

Regulation on Nuclear and Radioactive Facilities

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and Radioactive
Facilities

**Royal Decree 1838/1999, of
3 December, approving the
Regulation on Nuclear and
Radioactive Facilities,
modified by Royal Decree
35/2008, of 18 January**

Royal Decree 1838/1999, of 3 December, approving the Regulation governing Nuclear and Radioactive Facilities, modified by Royal Decree 35/2008, of 18 January

The current Regulation on Nuclear and Radioactive Facilities was approved by Royal Decree 1836/1999, of 3 December. Since it came into effect, the application thereof and the experience gained have revealed the existence of a series of aspects that could be improved and deficiencies that call for its revision. Likewise, the laws that constitute its frame of reference, that is, Law 25/1964, of 29 April, on Nuclear Energy and Law 15/1980, of 22 April, Creating the Nuclear Safety Council have been modified by means of Law 24/2005, of 18 November, on reforms to boost productivity and Law 33/2007, of 7 November, amending Law 15/1980, of 22 April.

The deregulation of the energy market has stressed the need to take into account the possible effect this may have on the safety of nuclear facilities associated with energy production; thus, a new responsibility of the licensee is to continuously ensure the inclusion of new techniques allowing to manage them under the most updated safety referents.

Likewise, mechanisms for coordination with the competent Administrations are put in place to authorise facilities and activities which, due to their characteristics and location, may entail an impact on a first-category nuclear or radioactive facility.

The requirement that the licensee set up a procedure for the personnel of the facility as well as that of contracted companies and that of external companies that provide their services at the facility to fulfil their duty of informing licensees of any known events that affect or may affect the safe operation thereof and the compliance with current regulations as regards nuclear safety or radiation protection has been envisaged.

As far as the permit regime is concerned, the provisions of Article 28 of Law 25/1964, of 29 April, on Nuclear Energy, whereby the Autonomous Communities with competence in terms of land use planning and the environment have to be listened to, have been developed.

In accordance with the increasing relevance that the aspects related to the physical protection of nuclear facilities and materials have taken on, the requirement of including a physical protection plan among the documentation that can be demanded for authorising facilities has been incorporated.

The procedure for granting radioactive facility permits has been expedited; the regime for granting nuclear facility decommissioning and dismantling permits is regulated in greater detail.

In relation to the inspecting function, the possibilities for acting in other fields with equipment or materials that require it have been expanded, and taking action in exceptional situations on facilities not subjected to the permit-granting regime of the Regulation on Nuclear and Radioactive Facilities is covered.

With regard to the operator- and supervisor-license regime, its regulation, in particular in the case of licenses relating to nuclear fuel cycle and nuclear facilities both in operation and when the dismantling thereof is carried out, as well as the conditions for the renewal and end of their validity, are expanded.

As a new feature, the control of contaminated areas is regulated, whereupon the control of plots of land or water resources that, not belonging to facilities regulated by the Regulation on Nuclear and Radioactive Facilities, have been affected by radiological contamination is expected to be solved.

Finally, another aspect of this modification to be highlighted is the regulation of the certification and validation of new designs or models by the Nuclear Safety Council.

The preparation of this Royal Decree was started at the suggestion of the Nuclear Safety Council, in accordance with that envisaged in Article 2) of Law 15/1980, of 22 April, Creating the Nuclear Safety Council, the social and economic sector stakeholders having been heard and the Autonomous Communities consulted.

The legal base for the Royal Decree that is being approved is Law 25/1964, of 29 April, on Nuclear Energy, particularly its Articles 28, 36, 37 and 94, and Article 13 of Law 15/1980, of 22 April, creating the Nuclear Safety Council, in the wording given in Point 9 of the Single Article of Law 33/2007, of 7 November, that reforms it.

Lastly, the statutory content has been notified to the European Union's Commission, in accordance with that stated in Article 33 of the Treaty establishing the European Atomic Energy Community (EURATOM).

Accordingly, at the suggestion of the Ministry of Industry, Tourism and Trade, with the prior approval of the Minister of Public Administrations, in accordance with the Council of State and following the deliberation of the Council of Ministers in its meeting of the 18th of January of 2008.

Regulation Governing Nuclear And Radioactive Facilities

First Title. General Provisions

Single Chapter

Application of the Regulation

Article 1. Purpose

The purpose of this Regulation is to regulate the regime of administrative permits for both nuclear and radioactive facilities and other specific activities related to the application of ionising radiations. Likewise, it integrates the regime of personnel credentials, of the obligations of the licensees of said facilities and of the inspection and control activities. All in accordance with Law

25/1964, of 29th April, on Nuclear Energy and Law 15/1980, of 22th April, creating the Nuclear Safety Council and with that stipulated in the Community legal order and in Spanish law on projects subjected to environmental impact assessments.

Article 2. Competent Authorities

1. The application of the precepts of this Regulation corresponds to the Ministry of Industry, Tourism and Trade and the Nuclear Safety Council, without affecting to the competences of other departments and of the Autonomous Communities.

2. The executive functions that in this Regulation are incumbent on the Ministry of Industry, Tourism and Trade in relation to second- and third-category radioactive facilities shall be understood as vested on the Autonomous Communities when they have said functions transferred to them.

3. The operation permits with regard to second- and third-category radioactive facilities shall have validity for the entire Spanish territory. Without prejudice to the above, the licensee that is going to carry out any of the activities for which it has a permit, in a specific part of the territory, must reliably notify the competent territorial Administration, it being authorised to begin its activity from the date of the notification, to which it must attach a certified copy of the permit.

It shall be understood that there is no opposition to the above if the Administration competent in said territory has not manifested said opposition by means of a justified resolution within three months starting from the date of notification.

Article 3. Register of Radioactive Facilities

1. All authorised facilities shall be registered in the Register of Radioactive Facilities attached to the Directorate General for Energy Policy and Mines. The Ministry of Industry, Tourism and Trade shall periodically send information on the contents of said register to the competent bodies.

2. The Autonomous Communities shall inform the Ministry of Industry, Tourism and Trade at least once a month of the permits they have granted, and they may set up, within their own territory and within the scope of their competences, their own registers.

Article 3 A. Duty to Inform

1. The Administrations competent for granting a permit or a significant modification of a facility or activity, which due to its characteristics or situation may entail an impact on a first-category nuclear or radioactive facility, shall serve notice, prior to the issue of said permit or modification, of the safety report or of sufficient information about the matter to the Nuclear Safety Council in order for this public body to issue a mandatory report that shall be binding in the terms established by Law 15/1980, of 22th April, Creating the Nuclear Safety Council⁽¹⁾.

If from the assessment of this information by the Nuclear Safety Council this body was to conclude that an increase of the risk of the nuclear or radioactive facility, as a result of the new facility or activity or the modification of the already existing facility or activity, cannot be ruled out, measures to be implemented in both the nuclear or radioactive facility and the non-nuclear facility or activity may be derived.

2. In the event that the communication envisaged in the foregoing section does not take place, the Nuclear Safety Council may officially address the bodies of the proper Administration and collect the information necessary to prepare said report.

Said bodies, in collaboration with the Nuclear Safety Council, shall set up communication protocols that ensure that the establishments so determined and the first-category nuclear and radioactive facilities considered adequately exchange the data necessary to enable licensees to take into consideration the character and magnitude of the overall risk of a serious accident

in their serious accident-prevention policies, safety management systems, safety reports and onsite emergency plans.

Article 4. Submission of Applications

1. Applications to obtain the permits granted by the Ministry of Industry, Tourism and Trade must be addressed thereto, meeting the requirements indicated in Article 70 of the Law on the Legal Regime of Public Administrations and the Common Administrative Procedure, and shall be accompanied by the documentation that is established in each case.

Should the Ministry of Industry, Tourism and Trade consider that the submitted documentation is incomplete or its contents insufficient, it shall require the interested party to complete, clarify or expand it within ten days.

2. Said Ministry shall send a copy of all the documentation to the Nuclear Safety Council for it to prepare its mandatory report.

Likewise, in accordance with that stipulated in Article 28 of Law 25/1964, of 29 April, on Nuclear Energy, the Ministry shall send, where appropriate, a copy of all the documentation to the Autonomous Communities with competences in terms land use planning and the environment in the territories of which the facility or planning zone envisaged in the basic rules on nuclear and radiological emergency planning is located, so that they can make allegations within one month, in accordance with that established in Article 12.3 of this Regulation.

Article 5. Renewal of Permits

1. The renewal of permits shall be dealt with by means of the same procedure whereby they were granted, enclosing the update of the documents that support them or, where appropriate, the documentation that is established for each permit.

2. In the cases of the renewal of nuclear facility

(1) Modified by Law 33/2007, of 7 November.

permits, the report from the Nuclear Safety Council must be sent to the Ministry of Industry, Tourism and Trade at least one month before the expiration date of the current permit.

Article 6. Mandatory Reports

1. The reports from the Nuclear Safety Council for the granting of permits of nuclear and radioactive facilities and for the manufacture of ionising radiation-generating devices, equipment or accessories shall be mandatory in all cases and, moreover, binding when they deny or refuse a granting, and, likewise, with regard to the conditions they establish, if they allow it.

2. Exceptionally, the procedures whereby said reports must be issued may be indefinitely suspended by the body competent to decide about them until they are issued or during the period of time that is deemed adequate for them to be issued, the suspension being properly justified.

3. The permits or licenses the granting of which is the responsibility of any Public Administration may not be denied or conditioned for nuclear safety or radiation protection reasons the assessment of which is incumbent on the Nuclear Safety Council.

4. Within the scope of its competences, the Nuclear Safety Council may directly remit to the licensees complementary technical instructions to ensure the safety conditions and requirements of the facilities are maintained and to better comply with the requirements established in the corresponding permits.

5. The Nuclear Safety Council may stop the work in the event of the appearance of anomalies affecting nuclear safety and until these are corrected; it may propose the cancellation of the permit if the anomalies cannot be corrected. Likewise, it has the authority to suspend, for nuclear safety and radiation protection reasons, the operation of the facilities or the activities that are being carried out.

6. The Nuclear Safety Council may require the additional documentation it deems necessary in relation to nuclear safety and radiation protection, and, following the appropriate studies and advices, it shall issue the corresponding technical safety report, which it shall remit to the Ministry of Industry, Tourism and Trade.

Article 7. Granting of Permits

Once the report from the Nuclear Safety Council is received, and following the opinions and reports that apply, the Ministry of Industry, Tourism and Trade shall take the appropriate resolution. The maximum period of time in which said resolution shall be notified shall be six months, unless the suspension to which Section 2 of the foregoing Article refers to applies, in which case said maximum period of time would be extended with the period of suspension.

The following must appear in the permits that are granted:

- a) The licensee.
- b) The location of the facility.
- c) The activities authorised by the granted permit.
- d) The period of validity and conditions for its renewal, when appropriate.
- e) The purpose of the facility and, where appropriate, basic characteristics thereof.
- f) When applicable, the nuclear substances and other ionising radiation-producing materials and equipment the possession or use of which is authorised.
- g) The official documents under which the corresponding permit is granted and the procedure necessary to review them.
- h) The requirements as regards personnel licenses for the operation of the facility.

- i) The licensee has to arrange with regard to civil liability for nuclear damages to third parties.
- j) The limits and conditions as regards nuclear safety and radiation protection.
- k) Other conditions that might suit the case.

Article 8. Responsibility of the Licensee

1. The holder of each permit shall be responsible for the operation of the facility or for the activity under safety conditions and always within that which is established in the official documents under which the corresponding permit is granted. It is incumbent on it to apply said documentation and keep it updated, inform the Ministry of Industry, Tourism and Trade and the Nuclear Safety Council of any questions that may affect permit conditions or nuclear safety and radiation protection and, in general, comply with current regulations. Likewise, the responsibility of the facility in the emergency situations that may take place falls on the licensee.

The licensee must ensure that all physical or legal persons that intervene as contractors or subcontractors also comply with the requirements of the foregoing paragraph, in those cases that are incumbent on them.

2. As regards safeguards and physical protection of nuclear materials, the licensee is required to perform the activities of monitoring, controlling and guarding said materials, to allow the inspections and verifications that are necessary, when they derive from the commitments undertaken by the Spanish State or from the internal legal order itself, and to notify the authorities any relevant event, in accordance with the specific rules on this matter.

3. The licensee must continuously ensure the improvement of the nuclear safety and radiation protection conditions of its facility. To this end, it must analyse current best techniques and practices, in accordance with the requirements that

the Nuclear Safety Council establishes, and implement those that are suitable in the opinion of said body.

The Nuclear Safety Council may require at any time the licensee's analysis for the implementation of improvements on nuclear safety and radiation protection.

Article 8 A. Notification of Deficiencies

In accordance with that envisaged in Article 13 of Law 15/1980, of 22 April, Creating the Nuclear Safety Council, for the purposes of the duty of the people at the service of nuclear and radioactive facilities of informing licensees of any event that might affect the safe operation thereof or the radiation protection:

a) The licensee shall set up a procedure to ensure that all personnel of the organisation of the facility, as well as that of contracted companies and that of external companies that provide their services at the facility, inform the licensee of those deficiencies or dysfunctions that, in the opinion of the informant, may affect nuclear safety or radiation protection, all of it without prejudice to the general rights of the citizen established in the corresponding laws.

This procedure shall be additional to the usual communication channels and its use is up to the informant. Likewise, the informant must resort to this procedure if, after notifying any deficiency over the usual communication channels, he/she reaches the conclusion that his/her report or claim has not been adequately dealt with.

In the procedure, all communications from both identified and anonymous informants must be dealt with, and said communications must be included in a numbered and dated register with a copy of the received communications and a reference of the information provided in response thereto and of the verification procedures or the measures taken by virtue of them. Radioactive facilities for scientific, medical, agricultural, commercial or industrial purposes, as they are defined in Title III

of this Regulation, may opt to register said communications and the answers and the verification procedures or measures taken in the operation log to which reference is made in Title VI of this Regulation.

If he/she has identified himself/herself, the informant must receive an answer in writing within 7 workdays from the facility licensee with the information on the adopted or planned measures.

If said period elapses without the licensee sending a written answer to the informant, the latter must convey the information in question to the Nuclear Safety Council.

The procedure shall guarantee the existence of an abbreviated procedure for those cases where the informant perceives reasons of urgency, for which the obligation of the licensee to immediately answer the informant shall be established; the latter may, if he/she deems it so, convey the information to the Nuclear Safety Council at the time when he/she notices the perceived deficiency or dysfunction.

Without prejudice to the above, Law 30/1992, of 26 November, on the Legal Regime of Public Administrations and the Common Administrative Procedure shall apply in this matter.

b) The exercise of this right may not have adverse effects on the worker in his/her workplace, except in those cases where it is proven that he/she acted in bad faith.

The decisions of the licensee taken to the detriment of the labour rights of workers that have exercised the right envisaged in this Article shall be understood as null and void and without effect.

Article 9. Coverage of Risks

1. In no event shall the admission of nuclear substances or other radioactive materials or the

operation of nuclear and radioactive facilities be allowed without the nuclear risk coverage being guaranteed, in accordance with current regulations.

2. In application of that stipulated in Article 57 of Lae 25/1964, of 29th April, on Nuclear Energy, second- and third-category radioactive facilities do not need to constitute the risk coverage which said article refers to. This exemption shall also be applicable to devices that produce X-rays for medical diagnosis purposes.

3. Any change, suspension or cancellation of the nuclear risk coverage must be immediately communicated by the operator to the Directorate-General for Energy Policy and Mines and the Nuclear Safety Council, said Directorate-General being who shall determine how to proceed in each case.

Article 10. Infractions

Infractions of the precepts contained in the present Regulation shall be punished in accordance with that established in Chapter XIV of Law 25/1964, of 29 April, on Nuclear Energy, modified by the fifth additional regulation of Law 54/1997, of 27th November, on Electricity Sector⁽²⁾.

Title II. Of Nuclear Facilities

First Chapter Classification and Permits

Article 11. Definitions

Nuclear facilities are:

a) Nuclear power plants: any permanent facility for the production of energy by means of a nuclear reactor.

b) Nuclear reactors: any structure containing nuclear fuels arranged such that a self-sustaining nuclear fission process may take place inside of it without the need for an additional neutron source.

(2) The phrasing given to this Chapter XIV by Law 33/2007, of 7 November, reforming Law 15/1980, of 22th April, Creating the Nuclear Safety Council, has to be followed.

c) Factories that use nuclear fuels to produce nuclear substances and factories where nuclear substances are treated, including spent nuclear fuel treatment or reprocessing facilities.

d) Nuclear substance storage facilities, except for the places where said substances are incidentally stored during the carriage thereof.

e) Devices and facilities that use fusion or fission nuclear reactions to produce energy or with a view to producing or developing new energy sources.

