Royal Decree 1836/1999, approving the Regulation on Nuclear and Radioactive Facilities

CSN

Royal Decree 1836/1999, approving the Regulation on Nuclear and Radioactive Facilities

The CSN provides users of this website with an unofficial translation of the law in question. You are therefore advised that this translation is for your information only and may not be entirely up to date when you consult it. For official texts, look up the law in the Boletín Oficial del Estado, where you can find laws in any of the official languages of the State of Spain.

CSN

El CSN pone a disposición de los usuarios de esta web una traducción no oficial del texto de la norma de referencia. Se advierte, por tanto, de su carácter puramente divulgativo, y de la posibilidad de que no se encuentre debidamente actualizada en el momento de su consulta. El texto oficial es el publicado en el Boletín Oficial del Estado en cualquiera de las lenguas oficiales del Estado español.

Royal Decree 1836/1999, of December 3rd, approving the Regulation on Nuclear and Radioactive Facilities

CONSOLIDATED TEXT
Latest modification: March 8th 2014

CSN CONSEJO DE SEGURIDAD NUCLEAR

© Copyright Consejo de Seguridad Nuclear, 2015

Published and distributed by:
Consejo de Seguridad Nuclear
Pedro Justo Dorado Dellmans, 11. 28040 - Madrid
http://www.csn.es
peticiones@csn.es

Printed by, Cofás, S. A.

Legal registration: M. 14.898-2015

 Printed on recycled paper

Royal Decree 1836/1999, of December 3rd, approving the Regulation on Nuclear and Radioactive Facilities

CONSOLIDATED TEXT
Latest modification: March 8th 2014

The Regulation on nuclear and radioactive facilities currently in force was approved by Decree 2869/1972, of July 21st of that year. Since then, various standards have been published that have modified the reference framework governing the activities of the different bodies of the Administration. The passing of Law 15/1980, of April 22nd, which created the Nuclear Safety Council as the organisation solely responsible for nuclear safety and radiological protection, makes it especially necessary to completely revise the text approved in 1972.

Events that also make such revision advisable are the establishment of the State of Autonomous Communities and the transfer to these Communities of certain functions and services; Spain's joining the European Community; the passing of the Industry Act, Law 21/1992, of July 16th, Law 6/1997, of April 14th, on the Organisation and Operation of the General State Administration, which integrates the territorial services of this General Administration in the Regional Councils of the Government, and Law 30/1992, of November 26th, on the Legal System of Public Administrations and General Administrative Procedure, modified by Law 4/1999, of January 13th, and the publication of Royal Legislative Decree 1302/1986, of June 28th, on the assessment of environmental impact.

As regards nuclear facilities, the main modifications introduced relate to the adaptation of the documentation required in the different phases of authorisation, the replacement of successive extensions to provisional operating permits with term-based operating permits and regulation of the procedure for dismantling and decommissioning permits.

The determination of the documentation required for the different permits has been made on the basis of the evolution of safety requirements over the period of validity of Decree 2869/1972, of July 21st, approving the Regulation now repealed, which have been established case by case by way of Resolutions of the Ministry of Industry and Energy and, since its constitution in 1981, by the Nuclear Safety Council.

As regards the replacement of the successive extensions to provisional operating permits, the regulation now repealed was the result of the scanty experience of nuclear power plant operation that was available in Spain in 1972. As a precautionary measure, the legislator introduced at that time the concept of the provisional operating permit as an alternative to the granting of a definitive operating permit, in order to provide the control bodies of the Administration with sufficient time to obtain the basic data required to assess the safety of the facility in question. National and international experience in this field points to the advisability of replacing these permits with an operating permit subject to a fixed period of validity, provisional only during such time as might be necessary for performance of the programme of nuclear tests.

The Regulation repealed contained no forecasts for the dismantling and decommissioning phases of nuclear and radioactive facilities, for which reason it is appropriate that the text approved address all the procedures to be adhered to and documentation to be provided by the licensees.

Another modification that affects especially waste disposal facilities, nuclear reactors and critical assemblies for research purposes is the inclusion of the need to obtain a preliminary authorisation, since it is obvious from experience

and as a result of the legislation on the declaration of environmental impact that, like other nuclear installations, these facilities should be subjected to the entire regulatory process.

As regards radioactive facilities, two main modifications have been introduced. One derives from the application of European Union standards, especially Council Directive 96/29/EURATOM, of May 13th, which establishes basic standards relating to the protection of the health of the workers and the general public against the risks posed by ionising radiations and updates the activities of radionuclides exempted from administrative controls, this affecting the classification of these facilities in categories and exempted installations and activities.

The second modification refers to the administrative arrangements applicable to these facilities, which are now graduated differently from what was contemplated in the Regulation now repealed. The procedures and documentation now required for nuclear fuel cycle radioactive facilities are the same as those required for nuclear installations.

For other radioactive facilities the procedures are significantly simplified and are now reduced to a single request or application that leads to the granting of an operating permit.

The need to obtain a manufacturing permit refers only to items of equipment incorporating radioactive materials or producing ionising radiations. As regards the approval of types of apparatus producing ionising radiations for their use to be exempt from authorisation as radioactive facilities, appendix II updates and revises the regulations established in this respect in the Order of March 20th 1975, adapting them to the provisions set out for this type of exceptions in the European Union Directive.

The text of the Regulation now includes procedures for the authorisation of technical assistance and sales companies operating in the field of radioactive facilities, extending the rules established in Royal Decree 1891/1991, of December 30th, and complementary provisions referring to radiodiagnosis facilities.

Also incorporated is the need for companies transporting nuclear substances and radioactive materials to be included on a Register to be set up by the Directorate General for Energy.

Finally, it should be pointed out that the project covering the present provision has been reported to the Commission of the European Union, in accordance with what is set out in article 33 of the Treaty establishing the European Atomic Energy Community (EURATOM).

Pursuant to the above, in response to a proposal by the Ministry of Industry and Energy, in keeping with the regulation proposed by the Nuclear Safety Council, with the approval of the Minister of Public Administrations, in agreement with the Council of State, and following deliberation by the Cabinet of Ministers during its meeting of December 3rd 1999,

I HEREBY ORDAIN AS FOLLOWS:

Single Article. Regulation on nuclear and radioactive facilities

The Regulation on nuclear and radioactive facilities attached hereto is hereby approved.

Derogatory provision

Single. Repeal of standards

Decree 2869/1972, of July 21st, approving the Regulation on nuclear and radioactive facilities, the Order of the Ministry of Industry of March 20th 1975 on the homologation of radioactive apparatus and all standards of equal or lower rank contradicting or opposing the provisions of the present Royal Decree are hereby made null and void.

Final provisions

One. Development of precepts

The Minister of Industry and Energy is authorised to approve whatever provisions might be required for the application and development of what is set out in the present Regulation.

The Nuclear Safety Council may draw up technical standards or guidelines to facilitate the application of this Regulation.

Two. Basic nature

The present Regulation is a basic standard and is drawn up pursuant to the provisions of articles 149.1.16.a and 25.a of the Constitution.

Three. Entry into force

The present Royal Decree shall enter into force on the day following its publication in the Official State Gazette.

Given in Madrid on December 3rd 1999.

JUAN CARLOS R.

The Minister of Industry and Energy,
JOSEP PIQUE I CAMPS

Regulation on Nuclear and Radioactive Facilities

Title I. General provisions

Single chapter
Application of the Regulation

Article 1. Objective

The objective of this Regulation is to regulate the system of administrative authorisations for both nuclear and radioactive facilities and other specific activities relating to the application of ionising radiations. It also covers the system of personnel accreditations, the obligations of the licensees of the facilities and inspection and control activities, all the above in accordance with the Nuclear Energy Act, Law 25/1964, of April 29th, Law 15/1980, of April 22nd, creating the Nuclear Safety Council, and the provisions of European Community and national legislation on projects subject to the assessment of environmental impact.

Article 2. Competent authorities *

1. The application of the precepts of this Regulation corresponds to the Ministry of Industry, Energy and Tourism and to the Nuclear Safety Council, without prejudice to the competences of other departments and of the autonomous communities.
2. The executive functions that in this Regulation correspond to the Ministry of Industry, Energy and Tourism, in relation to second and third category radioactive facilities, shall be understood to be attributed to the autonomous communities when the said functions have been transferred to the latter.
3. The operating permits for second and third category radioactive facilities shall be valid for the entire Spanish territory. Without prejudice to the above, licensees planning to carry out any of the activities for which they are authorized in any specific part of the said territory shall notify the competent territorial Administration in writing and may initiate the activity in question as from the moment of notification.

Article 3. Register of radioactive facilities

1. All authorised facilities shall be entered on the «Register of Radioactive Facilities» kept by the Directorate General for Energy. The Ministry of Industry and Energy shall periodically issue information on the content of the said register to the competent bodies.

2. At least once every month the autonomous communities shall notify the Ministry of Industry and Energy of the authorisations that they have issued, and may set up their own registers within their territory and realm of competence.

Article 3 b. Obligation to inform

1. Administrations competent to grant permits or approve significant modifications to facilities or activities that, in view of their characteristics or situation, might imply an impact on a first category nuclear or radioactive facility shall, prior to granting such permit or modification, provide the Nuclear Safety Council with the corresponding safety report or sufficient information on the matter for the said public body to issue its mandatory report, which shall be binding in the terms established by Law 15/1980, of April 22nd, creating the Nuclear Safety Council.

---

* Royal Decree 177/2015, of March 13th, *modifying the Regulation on nuclear and radioactive facilities, for adaptation to Law 20/2013, of December 9th, guaranteeing the unity of the market.*

2. If the Nuclear Safety Council were to conclude from its evaluation of this information that an increase in the risk of the nuclear or radioactive facility as a result of the new installation or activity, or modification of the existing installation or activity, cannot be ruled out, measures might be developed for implementation at both the nuclear or radioactive facility and non-nuclear facility or activity.

If the notification contemplated in the previous section were not to occur, the Nuclear Safety Council might officially contact the bodies of the competent Administration to obtain the information required to draw up the said report.

The bodies referred to above, in collaboration with the Nuclear Safety Council, shall establish communication protocols that ensure that the establishments thus determined and first category nuclear and radioactive facilities considered adequately exchange the data required to allow the licensees to take into consideration the nature and magnitude of the general risk of a serious accident in their severe accident prevention policies, safety management systems, safety reports and site emergency plans.

Article 4. Submittal of applications

1. Applications for the permits granted by the Ministry of Industry, Tourism and Trade shall be addressed to this Ministry and shall meet the requirements set out in article 70 of the Law on the Legal System of Public Administrations and General Administrative Procedure. Such applications shall be accompanied by the documentation established in each particular case.

If the Ministry of Industry, Tourism and Trade considers the documentation submitted to be incomplete or its content insufficient, it shall require the submitting party to complete, clarify or extend it within ten days.

2. The said Ministry shall provide a copy of all the documentation to the Nuclear Safety Council for the preparation of its mandatory report.

Likewise, and in accordance with the provisions of article 28 of the Nuclear Energy Act, Law 25/1964, of April 29th, it shall where appropriate submit a copy of all the documentation to those autonomous communities that have competences in town and country planning and the environment and in whose territory is located the facility or the planning area foreseen in the basic standards on planning for nuclear and radiological emergencies, in order to allow these communities to present allegations within one month, as established in article 12.3 of this Regulation.

