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NUCLEAR LEGISLATION IN OECD COUNTRIES

Regulatory and Institutional Framework for Nuclear Activities

Portugal

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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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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PORTUGAL

This chapter was last revised in 2003 and is correct as of that date.

The NEA Secretariat is currently revising this chapter in close consultation with the national authorities and plans to issue a new version in the near future.

PORTUGAL

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I. GENERAL REGULATORY REGIME

1. Introduction

Portugal does not have an electro-nuclear power programme. The Technological and Nuclear Institute (*Instituto Tecnológico e Nuclear* – ITN) owns and operates, for research purposes, a light-water pool reactor (1 MWe) that uses highly enriched uranium.

There is no single framework act governing the nuclear sector in Portugal; instead, a series of laws, regulations and decrees contain detailed provisions governing nuclear activities. Responsibility for these activities is shared between the Ministry for Economic Affairs, the Ministry for Health, the Ministry for Urban Affairs, Territorial Planning and Environment and the Ministry for Science and Higher Education.

The institutional framework for nuclear activities in Portugal has undergone a number of successive changes, the most recent of which took place in 2002. These changes are summarised below.

The Ministry for Industry was reorganised in 1977, with new departments being created and others closed down, including the *Junta de Energia Nuclear* (JEN) [Decree-Law No. 548/77 of 31 December 1977]. The tasks of the JEN were redistributed both amongst existing departments and new bodies created for that purpose [Order No. 126/78 of 31 May 1978]. The latter included the Protection and Nuclear Safety Bureau (*Gabinete de Protecção e Segurança Nuclear* – GPSN), the National Industrial Engineering and Technology Laboratory (*Laboratório Nacional de Engenharia e Tecnologia Industrial* – LNETI), and the General Directorate for Geology and Energy (*Direcção Geral de Geologia e Energia* – DGGE), all of which were placed under the responsibility of the Ministry for Industry. In 1996, another reorganisation took place: the Ministry for Industry and Energy and the Ministry for Trade and Tourism were merged together to form the Ministry of Economic Affairs.

The LNETI was reorganised in 1979, by Decree-Law No. 361/79 of 1 September 1979, following which it was transformed into a public institute, the National Industrial Engineering and Technology Institute (*Instituto Nacional de Engenharia e Tecnologia Industrial* – INETI) by Decree-Law No. 240/92 of 29 October 1992.

In 1995, control over INETI and the DGGE was transferred from the Ministry for Industry to the Ministry for Economic Affairs [Decree-Law No. 296/95 of 17 November 1995].

In 1987, the GPSN was transferred to the Ministry for the Environment and Natural Resources [Decree-Law No. 329/87 of 23 September 1987]. Following the reorganisation of the Ministry for the Environment by Decree-Law No. 189/93 of 24 May 1993, the GPSN was merged with other

directorates into a new General Directorate for the Environment (*Direcção Geral do Ambiente* – DGA). Under the provisions of this same decree-law the Department of Radiological Protection and Safety of INETI was also transferred to the DGA. In 1998, that Department was transferred to the Technological and Nuclear Institute pursuant to Decree-Law No. 311/98 of 14 October 1998 [Section 4]. Under Decree-Law No. 97/03 on the Ministry for Urban Affairs, Territorial Planning and Environment, adopted on 7 May 2003, the DGA was merged with the Environmental Promotion Institute into the Environment Institute (*Instituto do Ambiente* – IA).

Under Decree-Law No. 10/93 of 15 January 1993, the General Directorate for Fundamental Health Care (*Direcção Geral dos Cuidados de Saúde Primários*) and the General Directorate for Hospitals were merged into a single directorate, the General Directorate for Health (*Direcção Geral de Saúde*). The statute of this new general directorate was established by Decree-Law No. 345/93 of 1 October 1993.

Finally, Decree-Law No. 122/93 of 16 April 1993 restructured the General Directorate for Geology and Mines into a public institute, the Institute for Geology and Mines (*Instituto Geológico e Mineiro* – IGM).

For consistency, these bodies will generally be referred to by their new names in this study.

The main legislative instruments regulating nuclear activities are as follows: the above-cited Decree-Law No. 548/77, Decree-Law No. 49.398 of 24 November 1969 which lays down the licensing system for nuclear activities, Decree No. 487 of 5 December 1972, adopted in implementation of Decree-Law No. 49.398, which provides specifically for the licensing of nuclear power plants, Decree-Law No. 165/02 of 17 July 2002, Decree-Law No. 348/89 of 12 October 1989 (insofar as it does not conflict with Decree-Law No. 165/02) setting out the framework for radiation protection as implemented by Decree No. 9/90 of 19 April 1990 and amended by Decree No. 3/92 of 6 March 1992 and, to a certain extent, Decree-Law No. 186/90 on environmental protection of 6 June 1990 (insofar as it does not conflict with Decree-Law No. 165/02).

2. Mining Regime

In Portugal, a number of decree-laws have been issued since 1950 to regulate the prospecting for and exploitation of radioactive ores. Pursuant to Decree-Law No. 37.986 of 27 September 1950 and Decree-Law No. 40.135 of 20 April 1955, the Minister for Finance was authorised to fix export taxes for radioactive materials and their concentrates.

Decree-Law No. 426/83 of 7 December 1983 and Decree No. 34/92 of 4 December 1992 regulate radiation protection and environmental impacts in respect of uranium mining activities. The 1992 Decree sets out the radiation protection standards to be applied to such activities [Chapter III]. This decree, which repeals Decree No. 78/84 on the same subject, was adopted to take into account more recent international radiation protection standards. It sets out the obligations of persons in charge of such activities [Section 6] and those of workers performing such activities [Section 7]. It specifies that any unnecessary exposure to radiation or contamination of the environment must be avoided; it also provides that such exposure levels must be as low as possible and in any event always below the limits fixed by the national radiation protection standards [Section 9]. All mining projects or related treatment and recovery facilities must be for approved by the Institute for Geology and Mines [Section 43].