Article 12. Required Permits

1. Nuclear facilities shall require the following permits as appropriate:

a) Preliminary or site permit: it is an official recognition of the proposed objective and the suitability of the chosen site, the obtaining of which entitles the holder to request the facility construction permit and start the preliminary infrastructure work that is authorised.

b) Construction permit: it entitles the holder to start building the facility and to apply for the operating permit.

c) Operating permit: it entitles the holder to load nuclear fuel or to introduce nuclear substances in the facility, to carry out the nuclear testing programme and to operate the facility under the conditions established in the permit. It shall first be provisionally granted until the satisfactory completion of the nuclear tests.

Likewise, this permit entitles the holder to perform, once the operation for which the facility was conceived has ceased, the operations imposed to it by the Administration prior to obtaining the dismantling permit.

d) Modification authorisation: it entitles the holder to introduce modifications in the design of the facility or in its operating conditions, in the cases where the criteria, rules and conditions on which the operating permit is based are altered.

e) Modification execution and assembly permit: it entitles the holder to start carrying out, executing and assembling those modifications which, due to their wide scope or because they entail significant work or assemblies, it is deemed necessary to expressly authorise, in the opinion of the Directorate-General for Energy Policy and Mines or the Nuclear Safety Council.

f) Dismantling permit: once the operating permit has expired, it entitles the holder to start the decontamination, equipment disassembly, structure demolition and material removal activities to allow in the end the full or restricted release of the site. The dismantling process shall end with a decommissioning declaration, which shall release the licensee of a facility from its responsibility as operator thereof and shall define, in the case of the restricted release of the site, the use restrictions that are applicable and the entity responsible for maintaining them and watching they are complied with.

Additionally, the following must be authorised:

g) The temporary storage of nuclear substances at a facility in its construction phase that does not have an operating permit.

h) The title transfer of nuclear facilities. The new titleholder must provide evidence of having sufficient legal, technical and financial capacity to carry out the activities object of the permit.

The permits envisaged in the foregoing sections shall be granted following a report from the Nuclear Safety Council in accordance with that envisaged in this Regulation.

2. The nuclear facilities which letters b) and d) of Article 11 of this Regulation refer to, except final radioactive waste storage facilities, may apply for the preliminary and construction permits simultaneously.

3. Prior to granting the permits included in Section 1 of this Article, except for those referred to in letters e) and g) of said Section, notice shall

be served of the corresponding documentation to the Autonomous Community for a period of one month for allegations, in accordance with that stipulated in Article 4.2 of this Regulation.

4. It is incumbent on the Minister of Industry, Tourism and Trade to grant the permits included in Section 1 of this Article, except for those referred to in letters d), e) and g), the granting of which is incumbent on the Director-General of Energy Policy and Mines.

Article 13. Information Committee

1. During the construction, operation and dismantling of nuclear power plants an Information Committee shall be in place, which shall have the character of the collegial bodies envisaged in Article 40.3 of Law 6/1997, of 14 April, on the Organisation and Functioning of the General State Administration.

2. This Committee, the members of which shall be appointed by the Director-General of Energy Policy and Mines, shall be integrated by one representative each of the Ministry of Industry, Tourism and Trade, the facility licensee, the Nuclear Safety Council, the Government Regional Offices and the Autonomous Communities in the territory of which the facilities are located, the Directorate-General for Civil Defence and Emergencies and the Municipalities included in Zone 1 defined in the corresponding Emergency Plans offsite nuclear power plants.

It shall be chaired by the representative of the Ministry of Industry, Tourism and Trade, and the deputy chairman shall be the mayor of the municipality in the territory of which the facility is located. The secretary of the Committee shall be a civil servant from the Ministry of Industry, Tourism and Trade, also appointed by the Director-General for Energy Policy and Mines.

Likewise, other representatives designated by the Director-General for Energy Policy and Mines, either on their own initiative or at the suggestion of the Committee, may be a part of it.

3. The functions of this Committee shall be to inform the different represented entities of the progress of the activities regulated in the corresponding permits and to jointly deal with those other questions that are of interest to said entities.

Chapter II

Preliminary Authorisation

Article 14. Application

The preliminary authorisation application shall be accompanied by the following documentation:

a) A declaration on the needs to be satisfied and justification for the facility and the chosen site.

b) A descriptive report. Said report shall consist of a description of the basic elements comprising the facility, and generally it must include the basic information thereon, the technology to be used, the preliminary supply plan and the precautions for dismantling.

c) A preliminary construction Plan. Execution phases and deadlines. A preliminary economic study relating to financial investments and expected costs.

d) A study characterising the site and the area of influence of the facility, including enough data on the parameters of the site that may affect nuclear safety or radiation protection, including those of a demographic or ecological nature, as well as the activities related to land use planning.

e) The organisation envisaged by the applicant to supervise the project and ensure quality during construction.

f) A description of the preliminary infrastructure activities and work expected to be carried out once the preliminary authorisation is granted and prior to applying for the construction permit.

Article 15. Processing

1. Once the preliminary authorisation application is received, the Ministry of Industry, Tourism and

Trade shall send a copy thereof to the respective Government Regional Office so that it opens a period of public information, which shall start with the publication in the Official State Gazette and in the Gazette of the corresponding Autonomous Community of a summary advert in which the purpose and main characteristics of the facility shall be highlighted. The advert shall state that the people and entities that consider themselves affected by the project may submit within thirty days the written pleadings they deem fair before the corresponding Government Regional Office.

2. The public information procedure shall be jointly carried out with the one envisaged for the environmental impact study in its specific regulation.

3. Once the thirty-day period for public information has expired, the Government Regional Office shall make the appropriate verifications with regard to both the submitted documentation and the written pleadings and shall issue its report with regard to the former and the latter, sending the file to the Ministry of Industry, Tourism and Trade and a copy thereof to the Nuclear Safety Council.

Article 16. Reports

Prior to granting the corresponding permit, the Ministry of Industry, Tourism and Trade shall gather the reports from the other affected Public Administrations and Institutions as well as from other Ministries, provided the nature of said permit requires it.

Chapter III Construction Permit

Article 17. Application

The construction permit application shall be accompanied by the documentation specified below:

- a) The general project for the facility.
- b) A procurement programme, which shall contain a list of the elements and equipment and their provenance.

c) The budget, funding, completion deadline and technical collaboration regime.

d) An economic study, which shall update that submitted with the preliminary authorisation application.

e) A preliminary safety study, which must comprise:

1st. A description of the site and its surrounding area, with updated data on the parameters that affect nuclear safety and radiation protection, including those of a demographic, ecological and soil- and water-use nature, and any other data that may contribute to a better knowledge thereof, as well as the plans for monitoring and verifying the basic parameters representative of the site.

2nd. A description of the facility, in which the criteria followed in the design of those components or systems which the safety of the facility depends on are included.

3rd. An analysis of the foreseeable accidents and their consequences.

4th. An analytical radiological study, which theoretically estimates the potential radiological impact of the facility on the population and the environment.

5th. An update of the organisation envisaged by the applicant to supervise the development of the project and ensure quality during construction.

6th. The organisation envisaged for the future operation of the facility and the preliminary programme to train operating personnel.

7th. A preoperational environmental radiological monitoring programme, taking the conclusions reached in the analytical radiological study as a starting point, which allows establishing the radiological reference or background level of the monitored area.

8th. A construction quality assurance programme.

f) The technological, economic, and funding estimates of the decommissioning and dismantling.

g) The administrative concessions and permits to be granted by other Ministries and Public Administrations or the documents that prove they have been applied for with all the necessary requirements.

Article 18. Pre-Nuclear Tests

During the construction and assembly of the nuclear facilities and prior to proceeding to the loading of nuclear fuel or the admission of nuclear substances in the facility, the licensee is required to carry out a pre-nuclear testing programme that shall include the tests, verifications and checks to be conducted in the different systems the facility consists of.

The objective of said pre-nuclear testing programme is to provide evidence of the appropriate performance of the equipment or parts the facility consists of in relation to both nuclear safety and radiation protection and the applicable industrial and technical regulations.

Article 19. Approval and Execution

1. The pre-nuclear testing programme shall be proposed by the licensee. This programme, as well as the technical conditions of each test, shall have to be approved before its execution by the Directorate-General for Energy Policy and Mines, following a report from the Nuclear Safety Council.

2. The execution of the tests and verifications shall be carried out under the responsibility of the licensee. The procedures with which they are executed, as well as the obtained results, shall be duly documented. The Directorate-General for Energy Policy and Mines, following a report from the Nuclear Safety Council, shall indicate the tests and verifications in the pre-nuclear testing programme that shall have to be carried out in the presence of the inspection from the Nuclear Safety Council and the Ministry of Industry, Tourism and Trade.

3. The results of the pre-nuclear tests shall be submitted to the Directorate-General for Energy Policy and Mines and the Nuclear Safety Council to be analysed before the operating permit can be granted.

Chapter IV Operating Permit

Article 20. Application

The operating permit application must be accompanied by the following documents, which shall update, where appropriate, the contents of those submitted when applying for the construction permit:

a) A safety study. It shall contain the information necessary to perform an analysis of the facility from the nuclear safety and radiation protection standpoint as well as an analysis and assessment of the risks derived from the operation of the facility both in normal operation and under accident conditions. It shall also contain detailed descriptions of the safety functions, of all the safety systems and safety-related structures, systems and components, of their design bases and of their operation in all operating states, including shutdown and accident conditions. Likewise, it shall identify the regulations, codes and rules applicable to the facility. In particular, the documents must refer to the following subjects:

1st. Complementary data obtained during construction about the site and its characteristics.

2nd. A description of the facility as built and of the processes that are going to take place in it. The description of nuclear and non-nuclear instrumentation, of the control and protection systems, of the containment buildings or structures, of the auxiliary systems, of the radioactive waste collection and disposal systems and of any other systems or components that are significant for the safety of the installation shall be included.

3rd. An analysis of the foreseeable accidents derived from the malfunction of elements and

devices, from operational errors or from agents external to the facility and of their consequences.

4th. An analytical radiological study of the facility.

5th. An operational environmental radiological monitoring programme, in order to assess the impact derived from the operation of the facility.

b) An operation handbook. This document shall contain the following information:

1st. A list of the jobs with nuclear responsibility, from the Plant Manager or Operations Manager to supervisors, operators, people in charge of radiological monitoring and people that perform the nuclear tests.

2nd. The organisation. It shall specify the organisation and functions of the personnel attached to the facility under both normal and emergency conditions. It shall also describe the safety management in place. The basic training programmes for licensed and unlicensed personnel shall be defined and the technical competency for each specific mission, as well as the retraining programmes that are deemed adequate, shall be established.

3rd. Operating rules in normal operation and under accident conditions. These rules and the procedures that put them into practice must refer to the whole of the facility and to the different systems that comprise it.

c) Operating technical specifications. They shall contain the limit values of the variables that affect safety, the actuation limits of automatic protection systems, the minimum operating conditions, the programme of periodic checks, calibrations and inspections of systems and components, and the operational control.

d) An onsite emergency plan. It shall detail the measures envisaged by the licensee and the assignment of responsibilities to deal with accident conditions in order to mitigate their

consequences, protect the personnel of the facility and immediately notify its occurrence to the competent bodies, including the initial assessment of the circumstances and the consequences of the situation. Moreover, it shall establish the actions envisaged by the licensee to provide its help in protection interventions outside the facility, in accordance with the Offsite Emergency Plans established by the competent bodies, when the Nuclear Safety Council so determines it.

e) A nuclear testing programme. It shall describe said tests, their purpose, the specific techniques and the expected results. For it each test, the procedure to be followed, the data to be collected during its execution, and the maximum and minimum values expected for the variables of interest during the execution of the tests must be indicated. It shall also include the safety criteria applicable for the execution of these tests.

f) A quality assurance manual. It shall establish the scope and contents of the quality programme applicable to the tests and operation of safety-related systems, structures and components as well as to the design, manufacture, construction, testing and operation of the modifications thereto.

g) A radiation protection manual. This document shall include the radiation protection rules of the facility.

h) A spent fuel and radioactive waste management plan that incorporates, where appropriate, the contracts established with managing companies and includes, among other concepts, a system for the possible declassification of residual materials with radioactive content.

i) A final economic study, which shall analyse the fulfilment of the economic and financial estimates and express the total and true cost of the facility.

j) Decommissioning and dismantling estimates. They shall describe, among others, those relating to the final management of the radioactive waste that is generated and the study of the cost and the

economic and financial estimates to ensure the decommissioning.

k) A physical protection plan. It shall describe the organisational measures and the equipment, systems and components the purpose of which is to reach an acceptable physical safety level. It shall be treated as confidential.

Article 21. Nuclear Tests

1. The operating permit shall be provisionally granted for the necessary time to carry out the nuclear testing programme and analyse its results.

2. The nuclear testing programme shall include the series of tests, verifications and checks to be performed in each of the different systems the facility consist of, from the moment of the initial loading of nuclear fuel or from the introduction of nuclear substances therein to the moment full operability is reached, including those that must be conducted in nuclear power plants and reactors at full authorised thermal power.

That established in article 19 shall be applicable to the execution of the nuclear testing programme.

3. The official representation of the Nuclear Safety Council during the execution of the tests is entitled to suspend them at any time when, in his/her opinion, continuing with them is potentially dangerous. In such case, the Nuclear Safety Council shall adopt the measures that are appropriate, notifying the Directorate-General for Energy Policy and Mines.

Article 22. Result of the Tests

After having completed the nuclear testing programme, the licensee must send the following to the Directorate-General for Energy Policy and Mines and the Nuclear Safety Council:

- a) The results of the nuclear testing programme.
- b) A proposal for modifications to the operating technical specifications if, as a result of the tests

carried out, it is considered advisable to incorporate them

Article 23. Granting

The Nuclear Safety Council shall send to the Ministry of Industry, Tourism and Trade a report on both the results of the tests and the modifications that, where appropriate, are necessary to be introduced and the conditions of the renewal of the operating permit for the period of time that is established.

The Ministry of Industry, Tourism and Trade shall then issue the new operating permit for the appropriate period of time.

Article 24. Modifications of the Conditions

The Directorate-General for Energy Policy and Mines, officially or at the suggestion of the Nuclear Safety Council, within the scope of their respective competences, may require the holder of an operating permit to introduce new conditions or to alter those already imposed on the conditions of the current permit.

Chapter V

Modifications of the Facility

Article 25. Modification of the Facilities

1. The modifications to the design of the operating conditions affecting the nuclear safety or radiation protection of a facility as well as the execution of tests therein must be previously analysed by the licensee to verify if the criteria, rules and conditions on which its permit is based are still met.

If, from the analysis conducted by the licensee, it is concluded that the requirements listed in the foregoing paragraph are still guaranteed, the licensee may carry out the modification or tests, periodically informing the Ministry of Industry, Tourism and Trade and the Nuclear Safety Council of their execution.

In the event that the design modification entails a modification of criteria, rules and conditions on which the operating permit is based, the licensee

must request the Ministry of Industry, Tourism and Trade for a modification authorisation, which shall have to be in effect prior to the modification coming into service or the execution of the tests.

2. Regardless of the aforementioned authorisation, when in the opinion of the Directorate-General for Energy Policy and Mines or the Nuclear Safety Council the modification is far-reaching or entails significant construction or assembly work, the Directorate-General for Energy Policy and Mines shall require the licensee to apply for a modification execution and assembly authorisation.

In no case may activities of assembly or construction of this type of modification be performed prior to the granting of the corresponding authorisation.

3. The operator shall inform, with the periodicity determined in Title IV of this Regulation, the Directorate-General for Energy Policy and Mines and the Nuclear Safety Council of the planned, implemented or ongoing modifications and of the safety analyses thereof.

Article 26. Authorisation Application

The modification authorisation application shall be accompanied by the following documentation:

- a) A technical description of the modification, identifying the causes behind it.
- b) The safety analysis performed.
- c) An identification of the documents that would be affected by the modification, including the text proposed for the safety study and the operating technical specifications, when applicable.
- d) An identification of the tests that are required to be carried out prior to the restart of the operation.

Article 27. Documentation of the Execution and Assembly Authorisation

When it may be required in application of that established in article 25, the application for a

modification execution and assembly authorisation must be accompanied by the following documentation:

- a) A general description of the modification, identifying the causes behind it.
- b) The regulations to be applied in the design, construction, assembly and testing of the modification.
- c) The basic design of the modification.
- d) The envisaged organisation and the quality assurance programme to carry out the project.
- e) An identification of the scope and contents of the analyses required to prove the compatibility of the modification with the rest of the facility and to ensure that the safety levels thereof are still maintained.
- f) The destination of the equipment to be replaced, where appropriate.
- g) A procurement plan and a budget in the event of large modifications.

Article 28. Cessation of Operation

1. The holder of an operating permit shall notify the Ministry of Industry, Tourism and Trade, at least one year in advance of the expected date, its intention to permanently discontinue the activity for which the facility was conceived. Both in this case and when the cessation of the activity is due to another circumstance, the Ministry of Industry, Tourism and Trade, following a report from the Nuclear Safety Council, shall declare the permanent cessation of the operation and establish the conditions which the activities to be performed in the facility until the dismantling permit is obtained must meet and the deadline before which said permit must be applied for.