Article 5. Renewal of permits

1. The renewal of permits shall be governed by the same procedure as that by which they were originally granted, attaching updated versions of the documents on which such granting was based or, where appropriate, whatever documentation might be determined for each authorisation.

2. In the event of renewal of permits for nuclear facilities, the Nuclear Safety Council report shall be submitted to the Ministry of Industry, Energy and Tourism at least one month prior to the date of expiry of the permit in force. This term shall not be applicable in the event of renewal of the operating permit following shutdown as envisaged in section 1 of article 28.

Article 6. Mandatory reports

1. The reports of the Nuclear Safety Council for the granting of permits for nuclear and radioactive facilities and the manufacturing of apparatus, equipment or accessories generating ionising radiations shall in all cases be mandatory

and, furthermore, binding when negative or denying such award or as regards the conditions established when positive.

2. The procedures in which such reports are to be issued may, exceptionally, be suspended by the competent body for resolution, either indefinitely up to the time of their issuing or for such period as is considered adequate for their issuing, with the reasons for suspension being justified.

3. Permits or licences to be granted by any public Administration may not be denied or conditioned for reasons of nuclear safety or radiological protection, all decisions in this area corresponding solely to the Nuclear Safety Council.

4. Within its realm of competence the Nuclear Safety Council may issue complementary technical instructions directly to the licensees, in order to guarantee that the safety requirements and conditions applicable to the facilities are maintained and for better compliance with the requirements established in the corresponding permits.

5. The Nuclear Safety Council may interrupt ongoing work in the event of anomalies appearing and affecting nuclear safety, until such anomalies are corrected, and may propose cancellation of the permit if the anomalies are not susceptible to correction. Likewise, it is authorised to suspend the operation of facilities or activities for nuclear safety and radiological protection reasons.

6. The Nuclear Safety Council may require whatever additional documentation it considers to be necessary in relation to nuclear safety and radiological protection and shall, following the appropriate studies and consultations, issue the corresponding report, which shall be submitted to the Ministry of Industry and Energy.

Article 7. Granting of permits

Following reception of the report from the Nuclear Safety Council, and the corresponding decisions and reports, the Ministry of Industry, Tourism and Trade will adopt the appropriate resolution. The maximum period for notification of this resolution shall be six months, unless the suspension referred to in section 2 of the previous article is applicable, in which case the aforementioned maximum period shall be extended by the period of suspension.

The authorisations granted shall identify the following:

a) Licensee of the permit.

b) Location of the facility.

c) Activities that may be performed under the permit granted.

d) Period of validity and conditions for renewal, where appropriate.

e) Purpose of the facility and, where appropriate, its basic characteristics.

f) When applicable, nuclear substances and other materials and equipment producing ionising radiations whose possession or use is authorised.

g) Official documents under which the corresponding permit is granted and procedure for its revision.

h) Requirements regarding personnel licences for operation of the facility.

i) Guarantees to be contracted by the licensee with respect to civil liability for nuclear damage to third parties.

j) Limits and conditions regarding nuclear safety and radiological protection.
k) Other conditions that might be appropriate to the case.

Article 8. Licensee's responsibilities

1. The licensee of each permit shall be responsible for the safe operation of the facility or activity, in all cases in accordance with the provisions of the official documents under which the permit is granted. The licensee shall be responsible for applying this documentation and keeping it updated, for informing the Ministry of Industry, Tourism and Trade and the Nuclear Safety Council of whatever issues might affect the conditions of the permit or nuclear safety and radiological protection and, in general, for meeting the requirements of the regulations in force. The licensee shall also be responsible for the facility in whatever emergency situations might arise.

The licensee shall guarantee that all physical or legal persons intervening as contractors or subcontractors also meet the requirements of the previous paragraph, in the cases corresponding to them.

2. As regards safeguards and the physical protection of nuclear materials, the licensee shall be obliged to carry out activities relating to the monitoring, control and custody of these materials, to allow for the performance of whatever inspections and checks might be necessary, when these arise as a result of the commitments made by the Spanish State or of internal standards, and to inform the authorities of any relevant event, in keeping with the specific standards applicable in this area.

3. The licensee shall continuously strive to improve the nuclear safety and radiological protection conditions of his facility. In this respect he shall analyse technical improvements and existing practices, in accordance with the requirements established by the Nuclear Safety Council, and implement those considered most adequate by the latter.

The Nuclear Safety Council may at any time require the analysis of the licensee for the implementation of improvements to nuclear safety and radiological protection.

4. The licensees of nuclear or radioactive facilities or of activities relating to ionising radiations shall be responsible for their safety. With this ain in mind, the organisations responsible for the management of these facilities or activities shall avail themselves of human and/or material resources suitable for the maintenance of conditions of safety and, in this respect, shall require that all personnel performing services in such nuclear and radioactive facilities whose work is related to nuclear safety, radiological protection or physical protection, or whose activity might in some way interfere with the operation of the facility, meet the mandatory conditions of physical and psychological suitability to safeguard nuclear and radiological safety.

In this respect and regardless of their legal relationship with the facility, these personnel may be subjected to preventive analyses and controls to detect the consumption of toxic substances or drugs, these consisting of the performance of certain tests under the direction of professionally accredited personnel. The tests shall be performed on the basis of criteria of proportionality in relation to their objectives, with the minimum risk and maximum indemnity possible for the health of the individual affected and the right to information on the tests to be performed and their results, in all cases with full respect for the dignity, intimacy and integrity of the person.

The measures adopted shall be duly reported to the representatives of the workers of the facility, respecting the confidentiality of the results obtained.

What is contemplated in the previous paragraph is understood to be without prejudice to other corporate obligations arising from the health and safety standards applicable at the work centre.

Article 8 b. Reporting of deficiencies

In accordance with the provisions of article 13 of Law 15/1980, of April 22nd, creating the Nuclear Safety Council, and as regards the obligation of persons at the service of nuclear and radioactive facilities to inform the licensees of any event that might affect the safe operation of such facilities or radiological protection:

a) The licensee shall establish a procedure to guarantee that all the personnel of the facility's organisation, and of contractor companies and external companies rendering services at the facility, notify the licensee of those deficiencies and malfunctions that, in the opinion of the notifying party, might affect nuclear safety or radiological protection, all the above without prejudice to the general rights of citizens established in the corresponding laws.

This procedure shall be additional to the habitual reporting channels and may be used at the choice of the notifying party. Likewise, the notifying party may make use of this procedure if, having reported a deficiency using the habitual channels of communication, he were to conclude that his denouncement or claim had not received sufficient attention.

The procedure should include attention to all communications, regardless of whether the notifying parties are identified or anonymous, and the communications shall be included on a numbered and dated register with a copy of the notifications received and a reference to the information provided in response and the verification measures or steps taken as a result. Radioactive facilities having scientific, medical, agricultural, commercial or industrial functions, as described in Title III of this Regulation, may opt to register these notifications and the responses and verification measures or steps taken in the operations log referred to in Title VI of this Regulation.

If identified, the notifying party shall receive a written response from the licensee of the facility within 7 working days with information on the measures adopted or foreseen.

Following this period, without the licensee having provided a written response to the notifying party, the latter shall transmit the information in question to the Nuclear Safety Council.

The procedure shall guarantee the existence of an abbreviated arrangement for cases in which the notifying party considers there to be reasons for urgency, in which respect the licensee shall be obliged to reply to the notifying party immediately, and the latter may, if he considers it to be appropriate, transmit the information to the Nuclear Safety Council at the moment of identifying the deficiency or malfunction appreciated.

Without prejudice to the above, Law 30/1992, of November 26th, on the Legal System of Public Administrations and General Administrative Procedure shall be applicable as a supplementary measure in this area.

b) The exercising of this right shall not imply any adverse effects for the worker in his job post, other than in those cases in which he were determined to have acted in bad faith.

Any decision taken by the licensee that implies any damage or harm to the labour-related rights

of workers who have exercised the right contemplated in this article shall be considered null and void.

Article 9. Coverage of risks

1. In no case shall the entry of nuclear substances or other radioactive materials into nuclear or radioactive facilities or the operation of such facilities be permitted without the coverage of nuclear risks being guaranteed in accordance with the provisions in force.

2. **(Repealed)**

3. Any variation, suspension or cancellation of the coverage of nuclear risk shall be reported immediately by the operator to the Directorate General for Energy and the Nuclear Safety Council, the said Directorate General being responsible for determining how to proceed in each case.

Article 10. Infringements

Any infringements of the provisions of the present Regulation shall be penalised in accordance with chapter XIV of the Nuclear Energy Act, Law 25/1964, of April 29th, modified by the fifth additional provision of the Electricity Industry Act, Law 54/1997, of November 27th.

Title II. Nuclear facilities

Chapter I
Classification and permits

Article 11. Definitions

The following are nuclear facilities:

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

b) Nuclear reactors: any structure containing nuclear fuels arranged in such a manner as to allow for a self-sustaining process of nuclear fission without the need for any additional source of neutrons.

c) Manufacturing facilities using nuclear fuels to produce nuclear substances and facilities for the treatment of nuclear substances, including facilities for the treatment or reprocessing of irradiated nuclear fuels.

d) Facilities for the storage of nuclear substances, with the exception of locations at which these substances are stored incidentally during transport.

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

Article 12. Required authorisations

1. Nuclear facilities will require the following authorisations, as appropriate:

a) Preliminary or site authorisation: this is an official recognition of the proposed objective and of the suitability of the selected site, granting of which entitles the licensee to request a permit for construction of the facility and to initiate the preliminary infrastructure works authorised.

b) Construction permit: this entitles the licensee to initiate the construction of the facility and to apply for the operating permit.

c) Operating permit: this entitles the licensee to load the nuclear fuel or to introduce nuclear substances in the facility, to carry out the nuclear testing programme and to operate the facility within the conditions established in the permit. This permit will first be granted provisionally,

until such time as the nuclear tests have been successfully completed.

Likewise, and without prejudice to its eventually being renewed in accordance with the provisions of section 1 of article 28, this permit entitles the licensee, on shutdown of the activity for which the facility was originally conceived and in the terms established in the declaration of such shutdown, to carry out the operations imposed by the Administration prior to the granting of the dismantling permit or the dismantling and decommissioning permit in the case of facilities for the definitive disposal of spent nuclear fuel or radioactive waste.

d) Modification permit: this entitles the licensee to introduce modifications in the design of the facility or to its operating conditions, in those cases in which the criteria, standards and conditions on which the operating permit is based are altered.

e) Modification performance and assembly permit: this entitles the licensee to initiate the performance, execution and assembly of those modifications that, in view of their large scope or because they imply significant works and assembly operations, need to be expressly authorised, in the opinion of the Directorate General for Energy Policy and Mines or the Nuclear Safety Council.

f) Dismantling permit: on expiry of the operating permit, this entitles the licensee to initiate activities for decontamination, the disassembly of equipment, the demolition of structures and the removal of materials, in order ultimately to allow the site to be fully or partially cleared. The dismantling process will end with a declaration of decommissioning, which will release the licensee of the facility from his responsibility as operator and, in the event of restricted clearance of the site, will define the applicable limitations on its use and the responsibility to maintain them and monitor their compliance,

g) Dismantling and decommissioning permit: in the case of facilities for the definitive disposal of spent nuclear fuel and radioactive waste, this entitles the licensee to initiate the final engineering works and other tasks required to guarantee the long-term safety of the disposal system, as well as the dismantling of auxiliary installations when this is determined, ultimately allowing for the cordoning off of areas to be subjected to radiological surveillance and control or controls of other types over a given period, and for the release from control of the other areas of the site. The dismantling and decommissioning process will conclude with a decommissioning declaration issued by the Ministry of Industry, Energy and Tourism, following a report by the Nuclear Safety Council.