Two decisions define, respectively, the rules to be complied with when concluding contracts for the prospecting and exploitation of radioactive ore deposits and for the licensing of bodies engaged in such activities [Decisions Nos. 2 and 3 of 19 March 1971 of the JEN Presidency].

According to Decrees Nos. 348/89, 34/92, 187/93, 189/93, 345/93, 165/02 and 113/03, the responsible authorities for uranium mining and related activities are the Institute for Geology and Mines, the General Directorate for Health, the Ministry for Urban Affairs, Territorial Planning and Environment and the Regional Directorates for Economy.

The Technological and Nuclear Institute (ITN) is responsible for monitoring the environment in mining areas.

3. Radioactive Substances, Nuclear Fuel and Equipment

Activities involving production of and trade in radioactive substances and nuclear fuel are regulated by Decree-Law No. 49.398 of 24 November 1969.

The Institute for Geology and Mines (*Instituto Geológico e Mineiro* – IGM) is responsible for controlling the production of and trade in nuclear fuel for industrial uses [Order No. 126/78 of 31 May 1978, Section 1 and Decree No. 7/93 of 19 March 1993, Section 2].

The General Directorate for Geology and Energy is responsible for licensing nuclear fuel cycle facilities and for the transfer of nuclear fuel on national territory and between Portugal and other EU Member States.

The import, production, use and transport of radioactive substances and radiation-emitting equipment are subject to prior authorisation by the General Directorate for Health, in accordance with the conditions laid down by Sections 6, 7 and 8 of Decree-Law No. 348/89 and Section 34 of Decree No. 9/90 of 19 April 1990.

In accordance with Decree No. 9/90 [Section 35] substances and apparatus whose radioactivity does not exceed certain levels specified in Annex II of the decree are exempted from prior authorisation or licensing; such exemptions do not apply to radioactive substances for medical or diagnostic purposes or to radioactive substances added to toys, cosmetics or household products [Section 36 as amended by Decree No. 3/92 of 6 March 1992].

The import and export of concentrates of radioactive substances, the fabrication, import and export of nuclear fuel, the treatment of and trade in irradiated fuel and other activities of an industrial nature are subject to licensing [Decree-Law No. 49.398, Sections 1 and 2]. Licences are issued for a limited period on a case-by-case basis, upon proof that the establishment concerned has the necessary technical knowledge and financial resources. Its premises are subject to inspection by the competent authorities, being the regional delegations of the Ministries for Economic Affairs, Health and the Environment. In addition, contracts whose purpose is the establishment, modification or transfer of associations concerned with the above activities are subject to ministerial approval [Section 4].

The Technological and Nuclear Institute is responsible for the evaluation and inspection of the security conditions governing nuclear fuel transport.

4. Nuclear Installations

a) *Licensing and inspection, including nuclear safety*

Decree-Law No. 165/02 of 17 July 2002 designates the competent authorities for licensing nuclear installations and nuclear activities in Portugal. Decree-Law No. 487 of 5 December 1972 made in implementation of Decree-Law No. 49.398, sets out the licensing procedure for nuclear power plants. Decree-Law No. 48.568 of 4 September 1968 establishes the nuclear installations inspection regime (these provisions are not, however, applied at present as there are no nuclear power plants in Portugal).

The General Directorate for Geology and Energy (*Direcção General de Geologia e Energia – DGGE*) under the Ministry for Economic Affairs and the Environment Institute (IA) under the Ministry for Urban Affairs, Territorial Planning and Environment are the competent authorities for licensing activities related to the nuclear fuel cycle, and in particular the transfer and transit of nuclear fuel between Portugal and other EU Member States as well as on national territory. The DGGE is not responsible for licensing the detention, transfer, sale or any other transmission of radioactive sealed sources, as the Nuclear and Technology Institute carries out this task [Decree-Law No. 165/02, Sections 13 and 14(a)].

According to Decree No. 487/72 [Section 1], nuclear power plants must be established in compliance with Decree-Law No. 49.398 of 1969. The licensing procedure takes place in three stages, each one of which results in delivery of a preliminary licence for site approval, construction and operation, respectively.

The application for a preliminary licence for site approval must contain all the information required to assess the technological, economic and safety aspects of the installation concerned, and the local population must be informed of the application by notification in the Official Gazette [Sections 2 and 3]. When a preliminary licence is granted, the applicant must then apply for a construction licence and attach a preliminary safety report [Section 6]. Requests for a construction licence are examined from the viewpoint of the design of the facility, construction techniques, etc. The operating licence is then issued on the basis of a final safety report.

Nuclear facilities must be inspected regularly, in accordance with the provisions of Decree-Law No. 48.568 of 4 September 1968. The inspections are scientific and technical and are intended to check the effectiveness of radiation protection and nuclear safety measures. The Environment Institute (IA) is the authority in charge of inspections from the viewpoint of nuclear safety [Decree-Law No. 425/91, Section 1].

The General Directorate for Health, with the support of the General Labour Inspectorate and technical assistance from other bodies is responsible for inspections and controls from the radiation protection point of view [Decree No. 9/90, Section 54].

At the international level, Portugal is a Party to the 1994 Convention on Nuclear Safety which was ratified on 20 May 1998.

b) Protection of the environment against radiation effects

Act No. 11/87 of 7 April 1987 on the environment provides the basis for the environmental policy in Portugal. Section 25 of the act deals with radioactive substances and specifies that control of any contamination likely to be caused by such substances should be undertaken as follows, with a view to preventing its effects on the health and welfare of the population:

- the effects of radioactive substances on ecosystems should be assessed;
- disposal limits should be set for chemical and physical radioactive effluents resulting from activities involving extraction, transport, conversion and use of radioactive substances;
- preventive measures should be established to respond immediately to any radioactive contamination;
- the effects of transboundary contamination should be assessed and monitored;
- rules should be set governing the transit, transfer and deposit of radioactive substances on the national territory, in the territorial seas and the exclusive economic zone.