2. Before the dismantling permit is granted, the holder of the operating permit must:

- a) Have unloaded the fuel from the reactor and the

storage pools or, in the absence of the latter, have a spent fuel management plan approved by the Ministry of Industry, Tourism and Trade, following a report from the Nuclear Safety Council.

b) Have conditioned the waste generated during the operation.

Chapter VI Dismantling Permit and Declaration of Decommissioning

Article 29. Required Permits

The decommissioning of a nuclear facility shall require a dismantling permit and a declaration of decommissioning.

For the purposes of this Regulation, it shall be understood as dismantling the series of activities carried out once the corresponding permit allowing to apply for the declaration of decommissioning has been obtained, which shall mean the declassification of the facility and the full or restricted release of the site.

Article 30. Application

1. The dismantling permit application shall be accompanied by the documentation indicated in letters b), c), d), f), g), h) and k) of Article 20, adapting the contents thereof to the facility dismantling situation.

In any case, that stipulated in the applicable environmental legislation must be abided by.

Additionally, it shall be accompanied by the following documents:

a) A safety study, which shall contain:

1st. A descriptive study of the current state of the facility, the site and its area of influence containing the radiological characterisation of the facility and its site before the dismantling.

2nd. A general dismantling project containing the

scope of each phase of the proposed dismantling project, if there are several, as well as the description of the expected state of the facility during and after the execution thereof. The significant activities and work that may involve alterations of the nuclear safety or radiation protection conditions must be specified for the phase for which authorisation is requested.

3rd. An analysis of the safety of the dismantling project containing the applicable radiological and safety regulations and criteria, as well as an accident analysis, identifying the expected risks and the corresponding prevention measures.

4th. A study of the environmental radiological impact during the execution of the dismantling programme and once it is complete. It shall also contain an environmental radiological monitoring plan applicable during the execution of the dismantling programme.

b) A declassifiable material control plan including the description of the processes and equipment used to verify the observance of the radiological criteria to declassify the generated residual materials.

c) A site restoration plan including the proposal and justification of the methodology for the final radiological characterisation of the site in order to prove the observance of the radiological criteria established for the full or partial release or the release with use restrictions of the site, and the means for the establishment and upholding of the institutional legal controls that ensure the observance of the radiological criteria shall be proposed.

d) An economic study of the dismantling process, financial investments and expected costs to perform the dismantling operations until the decommissioning.

2. The Nuclear Safety Council shall define the scope, contents or development of the listed documentation by means of instructions or guides of a technical nature or of specific requirements.

Article 31. Title to the Dismantling

In the event that the licensee of the dismantling activities is going to be different from the operating permit holder, it shall be the former who shall submit the corresponding application. The title transfer shall be authorised together with the dismantling permit, and previously, the operating permit holder shall have met the conditions envisaged in article 28 of this Regulation.

Article 32. Content of the Permit

The dismantling permit shall include the general approach thereof, and if it is performed in different phases, the dismantling permit shall only regulate the activities envisaged in the immediate execution phase; the holder must apply for a new permit to carry out the subsequent phases.

Article 33. Declaration of Decommissioning

1. Once the dismantling activities are complete and when the performance of the estimates of the site restoration plan as well as the observance of the other technical conditions established in the dismantling programme have been verified, the Ministry of Industry, Tourism and Trade shall issue the declaration of decommissioning, following a report from the Nuclear Safety Council.

Prior to the declaration of decommissioning, said Ministry shall serve notice, in order for allegations to be lodged within a month, to the corresponding Autonomous Communities with competences regarding land use planning and the environment in the territory of which the facility is located, in accordance with Article 28 of Law 25/1964, of 29 April, on Nuclear Energy.

2. In those cases when it is necessary, the Ministry of Industry, Tourism and Trade, following a report from the Nuclear Safety Council, may agree the establishment of use restrictions on the plots of land where the decommissioned nuclear facility was on, said plots of land being inventoried in accordance with Article 81.

Title III. Of Radioactive Facilities

Chapter I

Definition, Classification and Permits

Article 34. Definitions

1. By radioactive facility it is understood:

- a) Facilities of any class that contain a source of ionising radiation.
- b) Ionising radiation-producing devices that operate at a voltage greater than 5 kilovolts.
- c) Premises, laboratories, factories and facilities where radioactive materials are produced, used, held, treated, handled or stored, except for the incidental storage during the carriage thereof.

2. Radioactive facilities are classified into three categories.

a) First-category radioactive facilities are:

1st. Factories that produce uranium, thorium or their compounds.

2nd. Factories that produce natural-uranium fuel assemblies.

3rd. Facilities that use radioactive sources for industrial irradiation purposes.

4th. Complex facilities where very large inventories of radioactive substances are handled or where radiation beams of very high-energy fluxes are produced such that the potential radiological impact of the facility is significant.

For the purposes of this Regulation, the facilities defined in Sections 1 and 2 are called nuclear fuel cycle radioactive facilities.

b) Provided they are not classified as belonging to the first category, second-category radioactive facilities are:

1st. Facilities where radioactive nuclides that can be used for scientific, medical, agricultural, commercial or industrial purposes are handled or stored, the total activity of which is equal or greater than one thousand times the exemption values that are established in Instruction IS-05 of the Nuclear Safety Council.

2nd. Facilities that use X-ray-generating devices that may operate with a peak voltage greater than 200 kilovolts.

3rd. Particle accelerators and facilities where neutron sources are stored.

c) Third-category radioactive facilities are:

1st. Facilities where radioactive nuclides are handled or stored the total activity of which is greater than the exemption values established in Instruction IS-05 of the Nuclear Safety Council and lower than one thousand times the exemption values.

2nd. Facilities that use X-ray-generating devices the peak voltage of which is lower than 200 kilovolts.

Article 35. Exemption as a Radioactive Facility

For the purposes of this Regulation, the facilities included in the cases of anexo I shall not have the consideration of radioactive facilities.

Article 36. Required Permits

1. Nuclear fuel cycle radioactive facilities shall require the following permits: preliminary authorisation, construction permit, operating permit, dismantling permit and declaration of decommissioning and, where appropriate, modification authorisation and title transfer authorisation.

2. Radioactive facilities for scientific, medical, agricultural, commercial or industrial purposes shall require an operating permit, a declaration of decommissioning and, where appropriate, a modification authorisation and a title transfer authorisation.

Chapter II

Nuclear Fuel Cycle Radioactive Facilities

Article 37. Applications

To apply for, process and grant preliminary authorisations, construction permits, operation permits, modification authorisations, title transfer authorisations, dismantling permits and declarations of decommissioning of first-category nuclear fuel cycle radioactive facilities, that stipulated in Title II of the present Regulation, in which the permits of nuclear facilities are regulated, must be observed, with the adaptation of the appropriate documents to the special characteristics of these facilities.

Chapter III

Radioactive Facilities for Scientific, Medical, Agricultural, Commercial or Industrial Purposes

Article 38. Applications

1. Radioactive facilities for scientific, medical, agricultural, commercial or industrial purposes shall apply for an operating permit. The application shall be accompanied by at least the following documentation:

a) A descriptive report of the facility. The site and the construction details of floors, walls, ventilation and other analogous elements shall be described.

The choice of radionuclides or radioactive sources to be used in the facilities and the solid, liquid or gas radioactive waste management systems planned for normal operation and the operation in case of accidents shall be justified where appropriate, including contracts with managing, re-export and other companies, as is appropriate in each case.

b) A safety study. It shall consist of an analysis and assessment of the risks that may be derived from the operation of the facility under operating conditions or due to an accident. Enough data to be able to carry out with them an analysis of the risks of the facility, independently of the one submitted by the applicant, shall be included.

c) A verification of the facility. Within that which is specifically applicable to each case, a description of the tests that the facility has to be subjected to and, in the necessary cases, of the envisaged maintenance plan shall be included.

d) An operation handbook. The work methods and handling rules that guarantee the safe operation of the facility shall be submitted. The applicable radiation protection measures shall also be described.

The planned list of personnel, the envisaged organisation and the definition of the responsibilities that go with each job, both under normal operation conditions and in case of emergency, shall be included.

e) An onsite emergency plan. It shall detail the measures envisaged by the licensee and the assignment of responsibilities to deal with accident conditions in order to mitigate their consequences, protect the personnel of the facility and immediately inform the competent bodies of its occurrence, including the initial assessment of the circumstances and the consequences of the situation. Moreover, it shall establish the actions envisaged by the licensee to provide its help in protection interventions outside the facility, in accordance with the offsite emergency plans established by the competent bodies, when the Nuclear Safety Council so determines.

f) Estimates for decommissioning and planned economic coverage to guarantee the former under safety conditions.

g) Economic budget of the investment to be made, which shall be comprised of the total and true value of the radioactive facility or the modification for which the permit is applied for; all those components which due to their nature are linked to the operation thereof are considered included.

2. For first-category facilities the following shall also be enclosed:

a) Information on the site and surrounding plots of land in the description of the site.

b) As part of the Operation Handbook:

1st. A quality assurance manual and the organisation envisaged by the applicant to ensure quality during construction and operation.

2nd. A Radiation Protection Manual with the radiation protection rules and procedures of the facility.

3rd. Operating Technical Specifications containing the limit values of the variables affecting safety, the actuation limits of automatic protection systems and the minimum operation conditions.

c) A physical protection plan, which shall describe the organisational measures and the equipment, systems and components the purpose of which is to reach an acceptable physical safety level. It shall be treated as confidential.

Article 39. Granting and Effects of the Permit

1. It is incumbent on the Ministry of Industry, Tourism and Trade to grant the operating permits and title transfer authorisations and the declarations of decommissioning of the first-category radioactive facilities regulated in this Chapter. In said permits notice shall be served of the documentation corresponding to the Autonomous Community, for it to lodge allegations within one month, in accordance with that stipulated in Section 2 of Article 4.

The granting of the remaining radioactive facility permits regulated in this Chapter is incumbent on the Director-General for Energy Policy and Mines.

2. The operating permit of the radioactive facility entitles its licensee to proceed to set up and prepare the operations to be carried out, in accordance with that stipulated in current regulations and in the conditions of the permit.

3. When the facility is ready to start operations, the

licensee shall notify this fact to the Nuclear Safety Council so that the latter may conduct an inspection visit. Once the Nuclear Safety Council has deemed that the facility can operate safely, it shall issue a notification for start-up, which it shall send to the licensee, informing the Ministry of Industry, Tourism and Trade thereof.

If from the inspection of the Nuclear Safety Council it is inferred that the facility does not have enough nuclear safety or radiation protection guarantees and the anomalies are not corrected by the licensee in the indicated period of time, this body shall inform the Ministry of Industry, Tourism and Trade of this fact in order for the appropriate measures to be taken.

4. No radioactive facility regulated in this Chapter may start its operation before the start-up notification, which shall entitle the licensee to start operations.

Article 40. Changes and Modifications

1. The changes and modifications affecting the following aspects shall require a permit from the Ministry of Industry, Tourism and Trade, following the same procedure expressed in Articles 38 and 39:

- a) The title to the facility.
- b) The location of the facility.
- c) The activities authorised by the granted permit.
- d) The category of the facility.
- e) The addition of new particle accelerating equipment that generate ionising radiations or the modification of current equipment.
- f) The inclusion of additional radioactive material, not previously authorised, with a total activity greater than 3.7 GigaBecquerels; for lower activities, that stipulated in Section 2 of this Article shall apply.
- g) The changes to the equipment and structural

changes requiring a substantial modification to the conditions of the permit that may significantly affect nuclear safety and radiation protection.

The Nuclear Safety Council shall establish the criteria to determine when the modification requires a preliminary inspection visit and the issue of a notification for start-up.

2. The changes and modifications affecting other aspects of the design or of the authorised operation conditions of the facility shall only require the express acceptance of the Nuclear Safety Council before their implementation, this body notifying the Ministry of Industry, Tourism and Trade.

3. Licensees are free to implement the rest of changes and modifications, of which they shall inform the Ministry of Industry, Tourism and Trade and the Nuclear Safety Council in the reports envisaged in section 2 of article 73.

4. In addition to the foregoing, in all cases the licensee shall send the Ministry of Industry, Tourism and Trade and the Nuclear Safety Council the review of the documents mentioned in Article 39 that are affected by the modification.

Article 41. Dismantling and Decommissioning

It shall be the responsibility of the licensee of the radioactive facility the dismantling and decommissioning thereof. The declaration of decommissioning application shall be accompanied by the following documentation:

- a) A technical study of the decommissioning conducted according to the characteristics of the facility, indicating the inventory of radioactive materials and waste and the ionising radiation-producing devices as well as their destination and the measures taken to dismantle and, where appropriate, decontaminate the facility.
- b) An economic report, in which the cost of the decommissioning and the estimates for the funding thereof are included.

Article 42. Declaration of Decommissioning

Once the Nuclear Safety Council verifies the absence of radioactive substances or ionising radiation-producing equipment and the results of the analysis of contamination in the facility, it shall issue a report intended for the Ministry of Industry, Tourism and Trade, who shall issue the corresponding declaration of decommissioning.

Title IV. Inspection of Nuclear and Radioactive Facilities

Single Chapter Inspection Action

Article 43. Inspectors

1. The specialised personnel from the Ministry of Industry, Tourism and Trade and the Nuclear Safety Council designated to perform the inspection and verification of nuclear and radioactive facilities shall be considered agents of the authority in all aspects relating to the course of their duties.

In the course of their mission, said specialised personnel may be accompanied by the accredited experts they deem necessary; they may access, without prior notice and after identifying themselves, the facilities object of inspection.

2. The Nuclear Safety Council may temporarily or permanently post at the nuclear facilities specialised personnel authorised to carry out inspection and control missions.

Article 44. Obligations of the Licensee

1. The licensee of a nuclear or radioactive facility shall be required to:

- a) Provide access to the inspectors to the parts of the facility they deem necessary to carry out their work.
- b) Facilitate the placement of the equipment and instrumentation that is required to conduct the necessary tests and verifications.
- c) Put at the inspectors' disposal the information,

documentation and technical means that are required to fulfil their mission.

d) Allow inspectors to take enough samples to perform the appropriate analyses and verifications. At the licensee's request, a control sample, appropriately sealed and marked, must be left in the possession thereof.

e) Provide access to the inspectors to the work centres of the suppliers of equipment and services related to the safety of the facility and the carrying out of their activities with the scope of the foregoing letters b), c) and d).

2. The obligations described in letters a), b), c) and d) of Section 1 shall be extended to the entity responsible for any establishment or place where the ionising radiation-producing equipment or radioactive materials may be located.

Article 45. Reports

1. The result of the inspections shall be recorded in a report, a copy of which shall be submitted to the Ministry of Industry, Tourism and Trade and to the facility licensee or the person who has witnessed the inspection on its behalf.

In any case, the facility licensee or the subordinate thereof shall be invited to witness the inspection and sign the report. With his/her signature, he/she can state the comments he/she deems appropriate. The refusal to do so shall not affect the processing and conclusions that are subsequently established nor the comments made without signature shall be taken into account.

2. The inspection reports that are written enjoy the presumption of veracity with regard to the facts that are stated therein, without prejudice to the evidence than the facility licensee may provide in defence of its rights and interests.

The mere writing of the report does not exempt the person that formalises or issues it from including in the file any elements of persuasion that allow to justify his/her assertions and clarify

the facts that have taken place, thus using in addition to the report as many means of proof as are necessary or appropriate.

Article 46. Actions in the Event of Risk

1. In those cases of evident danger, the Ministry of Industry, Tourism and Trade, as well as the Nuclear Safety Council or its accredited inspectors, may require, within the scope of their respective competences, the immediate cessation of the work, operation, or operations, informing the Ministry of Industry, Tourism and Trade of the fact and stating the causes that motivated said action.

2. When faced with exceptional or emergency situations that might arise and affect nuclear safety or radiation protection, when, in the opinion of the Nuclear Safety Council, they have their origin in facilities, equipment, companies or activities not subject to the permit regime of the nuclear legislation and may affect nuclear safety or radiation protection, the provisions of the present Chapter shall apply.

Title V. Of Nuclear and Radioactive Facility Personnel

First Chapter

Personnel Licenses and Credentials

1st Section. Nuclear Fuel Cycle Nuclear and Radioactive Facilities

Article 47. Licenses

1. Personnel running the operation and personnel operating the control and protection devices of a nuclear fuel cycle nuclear or radioactive facility must hold a supervisor and operator license respectively, granted by the Nuclear Safety Council.

In nuclear power plants it is understood by operation any manoeuvre affecting the reactivity or power level of the reactor or the integrity of barriers against the release of radioactive material, as is included in the operating procedures.

Alterations to the core, including the loading and unloading of fuel and its transfer, shall only

require supervision by a licensed person, which shall not have simultaneously assigned to him/her any other tasks other than the supervision of said activities. To this end, licenses exclusively limited to this purpose may be obtained.