Nuclear safety and radiological protection aspects will be regulated by the Nuclear Safety Council during the dismantling and decommissioning of the facility and during the stage of control and surveillance subsequent to decommissioning, including the scope and content of the safety demonstration or study in each stage.

In addition, the following should be authorised:

h) The temporary storage of nuclear substances at a facility in the construction phase not holding an operating permit.

i) Change of nuclear facility ownership. The new licensee shall accredit sufficient legal, technical and economic-financial capacity to undertake the activities contemplated in the permit.

The authorisations contemplated in the previous sections shall be granted following a report by the Nuclear Safety Council, as established in this Regulation.

2. The nuclear facilities referred to in paragraphs b) and d) of article 11 of this Regulation, with the exception of those for the definitive disposal of spent nuclear fuel and radioactive waste, may request the preliminary and construction permits simultaneously.

3. Prior to the granting of the permits referred to in section 1 of this article, with the exception of those dealt with in paragraphs e) and h) of the said section, the corresponding documentation shall be transferred to the autonomous community for a period of one month for the submittal of allegations, in accordance with the provisions of article 4.2 of this Regulation.

4. The Minister of Industry, Energy and Tourism shall be responsible for granting the authorisations contemplated in section 1 of this article, except for those referred to in paragraphs d), e) and h), which shall be granted by the Director General for Energy Policy and Mines.

Article 13. Information Committee

1. During the construction, operation and dismantling of nuclear power plants there shall be an Information Committee that shall operate as the collegiate bodies contemplated in article 40.3 of Law 6/1997, of April 14th, on the Organisation and Operation of the General State Administration.

2. This Committee, the members of which shall be appointed by the Director General for Energy Policy and Mines, shall be made up of representatives of the Ministry of Industry, Tourism and Trade, the licensee of the facility, the Nuclear Safety Council, the regional delegations of the Government and of the autonomous communities in which the facility is housed, the Directorate General for Civil Defence and Emergencies and the municipalities included in Zone 1 defined in the corresponding nuclear power plant off-site emergency plans.

3. The Committee shall be presided over by the representative of the Ministry of Industry, Tourism and Trade, and the vice president shall be the mayor of the municipality in whose territory the facility is located. A staff member of the Ministry of Industry, Tourism and Trade shall act as secretary of the Committee and shall also be appointed by the Director General for Energy Policy and Mines.

Other representatives appointed by the Director General for Energy Policy and Mines, on his/her own initiative or in response to a proposal by the Committee, may form part of the latter.

4. The functions of this Committee shall be to inform the different entities represented of the development of the activities regulated in the corresponding permits and jointly deal with other matters of interest to these entities.

Chapter II
Preliminary authorisation

Article 14. Application

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

a) Declaration of the requirements to be met and justification of the facility and the site selected.

b) Descriptive report. This report shall consist of a description of the fundamental elements of the facility and, in general, shall include basic information on the installation, the technology to be used, a preliminary supplies plan and forecasts for dismantling.

c) Preliminary construction project. Phases of performance and timeframe. Preliminary economic study relating to financial investments and costs foreseen.

d) Study characterising the site and the area of influence of the facility, including sufficient data on those parameters of the site that might affect nuclear safety or radiological protection, including demographic and ecological parameters and activities relating to town and country planning.

e) Organisation foreseen by the applicant for supervision of the project and to guarantee quality during construction.

f) Description of the activities and preliminary infrastructural works to be carried out following granting of the authorisation and prior to application for the construction permit.

Article 15. Procedure

1. On reception of the application for the preliminary authorisation, the Ministry of Industry and Energy shall send a copy to the corresponding regional delegation of the Government for the opening of a period of public information, which shall begin with publication of an extract announcement in the Official State Gazette and that of the affected autonomous community, underlining the purpose and the main characteristics of the facility. This announcement shall establish that those persons and entities who consider themselves to be affected by the project shall have thirty days in which to submit whatever written allegations they deem to be appropriate to the corresponding regional delegation of the Government.

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

3. On expiry of the thirty-day period for public information, the delegation of the Government will carry out appropriate checks in relation to both the documentation submitted and the written allegations and will issue a report on both, submitting the dossier to the Ministry of Industry and Energy, with a copy to the Nuclear Safety Council.

Article 16. Reports

Before issuing the corresponding authorisation, the Ministry of Industry and Energy will gather reports from the other affected public Administrations and Institutions and from other Ministries, whenever the nature of the authorisation so requires.

Chapter III
Construction permit

Article 17. Application

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

a) General facility project.

b) Programme of acquisitions, including a list of the different items and equipment and their origin.

c) Budget, financing, period for performance and technical collaboration regime.

d) Economic study, updating the study submitted with the application for the preliminary authorisation.

e) Preliminary safety analysis report, which shall include the following:

1. Description of the site and surrounding area, with current data on parameters affecting nuclear safety and radiological protection, includ-

ing data on demography, ecology and land and water use and any other data that might contribute to a better understanding of the site, along with plans for the surveillance and verification of basic parameters representative of the site.

2. Description of the facility, including the criteria adhered to in the design of those components or systems on which the safety of the facility depends.

3. Analysis of foreseeable accidents and their consequences.

4. Analytical radiological study estimating theoretically the potential radiological impact of the facility on the population and the environment.

5. Updating of the organisation foreseen by the applicant to supervise project performance and guarantee quality during construction.

5. Organisation foreseen for the future operation of the facility and preliminary operating personnel training programme.

7. Pre-operational environmental radiological surveillance programme, using as a basis the conclusions obtained from the analytical radiological study, allowing for the establishment of the reference or radiological background level of the area monitored.

8. Construction quality assurance programme.

f) Technological, economic and financial forecasts for dismantling and decommissioning.

g) Administrative concessions and authorisations to be granted by other Ministries and public Administrations, or documents accrediting application for such concessions and authorisations with all the necessary requirements.

Article 18. Pre-nuclear testing

During the construction and assembly of nuclear facilities, and prior to the loading of nuclear fuel or the acceptance of nuclear substances at the installation, the licensee shall be obliged to perform a programme of nuclear tests which shall include the tests, verifications and checks to be carried out on the different systems of the facility.

The objective of this pre-nuclear testing programme is to accredit the adequate performance of the different items of equipment or parts of the facility, as regards both nuclear safety and radiological protection and the applicable industrial and technical standards.

Article 19. Approval and performance

1. The pre-nuclear testing programme shall be proposed by the licensee of the authorisation. This programme, along with the technical conditions for each test, must be approved prior to performance by the Directorate General for Energy, following a report by the Nuclear Safety Council.

2. The tests and verifications shall be performed under the responsibility of the licensee. Both the procedures used for test performance and the results obtained shall be duly documented. The Directorate General for Energy shall, following a report by the Nuclear Safety Council, indicate which of the tests and verifications included in the pre-nuclear testing programme are to be carried out in the presence of inspectors from the Nuclear Safety Council and the Ministry of Industry and Energy.

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

Chapter IV
Operating permit

Article 20. Application

The application for the operating permit must be accompanied by the following documents, updating where appropriate the contents of those submitted when requesting the construction permit:

a) Safety analysis report. This shall contain the information required to carry out an analysis of the facility from the point of view of nuclear safety and radiological protection, as well as an analysis and assessment of the risks implied by operation of the facility under both normal and accident conditions. It shall also include detailed descriptions of the safety functions of all the safety-related structures, systems and components, their design basis and their operation under all operating conditions, including shutdown and accident conditions. The report shall also identify the regulations, codes and standards applicable to the facility. In particular, the documents shall refer to the following issues:

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

2. Description of the facility as constructed and of the processes that are to take place at the installation. Included shall be a description of the nuclear and non-nuclear instrumentation, control and protection systems, containment buildings or structures, auxiliary systems, radioactive waste collection and disposal systems and any other system or component of importance for the safety of the facility.

3. Analysis of foreseeable accidents arising as a result of the malfunctioning of items and apparatus, operating errors or off-site agents and their consequences.

4. Analytical radiological survey of the facility.

5. Operational environmental radiological surveillance programme, with a view to assessing the impact of operation of the facility.

b) Operating regulation. This document shall contain the following information:

1. List of job posts entailing nuclear responsibility, from operations manager or chief to supervisors, operators, persons responsible for radiological surveillance and persons responsible for nuclear test performance.

2. Organisation. The document shall specify the organisation and the functions of the personnel of the facility under both normal and emergency conditions. It shall also describe the safety management implemented. The basic educational and training programmes for licensed and non-licensed personnel shall be defined and the technical competence for each specific mission shall be established, along with the on-going training programmes considered suitable.

3. Operating standards under normal and accident conditions. These standards and the procedures through which they are developed must refer to the facility overall and to the different systems of which it is made up.

c) Operating technical specifications. These shall contain the limit values of variables affecting safety, the actuation limits of automatic protection systems, the minimum operating conditions, the programme of revisions, calibration and periodic inspections of systems and components and operational control.

d) Site emergency plan. This shall detail the measures contemplated by the licensee and the assignment of responsibilities to respond to accident conditions, with a view to mitigating the

consequences of such conditions, protecting the personnel of the facility and immediately notifying the competent bodies of their occurrence, including initial assessment of the circumstances and consequences of the situation. It shall also set out the actions foreseen by the licensee to aid in the protection interventions to be performed outside the facility, in accordance with the off-site emergency plans established by the competent bodies, when so determined by the Nuclear Safety Council.

e) Nuclear testing programme. This shall describe the tests, their objectives, specific techniques and foreseen results. For each test there shall be an indication of the procedure to be adhered to, the data to be gathered in their performance and the maximum and minimum values foreseen for the variables of interest during test performance. It shall also include the safety criteria applicable for the performance of these tests.

f) Quality assurance manual. This shall establish the scope and content of the quality programme applicable to the testing and operation of safety-related systems, structures and components, as well as to the design, manufacturing, construction, testing and operation of modifications thereto.

g) Radiological protection manual. This document shall include the radiological protection standards of the facility.

h) Radioactive waste and spent fuel management plan, incorporating where appropriate the contracts established with management companies and including, among other things, a system for the possible declassification or clearance of waste materials with radioactive contents.

i) Final economic study, which shall analyse compliance with the economic and financial forecasts and establish the total and effective sum of the facility.

j) Dismantling and decommissioning or shutdown forecasts. This shall describe, among others, the forecasts relating to the final management of the radioactive wastes generated and the cost study and economic and financial forecasts to guarantee such dismantling and decommissioning or shutdown. In this respect the applicant shall provide proportionate guarantees covering whatever costs and contingencies might arise as a result of the processes of dismantling and decommissioning or shutdown of the facility, even in the event of insolvency, shutdown of the business or any other contingency, specifying the amounts of the said guarantees and the manner in which they will be made effective, with the exception of those facilities for which the financing of dismantling and decommissioning or shutdown were contemplated by the sixth additional provision of the Electricity Industry Act, Law 54/1997, of November 27th, declared in force by the Electricity Industry Act, Law 24/2013, of December 26th.

