of the user, the supplier is required unconditionally to recover any source no longer needed or which has expired.

The conditions for the use of gammagraphy appliances were updated by the order of 2 March 2004, thereby abrogating the special conditions which had been stipulated by CIREA.

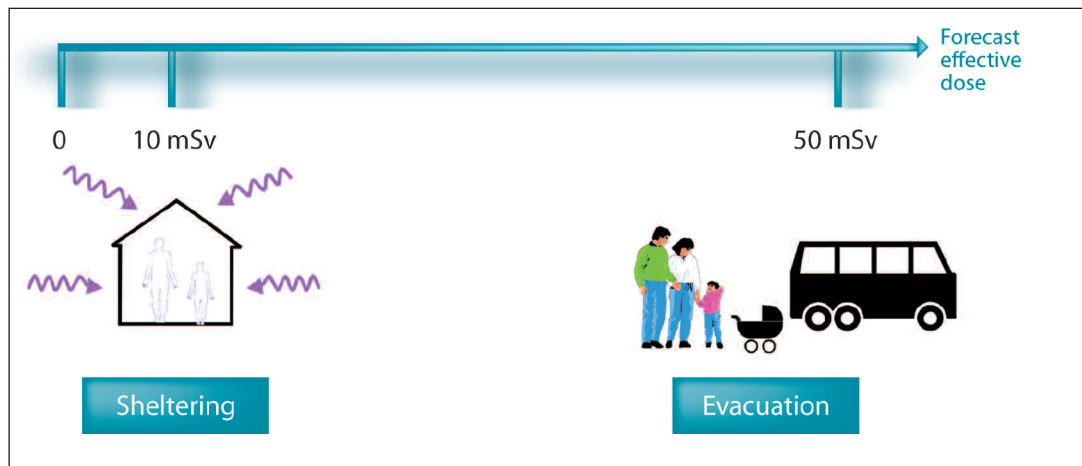
The question of financial guarantees will be dealt with in a decree implementing article L. 1333-7 of the Public Health Code which introduces the principle of source recovery by the supplier and the principle of financial guarantees. This new decree should also take account of the requirements of the new directive 2003/122/Euratom of 22 December 2003 concerning supervision of high-level sealed radioactive sources and orphan sources.

Protection of persons in a radiological emergency situation

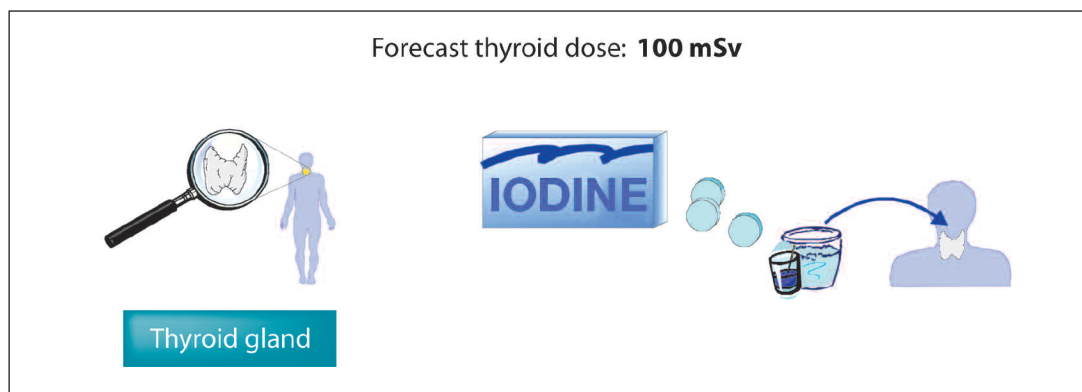
The population is protected against the hazards of ionising radiation in case of an accident or of radiological emergency situations through the implementation of specific actions (or countermeasures) appropriate to the nature and scale of the exposure. In the particular case of nuclear accidents, these actions were defined in the interministerial circular of 10 March 2000 which amended the off-site emergency plans applicable to basic nuclear installations, by expressing response levels in terms of doses. Exceeding these levels does not constitute a breach; such levels are simply a point of reference for the government authorities (Prefect), who are required on a case by case basis to decide on the feasibility of the action to be taken locally.

These actions are:

- sheltering, if the predicted effective dose exceeds 10 mSv;
- evacuation, if the predicted effective dose exceeds 50 mSv;
- administration of stable iodine, when the predicted dose in the thyroid is likely to exceed 100 mSv.



Response levels for population protection: sheltering and evacuation



Response levels for population protection: absorption of iodine

These response levels were included in the order of 13 October 2003 concerning response levels in a radiological emergency situation, implementing article R. 1333-80 of the Public Health Code. The reference exposure levels for persons intervening in a radiological emergency situation are also defined in the regulations (article R. 1333-86 of the Public Health Code) and two groups of response personnel are thus defined:

a) The first group comprises the personnel making up the special technical or medical response teams set up to deal with a radiological emergency. These personnel benefit from radiological surveillance, a medical aptitude check-up, special training and equipment appropriate to the nature of the radiological risk.

b) The second group comprises personnel who are not members of the special response teams but who are called in on the basis of their competence. They are given appropriate information.

The reference individual exposure levels for the participants, expressed in terms of effective dose, should be set as follows:

a) The effective dose which may be received by personnel in group 1 is 100 mSv. It is set at 300 millisieverts when the intervention measure is aimed at protecting other people.

b) The effective dose which may be received by personnel in group 2 is 10 millisieverts. In exceptional circumstances, volunteers informed of the risks involved in their acts may exceed the reference levels, in order to save human life.

Information of the population in a radiological emergency

The procedures for informing the population of a radiological emergency are detailed in a specific directive (directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency). This directive was transposed into French law by:

- decree 2001-470 of 28 May 2001 concerning information of the population and amending decree 88-622 of 6 May 1988 concerning emergency plans and two implementing orders (order of 30 November 2001 concerning the creation of an emergency alert system around a basic nuclear installation with an off-site emergency plan and the order of 21 February 2002 concerning information of the population);

- decree 2005-1179 of 13 September 2005 concerning radiological emergency situations.

Definition of a radiological emergency situation (article R. 1333-76 of the Public Health Code)

“There is a radiological emergency when an event is likely to lead to the emission of radioactive materials or to a level of radioactivity such as to constitute a hazard for public health, in particular with reference to the limits and response levels set in articles R. 1333-8 and R. 1333-80 respectively. This event may be the result of:

1°) an incident or accident occurring during the performance of a nuclear activity defined in article L. 1333-1, including the transport of radioactive substances;

2°) a malicious act;

3°) environmental contamination detected by the environmental radioactivity measurement network mentioned in article R. 1333-11;

4°) environmental contamination made known to the competent authority under the terms of international conventions or agreements, or decisions made by the European Community for information in the event of a radiological emergency.”

Two implementing orders were published:

- the order of 4 November 2005 concerning information of the population in the event of a radiological emergency situation;

- the order of 8 December 2005 concerning the medical aptitude check-up, radiological surveillance and training or information of the personnel involved in managing a radiological emergency situation.

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Protection of the population in a long-term exposure situation

In recent years, and on a case by case basis, the General Directorate for Health (Ministry for Health) set clean-up thresholds for sites contaminated by radioactive substances. These were sites which had been contaminated by a nuclear activity in the recent or more distant past (use of unsealed sources, radium industry, etc.) or an industrial activity using raw materials containing significant quantities of natural radioelements (uranium and thorium families). Most of these sites are listed in the inventory distributed and periodically updated by ANDRA.

This approach has today been abandoned in favour of a complete methodological approach defined in the IPSN guide (methodology guide for sites contaminated by radioactive substances, version 0, December 2000), produced at the request of the ministries for Health and the Environment, and distributed to the prefects (DRIRE and DDASS/DRASS). Based on the current and future uses of the land and premises, this guide proposes a number of steps for local definition of rehabilitation targets expressed in terms of doses. The parties concerned (owners of the site, local elected representatives,

local residents, associations) are involved in the process. Operational values for decontamination can then be set for each case.

This new approach now has a regulatory framework in article R. 1333-90 of the Public Health Code.

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Protection of persons exposed for medical and medico-legal purposes



Stamp commemorating the discovery of radium by Pierre and Marie Curie

The transposition of above-mentioned directive 97/43/Euratom into French legislation has led to a legislative and statutory framework geared to radiation protection for patients, whereas in the past this issue used to be a confidential subject handled exclusively by the medical practitioner carrying out the procedure. The new regulatory framework, created in March 2003, was completed at the end of 2005. At the same time medical practitioners have engaged major initiatives to ease implementation of this new device, promoting the establishment of good practices for procedures involving the use of ionising radiation.

Radiation protection for persons exposed for medical purposes is now based on two regulatory principles: justification of the procedures and optimisation of exposure, which are under the responsibility of both the practitioners prescribing medical imaging examinations entailing exposure to ionising radiation and the practitioners carrying out these procedures. They cover all the diagnostic and therapeutic applications of ionising radiation, including radiological examinations requested for screening, occupational health, sports medicine and in a medico-legal setting.

1 | 3 | 1

Procedures justification

A written exchange of information between the prescribing practitioner and the practitioner carrying out the procedure exposing the patient should justify the benefit of the exposure for each procedure. This “individual” justification is required for each procedure. However it will be based on a general justification of medical procedures using ionising radiation, set out in good practices guides currently finalised by the various learned societies.

As an example, under the principle of justification, the use of radioscopy appliances without image intensification was prohibited in 2003 (article R. 1333-58 of the Public Health Code); the procedures for decommissioning these appliances were specified in the order of 17 July 2003. Establishments

operating a total number of 35 installations of this type have confirmed that their equipment is no longer in use and has been scrapped.

Prescription and procedure guides for the performance of medical procedures involving exposure to ionising radiation

Articles R. 1333-70 and R. 1333-71 of the Public Health Code respectively refer to the publication of “prescription of routine procedures and examinations” guides (also called “indication guides”) and “performance of procedures involving exposure to ionising radiation” guides (called “procedure guides”). Under the impetus of the departments reporting to the Ministry for Health (DGSNR since 2002), the professionals represented by their learned societies, including the French radiotherapy and oncology society (SFRO), the French radiology society (SFR), the French biophysics and nuclear medicine society (SFBMN), the French medical radio-physics society (SFPM), have set up the necessary working frameworks for drafting these guides. As applicable, DGSNR coordinates or supports this work, or is simply kept informed. The progress of the various guides is presented in the following table.

| Specialty | Medical radiology | | Nuclear medicine | Radiotherapy | Dental radiology |
|------------------------|------------------------|-------------------------|---------------------------------|--------------------|---------------------------------|
| Documents | Procedure guide | Indication guide | Indication and procedure guides | Good practices | Indication and procedure guides |
| Start | 09.1999 | 06.2001 | 09.1999 | 04.2004 | 01.2004 |
| Interim reports | 07.2000 | 03.2004 | 06.2004 | 10.2005 | 08.2005 |
| Finalisation | 10.2001* (JFR 2001) | 10.2004 (JFR 2004) | | Scheduled for 2006 | Scheduled for 12.2006 |
| Availability | SFR and IRSN website | SFR publication website | SFBMN website | – | – |

*Currently being updated

Table giving progress of prescription and performance guides for medical procedures involving exposure to ionising radiation

1 | 3 | 2

Exposure optimisation

Optimisation in medical imaging (radiology and nuclear medicine) consists in delivering the lowest possible dose compatible with obtaining a quality image that provides the diagnostic information sought for. Optimisation in therapy (external radiotherapy, brachytherapy and nuclear medicine) consists in delivering the prescribed dose to the tumour to destroy cancerous cells while limiting the dose to healthy tissues to the strict minimum. The optimisation approach is thus a pledge of the quality of the procedures conducted. Standardised guides for conducting procedures using ionising radiation have or are being written by health professionals to make optimisation easier in practice (see table above).