Decree-Law No. 186/90 of 6 June 1990 was made in implementation of Council Directive 85/337/EEC on assessing the effects of certain public and private projects on the environment. It provides that approval of nuclear power plant projects and other nuclear reactor projects, as well as radioactive waste repositories, is subject to a prior environmental impact assessment [Section 2 and Annex I]. Decree No. 38/90 of 27 November 1990, made in implementation of the decree-law, specifies the procedure to be followed for environmental impact assessments. Prior to any licence being granted, the licensing authority, according to the type of project being assessed, must be provided with an environmental impact study of the planned project. The authority competent to direct the study is designated by order of the Minister for Urban Affairs, Territorial Planning and Environment [Section 3]. The study must include, *inter alia*, a description of the project, its site, operational characteristics, physical, geological, hydrogeological, ecological, and demographic data, as well as information on the quality of the environment (water, soil, etc.) [Section 2]. The public is consulted on the study and must provide its views within a given time limit [Section 4].

c) Emergency response

Decree No. 9/90 of 19 April 1990 provides for emergency response in the event of an accident or emergency. In the context of the radiation protection plan for installations to be submitted to the General Directorate for Health, the person responsible for the installation involved must include a plan of action in the event of accidental exposure to radiation or emergency situations in accordance with the intervention plan specified in the decree [Section 7]. The General Directorate for Health, on its own initiative or on proposal of the competent authority, the Environment Institute, and following consultation with the National Radiation Protection Commission, establishes intervention plans including measures to be adopted in emergency or accident situations likely to involve abnormal radiation levels for workers and members of the public [Section 46(1)]. Those measures must take into account radiation protection rules so as to be fully effective [Section 46(2)]. In an accident situation, the General Directorate for Health immediately informs the competent authorities, namely the National Service for Fire and Civil Protection, on the methods of intervention in terms of personnel and equipment it considers necessary for protecting public health [Section 46(3)].

The Environment Institute is the national contact point for radiological emergencies occurring outside Portugal's borders and the National Service for Fire and Civil Protection is the contact point for radiological emergencies occurring within Portuguese jurisdiction.

Where the magnitude of the accident so warrants, the competent authorities inform the EU Member States likely to be affected by its occurrence [Section 46(4)].

Portugal is a Party to the 1986 Convention on Early Notification of a Nuclear Accident, which was ratified on 30 April 1993. Portugal has also ratified the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, which was ratified on 12 September 2003.

5. Trade in Nuclear Materials and Equipment

The regulations on trade in nuclear materials and equipment in Portugal can be found in Decree-Law No. 375/90 which provides for the physical protection of nuclear materials on the national territory. The Environment Institute is the competent authority regarding physical protection matters.

Accordingly, the import, manufacture, possession, purchase, sale or transfer of nuclear material, as well as its transport whether national or international when it takes place on the national territory, are subject to prior licensing by the Environment Institute, without prejudice to the competence assigned to other authorities [Section 3].

Also, Decree No. 165/02 on radiation protection provides that the import of radioactive materials and that of equipment emitting radiation for scientific, medical or industrial purposes as well as for any activity involving the production of ionising radiation requires a prior licence from the General Directorate for Health following consultation of the National Radiation Protection Commission.

In accordance with Decree-Law No. 72/91 on medical products and equipment for human use, the marketing of medical products containing radionuclides requires a licence from the Ministry of Health, following consultation with the General Directorate for Pharmaceutical Questions [Sections 2 and 30]. Applications for such licences are described in Section 6 "Radiation Protection" *infra*.

6. Radiation Protection

The radiation protection of workers and the public is governed by several decree-laws including, *inter alia*, No. 348/89 of 12 October 1989, as well as 2002 Decree Nos. 165/02, 167/02 and 174/02. Decree-Law No. 348/89 established the National Radiation Protection Commission as an advisory body to the General Directorate for Health and set out the institutional framework for radiation protection. Decree-Law on the protection of the population against the dangers of ionising radiation [No. 165/02 of 17 July 2002] aims to implement part of 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 ionising radiation. It sets out the basic principles governing radiation protection and describes the powers and duties of the different authorities involved in this field. The General Directorate of Health is responsible for issuing licences for installations and equipment producing ionising radiation and the General Directorate for Geology and Energy is empowered to issue licences for nuclear fuel cycle installations. The Regional Health Authorities conduct inspections and control radiological installations. This decree-law applies to all practices involving natural or artificial ionising radiation sources. It incorporates the principles of justification,

dose limitation and the ALARA principle in respect of exposure and provides for the notification of any practice involving ionising radiation. Decree No. 9/90 of 19 April 1990, made in implementation of Decree-Law No. 348/89 [Section 15], establishes the basic principles of radiation protection applicable to occupationally exposed persons, to individuals and to the public at large. It implements Council Directives 80/836/, 84/467/ and 84/466/Euratom which contain basic radiation protection standards and lay down safety measures for radiation protection of persons undergoing medical treatment. It should be noted however that this decree-law is only applicable in accordance with Decree-Law No. 165/02. Radiation protection provisions are also to be found in Decree No. 34/92 relating to uranium mining and related activities, referred to under Section 2 “Mining Regime” *supra*.

Decree-Law No. 348/89 is still applicable in all areas not regulated by Decree-Law No. 165/02, for example, in matters concerned with nuclear third party liability.

As mentioned above, the Decree-Law No. 165/02 provides that the General Directorate for Health within the Ministry for Health is responsible for radiation protection on the national territory and sets up a National Radiation Protection Commission to advise the General Directorate on radiation protection matters and related legislation [Sections 1 and 2]. The operation of radiation-emitting devices or equipment is subject to a prior licence delivered by the General Directorate for Health [Section 1].

Decree No. 9/90 defines the duties of persons responsible for installations or activities likely to involve exposure to radiation [Sections 3 to 6]. In particular, they must submit to the General Directorate for Health, for approval, a radiation protection plan to be applied in their installations or which will cover their activities, as the case may be; the plan must include measures for regular control of all radiation protection devices [Section 7].

The decree makes a distinction between occupationally exposed persons, individual members of the public and the population as a whole [Section 2] and provides for different annual dose limits according to each category as specified in annex [Section 31]. The annual dose limit for occupationally exposed persons is 50 mSv (5 rem), subject to a cumulative limit of 100 mSv for any five consecutive years, while the limit for members of the public is 5 mSv (0.5 rem) [Annex IV].