The guarantee demanded in paragraph j) of the present article shall be put into place prior to granting of the operating permit. The Directorate General for Energy Policy and Mines may, following a report by the Nuclear Safety Council, authorise the updating of this guarantee in the event of circumstances or modifications to the facility that might have a significant impact on its dismantling and decommissioning or shutdown, or in accordance with the work already performed in relation to these activities. This guarantee shall be independent from any other guarantee required by the environmental or mining-related legislation.

Article 21. Nuclear testing

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

2. The nuclear testing programme shall include the set of tests, verifications and checks to be performed on each of the different systems of the facility, from the moment of the initial loading of the nuclear fuel or the acceptance of nuclear substances at the installation to full operability, including those to be carried out at nuclear power plants and reactors at one hundred percent of the authorised thermal power level.

The provisions of article 19 shall be applicable to the performance of the programme of nuclear tests.

3. During the performance of the tests, the official representatives of the Nuclear Safety Council shall be empowered to suspend them at any time when, in their opinion, their continuation would be potentially dangerous. In such cases, the Nuclear Safety Council shall adopt appropriate measures and inform the Directorate General for Energy.

Article 22. Test results

On completion of the nuclear testing programme, the licensee of the permit shall submit the following to the Directorate General for Energy and the Nuclear Safety Council.

a) Nuclear testing programme results.

b) Proposal regarding modifications to the operating technical specifications if the tests performed suggest that their incorporation would be advisable.

Article 23. Granting

The Nuclear Safety Council shall submit a report to the Ministry of Industry and Energy on both the results of the tests and the modifications to be made, where appropriate, and on the conditions for renewal of the operating permit for the period established.

The Ministry of Industry and Energy will then issue the new operating permit for the corresponding period.

Article 24. Modification of conditions

The Directorate General for Energy, officially or in response to a proposal by the Nuclear Safety Council, within the realms of their respective competences, may require the licensee of a permit to incorporate new conditions or alter those already included in the provisions of the permit in force.

Chapter V
Modifications to the facility

Article 25. Modification of facilities

1. Any modifications to the design or operating conditions that affect the nuclear safety or radiological protection of a facility, as well as the performance of tests at the facility, shall be previously analysed by the licensee in order to verify that there is continued compliance with the criteria, standards and conditions on which its authorisation is based.

If the analysis carried out by the licensee concludes that compliance with the requirements set out in the previous paragraph continues to be guaranteed, the licensee may then undertake the modification or tests, periodically reporting on performance to the Ministry of Industry and the Nuclear Safety Council.

In the event that the design modification were to imply modification of the criteria, standards and conditions on which the operating permit is based, the licensee shall request a modification authorisation from the Ministry of Industry and Energy, which must be effective before the entry into service of the modification or the performance of the tests.

2. Quite apart from the aforementioned authorisation, when in the opinion of the Directorate General for Energy or the Nuclear Safety Council the modification is major in scope or involves significant construction or assembly works, the Directorate General for Energy shall require the licensee to apply for a performance and assembly permit for the modification. In no case may assembly or construction activities for this type of modification be carried out prior to granting of the corresponding authorisation.

3. The operator shall, with the frequency determined in Title VI of the Regulation, inform the Directorate General for Energy and the Nuclear Safety Council of the modifications foreseen, implemented or in the course of implementation and of the corresponding safety assessments.

Article 26. Request for authorisation

The request for authorisation to undertake the modification shall be accompanied by the following documentation:

a) A technical description of the modification, identifying the underlying reasons for it.

b) The safety assessment performed.

c) Identification of the documents that would be affected by the modification, including the text proposed for the safety analysis and the operating technical specifications, where applicable.

d) Identification of the tests to be performed prior to reinitiating operation.

Article 27. Documentation of the authorisation

When required in application of the provisions of article 25, the request for authorisation for performance and assembly of the modification shall be accompanied by the following documentation.

a) General description of the modification, identifying the underlying reasons for it.

b) Standards to be applied in the design, construction, assembly and testing of the modification.

c) Basic design of the modification.

d) Organisation foreseen and quality assurance programme for project performance.

e) Identification of the scope and contents of the analyses required to demonstrate the compatibility of the modification with the rest of the facility and to guarantee continued maintenance of its levels of safety.

f) Destination of the equipment to be replaced, where appropriate.

g) Acquisitions plan and budget in the case of major modifications.

Article 28. Definitive shutdown

1. The licensee of an operating permit shall inform the Ministry of Industry, Energy and Tourism, with at least one year's notice of the foreseen date, of his intention to put an end to the activity for which the facility was designed. Both in this case and when the shutdown of the activity is due to some other circumstance, the Ministry of Industry, Energy and Tourism shall, following a report by the Nuclear Safety Council, declare the shutdown of the activity, establishing in the operating permit the conditions applicable to the activities to be performed at the facility as from that moment and the period for application for the dismantling or dismantling and decommissioning permit.

The said shutdown of activity shall be definitive, as from the date of entry into force of the cor-

responding declaration, when brought about for reasons of nuclear safety or radiological protection. When the said shutdown of activity is due to other reasons, the licensee may request the renewal of the operating permit within one year as from the date of entry into force of the aforementioned declaration. The procedure to be adhered to in this case shall be that established for renewal of the operating permit, attaching updates of the corresponding documents, to which shall be added the additional documentation or requirements determined in each case, taking into account the specific situation of the facility, scientific and technological progress, the applicable standards and the in-house and industry operating experience accumulated during the operating period of the facility, along with other safety-related aspects. If this request is not forthcoming within the aforementioned one-year period, the declaration of shutdown shall likewise become definitive.

2. Prior to granting of the dismantling permit the licensee of the operating permit shall have performed the following:

a) Unloading of the fuel from the reactor and the storage pools or, otherwise, availability of a spent fuel management plan approved by the Ministry of Industry and Energy, following a report by the Nuclear Safety Council.

b) Conditioning of wastes generated during operation.

Chapter VI
Dismantling permit and declaration of decommissioning

Article 29. Necessary authorisations

The decommissioning of a nuclear facility will require a dismantling permit and a declaration of decommissioning. For the purposes of this Regulation, dismantling shall be understood as being the series of activities performed after having obtained the corresponding authorisation, allowing the declaration of decommissioning to be requested, which will imply declassification of the facility and the total or restricted release of the site.

Article 30. Application

1. The application for the dismantling permit shall be accompanied by the documentation indicated in sections b), c), d), f), g), h) and k) of article 20, its contents being adapted to the dismantling situation of the facility.

In any case, the provisions of the applicable environmental legislation shall be complied with. In addition, the application shall be accompanied by the following documents:

a) Safety analysis, containing the following:

1. Descriptive study of the current status of the facility, the site and its area of influence, containing a radiological characterisation of the facility and its site prior to dismantling.

2. General dismantling project, containing the scope of each phase of the project proposed, if there are several, along with a description of the expected state of the facility during and after their performance. For the phase for which authorisation is sought, whatever significant activities and tasks might imply alterations to the conditions of nuclear safety or radiological protection should be specified.

3. Safety assessment of the dismantling project, which shall contain the applicable radiological standards and criteria and an analysis of accidents, identifying the foreseen risks and corresponding preventive measures.

4. Study of the environmental radiological impact during performance of the dismantling programme and after. This shall also contain an environmental radiological surveillance plan applicable during performance of the dismantling programme.

b) Declassifiable materials control plan, which shall include a description of the processes and equipment used to verify compliance with the radiological criteria for declassification of the waste materials generated.

c) Site restoration plan, which shall include the proposal and justification of the methodology for final radiological characterisation of the site, in order to demonstrate compliance with the radiological criteria established for its release, either complete, partial or with restrictions on use. There shall also be a proposal regarding the resources required to establish and maintain institutional legal controls guaranteeing compliance with the radiological criteria.

d) Economic study of the dismantling process, with the financial investments and costs foreseen for the performance of dismantling operations up to decommissioning.

2. The Nuclear Safety Council shall define the scope, content and preparation of the documentation listed through technical instructions or guidelines or specific requirements.

Article 31. Ownership of dismantling

If the licensee of the dismantling activities is to be different from the holder of the operating permit, the former shall submit the corresponding application. The transfer of ownership shall be authorised jointly with the dismantling permit and, previously, the holder of the operating permit shall have met all the conditions set out in article 28 of this Regulation.

Article 32. Content of the permit

The dismantling permit shall include the general approach to be adopted and, if the dismantling is to be carried out in different phases, shall regulate only the activities contemplated for the initial phase, the licensee being obliged to apply for a new permit for successive phases.

Article 33. Declaration of decommissioning

1. On completion of the dismantling activities, and following verification of compliance with what is established in the site restoration plan, and the other technical conditions set out in the dismantling programme, the Ministry of Industry, Tourism and Trade will issue the declaration of decommissioning, following a report by the Nuclear Safety Council.

Prior to issuing the declaration of decommissioning, the said Ministry shall transfer the matter to the corresponding autonomous communities with competence in relation to town and country planning and the environment and in whose territory the facility is located for them to submit allegations within a period of one month, in accordance with article 28 of the Nuclear Energy Act, Law 25/1964, of April 29th.

2. When necessary, the Ministry of Industry, Tourism and Trade may, following a report by the Nuclear Safety Council, opt to establish restrictions on use of the land on which the decommissioned nuclear facility was located, the said land being inventoried in accordance with article 81.

Title III. Radioactive facilities

Chapter I
Definition, classification and authorisations

Article 34. Definitions

1. Radioactive facilities are understood to be the following:

a) Installations of any type that contain a source of ionising radiation.

b) Apparatus producing ionising radiations and operating at a potential difference in excess of 5 kilovolts.

c) Establishments, laboratories, factories and facilities in which radioactive materials are produced, used, held, treated, handled or stored, with the exception of incidental storage during transport.

2. Radioactive facilities are classified in three categories.

a) First category radioactive facilities are:

1. Facilities producing uranium, thorium and their compounds.

2. Facilities producing natural uranium fuel assemblies.

3. Facilities using radioactive sources for industrial irradiation purposes

4. Complex installations in which very high inventories of radioactive substances are handled or very high energy flux radiation beams are produced, such that it have a significant potential radiological impact.

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

b) The following are second category radioactive facilities, as long as it is inappropriate to classify them as first category:

1. Installations in which radioactive nuclides that may be used for scientific, medical, agricultural, commercial or industrial purposes and whose total activity is equal to or greater than one thousand times the exception values established in Nuclear Safety Council Instruction IS-05 are handled or stored.

2. Installations using X-ray generating apparatus that might operate at a peak voltage in excess of 200 kilovolts.

3. Particle accelerators and facilities in which neutron sources are stored.

c) The following are third category radioactive facilities:

1. Installations in which radioactive nuclides whose total activity is greater than the exception values established in Nuclear Safety Council Instruction IS-05 are handled or stored.