Diagnostic reference levels

New statutory concepts specific to radiation protecting for patients have been introduced for this very purpose and reference diagnostic levels were set in the order of 12 February 2004. For radiolo-

gy, this consists of dose values, while for nuclear medicine it consists of activity levels administered in the course of the most common or most heavily irradiating examinations. These reference levels will be updated by conducting regular measurements or readings in line with the type of examination in each radiology and nuclear medicine department and centralizing them at the IRSN. Therefore, since June 2004, any new radiology appliances which enter service must be fitted with a device for estimating the dose delivered during an examination (article R. 5211-22 of the Public Health Code).

Dose constraints

In the field of biomedical research, where exposure to ionising radiation entails no direct benefit for the persons exposed, dose constraints designed to encompass the doses delivered must be established by the practitioner. An order currently being drafted will specify the methods for validating these dose constraints.

Medical radiological physics

Special medical physics skills are called for in optimising the dose delivered to patients. The employment of a specialised medical radiological physicist, formerly called a “radiophysicist”, has been extended to radiology having already been compulsory in radiotherapy and nuclear medicine. Qualification of such specialists involves obtaining a master's degree (the list of which was published in the order of 7 February 2005), followed by specialist training including clinical work placements.

The duties of this specialist have been specified and expanded (order of 19 November 2004). Thus medical radiological physics specialists must ensure the appropriateness of the equipment, data and computing processes for determining and delivering the doses and activity levels administered to the patient in any procedure involving ionising radiation. In the field of radiotherapy they guarantee that the radiation dose received by the tissues due to be irradiated matches that prescribed by the prescribing physician.

Furthermore, they estimate the dose received by the patient during diagnostic procedures and play a part in quality assurance including inspecting the quality of the medical devices. Finally they contribute to teaching and training the medical and paramedical personnel in medical radiological physics.

As part of the new measures, heads of establishments will have to draw up plans for medical radiological physics as of the year 2005, defining the resources allocated, primarily in terms of staffing, in the light of the medical practices carried out in the establishment, the actual or probable patient numbers, existing dosimetry skills and resources allocated to quality assurance and control.

Maintenance and quality control of medical devices

Maintenance and quality control, both internal and external, of medical devices using ionising radiation (articles R. 5211-5 to R. 5211-35 of the Public Health Code) have been mandatory since publication of the order of 3 March 2003. Outside quality control is entrusted to organisations approved by the Director General of the AFSSAPS who is responsible for issuing a decision to define the acceptability criteria, the monitoring parameters and the frequency of the inspections on the medical devices concerned.

Four decisions were published:

- decision of 2 March 2004 concerning outside quality control of external radiotherapy installations;
- decision of 2 March 2004 concerning electron accelerators for medical uses and tele-cobalt therapy devices.
- decision of 20 April 2005 setting the quality control procedures for bone mineral density test devices using ionising radiation;

-decision of 7 October 2005 concerning monitoring of mammography installations, modified by a decision of 16 December 2005.

Furthermore greater knowledge of the radiology appliances in use will be needed to further external quality control and assess how effective it is. Therefore a new ownership notification procedure was set up in 2004 for radiological equipment.

Training and information

Additional major factors in the optimisation approach are the training of health professionals and informing patients. Work is continuing on finalising the mechanism introduced in March 2003, through statutory channels.

Thus the objectives and content of training programmes for practitioners conducting procedures using ionising radiation, or who assist in these procedures, were defined in the order of 18 May 2004. This patients radiation protection training is already part of initial medical training programmes and extends to other medical professions involved in these procedures; on-the-job training, currently being devised by learned societies and professional bodies, will also be offered to working practitioners.

As regards the traceability of the data on the application of justification and optimisation, the report on the procedure, written by the medical practitioner carrying out the examination, must provide the information justifying the need for the exposure, the operations carried out and the data used to estimate the dose received by the patient. An order is awaited that will specify the nature of this data in detail.

Finally, before carrying out a diagnostic or therapeutic procedure using radionuclides, the physician must give the patient oral and written guidelines on radiation protection that are of use to him/herself, his/her relations, the public and the environment. In the event of a therapeutically-oriented nuclear medicine procedure, this information, issued in a written document, provides lifestyle hints to enable potential contamination to be minimised and states, for example, for how many days contacts with the spouse and children should be reduced. Recommendations (the French High Council on Public Health, or learned societies) are awaited to harmonise the content of information already given out.

1 | 3 | 3

Medico-legal applications of ionising radiation

In the medico-legal field, ionising radiation is used in a wide variety of sectors such as occupational medicine, sports medicine or for investigative procedures required by the courts or insurance companies. The principles of justification and optimisation defined apply both to the person requesting the examinations and to the person performing them.

In occupational medicine, ionising radiation is used for medical supervision of workers (whether or not professionally exposed to ionising radiation, for example workers exposed to asbestos). A working group set up by the ASN is examining the justification and optimisation of various procedures currently conducted, some of which are required by the regulations. The conclusions of this work will be available during the course of 2006.

For medical supervision of high-level athletes, radiographic examinations are stipulated in the regulations (order of 11 February 2004). On the basis of the work of an expert group, tasked jointly by the Minister for Sport, the Directorate-General for Health and the ASN with evaluating the justification for these examinations, a modification to this order is planned for 2006.

1 | 4

Protection of persons exposed to TENORM

1 | 4 | 1

Protection of persons exposed to radon

The regulatory framework applicable to management of the radon-related risk in premises open to the public (article R. 1333-15 of the Public Health Code) introduces the following clarifications:

- the radon monitoring obligation applies in geographical areas in which radon of natural origin is likely to be measured in high concentrations and in premises in which the public is likely to stay for extended periods;
- the measurements will be made by organisations approved by the Minister for Health, these measurements being repeated every 10 years and whenever work is carried out to modify the ventilation or the radon tightness of the building.



Stamp commemorating the centenary of the discovery of radium

In addition to introducing action trigger levels of 400 and 1000 Bq/m³, the implementing order of 22 July 2004 concerning management of the radon risk in premises open to the public defined geographical areas and premises open to the public for which radon measurements are now mandatory: the geographical areas correspond to the 31 departments classified as having priority for radon measurement (see map enclosed); the categories of premises open to the public cover teaching institutions, health and social institutions, spas and penitentiaries.

The obligations of the owner of the facility are also specified when the action trigger levels are found to have been exceeded.

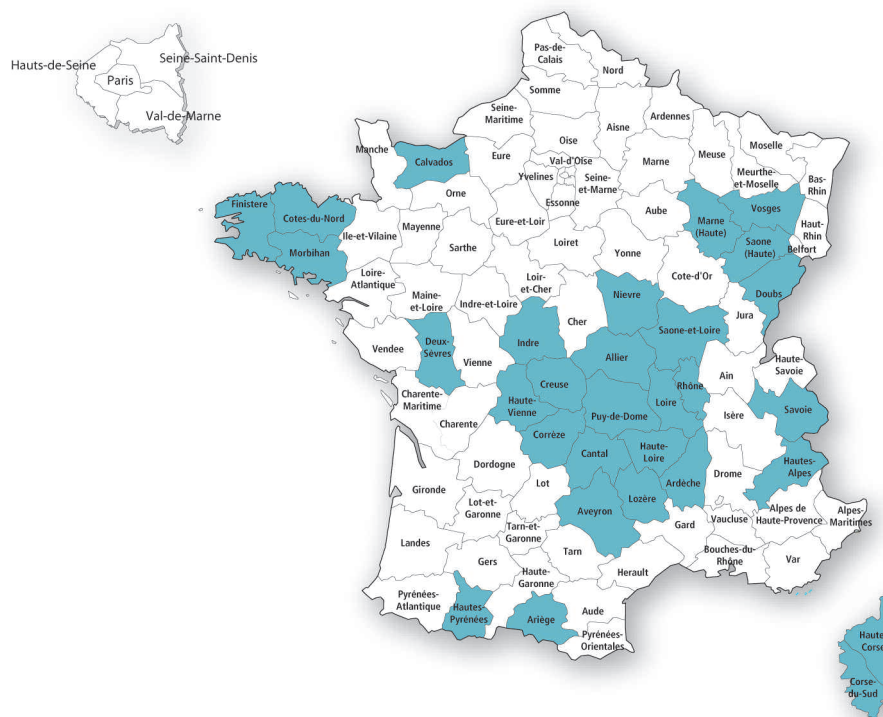
The conditions for accreditation of the organisations authorised to carry out activity concentration measurements were defined in the order of 15 July 2003 concerning the accreditation of organisations responsible for measuring radon. The list of accredited organisations was updated by three orders published in 2005, on the opinion of the accreditation committee comprising representatives of the ministries concerned, of technical bodies (IRSN, Building industry's scientific and technical centre, French higher public health council), construction professionals and professionals concerned by radon measurement.

The order of 22 July 2004 was accompanied by publication in the Official Gazette of a notice defining the applicable standards for radon measurement (Official Gazette of 12 August 2004) and another notice concerning definition of the actions and work to be carried out in the event of these 400 and 1000 Bq/m³ action trigger levels being exceeded (Official Gazette of 22 February 2005).

In the residential field, the National health and environment plan has defined a number of priorities which include regulatory action to deal with the radon risk:

- setting up a radon diagnosis to improve information made available to future real estate buyers and tenants;
- definition of construction rules for newly built accommodation located in the priority areas.

Finally, in the working environment, the new article R. 231-115 of the Labour Code requires the head of the facility to take radon activity measurements and take the steps needed to reduce exposure when the measurement results reveal an average radon concentration of more than 400 Bq/m³. An order defining the workplaces in which these measurements are required should be published in 2006.



Map of 31 departments with radon measurement priority

1 | 4 | 2

Other sources of exposure to TENORM

Professional activities which use materials which naturally contain radioelements not used for their intrinsic radioactive properties but which are likely to create exposure such as to harm the health of workers and the public (“enhanced” natural exposure) are subject to the provisions of the Labour Code (art. R. 231-114 of the Labour Code) and the Public Health Code (art. R. 1333-13 of the Public Health Code).

The order of 25 May 2005 defines the list of professional activities using raw materials naturally containing radioelements, the handling of which can lead to significant exposure of the population or of workers. The following are therefore concerned:

1. coal combustion in thermal power plants;
2. processing of tin, aluminium, copper, titanium, niobium, bismuth and thorium ores;
3. the production of refractory ceramics as well as glassmaking, foundry, steelmaking and metallurgical activities employing them;

4. the production or use of compounds comprising thorium;
5. the production of zircon and baddeleyite, and foundry and metallurgical activities employing them;
6. the production of phosphated fertilisers and the manufacture of phosphoric acid;
7. processing of titanium dioxide;
8. processing of rare earths and production of pigments containing them;
9. treatment of underground water by filtration intended for the production of:
 - water intended for human consumption
 - mineral waters;
10. Spas.

For these activities, the Public Health Code now contains an obligation to proceed with a study to estimate the doses to which the population is subjected. The Minister for Health may also implement measures to protect the public against ionising radiation, should this prove necessary in the light of the estimations made. When these activities fall into the category of classified installations, these measures will be defined by the corresponding applicable regulations.

In addition, and if protection of the public so warrants, it will also be possible to set radioactivity limits for the construction materials and consumer goods produced by some of these industries (art. R.1333-14 of the Public Health Code). This measure complements the ban on the intentional addition of radioactive substances to consumer goods.

For professional exposure resulting from these activities, a dose evaluation process, under the responsibility of the head of the facility, was introduced into the Labour Code. Should the dose limit of 1 mSv/year be exceeded, steps to reduce exposure should be taken. The above-mentioned order of 25 May 2005 offers clarification of the technical measurement procedures for evaluating the doses received by the workers.

Finally, the Labour Code (art. R. 231-116) stipulates that for aircrews likely to be exposed to more than 1 mSv/year, the head of the facility must evaluate the exposure, take steps to reduce the exposure (particularly in the event of a declared pregnancy) and inform the personnel of the health risks. The order of 7 February 2004 defines the procedures for implementing these measures.