The decree allows certain exemptions from the prior licensing requirements provided under Section 7 of Decree-Law No. 348/89 [Section 36]; these exemptions are listed in Annex II. Decree No. 3/92 of 6 March 1992 amends Section 36, specifying that such exemptions do not apply to radioactive substances administered for diagnosis, research or treatment or to foodstuffs, medical products, household articles, cosmetics or toys containing radioactive substances. Decree-Law No. 337/01 on the treatment of food by ionising radiation aims to implement Directive 1999/2/EC of 22 February 1999 of the European Parliament and of the Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation and Directive 1999/3/EC of 22 February 1999 of the European Parliament and of the Council on the establishment of a community list of foods and food ingredients treated with ionising radiation. It applies to the manufacture, trade and import of food and food ingredients treated with ionising radiation.

The decree-law establishes the conditions which must be fulfilled for authorisation of the treatment of foodstuffs with ionising radiation. It also establishes conditions governing the import of foods and food ingredients from third countries.

The General Directorate of Health has competence to approve the design and operation of installations where such treatment takes place. It is obliged to retain records for several years on each used radiation source, and on the nature and quantity of irradiated food and food ingredients.

Order No. 53/71 of 3 February 1971 approving general health and safety regulations for workers in industrial facilities provides that premises where radioactive substances or radiation-emitting devices are used, handled or produced must comply with the special safety regulations in force [Section 28].

As explained under Section 2 “Mining Regime” *supra*, Decree No. 34/92 of 4 December 1992 regulates radiation protection in uranium mining and related activities. Persons in charge of such activities must submit to the General Directorate for Health the protection and safety plan to be applied in their installations, or which will cover their activities, as the case may be; in particular, the plan must include measures for regular monitoring of radiation protection devices. Such persons must also inform workers of the possible risks and the measures to be complied with to avoid exposure to radiation, and ensure that they are observed [Section 6]. For their part, workers must comply with such measures and use the equipment and dosimeters provided for their protection; they must also take every precaution to keep such equipment in good condition [Section 7].

This decree also calls for an administrative service to ensure compliance with the safety provisions required by the decree as well as with specified radiation levels [Section 27]. The Radiological Protection Service must be made up of at least one technician specialised in radiation protection who will co-ordinate the Service, one physician and one ventilation specialist [Section 28].

Decree-Law No. 72/91 of 8 February 1991 lays down regulations for the manufacture, marketing and quality control of medical products and apparatus for human use. The regulations take account of a series of directives on this subject issued by the European Community and establish a licensing system for medical products and apparatus, including those containing radioisotopes [Section 4].

The manufacture of medical products containing radioactive substances and their marketing is subject to prior licensing [Sections 30 to 32]. In addition to information to be provided in licence applications for all medicines (e.g. information on the applicant, composition of medicine, intended use, etc.), applications for licences to market irradiating apparatus must also contain a general description of the system and the qualitative and quantitative characteristics of the radioactivity released [Section 31]. The Decree-Law provides that its provisions are without prejudice to the application of the radiation protection legislation in force [Section 35].

Decree-Law No. 36/95 of 14 February 1995 implements into national law Council Directive 89/618/Euratom of 27 November 1989 on informing the general public of the health protection measures to be applied and steps to be taken in the event of a radiological emergency.

Decree-Law No. 153/96, adopted on 10 August 1996, regulates activities involving the use of sealed radioactive sources which could pose a risk of ionising radiation exposure or of radioactive contamination, so as to ensure the protection of the public and of the environment [published in *Diario da Republica*, 30 August 1996].

With the entrance into force of Decree-Law No. 165/02, the Technological and Nuclear Institute (ITN) becomes the licensing authority for the possession, sale, transport, import and any other transfer of sealed sources. Persons responsible for such acts must submit a request for a licence to the ITN in accordance with the prescribed conditions of Decree No. 156/96 and the criteria set forth jointly by the Ministers for Health, for Urban Affairs, Territorial Planning and Environment, and for Science and Higher Education, or on the advice of the General Directorate for Health. A public register of all licensees is to be kept.

Decree-Law No. 492/99, of 17 November 1999 [as amended by Decree-Law No. 240/00, of 26 September 2000] approves the legal regime for licensing and inspection of private medical facilities that use ionising radiation for diagnostics, therapy and prevention. This decree-law sets out conditions governing installations and organisation of private medical facilities.

The Decree-Law on protection against ionising radiation in relation to medical exposure [No. 180/02 of 8 August 2002] aims to implement Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure. This decree-law sets out conditions governing the control and inspection of radiological equipment and installations and the duties and responsibilities of the owner and personnel of medical facilities.

7. Radioactive Waste Management

Decree-Law No. 348/89 of 12 October 1989 provides that the storage and disposal of radioactive products or waste require a licence from the General Directorate for Health, following consultation with the National Radiation Protection Commission [Section 8].

Decree No. 9/90, which implements Decree-Law No. 348/89, specifies the principles governing radioactive waste management. It provides that the disposal and storage of radioactive waste must be planned in such a way as to avoid or reduce its dispersal into the environment, whether under normal or emergency conditions [Section 44]. Furthermore, in order to obtain a licence from the General Directorate for Health, the applicant must submit an environmental impact assessment, information on the planned radiation protection and nuclear safety measures and operations as well as storage conditions, whether temporary or final [Section 45(1) and (2)]. The General Directorate for Health grants a licence, provided that all the radiation protection and nuclear safety measures it has approved have been complied with, and also fixes a dose limit for radioactive releases, taking into account the need to keep radioactivity levels in the environment as low as possible [Section 45(3) and (4)].