2. Those persons who, in the presence and under the guidance of a licensed operator or supervisor, take part in training practice as part of an operator- or supervisor-training programme are exempt from having to hold licenses.

3. In the case of facilities under dismantling, the Nuclear Safety Council shall define the system operation and supervision activities as well as the radioactive material handling activities that must be performed or directed by licensed personnel. The need for having licensed personnel, as well as the type and number of necessary licenses, may be determined throughout the execution of each phase of the dismantling according to the residual risks.

4. In the case of other nuclear facilities, the Nuclear Safety Council shall define the activities that must be carried out by licensed personnel.

5. Additionally, nuclear fuel cycle nuclear and radioactive facilities shall have a Radiation Protection Service, which a person authorised for this purpose with a Head of the Radiation Protection Service diploma issued by the Nuclear Safety Council shall be responsible of. This requirement shall apply both in the operating phase of said facilities and during the execution of the active phases of their dismantling. The need for a Radiation Protection Service in the inactive phases of the dismantling shall be determined, case by case, by the Nuclear Safety Council in view of the radiological implications of the work that is done in said phases.

Article 48. Characteristics of Licenses

Operator and supervisor licenses for these facilities shall be personal and non-transferable, shall have a maximum period of validity of six years and shall be specific to the facility in question; they may not be used in a different one

unless it is expressly authorised by the Nuclear Safety Council.

Article 49. Applications

1. Supervisor licenses may be applied for, according to the type of facility and the missions entrusted in the operation thereof, by individuals with at least a three-year university diploma or an equivalent degree.

2. Operator licenses may be applied for, according to the type of facility and the missions entrusted in the operation thereof, either by individuals with a three-year university diploma or an equivalent degree or by those individuals who have a comparable and adequate training in nuclear safety and radiation protection, which must be appraised in a reasoned manner by the Nuclear Safety Council.

3. The Head of the Radiation Protection Service diploma may be applied for by university graduates with the appropriate training in radiation protection.

Article 50. Processing of Applications

The application for the operator or supervisor license and the Head of the Radiation Protection Service diploma must be addressed to the Nuclear Safety Council, and the full name, nationality, national identity card number or, in the case of foreigners, foreigner identity number or, failing that, passport or travel document number, age, and address of the applicant shall be stated in it.

The application shall be accompanied by the following documentation:

- a) Information on the academic education and professional training and on the work experience of the applicant.
- b) A statement by the licensee of the facility in which the missions that are going to be assigned to the applicant and its favourable appraisal on the suitability required to perform them are stated.
- c) A medical fitness certificate, issued by an occupational risk prevention service, after the

physical health and psychological stability requirements to carry out the activities specific to the licensed job and those that entail an exposure risk associated with the job have been analysed.

Article 51. Granting of Licenses

1. The Nuclear Safety Council shall issue the licenses and diplomas to all those persons who have passed, in the opinion of an examination board designated thereby, the tests and practices established in the personnel training programmes that have been approved, at the suggestion of the licensee, as part of the operation regulations of the facility.

2. Said examination board shall be comprised of a president and four members, three of which shall be experts in the type of facility which the license is applied for, one of them shall be proposed by the operator, and the fourth member shall be an expert in nuclear safety or radiation protection, who shall act as secretary.

3. The limiting conditions that are deemed appropriate to each case shall be included in the licenses and diplomas.

Article 52. Renewal

Operator and supervisor licenses shall be renewed for maximum, successive six-year periods. To this end, those interested shall apply for such renewals at least two months in advance of the expiration date of the license they hold, enclosing a statement by the facility licensee confirming that:

- a) They have been effectively performing, and with the required competence, the missions specific to each license, fulfilling the conditions of active stay in the job that are established in the technical regulations approved by the Nuclear Safety Council.
- b) They have profitably taken part in the ongoing training programme.
- c) They are still qualified as apt for the licensed job by an occupational risk prevention service, in the terms established in letter c) of Article 50.

Article 53 is deleted

Article 54 is deleted

2nd Section. Radioactive Facilities for Scientific, Medical, Agricultural, Commercial or Industrial Purposes

Article 55. Licenses

1. Personnel handling radioactive material or equipment and personnel directing said activities in a facility regulated in this Section must hold a specific license granted by the Nuclear Safety Council.

2. There shall be two classes of licenses:

a) An operator license, which entitles to handle ionising radiation-producing materials or equipment in accordance with preestablished procedures and instructions.

b) A supervisor license, which entitles to direct and plan the operation of a radioactive facility and the activities of operators.

3. Personnel credentials to manage and operate X-ray facilities for medical diagnosis purposes shall be subject to that which is stipulated in the regulations that are specifically applicable to this type of facilities.

4. Licenses granted by the Nuclear Safety Council shall have validity for radiological safety and protection training recognition purposes, without prejudice to the qualifications and requirements that may be required, in each case, in the professional sphere and by reason of the applied techniques.

Article 56. Characteristics of Licenses

1. Operator and supervisor licenses for this type of facilities shall have a minimum period of validity of five years and shall be personal and non-transferable and specific by field of application. The Nuclear Safety Council shall establish the fields of application in which the activities of licensed personnel must be classed, on the basis of the different types of facility according to their purpose.

2. The Nuclear Safety Council shall keep a register in which the granted operator and supervisor licenses shall be registered by field of application and the facility to which they apply. For this purpose, licensees must notify the Nuclear Safety Council the data of the facilities where they provide or have a contract to provide their services.

Article 57. Other Services

Additionally, the Nuclear Safety Council, considering the radiological risk, may require licensees of radioactive facilities to have their own or a contracted radiation protection service, at the head of which there must be at least a person authorised for that purpose by the Nuclear Safety Council.

Article 58. Exceptions

The Nuclear Safety Council may exempt those persons that supervise or handle ionising radiation-producing materials or equipment in those facilities that, in its opinion, do not pose a significant risk from having to obtain a license.

Article 59. Applications

1. Operator licenses for the facilities envisaged in this Section may be applied for by individuals with at least mandatory secondary or equivalent education.

2. Supervisor licenses may be applied for by individuals with at least three-year university diplomas or equivalent degrees.

3. Head of the Radiation Protection Service diplomas may be applied for by university graduates with the appropriate training in radiation protection.

Article 60. Processing

1. The application for licenses and diplomas must be addressed to the Nuclear Safety Council, and the full name, nationality, national identity card or passport number, age, and address of the applicant shall be stated in it.

2. The application shall be accompanied by the following documentation:

a) Information on the academic education and professional training and on the work experience of the applicant, in accordance with the modes of accreditation envisaged in the following article.

b) A medical fitness certificate, issued by an occupational risk prevention service, after the physical health and psychological stability requirements to carry out the activities specific to the licensed job and those that entail an exposure risk associated with the job have been analysed.

Article 61. Granting

1. The Nuclear Safety Council shall issue the licenses, in their respective field of application, to and register in the corresponding register those who:

a) Prove that they have passed the courses previously sanctioned by the Nuclear Safety Council for each type of license and field of application.

b) Are in possession of academic degrees the curricula of which, in the opinion of the Nuclear Safety Council, contain the knowledge required for a type of license and field of application.

2. In the rest of cases, licenses and diplomas shall be granted by the Nuclear Safety Council at the suggestion of an examination board designated thereby, which shall consider if the applicants have enough training and experience in their field of application to carry out the job in question. Said board shall be comprised of a president and four members experts in radiation protection and in some of the fields of application of radioactive facilities, one of which shall act as secretary.

Article 62. Renewal

Operator and supervisor licenses shall be renewed for periods equal to that of the first granting. To this end, those interested shall apply for such renewals two months in advance of the expiration date of the license they hold, proving they are still qualified as apt to work in the presence of ionising radiations by a specialised medical service.

3rd Section. End of Validity and Suspension of Licenses and Diplomas

Article 63. End of Validity

Licenses and diplomas for any type of nuclear and radioactive facility shall stop being valid for the following reasons:

a) Due to expiry, if they have not been duly renewed.

b) Due to revocation, following the processing of the appropriate file, in the following cases when they affect nuclear safety or radiation protection:

1st. Due to the loss or substantial reduction of the physical health or psychological stability of the license holder, proven with the corresponding medical certificates.

2nd. Due to not voluntarily subjecting himself/herself to undergo the tests that are indicated to him/her by the licensee or the Nuclear Safety Council to check his/her fitness conditions.

3rd. Due to a serious action or omission, voluntary or negligent, when performing his/her duties.

4th. Due to the contractual relationship having ended, in the case of licenses relating to nuclear fuel cycle nuclear and radioactive facilities.

c) Due to the decommissioning of the facility, in the case of licenses relating to nuclear fuel cycle nuclear and radioactive facilities.

d) Due to the license holder's resignation.

e) Due to barring derived from the corresponding disciplinary action.

f) Due to any other circumstance in which it is deemed necessary for safety reasons, following the processing of the corresponding file.

Article 63 A. Suspension of Licenses and Diplomas

The Nuclear Safety Council may suspend licenses in the following cases:

- a) For safety reasons.
- b) Due to the loss of technical qualifications to carry out his/her duties.
- c) As a precautionary measure, when a disciplinary action has been brought against him/her, if deemed appropriate.
- d) Due to inactivity, when the job for which the license holder is authorised is not carried out under the conditions and in the periods of time established by the Nuclear Safety Council.

Article 63 B. Required Communications

Any alteration of the physical or psychological state of the holder of an operator or supervisor license or diploma that reduces the capacity and responsibility for the job must be formally notified to the Nuclear Safety Council within fifteen days from the date on which it was detected. This communication must be made, if possible, by the interested party himself/herself.

Chapter II
Of the Obligations of Operating Personnel

Article 64. Operating Personnel

- 1. At least the licensed personnel that are established in the corresponding permit must be on duty in every nuclear or radioactive facility subjected to the permit process described in the foregoing titles.
- 2. In the specific case of nuclear power plants, a permanent team, comprising at least a supervisor and an operator, shall be set up from the moment the loading of nuclear fuel starts, regardless of the state of operation of the facility.

Article 65. Supervisors and Operators

- 1. The supervisor is required to direct the operation observing the operating technical specifications, the operation handbook, the onsite emergency plan and any other documents under which the corresponding permit of the facility with regard to the operation thereof has been granted.

Likewise, he/she must faithfully follow operating procedures, of which an updated copy must be permanently kept at a predetermined place. When there is no procedure to carry out a certain unexpected operation that cannot be delayed, the supervisor shall proceed to write it before executing it and shall include it in the operation log. In the event of an urgency, he/she shall adopt the measures he/she considers appropriate, leaving written evidence thereof in said log.

- 2. The operator is required to operate the control and protection devices under the direction of the supervisor, faithfully following the operating procedures, the operating technical specifications, the operation handbook and any other official documents of the facility with regard to the operation thereof.

Article 66. Obligations and Powers

- 1. The supervisor of a nuclear or radioactive facility has the obligation to stop its operation at any time if he/she considers that the proper safety conditions of the facility have decreased.
- 2. The operator of a nuclear or radioactive facility is authorised to act in the same way if, in addition to the aforementioned circumstances arising, he/she is incapable of informing the supervisor with the required alacrity.
- 3. Supervisors and operators are required to inform the facility licensee of the defects that in their opinion exist in the official documents of the permit or in the operation handbook or of any other defects that may affect nuclear safety or radiation protection, through the procedure envisaged in Article 8 A.
- 4. Licensed personnel must know and authorise the work that is carried out at the facility whenever it directly affects the operation thereof.

Article 67. Information to Workers

Every person that works in a nuclear or radioactive facility must know and observe the rules of protection against ionising radiation and his/her

duty in case of emergency. Additionally, all personnel that carry out tasks related to nuclear safety or radiation protection must have the necessary information to adequately perform their duties. To this end, the facility licensee must clearly define the necessary knowledge and specialisation and set up the training programmes that are required, which shall be at the disposal of the inspection from the Nuclear Safety Council.

Article 68. Head of the Radiation Protection Service

The Head of the Radiation Protection Service is the person responsible for ensuring the observance of the officially approved rules in relation to radiation protection, informing the on-duty supervisor of that which is appropriate at any time as regards their application.

In the event those rules are not observed, he/she shall be required to notify it in writing to the facility licensee, keeping the corresponding register at the inspection's disposal.

Title VI. Of the Operation Log, Files and Reports

Single Chapter

Obligations of the Facility licensee

Article 69. Operation Log

The holder of the permit of a nuclear or radioactive facility is required to keep an operation log where all information regarding the operation of the facility is reflected in a clear and concise manner.

Article 70. Conditions

1. The operation log, numbered, must be authorised, stamped and registered by the Nuclear Safety Council; for this purpose, the licensee shall request this procedure from said Body with sufficient notice.

The operation log in use must be kept in an appropriate place. The volumes that have been completed shall be filed and shall remain under the custody of the licensee. Their destruction or loss

shall be notified as soon as possible to the Nuclear Safety Council in order to take the appropriate measures.

2. The operation log may be checked and reviewed by the specialised personnel which article 43 refers to when they deem it advisable, who shall note therein the appropriate observations if they think it is necessary.

Article 71. Contents

1. According to the nature of the facility and without limitation, the following must appear dated and timed: start-up, power and operating levels, shutdowns, incidents of any kind, checks, maintenance operations, modifications, activity levels, the offsite release of radioactive effluents, and the storage and disposal of solid radioactive waste.

The name and signature of the on-duty supervisor or, as the case may be, operator must appear in the operation log, the corresponding changes or replacements being noted.

2. Before starting an operation that may put a piece of equipment, instrument or system affecting nuclear safety or radiation protection out of service, said operation must be explicitly authorised by the on-duty supervisor, who shall note on the log the date and time when the indicated operation starts and ends and the name of the person responsible for performing it.

Article 72. Filing of Documents

The licensee is obliged to file all documents and registers that are required in this Regulation, in other applicable provisions and in the granted permits for the periods of time that are established in each case.

Article 73. Reports

The licensee is required to submit to the Directorate-General for Energy Policy and Mines and the Nuclear Safety Council the following reports:

1. Nuclear Facilities:

a) A monthly report, submitted within the first fifteen days of the following month, describing the operation of the facility and the most remarkable activities.

b) Reports on any events that entail an alteration of the normal operation of the facility or that may affect nuclear safety or radiation protection.

c) Annual reports, submitted in the first quarter of every calendar year, on operating experience; design modifications; the adaptation to the new requirements of Spanish law, the international regulations that are applicable to them or the regulations of the country of origin of the project that apply; the activities of the personnel training and retraining programme; the results of the environmental radiological monitoring programme; and the statistical results of the dosimetric personnel controls.

d) When talking about nuclear power plants, and before every refuelling or maintenance outage, a report with the schedule of activities to be performed during the outage. Likewise, prior to the start-up after the refuelling, a refuelling safety report that covers the next operation cycle.

2. Radioactive Facilities:

a) An annual report, submitted in the first quarter of every calendar year, which must contain a summary of the operation log and the statistical results of the dosimetric personnel controls.

b) Reports on any anomalies that may affect nuclear safety or radiation protection as well as on the occurrence of accidents, in which the circumstances thereof shall be detailed.

c) For nuclear fuel cycle first-category radioactive facilities, the annual report mentioned in the foregoing Paragraph a) shall be submitted every three months. In addition, these facilities shall submit annual reports, in the first quarter of every year, relating to the results of the environmental radiological monitoring programmes and the

adaptation to the new requirements of Spanish law or to the international regulations that apply to them.

Title VII. Other Regulated Activities

First Chapter

Authorisation of Other Activities

Article 74. Radioactive Materials, Equipment, Devices and Accessories

1. The following shall require authorisation from the Directorate-General for Energy Policy and Mines, following a report from the Nuclear Safety Council, without prejudice to the competences of other Departments:

a) The manufacturing of devices, equipment and accessories that include radioactive materials or generate ionising radiation, even though the use thereof is included in the exemptions envisaged in Annex I.

b) The introduction in the Spanish market of consumer products that include radioactive materials, even though the use thereof is included in the exemptions envisaged in Annex I.

c) The marketing of radioactive materials and devices, equipment, accessories or any other elements that include radioactive materials or generate ionising radiations, even though the use thereof is included in the exemptions envisaged in Annex I, with the exemption of the consumer products considered in letter b).

d) The transfer of radioactive materials without licensee to any authorised entity. In this case, it shall not be necessary to enclose the documentation referred to in Section 2.

e) The technical support of radioactive devices and ionising radiation-generating equipment.

2. The permit application shall be accompanied by the following documentation:

a) The ID of the company or entity: registered

name, fiscal identification number, address, certification of inscription in the Mercantile Register, and justification for the object of the company or entity.

b) A report on the activities that are going to be performed.

c) Where appropriate, the experience of the company in activities of the same nature.

d) The personnel organisation and the operating rules of the company.

e) A list of the permanent technical staff, stating their qualifications and professional experience.

f) A list of the facilities, equipment and material means the company or entity has to perform its activities.

g) Where appropriate, procedures to ensure the radiation protection of workers exposed because of the tasks that are going to be carried out.