Stamp illustrating uranium ore mining in the Limousin region

1 | 5

Radiological quality of water intended for human consumption and foodstuffs

• Council directive 98/83/CE of 3 November 1998 concerning the quality of water intended for human consumption, transposed into national law by decree 2001-1220 of 20 December 2001 on water intended for human consumption, with the exception of natural mineral waters, set radiological quality criteria for waters intended for human consumption. Two quality indicators concerning radioactivity were taken into account: tritium and the total indicative dose (TID). The reference level

for tritium was set at 100 Bq/l, and that of the TID at 0.1mSv/year. Tritium is considered to be an indicator capable of revealing the presence of other artificial radionuclides, while the TID covers both natural radioactivity and radioactivity due to the presence of artificial radionuclides.

Appendices 2 and 3 of above-mentioned directive 98/83/EC should shortly be completed to clarify the radiological analyses strategy associated with TID. The document which should soon be adopted by the committee composed of representatives of the Member States created by directive 98/83/EC recommends introducing the measurement of gross alpha and beta activity indicators and the corresponding values adopted by the World Health Organisation (0.1 Bq/l and 1 Bq/l respectively), and a search for specific natural and artificial radionuclides, when one or other of these gross activity values is not met.

On this basis, the order of 12 May 2004 setting radiological quality control procedures for water intended for human consumption, implementing the above-mentioned decree of 20 December 2001, defines the new radiological monitoring programmes for public mains water and non-mineral bottled waters.

•Several European regulations (Council Regulations n° 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedstuffs following a nuclear accident or in any other case of radiological emergency, Council Regulation n° 2219/89/EEC of 18 July 1989 on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency) were adopted subsequent to the Chernobyl accident, to establish the maximum allowable levels of radioactivity in contaminated foodstuffs. These levels, along with the values of the Codex alimentarius for international trade, are appended to this chapter.

At the end of 2004, as soon as it became aware of the issue, the ASN made known its opposition to the project to revise the indicative limits for radionuclides in foodstuffs applicable to international trade, as established by the FAO/WHO/IAEA¹ expert group.

The ASN in particular criticised the approach taken by the expert group, which deals with the long-term consequences of an accident (or malicious act) in the same way as those resulting from authorised discharges of radioactive effluent from the installations into the environment. In environmental terms, it would seem preferable to limit and control releases at source rather than after their dilution in the environment through the food chain. During normal operation of the installations, the radiological impact of releases via foodstuffs must remain as low as possible.

Apart from in accident situations, the adoption of foodstuff contamination standards is not an effective means of limiting and controlling nuclear installation discharges, because a very slight rise in the contamination of foodstuffs would be indicative of a serious and totally unacceptable malfunction of the installations, which should in any case be detected by the alert systems.

The concerns of the French authorities were similar to those expressed by the departments of the European Commission. Through their mouthpiece, the ASN, the French authorities therefore expressed their support for the Commission's position during the meeting of the Member States of the European Union on 31 January 2005 in Brussels. During the Codex meeting at The Hague (Netherlands) from 25 to 29 April 2005, intervention by the Commission, supported in particular by France, Belgium, Germany and the United Kingdom, enabled the process to adopt the project drafted by the FAO/WHO/IAEA expert group to be blocked. The decision was finally taken to revise the project, with the contribution of experts from the European countries which opposed its adoption. The ASN is taking part in this revision work.

1. FAO : Food and Agriculture Organisation, WHO: World Health Organisation, IAEA: International Atomic Energy Agency.

2 BNI REGULATORY PROVISIONS

Without prejudice to application of the general regulations, such as those dealing with radiation protection described in the first part of this section, and pending a law specific to nuclear activities, BNIs are governed by amended decree 63-1228 of 11 December 1963 concerning nuclear facilities, which determines their licensing procedures. This system is supplemented by technical rules.

2 | 1

Licensing

The unlicensed operation of a basic nuclear installation is prohibited by French law and the relevant regulations. Therefore, the above-mentioned decree of 11 December 1963, implementing law 61-842 of 2 August 1961, as modified, on the abatement of atmospheric pollution and offensive odours, in particular provides for an authorisation decree procedure followed by a series of licences issued at key stages in the life of these facilities: loading with fuel or pre-commissioning, commissioning, possible modification of the installation, final shutdown and dismantling. The ministers in charge of nuclear safety (at present the ministers for the Environment and for Industry) may also at all times ask the operator to review the safety of its installation.

BNIs are also subject to the requirements of decree 95-540 of 4 May 1995 concerning discharges of liquid and gaseous effluent from and water intake by basic nuclear installations implementing on the one hand the above-mentioned law of 2 August 1961 and, on the other, the law 92-3 of 3 January 1992 on water, as modified, which is codified in articles L. 210-1 to L. 217-1 of the Environment Code. This decree, modified in particular by article 3 of decree 2002-460 of 4 April 2002 concerning the general protection of individuals against the dangers arising from ionising radiation, sets the licensing procedure for liquid and gaseous effluent discharge and water intake for these installations.

A person operating a BNI without the required licences, or in breach of the provisions of these licences, is liable to administrative and legal sanctions. These are primarily stipulated in articles 5 to 7-1 of the above-mentioned law of 2 August 1961 and articles 12 and 13 of the above-mentioned decree of 11 December 1963 regarding breaches of the requirements of these texts or the authorisation decree, and by articles L. 216-6 to L. 216-13 of the Environment Code, which codify articles 22 to 30 of the above-mentioned law of 3 January 1992, concerning violations of the regulations on effluent discharge and water intake.

Application of these various procedures starts with siting and plant design and ends with ultimate dismantling of the installation. The installation must first have been identified as a BNI as defined in article 2 of the above mentioned decree of 11 December 1963 and its implementing texts, that is the order of 27 April 1982 setting the characteristics of particle accelerators as basic nuclear installations and the order of 11 March 1996 setting the limits above which plants preparing, manufacturing or transforming radioactive substances, and facilities designed for the disposal, storage or use of radioactive substances, including waste, are to be considered basic nuclear installations.

2 | 1 | 1

Siting

Well before applying for a BNI authorisation decree, the operator informs the administration of the site(s) on which it plans to build this installation.

This analysis deals with socio-economic aspects and safety. If the planned BNI is intended for power generation, the General Directorate for Energy and Raw Materials of the Ministry for Industry will be directly involved. For its part, the ASN analyses the safety-related characteristics of the sites: seismicity, hydrogeology, industrial environment, cold water sources, etc.

In application of part IV of law 2002-276 of 27 February 2002 on local democracy (codified in articles L. 121-1 to L. 121-15 of the Environment Code), decree 2002-1275 of 22 October 2002 on the organisation of public debates and the National Public Debates Commission (codified in articles R. 121-1 to R. 121-16 of the Environment Code) specifies that creation of a BNI is subject to the public debate procedure:

- systematically, when dealing with a new nuclear electricity generating site or a new site not generating electricity and costing more than € 300 million;
- possibly, when dealing with a new site not generating electricity from nuclear power and costing between € 150 million and € 300 million.

2 | 1 | 2

Safety options

When an operator intends to build a new type of BNI, it is expected to present the relevant safety objectives and the main characteristics as early as possible, well before submitting its authorisation application.

The ASN generally asks the competent Advisory Committee (GP) to examine the project and then informs the operator of issues to be covered in its authorisation decree application.

This preparatory procedure in no way exempts the applicant from the subsequent regulatory examinations but simply facilitates them.

2 | 1 | 3

Plant authorisation decrees

Submission of the plant authorisation application

The application for a BNI authorisation decree is sent to the ministers in charge of nuclear safety, who forward it to the other ministers concerned (Interior, Health, Agriculture, Town Planning, Transport, Labour, etc.). Each application file comprises a preliminary safety analysis report.

Processing of this application includes a public inquiry (unless the installation has already been through an enquiry prior to a declaration of public interest and is in conformity with the project subjected to this inquiry) and a technical assessment.

• Consultation of the public and the local authorities

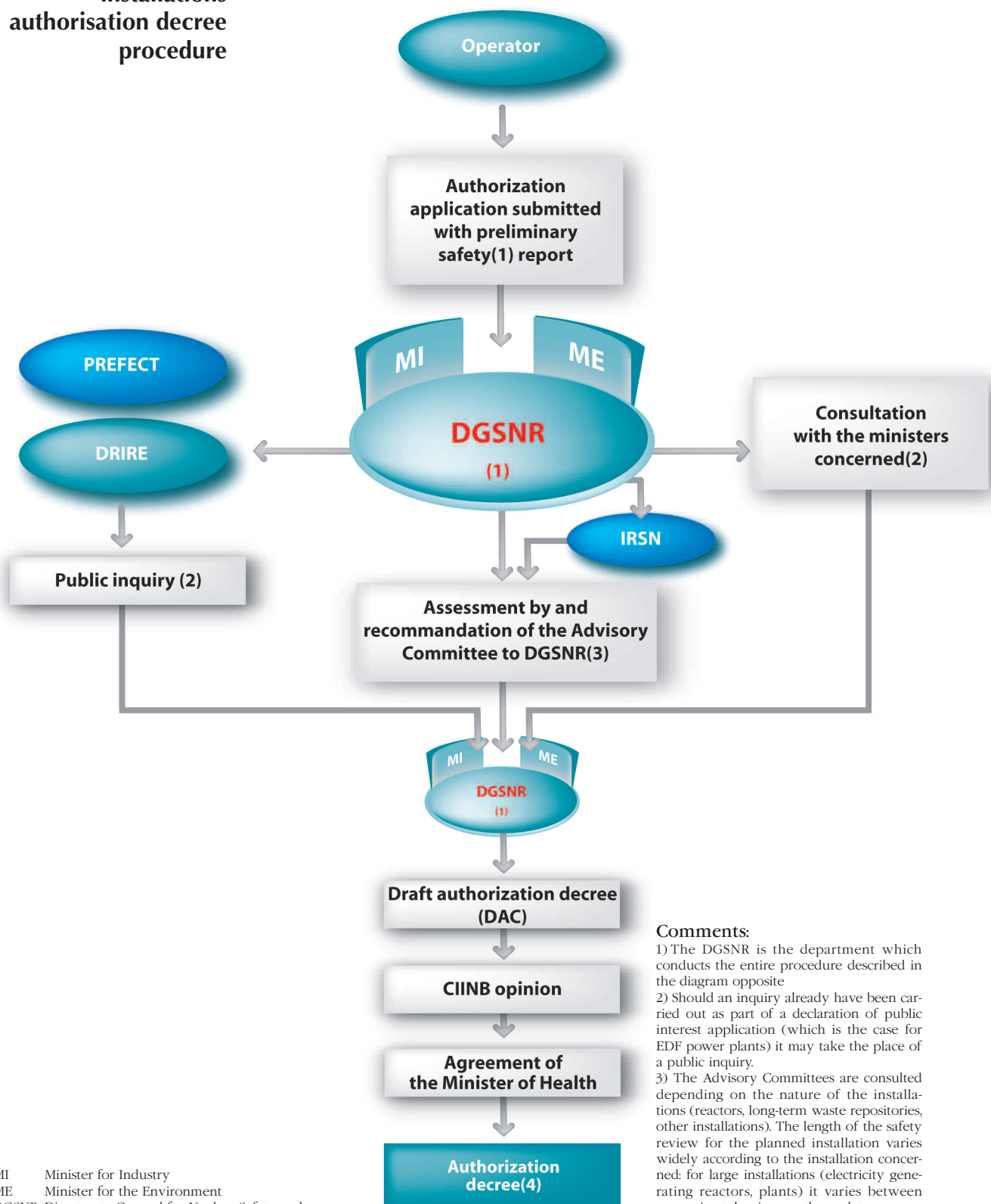
The public inquiry is opened by the Prefect of the department where the installation is to be built. The documents submitted to the inquiry must notably include the authorisation application, specify the identity of the applicant, the purpose of the inquiry, the nature and basic characteristics of the installation and comprise a plan of it, a map of the region, a hazard analysis and an environmental impact assessment.

In addition to the prefecture concerned, a descriptive file and an inquiry register are made available in all *communes*¹ completely or partially within a 5 km radius around the planned installation. If this radius encompasses the territory of several departments, a joint order of the Prefects concerned organises the inquiry in each department, with the Prefect of the main site of the operation co-ordinating the procedure.

