CHAPTER 3

The legislation applicable to radiation protection can be found in chapter III of part III of book III of the first part of the Public Health Code, the provisions of which are taken mainly from ordinance 2001-270 of 28 March 2001 concerning the transposition of community directives dealing with protection against ionising radiation.

This legislation is based on internationally adopted rules, whether regulations or community directives such as Council directive 96/29/Euratom dated 13 May 1996 and setting basic standards for health protection of the population and workers against the dangers of ionising radiation. It is also based on a variety of norms, standards and recommendations, such as the recommendations from the International Commission on Radiation Protection (ICRP) or the standards issued by the International Atomic Energy Agency (IAEA), in particular the International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources (Safety Series n° 115).

Legislative requirements concerning nuclear safety were contained in law 61-842 of 2 August 1961 concerning the reduction of atmospheric pollution and odours, in decree 63-1228 of 11 December 1963 concerning nuclear installations and in decree 95-540 of 4 May 1995 concerning liquid and gaseous effluent discharges and water intake by BNIs. Law 2006-686 of 13 June 2006 concerning nuclear transparency and safety, which created the Nuclear Safety Authority (ASN) and introduced new measures dealing with information, establishes a new system of BNI licensing. It will be supplemented by various implementing texts.

Following on from the law of 30 December 1991, programme law 2006-739 of 28 June 2006 concerning long-term management of radioactive materials and waste, defined three main areas of research: separation/transmutation, deep geological disposal and long-term storage.

This chapter presents the current regulations applicable to radiation protection, nuclear safety and the transport of radioactive materials.

1 THE REGULATION OF RADIATION PROTECTION

1 | 1

The regulatory basis

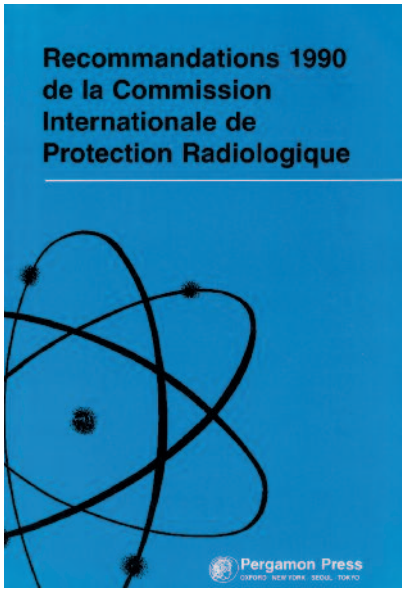
1 | 1 | 1

The international reference framework (ICRP, IAEA, Euratom)

The specific legal framework for radiation protection is based on various norms, standards and recommendations issued internationally by various organisations. The following in particular should be mentioned:

- the International Commission on Radiation Protection (ICRP), a non-governmental organisation comprising experts in various fields from around the world. It publishes recommendations concerning the protection of workers, the population and patients against ionising radiation, based on an analysis of the available scientific and technical knowledge. The latest recommendations from the ICRP are to be found in ICRP Publication 60, which came out in 1991. The ICRP has begun revision of this work and this should in 2007 lead to a new publication taking account of changing professional knowledge and experience;

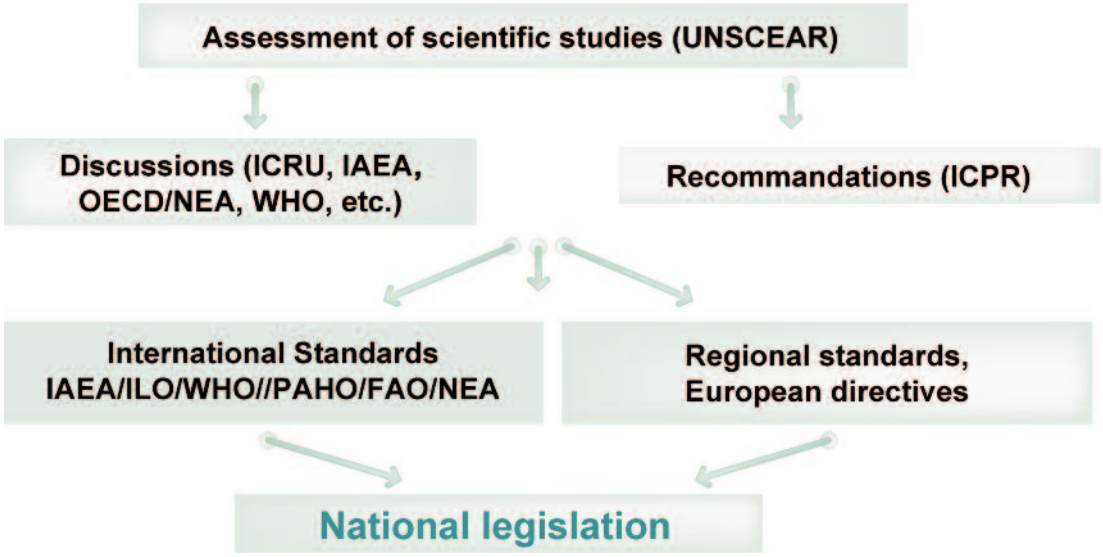
- the International Atomic Energy Agency (IAEA) which regularly publishes and revises standards in the fields of nuclear safety and radiation protection. The International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources (Safety Series n° 115), based on the ICRP recommendations, were published in 1996, in partnership with the United Nations Food and Agriculture Organisation (FAO), the International Labour Organisation (ILO), the OECD Nuclear Energy Agency (NEA), the Pan-American Health Organisation (PAHO) and the World Health Organisation (WHO). IAEA has also begun a process to revise the International Basic Standards for Protection against Radiation, while a new standard concerning the basic safety principles was published at the end of 2006;



ICPR 60

- the International Standards Organisation (ISO) which publishes international technical standards. These are a key element in the radiation protection of individuals and are the cornerstone between the principles, concepts and units, and the body of regulatory texts for which they guarantee harmonised application.

At a European level, the Euratom Treaty, and more particularly articles 30 to 33, specifies how the standards for protection against radiation are drafted and defines the powers and obligations of the European Commission with respect to how they are applied. The corresponding directives are binding on the various countries, such as directive 96/29/Euratom of 13 May 1996 setting basic standards for health protection of the population and workers against the dangers of ionising radiation, directive 97/43/Euratom of 30 June 1997 concerning the health protection of persons against the dangers of ionising radiation during exposure for medical purposes, and directive 2003/122/Euratom of 22 December 2003 concerning supervision of high-level sources and stray sources.