In accordance with Decree No. 34/92 of 4 December 1992 on radiation protection in uranium mining and related activities, products resulting from prospecting deposited in slag heaps must be monitored to control their radioactivity levels; adjacent areas must also be monitored so as to detect the quantity of radionuclides released into bodies of water, sediments or the air [Section 64(1)]. Premises where radioactive residues from uranium treatment are stored must be kept in such a way as to ensure that dust releases are reduced to a minimum [Section 64(2)]. Repositories for radioactive waste must be established in accordance with the most recent recommendations of the International Atomic Energy Agency. Plans for repositories must provide guarantees that they will remain stable for periods running from 200 to 1 000 years, taking into account extreme technical and meteorological phenomena [Section 65(1)]. The disposal into the environment of radioactive materials from facilities for the treatment of ores and uranium recovery must be carried out in compliance with the radiation dose limits set by the Environment Institute (*Instituto do Ambiente – IA*) [Section 67].

Also, Order No. 16/90 of 21 August 1990 provides for the treatment of solid hospital residues of all types. It specifies that radioactive waste must be disposed of in accordance with the regime established by Decree-Law No. 348/89 and Decree No. 9/90 [Section 3(5)].

Decree-Law No. 138/96 of 25 July 1996 aims to incorporate into Portuguese domestic law Council Directive 92/3/Euratom on the monitoring and control of shipments of radioactive waste between Member States, as well as their entry into and exit from the European Community [published in *Diário da República*, 14 August 1996]. The decree-law describes in detail the licensing procedure

for each import, export or shipment of radioactive waste within the Community, between a third country and the Community, or between two third parties where part of the shipment crosses the territory of a Member State of the Community. The Environment Institute is, in principle, the agency with jurisdiction to grant licences and to define the transfer of procedures. Permission may be given to return waste resulting from the reprocessing of irradiated fuel to the country of origin where such fuel originated in that country or it was agreed in advance by the parties that such waste would be returned.

The Technological and Nuclear Institute is responsible for the temporary storage of solid radioactive waste and for authorising the transfer of radioactive waste inside its borders and within the European Union [Decree-Law No. 165/02 – Section 14(c) and (j)].

Finally, Portugal is a Party to the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter, which it ratified on 14 April 1978.

8. Non-Proliferation and Physical Protection

Portugal has no domestic legislation on non-proliferation. However, it is a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT), which it ratified on 15 December 1977, and has concluded the subsequent safeguards arrangement with the International Atomic Energy Agency on 7 August 1978 [IAEA INFCIRC/272]. Resolution No. 102/01 of 29 August 2001 establishes the National Authority for matters related to the NPT.

Decree-Law No. 319/03 of 20 December 2003 establishes the ITN as the entity responsible for implementation of the Additional Protocol to the NPT Treaty and as national contact for issues related to the Additional Protocol.

Portugal is also a Party to the 1979 Convention on the Physical Protection of Nuclear Material, ratified on 6 September 1991. Following the adoption of Presidential Decree No. 14/90 of 15 March 1990 authorising ratification of the Convention, Decree-Law No. 375/90 of 27 November 1990 designates, in accordance with the Convention, the Office for Nuclear Protection and Safety (*Gabinete de Protecção e Segurança Nuclear – GPSN*) as the competent authority in relation to physical protection matters [Section 2]. Subsequently, the Environment Institute has assumed the rights and responsibilities of the GPSN.

9. Transport

The Regulations for the Transport of Dangerous Goods [Order No. 977/87 of 31 December 1987] deal with radioactive substances under Class 7, in accordance with the recommendations of the International Atomic Energy Agency.

Decree-Law on the Transport of Dangerous Goods by Road [No. 267-A/03, of 27 October 2003] aims to implement Commission Directive 2001/7/CE of 29 January 2001 and Commission Directive 2003/28/CE, of 7 April 2003 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road. The decree-law creates sanctions for non-compliance with legal requirements. It further establishes the following bodies as competent to evaluate the technical condition of vehicles, traffic conditions and road security: the General Inspectorate for Public Construction, Transport and Communications, the General Directorate of Traffic, the regional Directorates for Economic Affairs, the Republic National Guard, the Public Security Police and the General Inspectorate for Economic Activities.

The Decree-Law on the Transport of Dangerous Goods by Sea [Law No. 169/00 of 8 August 2000], modifies Decree-Law No. 94/96 and aims to implement Council Directive 93/75/EEC of 13 September 1993 concerning minimum requirements for vessels bound for or leaving European Community ports and carrying dangerous or polluting goods.

The Decree-Law on the Transport of Dangerous Goods by Rail [No. 227-C/2000 of 22 September 2000] aims to implement Council Directive 96/49/EC of 23 July 1996 and Commission Directives 96/87/EC of 13 December 1996 and 1999/48/EC of 21 May 1999 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail. It applies to all activities involving the transport of dangerous goods or waste by rail taking place, in part or whole, on national territory. This includes all loading and unloading operations and also the transfer to another type of vehicle or breaks due to transport conditions. The National Institute of Rail Transport is responsible for enforcing these rules.

Decree-Law No. 348/89 provides that the regulations on radiation protection in force apply to the transport of radioactive substances [Section 1]. Decree No. 9/90, made in implementation of this decree-law specified that the transport of radioactive materials requires a licence delivered by the General Directorate for Health. These responsibilities have been taken over by the Environment Institute [Decree-Law No. 97/03], and the Technological and Nuclear Institute [Decree-Law No. 165/02] is the authority delivering licences for the transport of sealed radioactive sources.

Decree-Law No. 165/02 states that the Technological and Nuclear Institute assesses and examines the conditions for the safe transport of fresh or spent nuclear fuel and for the transport of radiation sources for nuclear installations as well as radioactive waste from such installations. [Section 14(i)].

Decree-Law No. 72/91 on medical products and apparatus for human use specifies, as regards medicines containing radionuclides and irradiating apparatus, that they must be packed in accordance with the requirements set out in the International Atomic Energy Agency's Regulations for the Safe Transport of Radioactive Materials, and that their labels must indicate their levels of radioactivity [Section 33].

10. Nuclear Third Party Liability

Portugal has not yet enacted specific nuclear third party liability legislation. However, Decree-Law No. 348/89 on radiation protection provides that the person responsible for installations, equipment or materials emitting ionising or non-ionising radiation is liable for damage resulting from their use, unless it is proved that at the time the damage was caused, the installations, equipment or materials had been used in conformity with the technical rules in force and were in perfect condition, or the damage was due to a case of *force majeure* [Section 10]. Such persons, with the exception of the state or public entities, must cover their liability through an insurance company authorised to operate in Portugal, in accordance with regulations to that effect, to be established by decree [Section 11].