In accordance with general provisions in this respect, the public inquiry shall proceed for a minimum period of one month and a maximum period of two months, with the possibility of a two week extension in the event of a well-founded decision in this matter on the part of the Inquiry

1. Smallest administrative subdivision administrated by a mayor and a municipal council.

**Basic nuclear
installations
authorisation decree
procedure**



Comments:

1) The DGSNR is the department which conducts the entire procedure described in the diagram opposite

2) Should an inquiry already have been carried out as part of a declaration of public interest application (which is the case for EDF power plants) it may take the place of a public inquiry.

3) The Advisory Committees are consulted depending on the nature of the installations (reactors, long-term waste repositories, other installations). The length of the safety review for the planned installation varies widely according to the installation concerned: for large installations (electricity generating reactors, plants) it varies between approximately six months and two years, depending on the degree of innovation of the project with respect to projects already examined.

4) In addition to the requirements of the authorisation decree, the MI and the ME may notify particular technical specifications

| | |
|-------|---|
| MI | Minister for Industry |
| ME | Minister for the Environment |
| DGSNR | Directorate General for Nuclear Safety and Radiation Protection |
| DRIRE | Regional Directorate for Industry, Research and the Environment |
| CIINB | Interministerial Commission for Basic Nuclear Installations |
| IRSN | Institute for Radiation Protection and Nuclear Safety |

Commissioner. Furthermore, a specific provision introduced by decree 93-816 of 12 May 1993, enables the government to issue a decree to extend the BNI inquiry period by a maximum of one month.

The purpose of the inquiry is to inform the public and collect opinions, suggestions and counter-proposals, in such a way as to provide the competent authority with all the elements necessary for its own information. So any interested person, whatever his nationality or place of residence, is invited to express his opinion.

An Inquiry Commissioner (or an Inquiry Committee, depending on the nature or extent of the operations) is nominated by the President of the competent Administrative Court. He may receive any document, visit the site, arrange to meet all people wishing to make statements, organise public meetings and request extension of the inquiry period.

When the inquiry is over, he examines the observations of the public entered into the inquiry register or sent to him directly. Within the month following the end of the inquiry, he sends a report containing his recommendations to the Prefect.

The departmental or regional offices of the ministries concerned by the project are also consulted by the Prefect.

Finally, within a period of one month from the date on which the documents were submitted to him, the Prefect submits the report and conclusions of the Inquiry Commissioner, accompanied by his recommendation, and the results of the administrative conference, to the ministers in charge of nuclear safety.

• Consultation of technical organisations

The preliminary safety analysis report appended to the authorisation decree application is transmitted to the ASN, which submits it for examination to one of the advisory committees reporting to it.

On the basis of recommendations of the Advisory Committee, and taking account of the results of the public inquiry and any observations by the other ministers consulted, the ASN will - if there is nothing to oppose it - prepare a draft decree authorising creation of the installation.

This draft decree is then sent to the Interministerial Commission for Basic Nuclear Installations (CIINB) by the ministers in charge of nuclear safety. The Commission is required to submit its opinion within two months.

The draft decree, if necessary amended, is then submitted to the assent of the Minister for Health who must state his position within three months.

Once this assent is given, the draft decree is presented to the Prime Minister for signature, by the ministers in charge of nuclear safety.

• Authorisation decree

The authorisation decree, issued on the basis of the report from the ministers in charge of nuclear safety, sets the perimeter and characteristics of the installation and any particular requirements with which the operator is required to comply. It also specifies the particular justifications the operator will have to present prior to:

- the various pre-commissioning stages;
- commissioning of its installation;
- the subsequent final shutdown and dismantling.

The authorisation decree includes an obligation on the part of the operator, at least six months before the date scheduled for initial loading with nuclear fuel in installations containing a reactor, or

use of a particle beam or radioactive substances in other installations, to submit the following to the Director General for Nuclear Safety and Radiation Protection:

- a provisional safety report, in particular containing data guaranteeing the conformity of the installation with the technical construction requirements of the authorisation decree;
- the general operating rules to be followed during the period prior to commissioning, to guarantee safe operation;
- an onsite emergency plan specifying the response organisation and resources to be deployed on the site in the event of an accident in the installation.

The authorisation decree for the installation sets the time within which it is to be commissioned.

Before commissioning, the operator will present the Director General for Nuclear Safety and Radiation Protection with a final safety report and the site's updated operating rules and on-site emergency plan.

If the installation is not commissioned within the specified time or if it is not operated for a consecutive period of two years, a further authorisation, taking the same form, will be required.

The specific requirements imposed for the installation shall under no circumstances be detrimental to compliance with the general technical regulations, regulations concerning discharge of effluent or any other texts applicable in particular with regard to environmental protection or worker health and safety issues.

These requirements may in particular concern the quality of the design, construction and operation of the installation, its protection and security systems, emergency resources, the ventilation and discharge systems, protection against earthquakes, radiological protection of the environment and workers, transport of radioactive products, installation modifications, final shutdown and dismantling.

• Installation modifications

The operator notifies the Director General for Nuclear Safety and Radiation Protection of all modifications to the installation leading to updating of the safety reports, the general operating rules or the on-site emergency plan.

A new authorisation decree, examined in exactly the same way as before, must be obtained when a BNI is to undergo modifications likely to lead to non-compliance with the above-mentioned requirements, if there is a change in the operator or a modification in the perimeter of the installation, or when, owing to a fire, explosion or any other accident occurring in a BNI, it is destroyed or is closed for a period in excess of two years.

In the case of modifications made to an existing or planned installation which has already undergone a public inquiry, and if these modifications do not appreciably alter the scale or purpose of the installation and do not increase its risks, examination of the application may omit the public inquiry.

No authorisation decree was issued for a basic nuclear installation in 2005.

Modification decree issued in 2005

| | | |
|--------------------------------------|------------------|---|
| REACTOR (Chinon – Indre-et-Loire) | 25 November 2005 | Decree modifying the decree of 27 August 1996 authorising EDF to modify the BNI known as Chinon A3, to keep it under surveillance |
|--------------------------------------|------------------|---|

Operating licences

• Power reactor commissioning

The first load of new fuel elements may only be delivered to the reactor's storage building after authorisation by the ministers in charge of nuclear safety. This authorisation is given after examination by the ASN:

- of the storage provisions made by the operator, as presented at least three months beforehand;
- of the conclusions of an inspection carried out shortly before the date set for delivery of the fuel elements.

Furthermore, six months prior to loading of the reactor, the operator must send the ministers in charge of nuclear safety a provisional safety analysis report, together with provisional general operating rules (RGE) and an on-site emergency plan (PUI) specifying the organisation and measures to be implemented on the site in the event of an accident. The ASN consults the Advisory Committee for nuclear reactors on these documents, and then drafts its own recommendation. Upon receipt of the latter, the ministers can authorise fuel loading and pre-commissioning tests.

For PWRs, at least four successive licences are required in the startup stages:

- a fuel loading licence, authorising fissile fuel elements to be installed in the reactor vessel, enabling fuelled testing to start (pre-critical cold tests);
- a licence for pre-critical hot testing, prior to first criticality. These tests are dependent on the satisfactory outcome of the pre-critical cold tests. They are carried out while the primary system is at nominal temperature and pressure, after heating of the primary fluid by starting up the primary pumps. They may only be initiated after issue of the primary system hydrotest report by the director of the Burgundy region DRIRE, under application of an order of 26 February 1974 (see below in chapter 4);
- a licence for first criticality and power build-up to 90% of nominal power;
- a licence for power build-up to 100% of nominal power.

After first startup, within a time limit set in the authorisation decree, the operator must request authorisation for final commissioning from the ministers in charge of nuclear safety. His request is substantiated by a final safety analysis report, final general operating rules and a revised version of the on-site emergency plan. These documents must reflect the experience acquired during the operating period since the initial startup.

• Commissioning of basic nuclear installations other than power reactors

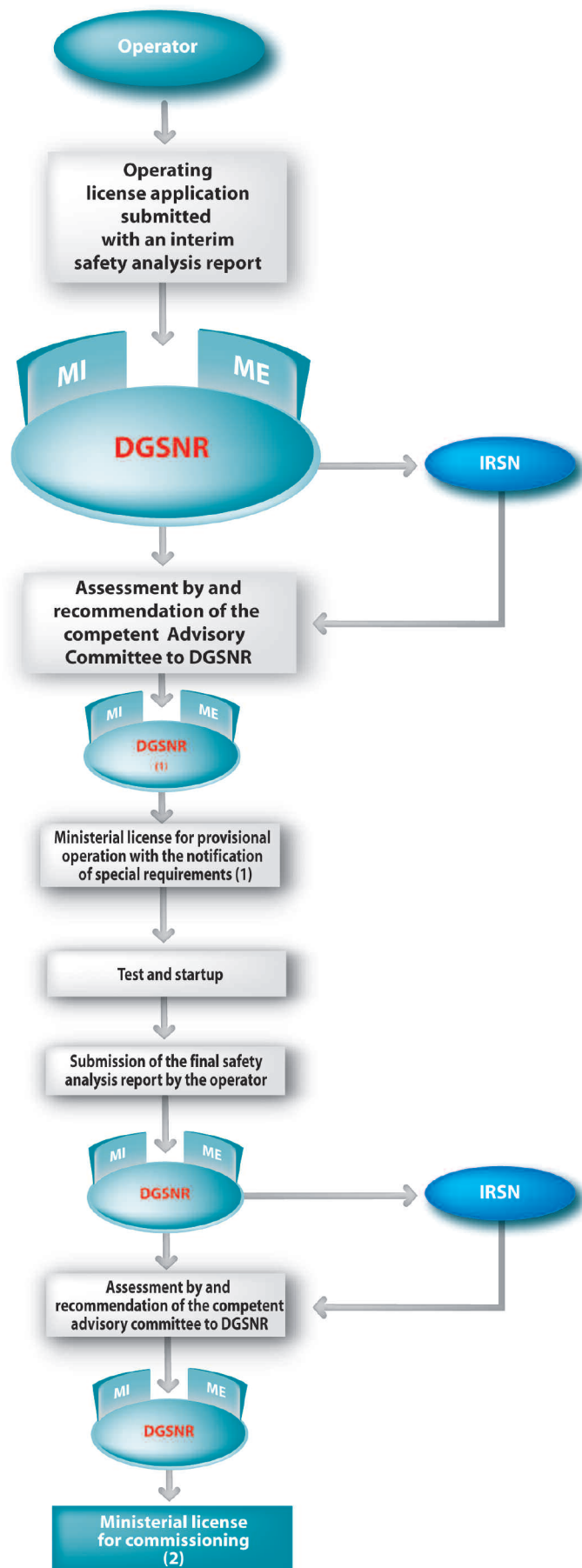
The authorisation decrees for BNIs other than power reactors stipulate that commissioning is dependent on authorisation by the ministers in charge of nuclear safety.

This pre-commissioning authorisation is accompanied by notification of technical requirements. It is granted after examination by the ASN and its technical support organisations, particularly the competent Advisory Committee, of the documents prepared by the operator. These documents include the provisional safety analysis report, the installation's general operating rules and the on-site emergency plan.

Moreover, before final commissioning of the installation, which must take place within a time set in the authorisation decree, the operator must submit a final safety analysis report to the ministers in charge of nuclear safety. This commissioning is subject to ministerial authorisation, where necessary involving updating of technical requirements and general operating rules, according to a procedure similar to that adopted for power reactors.

No BNI commissioning licence was issued in 2005.

Operating licence procedure for basic nuclear installations



Comments:

1) For pressurised water reactors, commissioning of the pressure vessel is also dependent on issue of a hydrotest report for the primary circuit, as specified in the regulatory provisions applicable to pressure vessels.

2) As defined in article 4 of the decree of 11 December 1963. This approval must take place within a time set by the authorisation decree. It is given by the Ministers for the Environment and Industry.