3. The intra-Community import, export and movement of radioactive materials shall be conducted observing the international agreements entered by Spain regarding this subject.

4. The manufacturing, marketing and technical support companies that, because of their activities, need to have an authorised radioactive facility may apply for a single permit.

Article 75. Conditions

1. In those cases where it is deemed convenient due to the nature of the devices, equipment or accessories, it may be possible to include in the respective permit for manufacturers, marketers and sales and technical support companies the obligation of keeping a register of the activities they conduct; they are required to send the Directorate-General for Energy Policy and Mines and the Nuclear Safety Council a quarterly list of the changes made to said register during such period.

2. No radioactive materials or ionising radiation-generating equipment may be supplied, when they require a permit as a radioactive facility for their possession or use, to entities that do not have said permit.

3. When the manufacturer or authorised supplier becomes aware that a model, piece of equipment or accessory marketed by it has a defect or non-conformity that may degrade the reliability of its function, it shall have to formally notify it to its customers and the Nuclear Safety Council as soon as possible and, in any case, within the thirty calendar days following the detection of the defect or non-conformity.

Article 76. Disposal and Treatment of Radioactive Substances

The disposal, recycling or reuse of radioactive substances or of materials that contain radioactive substances from any nuclear or radioactive facility shall be subject to a permit by the Directorate-General for Energy Policy and Mines, following a report from the Nuclear Safety Council.

However, the disposal, recycling or reuse of said substances or materials may be exempted from this requirement provided they contain or are contaminated with radionuclides in concentrations or activity levels equal or lower than those established by the Ministry of Industry, Tourism and Trade in relation to the definition of radioactive waste which the fourth additional provision of Ley 54/1997, de 27 de noviembre, del Sector Eléctrico, refers to.

Article 77. Carriage

The carriage of radioactive materials as well as the approval or validation of package models for the special carriage of said materials or radioactive sources, when it is so required by the specific regulations as regards the carriage of dangerous goods, shall be subject to a permit by the Directorate-General for Energy Policy and Mines, following a mandatory and binding report from the Nuclear Safety Council.

Article 78. Register of Carriers

1. Carriers of radioactive materials, in non-exempt packages, must declare this activity by registering in a register that for this purpose shall be established at the Directorate-General for Energy Policy and Mines called Register of Radioactive Material Carriers. The carrying out of the radioactive material carriage activity must comply with both the regulations on the carriage of dangerous goods and the Regulation on Health Protection against Ionising Radiations and other applicable nuclear legislation.

2. Companies that carry out expeditions under contract by another registered carrier company are exempt from registering in said register, the latter being responsible for the compliance of the former with the legislation applicable to the carriage of radioactive material.

3. Said carriers must apply for registration in said register, enclosing the following documentation:

- a) The registered office of the entity.
- b) The types of carriage, frequencies and usual routes.
- c) The location and characteristics of the facilities and buildings that may be used for receiving, distributing and storing radioactive materials in transit.

4. Carriers must notify the register of the changes made to the communicated data.

5. The Directorate-General for Energy Policy and Mines shall notify the Nuclear Safety Council and the Ministry of Public Works any variation that takes place in said register for their knowledge and purposes.

Article 79. Declaration

Those facilities where natural uranium or thorium or their compounds are used as chemical reagents, in a non-exempt amount no greater than three kilograms, shall be subjected

to a declaration procedure before the Nuclear Safety Council. Said declaration must contain the name of the licensee, the location of the facility, the reagent used and the amount thereof.

Article 80. Storage of Spent Fuel

Containers used to store spent fuel shall require their design to have been approved by the Directorate-General for Energy Policy and Mines, following a mandatory and binding report from the Nuclear Safety Council.

Chapter II Contaminated Areas

Article 81. Control of Contaminated Areas

1. Public Administrations or the licensees of the facilities or activities, subjected or not to the regime of permits envisaged in this Regulation, must inform the Nuclear Safety Council of any events from which the radiological contamination of plots of land or water resources is potentially derived.

2. Plans for mitigating the effects or decontaminating the affected plots of land or water resources that might occur, the preparation of which shall fall on the licensees thereof, must be subjected to the favourable opinion of the Nuclear Safety Council. After the corrective actions, the Nuclear Safety Council shall proceed to inspect and re-evaluate the radiological conditions of the area; it may issue a report for the appropriate purposes where it shall be determined whether the use restrictions corresponding to those plots of land or resources affected are appropriate, serving notice thereof to the corresponding Autonomous Community.

3. The Nuclear Safety Council shall prepare an inventory of the plots of lands or water resources it is aware of that have been affected by radiological contamination, informing the competent authorities of this for the appropriate purposes.

Chapter III

Design Appraisal, Certification and Validation

Article 82. Appraisal of New Designs or Models

1. Any person or entity may request the Nuclear Safety Council to issue a declaration of favourable appraisal on new designs, methodologies, simulation models or verification protocols related to the nuclear safety or radiation protection of the facilities or activities to which this Regulation refers to, for which he/she/it shall submit an application to said body accompanied by the documents necessary to make said declaration.

2. The declaration from the Nuclear Safety Council may be included as a reference in any subsequent processes for applying for any of the permits envisaged in this Regulation, provided the limits and conditions imposed in the declaration are met.

Article 83. Certification and Validation of New Designs or Models

1. For the purposes of this Regulation it is understood by:

a) Certification of conformity of a design: the acceptance by the Nuclear Safety Council of its use in Spain.

b) Validation of a design: the acceptance by the Nuclear Safety Council of a certification of conformity or equivalent documentation issued by the authority competent with regard to nuclear safety and radiation protection of another country, the technical regulations of which are compatible with those applied in Spain.

2. It shall be possible to certify or validate designs, generic or not, of among others:

a) Nuclear fuel.

b) Safety analysis methodologies.

c) Simulation models.

d) Verification protocols.

e) Spent fuel storage containers.

3. Any physical or legal person may request from the Nuclear Safety Council the certification of conformity or the validation of a design. The certification or validation application shall be accompanied by the following documents:

a) The description of the design to be certified or validated, justifying the intended use.

b) The studies that allow ensuring that the safety conditions that can be required are met.

c) In the case of validations, the documents that prove the certification of conformity or equivalent documentation.

d) Any other documents that the applicant considers necessary in support of his/her/it application.

Additional Provisions

First. Uranium Mine Permits and Restoration Plans

Operating permits and the execution of plans for restoring uranium mines shall require, prior to their granting by the competent authority, the mandatory and binding report from the Nuclear Safety Council with regard to radiation protection.

Second. Entities Providing Radiation Protection Services

The entities envisaged in this Regulation or in other regulations that develop the Law on Nuclear Energy centred on the provision of services in the field of radiation protection as technical, radiation protection services or units, technical support companies or dosimetry services, may be exempted from being considered radioactive facilities in connection with the radioactive calibration sources included in the measurement equipment the possession and use of which they require to carry out their duties, which shall be specified in the resolution that authorises them.

Third. Application of Other Provisions

1. The application of that established in the present Regulation is understood as being without prejudice to the fulfilment of the obligations that are derived from the agreements signed by Spain with regard to non proliferation as well as that stipulated in Royal Decree 158/1995, of 3 February, on the physical protection of nuclear materials.

2. Likewise, that established in the current Regulation on Health Protection against Ionising Radiations, as well as in Royal Decree 413/1997, of 21st March, on the occupational radiological protection of external exposed workers with risk of exposure to ionising radiations due to their intervention in radiological controlled area, shall apply in those aspects that are not contradicted by the present Regulation.

3. The provisions contained in the present Regulation shall be understood as being without prejudice of radioactive facilities for health purposes, authorised in accordance with that stipulated therein, complying with the specific regulations that apply in said sector as regards their subsequent operation.

4. Facilities with X-ray devices for medical diagnosis purposes and personnel credentials to manage or operate said facilities shall be subject to that specifically regulated in Royal Decree 1891/1991, of 30 December, and in complementary provisions.

5. Nuclear and radioactive facilities as a whole or in their parts, equipment and accessories are also subjected to the applicable industrial and technical regulations as far as those aspects that specifically affect them are concerned, in accordance with that established in Section 4 of Article 3 of Law 21/1992, of 16 July, on Industry. For these purposes, it shall be incumbent on the competent Administration in which the facilities are located to ensure their compliance.

Fourth. Environmental Impact Assessment Procedure

The environmental impact assessment procedure envisaged in Royal Decree-Law 1/2008, of 11

January, whereby the revised text of the Law on the Assessment of the Environmental Impact of Projects is approved, shall be included in the substantive authorisation procedures regulated in this Regulation.

Transitory Provisions

First. Facilities Currently with a Provisional Operating Permit

That which is established in article 20, Paragraphs e), i) and j), shall not be applicable to nuclear facilities that have, in accordance with Decree 2869/1972, of 21 July, a provisional operating permit on the date of the coming into effect of the present Regulation.

Second. Previous Procedures

The procedures included in the scope of application of the present Regulation started before it came into effect shall have to adapt to it the procedures that are to be carried out therefrom.

Third. Permit Validity

1. The validity of the permits in force when this Regulation comes into effect shall be preserved until their expiration.

2. For a period of two years from the coming into effect of this Regulation, licensees of radioactive facilities the category of which may be modified by the provisions thereof shall regularise their situation before the Ministry of Industry, Tourism and Trade, in accordance with the decisions that are made in application of this Regulation.

Fourth. License Validity

Current holders of operator or supervisor licenses or Head of the Radiation Protection Service diplomas who, at the coming into effect of the Regulation, lack the qualifications necessary to obtain them, according to that established in Title V thereof, may continue carrying out their duties and, where appropriate, proceed to renew them in compliance with that envisaged in the present Regulation, except for those aspects referring to

new qualification requirements, which shall not apply to them.

Fifth. Period of Adaptation to the New Requirements.

Licencees of activities or facilities subjected to that stipulated in the Regulation on Nuclear and Radioactive Facilities that, at the coming into effect of this Royal Decree, are in possession of a license or permit in force, as well as carriers of radioactive materials that are registered in the until now so-called Register of Carriers of Nuclear Substances and Radioactive Materials, shall have a period of six months to adapt to the new requirements established therein.

Single Repeal Provision. Statutory Repeal.

All provisions of the same or lower level that contradict that which is stipulated in this Royal Decree are repealed.

First Final Provision. Title of Competence.

This Royal Decree is announced under the protection of that stipulated in Article 149.1.16a and 25a of the Constitution, which ascribes to the State the authority over the bases and general coordination of public health and the bases of the mining and energy regime respectively.

Second Final Provision. Entry Into Force.

The present Royal Decree shall come into force the following day to its publication in the «Official State Gazette».

Madrid, 18 January 2008

JUAN CARLOS R.

The Minister of Industry, Tourism and Trade
Joan Clos i Matheu

ANNEX I

Radioactive Facilities: Classification and Exemption

1. For the purposes of this Regulation, those facilities where the following take part shall not have the consideration of radioactive facilities:

a) Radioactive substances, if their activity as a whole does not exceed the exemption values indicated in the second column of Table A of Instruction IS/05 of the Nuclear Safety Council.

b) Radioactive substances, if their activity per unit mass does not exceed the exemption values indicated in the third column of Table A of Instruction IS/05 of the Nuclear Safety Council.

c) The use of devices that contain radioactive substances exceeding the activities or activity values per unit mass that are specified in letters a) or b), provided they correspond to a type approved by the Ministry of Industry, Tourism and Trade, in accordance with that established in Annex II. The approval resolution must specify the conditions for the disposal thereof.

d) The use of any cathode tubes intended for displaying visual images or any other electrical devices that operate with a voltage no greater than 30 kV and electron microscopes, provided they do not have, under normal operating conditions, a dose rate greater than 1 $\mu\text{Sv/h}$ at any point located at 0.1 m from the accessible surface of the device.

e) The use of ionising radiation-emitting devices other than those envisaged in letter d), provided they correspond to a type approved by the Ministry of Industry, Tourism and Trade, in accordance with that established in Annex II.

f) Materials contaminated with radioactive substances from authorised disposals that have been declared by the Ministry of Industry, Tourism and Trade, following a report from the Nuclear Safety Council, as not subjected to subsequent controls.

g) The Ministry of Industry, Tourism and Trade, following a report from the Nuclear Safety Council, may declare other practices exempt when, even though they exceed the values of Table A of Instruction IS/05 of the Nuclear Safety Council, the following conditions are met:

1st. The foreseeable expected dose for any member of the public because of the exempted practice is in the order of 10 μSv a year or lower, and

2nd. The effective collective dose undertaken for every year of the execution of the practice is not greater than 1 Sv/person or an assessment of the optimisation of the radiation protection shows that the exemption is the optimum condition.

2. The following rules shall be taken into consideration in the use of Table A of Instruction IS/05 of the Nuclear Safety Council:

a) When necessary, the Nuclear Safety Council shall assign appropriate values for the activities and activities per unit mass in the case of radionuclides not included in Table A. The values thereby assigned shall be complementary with regard to those of Table A.

b) Nuclides of Table A with the "+" or "sec" suffix represent the parent nuclides in secular equilibrium with their corresponding daughter nuclides listed in Table B of Instruction IS/05 of the Nuclear Safety Council. In this case, the values given in said Table A only refer to the parent nuclide, although they already take into account the present daughter nuclide(s).

c) In the other cases of the mix of more than one nuclide, the exemption shall be maintained only if the sum of the ratios between the total activity present in each nuclide and the corresponding value that appears in Table A of Instruction IS/05 of the Nuclear Safety Council is equal or smaller than 1. This rule shall also be applied to activities per unit mass when the different affected nuclides are contained in the same matrix.

3. For the purposes of the classification of radioactive facilities into categories envisaged in Article 34, the activity contained in the second column of Table A of Instruction IS/05 of the Nuclear Safety Council shall be taken as a reference of the exempt activity per nuclide, such that:

- a) Facilities where an activity greater and one thousand times lower than the exemption activity takes place shall belong to the third category.
- b) Facilities where the activity is equal or greater than one thousand times the exemption activity shall be of second category.
- c) In isotope mixture cases, if the sum of the ratios between the current activity of each isotope and the exemption activity ranges from one to one thousand, the facility shall be of third category, and if it is equal or greater than one thousand, of second category.

Table A

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Hydrogen:		
Tritium Compounds (inc OBT)	1 10 ⁹	1 10 ⁶
Elemental	1 10 ⁹	1 10 ⁶
Beryllium:		
Be-7	1 10 ⁷	1 10 ³
Be-10	1 10 ⁶	1 10 ⁴
Carbon:		
C-11	1 10 ⁶	1 10 ¹
C-11 monoxide	1 10 ⁹	1 10 ¹
C-11 dioxide	1 10 ⁹	1 10 ¹
C-14	1 10 ⁷	1 10 ⁴
C-14 monoxide	1 10 ¹¹	1 10 ⁸
C-14 dioxide	1 10 ¹¹	1 10 ⁷
Nitrogen:		
N-13	1 10 ⁹	1 10 ²
Neon:		
Ne-19	1 10 ⁹	1 10 ²
Oxygen:		
O-15	1 10 ⁹	1 10 ²
Fluoride:		
F-18	1 10 ⁶	1 10 ¹
Sodium:		
Na-22	1 10 ⁶	1 10 ¹
Na-24	1 10 ⁵	1 10 ¹
Magnesium:		
Mg-28+	1 10 ⁵	1 10 ¹
Aluminium:		
Al-26	1 10 ⁵	1 10 ¹
Silicon:		
Si-31	1 10 ⁶	1 10 ³
Si-32	1 10 ⁶	1 10 ³
Phosphorus:		
P-32	1 10 ⁵	1 10 ³
P-33	1 10 ⁸	1 10 ⁵

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Sulphur:		
S-35	1 10 ⁸	1 10 ⁵
S-35 (organic)	1 10 ⁸	1 10 ⁵
S-35 (vapour).....	1 10 ⁹	1 10 ⁶
Chlorine:		
Cl-36.....	1 10 ⁶	1 10 ⁴
Cl-38.....	1 10 ⁵	1 10 ¹
Cl-39.....	1 10 ⁵	1 10 ¹
Argon:		
Ar-37	1 10 ⁸	1 10 ⁶
Ar-39	1 10 ⁴	1 10 ⁷
Ar-41	1 10 ⁹	1 10 ²
Potassium:		
K-40.....	1 10 ⁶	1 10 ²
K-42.....	1 10 ⁶	1 10 ²
K-43.....	1 10 ⁶	1 10 ¹
K-44.....	1 10 ⁵	1 10 ¹
K-45.....	1 10 ⁵	1 10 ¹
Calcium:		
Ca-41	1 10 ⁷	1 10 ⁵
Ca-45	1 10 ⁷	1 10 ⁴
Ca-47	1 10 ⁶	1 10 ¹
Scandium:		
Sc-43	1 10 ⁶	1 10 ¹
Sc-44	1 10 ⁵	1 10 ¹
Sc-44m.....	1 10 ⁷	1 10 ²
Sc-46	1 10 ⁶	1 10 ¹
Sc-47	1 10 ⁶	1 10 ²
Sc-48	1 10 ⁵	1 10 ¹
Sc-49	1 10 ⁵	1 10 ³
Titanium:		
Ti-44+	1 10 ⁵	1 10 ¹
Ti-45.....	1 10 ⁶	1 10 ¹
Vanadium:		
V-47	1 10 ⁵	1 10 ¹
V-48	1 10 ⁵	1 10 ¹
V-49	1 10 ⁷	1 10 ⁴

