

Nuclear Legislation in OECD and NEA Countries

Regulatory and Institutional
Framework for Nuclear Activities



Spain

Spain

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I. General regulatory regime

1. Introduction

In Spain, there are eight nuclear units in operation at six different sites all of which are located on the mainland. Together they provide an installed power of 7 728 MWe, this representing 8.14% of the total installed electricity generating capacity of the country. Six of these units are pressurised water reactors (PWRs) and two are boiling water reactors (BWR). There is also one nuclear power plant (José Cabrera NPP) that came to the end of its operating lifetime in 2006, and the dismantling activities for that reactor will begin soon. Another plant (Vandellós I NPP) has been dismantled to Level 2 and is currently in the dormancy period.

There are other nuclear facilities in operation in Spain:

- the Juzbado fuel assembly manufacturing facility (Salamanca) operated by the company ENUSA Industrias Avanzadas, S.A. which produces fuel assemblies for both the national market and for export;
- the low and intermediate level radioactive waste disposal facility at El Cabril (Córdoba) belonging to the Spanish national radioactive waste management agency Empresa Nacional de Residuos Radiactivos, S.A. (ENRESA); and finally
- the nuclear installation of the Centre for Energy-Related, Environmental and Technological Research (CIEMAT) in Madrid.

The spent nuclear fuel from the power plants is currently stored in the plant pools except in the case of the Trillo and José Cabrera plants which have a temporary storage facility on site especially designed for this purpose (IISF).

All installations in Spain dedicated to the extraction of uranium ore have ceased to operate, the mining sites have either been restored or will be restored in the near future. Following the closure of the "Quercus" Plant at Saelices el Chico in Salamanca, Spain has no uranium concentrates production installation. Other former concentrates manufacturing facilities, such as the "Lobo G" Plant (La Haba, Badajoz), have now been decommissioned or are in the late stages of dismantling and decommissioning, such as the "Elefante" Plant (Saelices el Chico, Salamanca) and the AUM (Andújar Uranium Mill, Jaén). Likewise, there is no enrichment facility.

In addition, there are some 1 400 radioactive facilities and around 28 600 medical radiodiagnosis facilities.

The most important organisations or bodies involved in nuclear activities as described in this study are the following:

- The Ministry of Industry, Tourism and Trade (hereinafter referred to as "MITYC") which among other things is responsible for issuing authorisations and permits for nuclear facilities, certain radioactive facilities and associated activities.
- Autonomous Communities which have functions and services commissioned to the MITYC and related to second and third category radioactive facilities assigned to them by Royal Decree.
- The Nuclear Safety Council (*Consejo de Seguridad Nuclear*, hereinafter referred to as "CSN") is the organisation responsible for nuclear safety and radiological protection.

- ENUSA Industrias Avanzadas, S.A. (hereinafter "ENUSA") which is responsible for certain activities relating to the front end of the nuclear fuel cycle.
- The Empresa Nacional de Residuos Radiactivos, S.A. (hereinafter "ENRESA"), as the mercantile public capital company that carries out activities related to the back end of the nuclear fuel cycle, authorised to undertake the disposal, transport and handling of radioactive waste and activities relating to both the dismantling and decommissioning of nuclear facilities.
- The Centre for Energy-related, Environmental and Technological Research (hereinafter "CIEMAT") which came about from the former Nuclear Energy Board (hereinafter "JEN")¹ and is currently responsible for research and development in this area.

In Spain the nuclear energy sector is governed by a large number of provisions in acts, royal decrees and ministerial orders which will be described in greater detail in this study. The main acts are listed below:

- The main legislation that regulates the development and control of nuclear energy in Spain is Act 25/1964 of 29 April² (hereinafter referred to as the Nuclear Energy Act) which defines basic concepts, *inter alia*, the following:
 - Allocation of responsibilities to authorities and organisations: the act identifies MITYC as the most significant authority as regards the application of the act, and JEN (now the CSN) as the technical body with competence in the area.
 - System of authorisations for nuclear and radioactive facilities and for the possession and use of radioactive materials: the act establishes the causes and circumstances that require a specific authorisation or permit and the system for verification and inspection.
 - Measures for safety and protection against ionizing radiations.
 - Nuclear third party liability for nuclear damages.
 - Sanction regime.
- The regulatory body CSN is governed by the provisions of Act 15/1980, of 22 April, creating the Nuclear Safety Council and by its Statute. This act has been modified on several occasions and has undergone an important revision through Act 33/2007 the objective of which was to modify the functions of the organisation and the administrative and organisational instruments, guaranteeing the effective independence of the body and reinforcing transparency and efficiency measures.
- Other provisions which regulate aspects relating to nuclear energy are as follows:
 - The Electricity Industry Act 54/1997, modified by Act 17/2007, regulates the electricity sector and the economic regulation of energy generating activities, including

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1. The JEN, founded in 1951, was the organisation in charge of verifying correct compliance with the standards and conditions imposed by the authorisations, but was subsequently split into different bodies with the setting up of ENUSA in 1971, the CSN in 1980 and ENRESA in 1984. In 1986 the JEN became CIEMAT.
 2. In recent years the act has been modified by Act 24/2005 on reforms to promote productivity; Act 17/2007 which modified Act 54/1997 in order to transpose the provisions of Directive 2003/54/EC of the European Parliament and Council on common standards for the interior electricity market; Act 33/2007, of 7 November, reforming Act 15/1980, of 22 April, creating the Nuclear Safety Council, or Act 11/2009, of 26 October, regulating Limited Investment Companies Quoted on the Real Estate Market.

the generation of electricity in nuclear power plants. The sixth additional provision of the act, modified by Act 11/2009, sets up a fund for the financing of the activities considered in the general radioactive waste plan. Likewise, its seventh additional provision updates the economic compensations for companies owning nuclear assets the construction of which was prevented by Act 40/1994 on arrangements in the national electricity system.

- - Royal Decree-Law 5/2005 on urgent reforms to promote productivity and improve public contracting modifies the sixth additional provision of Act 54/1997 in order to partially revise the procedure for the management and maintenance of the fund regulated therein, fundamentally with a view to apply the "the polluter pays" principle. It also establishes that the state shall assume the ownership of the radioactive waste, along with the required surveillance activities following the decommissioning of a nuclear or radioactive facility.
- - Act 17/2007 modifies the Electricity Industry Act 54/1997 and implements the provisions of Directive 2003/54/EC concerning common rules for the internal market in electricity. The first additional provision of this act modifies Article 57 of the Nuclear Energy Act establishing a limit for third party liability for nuclear damages of EUR 700 million. Likewise, the second additional provision introduces a new provision in the Nuclear Energy Act, establishing the civil liability of the licensees of nuclear facilities for damages caused to the environment within the national territory, also amounting to EUR 700 million. Both provisions establish a transitory period until the 2004 Protocols revising the Paris Convention on Nuclear Third Party Liability and the Brussels Supplementary Convention on Nuclear Third Party Liability come into force.
- - Act 33/2007 updates the system of sanctions relating to nuclear energy, by modifying chapter XIV of the Nuclear Energy Act.
- - Act 11/2009 regulates limited investment companies quoted on the real estate market, which, as regards the nuclear industry, modifies the Nuclear Energy Act, the modifications to which have been in force since 1 January 2010. According to these modifications, the management of radioactive waste, including spent nuclear fuel and the dismantling and decommissioning of nuclear facilities, constitutes an essential public service reserved solely to the state. ENRESA is assigned to undertake the management of this public service. Thus, ENRESA is established as a technical service and asset of the administration under the auspices of the MITYC and carries out the tasks assigned to it by the Government. Likewise, the fund for the financing of activities mentioned in the general radioactive waste plan will be made up of the tariffs collected for the rendering of the services.

2. Mining regime

In Spain, the mining regime is regulated by the Mines Act 22/1973, modified by Act 54/1980 and by Royal Decree 2857/1978. The investigation and use of radioactive ores is governed by this act in those areas that are not specifically considered in the Nuclear Energy Act, Chapter IV of which deals with the prospecting, investigation and use of radioactive ores as well as the commercialisation of such ores and their concentrates.

According to Article 2 of the Mines Act, all natural deposits and other geological resources in Spain are assets belonging to the public domain, investigation and use of which may be undertaken directly by the state or assigned in accordance with the rules. Pursuant to Article 1 of Act 54/1980, radioactive ores are part of Section D, i.e. resources of national energy interest.

Pursuant to Article 19 of the Nuclear Energy Act, the prospecting, investigation and use of radioactive ores and the obtaining of concentrates are declared to be free throughout the entire national territory, except in those areas set aside by the state. Individuals or companies who wish

to prospect for radioactive ores are required to request an investigation permit from the state and subsequently, if the existence of one or more resources open to national exploitation is revealed, to request an exploitation licence. This licence confers the right to exploit the resources and is granted for a thirty year period, extendable by similar periods to a maximum of ninety years. The permits and licences are granted by the Autonomous Communities, in keeping with the transfer to them of state competences in mining and energy issues, except when the mining activity in question affects several Autonomous Communities or state reserves in which case the competent authority is the MITYC, by virtue of the Mines Act.

In collaboration with the Territorial Services of the Autonomous Communities, and on the basis of data collected directly from the production units, the Directorate General for Energy Policy and Mines of the MITYC draws up mining statistics, included in the national statistics plan, that contain, *inter alia*, information on gross and saleable production, including uranium ore where appropriate. This is the most complete body of information on the production of the mining sector in Spain.

3. Radioactive substances, nuclear fuel and equipment

Article 31 of the Nuclear Energy Act establishes that radioactive materials and nuclear fuel may not be stored or used within the national territory by persons or entities without prior authorisation by the MITYC; the same applies to transfer or resale. Article 28 sets out that nuclear and radioactive facilities shall be subject to a system of authorisations issued by the MITYC, following a mandatory report by the CSN, after having heard the Autonomous Communities with competencies in relation to land planning and the environment. For its part the CSN, pursuant to Article 29 of the act, shall undertake the monitoring of the nuclear and radioactive facilities in each of the phases of their lifetimes in order to verify that they are developed in accordance with the aforementioned authorisations.

The procedure of authorising radioactive facilities is regulated by Royal Decree 1836/1999 approving the Regulation on Nuclear and Radioactive Facilities, as amended. The objective of this regulation is, among other things, to regulate the system of administrative authorisations, for both radioactive and nuclear facilities (for the latter the system is explained in the corresponding section), and other specific activities relating to the use of ionising radiations. Likewise, it defines the types and categories of facilities, includes the system for accreditation of the personnel and the obligations of the licensees of such installations and regulates inspection and control activities.

Article 2 of the Nuclear Energy Act defines “radioactive facilities” as installations of any type that contain a source of ionising radiations, devices producing ionising radiations, and premises, laboratories, factories and installations producing, handling or storing radioactive materials. This definition does not include those installations, devices and materials for which the intensity of the irradiation field created does not pose any risk.

Title I of Regulation on Nuclear and Radioactive Facilities (hereinafter “RNRF”) refers to general provisions common to all types of facilities, Title II refers to the specific regulation of radioactive facilities. In accordance with Article 34 of the RNRF, these facilities are classified into three categories:

- First category radioactive facilities are installations producing uranium, thorium and their compounds and manufacturing facilities for the production of natural uranium fuel assemblies (both are nuclear fuel cycle radioactive facilities), installations using radioactive sources for industrial irradiation purposes and complex installations handling very large inventories of radioactive substances or producing very high energy flux radiation beams.
- Second category radioactive facilities, as long as not classified as first category installations, are facilities storing or handling radioactive nuclides that may be used for scientific, medical, agricultural, commercial or industrial purposes and whose total

activity is equal to or higher than one thousand times the exemption values established in CSN Instruction IS-05, facilities using X-ray generating devices capable of operating with a peak voltage in excess of 200 kilovolts, and particle accelerators and installations storing neutron sources.

- Third category radioactive facilities are installations handling or storing radioactive nuclides with a total activity higher than the values established in IS-05 and lower than one thousand times these values and installations using X-ray generating devices with a peak voltage of less than 200 kilovolts.