2. Installations using X-ray generating apparatus with a peak voltage of less than 200 kilovolts.

Article 35. Exemption from consideration as a radioactive facility

For the purposes of this Regulation, installations covered by the assumptions of appendix I will not be considered radioactive facilities.

Article 36. Authorisations required

1. Nuclear fuel cycle radioactive facilities shall require the following authorisations: preliminary authorisation, construction permit, operating permit, dismantling permit and declaration of decommissioning or dismantling and shutdown

permit and declaration of shutdown and, where appropriate, authorisation for modification and change of ownership.

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

Chapter II
Nuclear fuel cycle radioactive facilities

Article 37. Applications

As regards the application and arrangements for and the granting of preliminary authorisations, construction, operating and modification permits, authorisations for change of ownership, dismantling permits, permits for dismantling and shutdown, declarations of decommissioning and declarations of shutdown of first category nuclear fuel cycle radioactive facilities, the provisions of Title II of the present Regulations shall apply, which regulate authorisations for nuclear facilities and adaptation of the corresponding documents to the special characteristics of such installations.

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) Descriptive report on the facility. This shall include a description of the site and details of the construction of the floors, walls, ventilation systems and other analogous items.

Where appropriate there shall be an explanation of the choice of the radionuclides or radioactive sources to be used at the facility and of the solid, liquid and gaseous radioactive waste management systems foreseen for normal operation and accident conditions, including contracts with management companies and for re-exporting and other arrangements, as appropriate in each case.

b) Safety assessment. This shall consist of an analysis and assessment of the risks that might arise as a result of operation of the facility under normal conditions or in the event of an accident. Sufficient data shall be included for an analysis of the risks of the facility, independently of that submitted by the applicant.

c) Verification of the facility. As specifically applicable in each case, a description shall be included of the tests to which the facility is to be subjected and, where necessary, the maintenance plan contemplated.

d) Operating regulation. The working methods and manipulation rules that guarantee the safe operation of the facility shall be submitted. The applicable radiological protection measures shall also be described.

A list of the personnel foreseen shall be included, along with a description of the organisation contemplated and a definition of the responsibilities corresponding to each job post under normal operating conditions and in the event of an emergency.

e) Site emergency plan. This will set out the measures contemplated by the licensee and the assignment of responsibilities to address accident conditions, the aim being to mitigate their consequences, protect the personnel of the fa-

cility and immediately notify the competent authorities of their occurrence, including an initial evaluation of the circumstances and the consequences of the situation. In addition, it will establish the actions foreseen by the licensee to assist in protection activities outside the facility, in accordance with the off-site emergency plans established by the competent authorities, when so determined by the Nuclear Safety Council.

f) Forecasts regarding decommissioning and economic coverage foreseen to guarantee this phase under conditions of safety.

g) Economic budget of the investment to be made, constituted by the full and effective value of the radioactive facility or modification for which authorisation is requested and including all those components that, given their nature, are affected by its operation.

h) Physical protection plan, if the facility has radioactive sources included within the scope of application of the standards governing physical protection.

This will describe the organisational measures, components, equipment and systems whose objective is to achieve an acceptable level of security. The treatment of the information contained in this plan shall be governed by specific standards.

2. In the case of first category installations the following shall also be attached:

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

c) As part of the Operating Regulation:

1. Quality assurance manual and organisation contemplated by the applicant to guarantee quality during construction and operation.

2. Radiological Protection manual with the radiological protection standards and procedures of the facility.

3. Operating technical specifications containing the limit values of variables affecting safety, the actuation limits of automatic protection systems and minimum operating conditions.

Article 39. Granting and effects of authorisation

1. The Ministry of Industry, Tourism and Trade is responsible for granting operating permits, authorisations of change of ownership and declarations of decommissioning for the first category radioactive facilities regulated in this chapter. The corresponding documentation shall be transferred to the Autonomous Community, such that it may issue allegations within a period of one month, in accordance with the provisions of section 2 of article 4.

The Directorate General for Energy Policy and Mines shall be responsible for issuing all other authorisations for radioactive facilities.

2. The operating permit for the radioactive facility entitles the licensee to undertake the assembly and preparation of the operations to be carried out, in accordance with the provisions of the regulations in force and the conditions of the permit.

3. When the facility is ready to start operation, the licensee shall notify the Nuclear Safety Council in order for the latter to perform an inspection visit.

At such time as the Nuclear Safety Council considers that the facility may operate safely, it will issue a notification for start-up, which it will provide to the licensee, informing the Ministry of Industry, Tourism and Trade thereof.

If the inspection performed by the Nuclear Safety Council determines that the facility does not provide sufficient guarantees of nuclear safety or radiological protection, and if the anomalies detected are not corrected by the holder of the permit within the period established, the Council shall notify the Ministry of Industry, Tourism and Trade in order for appropriate measures to be adopted.

4. No radioactive facility regulated in this chapter may start operation before issuing of the notification for start-up, which is what entitles the licensee to initiate operations.

Article 40. Changes and modifications

1. Changes and modifications affecting the following will require authorisation by the Ministry of Industry, Tourism and Trade, through the same arrangements as set out in articles 38 and 39:

a) Ownership of the facility.

b) Location of the facility.

c) Activities authorised by the permit granted.

d) The category of the facility.

e) The incorporation of new particle accelerating equipment generating ionising radiations or the modification of existing such equipment.

f) The incorporation of additional radioactive material not previously authorised with a total activity higher than 3.7 GigaBequerels; for lower levels of activity the provisions of section 2 of this article shall apply.

g) Changes to equipment and structural changes requiring substantial modification of the conditions of the permit that might significantly affect nuclear safety and radiological protection.

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

2. Changes and modifications affecting other aspects of design or of the operating conditions authorised for the facility will require only the express acceptance of the Nuclear Safety Council prior to implementation, the latter notifying the Ministry of Industry, Tourism and Trade.

2. All other changes and modifications may be freely implemented by the licensees, who shall inform the Ministry of Industry, Tourism and Trade and the Nuclear Safety Council thereof by way of the reports referred to section 2 of article 73.

2. In addition to the above, in all cases the licensee shall provide the Ministry of Industry, Tourism and Trade and the Nuclear Safety Council with a revision of the documents referred to in article 38 that are affected by the modification.

Article 41. Dismantling and decommissioning

The licensees of radioactive facilities shall be responsible for their dismantling and decommissioning.

Applications for the declaration of decommissioning shall be accompanied by the following documentation:

a) Technical study of decommissioning performed on the basis of the characteristics of the facility, indicating the inventory of radioactive wastes and materials and of apparatus producing ionising radiations, as well as their destination and the measures taken for the dismantling of the facility and, where appropriate, its decontamination.

b) Economic report, including the cost of decommissioning and forecasts for financing.

Article 42. Declaration of decommissioning

Once the Nuclear Safety Council has checked for the absence of radioactive substances and equipment producing ionising radiations, along with the results of the analysis of the contamination of the facility, it will issue a report to the Ministry of Industry and Energy, which will issue the corresponding declaration of decommissioning.

Title IV. Inspection of nuclear and radioactive facilities

Single chapter
Inspection activities

Article 43. Inspectors

1. The personnel of the Ministry of Industry and Energy and of the Nuclear Safety Council appointed and empowered for performance of the inspection and verification of nuclear and radioactive facilities shall be considered agents of the authority in all matters relating to the exercising of their tasks.

In the exercising of their mission, the said personnel may be accompanied by whatever accredited experts might be considered necessary and shall, having provided due identification, have access to the installations to be inspected without prior notice.

2. The Nuclear Safety Council may temporarily or permanently station accredited personnel at nuclear facilities for the performance of inspection and control missions.

Article 44. Licensee's obligations

1. The licensees of nuclear or radioactive facilities shall be obliged to:

a) Provide access for the inspectors to whatever parts of the facility they consider to be necessary for the performance of their tasks.

b) Facilitate the positioning of the equipment and instrumentation required for the performance of the necessary tests and checks.

c) Make available to the inspectors whatever information, documentation and technical resources might be required for the performance of their mission.

d) Allow the inspectors to take sufficient samples for the performance of the necessary analyses and checks. If the holder of the authorisation so requests, a duly sealed and marked control sample shall be left in his possession.

e) Provide access for the inspectors to the work centres of the suppliers of equipment and services relating to the safety of the facility and the performance of activities, with the scope set out in previous points b), c) and d).

2. The obligations described in points a), b), c) and d) in section 1 shall include also the organisation responsible for any establishment or location in which equipment generating ionising radiations or radioactive materials may be found.

Article 45. Minutes

1. The results of the inspections shall be included in minutes, copies of which shall be provided to the Ministry of Industry and Energy and the licensee, or the person witnessing the inspection on his behalf.

In any case, the licensee of the facility or his representative shall be invited to attend the inspection and sign the minutes. On signing, this person may set out whatever comments he considers to be appropriate. Refusal to do so shall not affect the proceedings or the conclusions established subsequently, and comments made without signing shall not be taken into consideration.

2. The inspection minutes drawn up shall be considered to be truthful as regards the matters dealt with therein, without prejudice to whatever evidence the licensee of the facility might provide in defence of his rights and interests.

The mere placing on record of the minutes shall not exempt the party responsible for their preparation or issuing from including whatever evidence might serve to justify the assertions made or clarify the events occurring, using for this purpose both the minutes themselves and whatever means of proof might be necessary or appropriate.

Article 46. Actions in the event of risk

1. In the event of manifest danger, the Ministry of Industry, Tourism and Trade, and the Nuclear Safety Council or its accredited inspectors, may, within their respective realms of competence, demand the immediate interruption of the works, operation or activities, informing the said Ministry of this action and explaining the underlying reasons for it.

2. In the event of exceptional or emergency situations potentially affecting nuclear safety or radiological protection, and when in the opinion of the Nuclear Safety Council such situations originate in installations, equipment, companies or activities not subject to the system of authorisations of the nuclear legislation and might potentially affect nuclear safety or radiological protection, the provisions of the present chapter shall apply.

Title V. Personnel of nuclear and radioactive facilities

Chapter I
Personnel licences and accreditations

Section 1. Nuclear fuel cycle nuclear and radioactive facilities

Article 47. Licences

1. The personnel directing the operation of and operating the control and protection devices of nuclear fuel cycle nuclear or radioactive facilities shall hold a supervisor and operator licence, respectively, issued by the Nuclear Safety Council.

In the case of nuclear power plants, operation is understood to mean any manoeuvre affecting reactivity, the power level of the reactor or the integrity of the barriers against the release of radioactive material, as set out in the operating procedures.

Alterations to the core, including the loading and unloading of fuel and its transfer, shall require only supervision by a licensed individual with no tasks other than such supervision assigned to him. It shall be possible to obtain limited licences exclusively for this purpose.

2. Persons involved in practical training exercises in the presence and under the supervision of a licensed operator or supervisor as part of an operator or supervisor training programme shall be exempted from the obligation to hold such a licence.

3. In the case of facilities in the dismantling phase, the Nuclear Safety Council will define the systems operation and supervision activities and the handling of radioactive materials to be performed or directed by licensed personnel. Throughout the performance of each dismantling

phase it will be possible to determine the need for licensed personnel and the number of licences required depending on the remaining risks.

4. In the case of other nuclear facilities, the Nuclear Safety Council will define what activities should be performed by the licensed personnel.