Drafting of radiation protection doctrine

1 | 1 | 2

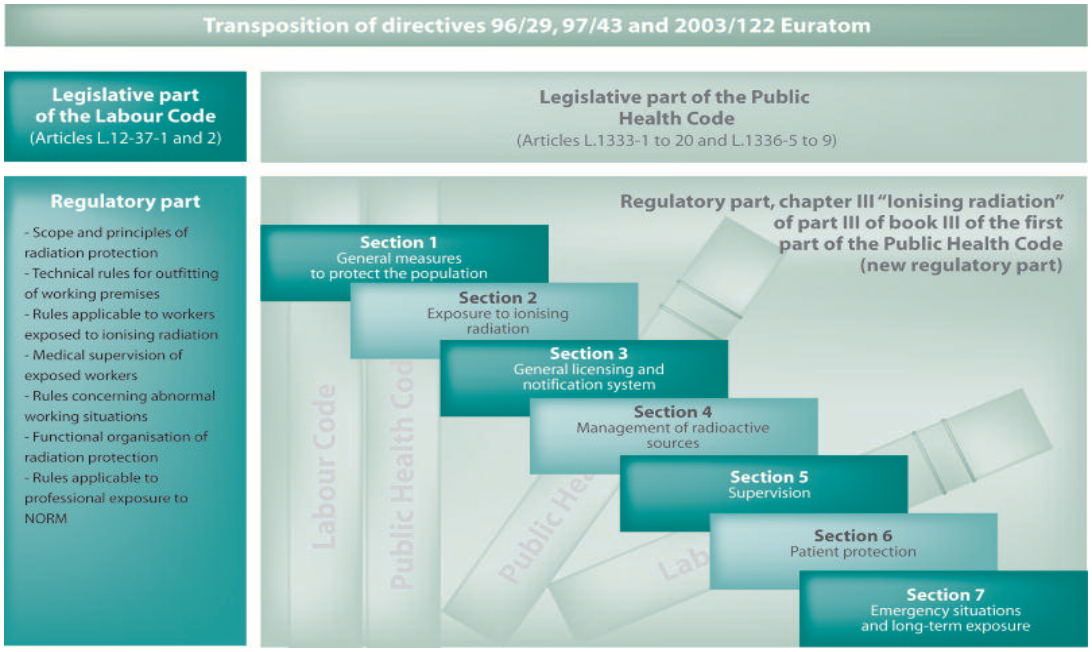
The Public Health Code and the Labour Code

DSince 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.

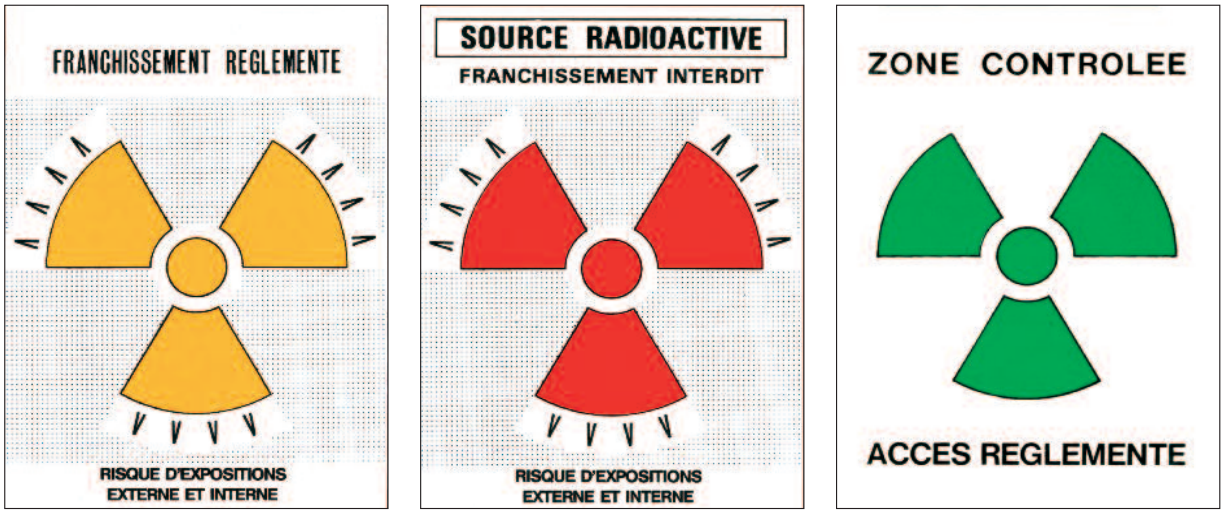
The update of the legislative part was completed with publication of the above-mentioned ordinance of 28 March 2001 and law 2004-806 of 9 August 2004 concerning public health policy, with the introduction of new articles concerning the radiation protection inspectorate and an update to take account of the creation of ASN (law of 13 June 2006).

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 (including forensic science, screening technologies, insurance and other related applications);
- 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.
- decree 2006-694 of 13 June 2006 setting the procedures for designating, approving and swearing-in radiation protection inspectors and modifying the Public Health Code.



Structure of the legislative and regulatory radiation protection framework



Signs indicating areas in which radioactive work is in progress

The decrees of 4 April 2002, 24 March 2003, 2003-295 of 31 March and 2006-294 of 13 June 2006, mentioned above, are codified in chapter 3 "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:

An initial update of chapter 3 "Ionising Radiation" of the Public Health Code, was carried out in 2005, with additions to section 7 "Emergency situations and long-term exposure" by decree 2005-1179 of 13 September 2005 concerning radiological emergencies, in order to complete the transposition of Council directive 89/618/Euratom of 27 November 1989 concerning public information about applicable heath protection measures and what to do in the event of a radiological emergency.

A second update is currently being prepared to take account of the following objectives:
- to transpose Council directive 2003/122/Euratom of 22 December 2003 on the control of high-level sealed radioactive sources and stray 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 take account of the prerogatives granted to ASN by the law of 13 June 2006.

Effective implementation of the new regulatory provisions remained dependent on the publication of numerous orders: 27 were published between July 2003 and December 2006, and 5 are still to be published. However, transposition of the above-mentioned directives 96/29/Euratom, 97/43/Euratom and 89/618/Euratom is considered to be complete.

a) 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 material or a device, or from a natural source when the natural radionuclides are or have been treated owing to their fis-

sile 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 ASN is responsible.

1°) The principle of justification

"A nuclear activity or intervention may only be undertaken or carried out if justified by the advantages it procures, particularly in health, social, economic or scientific terms, with respect to the risks inherent in the exposure to ionising radiation to which the individual are likely to be subjected."

Depending on the type of activity, the justification decision lies with various levels of authority: it lies with the government for issues of general interest, as in the case of whether or not to resort to nuclear energy; it lies with ASN in the case of sources used for medical, industrial and research purposes; it lies with the AFSSAPS for release to the market of a new irradiating medical device and with the physicians for prescribing and carrying out a diagnostic or therapeutic procedure.

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 materials 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 as the ALARA principle, for example leads to a reduction in the discharge licenses of the quantities of radionuclides present in the radioactive effluent from nuclear installations, to surveillance of exposure at the workstation in order to reduce it to the strict minimum, and to ensure that medical exposure as a result of diagnostic procedures remains close to the pre-determined reference levels.

3°) The principle of limitation

"Exposure of a person to ionising radiation as a result of a nuclear activity, cannot raise the sum of the doses received beyond limits set by the regulations, unless this person is exposed for medical purposes or for biomedical research."

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 of the *Conseil d'Etat* 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.

Exposure to Technologically Enhanced Naturally Occurring Radioactive Materials (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 ASN. The implementing decree of 13 June 2006 set the procedures for designating, approving and swearing-in the radiation protection inspectors. The law of 13 June 2006 now gives ASN Chairman the powers to designate radiation protection inspectors, chosen mainly from among ASN personnel. 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).

b) 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 ionising 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).