Fuel cycle radioactive facilities require the same authorisations and arrangements as those for nuclear facilities (preliminary authorisation, construction permit, operating permit, dismantling and decommissioning declaration and, where appropriate, authorisation for modification and change of ownership), as a result of which they are dealt with in the section referring to nuclear facilities. The rest of the nuclear facilities, however (for scientific, medical, agricultural, commercial or industrial purposes) require an operating permit, a declaration of decommissioning and, where appropriate, an authorisation for modification and change of ownership, which entails a more simplified process.

The MITYC is responsible for the granting of operating licences, changes of ownership and declarations of decommissioning for first category radioactive facilities. The documentation required for this is sent to the Autonomous Communities for comments to be submitted within one month. The Director General for Energy Policy and Mines is in charge of issuing the authorisations for radioactive facilities for scientific, medical, agricultural, commercial or industrial ends, although several Royal Decrees transfer the functions of the MITYC in relation to second and third category radioactive facilities to certain Autonomous Communities.

Before starting up the facility, the licensee is required to notify the CSN which subsequently makes an inspection visit. If this organisation establishes that the facility is capable of operating safely, it issues a start-up notification that entitles the licensee to initiate operations.

All authorised radioactive facilities are included on the register of radioactive facilities of the Directorate General for Energy Policy and Mines of the MITYC. Likewise, there is a register of medical diagnosis X-ray facilities at this same Directorate General as well as a register of companies providing technical assistance and selling X-ray equipment and installations for medical diagnosis purposes.

Furthermore, the following activities also require an authorisation (Title VII of the RNRF):

- the manufacturing of devices, equipment and accessories incorporating radioactive materials or generating ionising radiations;
- the introduction on the Spanish market of consumer products incorporating radioactive materials;
- the commercialisation of radioactive materials and devices, equipment, accessories or other items incorporating radioactive materials or generating ionizing radiations with the exception of the consumer products mentioned in section b);
- the transfer of orphan radioactive materials to any authorised entity; and
- technical assistance relating to radioactive devices and equipment generating ionizing radiations.

In addition to the RNRF, there are more specific regulations governing radioactive substances or facilities, in particular:

- Royal Decree 1085/2009 approving the Regulation on the installation and use of X-ray devices for medical diagnosis governs the use of X-ray equipment for medical diagnosis and installations (including medical-legal and veterinary use), the system of preliminary authorisation of sales and technical assistance activities relating to such equipment and installations, the accreditation of personnel rendering services at such installations and the performance of services and certification of technical characteristics by Radiological Protection Services or Technical Units (RPTU). Pursuant to Article 3 of the aforementioned regulation, the competent bodies of the Autonomous Communities are responsible for including the X-ray facilities on their corresponding register (this inscription to be reported to the MITYC for maintenance of the aforementioned central register), and for issuing authorisations for X-ray equipment sales and technical assistance companies, following a report by the CSN. The CSN, for its part, is responsible for the authorisation of RPTU's and Services.
- Royal Decree 229/2006 on the control of high activity encapsulated radioactive sources and orphan sources, constitutes the transposition to the Spanish legal system of Council Directive 2003/122/Euratom, of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources. The aim is also to achieve the control of this type of sources throughout their lifetime, from manufacturing to the end of their service lifetime as well as to address the risks posed by the existence of this type of sources. Among other issues the Royal Decree provides that all owners of sources are to be authorised in accordance with the RNRF and establishes the obligations of their holders, among which is the maintenance of an inventory sheet of sources including, among other, data, the identification number and the transfers and revisions to which it has been subjected. The CSN shall keep a national inventory of the holders of this type of sources and the sources which they have in their possession.

Furthermore, Royal Decree 1464/1999 on activities included in the front end of the nuclear fuel cycle governs the different activities relating to the production of nuclear fuel. The objective is to regulate the first part of the cycle as regards the obligations of the entities operating nuclear power plants and deriving from the need to guarantee electricity supply and the management and financing of the basic stock of uranium up to its complete elimination. Article 3 of this decree provides that the nuclear power plant operators must accredit guaranteed supply of enriched uranium for a minimum operating period of 5 years and storage of the fuel assemblies for refuelling at the plant at which they are to be used with at least 2 months in hand. Likewise, it is established that the operators should jointly constitute a physical reserve of enriched uranium oxide with a given oxide content, this being established by virtue of order ITC/2821/2005 at a minimum 721 tons of U₃O₈ and 363 000 Separation Work Units. Finally, ENUSA is empowered by this decree to carry out activities corresponding to the front end of the nuclear fuel cycle and to operate on the nuclear and radioactive materials market. In addition, it stipulates that the basic stock of uranium constituted by ENUSA would be reduced and fully abolished not later than 31 December 2005, the said stock has therefore been cancelled out.

In accordance with Article 3 of Act 15/1980, the MITYC grants the authorisations required for the manufacturing of nuclear or radioactive components, except as otherwise established, where appropriate, in its respective Statutes authorisations can also be granted by the Autonomous Communities.

4. Nuclear installations

a) **Licensing and inspection, including nuclear safety**

Chapter 5 of the 1964 Nuclear Energy Act, partially modified by Act 24/2005, refers to the authorisations required for nuclear and radioactive facilities. However, as point out earlier, the regulatory framework which regulates, among other things, the procedure for the granting of authorisations or the inspection of installations, for both nuclear and radioactive facilities is the RNRF, approved by Royal Decree 1836/1999 and modified by Royal Decree 35/2008.

The latest Royal Decree, which modifies 33 of the 81 articles of the 1999 Royal Decree, strengthens the safety and radiological protection control mechanism of the nuclear facilities and improves co-ordination between the organisations involved in the granting of authorisations and inspections, and it emphasises the effective exercising of the so-called "safety culture" by the licensees of the facilities. As regards the granting of authorisations, procedures are established for the more significant authorisations to be subject to reports by the Autonomous Communities. The procedure for the authorisation of radioactive facilities is streamlined and the system for the granting of dismantling and decommissioning authorisations for nuclear facilities is regulated in greater detail. Likewise, the decree requires now the documentation which licensing authorities may demand before authorising the facilities.

In accordance with Article 2 of the Nuclear Energy Act, "nuclear facilities" are nuclear power plants, nuclear reactors, manufacturing facilities using nuclear fuels to produce nuclear substances or those at which nuclear substances are treated, including facilities for the regeneration of irradiated nuclear fuels and nuclear substance storage facilities, except those places in which such substances are stored incidentally during their transport.

The RNRF requires the following authorisations for nuclear facilities and nuclear fuel cycle radioactive facilities:

- preliminary or site authorisation;
- construction permit;
- operating permit;
- authorisation for modifications;
- authorisation for modification performance and assembly;
- dismantling permit; and
- declaration of decommissioning.

Certain aspects of the aforementioned authorisations are described below:

- The request for the preliminary or site authorisation must be accompanied by certain documents, *inter alia*, a declaration of the justified need for the facility and site, a descriptive report, the initial design of the construction indicating the phases and terms for performance, a site characterisation study or the organisation foreseen for the supervision of the project. Obtaining this authorisation entitles the licensee to request the construction permit and to initiate works on preliminary infrastructures.
- The request for the construction permit shall include, *inter alia*, the general design of the facility, the schedule for the acquisition of equipment and other items, the budget, financing and period for performance and an economic study or a preliminary safety analysis. This permit will entitle the licensee to initiate construction of the facility and to request the operating permit.
- The operating permit, which entitles the licensee to load the nuclear fuel or introduce nuclear substances into the facility, and to operate the facility within the conditions established in the said permit, is first granted provisionally pending the satisfactory completion of the tests. Upon completion of the testing programme, the operating permit is issued for the corresponding period. Requests for this permit should be accompanied by a final safety analysis, the operating regulation, the site emergency plan, the nuclear testing programme, quality assurance and radiological protection manuals, the waste and fuel management plan, the final economic study, dismantling

and decommissioning forecasts and the security plan (this last plan has been required since the approval of Royal Decree 35/2008). The operation of the facility ends with a declaration of definitive shutdown, establishing the operating conditions of the facility until such time as the dismantling permit is obtained.

- The dismantling permit entitles the licensee, once the operating permit has expired, to initiate activities for decontamination, the disassembly of equipment, the demolition of structures and the removal of materials in order to release the site partially or fully from nuclear supervision. In Spain, dismantling activities are the responsibility of ENRESA, which is why in accordance with the RNRF, the latter should submit the corresponding request. The transfer of ownership is authorised jointly with the issuing of the dismantling permit.
- The declaration of decommissioning releases the licensee from his responsibility as operator and, in the case of restricted site release, defines the applicable limitations on use. It is issued following verification of compliance with the requirements of the site restoration plan.

Pursuant to the RNRF, the preliminary or site authorisation, the construction permit and the operating permit for first category nuclear and radioactive facilities and their decommissioning will be issued by the Ministry of Industry, Tourism and Trade.

Requests for authorisations should be submitted to the MITYC, which sends a copy along with the associated documentation to the CSN for issuing of the corresponding report. Furthermore, the MITYC is required to send a copy of all the documentation to the Autonomous Communities which have competences in relation to land planning and the environment and in whose territory the facility or the planning area listed in the basic standards on the planning of nuclear and radiological emergencies will be located. The preliminary or site authorisation and the dismantling permit, require an environmental impact assessment which will be carried out jointly with the authorisation.

In addition to the aforementioned authorisations, the nuclear facilities may require other permits and licenses issued by other authorities in relation to the land use system, although these cannot be denied or conditioned for safety-related reasons since only the Council is qualified to judge this aspect, see Article 3 of Act 15/1980.

The CSN is the sole organisation responsible for nuclear safety and radiological protection in Spain. Among other competences, which will be detailed in the corresponding section, it issues mandatory reports to the MITYC on the authorisation of nuclear and radioactive facilities, proposes to the Government the regulations required within its realm of competence and undertakes the surveillance and control of these facilities.

At the international level, on 4 July 1995, Spain ratified the Convention on Nuclear Safety adopted in Vienna on 20 September 1994. This Convention entered into force on 24 October 1996.

b) Protection of the environment against radiation effects

The legal provisions relating to the evaluation of environmental impacts are basically contained in Royal Legislative Decree 1/2008 which approves the reworded text of the project Environmental Impact Assessment Act.

The aim of this decree is to ensure the integration of environmental aspects in the project in question through the incorporation of environmental impact assessment in the project authorisation or approval procedure, including projects in the nuclear field such as nuclear power plants, other nuclear reactors, their final dismantling and decommissioning, irradiated nuclear fuel reprocessing facilities, installations designed for the production or enrichment of nuclear fuel, spent fuel or high level waste management, the final disposal of spent nuclear fuel, the final disposal of

radioactive waste and the storage (for projected period of more than ten years) of spent nuclear fuel or radioactive waste at locations other than those at which they were produced.

Pursuant to Article 7 of the decree, projects which are subject to environmental impact assessments shall include an environmental assessment study containing the following information:

- general description of the project and demands foreseeable over time in relation to the use of the land and other natural resources and an estimate of the types and quantities of waste released and resulting emissions of material or energy;
- presentation of the main alternatives and justification of the main reasons for the solution adopted taking into account environmental effects;
- evaluation of the foreseeable direct or indirect effects of the project on the population, fauna, flora, soil, air, water, climate factors, landscape and material assets, including the historic artistic and archaeological heritage and interaction between these factors;
- measures foreseen to reduce, eliminate or compensate significant environmental effects;
- environmental surveillance programme; and
- summary of the study and conclusions in easily comprehensible terms and, where appropriate, a report on the informative or technical difficulties encountered during its preparation.