MI Minister for Industry
ME Minister for the Environment
DGSNR Directorate General for Nuclear Safety and Radiation Protection
IRSN Institute for Radiation Protection and Nuclear Safety

Final shutdown and dismantling licenses

• The final shutdown and dismantling licensing procedure

As specified in article 6b of the above-mentioned decree of 11 December 1963, when an operator decides, for any reason, to close down its installation, it must inform the Director General for Nuclear Safety and Radiation Protection, by sending him:

- a document justifying the selected configuration in which the installation will be left after final shutdown, and indicating the various stages of subsequent dismantling;
- a safety analysis report covering the final shutdown procedures and indicating subsequent plant safety provisions;
- the general surveillance and servicing rules to ensure that a satisfactory level of safety is maintained;
- an updated on-site emergency plan for the installation concerned.

In accordance with articles R. 122-1 to R. 122-16 of the Environment Code, the operator must also submit an environmental impact assessment of the proposed measures.

The above-mentioned decree of 11 December 1963 does not require a public inquiry as part of the examination of these applications. However, in the light of France's new international obligations under the Convention on access to information, public participation in decision-making and access to justice in environmental matters of 25 June 1998 (known as the Aarhus Convention), and of environmental protection regulations, the ASN requires that a public inquiry be conducted on BNI final shutdown and dismantling licence applications when the investigating department feels that the final shutdown and dismantling operations substantially affect the scope or purpose of the installation and that the risk presented by the BNI during the dismantling phase is appreciably greater than that which existed during its operating phase.

Performance of the final shutdown and dismantling operations as presented in the documents accompanying the licence application is dependent on their approval by decree countersigned by the ministers in charge of nuclear safety, further to assent by the Minister for Health, after prior consultation of the CIINB.

• Performance of final shutdown and dismantling operations

The final shutdown and dismantling operations, which only begin after any decommissioning operations, comprise two successive sets of operations:

- final shutdown operations, which mainly consist of disassembly of the equipment outside the nuclear island and not required for continued monitoring of nuclear island safety, maintaining or reinforcing of the containment barriers or establishing a radioactivity balance;
- dismantling work on the nuclear part of the plant. This work can start as soon as the final shutdown operations are completed or can be delayed with a view to taking advantage of radioactive decay in certain activated or contaminated materials.

In some cases, operations such as the unloading and removal of nuclear material, the disposal of fluids, or decontamination and clean-up operations can be performed under the provisions of the authorisation decree for the plant considered. To do so, these operations must involve compliance with previously imposed requirements and with the safety analysis report and general operating

rules currently in force. In all other cases, such operations come under the provisions of the final shutdown and dismantling decree.

• Installation declassification and contractual easements

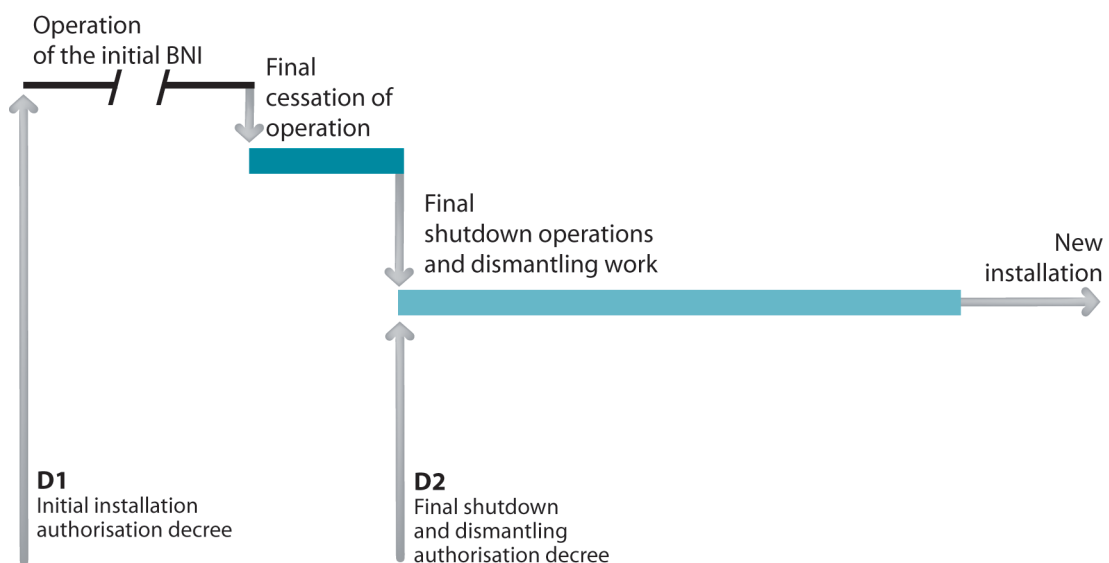
If dismantling work reaches the stage where the total radioactivity of the remaining radioactive substances is below the minimum level necessitating classification as a Basic Nuclear Installation, the plant can be declassified and removed from the list of BNIs in accordance with the procedure laid down in its final shutdown and dismantling decree.

Depending on the residual level of radioactivity, the installation may then be subject to the legislation applicable to ICPEs (articles L. 511-1 to L. 517-2 of the Environment Code) and therefore subject to a registration or licensing procedure.

In order to retain a trace of the past existence of a BNI on a site, and provide for any possible future restrictions on use of the installation, the ASN may consider establishment of an easement as a precondition for declassification of the installation.

The final shutdown and dismantling decree for an installation therefore requires that after the dismantling operations and to support its installation declassification application, the operator submit an updated study of the impact of the installation on its environment, in order to assess the need for any restrictions on the future use of the installation and/or site. If this does prove necessary, a contractual easement on behalf of the State may be established by the ASN, after discussion with the local State services concerned, proposed to the landowner and, as applicable, the owner of the remaining buildings. This proposed easement may comprise general precautionary easements (minimum inspections required when earthworks are carried out on the land, ban on construction of buildings housing vulnerable persons, inclusion of the easement in the land registry) and may, as required, provide for procedures specific to the site concerned, according to its state after dismantling.

When such a contractual easement is put in place, it is communicated by the ASN when the ministerial decision is made to declassify the installation from its BNI status.



Final shutdown and dismantling of basic nuclear installations

Final shutdown and dismantling decrees issued in 2005

| | | |
|---|-----------------|--|
| SILOÉ RESEARCH REACTOR (Grenoble – Isère) | 26 January 2005 | Decree authorising the CEA to proceed with final shutdown and dismantling of BNI n° 20 |
| SILOETTE RESEARCH REACTOR (Grenoble – Isère) | 26 January 2005 | Decree authorising the CEA to proceed with final shutdown and dismantling of BNI n° 21 |

Contractual easements on behalf of the State established in 2005

| | | |
|---|----------------|--|
| SATURNE SYNCHROTRON (Saclay – Essonne) | 6 Octobre 2005 | Instrument creating an contractual easement on behalf of the State concluded between the department Prefect, the ASN and the CEA |
|---|----------------|--|

2 | 1 | 6

Liquid and gaseous effluent discharge and water intakes licences

The normal operation of nuclear plants produces radioactive effluent, for which discharge to the environment is subject to stringent conditions stipulated in an administrative licence devised for the protection of staff, the public and the environment. The licence concerns liquid and gaseous radioactive effluent, covering both their activity level and their chemical characteristics.

The operation of most nuclear installations also involves intake of water from the site's immediate environment and discharge of non-radioactive liquid and gaseous effluent.

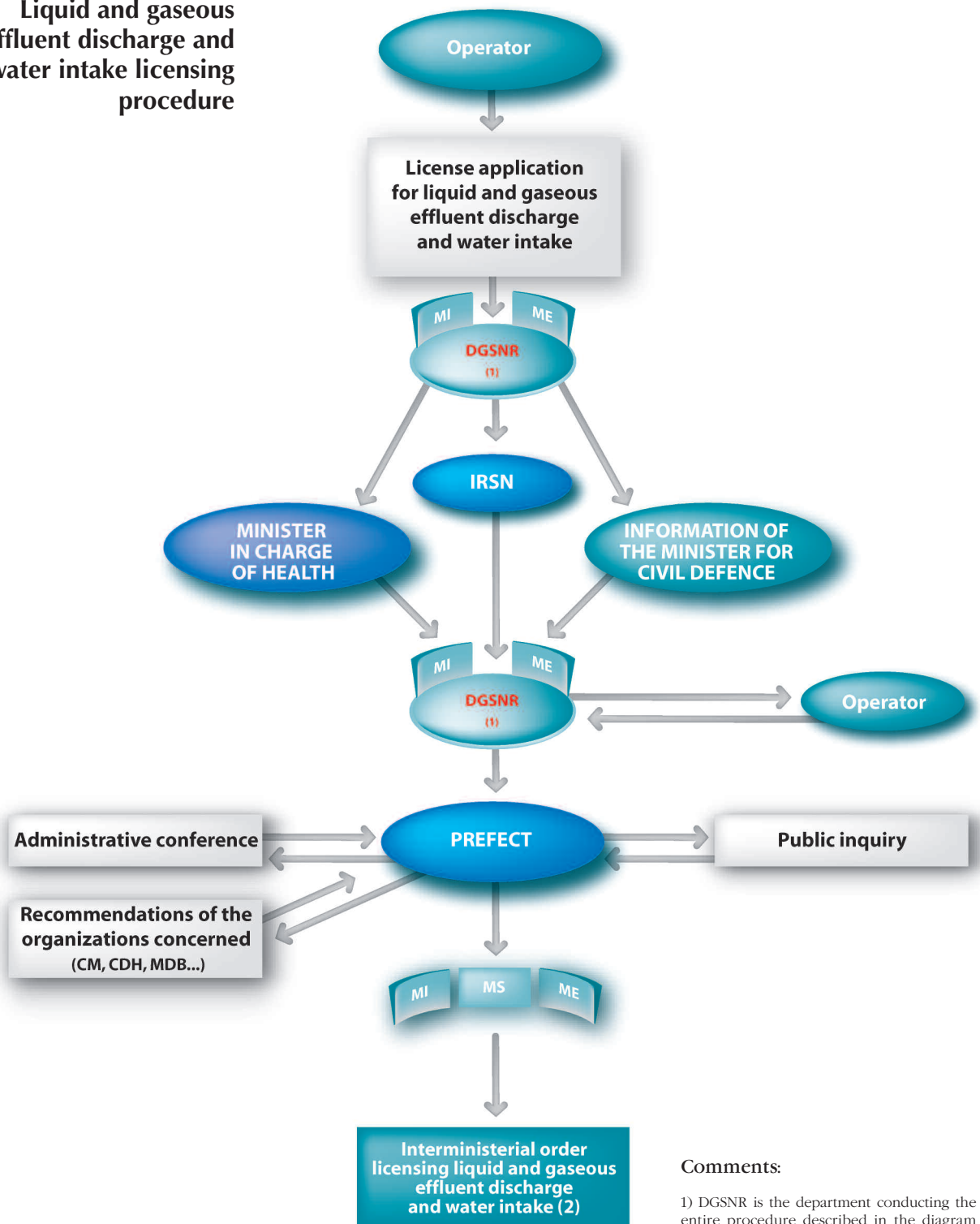
In application of decree 95-540 of 4 May 1995, as modified, on BNI liquid and gaseous effluent discharge and water intake, the same licence, issued at ministerial level, can where necessary cover both radioactive and non-radioactive liquid and gaseous discharge and water intake for a given BNI. The procedure, explained in two interministerial circulars (Health, Industry and Environment) of 6 November 1995 and 20 May 1998, is carried out on the basis of a single application drafted accordingly, with the investigating department in any case being the ASN.

The procedures stipulated in the above-mentioned decree also apply to the installations classified for environmental protection grounds located within the perimeter of a BNI. This decree thus also enables assessment of the overall environmental impact of an installation's effluent discharge and water intake.

• Submission of the plant authorisation

The effluent discharge and water intake licence application covers all such operations for which authorisation is required. It is sent to the ministers in charge of nuclear safety. In addition to various drawings, maps and information, it comprises a description of the operations or activities envisaged and an assessment of their impact on human health and on the environment, comprising a list of proposed compensatory measures and the intended surveillance provisions.

Liquid and gaseous effluent discharge and water intake licensing procedure



Comments:

1) DGSNR is the department conducting the entire procedure described in the diagram opposite.