5. In addition, nuclear fuel cycle nuclear and radioactive facilities shall be equipped with a Radiological Protection Service, run by a person accredited for this post by means of a Head of Radiological Service Diploma issued by the Nuclear Safety Council. This requirement shall be applicable both during the operating phase of such facilities and during the active phases of dismantling. The need for a Radiological Protection Service during the inactive phases of dismantling shall be determined on a case by case basis by the CSN, in view of the radiological implications of the work performed in each such phase.

Article 48. Characteristics of licences

The operator and supervisor licences 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 for other installations unless this is expressly authorised by the Nuclear Safety Council.

Article 49. Applications

1. Supervisor licences may be requested, depending on the type of facility and the missions assigned during their operation, at least by university graduates or persons with equivalent academic qualifications.

2. Operator licences may be requested, depending on the type of facility and the missions assigned during their operation, at least by university graduates or persons with equivalent academic qualifications or by persons having comparable and adequate training in nuclear safety and radiological protection, this to be favourably assessed by the Nuclear Safety Council.

3. The Head of Radiological Service Diploma may be requested by post-graduates with adequate training in radiological protection.

Article 50. Processing of applications

Applications for operator or supervisor licences and for the Head of Radiological Service diploma shall be addressed to the Nuclear Safety Council and shall include the name and surname(s), nationality, national identity card or, in the case of foreign nationals, foreign resident identification number or, if this is unavailable, passport or travel document number, age and address of the applicant.

The application shall be accompanied by the following documentation:

a) Information on the academic and professional qualifications of the applicant and on his experience.

b) Declaration by the licensee of the facility setting out the missions to be assigned to the applicant and the licensee's favourable assessment regarding his suitability for performance thereof.

c) Medical certificate of aptitude, issued by an occupational risk prevention service following analysis of the physical health and psychological stability requirements for performance of the activities involved in the job post of the licensed person and those involving a risk of exposure associated with the job post.

Article 51. Granting of licences

1. The Nuclear Safety Council shall grant licences and diplomas to all those persons who have, in

the opinion of a panel set up by it, passed the tests and practical examinations established in the personnel training programmes approved, in response to a proposal by the licensee, as part of the operating regulation of the facility.

2. The aforementioned panel shall be made up of a chairman and four members, three of which shall be experts in the type of facility for which the license is requested, one of them proposed by the operator, and the fourth an expert in nuclear safety or radiological protection, who shall act as secretary.

3. The licences and diplomas shall include the limiting conditions considered to be suitable in each case.

Article 52. Renewal

Operator and supervisor licences shall be renewed for maximum successive periods of six years. Applicants for renewal shall request it at least two months prior to the expiry date of their current licence, attaching a declaration by the licensee of the facility accrediting the following:

a) They have continued to exercise effectively and with due competence the specific missions corresponding to each licence, fulfilling the conditions of active presence in the job post established in the technical standards approved by the Nuclear Safety Council.

b) They have successfully attended the on-going training programme.

c) They continue to be qualified as suitable for the licensed job post by an occupational risk prevention service, in the terms established in point c) of article 50.

Article 53. Period of validity (Deleted)

Article 54. Necessary communications (Deleted)

Section 2. Radioactive facilities for scientific, medical, agricultural, commercial or industrial purposes

Article 55. Licences

1. All personnel handling radioactive material or equipment and those directing such activities at facilities regulated in this section shall hold a specific licence issued by the Nuclear Safety Council.

2. There shall be two types of licences:

a) Operator licence, entitling the holder to handle materials or equipment producing ionising radiations in accordance with previously established procedures and instructions.

b) Supervisor licence, entitling the holder to direct and plan the operation of a radioactive facility and the activities of the operators.

3. The personnel accreditations for the management and operation of X-ray facilities for medical diagnosis shall be governed by the provisions of the standards specifically applicable to this type of installations.

The licenses issued by the Nuclear Safety Council shall be valid for the purposes of recognising training on safety and radiological protection, without prejudice to the qualifications and requirements that might be demanded in each specific case, professionally or as a result of the techniques applied.

Article 56. Characteristics of licences

1. The operator and supervisor licences for this type of facilities shall have a minimum period of validity of five years and shall be personal

and non-transferable and specific to each field of application. The Nuclear Safety Council shall establish the fields of application into which the activities of the licensed personnel are to be included, on the basis of the different types of facility and depending on their purpose.

2. The Nuclear Safety Council shall keep a register of operator and supervisor licences issued by fields of application and facility. In this respect, the holders of licences shall provide the Nuclear Safety Council with data on the installations at which they work or have a contract to work.

Article 57. Other services

In addition, and depending on the existing radiological risk, the Nuclear Safety Council may require the licensees of radioactive facilities to have an in-house or contracted radiological protection service, to be led by at least one person accredited for the post by the Nuclear Safety Council.

Article 58. Exceptions

The Nuclear Safety Council may exempt persons directing or handling materials and equipment producing ionising radiations from the obligation to obtain a licence at facilities which, in its opinion, do not pose a significant risk.

Article 59. Applications

1. Operator licences for the facilities contemplated in this section may be requested by persons who have completed at least their obligatory secondary education, or equivalent.

2. Supervisor licences may be requested by persons who have completed at least a university degree course, or equivalent.

3. Head of Radiological Service diplomas may be requested by persons who have completed a post-graduate university degree course and have been adequately trained in radiological protection.

Article 60. Processing of applications

1. Applications for licences and diplomas shall be addressed to the Nuclear Safety Council and include the applicant's name and surname(s), nationality, national identity card or passport number, age and address.

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

a) Information on the academic and professional training of the applicant and his experience, in keeping with the accreditation modes contemplated in the next article.

b) Medical certificate of aptitude, issued by an occupational risk prevention service following analysis of the physical health and psychological stability requirements for performance of the activities involved in the job post of the licensed person and those involving a risk of exposure associated with the job post.

Article 61. Granting

1. The Nuclear Safety Council shall issue the licences, in their respective fields of application, and shall enter on the corresponding register those who:

a) Accredit having passed the courses homologated previously by the Nuclear Safety Council for each type of licence and field of application.

b) Hold academic qualifications based on programmes that, in the opinion of the Nuclear Safety Council, include the knowledge required for a type of licence and field of application.

2. In all other cases, the licences and diplomas shall be granted by the Nuclear Safety Council in response to a proposal from a panel set up by it, which shall judge whether the applicants have, in their field of application, sufficient training and experience for the performance of the job post in question. This panel shall be made up a chairman and four members, experts in radiological protection and in one of the fields of application of the radioactive facilities, one of whom shall act as secretary.

Article 62. Renewal

Operator and supervisor licences shall be renewed for periods equal to that of the initial issue. In this respect, applicants shall request such renewal two months prior to the date of expiry, accrediting that they continue to be qualified as suitable to work in the presence of ionising radiations by a specialist medical service.

Section 3. Period of validity and suspension of licences and diplomas

Article 63. Termination of validity

The licences and diplomas for all types of nuclear and radioactive facilities shall cease to be valid for the following reasons:

a) On expiry, if not duly renewed.

b) On revocation, following appropriate proceedings, in the following cases and when affecting nuclear safety or radiological protection:

1. Due to loss or substantial decrease of the physical health or psychological stability of the holder, accredited by the corresponding medical certificates.

2. Due to the holder's not voluntarily accepting performance of the tests indicated by the licensee or the Nuclear Safety Council to check his suitability.

3. Due to serious voluntary or negligent action or omission in the performance of his functions.

4. Due to expiry of the contractual relationship, in the case of nuclear and radioactive facilities belonging to the nuclear fuel cycle.

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

d) Due to the renouncement of the licence holder.

e) Due to disqualification deriving from sanctions proceedings.

f) Due to any other circumstance, when considered necessary for reasons of safety, following the corresponding sanctions proceedings.

Article 63 b). Suspension of licences and diplomas

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

a) For reasons of safety.

b) Due to loss of the technical qualifications required for the performance of the corresponding functions.

c) As a precautionary measure whenever sanctions proceedings have been initiated, if it considers this to be appropriate.

d) Due to inactivity whenever the job post for which it was issued is not being performed under the conditions and in accordance with the terms established by the Nuclear Safety Council.

Article 63 c). Necessary communications

Any alteration in the physical or psychological conditions of the holder of an operator or supervisor licence or diploma that reduces his capacity or responsibility for performance of his work shall be formally reported to the Nuclear Safety Council within at most fifteen days as from the date on which such alteration is detected. If possible, this notification shall be made by the affected person himself.

Chapter II
Obligations of the operating personnel

Article 64. Operating personnel

1. At all nuclear or radioactive facilities subjected to the authorisation process described in the previous sections, at least the licensed personnel established in the corresponding permit shall be on duty.

2. In the specific case of nuclear power plants, a permanent team including at least one supervisor and one operator shall be set up as from the moment in which the loading of nuclear fuel begins, regardless of the operating status of the facility.

Article 65. Supervisors and operators

1. The supervisor shall be obliged to direct operations in compliance with the operating technical specifications, the operating regulation, the site emergency plan and any other document pursuant to which the corresponding authorisation of the facility has been granted, as regards its operation. Likewise, he shall adhere strictly to the operating procedures, of which an updated copy shall be kept permanently in a previously established location. When there is no procedure for the performance of a given unforeseen operation that cannot be delayed, the supervisor shall undertake to write up such a procedure prior to performance and shall include it in the operations log. In the event of an urgent situation, he shall adopt whatever measures he considers to be appropriate and place them on record in the said log.

2. The operator shall be obliged to operate the control and protection devices, under the direction of the supervisor, adhering strictly to the operating procedures, the operating technical specifications, the operating regulation and any other official document of the facility, as regards its operation.

Article 66. Obligations and faculties

1. The supervisors of nuclear or radioactive facilities are obliged to interrupt their operation at any moment if they consider that the necessary conditions of safety of the installation have been reduced.

2. The operators of nuclear or radioactive facilities are authorised to act in this same way if, in addition to being faced with the circumstances described above, they are unable to inform the supervisor with the necessary haste.

3. The supervisors and operators are obliged to inform the licensee of the facility of any defects that, in their opinion, are to be found in the official documents of the authorisation or in the operating procedures, or of any other that might affect nuclear safety or radiological protection, via the procedure described in article 8 b).

4. The licensed personnel should be aware of and authorise works carried out at the facility, whenever these directly affect its operation.

Article 67. Information for workers

All persons working at nuclear or radioactive facilities must know and adhere to the standards

on protection against ionising radiations and emergency response. In addition, all persons performing tasks relating to nuclear safety or radiological protection must have received the training required for the suitable performance of their functions. In this respect, the licensee of the facility shall clearly define the necessary knowledge and expertise and set up the necessary training programmes, which shall be available to the Nuclear Safety Council for inspection.

Article 68. Head of Radiological Protection Service

The Head of the Radiological Protection Service is responsible for overseeing compliance with the officially approved standards in relation to radiological protection, keeping the supervisor on duty duly informed at all times as regards their application.

In the event of these standards not being adhered to, he shall be obliged to notify the licensee of the facility in writing, keeping the corresponding register available for inspection.

Title VI. Operations log, archives and reports

Single chapter
Obligations of the licensee of the facility

Article 69. Operations log

The holder of a permit for a nuclear or radioactive facility shall be obliged to keep an operations log clearly and specifically reflecting full information on the operation of the installation.