Several authorities are involved in the environmental impact assessment process, among them, the MITYC and the Ministry of the Environment and Rural and Marine Affairs (hereinafter "MARM"). In accordance with the Royal Legislative Decree, the main body is the body of the state, autonomous community or local public administration responsible for authorising or approving projects subject to environmental impact assessment (i.e. the MITYC in the case of nuclear facilities), and the environmental body is the body of the state or public administration responsible for assessing the environmental impacts of the projects (i.e. the MARM) which will issue the environmental impact statement as the final step in the process. This statement is the culmination of a process that begins when the initiator of the project requests the carrying out of an environmental impact assessment and submits the preliminary information. The environmental body establishes the scope of the impact study, which will be drawn up by the initiator, following consultations with the affected public administrations and, where appropriate, interested stakeholders. This study is submitted to the main responsible body in the context of the authorisation procedure. This body then begins the process of public information and consultation with the affected public administrations and other stakeholders, this being carried out jointly for both the impact analysis and the authorisation of the activity. Following public information process, the responsible body submits the proceeding to the environmental body which formulates the environmental impact statement. This latter document, which is drawn up in co-ordination with the Nuclear Safety Council, within its realm of competence, is issued jointly with the authorisation for the project and is published in the *Official State Gazette*. In the event of any discrepancy between the main regulatory and environmental bodies, the Cabinet of Ministers or the Governing Body of the corresponding Autonomous Community will decide depending on the administration that has dealt with the proceedings.

In addition, Article 11 of the aforementioned Legislative Royal Decree establishes the applicable procedures if a project might have significant effects on the environment of another member state of the European Union.

Furthermore, certain aspects relating to the protection of the environment against the effects of ionizing radiations are regulated in Royal Decree 783/2001 which approves the Regulation on the protection of health against ionising radiations (hereinafter "RPHIR"), particularly in Articles 51 and 52.

Article 51 of the RPHIR provides that any release of radioactive effluents and solid waste to the environment requires the express authorisation of the MITYC, following a report from the CSN, and must adhere to the limits and conditions established in such authorisation depending on the characteristics of the activity. In this respect, the party requesting the authorisation should attach studies relating to the release of radioactive effluents to the environment and to the capacity of the area to receive radioactive contaminants depending on its characteristics.

Likewise, in accordance with Article 52, the levels of activity for the emission of radioactive effluents to the environment must be such that the activity concentrations of the radionuclides they contain and the doses that may be received by the potentially affected population be as low as reasonable achievable taking into account economic and social factors.

Article 57 of RPHIR establishes that one of the responsibilities of the licensee of practices entailing a risk from ionising radiations is to achieve and maintain an optimum level of protection of the environment, as well as to guarantee the effectiveness of the technical devices providing such protection.

In addition, and although it relates to a more general area than protection against radiations, mention may be made of Act 27/2006 providing for the right to access to information, public participation and the right to access to justice in environment matters. This transposes Directive 2003/4/EC of 28 January 2003 on public access to environmental information and Directive 2003/35/EC of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment, as well as the commitments of Spain as a contracting party to the Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters of 25 June 1998. The objective of this act is to allow the public to participate individually or collectively in the protection of the environment in an effective manner.

c) ***Emergency response***

The planning and preparation for nuclear emergency situations is regulated by the Basic Nuclear Emergency Plan (PLABEN).³

Emergency planning at the nuclear power plants is organised at two different but complementary levels:

- Site response level, the actions of which are established in the Site Emergency Plan (SEP) of each plant. The SEPs detail the measures foreseen by the licensee and the assignment of responsibilities to address accident conditions with a view to mitigating the consequences of an accident, protecting the personnel of the facility and immediate reporting to the competent bodies, including the initial assessment of the circumstances and consequences of the situation. Also established are the actions required from the licensee to provide assistance in protective interventions off-site, in accordance with the off-site emergency plans established by the competent authorities, when so determined by the CSN.
- Pursuant to Article 8 of the RNRF, the holder of each authorisation is responsible for the facility whatever emergency situations might arise. As has been pointed out above, the RNRF requires the licensees of nuclear facilities to draw up a SEP in order to obtain the corresponding operating permit. This requirement has been reinforced with approval of the Basic Self-protection Standard (not referring exclusively to the nuclear field), approved by Royal Decree 393/2007 since the nuclear and radioactive facilities regulated by Royal Decree 1836/1999 are included within the scope of application of

3. Approved by Royal Decree 1546/2004 and modified by Royal Decree 1428/2009 and by the RNRF, approved by Royal Decree 1836/1999 and modified by Royal Decree 35/2008.

this standard. The SEP proposed by the licensee is approved by MITYC following a report by the CSN on the issuing of the corresponding authorisation.

- At the off-site response level, the activities for the preparation and response to emergency situations are established in the following plans:
 - Off-site response level Nuclear Emergency Plans (NEP) are approved by the Cabinet of Ministers following a favourable report by the CSN and the National Commission for Civil Defence, which in turn include the Municipal Nuclear Emergency Action Plans (PAMEN).
 - Central Response and Support Nuclear Emergency Plan (PENCRA), drawn up by the Directorate General for Civil Defence and Emergencies of the Ministry of the Interior (hereinafter "MIR"), which defines the national organisation, structure and functions in response to emergency situations and provides support to the former, including international assistance.

The aforementioned emergency plans establish the objectives and their specific scope, organisation, structure and functions, the human and material resources required, the operational action procedures for their mobilisation and orderly and efficient actuation and the scheme for co-ordination between the different public administrations required to intervene in the event of an accident.

The PLABEN is the guideline which serves as a directive and contains the essential standards and criteria for the drawing up, effective implementation and continued efficiency of the off-site civil defence nuclear emergency plans, the responsibility for which lies with the General State Administration with the participation of the other public administrations.

The PLABEN also determines the different competent authorities and public organisations concerned in emergency cases:

- The MIR has been assigned the responsibilities in all matters relating to civil defence, through the Directorate General for Civil Defence and Emergencies which draws up the PENCRA and co-ordinates national resources in support of the NEPs. The Secretariat of State for Security is also a competent body of this Ministry, through the Directorate General of the Police and the Civil Guard.
- The CSN has been assigned those responsibilities that correspond to its role as the organisation solely responsible for nuclear safety and radiological protection. Article 2(f) of the act creating the CSN assigns to the latter the function of collaborating with the competent authorities in developing the criteria to which the NEPs are required to adhere as well as of co-ordinating, within its realm of competence, the measures for support and response to emergency situations.
- The autonomous and local administrations have been assigned responsibilities in relation to, *inter alia*, civil defence, public security, health, transport and communications, supplies and shelter.
- ENRESA is responsible for acting in support of the civil defence services in the required manner and under the required circumstances.

The PLABEN contains a series of annexes that establish the different levels of intervention, the standards and models for the notification of nuclear emergencies and the definition of the terms contained in the PLABEN.

The Nuclear Emergency Plans drawn up for each of the provinces having nuclear facilities are required to adapt to the provisions of the PLABEN and are approved following favourable reports

from the CSN and the National Commission for Civil Defence. The title of the plans follow the names of the province in which each plant is located, i.e. Sta. M^a de Garoña, Burgos (PENBU); Almaraz, Cáceres (PENCA); José Cabrera and Trillo, Guadalajara (PENGUA); Ascó and Vandellós, Tarragona (PENTA); Cofrentes, Valencia (PENVA). The latest revision of these plans was approved by an agreement of the Cabinet of Ministers on 16 October 2009.

Furthermore, Title VI of the RPHIR, approved by Royal Decree 783/2001, includes the general principles of radiological protection that must be considered during interventions, including those relating to nuclear or radiological emergencies in general. Pursuant to Article 60 of the said regulation, the CSN establishes the emergency levels of exposure, taking into account the technological requirements and risks for health.

At the international level, on 13 September 1989, Spain ratified the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

5. Trading in nuclear materials and equipment

The general commercial regime for imports and exports, applicable in Spain, is determined by the common commercial policy and is set out in numerous community regulations. The application of the community systems for the authorisation, tracking and certification of imports and exports is accomplished depending on the products and/or the country of origin and destination of the materials.

Nuclear materials, facilities and equipment constitute one of the categories of dual-use materials subject to restrictions on exports and, therefore, to specific legislation. This legislation includes Council Regulation (EC) No 428/2009 of 5 May 2009, setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.⁴

Annex I of the Regulation defines ten categories of products that require a licence for export (this being understood as the exit of the products or technology from the Community customs and excise territory). Category 0 includes nuclear materials, facilities and equipment, including nuclear reactors, plants for the separation of uranium isotopes, uranium conversion, the production or concentration of heavy water, deuterium and deuterium compounds, the manufacturing of fuel assemblies for nuclear reactors, the reprocessing irradiated fuel assemblies from nuclear reactors, software designed specifically or modified for the development, production or use of products belonging to this category or technology for this purpose.

Other dual-use items or technologies not mentioned in the aforementioned annex require an export licence when the so-called "catch-all clause" is applied to them under the conditions described in Article 4 of the regulation. In addition, and pursuant to Article 8, the member states may prohibit exports of dual-use items not included in Annex I or impose upon them the requirement that they be authorised, for reasons of public security or considerations relating to human rights.

Annex IV of the regulation also defines the subgroup of dual-use items and technologies which, in view of their special sensitivity, require authorisation for shipments within the European Union.

Within the national legal framework, Act 53/2007 on the control of overseas trading of defence and dual-use materials aims to contribute to the better regulation of overseas trade relating to defence materials or other dual-use materials, products and technologies, preventing

4. "Dual-use items" are understood as being items, including software and technology, which can be used for both civil and military purposes, and that include all goods which can be used for both non-explosive purposes and assisting in any way in the manufacturing of nuclear weapons or other nuclear explosive devices [Regulation (EC) No 428/2009].

them from being diverted to the illicit market and combating their proliferation, while also complying with international commitments in this area. With this aim in mind, it regulates the procedure for the control of transfers of this type of material and their link with the customs deposits regime, as well as brokerage, agreements regarding production under licence and technical assistance.

In accordance with this act, the transfer of such materials requires administrative authorisation, issued by the MITYC following a mandatory and binding report by the Inter-ministerial Regulatory Board for Overseas Trade of Defence and Dual-Use Materials (JIMDDU) which reports functionally to the said Ministry, with the exception of certain transfers, listed in Article 6, whose authorisation is the responsibility of the Ministry of Economy and the Exchequer (hereinafter "MEH"). A prerequisite for granting of the aforementioned authorisation is that the exporters of these materials be included on the Special Register of Operators for Overseas Trade of Defence and Dual-Use Materials, maintenance of which is the responsibility of the Secretariat General for Overseas Trade of the MITYC.

In addition, the conditions, requirements and procedure for the control of overseas trade are established in Royal Decree 2061/2008 approving the Regulation on the control of overseas trade in defence materials and other dual-use materials, products and technologies, which further develops Act 53/2007.

Furthermore, Spain is a member of the Nuclear Suppliers Group (NSG) the aim of which is to contribute to the non-proliferation of nuclear weapons through application of the following Guidelines on exports of nuclear products and related materials:

- Guidelines for Nuclear Transfers (INFCIRC/254/, Part 1), which regulates the exports of items specifically designed or prepared for nuclear use (including nuclear material, nuclear reactors and equipment therefor, non-nuclear material for reactors, plants and equipment for the reprocessing, enrichment and conversion of nuclear material and for the fuel fabrication and heavy water production, and technology associated with each of the aforementioned items); and
- Guidelines for Nuclear-related Dual-Use Equipment, Materials, Software and Related Technology (INFCIRC/254, Part 2) which regulates the exports of products possibly contributing significantly to nuclear fuel cycle activities not subject to safeguards or to activities relating to explosive nuclear devices.

6. Radiation protection

Since the first regulations on radiological protection, the legislation governing this matter has evolved and undergone numerous modifications. The provisions currently in force are included mainly in Act 15/1980, modified by Act 33/2007, and in Royal Decree 783/2001 approving the Regulation on the protection of health against ionising radiations (RPHIR).