Some special provisions of Decree-Law No. 153/96 of 10 August 1996, concerning the use of sealed radioactive sources, also cover third party liability. This decree-law establishes that licence-holders are strictly liable for damage caused to persons, to property and to the environment by a sealed radioactive source, even if they have complied with applicable legal requirements [Section 3]. At the international level, Portugal is a Party to the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, which it ratified on 29 September 1977.

II. INSTITUTIONAL FRAMEWORK

In Portugal, responsibility for the control and management of nuclear activities is vested in the Minister for Economic Affairs and the Minister for Finance, the Minister for Urban Affairs, Territorial Planning and Environment, the Minister for Health and the Ministry for Science and Higher Education as mentioned in Part I of this Study.

Decree-Law No. 358/76 of 14 May 1976 provides for the general organisation of the Ministry for Industry and Energy and also provides for greater involvement of the state in such matters. Based on that decree-law, Decree-Law No. 548/77 of 31 December 1977 set up new departments within the Ministry and closed down others, in particular the *Junta de Energia Nuclear*. Order No. 126/78 of 31 May 1978 reorganised the energy sector, in particular to combine nuclear energy with the overall energy sector and to merge nuclear activities with other industrial and research activities.

1. Regulatory and Supervisory Authorities

a) Minister for Economic Affairs

The Minister for Economic Affairs is responsible for nuclear policy in Portugal. He is empowered to prepare and propose the energy and industry plan within the general national development programme; he supervises and directs the management of public and nationalised companies in the industry and energy sector, without prejudice to the competence of other ministers concerned, and he promotes research and development in that sector as well as agreements on technical and scientific co-operation; he also controls activities in the industrial and energy sectors [Decree-Law No. 186/03 of 20 August 2003, Chapter 1].

More generally, he makes proposals in respect of industrial and technological policy and is responsible for the implementation of these policies in the framework of the general policy determined by the government.

b) Minister for Health

The Minister for Health is competent for all questions of radiation protection through the General Directorate for Health [Decree-Law Nos. 165/02, 167/02, 174/02, 180/02 and Decree-Law No. 348/89]. The Minister is empowered to make regulations in his field of competence [Decree-Law No. 10/93 of 15 January 1993, Section 1].

c) Minister for Urban Affairs, Territorial Planning and Environment

The Minister is the supervising authority of the Environment Institute. It is also responsible for uranium mining and related activities [Decree-Law No. 97/03 of 7 May 2003]. According to Decree-Law No. 165/02, it is the competent authority for the approval of mining areas that need to be recovered.

According to Decree No. 38/90 of 27 November 1990, implementing Decree-Law No. 186/90 of 6 June 1990, it plays a direct role in the protection of environment against radiation effects, since it

designates the competent authority to direct the environmental impact study that is required prior to any licence being granted for nuclear power plant projects and other nuclear reactor projects [Section 3].

d) *Minister for Science and Higher Education*

The Ministry for Science and Technology [Decree-Law No. 296-A/95 of 17 November 1995] is now the Ministry for Science and Higher Education [Decree-Law No. 205/02 of 7 October 2002]. The latter is involved in Portuguese nuclear energy policy through the activities of the Technological and Nuclear Institute [Decree-Law 324-A/94], for which it is responsible.

e) *Minister for Finance*

The Minister for finance is involved in the nuclear energy policy as, in this field, the Minister for Economic Affairs acts in co-ordination with it. The Minister for finance is generally competent, together with the Minister for Economic Affairs, for financing public industrial activities [Decree-Law No. 40.135 of 20 April 1955], and for establishing customs duties in connection with radioactive ores and products made therefrom.

As regards the National Uranium Enterprise (*Empresa Nacional de Urânio – ENU*), the Minister for Economic Affairs, jointly with the Minister for Finance had originally established by decree the authorised capital of the Company [Decree No. 490/76 of 23 June 1976], before it was transformed into a private limited company (see *infra*, under Section 3 “Public and Semi-Public Agencies”).

In connection with the National Industrial Engineering and Technology Institute (*Instituto Nacional de Engenharia e Tecnologia Industrial – INETI*), the Minister for Finance and the Minister for Economic Affairs are empowered to establish by order the conditions of operation of the INETI Administrative Board [Decree-Law No. 361/79 of 1 September 1979, Section 13].

2. *Advisory Bodies*

a) *National Radiation Protection Commission (CNPCR)*

The National Radiation Protection Commission (*Comissão Nacional de Protecção contra Radiações – CNPCR*) was originally set up within the General Directorate for Health by Decree-Law No. 348/89 [Section 4]. Decree-Law No. 165/02 granted additional competences to the Commission. It has an advisory task and is made up of representatives of the following:

- the General Directorate for Health, which holds the chair;
- specialists in nuclear medicine, radiology, radiotherapy and dermatology from departments of the College of Physicians;
- the College of Dentists;
- the Technological and Nuclear Institute;

- the Institute for Development and the Inspectorate for Working Conditions;
- the General Directorate for Geology and Energy.

The CNPCR advises the General Directorate for Health on all questions within its competence. The Chairman of the CNPCR may set up working groups made up of members of the Commission and other specialists to study and assess specific questions in its field [Section 21].

b) *Commission for Radiological Protection and Nuclear Safety*

Decree-Law No. 311/98 of 14 October 1998 established the Commission for Radiological Protection and Nuclear Safety (*Comissão para a Protecção Radiológica e Segurança Nuclear*) whose principal objective is to minimise risks to public health and to the environment as a result of ionising radiation, radioisotopes and nuclear installations.

This Commission comprises representatives from the three ministries competent in this field, namely the Ministry for Urban Affairs, Territorial Planning and Environment, the Ministry for Health and the Ministry for Science and Higher Education.