Article 70. Conditions

1. The numbered operations log shall be authorised, sealed and registered by the Nuclear Safety Council; in this respect, the licensee shall request this process from the said Organisation with sufficient notice.

The operations log in use shall be kept in a suitable location. Copies that have been completed shall be filed and shall remain in the custody of the holder of the authorisation. Destruction or loss of the log shall be reported as soon as possible to the Nuclear Safety Council for its appropriate response.

2. The operations log may be checked and revised by the personnel referred to in article 43 whenever they consider this to be appropriate, and, if they consider it to be necessary, they shall note down any pertinent observations.

Article 71. Contents

1. Depending on the nature of the facility, and without limitation, the following information shall be included, with the time and date: start-up, power level and operation, shutdowns, incidents of any type, checks, maintenance operations, modifications, levels of activity, off-site releases of radioactive effluents and storage and disposal of solid radioactive wastes.

Included in the operations log shall be the name and signature of the supervisor or, where appropriate, the operator on duty, and any turnovers or replacements shall be shall be noted down.

2. Before initiating any operation that might leave out of service an item of equipment, instrument or system affecting nuclear safety or radiological protection, this operation shall be explicitly authorised by the supervisor on duty, who shall note down in the log the date and time of the beginning and end of the operation in question and the name of the person responsible for its performance.

Article 72. Filing of documents

The holder of the permit shall be obliged to file all the documents and records required in this Regulation, in other applicable provisions and in the permits issued for the time periods established in each case.

Article 73. Reports

The holder of the permit shall be obliged to submit the following reports to the Directorate General for Energy and the Nuclear Safety Council:

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 significant activities.

b) Reports on any event implying an alteration in the normal operation of the facility or potentially affecting nuclear safety or radiological protection.

c) Annual reports, submitted within the first quarter of each calendar year, on operating experience, design modifications; adaptation to the new requirements of the Spanish legislation, applicable international standards or applicable standards of the country of origin of the project; personnel initial and on-going training programme activities; the results of the environmental radiological surveillance programme and the statistical results of personnel dosimetry controls.

d) In the case of nuclear power plants, and prior to each refuelling or maintenance outage, a report containing the activities foreseen for performance during such outage. Likewise, prior to start-up following the refuelling outage, a safety report on refuelling covering the next operating cycle.

2. Radioactive facilities:

a) An annual report, submitted within the first quarter of each calendar year, containing a summary of the operations log and the statistical results of the personnel dosimetry controls.

b) Reports on any anomalies that might affect safety or radiological protection and on the occurrence of accidents, with details of their circumstances.

c) In the case of first category radioactive facilities belonging to the nuclear fuel cycle, the annual report referred to in previous paragraph a) shall be quarterly. These facilities shall also submit annual reports, within the first quarter of each year, on the results of the environmental radiological surveillance programmes and adaptation to the new requirements of the Spanish legislation or applicable international standards.

Title VII. Other regulated activities

Chapter I
Authorisation of other activities

Article 74. Radioactive materials, equipment, apparatus and accessories

1. The following shall require authorisation from the Directorate General for Energy Policy and Mines, following a report by the Nuclear Safety Council,__without prejudice to the competences of other departments:

a) The manufacturing of apparatus, equipment and accessories incorporating radioactive materials or generating ionising radiations, even though their use be included among the exemptions contemplated in appendix I.

b) Introduction on the Spanish market of consumer goods incorporating radioactive materials, even though their use be included among the exemptions contemplated in appendix I.

c) The commercialisation of radioactive materials and apparatus, equipment, accessories or any other items incorporating radioactive materials or generating ionising radiations, even though their use be included among the exemptions contemplated in appendix I, with the exception of the consumer goods considered in point b).

d) The transfer of radioactive materials without a license to any authorised entity. In this case it will not be necessary to submit the documentation referred to in section 2.

e) Technical assistance with regard to radioactive apparatus and equipment generating ionising radiations.

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

a) Identification of the company or entity: company name, tax identification number, address, certificate of entry on the Mercantile Register and description of business purpose.

b) Report on the activities to be carried out.

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

d) Organisation of the personnel and operating standards of the company.

e) List of technical personnel on the payroll, with information on their academic qualifications and professional experience.

f) List of the facilities, equipment and material resources available to the company or entity for the performance of its activities.

g) Where appropriate, procedures to guarantee the radiological protection of the professionally exposed workers, depending on the tasks to be performed.

3. Intracommunity imports, exports and movements of radioactive materials shall be carried out in compliance with the international commitments entered into by Spain in this respect.

4. Those manufacturing, commercialisation and technical assistance companies that, in view of their activities, need to have available an authorised radioactive facility may request a single authorisation.

Article 75. Conditions

1. In those cases in which it is considered appropriate in view of the nature of the apparatus, equipment or accessories, the authorisation granted to manufacturing, commercialisation and technical assistance companies may include the obligation to keep a register of the activities performed. They shall likewise be obliged to submit to the Directorate General for Energy and the Nuclear Safety Council a quarterly list of variations on the register during the period.

2. Neither radioactive materials nor equipment generating ionising radiations may be supplied to entities not possessing such authorisation when such materials or equipment require authorisation as a radioactive facility for their possession or use.

3. Whenever the authorised manufacturer or supplier becomes aware that a model, item of equipment or accessory commercialised by him has a defect or non-conformity that might negatively affect the reliability of its operation, he shall formally notify his clients and the Nuclear Safety Council as soon as possible and, in all cases, within thirty calendar days of the detection of the said defect or non-conformity.

Article 76. Disposal and treatment of radioactive substances

The disposal, recycling or reuse of radioactive substances or of materials containing radioactive substances from any nuclear or radioactive facility shall be subject to authorisation by the Directorate General for Energy, following a report by the Nuclear Safety Council.

Nevertheless, the disposal, recycling or reuse of such substances or materials may be exempted from this requirement, as long as they contain or are contaminated with radionuclides in concentrations or levels of activity equal to or lower than those established by the Ministry of Industry and Energy, in relation to the definition of radioactive waste referred to in the fourth additional provision of the Electricity Industry Act, Law 54/1997, of November 27th.

Article 77. Transport

The transport of radioactive materials, and the approval or validation of models of packages for the transport of such materials, or special transport of radioactive sources, when so required by the specific regulations on the transport of hazardous goods, shall be subject to authorisation by the Directorate General for Energy, following a mandatory and binding report by the Nuclear Safety Council.

Article 78. Registration of transporters

1. The transporters of radioactive materials, in non-excepted packages, shall declare this activity by entry on a register that will be set up for this purpose at the Directorate General for Energy Policy and Mines, known as the «Register of Transporters of Radioactive Materials». The performance of radioactive materials transport activities shall meet the requirements of both the regulations on the transport of hazardous goods and the regulation on the protection of health against ionising radiations and other applicable nuclear legislation.

2. Companies carrying out transport operations under contract to other registered transporters shall be exempted from entry on this register, the latter being responsible for ensuring that the former comply with the legislation applicable to the transport of radioactive material.

3. Such transporters shall apply for entry on the aforementioned register, attaching the following documentation:

a) Business address of the entity.

b) Types of transport, frequencies and habitual routes.

c) Location and characteristics of facilities and installations that may be used for the reception, distribution and storage in transit of radioactive materials.

4. Transporters shall notify the register of any variations to the data reported.

5. The Directorate General for Energy Policy and Mines shall notify the Nuclear Safety Council and the Ministry of Public Works of any variation on the said register, for their information and appropriate effects.

Article 79. Declaration

Facilities using natural thorium or uranium or their compounds as chemical reagents, in non-exempt quantities not exceeding three kilograms, shall be subject to a procedure of declaration before the Nuclear Safety Council.
This declaration shall include the name of the licensee, the site of the facility, the reagent used and the quantity of same.

Article 80. Storage of spent fuel

The design of casks used for the storage of spent fuel must have been approved by the Directorate General for Energy Policy and Mines, following a mandatory and binding report by the Nuclear Safety Council.

Chapter II
Contaminated Areas

Article 81. Control of contaminated areas

1. The public Administrations or the licensees of facilities or activities, regardless of whether or not they are subject to the system of authorisations contemplated in this Regulation, shall inform the Nuclear Safety Council of any event that might potentially lead to the radiological contamination of land or hydrological resources.

2. Whatever plans might be drawn up for the mitigation of effects or the decontamination of affected land or hydrological resources, this to be undertaken by the licensees, shall be submitted to the Nuclear Safety Council for its favourable appreciation. Following the application of corrective actions, the Nuclear Safety Council shall inspect the area and re-evaluate its radiological conditions, and may issue a report for appropriate action to be taken, determining whatever limitations on use might be appropriate for the affected land or resources, which it shall refer to the corresponding autonomous community.

3. The Nuclear Safety Council shall draw up an inventory of plots or hydrological resources that it knows to have been affected by radiological contamination, notifying the competent authorities for appropriate action to be taken.

Chapter III
Appreciation, certification and validation of designs

Article 82. Appreciation of new designs or models

1. Any person or entity may request that the Nuclear Safety Council issue a favourable declaration regarding new designs, methodologies, simulation models or verification protocols relating to the nuclear safety or radiological protection of the facilities or activities referred to in this Regulation, for which it shall submit an application to the said organisation accompanied by the documents necessary for such declaration to be made.

2. The declaration of the Nuclear Safety Council may be included as a reference in any subsequent process of application for any of the authorisations contemplated in this Regulation, as long as the limits and conditions imposed in the declaration are fulfilled.

Article 83. Certification and validation of new designs and models

1. The following definitions are used for the purposes of this Regulation:

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

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

2. Designs, generic or otherwise, for the following may be certified or validated, among others:

a) Nuclear fuel.

b) Safety assessment methodologies.

c) Simulation models.

d) Verification protocols.

e) Spent fuel storage casks.

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

a) A description of the design to be certified or validated, justifying the foreseen use.

b) Studies making it possible to guarantee that the required conditions of safety are met.

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

d) Any others that the applicant considers to be necessary in support of his request.

Additional provisions

One. Uranium mine permits and restoration plans

The operating permits and the performance of restoration plans for uranium mines will require a mandatory and binding report by the Nuclear Safety Council in relation to radiological protection prior to granting by the competent authority.

Two. Entities providing radiological protection services

Entities contemplated in this Regulation or in others developing the Nuclear Energy Act and providing services in the field of radiological protection, such as radiological protection services or technical units, technical assistance companies or dosimetry services, may be exempted from consideration as radioactive facilities in relation to radioactive calibration sources incorporated in measuring equipment whose possession and use are required for the performance of their functions, this to be specified in the resolution by which they are authorised.

Three. Application of other provisions

1. The application of what is established in the present Regulation is understood to be without prejudice to compliance with the obligations arising from the commitments subscribed to by Spain in relation to non-proliferation and to the provisions of Royal Decree 158/1995, of February 3rd, on the physical protection of nuclear materials.

2. Also applicable shall be what is established in the current Regulations on the Protection of Health against Ionising Radiations and in Royal Decree 413/1997, of March 21st, on the operational protection of external workers running the risk of exposure to ionising radiations due to their intervening in the controlled zone, inasmuch as they do not contradict the present Regulation.