The aforementioned Regulation, along with the RNRF, approved by Royal Decree 1836/1999 and modified by Royal Decree 35/2008, transfers to the internal legal framework Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. The RPHIR sets out the standards applicable to the protection of the health of workers and the general public against the risks posed by ionizing radiations systematically and in accordance with the principles of justification, optimisation and limitation of dose referred to in the Directive. It also introduces new dose limits for professionally exposed workers, workers undergoing training and the public, in accordance with the recommendations of the International Commission on Radiological Protection in its publication number 60 (ICRP-60). Individual doses must be kept at the lowest reasonably achievable level (ALARA principle).

The regulation classifies workers depending on their working conditions, it also classifies places of work into different areas on the basis of the annual doses that may be received in them and establishes the control standards and measures to be applied in the different areas and to the different categories of workers. It also establishes requirements for the determination of doses, and their recording as well as for the training and surveillance of the workers. The doses received during the professional lifetime of exposed workers are necessarily registered on an individual dosimetry record.

As regards the radiological protection of the public, the regulation establishes general standards aimed at the prevention or minimisation of releases of radioactive substances into the environment as well as the obligation to estimate regularly and in the most realistic way possible the doses received by the overall population and by the reference groups in all places in which such groups may exist.

Exposures to radon at home, natural radiation levels and the protection of persons exposed to radiations in medical diagnosis or treatment processes remain outside the scope of the regulation.

It should also be pointed out that, in accordance with the RNRF, the licensees of nuclear and radioactive facilities involved in the fuel cycle are required to submit, along with their request for the construction permit, a radiological analytical study theoretically estimating the potential radiological impact of the facility on the population and the environment, as well as the pre-operational environmental radiological surveillance programme. The request for the operating permit should be accompanied by a radiological protection manual including the standards of protection of the installation. Also required for granting of the dismantling authorisation is a study of the environmental radiological impact during dismantling activities and on their completion, as well as an environmental radiological surveillance plan.

Once in operation, the radiological surveillance of the areas surrounding the plants is carried out by means of two independent programmes. The first of these is carried out by the licensee in accordance with the regulatory framework and the conditions of the authorisation, and is subject to regulatory control by the CSN. The second, which is complementary to the first and independent from it, is carried out by the CSN itself, in certain cases through the assignment of functions to the Autonomous Communities.

In addition to the aforementioned standards, the Spanish legislation includes other standards relating to radiological protection, in particular the following:

- Royal Decree 1132/1990 establishes basic measures for the radiological protection of persons undergoing medical examinations and treatments, it transposes Council Directive 84/466/Euratom of 3 September, laying down basic measures for the radiation protection of persons undergoing medical examination. It allows the quality and efficiency of medical interventions to be improved without preventing the use of ionizing radiations for the prompt detection, diagnosis or treatment of illnesses, thus complying with the recommendations of the International Commission on Radiological Protection, the World Health Organization and the United Nations Scientific Committee on the Effects of Atomic Radiation.
- Royal Decree 413/1997 on operational protection of off-site workers exposed to ionizing radiations as a result of their intervention in the controlled zone regulates the obligations of the licensee in order to comply with the requirement that all persons intervening in a controlled zone at a nuclear facility be protected. It transposes Council Directive 90/641/Euratom on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas.
- Royal Decree 815/2001 on justification of the use of ionizing radiation for the radiological protection of persons subject to medical exposures incorporates into

Spanish legislation Council Directive 97/43/Euratom of 30 June, on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure.

- Royal Decree 229/2006 on the control of high activity sealed radioactive sources and orphan sources, mentioned above, which is to be applied jointly with the RNRF and the RPHIR.
- Royal Decree 1085/2009 approving the Regulation on the installation and use of X-ray devices for medical purposes, mentioned in a previous section.

As regards the competent bodies, the MITYC is in charge of adopting provisions for the development of acts, regulations and actions. It is the competent authority for the granting of authorisations, except those for second and third category radioactive facilities, for which these functions have been transferred to the majority of the Autonomous Communities. For its part, the Ministry of Health and Social Policy adopts provisions relating to the protection of persons undergoing medical examinations or treatments. Finally, the CSN has the responsibilities corresponding to its role as the organisation solely responsible for radiological protection.

7. Radioactive waste management

Pursuant to Article 2 of the Nuclear Energy Act of 1964, as amended by Act 54/1997, "radioactive waste" means "any waste material or product for which no further use is foreseen and that contains or is contaminated by radionuclides in activity concentrations or levels in excess of those established by the MITYC, following a report by the CSN".

For its part, Article 38 of the Nuclear Energy Act provides that nuclear and radioactive facilities working with radioactive substances are obliged to have special installations for the storage, transport and handling of radioactive wastes. Following the amendment by Act 33/2007, it is added that appropriate measures should be adopted in all stages of the management of spent nuclear fuel and radioactive wastes in order to provide adequate protection for persons, property and the environment against radiological risks, both today and in the future, such that the production of wastes, in quantity and activity, be as low as possible in keeping with the scientific practice existing at the given time.

Since 1984, the management of radioactive waste in Spain has been the responsibility of ENRESA, set up by Royal Decree 1522/1984 which authorised the establishment of the "Empresa Nacional de Residuos Radiactivos, S.A." whose activities are currently set out by Royal Decree 1349/2003 governing the activities of the Empresa Nacional de Residuos Radiactivos, S.A. (ENRESA). This latter decree brought together in a single text the regulation of the activities carried out by the said company and their financing.

Recently, Act 11/2009 added a new Article 38(b) to the aforementioned Nuclear Energy Act, providing with respect to radioactive waste management the following:

- The management of radioactive waste, including spent nuclear fuel, and the dismantling and decommissioning of nuclear facilities constitute an essential public service that is exclusively the state's competency; the management of this public service is commissioned to ENRESA in accordance with the general radioactive waste plan approved by the Government.
- ENRESA is established as a technical service and resource of the administration, carrying out the functions assigned to it by the Government. It reports to the MITYC, via the Secretariat of State for Energy which is responsible for strategic management and the monitoring and control of its activities and plans both technical and economic.
- The Government is responsible for establishing policy on the management of radioactive waste, including spent nuclear fuel, and on the dismantling and decommissioning of

nuclear facilities through the adoption of the general radioactive waste plan, submitted to it by the MITYC, following a report by the CSN and having heard the Autonomous Communities in relation to land planning and the environment. The plan has to be reported to the Parliament. In accordance with Royal Decree 1349/2003, ENRESA is responsible to revise, every four years and whenever so required by the MITYC, the said plan dealing with the necessary actions and the technical solutions developed during its timeframe and aimed at ensuring the suitable management of radioactive waste and dismantling and decommissioning of nuclear and, where appropriate, radioactive facilities with the economic and financial forecasts regarding these activities. The current plan (Sixth GRWP) was approved by the Cabinet on 23 June 2006.

- The state will assume ownership of the radioactive waste once these have been definitively disposed of. It shall also undertake whatever surveillance might be required following the decommissioning of a nuclear facility, following the period of time established in the corresponding declaration of decommissioning.

Furthermore, Act 11/2009 modifies the sixth additional provision of Act 54/1997, which regulates the fund for the financing of radioactive waste and spent fuel management, including the dismantling and decommissioning of nuclear facilities, known as the "fund for the financing of activities included in the general radioactive waste plan". This fund is made up of a series of fees, as well as other payments or revenues from the rendering of services by ENRESA, including also the yield on transitory financial investments. Without prejudice to these transitory financial investments, the sums deposited in the fund may be used only for expenses, works, projects and fixed assets deriving from the activities set up in the general radioactive waste plan, approved by the Government. The financial management of the fund is governed by the principles of security, profitability and liquidity, and the supervision and control of the transitory investments relating to its financial management is the responsibility of a Monitoring and Control Committee which reports to the MITYC via the Secretariat of State for Energy.

Although the system establishing the income for the fund has been modified on several occasions (fundamentally by Royal Decree-Law 5/2005, Act 33/2007 or Royal Decree-Law 6/2009), the fund is currently fed, pursuant to Act 11/2009, by several mechanisms depending on the services covered:

- To be paid by the operator of the nuclear power plants by way of a fee calculated as a percentage on the tolls for access to the electricity grid, for the rendering of the following services or to cover the following costs:
 - services for the management of radioactive waste and spent fuel generated at nuclear power plants whose operation came to an end prior to 1 January 2010, along with their dismantling and decommissioning;
 - future costs corresponding to nuclear power plants or fuel assembly manufacturing facilities which have been finally shut down and which were not foreseen during their operation;
 - services for the management of waste arising from research activities directly related to electricity generation by nuclear means, determined by the MITYC;
 - costs of dismantling and decommissioning operations to be carried out as a result of uranium mining and concentrates production activities performed prior to 4 July 1984;
 - costs deriving from reprocessing of the spent fuel sent abroad before the entry into force of Act 54/1997 (29 November 1997); and

- financial deficit due to the premature closing down of a nuclear power plant, with respect to the provisions of the general radioactive waste plan, for reasons beyond the control of the licensee.
- To be paid by the operators of the nuclear power plants by way of a fee calculated on the basis of gross nuclear electricity generation by each of the plants (measured in gross kWh generated), a fixed unit tariff and a coefficient of correction, depending on the gross power of the plant and type of reactor, for the rendering of the following services or to cover the following costs:
 - management of radioactive waste and spent fuel, generated at the operating nuclear power plants regardless of the date of generation, dismantling and decommissioning activities;
 - assignments for municipalities affected by nuclear power plants or spent fuel or radioactive waste storage or disposal facilities under the terms established by the MITYC;
 - taxes levied in relation to radioactive waste and spent fuel and dismantling activities; and
 - financial deficit due to the early shutdown of a nuclear power plant upon decision of the licensee under the provisions established in the general radioactive waste plan.
- To be paid by fuel assembly manufacturing facilities (in practice the only one in existence is the Juzbado facility in Salamanca) for the rendering of services for the management of waste deriving from the manufacturing of fuel assemblies at these facilities, including their dismantling, and early shutdown upon decision of the licensee. This fee is calculated on the basis of the amount of nuclear fuel produced each year (in metric tons) or, where appropriate, the financial deficit existing as of the time of its shutdown.
- To be paid by other facilities not included in the previous cases for services for the management of waste generated by them by means of a fee calculated on the basis of the quantity or units of waste delivered for management and depending on the nature of the waste.

Pursuant to Article 5 of Royal Decree 1349/2003, the radioactive waste management services rendered by ENRESA to the operators of nuclear and radioactive facilities are governed by contracts that are to be approved by the MITYC. The functions of ENRESA are detailed below in the corresponding section.

Low and intermediate level radioactive waste are finally disposed of at the "El Cabril" facility which belongs to ENRESA. As regards the storage of spent fuel and high level waste, the Sixth General Radioactive Waste Plan stipulates a Centralised Temporary Storage (CTS) facility with an operating lifetime of some 60 years. In this respect, Royal Decree 775/2006 set up an Inter-ministerial Commission to carry out the following functions:

- establishment of the reference framework with the technical, environmental and socio-economic conditions to be fulfilled by potential candidate sites for a CTS facility;
- establishment and promotion of public information and participation processes;
- development of the procedure by which interested municipalities may opt to be candidates for the site; and

- drawing up, for submittal to the Government, of a proposal regarding candidate sites, selected from among the interested municipalities, on the basis of the technical evaluations regarding their suitability and taking into account, where appropriate, the proposals made by the affected Autonomous Communities.

On 29 December 2009, the *Official State Gazette* published the Resolution issued on 23 December by the Secretariat of State for Energy launching a public call for the selection of candidate municipalities for the site of the Centralised Temporary Storage (CTS) facility for spent nuclear fuel and high-level radioactive waste and an associated technology centre.

In accordance with this call, the interested municipalities had one month, as from the day following publication, to submit their candidatures.

Following this, the Inter-ministerial Commission studies the candidatures with support from the Technical Advisory Committee, taking into account the proposals made by the Autonomous Communities, where appropriate. It will pass on the selected candidatures to the Government. Finally, the Government will designate the site selected from among these candidatures.

Furthermore, for the purposes of economic planning and calculation, the Sixth General Radioactive Waste Plan provides for the possibility of a final disposal facility for spent fuel and high-level radioactive waste to be in operation around the year 2050 in keeping with the concept of Deep Geological Disposal (DGD).