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Chromium:		
Cr-48	1 10 ⁶	1 10 ²
Cr-49	1 10 ⁶	1 10 ¹
Cr-51	1 10 ⁷	1 10 ³
Manganese:		
Mn-51	1 10 ⁵	1 10 ¹
Mn-52	1 10 ⁵	1 10 ¹
Mn-52m	1 10 ⁵	1 10 ¹
Mn-53	1 10 ⁹	1 10 ⁴
Mn-54	1 10 ⁶	1 10 ¹
Mn-56.....	1 10 ⁵	1 10 ¹
Iron:		
Fe-52	1 10 ⁶	1 10 ¹
Fe-55	1 10 ⁶	1 10 ⁴
Fe-59	1 10 ⁶	1 10 ¹
Fe-60+	1 10 ⁵	1 10 ²
Cobalt:		
Co-55	1 10 ⁶	1 10 ¹
Co-56	1 10 ⁵	1 10 ¹
Co-57	1 10 ⁶	1 10 ²
Co-58	1 10 ⁶	1 10 ¹
Co-58m	1 10 ⁷	1 10 ⁴
Co-60	1 10 ⁵	1 10 ¹
Co-60m	1 10 ⁶	1 10 ³
Co-61	1 10 ⁶	1 10 ²
Co-62m	1 10 ⁵	1 10 ¹
Nickel:		
Ni-56	1 10 ⁶	1 10 ¹
Ni-57	1 10 ⁶	1 10 ¹
Ni-59	1 10 ⁸	1 10 ⁴
Ni-63	1 10 ⁸	1 10 ⁵
Ni-65	1 10 ⁶	1 10 ¹
Ni-66	1 10 ⁷	1 10 ⁴
Copper:		
Cu-60	1 10 ⁵	1 10 ¹
Cu-61	1 10 ⁶	1 10 ¹
Cu-64	1 10 ⁶	1 10 ²
Cu-67	1 10 ⁶	1 10 ²

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Zinc:		
Zn-62	1 10 ⁶	1 10 ²
Zn-63	1 10 ⁵	1 10 ¹
Zn-65	1 10 ⁶	1 10 ¹
Zn-69	1 10 ⁶	1 10 ⁴
Zn-69m	1 10 ⁶	1 10 ²
Zn-71m	1 10 ⁶	1 10 ¹
Zn-72	1 10 ⁶	1 10 ²
Gallium:		
Ga-65	1 10 ⁵	1 10 ¹
Ga-66	1 10 ⁵	1 10 ¹
Ga-67	1 10 ⁶	1 10 ²
Ga-68	1 10 ⁵	1 10 ¹
Ga-70	1 10 ⁶	1 10 ³
Ga-72	1 10 ⁵	1 10 ¹
Ga-73	1 10 ⁶	1 10 ²
Germanium:		
Ge-66	1 10 ⁶	1 10 ¹
Ge-67	1 10 ⁵	1 10 ¹
Ge-68+	1 10 ⁵	1 10 ¹
Ge-69	1 10 ⁶	1 10 ¹
Ge-71	1 10 ⁸	1 10 ⁴
Ge-75	1 10 ⁶	1 10 ³
Ge-77	1 10 ⁵	1 10 ¹
Ge-78	1 10 ⁶	1 10 ²
Arsenic:		
As-69	1 10 ⁵	1 10 ¹
As-70	1 10 ⁵	1 10 ¹
As-71	1 10 ⁶	1 10 ¹
As-72	1 10 ⁵	1 10 ¹
As-73	1 10 ⁷	1 10 ³
As-74	1 10 ⁶	1 10 ¹
As-76	1 10 ⁵	1 10 ²
As-77	1 10 ⁶	1 10 ³
As-78	1 10 ⁵	1 10 ¹
Selenium:		
Se-70	1 10 ⁶	1 10 ¹
Se-73	1 10 ⁶	1 10 ¹
Se-73m	1 10 ⁶	1 10 ²

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Se-75	1 10 ⁶	1 10 ²
Se-79	1 10 ⁷	1 10 ⁴
Se-81	1 10 ⁶	1 10 ³
Se-81m	1 10 ⁷	1 10 ³
Se-83	1 10 ⁵	1 10 ¹
Bromine:		
Br-74	1 10 ⁵	1 10 ¹
Br-74m	1 10 ⁵	1 10 ¹
Br-75	1 10 ⁶	1 10 ¹
Br-76	1 10 ⁵	1 10 ¹
Br-77	1 10 ⁶	1 10 ²
Br-80	1 10 ⁵	1 10 ²
Br-80m	1 10 ⁷	1 10 ³
Br-82	1 10 ⁶	1 10 ¹
Br-83	1 10 ⁶	1 10 ³
Br-84	1 10 ⁵	1 10 ¹
Krypton:		
Kr-74	1 10 ⁹	1 10 ²
Kr-76	1 10 ⁹	1 10 ²
Kr-77	1 10 ⁹	1 10 ²
Kr-79	1 10 ⁵	1 10 ³
Kr-81	1 10 ⁷	1 10 ⁴
Kr-81m	1 10 ¹⁰	1 10 ³
Kr-83m	1 10 ¹²	1 10 ⁵
Kr-85	1 10 ⁴	1 10 ⁵
Kr-85m	1 10 ¹⁰	1 10 ³
Kr-87	1 10 ⁹	1 10 ²
Kr-88	1 10 ⁹	1 10 ²
Rubidium:		
Rb-79	1 10 ⁵	1 10 ¹
Rb-81	1 10 ⁶	1 10 ¹
Rb-81m	1 10 ⁷	1 10 ³
Rb-82m	1 10 ⁶	1 10 ¹
Rb-83+	1 10 ⁶	1 10 ²
Rb-84	1 10 ⁶	1 10 ¹
Rb-86	1 10 ⁵	1 10 ²
Rb-87	1 10 ⁷	1 10 ⁴
Rb-88	1 10 ⁵	1 10 ¹
Rb-89	1 10 ⁵	1 10 ¹

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Strontium:		
Sr-80	1 10 ⁷	1 10 ³
Sr-81	1 10 ⁵	1 10 ¹
Sr-82+	1 10 ⁵	1 10 ¹
Sr-83	1 10 ⁶	1 10 ¹
Sr-85	1 10 ⁶	1 10 ²
Sr-85m	1 10 ⁷	1 10 ²
Sr-87m	1 10 ⁶	1 10 ²
Sr-89	1 10 ⁶	1 10 ³
Sr-90+	1 10 ⁴	1 10 ²
Sr-91	1 10 ⁵	1 10 ¹
Sr-92	1 10 ⁶	1 10 ¹
Yttrium:		
Y-86	1 10 ⁵	1 10 ¹
Y-86m	1 10 ⁷	1 10 ²
Y-87+	1 10 ⁶	1 10 ¹
Y-88	1 10 ⁶	1 10 ¹
Y-90	1 10 ⁵	1 10 ³
Y-90m	1 10 ⁶	1 10 ¹
Y-91	1 10 ⁶	1 10 ³
Y-91m	1 10 ⁶	1 10 ²
Y-92	1 10 ⁵	1 10 ²
Y-93	1 10 ⁵	1 10 ²
Y-94	1 10 ⁵	1 10 ¹
Y-95	1 10 ⁵	1 10 ¹
Zirconium:		
Zr-86	1 10 ⁷	1 10 ²
Zr-88	1 10 ⁶	1 10 ²
Zr-89	1 10 ⁶	1 10 ¹
Zr-93+	1 10 ⁷	1 10 ³
Zr-95	1 10 ⁶	1 10 ¹
Zr-97+	1 10 ⁵	1 10 ¹
Niobium:		
Nb-88	1 10 ⁵	1 10 ¹
Nb-89 (2.03 hours)	1 10 ⁵	1 10 ¹
Nb-89 (1.01 hour)	1 10 ⁵	1 10 ¹
Nb-90	1 10 ⁵	1 10 ¹
Nb-93m	1 10 ⁷	1 10 ⁴
Nb-94	1 10 ⁶	1 10 ¹
Nb-95	1 10 ⁶	1 10 ¹

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Nb-95m	1 10 ⁷	1 10 ²
Nb-96	1 10 ⁵	1 10 ¹
Nb-97	1 10 ⁶	1 10 ¹
Nb-98	1 10 ⁵	1 10 ¹
Molybdenum:		
Mo-90	1 10 ⁶	1 10 ¹
Mo-93	1 10 ⁸	1 10 ³
Mo-93m	1 10 ⁶	1 10 ¹
Mo-99	1 10 ⁶	1 10 ²
Mo-101	1 10 ⁶	1 10 ¹
Technetium:		
Tc-93	1 10 ⁶	1 10 ¹
Tc-93m	1 10 ⁶	1 10 ¹
Tc-94	1 10 ⁶	1 10 ¹
Tc-94m	1 10 ⁵	1 10 ¹
Tc-95	1 10 ⁶	1 10 ¹
Tc-95m+	1 10 ⁶	1 10 ¹
Tc-96	1 10 ⁶	1 10 ¹
Tc-96m	1 10 ⁷	1 10 ³
Tc-97	1 10 ⁸	1 10 ³
Tc-97m	1 10 ⁷	1 10 ³
Tc-98	1 10 ⁶	1 10 ¹
Tc-99	1 10 ⁷	1 10 ⁴
Tc-99m	1 10 ⁷	1 10 ²
Tc-101	1 10 ⁶	1 10 ²
Tc-104	1 10 ⁵	1 10 ¹
Ruthenium:		
Ru-94	1 10 ⁶	1 10 ²
Ru-97	1 10 ⁷	1 10 ²
Ru-103	1 10 ⁶	1 10 ²
Ru-105	1 10 ⁶	1 10 ¹
Ru-106+	1 10 ⁵	1 10 ²
Rhodium:		
Rh-99	1 10 ⁶	1 10 ¹
Rh-99m	1 10 ⁶	1 10 ¹
Rh-100	1 10 ⁶	1 10 ¹
Rh-101	1 10 ⁷	1 10 ²
Rh-101m	1 10 ⁷	1 10 ²
Rh-102	1 10 ⁶	1 10 ¹

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Rh-102m	1 10 ⁶	1 10 ²
Rh-103m	1 10 ⁸	1 10 ⁴
Rh-105	1 10 ⁷	1 10 ²
Rh-106m	1 10 ⁵	1 10 ¹
Rh-107	1 10 ⁶	1 10 ²
Palladium:		
Pd-100	1 10 ⁷	1 10 ²
Pd-101	1 10 ⁶	1 10 ²
Pd-103	1 10 ⁸	1 10 ³
Pd-107	1 10 ⁸	1 10 ⁵
Pd-109	1 10 ⁶	1 10 ³
Silver:		
Ag-102	1 10 ⁵	1 10 ¹
Ag-103	1 10 ⁶	1 10 ¹
Ag-104	1 10 ⁶	1 10 ¹
Ag-104m	1 10 ⁶	1 10 ¹
Ag-105	1 10 ⁶	1 10 ²
Ag-106	1 10 ⁶	1 10 ¹
Ag-106m	1 10 ⁶	1 10 ¹
Ag-108m+	1 10 ⁶	1 10 ¹
Ag-110m	1 10 ⁶	1 10 ¹
Ag-111	1 10 ⁶	1 10 ³
Ag-112	1 10 ⁵	1 10 ¹
Ag-115	1 10 ⁵	1 10 ¹
Cadmium:		
Cd-104	1 10 ⁷	1 10 ²
Cd-107	1 10 ⁷	1 10 ³
Cd-109	1 10 ⁶	1 10 ⁴
Cd-113	1 10 ⁶	1 10 ³
Cd-113m	1 10 ⁶	1 10 ³
Cd-115	1 10 ⁶	1 10 ²
Cd-115m	1 10 ⁶	1 10 ³
Cd-117	1 10 ⁶	1 10 ¹
Cd-117m	1 10 ⁶	1 10 ¹
Indium:		
In-109	1 10 ⁶	1 10 ¹
In-110 (4.9 hours)	1 10 ⁶	1 10 ¹
In-110 (69.1 minutes)	1 10 ⁵	1 10 ¹
In-111	1 10 ⁶	1 10 ²

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
In-112	1 10 ⁶	1 10 ²
In-113m	1 10 ⁶	1 10 ²
In-114	1 10 ⁵	1 10 ³
In-114m	1 10 ⁶	1 10 ²
In-115	1 10 ⁵	1 10 ³
In-115m	1 10 ⁶	1 10 ²
In-116m	1 10 ⁵	1 10 ¹
In-117	1 10 ⁶	1 10 ¹
In-117m	1 10 ⁶	1 10 ²
In-119m	1 10 ⁵	1 10 ²
Tin:		
Sn-110	1 10 ⁷	1 10 ²
Sn-111	1 10 ⁶	1 10 ²
Sn-113	1 10 ⁷	1 10 ³
Sn-117m	1 10 ⁶	1 10 ²
Sn-119m	1 10 ⁷	1 10 ³
Sn-121	1 10 ⁷	1 10 ⁵
Sn-121m+	1 10 ⁷	1 10 ³
Sn-123	1 10 ⁶	1 10 ³
Sn-123m	1 10 ⁶	1 10 ²
Sn-125	1 10 ⁵	1 10 ²
Sn-126+	1 10 ⁵	1 10 ¹
Sn-127	1 10 ⁶	1 10 ¹
Sn-128	1 10 ⁶	1 10 ¹
Antimony:		
Sb-115	1 10 ⁶	1 10 ¹
Sb-116	1 10 ⁶	1 10 ¹
Sb-116m	1 10 ⁵	1 10 ¹
Sb-117	1 10 ⁷	1 10 ²
Sb-118m	1 10 ⁶	1 10 ¹
Sb-119	1 10 ⁷	1 10 ³
Sb-120 (5.76 days)	1 10 ⁶	1 10 ¹
Sb-120 (15.89 minutes)	1 10 ⁶	1 10 ²
Sb-122	1 10 ⁴	1 10 ²
Sb-124	1 10 ⁶	1 10 ¹
Sb-124m	1 10 ⁶	1 10 ²
Sb-125	1 10 ⁶	1 10 ²
Sb-126	1 10 ⁵	1 10 ¹
Sb-126m	1 10 ⁵	1 10 ¹
Sb-127	1 10 ⁶	1 10 ¹

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Sb-128 (9.01 hours)	1 10 ⁵	1 10 ¹
Sb-128 (10.4 minutes) . .	1 10 ⁵	1 10 ¹
Sb-129	1 10 ⁶	1 10 ¹
Sb-130	1 10 ⁵	1 10 ¹
Sb-131	1 10 ⁶	1 10 ¹
Tellurium:		
Te-116	1 10 ⁷	1 10 ²
Te-121	1 10 ⁶	1 10 ¹
Te-121m	1 10 ⁶	1 10 ²
Te-123	1 10 ⁶	1 10 ³
Te-123m	1 10 ⁷	1 10 ²
Te-125m	1 10 ⁷	1 10 ³
Te-127	1 10 ⁶	1 10 ³
Te-127m	1 10 ⁷	1 10 ³
Te-129	1 10 ⁶	1 10 ²
Te-129m	1 10 ⁶	1 10 ³
Te-131	1 10 ⁵	1 10 ²
Te-131m	1 10 ⁶	1 10 ¹
Te-132	1 10 ⁷	1 10 ²
Te-133	1 10 ⁵	1 10 ¹
Te-133m	1 10 ⁵	1 10 ¹
Te-134	1 10 ⁶	1 10 ¹
Iodine:		
I-120	1 10 ⁵	1 10 ¹
I-120m	1 10 ⁵	1 10 ¹
I-121	1 10 ⁶	1 10 ²
I-123	1 10 ⁷	1 10 ²
I-124	1 10 ⁶	1 10 ¹
I-125	1 10 ⁶	1 10 ³
I-126	1 10 ⁶	1 10 ²
I-128	1 10 ⁵	1 10 ²
I-129	1 10 ⁵	1 10 ²
I-130	1 10 ⁶	1 10 ¹
I-131	1 10 ⁶	1 10 ²
I-132	1 10 ⁵	1 10 ¹
I-132m	1 10 ⁶	1 10 ²
I-133	1 10 ⁶	1 10 ¹
I-134	1 10 ⁵	1 10 ¹
I-135	1 10 ⁶	1 10 ¹