The decree-law entrusts the Commission with the following duties:

- to draft bills and regulations in the above-mentioned sectors;
- to verify compliance with conditions set out in licences for the storage, production or transport of radioactive material and equipment or for nuclear installations which generate radioactive residues or nuclear waste;
- to guarantee the respect of international obligations related to radiological protection and nuclear safety;
- to co-operate with similar bodies working in these fields in other countries and with the competent international organisations;
- to assist in the preparation of national radiological and nuclear emergency plans.

Technical assistance is provided to the Commission by the Technological and Nuclear Institute (*Instituto Tecnológico e Nuclear – ITN*), through its Department of Radiological Protection and Nuclear Safety. This Department was formerly part of the General Directorate for the Environment, before its transfer to the ITN pursuant to Section 4 of Decree-Law No. 311/98 mentioned above. The tasks assigned to this Department are listed in the decree-law and are of a strictly technical nature in order to guarantee that it complement the Commission's duties.

c) *National Commission for Radiological Emergencies (CNER)*

Decree-Law No. 165/02 established the National Commission for Radiological Emergencies (*Comissão Nacional para Emergências Radiológicas*). It carries out advisory functions and is made up of representatives from the following organisations:

- the National Service for Fire and Civil Protection, which holds the chair;
- the General Directorate for Health;
- the National Institute for Medical Emergencies;
- the Environment Institute;
- the Meteorology Institute;
- the Commission for the Planning of Agriculture, Fisheries and Emergency Food ;
- the Technological and Nuclear Institute;
- the General Directorate for Geology and Energy.

The CNER advises the National Service for Fire and Civil Protection on all questions within its competence. The Chairman of the National Radiation Protection Commission (CNPCR) may establish working groups comprised of members of the CNER and other specialists to study and assess specific questions in its field [Section 23].

The Commission has competence to enter opinions on emergency plans and to collaborate with the National Service for Fire and Civil Protection in preparatory actions for radiological national emergencies.

3. Public and Semi-Public Agencies

The different departments under the Ministries for Economic Affairs, Health and Urban Affairs, Territorial Planning and Environment enjoy a certain extent of autonomy and, in view of their responsibilities, it is appropriate to discuss them in this part of the study.

a) General Directorate for Geology and Energy (DGGE)

The General Directorate for Geology and Energy (*Direcção Geral de Geologia e Energia – DGGE*), is under the authority of the Ministry for Economic Affairs [Decree-Law No. 186/03, of 20 August 2003]. It covers the operational aspects of the whole energy sector, namely, the production, transport, distribution and use of various forms of energy, including nuclear energy

The DGGE is run by a director-general and two deputy-directors.

b) Institute for Geology and Mines (IGM)

As explained in Part I, Section 1 “Introduction” *supra*, the General Directorate for Geology and Mines was restructured into the Institute for Geology and Mines (*Instituto Geológico e Mineiro – IGM*) by Decree-Law No. 122/93 of 16 April 1993. The IGM is under the authority of the Ministry of Economic Affairs and is generally responsible for the management of mineral resources [Decree-Law No. 548/77, Section 7]. In particular, it is responsible for prospecting for, inventorying and assessing radioactive ores [Decree-Law No. 122/93 of 16 April 1993, Section 18].

c) *Environment Institute (IA)*

The Environment Institute (*Instituto do Ambiente*) is a public entity created under the Ministry for Urban Affairs, Territorial Planning and Environment, which is responsible for continuing environment and sustainable development policies [Decree-Law No. 97/03 approving the Organic Law of Ministry for Urban Affairs, Territorial Planning and Environment, 7 May 2003]. The Environment Institute was established by merging the former Directorate for the Environment (*Direcção Geral do Ambiente – DGA*) with the Environmental Promotion Institute.

Decree-Law No. 97/03 defines, *inter alia*, the IA's responsibilities, which are to co-ordinate activities related to environment and public safety. In this respect, it is in charge of early notification in the event of a nuclear accident and is in charge of the assessment of the risks posed by radiation emissions. The Environment Institute is chaired by a president and two vice-presidents. Decree-Law No. 113/03 details the internal structure of the Environment Institute.

d) *National Industrial Engineering and Technology Institute (INETI)*

The National Industrial Engineering and Technology Institute (*Instituto Nacional de Engenharia e Tecnologia Industrial – INETI*), previously under the authority of the Ministry for Industry and Energy [Decree-Law No. 548/77], is now under the authority of the Ministry for Economic Affairs [Decree-Law No. 296/95 of 17 November 1995]. It incorporates the Nuclear Energy and Engineering Institute, formerly the Research Centre of the JEN.

As already explained, the National Laboratory of Industrial Engineering and Technology was merged into the above Institute (INETI) by Decree-Law No. 240/92 of 29 October 1992. Order No. 592-A/93 of 15 June 1993 sets out the internal organisation and operation of the Institute.

i) *Legal Status*

The INETI is an institute for technological research and development which provides support to the different industrial sectors in the ambit of the Ministry of Economic Affairs [Section 24]. It is endowed with the status of a separate legal entity, owns property and enjoys administrative and financial autonomy [Decree-Law No. 361/79 of 1 September 1979, Sections 1 and 2].

ii) *Responsibilities*

The responsibilities of the INETI are the following [Decree-Law No. 548/77, Section 24]:

- to undertake applied research in accordance with the objectives of the national programme;
- to provide technological assistance to industrial undertakings, with a view to improving manufacturing processes and supplying innovative techniques;
- to provide the analytical assistance required for quality control of products and related inspection and technical surveillance;

- to collect, co-ordinate and disseminate information of interest to the ministerial services and undertakings concerned;
- to train specialists in techniques of interest to the different industry sectors.

In particular, the INETI co-ordinates and carries out research and development programmes and projects directly related to industrial development, through contracts with industrial undertakings or in association with national or international bodies [Decree-Law No. 361/79, Sections 5 and 6]. INETI is also responsible for promoting, participating in and ensuring co-operation with similar foreign and international agencies in the technological, energy and industrial fields, and participates in international scientific and technical co-operation agreements [Ordinance No. 172/79].

iii) Structure

The INETI is made up of institutes, technical and scientific services, central services and regional delegations [Order No. 592-A/93, Annex, Section 4].