At the international level, Spain is party to the 1997 Joint Convention on the safety of spent fuel management and on the safety of radioactive waste management which it ratified on 11 May 1999, and to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter (London Convention of 1972), ratified on 31 July 1972, and the 1996 Protocol, ratified on 24 March 1999.

8. Non-proliferation and physical protection

Article 84 of the 1964 Nuclear Energy Act of Chapter XIII in relation to nuclear non-proliferation and physical protection (security) of nuclear materials, as amended by Article 16 of Act 24/2005, provides that all physical and legal persons shall be subject to compliance with the obligations deriving from the commitments made by the Spanish state or the internal legal system itself in relation to nuclear non-proliferation and physical protection of nuclear materials, in particular as regards the performance of nuclear material monitoring, control and custody activities, allowing for whatever inspections and checks might be required at premises or facilities and reporting to the competent authorities. In turn, Article 8(2) of the RNRF covers the specific responsibility of the licensees of nuclear and radioactive facilities in this respect. Quite clearly, as regards non-proliferation and security, the Spanish standards derive from international or European commitments.

a) Safeguards and Non-proliferation

“Nuclear safeguards” are the set of measures put in place to ensure that there is no deviation for undeclared use of nuclear materials. At the international level, Spain has ratified the following instruments:

- Treaty on the Non-Proliferation of Nuclear Weapons, of 1968, ratified by Spain on 5 November 1987;
- Comprehensive Nuclear-Test-Ban Treaty, of 1996, ratified on 31 July 1998; and
- International Convention for the Suppression of Acts of Nuclear Terrorism, of 2005, which was ratified in 2007 and which came into force on 22 February of that year.

Safeguards are applied by two organisations: Euratom and the IAEA. The Euratom Treaty establishes a control for the security of nuclear materials. The European Commission inspectors verify compliance with the safeguards and inspect facilities pursuant to Euratom Regulation No. 302/2005 on the application of Euratom Safeguards, which enacts Chapter VII on the control of security of the Treaty establishing the European Atomic Energy Community.

At international level, the IAEA applies the safeguards measures deriving from the Treaty on the Non-Proliferation of Nuclear Weapons (NPT). Among other obligations, this treaty provides that states not possessing nuclear weapons should reach agreement with the IAEA for the application of its safeguards system. The safeguards are applicable to all basic materials or special fissile materials in all nuclear activities performed for peaceful purposes in the territory of the said states, under their jurisdiction or carried out under their control in any place.

In view of the above, for the application of the safeguards in the territory of the European Union, Euratom and those member states that do not possess nuclear weapons (Spain included) signed jointly with the IAEA a Safeguards Agreement that makes extensive use of the Euratom safeguards system. They subsequently, also jointly, signed Additional Protocol to the said agreement which substantially increases the information to be provided to the IAEA and confers upon the inspectors ample access rights to any part of the sites to be inspected.

Given that part of the obligations established in the Additional Protocol are the responsibility of each member state, and that there is no legal basis in the Euratom Treaty allowing the Community legislation to govern the full scope of the Additional Protocol, Spain adopted Royal Decree 1206/2003 for the application of the commitments undertaken in the Additional Protocol to the Safeguards Agreement deriving from the Treaty on the Non-proliferation of Nuclear Weapons. The said Protocol establishes certain national measures ensuring compliance with the obligations. Likewise, and since the Protocol allows each state to assign to the European Commission the application of provisions that are initially the responsibility of the former, the Royal Decree is developed by means of Order ITC/2637/2004 relating to the application of certain provisions of Royal Decree 1206/2003 allowing for its assignment to the European Commission.

A distinction is made in the provisions between the obligations of facilities handling nuclear materials and those not involving such material, which are also subject to certain obligations. All these facilities or activities are obliged to submit information to the authorities (especially to the MITYC, via the Directorate General for Energy Policy and Mines) or to Euratom, as the case may be, and to provide access for the IAEA inspectors to their installations or to places in which the activities are carried out.

Since 2004, both the IAEA and the Commission have promoted a reform of their respective safeguards systems with a view to improving their efficiency and effectiveness. The idea is to introduce what is known as "integrated safeguards", made up of a set of measures optimising resources and using all the available sources of information and media (inspections, declarations, satellite images etc.). The integrated safeguards provide for unannounced and immediate access to the facilities or access at short notice, continuous supervision and the application of this philosophy to all activities in the nuclear area, reducing the number of inspections and introducing the factor of "surprise". In 2008, a set of generic procedures per type of facility were approved for application of the integrated safeguards in the European Union. Since then, the system of integrated safeguards has been progressively and gradually implemented in the different countries and since 1 January 2010, Spain has been included under the integrated safeguards system like all other EU member states.

b) Physical Protection

The term "physical protection" or "security" refers to ways to prevent, detect and promptly respond to robberies, sabotage or illegal transfers of nuclear material.

At the international level, Spain ratified the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991. In accordance with the Convention, each state is required to adopt appropriate measures within the framework of its national legislation to guarantee that nuclear materials are protected in accordance with the levels established in Annex I of the said Convention, as regards both international shipments and internal storage, handling and movements within the territory under national sovereignty and in its jurisdictional waters and air space.

At the national level, Royal Decree 158/1995 on the physical protection of nuclear materials, establishes the basis for the creation, implementation and maintenance of a complete control and security system for the nuclear facilities and materials in Spain. The transposition of the aforementioned Convention was accomplished by this Royal Decree, establishing that activities for the handling, processing, storage, transport through the territory, waters or air space under Spanish sovereignty or jurisdiction and importing and exporting of nuclear materials require a specific authorisation, to be granted in response to a request from the interested party by the Directorate General for Energy Policy and Mines, following reports from the CSN and MIR. This authorisation is valid for two years, extendable for same period upon request, although in practice it is granted only for the transport of Category III nuclear materials, Category I and II materials requiring a specific authorisation for each shipment. Likewise, the Royal Decree obliges the licensee to take certain measures with respect to the material, such as its monitoring and accountability, confinement, surveillance and physical protection, and establishes the minimum levels of protection for the different categories of nuclear material, depending on the quantity of fissile material contained therein.

More recently, on 8 July 2005, an Amendment to the Convention on the Physical Protection of Nuclear Material was approved by consensus, substantially increasing the controls regarding physical protection and incorporating the physical protection of nuclear facilities. Specifically, definitions of nuclear facilities and sabotage are added, reference is made to nuclear facilities in all the protection obligations established in the Convention for nuclear materials, and a section is included on the fundamental principles to be adhered to by all states in application of the Convention, the setting up of points of contact in each state and measures for co-operation between the states in this area. The commitment to comply with the provisions of the second article of the aforementioned amendment, as well as the need to undertake an in-depth review of Royal Decree 158/1995 and develop Chapter XIII of the Nuclear Energy Act have made it necessary to draft a new Royal Decree which is currently under development.

9. Transport

Chapter VI of the Nuclear Energy Act contains certain provisions relating to the transport of radioactive material in general, especially Article 41. Shipments of these substances are subject to specific provisions relating to the transport of hazardous goods, which depend on the means of transport used. Furthermore, Article 77 of the RNRF provides that the transport of radioactive materials, as well as the approval or validation of packages for the special transport of such materials or radioactive sources, when so required by the specific regulations, are subject to authorisation by the Directorate General for Energy Policy and Mines, following a mandatory and binding report by the CSN. Article 78 of the said regulation points out that the carriers of radioactive materials, in non-exempted packages, should declare this activity and be included on a register, set up for this purpose at the said Directorate General, known as the Register of Carriers of Radioactive Material. Companies carrying out shipments under contract to registered transport companies are exempted from inclusion on this register, the registered company being responsible for ensuring compliance with the legislation by the contracted company. The Directorate General for Energy Policy and Mines must in turn notify the CSN and the Ministry of Civil Works of any variation on the said register.

In addition, and as an activity involving a risk of exposure to ionizing radiations, its performance should comply with the Regulation on the Protection of Health against Ionizing Radiations.

The standards applicable in Spain to the transport of hazardous goods are as follows:

- As regards transport by road:

- The new European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR 2009), published in the *Official State Gazette* on 29 July 2009, and in force since 1 July 2009, which affects the transport of radioactive materials (which constitute Class 7 of a total of 9 classes). This agreement regulates the conditions imposed on hazardous goods whose international transport is regulated, and especially their classification (including criteria for classification and testing methods), the use of packaging (including common packaging) and tankers (including their filling), shipping procedures (including the marking and labelling of packages, the signposting of means of transport or documentation), provisions relating to the construction, testing and approval of wrappings, packages and tankers, and the use means of transport (including loading, loading in common and unloading).
- Royal Decree 551/2006 regulates road transport operations with hazardous goods in the Spanish territory. The Royal Decree establishes that the provisions of the ADR are applicable to shipments carried out entirely within the Spanish territory, with certain specialities. Likewise, the standards included in the international bilateral or multilateral agreements adhered to by Spain are applicable to internal transport. In addition to the aforementioned Register of transporters, this Royal Decree sets up a centralised Register of passwords for types of wrappings and packaging and other special recipients or containers for certain products, which is kept by the Directorate General for Industry of the MITYC.

- As regards rail transport:

- Regulation concerning the International Carriage of Goods by (RID 2009), published in the *Official State Gazette* on 14 August 2009 which regulates the same aspects as those regulated by the ADR on this means of transport.
- Royal Decree 412/2001 regulates various aspects relating to the transport of hazardous good by rail, updated by Order ITC/254/2007. Pursuant to this, the standards in force in Spain at any time and deriving from the aforementioned International Regulation on the Rail Transport of Hazardous Goods shall be applicable to shipments made entirely within the national territory, as well as the standards contained in the international bilateral or multilateral agreements adhered to by Spain.

- As regards air transport:

- Royal Decree 1749/1984 approves the National Regulation on the Transport without Risk of Hazardous Goods by Air, updated by the Ministerial Order of 28 December 1990, and is applicable to all national or international flights made by civil aircraft. This incorporates into the national standards the detailed provisions contained in the technical instructions for the transport without risk of hazardous good by air of the International Civil Aviation Organisation (ICAO).
- Order FOM/808/2006 which updates the technical instructions for the transport without risk of hazardous goods by air, repealing Order FOM/3416/2003 in accordance with the amendments contained in the 2005-2006 edition of the technical instructions of the ICAO.

- As regards maritime transport:

The International Maritime Dangerous Goods (IMDG) Code, published in the *Official State Gazette* on 21 December 2005 and its amendments of 2006.

- Other regulations applicable to the transport of hazardous goods and, including radioactive material:

- Royal Decree 1256/2003 which determines the competent authorities of the General State Administration in relation to the transport of hazardous goods and regulates the commission for the co-ordination of such transport. The said Royal Decree determines the ministries responsible for this issue, among them the following:
 - The Ministry of Foreign Affairs and Co-operation, which is responsible for representing Spain before the international organisations in relation to the transport of hazardous goods and for dealing with any modifications to the IMDG, ADR or RID, among other regulations.
 - The MIR, responsible for the control and surveillance of standards and guidelines relating to emergency response.
 - The Ministry of Public Works, responsible for the ordering of the transport of hazardous good or standards relating to the documentation required or shipping bill, as well as for authorisations for the performance of transport.
 - The MITYC, responsible for the conditions under which transport is carried out and for the circulation of radioactive products.
- Royal Decree 1566/1999 on safety counsellors for the transport of hazardous good by road, rail or shipping route, modified by Royal Decree 551/2006.
- Royal Decree 818/2009 approving the General Regulation on Drivers, which transposes Directive 2006/126/EC on Driving Licences.

Furthermore, Council Regulation (Euratom) No 1493/93 of 8 June on shipments of radioactive substances between member states, which is directly applicable, is applied to the transfers between member states of sealed sources and other pertinent sources, when the quantities and concentrations are higher than a given level. It establishes for such transfers a Community declaration system.