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Xenon:		
Xe-120	1 10 ⁹	1 10 ²
Xe-121	1 10 ⁹	1 10 ²
Xe-122+	1 10 ⁹	1 10 ²
Xe-123	1 10 ⁹	1 10 ²
Xe-125	1 10 ⁹	1 10 ³
Xe-127	1 10 ⁵	1 10 ³
Xe-129m	1 10 ⁴	1 10 ³
Xe-131m	1 10 ⁴	1 10 ⁴
Xe-133m	1 10 ⁴	1 10 ³
Xe-133	1 10 ⁴	1 10 ³
Xe-135m	1 10 ⁹	1 10 ²
Xe-135	1 10 ¹⁰	1 10 ³
Xe-138	1 10 ⁹	1 10 ²
Caesium:		
Cs-125	1 10 ⁴	1 10 ¹
Cs-127	1 10 ⁵	1 10 ²
Cs-129	1 10 ⁵	1 10 ²
Cs-130	1 10 ⁶	1 10 ²
Cs-131	1 10 ⁶	1 10 ³
Cs-132	1 10 ⁵	1 10 ¹
Cs-134	1 10 ⁴	1 10 ¹
Cs-134m	1 10 ⁵	1 10 ³
Cs-135	1 10 ⁷	1 10 ⁴
Cs-135m	1 10 ⁶	1 10 ¹
Cs-136	1 10 ⁵	1 10 ¹
Cs-137+	1 10 ⁴	1 10 ¹
Cs-138	1 10 ⁴	1 10 ¹
Barium:		
Ba-126	1 10 ⁷	1 10 ²
Ba-128	1 10 ⁷	1 10 ²
Ba-131	1 10 ⁶	1 10 ²
Ba-131m	1 10 ⁷	1 10 ²
Ba-133	1 10 ⁶	1 10 ²
Ba-133m	1 10 ⁶	1 10 ²
Ba-135m	1 10 ⁶	1 10 ²
Ba-137m	1 10 ⁶	1 10 ¹
Ba-139	1 10 ⁵	1 10 ²
Ba-140+	1 10 ⁵	1 10 ¹

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Ba-141	1 10 ⁵	1 10 ¹
Ba-142	1 10 ⁶	1 10 ¹
Lanthanum:		
La-131	1 10 ⁶	1 10 ¹
La-132	1 10 ⁶	1 10 ¹
La-135	1 10 ⁷	1 10 ³
La-137	1 10 ⁷	1 10 ³
La-138	1 10 ⁶	1 10 ¹
La-140	1 10 ⁵	1 10 ¹
La-141	1 10 ⁵	1 10 ²
La-142	1 10 ⁵	1 10 ¹
La-143	1 10 ⁵	1 10 ²
Cerium:		
Ce-134	1 10 ⁷	1 10 ³
Ce-135	1 10 ⁶	1 10 ¹
Ce-137	1 10 ⁷	1 10 ³
Ce-137m	1 10 ⁶	1 10 ³
Ce-139	1 10 ⁶	1 10 ²
Ce-141	1 10 ⁷	1 10 ²
Ce-143	1 10 ⁶	1 10 ²
Ce-144+	1 10 ⁵	1 10 ²
Praseodymium:		
Pr-136	1 10 ⁵	1 10 ¹
Pr-137	1 10 ⁶	1 10 ²
Pr-138m	1 10 ⁶	1 10 ¹
Pr-139	1 10 ⁷	1 10 ²
Pr-142	1 10 ⁵	1 10 ²
Pr-142m	1 10 ⁹	1 10 ⁷
Pr-143	1 10 ⁶	1 10 ⁴
Pr-144	1 10 ⁵	1 10 ²
Pr-145	1 10 ⁵	1 10 ³
Pr-147	1 10 ⁵	1 10 ¹
Neodymium:		
Nd-136	1 10 ⁶	1 10 ²
Nd-138	1 10 ⁷	1 10 ³
Nd-139	1 10 ⁶	1 10 ²
Nd-139m	1 10 ⁶	1 10 ¹
Nd-141	1 10 ⁷	1 10 ²
Nd-147	1 10 ⁶	1 10 ²

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Nd-149	1 10 ⁶	1 10 ²
Nd-151	1 10 ⁵	1 10 ¹
Promethium:		
Pm-141	1 10 ⁵	1 10 ¹
Pm-143	1 10 ⁶	1 10 ²
Pm-144	1 10 ⁶	1 10 ¹
Pm-145	1 10 ⁷	1 10 ³
Pm-146	1 10 ⁶	1 10 ¹
Pm-147	1 10 ⁷	1 10 ⁴
Pm-148	1 10 ⁵	1 10 ¹
Pm-148m+	1 10 ⁶	1 10 ¹
Pm-149	1 10 ⁶	1 10 ³
Pm-150	1 10 ⁵	1 10 ¹
Pm-151	1 10 ⁶	1 10 ²
Samarium:		
Sm-141	1 10 ⁵	1 10 ¹
Sm-141m	1 10 ⁶	1 10 ¹
Sm-142	1 10 ⁷	1 10 ²
Sm-145	1 10 ⁷	1 10 ²
Sm-146	1 10 ⁵	1 10 ¹
Sm-147	1 10 ⁴	1 10 ¹
Sm-151	1 10 ⁸	1 10 ⁴
Sm-153	1 10 ⁶	1 10 ²
Sm-155	1 10 ⁶	1 10 ²
Sm-156	1 10 ⁶	1 10 ²
Europium:		
Eu-145	1 10 ⁶	1 10 ¹
Eu-146	1 10 ⁶	1 10 ¹
Eu-147	1 10 ⁶	1 10 ²
Eu-148	1 10 ⁶	1 10 ¹
Eu-149	1 10 ⁷	1 10 ²
Eu-150 (34.2 years) ...	1 10 ⁶	1 10 ¹
Eu-150 (12.6 hours) ...	1 10 ⁶	1 10 ³
Eu-152	1 10 ⁶	1 10 ¹
Eu-152m	1 10 ⁶	1 10 ²
Eu-154	1 10 ⁶	1 10 ¹
Eu-155	1 10 ⁷	1 10 ²
Eu-156	1 10 ⁶	1 10 ¹
Eu-157	1 10 ⁶	1 10 ²
Eu-158	1 10 ⁵	1 10 ¹

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Gadolinium:		
Gd-145	1 10 ⁵	1 10 ¹
Gd-146+	1 10 ⁶	1 10 ¹
Gd-147	1 10 ⁶	1 10 ¹
Gd-148	1 10 ⁴	1 10 ¹
Gd-149	1 10 ⁶	1 10 ²
Gd-151	1 10 ⁷	1 10 ²
Gd-152	1 10 ⁴	1 10 ¹
Gd-153	1 10 ⁷	1 10 ²
Gd-159	1 10 ⁶	1 10 ³
Terbium:		
Tb-147	1 10 ⁶	1 10 ¹
Tb-149	1 10 ⁶	1 10 ¹
Tb-150	1 10 ⁶	1 10 ¹
Tb-151	1 10 ⁶	1 10 ¹
Tb-153	1 10 ⁷	1 10 ²
Tb-154	1 10 ⁶	1 10 ¹
Tb-155	1 10 ⁷	1 10 ²
Tb-156	1 10 ⁶	1 10 ¹
Tb-156m (24.4 hours) ..	1 10 ⁷	1 10 ³
Tb-156m (5 hours)	1 10 ⁷	1 10 ⁴
Tb-157	1 10 ⁷	1 10 ⁴
Tb-158	1 10 ⁶	1 10 ¹
Tb-160	1 10 ⁶	1 10 ¹
Tb-161	1 10 ⁶	1 10 ³
Dysprosium:		
Dy-155	1 10 ⁶	1 10 ¹
Dy-157	1 10 ⁶	1 10 ²
Dy-159	1 10 ⁷	1 10 ³
Dy-165	1 10 ⁶	1 10 ³
Dy-166	1 10 ⁶	1 10 ³
Holmium:		
Ho-155	1 10 ⁶	1 10 ²
Ho-157	1 10 ⁶	1 10 ²
Ho-159	1 10 ⁶	1 10 ²
Ho-161	1 10 ⁷	1 10 ²
Ho-162	1 10 ⁷	1 10 ²
Ho-162m	1 10 ⁶	1 10 ¹
Ho-164	1 10 ⁶	1 10 ³
Ho-164m	1 10 ⁷	1 10 ³

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Ho-166	1 10 ⁵	1 10 ³
Ho-166m	1 10 ⁶	1 10 ¹
Ho-167	1 10 ⁶	1 10 ²
Erbium:		
Er-161	1 10 ⁶	1 10 ¹
Er-165	1 10 ⁷	1 10 ³
Er-169	1 10 ⁷	1 10 ⁴
Er-171	1 10 ⁶	1 10 ²
Er-172	1 10 ⁶	1 10 ²
Thulium:		
Tm-162	1 10 ⁶	1 10 ¹
Tm-166	1 10 ⁶	1 10 ¹
Tm-167	1 10 ⁶	1 10 ²
Tm-170	1 10 ⁶	1 10 ³
Tm-171	1 10 ⁸	1 10 ⁴
Tm-172	1 10 ⁶	1 10 ²
Tm-173	1 10 ⁶	1 10 ²
Tm-175	1 10 ⁶	1 10 ¹
Ytterbium:		
Yb-162	1 10 ⁷	1 10 ²
Yb-166	1 10 ⁷	1 10 ²
Yb-167	1 10 ⁶	1 10 ²
Yb-169	1 10 ⁷	1 10 ²
Yb-175	1 10 ⁷	1 10 ³
Yb-177	1 10 ⁶	1 10 ²
Yb-178	1 10 ⁶	1 10 ³
Lutetium:		
Lu-169	1 10 ⁶	1 10 ¹
Lu-170	1 10 ⁶	1 10 ¹
Lu-171	1 10 ⁶	1 10 ¹
Lu-172	1 10 ⁶	1 10 ¹
Lu-173	1 10 ⁷	1 10 ²
Lu-174	1 10 ⁷	1 10 ²
Lu-174m	1 10 ⁷	1 10 ²
Lu-176	1 10 ⁶	1 10 ²
Lu-176m	1 10 ⁶	1 10 ³
Lu-177	1 10 ⁷	1 10 ³
Lu-177m	1 10 ⁶	1 10 ¹
Lu-178	1 10 ⁵	1 10 ²

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Lu-178m	1 10 ⁵	1 10 ¹
Lu-179	1 10 ⁶	1 10 ³
Hafnium:		
Hf-170	1 10 ⁶	1 10 ²
Hf-172+	1 10 ⁶	1 10 ¹
Hf-173	1 10 ⁶	1 10 ²
Hf-175	1 10 ⁶	1 10 ²
Hf-177m	1 10 ⁵	1 10 ¹
Hf-178m	1 10 ⁶	1 10 ¹
Hf-179m	1 10 ⁶	1 10 ¹
Hf-180m	1 10 ⁶	1 10 ¹
Hf-181	1 10 ⁶	1 10 ¹
Hf-182	1 10 ⁶	1 10 ²
Hf-182m	1 10 ⁶	1 10 ¹
Hf-183	1 10 ⁶	1 10 ¹
Hf-184	1 10 ⁶	1 10 ²
Tantalum:		
Ta-172	1 10 ⁶	1 10 ¹
Ta-173	1 10 ⁶	1 10 ¹
Ta-174	1 10 ⁶	1 10 ¹
Ta-175	1 10 ⁶	1 10 ¹
Ta-176	1 10 ⁶	1 10 ¹
Ta-177	1 10 ⁷	1 10 ²
Ta-178	1 10 ⁶	1 10 ¹
Ta-179	1 10 ⁷	1 10 ³
Ta-180	1 10 ⁶	1 10 ¹
Ta-180m	1 10 ⁷	1 10 ³
Ta-182	1 10 ⁴	1 10 ¹
Ta-182m	1 10 ⁶	1 10 ²
Ta-183	1 10 ⁶	1 10 ²
Ta-184	1 10 ⁶	1 10 ¹
Ta-185	1 10 ⁵	1 10 ²
Ta-186	1 10 ⁵	1 10 ¹
Tungsten:		
W-176	1 10 ⁶	1 10 ²
W-177	1 10 ⁶	1 10 ¹
W-178+	1 10 ⁶	1 10 ¹
W-179	1 10 ⁷	1 10 ²
W-181	1 10 ⁷	1 10 ³
W-185	1 10 ⁷	1 10 ⁴

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
W-187	1 10 ⁶	1 10 ²
W-188+	1 10 ⁵	1 10 ²
Rhenium:		
Re-177	1 10 ⁶	1 10 ¹
Re-178	1 10 ⁶	1 10 ¹
Re-181	1 10 ⁶	1 10 ¹
Re-182 (64 hours)	1 10 ⁶	1 10 ¹
Re-182 (12.7 hour)	1 10 ⁶	1 10 ¹
Re-184	1 10 ⁶	1 10 ¹
Re-184m	1 10 ⁶	1 10 ²
Re-186	1 10 ⁶	1 10 ³
Re-186m	1 10 ⁷	1 10 ³
Re-187	1 10 ⁹	1 10 ⁶
Re-188	1 10 ⁵	1 10 ²
Re-188m	1 10 ⁷	1 10 ²
Re-189+	1 10 ⁶	1 10 ²
Osmium:		
Os-180	1 10 ⁷	1 10 ²
Os-181	1 10 ⁶	1 10 ¹
Os-182	1 10 ⁶	1 10 ²
Os-185	1 10 ⁶	1 10 ¹
Os-189m	1 10 ⁷	1 10 ⁴
Os-191	1 10 ⁷	1 10 ²
Os-191m	1 10 ⁷	1 10 ³
Os-193	1 10 ⁶	1 10 ²
Os-194+	1 10 ⁵	1 10 ²
Iridium:		
Ir-182	1 10 ⁵	1 10 ¹
Ir-184	1 10 ⁶	1 10 ¹
Ir-185	1 10 ⁶	1 10 ¹
Ir-186 (15.8 hours)	1 10 ⁶	1 10 ¹
Ir-186 (1.75 hour)	1 10 ⁶	1 10 ¹
Ir-187	1 10 ⁶	1 10 ²
Ir-188	1 10 ⁶	1 10 ¹
Ir-189+	1 10 ⁷	1 10 ²
Ir-190	1 10 ⁶	1 10 ¹
Ir-190m (3.1 hours)	1 10 ⁶	1 10 ¹
Ir-190m (1.2 hour)	1 10 ⁷	1 10 ⁴
Ir-192	1 10 ⁴	1 10 ¹
Ir-192m	1 10 ⁷	1 10 ²

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Ir-193m	1 10 ⁷	1 10 ⁴
Ir-194	1 10 ⁵	1 10 ²
Ir-194m	1 10 ⁶	1 10 ¹
Ir-195	1 10 ⁶	1 10 ²
Ir-195m	1 10 ⁶	1 10 ²
Platinum:		
Pt-186	1 10 ⁶	1 10 ¹
Pt-188+	1 10 ⁶	1 10 ¹
Pt-189	1 10 ⁶	1 10 ²
Pt-191	1 10 ⁶	1 10 ²
Pt-193	1 10 ⁷	1 10 ⁴
Pt-193m	1 10 ⁷	1 10 ³
Pt-195m	1 10 ⁶	1 10 ²
Pt-197	1 10 ⁶	1 10 ³
Pt-197m	1 10 ⁶	1 10 ²
Pt-199	1 10 ⁶	1 10 ²
Pt-200	1 10 ⁶	1 10 ²
Gold:		
Au-193	1 10 ⁷	1 10 ²
Au-194	1 10 ⁶	1 10 ¹
Au-195	1 10 ⁷	1 10 ²
Au-198	1 10 ⁶	1 10 ²
Au-198m	1 10 ⁶	1 10 ¹
Au-199	1 10 ⁶	1 10 ²
Au-200	1 10 ⁵	1 10 ²
Au-200m	1 10 ⁶	1 10 ¹
Au-201	1 10 ⁶	1 10 ²
Mercury:		
Hg-193	1 10 ⁶	1 10 ²
Hg-193m	1 10 ⁶	1 10 ¹
Hg-194+	1 10 ⁶	1 10 ¹
Hg-195	1 10 ⁶	1 10 ²
Hg-195m+(organic) ...	1 10 ⁶	1 10 ²
Hg-195m+(inorganic)..	1 10 ⁶	1 10 ²
Hg-197	1 10 ⁷	1 10 ²
Hg-197m (organic)	1 10 ⁶	1 10 ²
Hg-197m (inorganic)...	1 10 ⁶	1 10 ²
Hg-199m	1 10 ⁶	1 10 ²
Hg-203	1 10 ⁵	1 10 ²