1 | 2

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.

1 | 2 | 1

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;

- 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 seven implementing orders since March 2003 has provided the clarification necessary for these new measures to be put into practice.

Zoning

New provisions concerning the boundaries of monitored zones, controlled zones and specially regulated zones (subject to special checks) were issued, regardless of the activity sector, by the order of 15 May 2006 (O.G. of 15 June 2006). This order also defines the health, safety and maintenance rules to be observed in these zones. When marking out the regulated zones, three levels of protection are now taken into account. They are the effective dose for external and, as applicable, internal exposure of the whole organism, the equivalent doses for external exposure of the extremities and, as applicable, the dose rates for the whole organism. The order thus sets reference values that the head of the establishment is required to compare with the external and internal exposure levels encountered at the workstations, when determining the 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 assessing 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 arrangements for accreditation of organisations responsible for worker dosimetry have also been published (order of 6 December 2003); the arrangements 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 the French Institute for Radiation Protection and Radiation Safety (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 licensee's in-house inspection processes and partly by outside organisations (the outside checks must be performed by 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 an order dated 20 March 2006.

Radon in the working environment (see point 1|4|1)

1 | 2 | 2

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.

Old advertisement for now prohibited uses of radionuclides in consumer goods

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 15 mSv/year and 50 mSv/year respectively (average value for any 1 cm 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.

Old advertisement for agricultural fertiliser containing radium

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 IRSN, with guidelines being defined by ASN (order of 27 June 2005 organising 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 benchmarking 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). This waste and effluent must be disposed 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).

The licensing and notification procedures for sources of ionising radiation

The system of licensing or notification, which covers all sources of ionising radiation, is described in full in section 3 of chapter III of part III of book III of the Public Health Code. This section will be updated in 2007 to take account of the experience acquired by ASN since 2002 and the new prerogatives granted to it by the law of 13 June 2006. All licenses will from now on be issued by ASN and notifications will be filed with ASN regional departments.

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 the prevention of 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. The list of classified installations concerning certain nuclear installations was modified by decree 2006-1454 of 24 November 2006; it should in particular be noted that establishments other than industrial and commercial facilities (health institutions for instance) are no longer a part of this list and that for industrial activities, ICPE classification becomes mandatory only if the installation which uses radioactive sources is subject to licensing under another section of the list.

The procedures for submitting licensing applications or notifications, specified by the order of 14 May 2004, will need to be updated by ASN in order to introduce the content of the files enclosed with the licensing application and the submission of notification, along with the content of the licenses.

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, currently issued by the French Health Products Safety Agency (AFSSAPS), will in the future be issued by ASN;

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

- ASN must be notified of X-ray generators if they are of low-intensity (radiology or dental surgery). Larger scale equipment (scanners) requires a license issued by ASN.

The list of appliances subject to notification should shortly be updated by ASN, after approval by the Minister for Health.

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, in order to be able to carry out biomedical research, the "researcher" must have prior authorisation from the place of research (L.1121-13) in the following highly particular cases:
- when this is not a place of health care;
- when this is a place of health care but:
  - the research involves the performance of procedures not usual in this place,
  - the person being treated has a clinical condition other than that for which the department is competent.

The license is granted by the regional *préfet*[1] for a 5-year period, after investigation by a public health physician-inspector and, as necessary, a public health pharmacist-inspector.

b) The industrial and non-medical research fields

ASN is also in charge of issuing licenses for non-medical industrial and research applications, and for receiving the notifications. For these areas, 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.

The update scheduled for 2007 should lead to the introduction of a notification system for the installations on a list drawn up by ASN, after approval by the Minister for Health.

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 by 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, a mass limitation was introduced (the mass of material used must be less than 1 ton), which is the reference criterion used when preparing the scenarios on which the exemption values were based. 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. Finally, a new possibility for exemption from the licensing and notification requirement should be introduced in 2006 for equipment covered by a certificate issued by ASN, after approval by the Ministers for Health and Labour.

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.

1. *préfet*: regional government representative.

1 | 2 | 4

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 the CIREA (Interministerial commission on artificial radioelements) and their supervision is now the responsibility of ASN. However, the CIREA radioactive source inventory duties have been transferred to IRSN (article L.1333-9 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 the 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 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 methods for calculating the financial guarantees required from source suppliers will shortly be introduced into the Public Health Code. The national table for all the source families should be determined by order of the Ministers for Health and Finance, on the basis of recommendations from ASN, IRSN and ANDRA.

1 | 2 | 5

Protection of persons during a radiological emergency

The population is protected against the hazards of ionising radiation in the event 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. These levels constitute reference points for the public authorities (préfets) who have to decide locally, on a case by case basis, on what action is to be taken.

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 thyroid dose is liable to exceed 100 mSv;

Stamp commemorating the discovery of radium by Pierre and Marie Curie

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.

Public information in a radiological emergency

The ways in which the population is informed in a radiological emergency situation are covered by a specific community directive (directive 89/618/Euratom of 27 November 1989 concerning public information about health protection measures and how to act in the event of a radiological emergency). This directive was transposed into French law by:
- decree 2001-470 of 28 May 2001 concerning public information and modifying decree 88-622 of 6 May 1988 dealing with 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 its own off-site emergency plan (PPI) and the order of 21 February 2002 concerning information to the populations);
- decree 2005-1179 of 13 September 2005 concerning radiological emergency situations.

Two implementing orders were published:
- the order of 4 November 2005 concerning public information 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 to the personnel involved in managing a radiological emergency situation.

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 materials;

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 as defined by international conventions or agreements, or decisions taken by the European Community on the subject of information in the event of a radiological emergency."

1 | 2 | 6

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 materials. 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 materials, version 0, December 2000), produced at the request of the ministries for Health and the Environment, and distributed to the *préfets* (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.

1 | 3

Protection of persons exposed for medical and medico-legal purposes

The new regulatory framework, implemented in March 2003, transposing above-mentioned directive 97/43/Euratom, 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 expo-

sure 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 Justification of procedures

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.

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 Nuclear Medicine and Molecular Imaging Society (SFMN), the French medical Radio-physics Society (SFPM), and various organisations representing dental practitioners, have set up the necessary working frameworks for drafting these guides. IRSN, the High Health Authority (HAS) and the National Cancer Institute (INCa) are also involved in this approach. As applicable, ASN coordinates or supports this work, or is simply kept informed. The progress of the various guides is presented in the following table.

Speciality	Medical radiology		Nuclear medicine	Radiotherapy	Dental radiology
Documents	**Procedure guide**	**Referral criteria for imaging guide**	**Referral criteria for imaging guide**	**Tumour radiotherapy guide – Optimisation of procedures**	**Indication and procedure guide**
Start	09.1999	06.2001	09.1999	04.2004	01.2004
Interim reports	07.2000	03.2004	06.2004	10.2006	08.2005
Finalisation	10.2001* (JFR 2001)	10.2004 (JFR 2004)		Scheduled for end 2007	05.2006
Availability	SFR and IRSN website www.sfrnet.org www.irsn.org	SFR publication website www.sfrnet.org	SFBMN website www.sfbmn.org	–	Distribution procedures currently under examination with the various participating societies

*Currently being updated

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

Optimisation of exposure

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 protection for patients have been introduced for this very purpose and reference diagnostic levels were set in the order of 12 February 2004. For radiology, 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 centralising them at 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 is of no direct benefit to the persons exposed, dose constraints designed to limit the doses delivered must be established by the physician.