Recently, Royal Decree 243/2009 was passed on the surveillance and control of transfers of radioactive waste and spent nuclear fuel between member states or originating from or having their destination outside the Community, this implying transposition to the Spanish legal system of Council Directive 2006/117/Euratom. With this Royal Decree a common and obligatory regime is adopted for the previous authorisation of transfers of radioactive waste or spent fuel between member states and for transfers entering or leaving the Community, establishing the procedures for the actions and communications required between the competent authorities of the member states, such that any transfer of such materials be known to them and approved by them.

The novelties in the Royal Decree refer mainly to simplification and clarification of the procedures to be adhered to, extension of its field of application to include transfers of spent fuel – not only when this is to be finally disposed of but also when it is determined for reprocessing – and implementation of other Community and international provisions after the entry into force of the repealed Royal Decree (for example the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and Directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources).

The Royal Decree includes a chapter on intra-Community and extra-Community transfers. While intra-community transfers are subject to a standard based on the fundamental principles established within the Community and referring to security in the transport of these materials and the conditions under which they are stored (final disposal or otherwise), in the case of extra-Community transfers consideration is given to the fact that when the materials are going to leave the European Union, the third-party destination state must, in addition to possessing the technical and administrative resources and the regulatory structure required for the safe management of the materials, be informed of the transfer and give its consent.

The authority competent to issue the corresponding authorisations is the Directorate General for Energy Policy and Mines, following a favourable report by the CSN.

10. Nuclear third party liability

The 1964 Nuclear Energy Act establishes the basis governing civil liability for nuclear damage, in its Chapters VII to X.

As is pointed out in Article 45, the basic principle of the act is that the operator of a nuclear facility or any other installation producing or working with radioactive materials or that has devices capable of producing ionizing radiations is liable for nuclear damage, this liability being limited in its amount, and that in accordance with Article 55 the said operator is obliged to establish coverage for whatever risks might arise. However, according to Article 1 of Decree 2177/1967 approving the Regulation on the Coverage of Nuclear Risk, those using, handling or storing radioactive materials or producing or possessing installations and devices capable of issuing ionizing radiations that, in view of the intensity of the irradiation field, do not pose any risk are excluded from the scope of this civil liability provision. Likewise, Article 9(2) of the RNRF provides that second and third category radioactive facilities and X-ray producing devices do not need to take out this coverage of risks, in which respect and in accordance with the said regulation, only radioactive material shipments are obliged to have coverage for whatever nuclear damage might occur during transport, in this case up to the sum of EUR 6 000.

In the case of nuclear facilities, Article 57 of the act, as amended by Act 17/2007, provides that the coverage that may be required of the operator may be modified by the Government, in response to a proposal from the MITYC, in order to take into account the evolution of the international conventions adhered to by Spain and the passing of time or variation in the consumer price index. The coverage has been modified on several occasions: the original act set it at ESP 300 million,⁵ this amount being increased to 25 000 MESP by Act 54/1997 (which corresponds to approximately SDR 150million),⁶ and subsequently to the current sum of EUR 700 million in 2007. Nevertheless, the MITYC may impose another limit, not less than EUR 30 million, in the case of shipments of nuclear substances or any other activity whose risk, in the judgement of the CSN, does not require higher coverage.

At the international level, on 31 October 1961 Spain ratified the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, and subsequently the amendments to the convention in 1964 and 1982. Spain also ratified the Brussels Supplementary Convention of 1963, and its amendments of 1964 and 1982, both under the auspices of the OECD Nuclear Energy Agency. Finally, on 21 May 1974, Spain ratified the 1971 Convention on Civil Liability in the Maritime Carriage of Nuclear Material.

Both the Paris and the Brussels Conventions were amended by virtue of the 2004 Protocols. The main modifications introduced by the Paris Protocol are as follows:

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- 5. ESP: Spanish pesetas.
 - 6. SDR: Special Drawing Rights.

- The minimum liability amount has been increased to EUR 700 million;
- introduction of a broader definition of nuclear damage, including among others the damage caused to the environment and the economic losses directly related to the use and enjoyment thereof;
- extension of the geographical application of the Convention to include as beneficiaries, under certain conditions, victims in states that are not party to the convention; and
- extension of the period during which victims may make claims for injuries, which changes from 10 to 30 years with respect to loss of life and personal injury.

In parallel, the most significant improvement introduced by the Brussels Protocol is the new increase in the amounts assigned to the three-tier compensation system, along with an identical modification to the accounting unit.

In this respect, it should be pointed out that Act 26/2007 on Environmental Liability, which transposes Directive 2004/35/EC of 21 April 2004, expressly excludes nuclear damages in its Article 3(5), stating that the act shall not be applied, *inter alia*, to nuclear risks, environmental damage or imminent threats of such damage occurring, caused by activities using materials whose use is regulated by the standards deriving from the Treaty establishing the European Atomic Energy Community, or to incidents or activities for which liability is established by one of the international conventions dealt with in Annex V (among them the Paris and Brussels Conventions), including eventual future modifications, in force in Spain.

With a view to the entry into force of the aforementioned 2004 Protocols to amend the Paris and Brussels Conventions, an Act on Nuclear Third Party Liability is being drafted which will replace the corresponding chapters of the Nuclear Energy Act, incorporating all the modifications implied by the amendment for the nuclear third party liability regime and affecting also certain shipments of radioactive materials and, although not included within the scope of the said conventions, radioactive facilities.

As regards nuclear third party liability for environmental damage, it should be remembered that on the one hand Act 26/2007 expressly excludes nuclear facilities from its scope and that, on the other hand, the Act on Nuclear Third Party Liability is in process. Therefore, Act 17/2007 introduces in its second additional provision a new additional transitional provision to the Nuclear Energy Act, with a view to covering nuclear third party liability for environmental damage on the Spanish territory, pending approval of the definitive Act on Nuclear Third Liability. This modification obliges the licensees to have a coverage of risk amounting to EUR 700 million to cover environmental damage in Spain resulting from the accidental release of ionizing radiations to the environment (with the possibility of establishing lower limits for transport or low risk activities). Until the adoption of the final act, this coverage will be added to the EUR 700 million for "conventional" damage.

II. Institutional framework

Several ministries are involved in the control and supervision of nuclear and radiation related activities in Spain and are responsible for different areas in accordance with the legislation. Nevertheless, it should be pointed out that the Ministry of Industry, Tourism and Trade (MITYC) undertakes most of the activities relating to this issue, especially as regards the drafting of nuclear legislation and the granting of authorisations, without prejudice to the responsibilities that in certain cases are transferred to the Autonomous Communities.

The Nuclear Energy Board ("Junta de Energía Nuclear" - JEN), created in 1951 by Decree-Law of 22 October, was the first specialised body with full powers for nuclear matters. In view of the increase of nuclear activities and with it the multiplication of regulations in this area, the functions assigned to the JEN were transferred to other organisations or entities that currently play an important part in this area, such as the Nuclear Safety Council (CSN), ENUSA Industrias Avanzadas, S.A. (ENUSA) or the Empresa Nacional de Residuos Radiactivos (ENRESA). The Board was finally replaced by the Centre for Energy-related, Environmental and Technological Research (CIEMAT) by virtue of Act 13/1986 on the Promotion and General Co-ordination of Scientific and Technical Research.

1. Regulatory and supervisory authorities

a) Ministry of Industry, Tourism and Trade (MITYC)

The MITYC is the department of the central state administration which is responsible for nuclear energy. It is responsible for the granting of various authorisations relating to nuclear facilities – this being subject to the mandatory and binding reports by the CSN and, where appropriate, other ministerial departments –, for issuing proposals for standards, adopting provisions for the enactment of the standards in force and applying the system of sanctions relating to nuclear energy.

In accordance with Royal Decree 1182/2008 developing its basic organisational structure, amended by Royal Decree 1038/2009, the MITYC carries out, *inter alia*, the following functions:

- Drafting of arrangements for the authorisations of nuclear and radioactive facilities, following mandatory and binding reports by the CSN, except in the case of authorisations for second and third category radioactive facilities located in Autonomous Communities where executive functions were transferred to the Central Administration. The authorisations are granted by the Minister or by the Director General for Energy Policy and Mines, as the case may be.
- Drafting of initiatives for standards and their tracking within the framework of the competences of the central state administration. The MITYC drafts the Government's proposals for nuclear energy-related acts, as well as the white papers that the Government submits to Parliament for consideration. When the regulatory developments refer to nuclear safety or radiological protection, the proposals are made by the CSN.
- Application of the system of sanctions established by Chapter XIV of the Nuclear Energy Act, modified by Act 33/2007, for application of infringements committed within the realm of the state administration. The procedure to be adhered to is based, additionally, on the principles of Act 30/1992 on the Legal System of the Public Administrations and Common Administrative Procedure and on Royal Decree 1398/1993 approving the Regulation on the Procedure for the Exercising of Penal Powers.

- Management of the administrative registers assigned to the central state administration in relation to the transport of nuclear and radioactive materials, radioactive facilities, activities relating to the commercialisation of radioactive materials and devices etc.
- Proposals to the Government regarding radioactive waste management policy established by the latter in the general radioactive waste plan. ENRESA is in charge of drawing up the proposal for the plan and for submitting it to the MITYC for the necessary proceedings and its submittal to the Government for approval. This plan is subsequently submitted to the Parliament.
- Contribution to the definition of the research and development policy. Although the performance of nuclear-related R&D projects (or energy-related projects in general) does not fall under the functions of the MITYC, it is responsible for contributing, in co-ordination with the Ministry of Science and Innovation, to the definition of the national R&D policy in this area. For this purpose, a National R&D Technology Platform for Nuclear Fission (CEIDEN) was set up in 2007 with the intervention of the MITYC, the objectives of which are to co-ordinate the different national R&D plans and programmes and to participate in international programmes, this implying the continuation of the previous strategic committee of the same name.
- Tracking and control of technical and economic actions and plans in relation to the activities set in the general radioactive waste plan and drafting of proposals for authorisations relating to shut down nuclear power plants, in accordance with Act 54/1997.
- Strategic management of ENRESA and tracking and control of its technical and economic actions, by virtue of the trusteeship of this company corresponding to the MITYC via the Secretariat of State for Energy Policy and Mines, in accordance with Act 11/2009.
- Tracking of compliance with the international commitments of Spain in the field of nuclear energy, in particular as regards nuclear non-proliferation, the physical protection of nuclear materials and facilities (in this last case in co-ordination with the MIR) and third party liability for nuclear damage.
- Follow-up of the bilateral agreements between Spain and third countries in relation to the peaceful uses of nuclear energy and representation at assemblies of contributors to different international funds to which Spain contributes.
- Relationships with specialised international organisations in the area (e.g. Euratom, IAEA or NEA).

Within the MITYC, the Secretariat of State for Energy is the governing body in energy matters, including nuclear energy. Within this Secretariat, the Directorate General for Energy Policy and Mines is the management body responsible for the aforementioned functions in the specific field of nuclear energy. In turn, the Directorate General for Energy Policy and Mines is composed of several Deputy Director Generals, among which the Deputy Director General for Nuclear Energy is the executive body.

Pursuant to Royal Decree 1182/2008, the relations between the CSN and the Government are established through the MITYC. In addition, and pursuant to Act 11/2009, the MITYC exercises trusteeship of ENRESA via the Secretariat of State for Energy, the said company being a technical service and resource of the administration and carrying out the functions commissioned to it by the Government.

b) Ministry of the Interior (MIR)

The MIR has responsibilities in all matters relating to civil defence and emergencies. Within the Ministry, the Directorate General for Civil Defence and Emergencies is the body in charge of drawing up national civil defence plans, preparing for and managing drills and exercises within the framework of these plans as well as managing all national resources in response to emergencies.

Consequently, the Ministry is responsible for the drafting of the PLABEN or the basic nuclear emergency plan, following a report by the CSN and the National Civil Defence Commission, or the PENCRA or central response and support level nuclear emergency plan.