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Thallium:		
Tl-194	1 10 ⁶	1 10 ¹
Tl-194m	1 10 ⁶	1 10 ¹
Tl-195	1 10 ⁶	1 10 ¹
Tl-197	1 10 ⁶	1 10 ²
Tl-198	1 10 ⁶	1 10 ¹
Tl-198m	1 10 ⁶	1 10 ¹
Tl-199	1 10 ⁶	1 10 ²
Tl-200	1 10 ⁶	1 10 ¹
Tl-201	1 10 ⁶	1 10 ²
Tl-202	1 10 ⁶	1 10 ²
Tl-204	1 10 ⁴	1 10 ⁴
Lead:		
Pb-195m	1 10 ⁶	1 10 ¹
Pb-198	1 10 ⁶	1 10 ²
Pb-199	1 10 ⁶	1 10 ¹
Pb-200	1 10 ⁶	1 10 ²
Pb-201	1 10 ⁶	1 10 ¹
Pb-202	1 10 ⁶	1 10 ³
Pb-202m	1 10 ⁶	1 10 ¹
Pb-203	1 10 ⁶	1 10 ²
Pb-205	1 10 ⁷	1 10 ⁴
Pb-209	1 10 ⁶	1 10 ⁵
Pb-210+	1 10 ⁴	1 10 ¹
Pb-211	1 10 ⁶	1 10 ²
Pb-212+	1 10 ⁵	1 10 ¹
Pb-214	1 10 ⁶	1 10 ²
Bismuth:		
Bi-200	1 10 ⁶	1 10 ¹
Bi-201	1 10 ⁶	1 10 ¹
Bi-202	1 10 ⁶	1 10 ¹
Bi-203	1 10 ⁶	1 10 ¹
Bi-205	1 10 ⁶	1 10 ¹
Bi-206	1 10 ⁵	1 10 ¹
Bi-207	1 10 ⁶	1 10 ¹
Bi-210	1 10 ⁶	1 10 ³
Bi-210m+	1 10 ⁵	1 10 ¹
Bi-212+	1 10 ⁵	1 10 ¹
Bi-213	1 10 ⁶	1 10 ²
Bi-214	1 10 ⁵	1 10 ¹

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Polonium:		
Po-203	1 10 ⁶	1 10 ¹
Po-205	1 10 ⁶	1 10 ¹
Po-206	1 10 ⁶	1 10 ¹
Po-207	1 10 ⁶	1 10 ¹
Po-208	1 10 ⁴	1 10 ¹
Po-209	1 10 ⁴	1 10 ¹
Po-210	1 10 ⁴	1 10 ¹
Astatine:		
At-207	1 10 ⁶	1 10 ¹
At-211	1 10 ⁷	1 10 ³
Francium:		
Fr-222	1 10 ⁵	1 10 ³
Fr-223	1 10 ⁶	1 10 ²
Radon:		
Rn-220+	1 10 ⁷	1 10 ⁴
Rn-222+	1 10 ⁸	1 10 ¹
Radium:		
Ra-223+	1 10 ⁵	1 10 ²
Ra-224+	1 10 ⁵	1 10 ¹
Ra-225	1 10 ⁵	1 10 ²
Ra-226+	1 10 ⁴	1 10 ¹
Ra-227	1 10 ⁶	1 10 ²
Ra-228+	1 10 ⁵	1 10 ¹
Actinium:		
Ac-224	1 10 ⁶	1 10 ²
Ac-225+	1 10 ⁴	1 10 ¹
Ac-226	1 10 ⁵	1 10 ²
Ac-227+	1 10 ³	1 10 ⁻¹
Ac-228	1 10 ⁶	1 10 ¹
Thorium:		
Th-226+	1 10 ⁷	1 10 ³
Th-227	1 10 ⁴	1 10 ¹
Th-228+	1 10 ⁴	1 10 ⁰
Th-229+	1 10 ³	1 10 ⁰
Th-230	1 10 ⁴	1 10 ⁰
Th-231	1 10 ⁷	1 10 ³
Th-232	1 10 ⁴	1 10 ¹

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Th-232sec	1 10 ³	1 10 ⁰
Th-234+	1 10 ⁵	1 10 ³
Protactinium:		
Pa-227	1 10 ⁶	1 10 ³
Pa-228	1 10 ⁶	1 10 ¹
Pa-230	1 10 ⁶	1 10 ¹
Pa-231	1 10 ³	1 10 ⁰
Pa-232	1 10 ⁶	1 10 ¹
Pa-233	1 10 ⁷	1 10 ²
Pa-234	1 10 ⁶	1 10 ¹
Uranium:		
U-230+	1 10 ⁵	1 10 ¹
U-231	1 10 ⁷	1 10 ²
U-232+	1 10 ³	1 10 ⁰
U-233	1 10 ⁴	1 10 ¹
U-234	1 10 ⁴	1 10 ¹
U-235+	1 10 ⁴	1 10 ¹
U-236	1 10 ⁴	1 10 ¹
U-237	1 10 ⁶	1 10 ²
U-238+	1 10 ⁴	1 10 ¹
U-238 sec	1 10 ³	1 10 ⁰
U-239	1 10 ⁶	1 10 ²
U-240	1 10 ⁷	1 10 ³
U-240+	1 10 ⁶	1 10 ¹
Neptunium:		
Np-232	1 10 ⁶	1 10 ¹
Np-233	1 10 ⁷	1 10 ²
Np-234	1 10 ⁶	1 10 ¹
Np-235	1 10 ⁷	1 10 ³
Np-236 (1.15 10 ⁵ years) ..	1 10 ⁵	1 10 ²
Np-236 (22.5 hours) ...	1 10 ⁷	1 10 ³
Np-237+	1 10 ³	1 10 ⁰
Np-238	1 10 ⁶	1 10 ²
Np-239	1 10 ⁷	1 10 ²
Np-240	1 10 ⁶	1 10 ¹
Plutonium:		
Pu-234	1 10 ⁷	1 10 ²
Pu-235	1 10 ⁷	1 10 ²
Pu-236	1 10 ⁴	1 10 ¹

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Pu-237	1 10 ⁷	1 10 ³
Pu-238	1 10 ⁴	1 10 ⁰
Pu-239	1 10 ⁴	1 10 ⁰
Pu-240	1 10 ³	1 10 ⁰
Pu-241	1 10 ⁵	1 10 ²
Pu-242	1 10 ⁴	1 10 ⁰
Pu-243	1 10 ⁷	1 10 ³
Pu-244	1 10 ⁴	1 10 ⁰
Pu-245	1 10 ⁶	1 10 ²
Pu-246	1 10 ⁶	1 10 ²
Americium:		
Am-237	1 10 ⁶	1 10 ²
Am-238	1 10 ⁶	1 10 ¹
Am-239	1 10 ⁶	1 10 ²
Am-240	1 10 ⁶	1 10 ¹
Am-241	1 10 ⁴	1 10 ⁰
Am-242	1 10 ⁶	1 10 ³
Am-242m+	1 10 ⁴	1 10 ⁰
Am-243+	1 10 ³	1 10 ⁰
Am-244	1 10 ⁶	1 10 ¹
Am-244m	1 10 ⁷	1 10 ⁴
Am-245	1 10 ⁶	1 10 ³
Am-246	1 10 ⁵	1 10 ¹
Am-246m	1 10 ⁶	1 10 ¹
Curium:		
Cm-238	1 10 ⁷	1 10 ²
Cm-240	1 10 ⁵	1 10 ²
Cm-241	1 10 ⁶	1 10 ²
Cm-242	1 10 ⁵	1 10 ²
Cm-243	1 10 ⁴	1 10 ⁰
Cm-244	1 10 ⁴	1 10 ¹
Cm-245	1 10 ³	1 10 ⁰
Cm-246	1 10 ³	1 10 ⁰
Cm-247	1 10 ⁴	1 10 ⁰
Cm-248	1 10 ³	1 10 ⁰

Table A (continuation)

Element/nuclide	Activity – (Bq)	Activity per unit mass (kBq/kg)
Cm-249	1 10 ⁶	1 10 ³
Cm-250	1 10 ³	1 10 ⁻¹
Berkelium:		
Bk-245	1 10 ⁶	1 10 ²
Bk-246	1 10 ⁶	1 10 ¹
Bk-247	1 10 ⁴	1 10 ⁰
Bk-249	1 10 ⁶	1 10 ³
Bk-250	1 10 ⁶	1 10 ¹
Californium:		
Cf-244	1 10 ⁷	1 10 ⁴
Cf-246	1 10 ⁶	1 10 ³
Cf-248	1 10 ⁴	1 10 ¹
Cf-249	1 10 ³	1 10 ⁰
Cf-250	1 10 ⁴	1 10 ¹
Cf-251	1 10 ³	1 10 ⁰
Cf-252	1 10 ⁴	1 10 ¹
Cf-253	1 10 ⁵	1 10 ²
Cf-254	1 10 ³	1 10 ⁰
Einsteinium:		
Es-250	1 10 ⁶	1 10 ²
Es-251	1 10 ⁷	1 10 ²
Es-253	1 10 ⁵	1 10 ²
Es-254	1 10 ⁴	1 10 ¹
Es-254m	1 10 ⁶	1 10 ²
Fermium:		
Fm-252	1 10 ⁶	1 10 ³
Fm-253	1 10 ⁶	1 10 ²
Fm-254	1 10 ⁷	1 10 ⁴
Fm-255	1 10 ⁶	1 10 ³
Fm-257	1 10 ⁵	1 10 ¹
Mendelevium:		
Md-257	1 10 ⁷	1 10 ²
Md-258	1 10 ⁵	1 10 ²

Tabla B. List of radionuclides in secular equilibrium with Section 2.b) of this Annex refers to

Parent nuclide	Daughter nuclides
Ac-225+	Fr-221, At-217, Bi-213, Po-213(0.978), Tl-209(0.0216), Pb-209 (0.978)
Ac-227+	Fr-223(0.0138)
Ag-108m+	Ag-108(0.089)
Am-242m+	Am-242
Am-243+	Np-239
Ba-140+	La-140
Bi-210m +	Tl-206
Bi-212+	Tl-208(0.36), Po-212(0.64)
Ce-144+	Pr-144
Cs-137+	Ba-137m
Fe-60+	Co-60m
Gd-146+	Eu-146
Ge-68+	Ga-68
Hf-172+	Lu-172
Hg-194+	Au-194
Hg-195m+	Hg-195(0.542)
Ir-189+	Os-189m
Mg-28+	Al-28
Np-237+	Pa-233
Os-194+	Ir-194
Pb-210+	Bi-210, Po-210
Pb-212+	Bi-212, Tl-208(0.36), Po-212(0.64)
Pm-148m +	Pm-148(0.046)
Pt-188+	Ir-188
Ra-223+	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224+	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po 212(0.64)
Ra-226+	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228+	Ac-228
Rb-83+	Kr-83m
Rn-220+	Po-216
Rn-222+	Po-218, Pb-214, Bi-214, Po-214
Ru-106+	Rh-106
Re-189+	Os-189m(0.241)

Tabla B (continuation)

Parent nuclide	Daughter nuclides
Sn-121m+	Sn-121(0.776)
Sn-126+	Sb-126m
Sr-82+	Rb-82
Sr-90+	Y-90
Tc-95m+	Tc-95(0.04)
Ti-44+	Sc-44
Th-226+	Ra-222, Rn-218, Po-214
Th-228+	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212(0.64)
Th-229+	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213(0.978), Pb-209(0.978)
Th-sec	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212(0.64)
Th-234+	Pa-234m
U-230+	Th-226, Ra-222, Rn-218, Po-214
U-232+	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212(0.64)
U-235+	Th-231
U-238+	Th-234, Pa-234m
U-sec	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-240+	Np-240m
W-178+	Ta-178
W-188+	Re-188
Xe-122+	I-122
Y-87+	Sr-87m
Zr-93+	Nb-93m
Zr-97+	Nb-97

Note

a) The number in between brackets is the produced basis point of that isotope.

ANNEX II

Approval of Types of Radioactive Devices

General Conditions

1. In order to approve the type of a device that includes radioactive substances or generates ionising radiations, with a view to exempt it as a radioactive facility, it must provide sufficient safety measures against the release of ionising radiations under both normal operating conditions and any others conditions that may accidentally arise, including possible improper uses.

2. The device must provide advantages that justify its use in relation to its potential risk.

3. In the event of containing radioactive substances, they must be arranged as an encapsulated source such that a protection against any releases or leaks of the radioactive substance is ensured.

4. The device shall not have, under normal operating conditions, a dose rate greater than 1 $\mu\text{Sv/h}$ in any point located at 0.1 m from the accessible surface thereof.

5. The approval of the type has to be applied for by the Spanish manufacturer or, where appropriate, by the importer.

For the type approval of a device of foreign manufacture, it shall be required that its manufacture or distribution is authorised in the country of origin or that it meets the legal requirements established in it, which shall be proven with the appropriate supporting documentation.

6. The application for the approval of the type shall be processed in accordance with Article 4 of the present Regulation.

Devices from the same manufacturer and for the same field of application may be covered by a

single type approval; devices containing radioactive substances cannot be included in the same approval with ionising radiation-generating devices.

The application shall be accompanied by the following documents:

a) Documentation providing evidence that the applicant, if it is a Spanish manufacturer, has a radioactive facility permit.

b) Documentation that allows to have full knowledge of the type to be approved. Said documentation shall have to contain, at least:

1st. The identification of the make and model of the device.

2nd. A detailed description of the device and its safety systems. Where appropriate, the characteristics of the radioactive material and its encapsulation and the possibility of access thereto.

3rd. Supporting documentation in which the results obtained in the tests verified with the prototype with regard to radiation safety conditions appear.

4th. Drawings of the device.

5th. The use for which it is intended and its expected operational life.

6th. Documentation providing evidence that the device fulfils the purpose which it is intended for. In the case of new practices, the use of the device versus non-radioactive alternatives shall be justified and an analysis of its advantages versus the potential risks it entails shall be submitted.

7th. An analysis of the risks in situations that might accidentally arise, including improper uses. In the case of devices provided with radioactive material, the analysis shall consider the access to the population due the loss of control thereover.

8th. An operation manual, in Spanish, which shall be given to users and that includes its technical

features and instructions for use, information about its risks, and the basic radiation protection recommendations to be taken into account during its use or, where appropriate, in case of emergency, failure or break.

9th. A maintenance programme, in Spanish, which includes, where appropriate, the periodic verifications that the manufacturer recommends performing on the systems or parameters affecting the safety of the devices, expressly indicating those that, on the basis of their risks, the user may not be able to carry out.

c) For devices provided with radioactive material, a proposal for the management thereof at the end of its operational life shall be put forth. Where appropriate, the proposal shall be supported with an analysis of the risks that said management might mean for the population. In the event that the removal by the supplier of origin is expected, an original document issued thereby guaranteeing said removal shall be provided.

d) Documentation providing evidence of the quality assurance rules applied by the manufacturer of the ionising radiation-producing device.

e) In the case of Spanish manufacture, an ionising radiation-producing device manufacturing permit.

f) In the case of imported goods, the Directorate-General for Energy Policy and Mines or the Nuclear Safety Council may require the translation into Spanish of the documentation that it considers necessary, endorsed by the Spanish Consulate in the country of origin.

7. Once the copy of all the documentation is received, the Nuclear Safety Council shall proceed to issue its technical report on safety, for which it may request from the petitioner, if it considers it appropriate, the clarifications it deems necessary.

8. The report from the Nuclear Safety Council, together with the clarification that the petitioner

has provided, if any, shall be sent by said body to the Directorate-General for Energy Policy and Mines.

9. Once it receives the report from the Nuclear Safety Council, the Directorate-General for Energy Policy and Mines shall adopt the appropriate resolution.

10. In type-approving resolutions, the Directorate-General for Energy Policy and Mines shall describe the features of the type, the use that it is accepted for, the conditions and obligations which it is subject to and the abbreviations and number corresponding to it, reserving the right to impose new conditions. Said approval resolutions shall be published in the Official State Gazette.

11. At the suggestion of the Nuclear Safety Council, the Directorate-General for Energy Policy and Mines may require from the importer or the Spanish manufacturer that tests be conducted on certain supplied units, leading to verifying that the safety conditions of the approved type are maintained. In the event that deviations are detected, the Directorate-General for Energy Policy and Mines may cancel the approval of the type.

12. The Spanish manufacturer or the importer of a device of the approved type are required to supply with each unit the following documentation:

a) A certificate where the following appears:

1st. The serial number of the device and its date of manufacture.

2nd. A statement saying that the type has been approved by the Directorate-General for Energy Policy and Mines, indicating the approval number and the date of the resolution and that of the Official State Gazette in which it has been published.

3rd. That the device exactly matches the approved type.

4th. The use for which it has been authorised.

5th. The handling or destination of the device and, where appropriate, of the radioactive substance it contains at the end of its operational life.

6th. Any other information established in the approval of the type.

b) Specifications and conditions established in the approval of the type.

c) An operation manual in Spanish.

d) Any other information established in the approval of the type.

13. Ionising radiation-producing devices that are supplied must be indicated as is established in the corresponding approval of the type.

14. The user of the device is required to observe the conditions imposed by the Directorate-General for Energy Policy and Mines in the resolution whereby the type is approved.