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

Referral criteria for imaging guide

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.

Six decisions have been 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 quality control procedures for analog mammography installations, amended by a decision of 16 December 2005;
- decision of 30 January 2006 concerning quality control procedures for digital mammography installations;
- decision of 20 November 2006 setting internal quality control procedures for certain radiodiagnosis installations.

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 the justification and optimisation principles, the report on the procedure, written by the medical practitioner carrying out the examination, must provide information justifying the procedures and the operations carried out and the data used to estimate the dose received by the patient (order of 22 September 2006).

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 (French High Public Health Council, learned societies) were distributed by ASN (January 2007) to enable the content of the information already sent out to be harmonised.

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 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 in 2007.

1 | 4

Protection of persons exposed to "enhanced" natural radiation

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:

Map of 31 *départements* for radon measurement

- 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.

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 départements 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 14 July 2006 concerning the accreditation of organisations responsible for measuring radon. The list of approved organisations was updated in the order of 25 July 2006, after obtaining the opinion of the approval commission consisting of representatives of the Ministries concerned, technical organisations (IRSN, Scientific and Technical Centre for the Building Industries, French High Public Health Council), building professionals and professionals involved in radon measurements.

The order of 22 July 2004 was accompanied by publication in the Official Gazette of an opinion defining the standards applicable to radon measurement (O.G. of 12 August 2004) and an opinion concerning the definition of actions and work required in the event of the action trigger levels of 400 and 1000 Bq/m^3 being exceeded (O.G. 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/m^3. An order defining the workplaces in which these measurements are required should be published in 2007.

1 | 4 | 2

Other sources of exposure to “enhanced” natural radiation

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) and the Public Health Code (art. R. 1333-13).

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 materials 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.

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 0.1 mSv/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. An ASN/DGS circular should in 2007 clarify the doctrine associated with this new regulation.

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.

In 2004, in line with the concerns of the European Commission and several European countries, ASN had made known its opposition to the project to revise the indicative limits on radionuclides in foodstuffs applicable to international commerce, established by the FAO/WHO/IAEA group of experts. In 2006, new limits were proposed and then validated by the Codex in The Hague (Netherlands).

2 BNI REGULATORY PROVISIONS

Law 61-842 of 2 August 1961 concerning the reduction of atmospheric pollution and odours was abrogated by law 2006-686 of 13 June 2006 on nuclear transparency and safety. However, the licenses and requirements relating to basic nuclear installations delivered pursuant to the law of 2 August 1961 or its implementing regulatory texts are equivalent to licenses and requirements as defined in the law of 13 June 2006. They are modified in the conditions laid down by this law and by its implementing texts.

Decree 63-1228 of 11 December 1963 concerning nuclear installations and decree 95-540 of 4 May 1995 concerning liquid and gaseous effluent discharges and water intake by BNIs will be abrogated by a decree implementing the above-mentioned law of 13 June 2006, except with respect to defence-related nuclear activities and installations.

New regulations covering BNIs and transportation of radioactive materials were created by part IV of the above-mentioned law of 13 June 2006, which will be supplemented by a decree covering basic nuclear installations and supervision of the nuclear safety of radioactive material transports ("INB-TSR decree") and by the decree covering the BNI list. The law of 13 June 2006 reaffirms the particular conditions applying to basic nuclear installations, provides a more consistent legislative basis and

reinforces the system of inspections and penalties, bringing it into line with the relevant international standards.

BNI regulations are to a large extent based on international agreements and standards published by IAEA.

The Nuclear Safety Convention, in force since 1996, concerns civil nuclear power generating reactors. It defines a certain number of safety objectives and appropriate measures. Its counterpart in the field of spent fuel and radioactive waste management is the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management, in force since 2001.

IAEA publishes reference texts, called "Basic Safety Standards", describing the safety principles and practices that can be used by States as the foundation for their own national regulations. These documents are not binding. They concern installation safety and radiation protection, the safety of waste management and the safety of radioactive materials transportation.

At a Community level, the only two texts dealing with nuclear safety are Council resolutions of 22 July 1975 and 18 June 1992 concerning technological nuclear safety problems and asking the member States and the Commission to reinforce cooperation through significant joint actions to tackle fundamental safety issues. For their part, the members of WENRA (association created at the initiative of ASN in 1999), which brings together the 17 heads of the safety authorities in the "nuclear" countries of the European Union plus Switzerland, have for the past few years being working on a programme to harmonise technical rules in both areas of nuclear installation safety and the management of spent fuel and radioactive waste.

2 | 1

Authorisations and licenses

Section IV of the above-mentioned law of 13 June 2006 makes provision for an authorisation decree procedure, followed by a series of licenses issued at the main stages marking the life of a BNI: creation for BNIs, commissioning, possible modification of the installation, final shutdown and decommissioning.

With the previous system, two different procedures existed alongside each other, depending on whether one was dealing with creation of a BNI (decree of 11 December 1963) or a discharge license (decree of 4 May 1995).

2 | 1 | 1

Siting

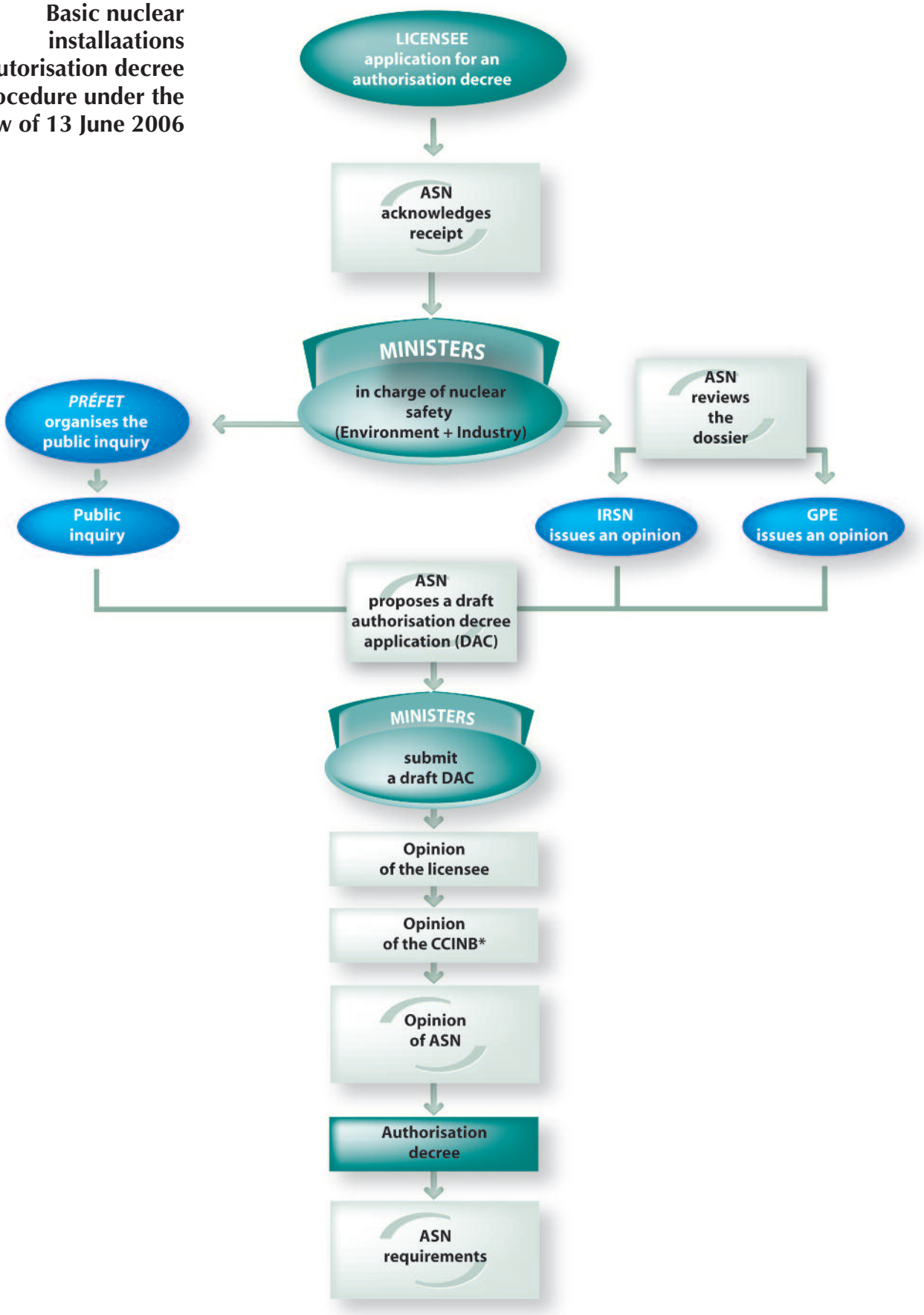
Well before applying for a BNI authorisation decree, the licensee informs the administration of the site(s) on which it plans to build this installation.