The Ministry also plays an important role in relation to the physical protection of nuclear materials through the Secretariat of State for Security, to which the Directorate General of the Police and Civil Guard reports.

In co-operation with the MITYC, this Ministry is responsible for controlling the transport of nuclear materials and for drawing up reports as part of the procedure for the granting of authorisations for the handling, processing, storage, transport within the Spanish national territory and import and export of nuclear materials.

c) Ministry of Economy and the Exchequer (MEH)

In the nuclear field, the MEH takes decisions regarding the financing of the expenses to be covered by the state pursuant to the legislation, including nuclear legislation. Article 68 of the Nuclear Energy Act attributes to this Ministry powers to arbitrate whatever systems or procedures it considers to be appropriate to cover the amounts to be paid by the state to compensate nuclear damage. This Ministry is also responsible for approving the financial guarantees established to cover nuclear damage other than insurance policies, pursuant to Article 56 of the said act, and for supervising the insurance companies operating in the sector.

In addition, the Directorate General for Insurance and Pension Funds of the MEH is responsible for the Insurance Compensation Consortium, a public business entity reporting to the Secretariat of State for Economy via the said Directorate General. Its function in the field of nuclear energy is to provide coverage for third party liability damage arising as a result of a nuclear accident in Spain. In the event that the insurance entities were unable to cover the minimum limit for third party liability as required in the legislation, it will cover the difference up to the said limit. It also acts as reinsurer of the insurers of nuclear risk in the manner and to the amount determined by the MEH.

Furthermore, the MEH is responsible for managing the fees that are to be paid to the fund for financing of the activities included in the general radioactive waste plan.

d) Ministry of the Environment and Rural and Marine Affairs (MARM)

The MARM intervenes in the process of environmental impact assessment to which many projects are subject to in relation to nuclear or radioactive matters, this being regulated by the amended text of the Act on Project Environmental Impact Assessment, approved by Royal Legislative Decree 1/2008, and detailed in the corresponding section.

If the competence for the assessment of environmental impacts falls within the responsibility of the general state administration, the MARM acts as the environmental body (the body competent to undertake the environmental assessment) and issues an impact statement on the basis of the environmental impact study drafted by the initiator of the project.

Within the MARM, the Directorate General for Environmental Quality and Assessment performs the assessment of the environmental impact of projects for which the state is responsible; it reports to the Secretariat of State for Climate Change.

2. Public and semi-public agencies

a) Nuclear Safety Council (CSN)

The CSN, set up by Act 15/1980, reformed by Act 33/2007, is the organisation solely responsible for nuclear safety and radiological protection.

i) Legal status

Article 1 of the Act Creating the CSN provides that the CSN is an entity under Public Law, independent from the central administration of the state, with its own legal standing and equity, independent from those of the state, governed by a statute drawn up by the CSN itself and approved by the Government.

For the fulfilment of its functions, the CSN possesses the human resources as foreseen in its statute, approved by Royal Decree 1157/1982, passed following the approval of Act 15/1980 and subsequently modified on several occasions (Royal Decree 643/1989, Royal Decree 2209/1995 and Royal Decree 469/2000).

In accordance with Article 4 of the Act Creating the CSN, the legal regime of the Council is as set out in its statute, and additionally, as regards the adoption of agreements, in Chapter II of Act 30/1992.

A new statute is currently being developed which will update the previous one and incorporate the modifications introduced by Act 33/2007.

ii) Responsibilities

The CSN, as an independent body exclusively responsible for nuclear safety and radiological protection, may however assign to the Autonomous Communities the exercising of the functions attributed to it in accordance with the general criteria for such performance agreed to by the Council itself, pursuant to the third additional provision of the act by which it was set up.

In accordance with Article 2 of the Act Creating the CSN, as amended by Act 33/2007, the main competences of the Council are as follows:

- It proposes to the Government the regulations that it considers to be necessary within its realm of competence, along with whatever revisions it deems to be appropriate. Within this regulation, objective criteria are established for the selection of sites for nuclear and first category radioactive facilities, following reports by the Autonomous Communities. Likewise, it drafts and approves the technical instructions, guidelines and circulars⁷ relating to nuclear and radioactive facilities and activities relating to nuclear safety and radiological protection.
- It issues reports to the MITYC on nuclear safety, radiological protection and physical protection, prior to the resolutions adopted by the latter regarding the granting of authorisations for nuclear and radioactive facilities, the transport of nuclear substances or radioactive materials, the manufacturing and homologation of equipment incorporating radioactive sources or generating ionizing radiations, the operation, restoration or closure of uranium mines and, in general, all activities relating to the

7. The technical instructions are binding upon the parties affected by their scope of application once published in the *Official State Gazette*. The safety guides are non-obligatory technical documents by which the CSN provides guidance for the parties affected by the standards in force, with a view to orienting and facilitating the application of such standards. The circulars are technical documents of an informative nature that the CSN may issue to one or several parties to notify them of events or circumstances relating to its realm of competence and of interest for their facilities.

handling, processing, storage and transport of nuclear and radioactive substances, including the authorisation of companies selling or providing technical assistance for X-ray facilities for medical diagnosis. These reports are mandatory in all cases and binding when negative in their findings or denying authorisation, or as regards the conditions established when they are positive.

- It undertakes the surveillance and control of nuclear and radioactive facilities, carrying out inspections and controls throughout all their phases and inspecting activities relating to transport and to the manufacturing and homologation of equipment incorporating radioactive sources or generating ionizing radiations, and approving or validating packages for the transport of radioactive substances. It also has the authority to suspend the operation of facilities or the activities they carry out for reasons of safety.
- It proposes the initiation of sanctions proceedings within its realm of competence. It also issues mandatory reports within three months for the adequate qualification of events when the sanctions proceedings relating to nuclear safety, radiological protection or physical protection have been initiated by another organisation or in response to a justified request by the CSN itself, and in this case includes in the proceedings data additional to those provided by the said organisation. It is also empowered to issue directives to the licensees and to demand corrective measures when the circumstances so require, in the case of presumed infringements classified as slight in accordance with Article 91 of the Nuclear Energy Act, as amended by Act 33/2007.
- It controls the measures for the radiological protection of professionally exposed workers, the members of the public and the environment, and oversees and controls the radiation doses received by the operating personnel and off-site releases of radioactive materials from nuclear and radioactive facilities, as well as their specific or accumulated impact in the area of influence of these installations. It also controls and oversees the environmental radiological quality of the entire national territory and collaborates with the competent authorities in relation to programmes for the radiological protection of persons subjected to medical diagnosis or treatment procedures with ionizing radiations. The CSN tracks incidents caused by radiations and issues its opinion regarding the steps to be taken.
- It collaborates with the competent authorities in developing the criteria to be met by the off-site emergency and physical protection plans of nuclear and radioactive facilities, co-ordinating within its realm of competence the support and emergency response measures and the organisations and companies involved. It also inspects, evaluates, controls, proposes and, where necessary, adopts the prevention and correction measures for exceptional or nuclear or radiological emergency situations when such situations arise in facilities, equipment, companies or activities not subject to the system of authorisations in the nuclear legislation.
- It issues favourable declarations regarding new designs, methodologies, simulation models or verification protocols relating to nuclear safety and radiological protection.
- It grants and renews operator and supervisor licences for nuclear and radioactive facilities, as well as other accreditations within its realm of competence.
- It carries out studies, evaluations and inspections of the plans, programmes and projects required in all phases of radioactive waste management.
- It maintains official relations with similar organisations overseas and participates in international organisations responsible for nuclear safety or radiological protection, possibly collaborating with them in assistance programmes in these areas and advising the Government with respect to commitments to them or to other countries.

- It informs the public regarding matters within its realm of competence, without prejudice to the promotion of its administrative activities. The modifications introduced by Act 33/2007 reinforce the public's right to information and participation. In this respect, the CSN is obliged to inform the public of all relevant events relating to nuclear and radioactive facilities. Its reports are made public, along with those issued as a result of inspections, public information is carried out during the phase of preparation of technical instructions and guidelines, and an advisory committee is set up for public information and participation regarding nuclear safety and radiological protection in order to improve the information provided, the participation of the public and transparency of the decisions taken by the CSN.
- It establishes and monitors nuclear safety and radiological protection research plans.

The CSN maintains relations with the Parliament (Congress and Senate) and with the Government, as well as with the competent ministerial departments and Autonomous Communities. As regards relations with Parliament, the competent Congressional Commission monitors the CSN's affairs through periodic and other appearances, on request by the Congress or by the CSN itself. In addition, the CSN issues reports to the National Parliament and to the Parliaments of those Autonomous Communities in which there are nuclear facilities on the performance of its activities, in accordance with Article 11 of the act by which it was created.

Furthermore, the CSN is linked to the Government fundamentally through the MITYC which is, as pointed out above, responsible for the arrangements for the mandatory and binding reports issued by the CSN within its realm of competence, prior to the granting of authorisations for installations, along with proposals for regulatory developments and initiation of the corresponding sanctions proceedings. Likewise, it maintains relationships with other ministerial departments (with the MARM for participation in the procedure for the environmental impact assessment, with the MIR in relation to the management of emergencies and physical protection, with the Ministry of Health and Social Policy in relation to radiological protection etc.).

iii) Structure

Pursuant to the act by which it was created, the CSN is constituted by a President and four Counsellors who together constitute the Plenary. One of the Counsellors is the Vice-President and replaces the President in cases of absence, vacancy of his/her post or illness.

The Plenary is the governing body of the CSN, which adopts the Council's agreements. The Government and Parliament intervene in the process of appointments to and retirement from the Plenary. The President and Counsellors are appointed by the Government from among persons of recognised standing in the matters assigned to the Council upon proposal by the MITYC and, following acceptance by the Congress, through the competent Commission, on agreement by three fifths of its members.

The CSN is assisted by a Secretariat General to which the Technical Division for Nuclear Safety and the Technical Division for Radiological Protection, among other units, reports. The Secretary General and those responsible for other technical units, as described in the statute, are appointed by the Government in response to a proposal by the MITYC following a favourable report of the Council itself.

The technical personnel of the CSN is made up of civil servants belonging to the nuclear safety and radiological protection corps, although the services of national or overseas personnel, companies and organisations may be contracted for the performance of specific tasks or studies.

The structure, composition and operation of the CSN are detailed in its current statute which, as pointed out above, is under review to adapt it to the provisions of Act 33/2007.

iv) Financing

Pursuant to Article 9 of the Act Creating the CSN, the Council's economic assets and resources are those arising from collection of the fees established for payment of the services it renders, created by Act 15/1980 (main source of financing), the assignments established annually and covered by the general state budget and whatever others might be attributed to it.

Details of this financing are established in Act 14/1999 on Public Tariffs and Prices for services rendered by the Nuclear Safety Council and, where applicable, shall be governed by Act 8/1989 on Public Tariffs and Prices, Act 58/2003 on General Tax Provisions and other complementary provisions.

b) Centre for Energy-related, Environmental and Technological Research (CIEMAT)

CIEMAT is a public research organisation of excellence in energy-related and environmental matters and in multiple state-of-the-art technologies and different areas of basic research.

CIEMAT carries out various activities in different areas relating to nuclear energy. It emerged from the aforementioned Nuclear Energy Board (JEN), created in 1951 and subsequently replaced by the Centre by virtue of Act 13/1986.

i) Legal status

CIEMAT is an independent public research organisation that reports to the Ministry of Science and Innovation via the Secretariat of State for Research. It has its separate public legal standing, equity and resources and autonomy as regards management and the full legal capacity to act.