3. The forecasts contained in the present Regulation shall be understood as being without prejudice to the radioactive facilities for medical purposes authorised in accordance with its provisions meeting the requirements of the specific standards applicable in the said sector in their subsequent operation.

4. Facilities containing X-ray apparatus for the purposes of medical diagnosis, and the accreditations of the personnel to direct or operate such facilities, shall be governed by what is specifically regulated in Royal Decree 1891/1991, of December 30th, and complementary provisions.

5. Nuclear and radioactive facilities, overall or in their parts, equipment and accessories, are also subject to the applicable industrial and technical standards, to the extent that they are specifically affected thereby, in accordance with the provisions of section 4 of article 3 of the Industry Act, Law 21/1992, of July 16th. In this respect, the competent Administration of the area in which the facilities are located shall be responsible for guaranteeing their compliance.

Four. Environmental impact assessment procedure

The environmental impact assessment procedure contemplated in Royal Legislative Decree 1/2008, of January 11th, approving the adapted text of the Project Environmental Impact Assessment Law, shall be incorporated in the substantive procedures for authorisation dealt with in this Regulation.

Transitory provisions

One. Facilities currently holding provisional operating permits

The provisions of article 20, paragraphs e), i) and j), will not be applicable to nuclear facilities holding a provisional operating permit as of the date of entry into force of the present Regulation, in accordance with Decree 2869/1972, of July 21st.

Two. Previous procedures

Procedures included within the scope of application of the present Regulation and initiated prior to its entry into force shall ensure compliance with the said Regulation by whatever activities are to be performed subsequent to such entry into force.

Three. Period of validity of authorisation

1. Authorisations valid as of the date of entry into force of this Regulation shall remain valid up to their date of expiry.

2. Over a period of two years as from the entry into force of this Regulation, the licensees of radioactive facilities whose category might be modified by its provisions shall regularise their situation before the Ministry of Industry and Energy, in keeping with the determinations adopted in application of this Regulation.

Four. Period of validity of licences

Current holders of operator or supervisor licences or Head of Radiological Protection Service diplomas who, as of the entry into force of this Regulation, do not have the academic qualifications required to obtain such licences or diplomas, in accordance with the provisions of its title V, may continue to carry out their functions and, where appropriate, undertake the renewal of their accreditation in accordance with the provisions of the present Regulation, except as regards the new academic or qualification requirements, which shall not be applicable to them.

Five. Term for adaptation to new requirements

The licensees of activities and facilities subject to the provisions of this Regulation on nuclear and radioactive facilities who, as of the date of entry into force of this Royal Decree, hold a valid licence or permit, along with the transporters of radioactive materials who are entered on what has to date been called the Register of Transporters of Nuclear Substances and Radioactive Materials, shall have a period of six months to adapt to the new requirements established therein.

Six. Nuclear facilities in which definitive shutdown has been declared

All those facilities that, as of the entry into force of Royal Decree 102/2014, of February 21st, on the responsible and safe management of spent nuclear fuel and radioactive wastes, were to have obtained the declaration of definitive shutdown for reasons other than nuclear safety or radiological protection, may use the established procedure to request the renewal of their operating permits, in the terms set out in the new wording of section 1 of article 28 of this Regulation, as long as a period of one year as from the issuing of the declaration of shutdown has not elapsed.

APPENDIX I

Radioactive facilities: classification and exemption

1. For the purposes of this Regulation, installations in which the situations set out below exist shall not be considered radioactive facilities:

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

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

c) The use of apparatus containing radioactive substances exceeding the activities or values of activity per unit of mass specified in points a) or b), as long as they correspond to a type approved by the Ministry of Industry, Tourism and Trade, in accordance with the provisions of appendix II. The resolution of approval shall specify the conditions for their disposal.

d) The use of all cathode ray tubes used to provide visual images or any other electrical apparatus operating with a potential difference of no more than 30 kV and electron microscopes, as long as under normal operating conditions they do not imply a dose rate of more than 1 µSv/h at any point located at a distance of 0.1 m from the accessible surface of the apparatus.

e) The handling of apparatus emitting ionising radiations different from those contemplated in point d), as long as they correspond to a type approved by the Ministry of Industry, Tourism and Trade, in accordance with the provisions of appendix II.

f) Material contaminated with radioactive substances arising from authorised releases declared by the Ministry of Industry, Tourism and Trade, following a report by the Nuclear Safety Council, as not subject to subsequent controls.

g) The Ministry of Industry, Tourism and Trade, following a report by the Nuclear Safety Council, may declare other practices to be exempt when, despite exceeding the values indicated in table A of Nuclear Safety Council Instruction IS/05, the following conditions are met:

1. The effective dose expected for any member of the public as a result of the exempted practice is around 10 µSv/year or lower, and

2. The collective effective committed dose per year of performance of the practice does not exceed 1 Sv/person, or an evaluation of the optimisation of radiological protection shows that exemption is the optimum condition.

3. The following rules shall be taken into account when using table A of Nuclear Safety Council Instruction IS/05:

a) When necessary, the Nuclear Safety Council shall assign suitable values for the activities and

activities per unit of mass in the case of radionuclides not included in the said table A. The values assigned in this way shall be complementary to those of table A.

b) Nuclides bearing the suffix «+» or «sec» in table A represent the parent nuclides in secular equilibrium with the corresponding daughter nuclides listed in table B of Nuclear Safety Council Instruction IS/05. In this case, the values included in table A refer only to the parent nuclide but already take into account the daughter nuclide(s) present.

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

3. For the purposes of classification of radioactive facilities in categories, as contemplated in article 34, the reference as regards exempt activity per nuclide shall be what is included in the second column of table A of Nuclear Safety Council Instruction IS/05, such that:

a) Third category facilities will be those at which the activity is higher than the exemption value and lower than one thousand times this value.

b) Second category facilities will be those at which the activity is equal to or higher one thousand times the exemption value.

c) In the case of mixes of isotopes, if the sum of the quotients between the activity present in each isotope and the exemption activity is between one and one thousand, the facility will be classified as third category, and if equal to or higher than one thousand, as second category.

APPENDIX II

Approval of types of radioactive apparatus

General conditions

1. In order for a type of apparatus incorporating radioactive substances or generating ionising radiations to be approved with a view to its being exempted as a radioactive facility, it must offer sufficient guarantees against the leakage of ionising radiations, under both normal conditions of use and others that might accidentally arise, including possible incorrect use.

2. The apparatus must provide advantages justifying its use, given its potential risk.

3. If radioactive substances are contained, these must exist in the form of an encapsulated source, such that protection against any escape or leakage of the said radioactive substance is ensured.

4. Under normal operating conditions the apparatus shall not present a dose rate higher than 1 μSv/h at any point located at a distance of 0.1 m from its accessible surface.

5. Type approval must be requested by the national manufacturer or, where appropriate, by the importer.

Type approval for apparatus manufactured overseas will require its manufacture or distribution to be authorised in the country of origin, or comply with the legal requirements established in that country, this to be demonstrated by way of appropriate justifying documentation.

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

Coverage may be provided by way of a single type approval for apparatus from one same man-

ufacturer and for one same field of application; apparatus incorporating radioactive substances may not be included in the same approval as apparatus generating ionising radiations.

The application shall be accompanied by the following documents:

a) Documentation accrediting that the applicant has authorisation for a radioactive facility, in the case of national manufacture.

b) Documentation allowing in-depth insight to be gained into the type to be approved. This documentation shall contain at least the following:

1. Identification of the make and model of the apparatus.

2. Detailed description of the apparatus and of its safety systems. Where appropriate, characteristics of the radioactive material and its encapsulation, and of the possibility of gaining access to it.

3. Accrediting documentation including the results obtained from tests verified using the prototype, with respect to the conditions of radiological safety.

4. Drawings of apparatus.

5. Use to which it is to be put and foreseen service lifetime.

6. Documentation accrediting that the apparatus fulfils the purpose for which it is to be used. In the case of new practices, the use of the apparatus shall be justified compared to non-radioactive alternatives and an analysis shall be presented of its advantages compared to the potential risks that it entails.

7. Analysis of risks in situations that might arise accidentally, including incorrect use. In the case of apparatus containing radioactive material, the analysis will consider access to the population as a result of loss of control over it.

8. Operating manual, in Spanish, which will be provided to users and will include the technical characteristics of the apparatus and instructions on use, information on risks and basic recommendations regarding radiological protection to be considered during use or, where appropriate, in the event of an emergency, fault or breakdown.

9. Maintenance programme, in Spanish, including where appropriate the periodic checks that the manufacturer recommends be carried out on systems or parameters affecting the safety of the apparatus, expressly identifying those that, in view of the risks involved, cannot be performed by the user.

c) In the case of apparatus containing radioactive material, a proposal shall be made for its management at the end of its service lifetime. Where appropriate, this proposal will be supported by an analysis of the risks that such management might imply for the population. If removal by the original supplier is foreseen, an original document issued by the latter and guaranteeing such removal shall be provided.

d) Documentation accrediting the quality assurance standards applied by the manufacturer of the apparatus producing ionising radiations.

e) In the case of national manufacture, authorisation for the manufacturing of apparatus producing ionising radiations.

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 whatever documentation is deemed necessary, endorsed by the consulate in Spain of the country of origin.

7. On reception of a copy of all the documentation, the Nuclear Safety Council shall undertake to issue its technical determination regarding safety, for which purpose it may request whatever clarifications it deems to be necessary from the applicant, if this is considered appropriate.

8. The decision of the Nuclear Safety Council, along with whatever clarifications have been provided by the applicant, where appropriate, shall be provided by the said organisation to the Directorate General for Energy Policy and Mines.

9. On reception of the decision of the Nuclear Safety Council, the Directorate General for Energy Policy and Mines shall adopt the appropriate resolution.

10. In its type approving resolutions, the Directorate General for Energy Policy and Mines will describe the characteristics of the type, the use to which it may be put, the conditions and obligations to which it is subject and its corresponding letters and numbers, reserving the right to impose new conditions. The aforementioned approving resolutions shall be published in the Official State Gazette.

11. The Directorate General for Energy Policy and Mines, in response to a proposal by the Nuclear Safety Council, may require the importer or national manufacturer to carry out tests or checks on certain supplied units, in order to verify that the conditions of safety of the type approved are maintained. If deviations are detected, the Directorate General for Energy Policy and Mines may cancel the type approval.

12. The Spanish manufacturer or the importer of apparatus with type approval shall be obliged to provide the following documentation with each individual unit:

a) A certificate setting out the following:

1. The serial number of the apparatus and its date of manufacture.

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

3. That the apparatus corresponds exactly to the type approved.

4. Use for which it has been authorised.

5. Treatment or destiny of the apparatus, and where appropriate of the radioactive substance it contains, at the end of its service lifetime.

6. Any other information established in the type approval.

b) Specifications and conditions established in the type approval.

c) Operating manual in Spanish.

d) Any other documentation established in the type approval.

13. The apparatus producing ionising radiations supplied shall be labelled as established in the corresponding type approval.

14. The user of the apparatus shall be obliged to adhere to the conditions imposed by the Directorate General for Energy Policy and Mines in the resolution by which the type is approved.

This document is purely informative in nature and has no legal value.

CSN CONSEJO DE SEGURIDAD NUCLEAR