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, 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

1. FAO: *Food and Agriculture Organisation* (Organisation des Nations unies pour l'alimentation et l'agriculture), OMS: Organisation mondiale pour la santé, AIEA: Agence internationale pour l'énergie atomique.

Basic nuclear installaations autorisation decree procedure under the law of 13 June 2006



*it to replace the Interministerial Commission for Basic Nuclear Installations (CIINB)

R. 121-16 of the Environment Code) specifies that creation of a BNI is subject to the public debate procedure:
- systematically, in all cases when dealing with a new 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.

Public debates were held in 2006 to discuss the building of an EPR type nuclear reactor at Flamanville and location of the ITER research reactor in Cadarache.

2 | 1 | 2

Safety options

When a licensee 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.

ASN generally asks the competent Advisory Committee of Experts (GPE) to examine the project and then informs the licensee 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

The application for authorisation to create a basic nuclear installation is submitted by the licensee to ASN, which will then investigate it along with the Ministers responsible for nuclear safety. This is followed by a period of parallel consultation of the public and technical experts.

a) Public consultation

The authorisation may only be delivered after a public enquiry as specified in article 29-I of the above-mentioned law of 13 June 2006.

The public inquiry is opened by the préfet of the *département* 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 *préfecture*[3] concerned, a descriptive file and an inquiry register are made available in all *communes*[4] completely or partially within a 5 km radius around the planned installation. If this radius encompasses the territory of several *départements*, a joint order of the *préfets* concerned organises the inquiry in each département, with the *préfet* 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 Commissioner.

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 *préfet*.

In each *département* concerned by the public enquiry, the *préfet* also consults the General Council and the Local Councils in those *communes* where the public enquiry is taking place, as well as the State regional offices he feels to be concerned by the application.

If there is a local information committee, it is consulted by the *préfet* or *préfets* of the *départements* in which the facility is to be located (see below).

No later than fifteen days following receipt of the report and the conclusions of the enquiry commissioner, the *préfet* forwards them to the Ministers responsible for nuclear safety and to ASN, with his opinion, along with the results of all the consultations carried out.

b) Creation of a local information committee

A local information committee is set up for any site comprising one or more basic nuclear installations. Its general role is to monitor, inform and discuss nuclear safety, radiation protection and the impact of nuclear activities on both humans and the environment. It comprises representatives from the general councils, local councils or joint council assemblies and the regional councils concerned, elected members of Parliament from the region, representatives of environmental protection associations, economic interests and pertinent employee trade unions and the medical professions, as well as qualified personalities. Representatives of ASN and other State departments concerned, as well as representatives of the licensee, may attend the sessions of the local information committee on a consultative basis.

c) Consultation of technical organisations

The preliminary safety report appended to the authorisation decree application is transmitted to ASN, which submits it for examination to one of the Advisory Committees of Experts reporting to it, following a report from IRSN.

Further to its investigation and the results of the consultations, ASN sends the Ministers responsible for nuclear safety a proposal for drafting of a decree either authorising or rejecting creation of the installation.

d) Authorisation decree

The Ministers responsible for nuclear safety send the licensee a draft decree granting or rejecting the authorisation decree.

After consulting the licensee, the Ministers responsible for nuclear safety submit the draft to the Interministerial Commission for Basic Nuclear Installations (CIINB) for its opinion. The commission is required to submit its opinion within two months of having the matter referred to it (the draft INB-TSR decree states that CIINB is to be replaced by the CCINB, the BNI consultative commission).

The Ministers responsible for nuclear safety ask ASN for its opinion concerning the draft authorisation or rejection decree, possibly as amended to take account of the opinion of the CIINB. ASN delivers its recommendation within two months, failing which, a favourable opinion is deemed to have been given.

The creation authorisation decree is passed after consulting ASN, following a report from the Ministers responsible for nuclear safety.

The decree sets the perimeter and characteristics of the installation and the particular rules by which the licensee is bound.

There are however a number of significant differences with respect to the above-mentioned 1963 decree:
- the creation authorisation decree (DAC) now also constitutes the discharge license. The discharge limits are set by an approved decision of ASN;
- the DAC may now set a time limit for operations.

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 materials, installation modifications, final shutdown and decommissioning.

Applications for authorisation decrees, decommissioning decrees and amendments to authorisation or decommissioning decrees submitted before publication of the INB-TSR decree and in the process of being examined on that date, will continue to be examined in accordance with the procedures laid down by the above-mentioned 1963 decree.

e) Installation modifications

The licensee advises ASN of any modifications to the installation entailing an updating of the general operating rules or the site on-site emergency plan.

A new authorisation decree, examined as previously described, must be obtained if there is a change in licensee, a modification of the perimeter or a significant change to the installation.

A modification is considered to be significant if:
- there is a change in the nature of the installation or an increase in its maximum capacity;
- there is a change in the key elements regarding protection of the interests mentioned in I of article 28 of the law of 13 June 2006, mentioned in the authorisation decree;
- a new BNI mentioned in III of article 28 of the above-mentioned law of 13 June 2006 is added within the perimeter of the installation and its operation is linked to that of the installation in question.

f) 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, listed by type in a document regularly updated by the Ministry for the Environment, are the subject of special arrangements when they are located within the perimeter of a.