2) Signed by the Ministers for the Environment, Industry and Health.

| | |
|-------|---|
| MI | Minister for Industry |
| ME | Minister for the Environment |
| MS | Minister for Health |
| DGSNR | Directorate General for Nuclear Safety and Radiation Protection |
| IRSN | Institute for radiation protection and nuclear safety |
| CM | Town councils |
| CDH | Departmental health council |
| MDB | River authority |

• Recommendations of the ministers concerned

After asking the operator for additional data or for modifications to the documents, whenever necessary, the application is sent for their opinion to the ministers for Health (Directorate General for Health) and Civil Security (Nuclear risk management support delegation - MARN).

• Consultation of the public and local authorities and organisations

The ministers in charge of nuclear safety transmit the application and the recommendations of the ministers to the Prefect of the department concerned, for his opinion.

The Prefect organises an administrative conference between various regional offices which he feels should be consulted and subjects the application to a public inquiry under conditions similar to those described in point 2|1|3 above for authorisation decrees.

However, in the present procedure, the inquiry is opened in the commune where the operations in question are to be carried out and also in other communes where the impact of these operations would probably be felt.

Furthermore, the Prefect consults the town councils concerned and, if necessary, the person with responsibility for managing the public domain and the departmental health council, as well as the local river authority (Mission déléguée de bassin) if necessary. He also sends the application file, for information, to the local water commission.

The Prefect then transmits the results of the administrative conference, consultations and inquiry, with his recommendation, to the ministers in charge of nuclear safety.

In application of article 37 of the Treaty instituting the European Atomic Energy Community, known as "Euratom", France provides the European Commission with general data about any plans for discharge of radioactive effluent, so that it can be determined whether implementation of this project is likely to lead to radioactive contamination of the water, soil or airspace of another Member State. This transmission is required for any new project or any project leading to a rise in radioactive discharges and takes place at least six months before the licence is granted. France is bound by the opinion issued by the European Commission.

• Interministerial authorisation

Authorisation is granted by a joint order signed by the ministers for Health, Industry and the Environment.

Within the framework of general technical rules defined by an order of the ministers for Industry, the Environment and Health of 26 November 1999, which has been further clarified by a circular sent out to the prefects, signed by the same ministers on 17 January 2002 (see below in point 2|2|1) this document stipulates:

- the intake and discharge limits for which the operator is authorised;
- the approved methods of analysis, measurement and monitoring of the installation, work or activity and of surveillance of environmental effects;
- the conditions under which the operator shall report to the ministers for Health and the Environment and to the Prefect, concerning the water intakes and discharges it has performed together with environmental impact surveillance results;
- the methods to be used for public information.

At the request of the licensee or on their own initiative, the ministers for Health, Industry and the Environment may, after consultation with the health council for the concerned department, use a ministerial order to modify the conditions provided for in the authorisation order.

Finally, any modification made by the operator to the installation or its operating procedures, such as to have consequences on effluent discharges or water intake, must be notified beforehand to the ministers in charge of nuclear safety, who consult the Minister for Health. If it is then considered that the modification could cause environmental hazards or difficulties, the operator may be required to submit a new licence application.

Main licences issued in 2005

| | | |
|---|------------------|---|
| Nuclear maintenance shop (SOMANU), Maubeuge – Nord) | 16 February 2005 | Modification of the liquid radioactive effluent discharge licence for the nuclear maintenance shop |
| Nuclear site (Tricastin – Drôme) | 16 August 2005 | Order authorising EURODIF Production to continue with water intake and discharge of liquid and gaseous effluent for operation of a uranium isotope separating plant using gaseous diffusion on the Tricastin site |
| Nuclear site (Tricastin – Drôme) | 16 August 2005 | Order authorising SOCATRI to carry-out water intake and make liquid and gaseous effluent discharges for operation of a purification and uranium recovery installation on the Tricastin site |
| Nuclear site (Tricastin – Drôme) | 17 August 2005 | Order authorising COMURHEX to continue with liquid and gaseous effluent discharges for operation of a uranium hexafluoride preparation plant on the Tricastin site |
| Nuclear site (Chinon – Indre-et-Loire) | 17 August 2005 | Modification of the order authorising water intake and liquid and gaseous effluent discharge on the Chinon nuclear site |

2 | 2

General technical regulations

The general technical regulations comprise all texts of a general nature establishing the technical rules applicable to nuclear safety, whether regulatory (orders) or related (circulars, basic safety rules, guides). However, texts defining the administrative and procedural rules applicable to BNIs and individual letters to the operators are not considered to be a part of the general technical regulations.

In 2005, the ASN began to look at ways of clarifying the structure of the general technical regulations as applicable to BNI safety. With a view to harmonising and simplifying access by professionals and the public to the stipulations and recommendations issued concerning nuclear safety, the ASN proposed that the general technical regulations henceforth comprise only two categories of texts:

- ministerial or interministerial orders, containing legally binding requirements specifying long-term safety objectives;
- guides, containing non-legally binding provisions on how to apply a regulatory text by stipulating recommended resources or procedures considered to be acceptable for achieving the safety objectives.

On this basis, the current body of general technical regulations will need to evolve and the ASN aims to broaden the scope of application.

All the texts making up the general technical regulations for the safety of basic nuclear installations are available in the Texts part of the ASN's website (asn.gouv.fr).

Ministerial and interministerial orders

These orders, based on article 10 bis of the above-mentioned decree of 11 December 1963, currently deal with four important subjects: pressure vessels, quality organisation, BNI water intake and effluent discharges, off-site detrimental effects and hazards resulting from BNI operation.

• Pressure vessels

BNIs comprise two types of pressure vessels: those which are specifically nuclear, in other words those which contain radioactive products, and those which are more conventional and which are not specific to nuclear facilities.

The applicable regulations are detailed in the following table:

| | Nuclear | | | Conventional |
|--------------|---|---|--|--|
| | Main primary system of pressurised water reactors | Main secondary systems of pressurised water reactors | Other equipment | |
| Construction | <ul style="list-style-type: none"> Decree of 2 April 1926 Order of 26 February 1974 (1) | <ul style="list-style-type: none"> Decree of 2 April 1926 RFS II.3.8 of 8 June 1990 (1) | <ul style="list-style-type: none"> Decree of 2 April 1926 Decree of 18 January 1943 | <ul style="list-style-type: none"> Decree of 13 December 1999 |
| Operation | <ul style="list-style-type: none"> Order of 10 November 1999 | | <ul style="list-style-type: none"> Decree of 13 December 1999 Order of 15 March 2000 | |

(1) The ASN has prepared a new regulatory text which, for nuclear pressure vessels, specifies construction and inspection procedures similar to those of decree 99-1046 of 13 December 1999 concerning pressure vessels, with the addition of aspects specific to nuclear facilities. This order concerning nuclear pressure vessels, dated 12 December 2005, will apply as of 2006 to the construction of pressure vessels for use in the nuclear field.

• Quality organisation

The order of 10 August 1984 concerning the quality of the design, construction and operation of basic nuclear installations specifies the steps to be taken by a BNI operator for defining, obtaining and maintaining the necessary quality of its installations and operating conditions, in order to guarantee safety.

It thus stipulates that the operator must define quality requirements for each activity concerned, employ the appropriate skills and methods for meeting these quality requirements and finally, guarantee quality by checking appropriate compliance with these requirements.

It also specifies:

- that detected discrepancies and incidents be thoroughly corrected and that preventive action be taken;
- that suitable documents testify to results obtained;
- that the operator supervise the service companies used and check compliance with procedures adopted to guarantee quality.

Experience feedback from incidents and accidents occurring in BNIs and the findings of the inspections conducted, enable the ASN to analyse the various problems in order to assess the application of the above-mentioned order of 10 August 1984.

• **Water intake and effluent discharge by BNIs**

BNI water intake and effluent discharges which - under application of the decree of 4 May 1995 mentioned above in point 2.1.6 - are subject to joint licensing by the ministers for Health, Industry and the Environment, are managed by technical rules defined in an order signed by the same ministers on 26 November 1999, setting the general technical rules concerning the limits and procedures for these BNI intakes and discharges subject to licensing. This text, which abrogates and replaces a number of orders dated 10 August 1976, comprises requirements which in particular concern proactive reduction of water intake and effluent discharge, enhancement of analysis resources and reinforcement of inspections, information of the various government services and of the public. Its implementation is explained in an inter-ministerial circular of 17 January 2002, in particular with regard to the objectives and to application of the new regulations, depending on whether one is dealing with an initial application or a modification.

• **Prevention of off-site detrimental effects and hazards resulting from BNI operation**

BNI operation can entail detrimental effects and hazards for the environment in the broadest sense, that is for the surrounding installations and their workers, but also for the public and the environment off the site. The policy conducted by the ASN with respect to environmental protection is described in Chapter 5. It primarily aims to prevent and minimise the risks for the installations by ensuring that the following are applied:

- the above-mentioned decree of 11 December 1963, clarified by its implementing order of 31 December 1999 setting the general technical regulations designed to prevent and mitigate off-site detrimental effects and hazards resulting from operation of basic nuclear installations;
- ICPE legislation for installations of this type within the BNI perimeter.

The above-mentioned order by the ministers for the Environment and Industry of 31 December 1999 sets the general technical regulations for preventing and mitigating off-site detrimental effects and hazards resulting from BNI operation, with the exception of water intake and discharge of effluent. It introduces principles concerning waste management, prevention of accidental pollution, fire, lightning, criticality and radiolysis applicable to all nuclear equipment, including that which is situated outside the sensitive parts of the BNIs. Application of this text ensures that environmental protection concerns are taken into account by the operators at a level comparable with that required for non-nuclear industrial installations.

A revision of this order was finalised in 2005, clarifying fire risk management and introducing general technical rules concerning cooling installations, to prevent the risk of the spread of legionella. At the same time, work carried out with the DSND and the main nuclear operators led to preparation of a fire risk management guide specifying the corresponding goals defined in the amended version of the order of 31 December 1999 (see below in point 2.2.2).

2 | 2 | 2

Basic safety rules and ASN guides

• **Nature and legal value of the RFS and ASN guides**

On a variety of technical subjects, concerning both PWRs and other BNIs, the ASN has drafted basic safety rules (RFS). These are recommendations which specify safety objectives and describe practices the ASN considers to be adequate for compliance with them.

They are not, strictly speaking, regulatory documents. An operator may decide not to follow the specifications of an RFS if it can demonstrate that the alternatives it proposes employing enable the stipulated safety objectives to be met.

The flexibility of this type of text enables the technical requirements to evolve in line with changing technology and knowledge.

Given the restructuring of the general technical regulations described in point 2.2 above, the RFS will be gradually replaced by guides.

There are currently about forty RFS and other technical rules issued by the ASN, which can be consulted in the Texts part of the ASN's website (asn.gouv.fr).

• **The RFS and guides currently being revised or drafted**

RFS revision work is currently in progress, in particular concerning:

-RFS III.2.e of 31 October 1986, revised on 29 May 1995, concerning the preconditions for approval of encapsulated solid waste packages intended for surface disposal: changes to the rule should enable experience feedback from the first ten years of operation of the Aube repository to be taken into account. The ASN will ensure that the Advisory Committee for waste's examination of the revised RFS leads to conclusions that are consistent with the information obtained from examination of the safety analysis report on the Aube repository submitted by the ANDRA in October 2004.

-RFS I.4.a of 28 February 1985 on fire protection of BNIs other than reactors: a guide concerning management of the fire risk explaining the requirements of the above-mentioned order of 31 December 1999 and setting fire risk prevention goals, was drafted by the ASN in 2005.

2 | 2 | 3

French nuclear industry codes and standards

In the industrial field, the rules of industrial and professional good practice are codified in standards by standardisation bodies or in industrial codes by professional associations. The codes and standards allow concrete transposition of the requirements of the general technical regulations, while reflecting good industrial practice, thus facilitating contractual relations between customers and suppliers.

In the particular field of nuclear safety, the industrial codes used by the manufacturers and nuclear operators are drafted by the *Association française pour les règles de conception, de construction, et de surveillance en exploitation des matériels des chaudières électronucléaires* (AFCEN), of which EDF and Framatome ANP are members. The RCC codes of design and construction rules were drafted for the design, manufacture and commissioning of electrical equipment (RCC-E, 4th edition), civil engineering (RCC-G) and mechanical equipment (RCC-M, 2000 edition). As of 1990, a code of mechanical equipment in-service monitoring rules (RSE-M) was drafted to deal with this subject.