The Ministry of Science and Innovation is responsible for its strategic management and the evaluation and control of the results of its activities, without prejudice to the functions attributed to the General Comptroller of the state administration as regards the evaluation and control of the results of the public organisations of the state.

ii) Responsibilities

In accordance with Article 3 of its statute, approved by Royal Decree 1952/2000 and modified by Royal Decree 1086/2005, CIEMAT carries out the following general functions:

- development of the R&D policy, within its realm of competence, in accordance with the directives of the Secretariat of State for Research;
- management and performance of co-operative R&D programmes;
- management and performance of R&D programmes on energy matters, agreed on jointly with national or overseas companies or other public or private institutions;
- participation and collaboration, in co-ordination with the Secretariat of State for Research, with the Ministries of Foreign Affairs and Co-operation, and Economy and the Exchequer, and with the Inter-ministerial Commission of Science and Technology, in international organisations and programmes whose activities are linked to research and development on energy-related and environmental issues, especially within the framework of the European Union;
- collaboration with the Autonomous Communities for the performance of R&D programmes, providing advice and support for their activities and promoting the existence of suitable channels of information or the creation of mixed centres;

- rendering of technical support, services and the issuing of certifications for measurements, tests and calibrations carried out at its laboratories, on request and under the conditions established in each case;
- patenting of results, signing of technology transfer agreements and performance of diffusion activities and training in relation to its work; and
- co-ordination of and co-operation in international research programmes, via the Secretariat of State for Research, without prejudice to the competences assigned to the Ministry of Foreign Affairs and Co-operation.

Mention should be made of certain functions in relation to nuclear energy, such as providing support to ENRESA and the CSN in the treatment of radioactive waste and in relation to nuclear safety; the performance of activities in the field of radiological protection (radioecology studies, the evaluation and reduction of radiological impact, the quality of environmental radioactivity measures, personal and environmental dosimetry control); the study of radioactive waste disposal, including research into the behaviour of engineered and geological barriers; developments in the field of medical physics, particularly in nuclear medicine and new radiation detectors and automated systems; R&D activities for the development of fusion by magnetic confinement as a future energy source, through scientific exploration of the Heliac Flexible TJ-II facility; contributing to the development of future fusion reactors and participation in the construction and operation of the ITER; dismantling of the facilities currently shut down and the rehabilitation and updating of its general infrastructures, as part of the Integrated Plan for the Improvement of the CIEMAT Installations (PIMIC).

iii) Structure

The governing bodies of the Centre are a Governing Council and a Management Committee, in addition to the President (who is the Secretary of State for Research), the Vice-President and the General Manager.

The CIEMAT is structured around three management bodies and five scientific-technological departments:

- Energy, responsible for co-ordinating research, development and technical support activities in the field of energy sources, to which the National Fusion Laboratory reports directly.
- Environment, responsible for co-ordinating R&D and technical support activities in relation to the conservation of health and the environment in relation to energy-related and industrial effects.
- Technology, responsible for co-ordinating R&D activities in technologies that, being related to energy, the environment and other areas of social interest, are in themselves areas of technology that require development, to which the technology facilities of the Centre report.
- Basic Research, including co-ordination of research activities in the area of basic research, specifically in the fields of elementary particle physics, molecular and cellular biology and associated technologies.
- Safety and PIMIC, responsible for co-ordinating the PIMIC, a plan that started in 2002 for the dismantling of certain disused nuclear and radioactive facilities and the rehabilitation of the general infrastructures of the Centre in order to adapt them to current and future needs.
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iv) *Financing*

The contributions to the CIEMAT budget come from external and in-house sources. Its economic resources may come mainly from the following sources:

- the assets and securities that constitute its equity;
- products and yield on this equity;
- specific items assigned to the general state budget;
- transfers of capital from the public entities or administrations;
- revenues deriving from the participation of CIEMAT as a shareholder in mercantile companies having purposes linked to the activity of the organisation; and
- ordinary and extraordinary income, including those from the rendering of services.

By virtue of paragraph m) of Article 3.2 of its statute, introduced by means of Royal Decree 246/2009, CIEMAT may also undertake management commissions for the performance of management activities relating to aid programmes or activities for the promotion of research, technological development and innovation by the ministerial departments responsible for the matter. This is remunerated by means of tariffs established by the Ministry of Science and Innovation.

Furthermore, CIEMAT holds 80% of shares in ENRESA and 40% of ENUSA.

c) ***National Energy Commission (CNE)***

The National Energy Commission (*Comisión Nacional de Energía*, hereinafter "CNE") is the regulatory body in charge of energy systems and was set up by the 11th additional provision of the Hydrocarbons Industry Act, Act 34/1998, replacing the former National Electricity System Commission, established by Act 40/1994. Its objective is to ensure effective competition among the energy systems (electricity and liquid and gaseous hydrocarbons markets) and objectiveness and transparency in their operations, to the benefit of all those operating these systems and of the consumers.

The legal framework and organisational structure of the CNE are specified by Royal Decree 1339/1999 which approves its statute, and modified by Royal Decree 3487/2000 and by Royal Decree 1204/2006.

i) *Legal status*

The CNE is a public organisation with its own legal standing, equity and full powers to act. It reports to the MITYC, which exercises control over the efficiency of its activity in order to verify the degree of compliance with its objectives and the adequate use of the resources assigned to it.

ii) *Structure*

The CNE is governed by a Board of Directors, made up of the President, eight Board Members, from among whom a Vice-President and a Secretary are nominated. The President and the Board Members are appointed for a period of six years from among persons of recognised technical and professional competence by Royal Decree, upon proposal by the Minister of Industry, Tourism and Trade and following his appearance before and debate by the competent Congressional Commission.

The CNE has several divisions, such as the Division of Inspection, Liquidations and Compensations, the Management Division and the Divisions of Institutional Relations, Electricity, Gas, Oil, Regulation and Competition, and Energy Derivatives Markets.

The Electricity Advisory Board and the Hydrocarbon Advisory Board are advisory bodies of the CNE.

iii) Responsibilities

Pursuant to the act by which it was created, the CNE is assigned with a series of functions relating to the energy markets. Among others, and as the consultancy body for energy matters, it is responsible for issuing the reports requested by the MITYC and by the Autonomous Communities in exercising of their competences. Likewise, its participation is required in the process of drawing up the general provisions affecting the energy markets or projects for the determination of tariffs, tolls and the remuneration of energy activities, as well as in energy planning and in the procedure for the granting of authorisations for energy installations when they are the responsibility of the central state administration.

iv) Financing

The financing of the CNE is ensured, among others, of fees applicable to the rendering of services and the performance of activities relating to the liquid hydrocarbon and gaseous hydrocarbon sectors and to the electricity industry in general, in accordance to Act 34/1998 as amended by Act 24/2001 on Fiscal, Administrative and Social Measures.

The economic and financial control of the CNE is undertaken by the General Comptroller of the State Administration, without prejudice to the functions corresponding to the Court of Auditors.

3. Public capital companies

a) ENUSA Industrias Avanzadas, S.A. (ENUSA)

ENUSA was created by Decree 3322/1971 as the *Empresa Nacional del Urano Sociedad Anónima*, and took over aspects relating to the front-end of the nuclear fuel cycle that had previously been the responsibility of the JEN.

The core of ENUSA's main business is the front-end of the nuclear fuel cycle which includes the management and supply of enriched uranium to the manufacturing of fuel and the rendering of engineering and fuel services to nuclear power plants.

i) Legal status

ENUSA is a public company whose shareholders are the *Sociedad Estatal de Participaciones Industriales* (SEPI), which reports to the MEH (60%), and CIEMAT which belongs to the Ministry of Science and Innovation (40%). The company belongs to the ENUSA Group, which also includes ETSA/Enusegur, Molypharma, TECONMA and EMGRISA.

ii) Structure and responsibilities

The single additional provision of Royal Decree 1464/1999 empowers ENUSA to carry out activities related to the front-end of the nuclear fuel cycle and to act on the nuclear and radioactive materials market, supplying the goods and services required of it and adjusting its activity to the requirements of the mercantile legislation on limited companies and applicable administrative provisions.

ENUSA is structured into three business areas:

- Front-end of the nuclear fuel cycle: this is the company's most important and traditional activity. It consists fundamentally of supplying enriched uranium to the Spanish nuclear power plants, acting as a purchasing centre for the electricity utilities. It also includes the design and manufacturing of nuclear fuel at its Juzbado facility for national and overseas plants. ENUSA also provides engineering services in relation to the management and optimisation of the use of fuel in the reactor, and fuel services in the inspection, repair and handling of fresh and irradiated fuel, providing support to the nuclear power plants. Furthermore, ENUSA has two minor financial participations in the European uranium enrichment consortium EURODIF and in the company COMINAK.
- Environment: taking advantage of its know-how and experience in the exploitation of mining facilities, the company has developed an area of business dedicated to environmental management projects structured around two fields of work: the restoration of disused uranium mining installations and an environmental technical office.
- Industrial participations: the company participates financially in industrial companies such as ETSA/Enusegur (the transport of hazardous or high responsibility goods) and Molypharma (radiopharmacy and the production of PET radiopharmacological products).

iii) Financing

ENUSA is financed through billing to companies for the services rendered.

b) Empresa Nacional de Residuos Radiactivos, S.A. (ENRESA)

ENRESA is the company authorised in Spain for the rendering of radioactive waste and spent nuclear fuel storage and disposal, transport and handling services. This company, based entirely on public capital, was set up by Royal Decree 1522/1984, repealed by Royal Decree 1349/2003 on the ordering of the activities of the *Empresa Nacional de Residuos Radiactivos, S.A.* (ENRESA) and its financing in order for it to take over functions previously assigned to the JEN.

i) Legal status

ENRESA is a limited company whose shareholders are CIEMAT (80%) and SEPI (the remaining 20%). The legal regime of ENRESA has recently been modified by Act 11/2009 which establishes it as a technical service and resource of the Administration, which carries out the functions assigned to it by the Government and is commissioned to undertake the management of radioactive waste, which is an essential public service. The trusteeship of ENRESA corresponds to the MITYC via the Secretariat of State for Energy, which carries out its strategic management and the tracking and control of its technical and economic actions and plans.

ii) Structure and responsibilities

ENRESA's responsibilities, established in Article 4 of Royal Decree 1349/2003, are as follows:

- treatment and conditioning of radioactive waste;
- selection of sites and design, construction and operation of centres for the storage and disposal of radioactive wastes;
- establishment of systems for the removal, transfer and transport of radioactive waste;
- adoption of safety and security measures in the transport of radioactive waste, in accordance with the provisions of the specific regulations governing the transport of hazardous goods and with what is determined by the competent authorities and organisations;

- management of operations relating to the dismantling and decommissioning of nuclear and radioactive facilities;
- intervention in the event of nuclear or radiological emergencies in support of the national civil defence system and security services, in the manner and under the circumstances required by the competent organisations and authorities;
- final safe conditioning of tailings arising from uranium mining and concentrates manufacturing activities, in the manner and under the circumstances required by the competent organisations and authorities, taking into account, where appropriate, the plans and forecasts of the operator;
- establishment of systems guaranteeing the safe long-term management of its radioactive waste storage and disposal facilities;
- establishment of the research and development plans required for the performance of its functions;
- performance of the necessary technical and economic-financial studies taking into account the deferred costs deriving from its functions in order to establish the corresponding economic needs;
- management of the fund for the financing of activities included in the general radioactive waste plan; and
- any other activity required for the performance of the above.

The radioactive waste management services that ENRESA provides for the operators of nuclear and radioactive facilities are governed by type contracts approved by the MITYC.

Every year, in accordance with Article 6 of Royal Decree 1349/2003, ENRESA drafts and submits to the MITYC a report on the technical and economic aspects of its activities during the previous financial year, comparing them to the corresponding budget, along with an updated economic-financial study of the cost of the activities as set in the general radioactive waste plan. Likewise, it drafts a revision of this plan every four years or whenever required by the Ministry.

iii) Financing

ENRESA's radioactive waste management activities are financed by means of a fund (fund for the financing of activities included in the general radioactive waste plan) which consists of a series of fees whose composition and operation are detailed in the section on radioactive waste management.

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

The OECD is a unique forum where the governments of 31 democracies work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

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The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full member. NEA membership today consists of 28 OECD member countries: Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Portugal, Republic of Korea, the Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities also takes part in the work of the Agency.

The mission of the NEA is:

- to assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information.

The NEA Data Bank provides nuclear data and computer programme services for participating countries. In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

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