In the same way as the above-mentioned 1963 decree, the INB-TSR decree makes the following distinction:
- "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 the procedure applicable to BNIs;
- classified installations falling within the perimeter of a BNI but which are not necessarily linked to it are covered by legislation concerning installations classified on environmental protection grounds.

2 | 1 | 4

Operating licences

These are issued by ASN.

Commissioning corresponds to first use of radioactive materials in the installation or the first operation of a particle beam.

Partial commissioning may however be authorised by ASN for a limited period, for one of the following categories of operations:
- performance of particular installation operating tests requiring that radioactive materials be brought into it;
- arrival of nuclear fuel within the perimeter of a reactor, prior to first loading of fuel into this reactor.

2 | 1 | 5

Final shutdown and decommissioning licences

a) The final shutdown and decommissioning licensing procedure

Final shutdown and decommissioning of nuclear installations are subject to prior licensing. A public enquiry is now necessary in any case.

Two licensing systems coexist, one for general cases and one for radioactive waste disposal facilities:

· General case:
- the license application contains requirements concerning the shutdown conditions, the decommissioning and fuel management procedures, and the surveillance and subsequent maintenance of the installation site;
- the license is granted by decree, subject to the opinion of ASN, setting the dismantling characteristics, the time allotted for decommissioning and the types of operations for which the licensee is responsible after decommissioning.

· Radioactive waste disposal facilities:
- the license application contains requirements concerning final shutdown and subsequent maintenance and surveillance of the site;
- the license is issued by decree, subject to the opinion of ASN, setting the types of operations for which the licensee is responsible after final shutdown.

b) Performance of decommissioning and decommissioning operations

For installations other than radioactive waste disposal facilities, the decommissioning and decommissioning operations comprise two successive phases of work:

- decommissioning 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;

- decommissioning work on the nuclear part of the plant. This work can start as soon as the decommissioning 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 ensure compliance both with previously imposed requirements and with the safety case and general operating rules currently in force, albeit with minor modifications if necessary. In all other cases, such operations come under the provisions of the final shutdown and decommissioning decree.

c) Installation delicensing and public easements

If decommissioning work is taken as far as the final target state, as validated by ASN, the installation can be delicensed and removed from the BNI list in accordance with the procedure specified in its final shutdown and decomissioning license.

The installation may possibly be subject to the legislation concerning ICPEs (articles L. 511-1 to L. 517-2 of the Environment Code), in which case either a notification or a licensing procedure is required.

The delicensing application in particular contains a presentation of the site after decommissioning, giving an analysis of the state of the soil and a description of any remaining installation constructions and their state.

In order to keep a trace of the past existence of a BNI on a site and make provision for any restrictions on the future use of the installation, public easements may be implemented after delicensing or disappearance of the installation and concern the use of the soil in and around the installation. These easements are created in accordance with article 31 of the above-mentioned law of 13 June 2006, further to the opinion of ASN, in the conditions laid down in articles L. 515-8 to L. 515-12 of the Environment Code.

Public easements concerning the use of the soil and performance of work subject to notification or administrative authorisation may also be implemented, pursuant to article 31 of the law of 13 June 2006, on existing installations, including installations in service.

2 | 1 | 6

ASN requirements for implementation of the authorisation decrees

For implementation of the authorisation decrees, ASN defines the requirements concerning the design, construction and operation of the installations.

Although these authorisation decrees (creation, final shutdown and decommissioning) now also constitute the liquid and gaseous effluent discharge and water intake license, ASN – on the basis of article 29-I – stipulates the requirements concerning water intake by the installation and the radioactive materials discharged from it. The requirements setting limits on the discharges from the installation into the environment must be approved by the Ministers responsible for nuclear safety.

As mentioned above, decree 95-540 of 4 May 1995 concerning liquid and gaseous effluent discharge and water intake by basic nuclear installations will be abrogated by the INB-TSR decree, except with respect to defence-related nuclear activities and installations.

2 | 2

General technical regulations

The general technical regulations comprise all general texts laying down technical rules for nuclear safety, whether regulatory (orders) as specified in article 30 of the above-mentioned law of 13 June 2006 or related (circulars, basic safety rules, guides).

2 | 2 | 1

Ministerial and government orders

a) Pressure vessels

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

The applicable regulations are detailed in the following table:

<table>
<tr><th></th><th colspan="3">Nuclear</th><th>Conventional</th></tr>
<tr><th></th><th>Main primary system of pressurised water reactors</th><th>Main secondary systems of pressurised water reactors</th><th>Other equipment</th><th></th></tr>
<tr><td rowspan="2">Construction</td><td>• Decree of 2 April 1926
• Order of 26 February 1974 (1)</td><td>• Decree of 2 April 1926
• RFS II.3.8 of 8 June 1990 (1)</td><td>• Decree of 2 April 1926
• Decree of 18 January 1943 or
• Decree of 13 December 1999 (1)</td><td rowspan="2">• Decree 99-1046 of 13 December 1999</td></tr>
<tr><td colspan="3">or Order of 12 December 2005</td></tr>
<tr><td>Operation</td><td colspan="2">• Order of 10 November 1999</td><td>• Decree of 2 April 1926
• Decree of 18 January 1943
(1)</td><td>• Decree 99-1046 of 13 December 1999
• Order of 15 March 2000</td></tr>
</table>

(1) As of 2011, the order of 12 December 2005 will apply to the operation of nuclear pressure vessels, except for the main primary and secondary systems of pressurised water reactors.

b) Quality organisation

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

It thus stipulates that the licensee 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 licensee 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 ASN to analyse the various problems in order to assess the application of the above-mentioned order of 10 August 1984.

A draft revision of the quality order has been produced, aiming to bring it into line with the WENRA reference levels. This order should be replaced by one dealing with BNI safety policy and management. As part of the WENRA reference levels transcription process, five working groups have been drafting texts (order and guides) since the beginning of 2006 in the following areas: safety policy and management (all BNIs); safety approach; pressurised water reactor (PWR) design; PWR operations and emergency situations.

c) 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 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 order of 31 December 1999 stipulating the general technical regulations designed to prevent and mitigate the harmful effects and external hazards resulting from operation of basic nuclear installations specifies:
- ICPE legislation for installations of this type within the BNI perimeter.

The order by the ministers for the Environment and Industry of 31 December 1999, as amended by the above-mentioned order of 31 January 2006, 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 licensees at a level comparable with that required for non-nuclear industrial installations.

2 | 2 | 2

Documents produced by ASN

a) Technical regulatory decisions

Pursuant to article 4.1 of the above-mentioned law of 13 June 2006, ASN could issue decisions to supplement the implementation procedures for the decrees and orders issued concerning nuclear safety or radiation protection, except for those dealing with occupational medicine.

They require approval by the Ministers responsible for nuclear safety when they concern nuclear safety, or by the Ministers responsible for radiation protection when they concern radiation protection.

These ASN decisions, as well as the mandatory opinions it is required to issue concerning draft decrees, are published in its Official Bulletin, available on-line from its website.

b) Basic safety rules and ASN guides

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

They are not, strictly speaking, regulatory documents. A Licensee 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.

In the light of the restructuring of the general technical regulations described in point 2|2, the RFS will be gradually replaced by guides.