Production of these documents is the responsibility of industry and not the ASN, which is nonetheless tasked with examining them to ensure their conformity with the general technical regulations, in most cases leading to drafting of RFS, a guide or a decision, recognising the overall acceptability on the date of the edition concerned.

The new version of the RCC-E code was accepted by the ASN in 2003. The ASN in particular checked that this fourth edition of the code was consistent with RFS II.4.1.a of 15 May 2000 concerning software in PWR safety-classified electrical systems.

The 2000 edition of the RCC-M code was accepted with reserves by the ASN in a decision of 10 July 2001 (available in the Texts part of the ASN's website: asn.gouv.fr). A modification of the code is currently being examined in order to lift the reserves expressed at its acceptance in 2001 and take account of some of the new technical rules applicable to nuclear steam supply system construction.

The 2000 edition of the RSE-M code was accepted by the ASN in June 2002 and has been applicable to all nuclear power plants since January 2003. A modification to this code is also being examined in order to deal with the discrepancies observed at its acceptance in 2002, with respect to the order of 10 November 1999 concerning monitoring of operation of the main primary system and the main secondary systems of pressurised water reactors.

Until such time as it issues a position on the proposed changes to these codes, the ASN considers that the accepted versions of these codes, supplemented by any particular restrictions and measures imposed, remain in force.

2 | 3

Installations classified on environmental protection grounds

Installations liable to entail hazards and detrimental effects on the environment are governed by part I of book V of the Environment Code (which codified law 76-663 of 19 July 1976, as modified, concerning installations classified on environmental protection grounds). The installations concerned, mentioned in a list regularly updated by the Ministry for the Environment, and recently modified by decree 2005-989 of 10 August 2005, are subject to special conditions when located within a BNI perimeter.

The above-mentioned decree of 11 December 1963 in effect makes the following distinction, clarified by an opinion of the Council of State on 4 October 1983:

- “equipment which is part of a basic nuclear installation” is that which, within the perimeter of the BNI, constitutes an element of this installation which is necessary for it to operate; depending on its type, this equipment can in technical terms be compared to classified installations but, as a part of the BNI, it is subject to articles 2 and 3 of the above-mentioned decree of 11 December 1963 and to the procedure applicable to BNIs. In particular, in all cases where new or modified equipment would be such as to substantially alter the initial capacity or purpose of a BNI or would increase the risks it entails, a public inquiry must be held;
- the classified installations included within the perimeter of a BNI but which are not necessarily linked to it, are covered by the legislation concerning installations classified on environmental protection grounds, with the exception of three particular points specified in article 6 bis of the above-mentioned decree of 11 December 1963:

- the ministers in charge of nuclear safety take the place of the Prefects in granting licences and registering the notifications required by ICPE regulations;
- operating permit applications may be substantiated by the public inquiry documents submitted in the course of the initial BNI authorisation procedure and the permit may be granted by the BNI authorisation decree;
- the technical requirements with which the operator must comply are notified by the ministers in charge of BNIs.

Furthermore, as mentioned in point 2|1|6 above, effluent discharges from ICPEs located within the perimeter of a BNI are regulated by the above-mentioned decree of 4 May 1995.

The ASN examines the relevant documents and the BNI inspectors are responsible for the supervision specified in the ICPE legislation, with regard to the relevant installations.

3 OUTLOOK

In the field of radiation protection in 2005, the ASN completed transposition of three Euratom directives (89/618, 96/29 and 97/43) and continued with work to transpose Council directive 2003/122/Euratom of 22 December 2003 on the control of high-level sealed radioactive sources and orphan sources. This work should be completed during the first half of 2006. At the same time,

based on the experience acquired since 2002, it has already begun to update the regulatory part of the Public Health Code dealing with ionising radiation, in order to simplify it. The proposed simplifications are aimed at greater accountability on the part of the users of sources of ionising radiation, but also reinforcement of supervision by approved organisations.

Updating of the new ICRP recommendations will be very closely monitored by the ASN. At the same time, it will play an active part in the international work of the IAEA and the European Commission, which have already announced their desire to coordinate updating of the international standards constituting the reference for radiation protection regulations, in particular by using the new ICRP recommendations as a basis.

The WENRA working groups have finalised their preparatory work for setting reference nuclear safety levels for power reactors and management of radioactive waste. The reports from the two working groups will be presented at a seminar in February 2006 in Brussels, bringing together representatives of the nuclear safety authority members of WENRA, the representatives of the European Commission, the IAEA, the NEA and the nuclear operators.

These reference levels will be debated during the course of 2006 and will be formalised at the end of the year, so that the WENRA members can initiate work to revise their national regulations, leading to harmonisation of nuclear safety supervisory practices in 2010.

The bill on nuclear transparency and safety should also be brought before Parliament at the beginning of 2006. This bill, tabled before the Senate on 18 June 2002, completes the general legislative framework for nuclear activities as defined by the Public Health Code. The bill has three key goals:

- it defines the main principles applicable to nuclear activities;
- it organises operator transparency in the field of nuclear activities;
- it overhauls the legislative basis concerning regulation and supervision of the safety of BNIs and radioactive material transport.

In accordance with law 91-1381 of 30 December 1991 concerning research into radioactive waste management, a parliamentary debate is scheduled for 2006 on a radioactive waste management bill. This bill could incorporate the main orientations of the national radioactive waste and reusable materials management plan (PNGDR-MV), the preparation of which was entrusted to the ASN in 2003 (see below chapter 16, point 1|6).

2006 will also be devoted to regulatory work aimed at:

- completing the simplification of licensing procedures for activities covered both by the list of installations classified on environmental protection grounds (ICPE) and the Public Health Code;
- redefining the procedures for BNI classification following abrogation of decree 66-450 of 20 June 1966, as modified, concerning the general principles of protection against ionising radiation and the subsequent disappearance of all reference to the radiotoxicity groups used to defined the activity levels above which an installation is considered to be a basic nuclear installation.

APPENDIX 1

VALUES AND UNITS USED IN RADIATION PROTECTION

1 The main values used in radiation protection

It is impossible to apply radiation protection rules without metrology, as the most important exposure indicators for radiation protection are the doses received by man. Transposition of Council directive 96/29/Euratom of 13 May 1996 laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation enabled the definitions of the main values used in radiation protection to be updated (appendix 13-7, regulatory part of the Public Health Code).

Activity and becquerel

Activity (A): the activity A of an amount of a radionuclide in a particular energy state at a given time is the quotient of dN by dt, where dN is the expectation value of the number of spontaneous nuclear transitions with emission of ionising radiation from that energy state in the time interval dt.

$$A = \frac{dN}{dt}$$

The unit of activity of a radioactive source is the becquerel (Bq).

Absorbed dose and gray

Absorbed dose (D): energy absorbed per unit mass

$$D = \frac{dE}{dm}$$

where:

dE is the mean energy communicated by the ionising radiation to the matter in a volume element;

dm is the mass of the matter in this volume element.

The term "absorbed dose" designates the mean dose received by a tissue or an organ.

The absorbed dose unit is the gray (Gy).

The absorbed dose D represents the quantity of energy absorbed per unit mass of tissue. 1 gray (Gy) corresponds to the absorption of 1 joule per kilogram. This quantity designates the mean dose absorbed by a tissue, organ or the whole body. However, the absorbed dose cannot be directly used in radiation protection because it does not take account of the fact that the biological effects of the energy intake depend on a number of parameters:

- the quality of the radiation, in other words how it loses its energy in the micro-volumes along its path. This depends on its nature, whether electromagnetic (X or gamma rays) or electrically charged or uncharged particle (alpha, beta or neutrons);
- the characteristics of the organ or tissue into which the energy is taken, as not all tissues have the same sensitivity to radiation;
- the dose rate, that is the inclusion of the time factor in the energy intake.

A large number of experiments have analysed the importance of each of these factors with regard to the biological effects of irradiation. To manage all the doses received by an individual, equivalent dose must be used which take account of these exposure parameters. Weighting factors are thus applied to the "absorbed dose" when one wishes to define the "equivalent dose" which takes account of the nature of the radiation and the "effective dose" which concerns the whole body.

Equivalent dose, committed equivalent dose and sievert

Equivalent dose (H_T): dose absorbed by the tissue or organ T, weighted according to the type and energy of the radiation R. It is given by the following formula:

$$H_{T,R} = w_R D_{T,R}$$

where:

$D_{T,R}$ is the mean for the organ or tissue T of the absorbed dose of radiation R;

w_R is the weighting factor for radiation R.

When the radiation field comprises radiation of types and energies corresponding to different values of w_R the total equivalent dose H_T is given by the formula:

$$H_T = \sum_R w_R D_{T,R}$$

The equivalent dose unit is the sievert (Sv).

The ICRP's w_R values, published in the order of 1 September 2003, are given in the following table. For the types of radiation which do not appear in the table, an approximate w_R value is obtained from the mean quality factor determined by the ICRU.

| Type of radiation and energy range | w_R |
|------------------------------------|-------|
| Photons all energies | 1 |
| Electrons and muons all energies | 1 |
| Neutrons of less than 10 keV | 5 |
| Neutrons from 10 to 100 keV | 10 |
| Neutrons from 100 keV to 2 MeV | 20 |
| Neutrons from 2 MeV to 20 MeV | 10 |
| Neutrons of more than 20 MeV | 5 |
| Protons of more than 2 MeV | 5 |
| Alpha particles | 20 |

Committed equivalent dose [$H_T(\tau)$]: integral over time (τ) of the equivalent dose rate in the tissue or organ T to be received by an individual following the intake of radioactive material. For an intake or activity at time t_0 , it is defined by the formula:

$$H_T(\tau) = \int_{t_0}^{t_0 + \tau} H_T(t) dt$$

where:

$H_T(t)$ is the equivalent dose rate in the organ or tissue T at time t;

τ the period over which intake is carried out.

Dans $H_T(\tau)$, τ is given in years. If the value of τ is not given, for adults it is implicitly taken at fifty years and for children as the number of years remaining until the age of 70.

The committed equivalent dose unit is the sievert (Sv).

Effective dose, committed effective dose and sievert

Effective dose (E): sum of the weighted equivalent doses delivered by internal and external exposure to the various tissues and organs of the body. It is defined by the formula:

$$E = \sum_T w_T H_T = \sum_T w_T \sum_R w_R D_{T,R}$$

where:

$D_{T,R}$ is the mean for organ or tissue T of the absorbed dose of radiation R;

w_R is the weighting factor for radiation R;

w_T is the weighting factor for the tissue or organ T.

The effective dose unit is the sievert (Sv).

Committed effective dose [E(τ)]: sum of the committed equivalent doses in the various tissues or organs [$H_T(\tau)$] following intake, each multiplied by the appropriate weighting factor w_T . It is given by the formula:

$$E(\tau) = \sum_T w_T H_T(\tau)$$

In $E(\tau)$, τ is the number of years of integration.

The committed effective dose unit is the sievert (Sv).

The choice made in 1990 by the International Commission on Radiological Protection (ICRP) is to express doses by the effective dose, which is the result of an equivalence calculated in terms of a belated risk of radiation-induced fatal cancers and serious genetic consequences. The effective dose E is the result of a second weighting by a factor describing the relative importance of the effects on the tissues in which the dose is distributed. It is thus already the result of a modelling of the risk. The values of w_T are given in the following table.

| Tissue or organ | w_T |
|---------------------|-------|
| Gonads | 0.20 |
| Red marrow | 0.12 |
| Colon | 0.12 |
| Lungs | 0.12 |
| Stomach | 0.12 |
| Bladder | 0.05 |
| Breasts | 0.05 |
| Oesophagus | 0.05 |
| Thyroid | 0.05 |
| Liver | 0.05 |
| Skin | 0.01 |
| Bone surface | 0.01 |
| Others ¹ | 0.05 |

Comments - The choice of the same unit to express the equivalent dose, defined in an organ, and the effective dose which takes account of all irradiated organs, is frequently a source of confusion.