The governing bodies of INETI are the Board of Management, the Technical Board and the Inspectorate [Section 2].

iv) Financing

In addition to funds allotted from the general state budget, the revenue of INETI is derived from remuneration for services supplied to public and private undertakings as well as income from property and profits from patented inventions.

e) Technological and Nuclear Institute (ITN)

Decree-Law No. 324-A/94 of 30 December 1994 established the Technological and Nuclear Institute (*Instituto Tecnológico e Nuclear – ITN*) to replace the Nuclear Energy and Engineering Institute (ICEN).

i) Legal Status

The Institute has the status of a separate legal entity and was given scientific, technical and administrative autonomy under the supervising authority of the Ministry for Land Planning and Administration. Following the establishment of the thirteenth Portuguese constitutional government in 1995, supervision over ITN was transferred to the Ministry for Science and Technology [Decree-Law No. 296-A/95 of 17 November 1995], which is now the Ministry for Science and Higher Education [Decree-Law No. 205/02 of 7 October 2002].

ii) Responsibilities

The ITN is, in particular, responsible for:

- promoting and undertaking scientific research and technical development in the peaceful applications of nuclear energy;
- providing scientific and technical assistance to the government when implementing its policies on nuclear safety, pharmaceutical and meteorological control, as well as in the application of both radioisotopes and ionising radiation;
- organising and undertaking training in the above fields;
- ensuring technology transfers to public and private agencies;
- establishing exchanges with national, international and foreign institutes pursuing the same objectives; and
- studying and implementing bilateral and multilateral co-operational programmes in its field of competence.

Decree-Law No. 165/02 and Decree-Law No. 167/02 entrusted the ITN with further tasks. It is the now responsible for monitoring the environment in mining areas and for licensing possession, sale, transport, import and any other transmission of sealed sources. In particular, Decree-Law No. 165/02 states that the Technological and Nuclear Institute shall assess and examine the conditions for the safe transport of fresh or spent nuclear fuel and for the transport of radiation sources for nuclear installations as well as radioactive waste from such installations [Section 14(i)]. It is also responsible for the temporary storage of solid radioactive waste and for authorising the transfer of radioactive waste on national territory and within the European Union [Decree-Law No. 165/02 – Section 14 (c) and (j)].

In addition, Decree-Law No. 319/03, of 20 December 2003 establishes the ITN as the entity responsible for implementation of the Additional Protocol to the NPT treaty and as national contact for issues related to the Additional Protocol.

iii) Structure

The structure and internal organisation of ITN is established by Decree-Law No. 324-A/94 of 30 December 1994.

iv) Financing

The ITN is financed in two ways: partly through the General State Budget that allocates funds annually and partly through income from the supply of services to public and private organisations [Decree-Law No. 324/94 of 30 December 1994, Sections 1 and 5].

f) National Uranium Enterprise (ENU)

i) Legal Status

Originally the National Uranium Enterprise (*Empresa Nacional de Urânio* – ENU) was a public corporation pursuant to Decree No. 67/77 of 6 May 1977 which established this Enterprise. However, Decree-Law No. 376/90 of 30 November 1990 of the Minister for Economic Affairs converted it into a private limited company, with the majority of shares held by the state [Section 1]. It retains its legal personality and the rights and obligations it held when it was converted [Section 2].

ii) Responsibilities

According to its Statute [Decree-Law No. 376/90, Annex, Chapter I, Section 3], the purpose of the ENU is to prospect for uranium and other nuclear ores, market those substances and provide related services and supplies, study the advantages of other natural and energy sources and related activities.

iii) Structure

The governing bodies of the ENU are a General Assembly, made up of its shareholders which hold voting rights (one hundred shares equals one vote), a board of directors, made up of a chairperson, and a maximum of six members and a board of controllers made up of one chairperson, two members holding voting rights and an alternate member, elected by the General Assembly [Statute of the ENU].

The General Assembly examines the reports of the board of directors and the board of controllers, and studies the application of measures requested; it elects from among the shareholders and other persons the directors and members of the board of controllers. It may furthermore authorise the setting up of companies and deals with any business for which it has been convened, within the limits of its legal attributions [Statute of the ENU, Section 10].

The General Assembly is convened and chaired by the chairperson of the Assembly's Bureau, made up of the chairperson and vice-chairperson and a secretary, elected by the General Assembly [Section 11(1)]. It is convened at thirty days' notice, and has a specific agenda [Section 11(2)]. It meets at least once a year; extraordinary meetings are held if the board of directors or the board of controllers consider it necessary, or at the request of shareholders representing at least 20% of the authorised capital [Section 12]. Decisions are adopted by a majority of the votes present or represented [Section 10(2)].

The board of directors is responsible for managing the assets of the ENU and may acquire or sell all the ENU's physical or real property, represent the ENU in court proceedings, set up companies or participate in established ones, set up the technical and administrative organisation of the Enterprise and internal operating rules, determine salaries of personnel, etc. [Statute of the ENU, Section 14(1)].

The board sets the dates and frequency of its ordinary meetings; extraordinary meetings are held at the request of the chairperson or that of two directors or two members of the board of controllers [Section 16(1)].

The board of controllers may be assisted by experts or auditors nominated specifically for this purpose. Its decisions are adopted by a majority of the votes expressed, the majority of members being present; the chairperson has a casting vote [Statute of the ENU, Section 19]. Every three months, the board of controllers must send to the Ministries for Finance and Economic Affairs a report on the controls carried out, the anomalies detected and the differences noted as compared to the estimates [Decree-Law No. 376/90, Section 6(2)].

On 2 October 1992, the ENU was merged with the holding company entitled Development Mining Enterprise (*Empresa de Desenvolvimento Mineiro – EDM*).

iv) Financing

The authorised capital of the ENU is set at Portuguese Escudos (PTE) 1 billion at present entirely subscribed by the state and made up of one million shares, each with a nominal value of PTE 1 000 [Statute of the ENU, Section 4]. The board of directors may increase the authorised capital up to a maximum of PTE 3 billion [Section 5].