There are currently about forty RFS and other technical rules issued by ASN, which can be consulted on the ASN website (www.asn.fr).

2 | 2 | 3

French nuclear industry professional codes and standards

The nuclear industry produces detailed rules dealing with the state of the art and industrial practices. It groups these rules in "Industrial codes". These rules 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 licensees 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 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 ASN in 2003. 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.

In the field of nuclear pressure vessels, these requirements changed with the publication of the 12 December 2005 order implementing the 13 December 1999 decree on pressure vessels. The use of a code is now dependent on a demonstration of its conformity with the essential safety requirements defined in these texts. This arrangement thus enables the use of other construction codes to be envisaged.

With regard to the RCC-M code, the AFCEN has undertaken a number of changes aimed to bring it into line with the previously mentioned requirements. ASN will examine these changes.

The RSE-M code changed in October 2005, in particular to ensure conformity with the 10 November 1999 order concerning supervision of the operation of PWR reactor main primary system and main secondary systems. ASN carried out an overall analysis of these changes. With regard to the most important changes, this analysis concluded that the 2005 version of this code can today be applied.

However, this analysis will continue in 2007 in order to reach an exhaustive ruling on all the modifications presented.

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

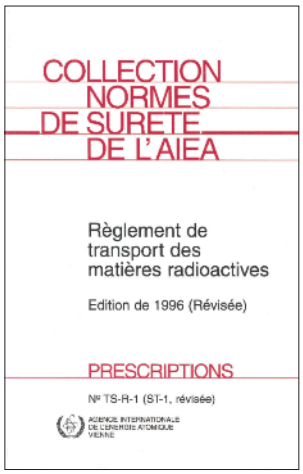
3 Regulations for the transport of radioactive materials

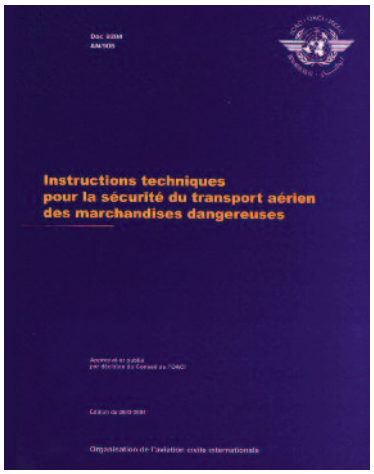
The drafting of the safety regulations applicable to the various modes of transport of radioactive materials are drafted on the basis of international texts produced by IAEA and defined in the radioactive materials transport regulations known as TS-R-1.

3 | 1 International regulations

These bases are used again in the drafting of the safety regulations applicable to the various modes of transport:
- the ADR agreement (European agreement on the transport of dangerous goods by road) for road transport;
- the RID regulations (regulations concerning the transport of dangerous goods by rail) for rail transport;
- the ADNR regulations (regulations for the transport of dangerous goods on the Rhine) for transport by inland waterway;
- the IMDG code (International Maritime Dangerous Goods code) for sea transport;
- the technical instructions of the ICAO (International Civil Aviation Organisation) for air transport.

These transport regulations have been fully transposed into French law and have been implemented by interministerial orders. ASN is for this reason in contact with the administrations responsible for the various modes of transport (General Directorate for the Sea and Transports - DGMT and General Directorate for Civil Aviation - DGAC) and has a representative on the Interministerial Commission for the Transport of Dangerous Goods - CITMD).





IAEA TS-R-1 regulations and maritime (IMDG) and air transport (IT ICAO) regulations

Transport safety is based on three main factors:
- first and foremost, on the engineered toughness of the packages,
- on transport reliability and certain specially equipped vehicles,
- on an efficient emergency response in the event of an accident.

Regulations are based on IAEA standards, which specify package performance criteria. The safety functions to be assured are containment, radiation protection, prevention of thermal hazards and criticality.

The degree of safety of the packages is adapted to the potential harmfulness of the material transported. For each type of package (excepted packages, industrial type packages, type A packages, type B packages, type C packages), the regulations define the associated safety requirements, together with test results to be obtained.

ASN aims to intervene as early as possible in the drafting of the regulations, jointly with IRSN, in particular by taking part in the various international or multinational working groups that exist to deal with the transport of hazardous or radioactive goods.

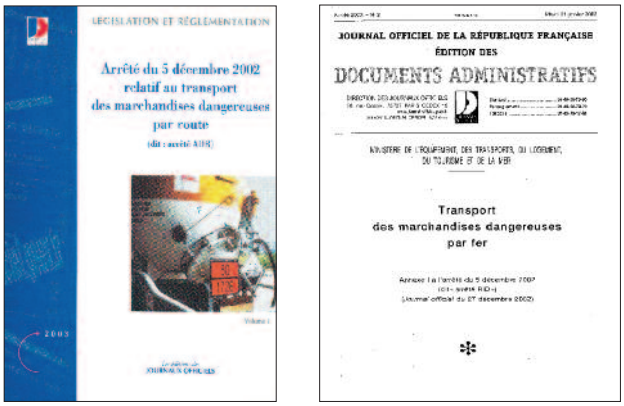
In this context, ASN is a member of the IAEA TRANSSC Committee (Transport Safety Standards Committee) and is represented as an expert in many working groups, organised according to transport mode, in cases where radioactive material transport is at issue. An ASN representative thus took part in the meetings of the TRANSSC group, held from 27 February to 3 March and from 4 to 7 September 2006 in Vienna. It also takes part in the "Regulatory transport safety group (RTSG)" which brings together the authorities of several countries and in principle meets every two years. The last meeting took place in Vienna in January 2006.

ASN is also a member of the safety of radioactive material transports standing working group of the DG Energy and Transport of the European Commission. In this capacity, it took part in the meeting of this working group on 12 October.

3 | 2 National regulations

The orders applicable to each mode of radioactive material transport are as follows:
- the order of 1 June 2001 as modified concerning the transport of dangerous goods by road (known as the "ADR order");
- the order of 5 June 2001 as modified, concerning the transportation of dangerous goods by rail (known as the "RID order");
- the order of 5 December 2002 as modified, concerning the transportation of dangerous goods by inland waterway (known as the "ADNR order");
- the order of 12 May 1997 as modified, concerning the technical conditions for the operation of aircraft by a public air transport operator (OPS1);
- the order of 23 November 1987 as modified, division 411 of the regulations for the safety of ships (RSN);
- the order of 18 July 2000 as modified, regulating the transport and handling of dangerous goods in sea ports.

These orders transpose in full the requirements of the international agreements and regulations in force.



ADR and RID regulations

The new orders which were signed or co-signed by the DGSNR during the course of 2006 are recalled below, in chronological order.

By delegation of the ministers for the Industry and for Ecology and Sustainable Development, ASN co-signed the following:

- the order of 15 March 2006 amending the order of 1 June 2001, concerning the transportation of dangerous goods by road (known as the "ADR order");
- the order of 12 April 2006 amending the order of 1 June 2001 as modified, concerning the transportation of dangerous goods by road (known as the "ADR order");
- the order of 12 April 2006 amending the order of 5 June 2001 as modified, concerning the transportation of dangerous goods by rail (known as the "RID order");
- the order of 12 April 2006 amending the order of 5 December 2002 concerning the transport of dangerous goods by inland waterway (known as the "ADNR order");
- the order of 12 April 2006 amending the order of 18 July 2000 concerning the transport and handling of dangerous goods in sea ports.