1. For the calculations, the "other" organs are represented by a list of 12 organs for which selective irradiation is possible by internal contamination. If one of them concentrates most of the radionuclides, a w_T of 0.025 is given to it and a factor of 0.025 assigned to the mean dose received by the other 11 organs.

The sum of the different w_T values is equal to 1, which corresponds to uniform irradiation of the whole body. The w_T values are adapted to the expression of internal contamination.

The effective dose can be used to compare irradiations of different types, with regard to both the nature of the radiation and whether irradiation is overall or partial. On the other hand, the effective dose comprises a weakness: that of not being a measurable value. In the case of external exposure, measurable operational values are defined (ambient equivalent dose, directional equivalent dose, etc.), which will be used to calculate the dose in variable volumes, according to whether or not the radiation is penetrating and according to the effects (dose on the eye, dose on the skin).

The means of calculating the effective dose also has the drawback of having varied with time, in line with the changes made by the ICRP to the w_R and w_T coefficients, which were reviewed in the light of fresh data as it became available. Comparing the effective doses calculated at intervals of several years means that the weighting coefficients used in the calculations must be known for each period.

In the case of internal contamination from a long-lived radionuclide, we use the committed dose (committed equivalent dose or committed effective dose). At the time of contamination, it expresses integration of all the tissue doses, up to complete elimination of the radionuclide or for 50 years in workers and 70 years in children. The committed effective dose is calculated using the dose coefficients of directive 96/29/Euratom published in France in the order of 1 September 2003 defining the methods for calculating effective and equivalent doses resulting from exposure of persons to ionising radiation. Radionuclide by radionuclide, these coefficients give the effective dose (in sieverts) committed per unit of activity taken in, expressed in becquerels.

Collective dose and man.sieverts

The collective dose for a given population or group is the sum of the individual doses in a given population; it is obtained by the formula:

$$S = \sum H_i P_i$$

H_i is the mean of the total doses or the doses in a given organ of the P_i members of the i th subgroup of the population or group.

The collective dose unit is the man.sievert.

Comment - For the ICRP, the advantage of the collective dose is to allow optimisation of exposure to the lowest possible collective level, which contributes to the advancement of society as a whole, with the exception of the cost generated, which was not taken into account. This value, little used in France, was not included in the European and national regulations.

2 Uncertainties

The values recognised for the various weighting factors (w_R and w_T) were chosen from a relatively wide range of values. These are approximations designed to provide a tool for risk management.

The w_R values are taken from physical measurements describing the intensity of ionisation per unit volume, a value which varies with the residual energy along the path. When choosing a single value for a given radiation, account is therefore only taken of the direct biological observations, comparing the effects of this radiation with those of a reference radiation. Depending on the dose level and the biological effects considered, the relative biological effectiveness (RBE) can vary widely.

The w_T were also chosen with a view to compromise and simplification. A few numerical values alone characterise them. Some are of debatable scientific value. Thus, the value of 0.2 for the gonads implies the existence of genetic effects which have not been observed and the animal experimentation data used are probably highly over-valued. Finally, the breakdown of the risk between the various organs is primarily the result of epidemiological observations in Hiroshima and Nagasaki and we do not know exactly on what bases these risks should be transposed to a human group with significantly different ways of life.

APPENDIX 2

LIMITS AND DOSE LEVELS

Annual exposure limits contained in the Public Health Code (CSP) and in the Labour Code (CT)

| | Definition | Values | Observation |
|---|---|---|---|
| Annual limits for the population Art. R.1333-8 of the CSP | <ul style="list-style-type: none"> • Effective whole-body doses • Equivalent doses for the lens of the eye • Equivalent doses for the skin (average dose over any area of 1 cm² of skin, regardless of the area exposed) | 1 mSv/year 15 mSv/year 50 mSv/year | ☞ These limits comprise the sum of effective or equivalent doses received as a result of nuclear activities. These are limits that must not be exceeded. |
| Limits for workers over 12 consecutive months Art. R.231-77 of the CT | <p><u>Adults:</u></p> <ul style="list-style-type: none"> • Effective whole-body doses • Equivalent doses for the hands, forearms, feet and ankles • Equivalent doses for the skin (average dose over any area of 1 cm² of skin, regardless of the area exposed) • Equivalent doses for the lens of the eye <p><u>Pregnant women</u> (exposure of the child to be born)</p> <p><u>Young people from 16 to 18 years old*:</u></p> <ul style="list-style-type: none"> • Effective whole-body doses • Equivalent doses for the hands, forearms, feet and ankles • Equivalent doses for the skin • Equivalent doses for the lens of the eye | 20 mSv 500 mSv 500 mSv 150 mSv 1 mSv 6 mSv 150 mSv 150 mSv 50 mSv | ☞ These limits comprise the sum of effective or equivalent doses received. These are limits that must not be exceeded. ☞ Exceptional waivers are accepted: <ul style="list-style-type: none"> • when justified beforehand, they are scheduled in certain working areas and for a limited period, subject to special authorisation. These individual exposure levels are planned according to a upper limit which is no more than twice the annual exposure limit value; • emergency occupational exposure is possible in an emergency situation, in particular to save human |

* Only if covered by waivers, such as for apprentices.

Optimisation levels for patient protection (Public Health Code)

| | Definition | Values | Observation |
|--|--|---|--|
| Diagnostic examinations Diagnostic reference level Art. R.1333-68, order of 16 February 2004 Dose constraint Art. R.1333-65, order expected in 2006 Radiotherapy Target dose level Art. R.1333-63 | Dose levels for standard diagnostic examinations Used when exposure offers no direct medical benefit to the person exposed Dose necessary for the target organ or tissue (target-organ or target-tissue) during radiotherapy (experimentation) | e.g., entry level of 0.3 mGy for an X-ray of the thorax | <p>☞ The diagnostic reference levels, the dose constraints and the target dose levels employ the principle of optimisation. They are no more than points of reference.</p> <p>☞ The reference levels are defined for standard patients by dose levels for standard radiological examinations and by radioactivity levels for radio-pharmaceutical products used in diagnostic nuclear medicine.</p> <p>☞ The dose constraint can be a fraction of a diagnostic reference level, in particular for exposure in the context of biomedical research or medico-legal procedures.</p> <p>☞ The target dose level (specialists talk of a target volume in radiotherapy) is used to adjust the equipment.</p> |

Intervention trigger levels in cases of radiological emergencies (Public Health Code)

| | Definition | Values | Observation |
|---|--|-----------------------------|---|
| Protection of the general public Intervention levels Art. R.1333-80, order of 14 October 2003, circular of 10 March 2000 | Expressed in effective dose (except for iodine), these levels are designed to assist with the relevant response decision to protect the population: <ul style="list-style-type: none"> • sheltering • evacuation • administration of stable iodine (thyroid dose) | 10 mSv 50 mSv 100 mSv | <p>☞ The Prefect can make adjustments to take account of local factors.</p> |
| Protection of participants Reference levels Art. R.1333-86 | These levels are expressed as effective dose: <ul style="list-style-type: none"> • for the special teams for technical or medical intervention • for the other participants | 100 mSv 10 mSv | <p>☞ This level is raised to 300 mSv when the intervention is designed to prevent or reduce exposure of a large number of people.</p> |

Action trigger levels (Public Health Code and Labour Code)
(Activity or dose levels above which action must be taken to reduce exposure)

| | Definition | Values | Observation |
|--|---|--|---|
| Long-term exposure (contaminated sites) Art. R.1333-89 of the CSP IRSN Guide 2000 | Selection level: individual dose above which the need for rehabilitation must be examined | Undefined | ⓘ The notion of selection level is introduced by the IRSN guide for management of industrial sites potentially contaminated by radioactive substances. |
| Exposure to radon Protection of the general public Art. R.1333-15 and R.1333-16 of the CSP, order of 22 July 2004 Protection des travailleurs Article R.231-115 du CT | Premises open to the public Working environments | 400 Bq/m ³ 1000 Bq/m ³ 400 Bq/m ³ | ⓘ See notice published in Official Gazette of 11 August 2004 defining radon measurement methods. ⓘ See notice published in Official Gazette of 22 February 2005 defining the corrective measures to be taken in the event of overshoot. |
| Enhanced natural exposure (excluding radon) Protection of the general public Art. R.1333-13 and R.1333-14 of the CSP Worker protection Art. R.231-114 of the CT | Effective dose | N/A 1 mSv/an | ⓘ Any population protection action to be taken will be defined on a case by case basis. |
| Water intended for human consumption Decree n° 2001-1220 of 20 December 2001, order of 12 May 2004 | Annual total indicative dose (TID) calculated based on the radioelements present in the water, except for tritium, potassium 40, radon and daughter products Tritium | 0,1 mSv 100 Bq/L | ⓘ The TID can be used to estimate the exposure attributable to the radiological quality of the water. Any corrective measures to be taken if the TID is exceeded depend on the value of the TID and the radioelements in question. ⓘ Tritium is a contamination indicator. |
| Foodstuffs (emergency situation) European regulations <i>Codex alimentarius</i> , etc. | Saleability limits | | See following table. |

Consumption restrictions on contaminated foodstuffs

In the event of an accident or any other radiological emergency situation, the restrictions on the consumption or sale of foodstuffs are determined in Europe by two regulations: Council regulation N° 3954/87/Euratom of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedstuffs following a nuclear accident or in any other case of radiological emergency, and Council Regulation 2219/89/EEC of 18 July 1989 on the special conditions for exporting foodstuffs and feedstuffs following a nuclear accident or any other case of radiological emergency. The purpose of these restrictions is to “safeguard the health of the population while maintaining the unified nature of the market”.

Thus maximum allowable levels in Bq/kg or Bq/L were set according to the nature of the radioelement concerned, the product concerned and its end-use (baby foods, foodstuffs and feedstuffs).

A list of foodstuffs of “lesser importance” was drawn up (foodstuffs for which consumption does not exceed 10 kg/year). Levels ten times higher are set for these items, such as thyme, garlic, cocoa paste, truffles, caviar, etc.

Foodstuffs or feedstuffs in which contamination exceeds these levels, may not be sold or exported. Nonetheless, in the event of an accident, “automatic” application of this regulation may not exceed a period of three months, after which time it would be replaced by more specific provisions.

| MAXIMUM ALLOWABLE LEVELS FOR FOODSTUFFS (Bq/kg or Bq/L) | Baby foods | Dairy products | Other foodstuffs except those of lesser importance | Liquids intended for consumption |
|---|---------------|-------------------|--|---|
| Isotopes of strontium, in particular ⁹⁰ Sr | 75 | 125 | 750 | 125 |
| Isotopes of iodine, in particular ¹³¹ I | 150 | 500 | 2,000 | 500 |
| Isotopes of plutonium and alpha-emitting <u>transuranic</u> elements, in particular ²³⁹ Pu and ²⁴¹ Am | 1 | 20 | 80 | 20 |
| Any other element with a half-life of more than 10 days, in particular ¹³⁴ Cs and ¹³⁷ Cs | 400 | 1,000 | 1,250 | 1,000 |

Maximum allowable levels of radioactive contamination for feedstuffs (caesium 134 and caesium 137):

Pork: 1,250 Bq/kg
Poultry, lamb, veal: 2,500 Bq/kg
Others: 2,500 Bq/kg.

The WHO also proposed indicative values to facilitate international trade. The national authorities may use these values as the basis for determining their own thresholds, thus helping to harmonise these intervention criteria.

Indicative values of the *Codex alimentarius* for foodstuffs offered for sale (FA91) Bq/kg

| | |
|--|-------|
| FOODSTUFFS INTENDED FOR GENERAL CONSUMPTION | |
| Americium 241, plutonium 239 | 10 |
| Strontium 90 | 100 |
| Iodine 131, caesium 134, caesium 137 | 1,000 |
| BABY FOODS AND MILK | |
| Americium 241, plutonium 239 | 1 |
| Iodine 131, strontium 90 | 100 |
| Caesium 134, caesium 137 | 1,000 |