Certification of organisations

By delegation of the ministers for Industry and the Environment, ASN co-signed the order of 8 July 2005 approving the Association of independent inspectors with regard to gas containers, tanks intended for the transport of dangerous goods and hoses.

New notification or licensing obligation

As part of the transposition of directive 96/29/Euratom, radioactive material transport companies should, as of 2007, be subject to ASN notification or licensing for land transports within France and for maritime transports stopping at a French port. An ASN decision should in particular determine the characteristics of the radioactive materials subject to notification or licensing, the composition of the license application and the items to be enclosed with the notification, the examination procedures and the conditions for renewal, withdrawal or suspension.

4 Outlook

The nuclear safety and radiation protection regulations have been completely overhauled over the course of the past five years.

The Public Health Code and the Labour Code were modified between 2001 and 2006 in order to transpose the Euratom directives concerning radiation protection.

The law of 13 June 2006 concerning nuclear transparency and safety brought about an in-depth overhaul of the regulations concerning BNI safety. Pursuant to this law, a number of decrees are under preparation to determine the new system applicable to BNIs. These decrees will abrogate the decree of 11 December 1963 concerning nuclear installations and the decree of 4 May 1995 concerning BNI liquid and gaseous effluent discharges and water intake.

To supplement the implementation of the decrees and orders dealing with nuclear safety and radiation protection by the Ministers responsible for nuclear safety and radiation protection, technical regulatory decisions will be taken by ASN.

With regard to individual decisions, if the main authorisations concerning the life of a BNI (creation, final shutdown and decommissioning) remain within the remit of the Ministers responsible for nuclear safety, it is up to ASN to authorise BNI commissioning and define the requirements regarding its design, construction and operation pursuant to the decrees. It is in this respect that ASN

defines the requirements concerning water intake into and liquid and gaseous discharge of materials from the installation, whether or not radioactive.

In the field of radiation protection, the new regulations were practically completed in 2006 with the publication of the final orders to implement the Public Health Code and the Labour Code. At the same time, ASN undertook to update the regulatory part of these two Codes, to ensure the transposition of European directive 2003/122/Euratom of 22 December 2003 concerning the supervision of high-level sources, include ASN new prerogatives and make a number of clarifications and simplifications based on the supervisory experience acquired. These changes should be published at the end of the first quarter of 2007.

ASN will also continue to play an active role in the work to revise the basic radiation protection standards initiated by IAEA and by the European Commission, which is preparing an update of European directive 96/29/Euratom of 13 May 1996. These revisions will take account of the future recommendations of the International Commission on Radiological Protection (ICRP) expected some time in 2007.

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 doses 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 the 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:

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

The equivalent dose unit is the sievert (Sv).

The ICRP 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_o, it is defined by the formula:

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

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.

In $H_T(\tau)$, 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

Efficace 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 the organ or tissue T of the absorbed dose of radiation R;
w_R is the weighting factor for the 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 equivalent doses in the various tissues or organs [$H_T(\tau)$] following integration, 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 there can be selective irradiation through 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 is given to the mean dose received by the other 11 organs. the sum of the various w_T is equal to 1, which corresponds to uniform irradiation of the whole body. The w_T values are appropriate to expressing 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 ith 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

REGULATION 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 general public Art. R.1333-8 of the CSP (Public Health Code)	• Effective doses for the body • Equivalent doses for the lens of the eye • Equivalent doses for the skin (average dose over any area of 1 cm^2 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.
Worker limits for 12 consecutive months Art. R.231-77 of the CT (Labour Code)	Adults: • Effective doses for the body • Equivalent doses for the hands, forearms, feet and ankles • Equivalent doses for the skin (average dose over any area of 1 cm^2 of skin, regardless of the area exposed) • Equivalent doses for the lens of the eye Pregnant women (exposure of the child to be born) Young people from 16 to 18 years old*: • Effective doses for the body • 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: • 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 ceiling 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 life.

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

Optimisation levels for patient protection (Public Health Code)

	Definition	Values	Observation
Diagnostic examinations Diagnostic reference levels Article R.1333-68, order of 16 February 2004	Dose levels for standard diagnostic examinations	E.g.: entry level of 0.3 mGy for an X-ray of the thorax	☞ The diagnostic reference levels, the dose constraints and the dose target levels are used by applying the principle of optimisation. They are simply guidelines. ☞ 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. ☞ 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. ☞ The target dose level (specialists talk of a target volume in radiotherapy) is used to adjust the equipment.
Dose constraint Art. R.1333-65, order expected in 2006	Used when exposure offers no direct medical benefit to the person exposed		
Radiotherapy Target dose level Art. R.1333-63	Dose necessary for the target organ or tissue (target-organ or target-tissue) during radiotherapy (experimentation)		

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: • sheltering • evacuation • administration of stable iodine (thyroid dose)	10 mSv 50 mSv 100 mSv	☞ The *préfet* can make adjustments to take account of local factors.
Protection of participants Reference levels Art. R.1333-86	These levels are expressed as effective dose: • for the special teams for technical or medical intervention • for the other participants	100 mSv 10 mSv	☞ This level is raised to 300 mSv when the intervention is designed to prevent or reduce exposure of a large number of people.

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
Lasting 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	Not defined	☞ The notion of selection level is introduced by the IRSN guide for management of industrial sites potentially contaminated by radioactive materials.
Exposure to radon			
Protection of the general public Article R.1333-15 and R.1333-16 of the Public Health Code, order of 22 July 2004	Premises open to the public	400 Bq/m³ 1000 Bq/m³	☞ See recommendation published in Official Gazette of 11 August 2004 defining the radon measurement methods. ☞ See recommendation published in Official Gazette of 22 February 2005 defining corrective action to be taken in the event of an overshoot.
Worker protection Art. R.231-115 of the CT	Working environments	400 Bq/m³	
Enhanced natural exposure (other than radon)			
Protection of the general public Article R.1333-13 and R.1333-14 of the CSP		None	☞ Any population protection action to be taken will be defined on a case by case basis.
Worker protection Art. R.231-114 of the CT	Effective dose	1 mSv/year	
Water intended for human consumption Decree 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	0,1 mSv	☞ 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.
	Tritium	100 Bq/L	
Foodstuffs (emergency situation) European regulations *Codex alimentarius…*	Saleability limits		See following table.

Consumption restrictions on contaminated foodstuffs

In the event of an accident or any other radiological emergency, the restrictions on the consumption or sale of foodstuffs are determined in Europe by two regulations: Council Regulations 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 feedingstuffs 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 feedingstuffs).

A list of foodstuffs said to be of "lesser importance" has been drawn up (foodstuffs which are not consumed in quantities exceeding 10 kg/year). For these items; thyme, garlic, cocoa paste, truffles, caviar, etc., levels ten times higher are set.

Foodstuffs or feedingstuffs 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 transuranic 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 radioactive contamination levels of feedingstuffs (caesium 134 and caesium 137):

Pork: 1250 Bq/kg
Poultry, lamb, veal: 2500 Bq/kg
Others: 2500 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