

Nuclear Legislation in **OECD and NEA Countries**

Regulatory and Institutional
Framework for Nuclear Activities



Poland

Portugal

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I. General regulatory regime

1. Introduction

Portugal does not have a 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 currently uses low enriched uranium (with less than 20% of U-235), after being converted from highly enriched uranium in September 2007.

Portugal is a member of the European Atomic Energy Community, the International Atomic Energy Agency and the OECD Nuclear Energy Agency.

There is no single framework act governing the nuclear sector in Portugal. Instead, more than 100 laws, regulations and decrees set out provisions governing nuclear activities, frequently derogating each other implicitly, to the point where it becomes a matter of doctrinal debate to identify which provisions are applicable.

Following the 1974 Revolution and the establishment of the third Republic, the *Junta de Energia Nuclear* (JEN) was extinct and its competencies were distributed between four different ministries. The following three decades brought several redistributions and reorganisation of entities, with the essential options remaining unchanged. Competencies in the nuclear area are currently shared between over 50 different bodies, with the bulk of which are allocated to the Ministry for Economic Affairs and Innovation, the Ministry for Health, the Ministry for Environment and Territorial Planning and the Ministry for Science, Technology and Higher Education.

The last significant adjustment to the institutional framework took place in 2005 (Decree-Law No. 139/2005 of 17 August), with the creation of the Independent Commission for Radiological Protection and Nuclear Safety. However, another institutional adjustment is currently in the final stages of adoption into law, i.e. within the framework of the transposition of Council Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations.

The main legal instruments governing nuclear activities, *lato sensu*, in Portugal are as follows:

- Decree-Law No. 49398/69, of 24 November, setting out the legal framework for the licensing of nuclear activities, including those of an industrial and commercial nature (hereinafter "Decree-Law 49398/69");
- Decree No. 487/72, of 5 December, defining the rules to be followed for the installation of nuclear power plants (hereinafter "Decree 487/72");
- Decree-Law No. 426/83, of 7 December, approving the regulation for radiological protection and safety at mines and annexes for the treatment of uranium ore and its recovery (hereinafter "Decree-Law 426/83");
- Decree-Law No. 348/89, of 12 October, setting out rules and directives concerning protection from ionising radiation (hereinafter "Decree-Law 348/89");
- Regulatory-Decree No. 9/90, of 19 April, amended by Regulatory-Decree No. 3/92, of 6 March, regulating the rules and directives concerning protection from ionising radiation (hereinafter "Regulatory-Decree 9/90");

- Decree-Law No. 375/90, of 27 November, setting out the legal framework relating to the physical protection of nuclear materials (hereinafter "Decree-Law 375/90");
- Regulatory-Decree No. 34/92, of 4 December, setting out rules on radiological safety and protection applicable to the extraction and treatment of radioactive ore (hereinafter "Regulatory-Decree 34/92");
- Decree-Law No. 36/95, of 14 February, transposing Directive 89/618/Euratom on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency (hereinafter "Decree-Law 36/95");
- Regulatory-Decree No. 29/97, of 29 July, setting out the legal framework for the protection of outside workers intervening in areas subject to regulation relating to protection against ionising radiation (hereinafter "Regulatory-Decree 29/97");
- Decree-Law No. 311/98, of 14 October, revised by Decree-Law No. 139/2005, of 17 August, setting out provisions concerning the institutional framework for the field of radiological protection and nuclear safety (hereinafter "Decree-Law 311/98");
- Decree-Law No. 492/99, of 17 November, revised by Decree-Law No. 240/2000, of 26 September, approving the legal framework for the licensing and control of activities carried out in private health units using ionising radiations, ultra-sound or magnetic fields for diagnostic, therapeutic or preventive purposes (hereinafter "Decree-Law 492/99") (see also Decree-Law No. 279/2009, of 6 October);
- Decree-Law No. 165/2002, of 17 July, amended by Decree-Law No. 215/2008, of 10 November, setting out the competencies of the bodies intervening in the field of protection against ionising radiation, as well as general principles of such protection (hereinafter "Decree-Law 165/2002");
- Decree-Law No. 167/2002, of 18 July, amended by Decree-Law No. 215/2008, of 10 November, setting out the legal framework for the licensing and functioning of entities active in the field of radiological protection (hereinafter "Decree-Law 167/2002");
- Decree-Law No. 174/2002, of 25 July, setting out the rules applicable to interventions in case of a radiological emergency (hereinafter "Decree-Law 174/2002");
- Decree-Law No. 180/2002, of 8 August, amended by Decree-Law No. 215/2008, of 10 November, setting out the legal framework for the protection of people's health against the dangers arising from ionising radiation in medical radiological exposures (hereinafter "Decree-Law 180/2002");
- Decree-Law No. 319/2003, of 20 December, appointing ITN as the competent authority for the implementation of the additional protocol to the safeguards agreement (hereinafter "Decree-law 319/2003");
- Decree-Law No. 138/2005, of 17 August, approving the system for the monitoring of environmental radioactivity (hereinafter "Decree-Law 138/2005");
- Decree-Law No. 140/2005, of 17 August, setting out the levels for dispensation from declaration of exercise or prior authorisation of practices associated to risks arising from ionizing radiation (hereinafter "Decree-Law 140/2005");
- Decree-Law 176/2006, of 30 August, setting out the legal framework for medications meant for human use (hereinafter "Decree-Law 176/2006");

- Decree-Law No. 38/2007, of 19 February, setting out the legal framework for the control of sealed radioactive sources, including orphan sources (hereinafter “Decree-Law 38/2007”);
- Decree-Law No. 222/2008, of 17 November, setting out basic security rules concerning the sanitary protection of the population and of workers against dangers arising from ionising radiation (hereinafter “Decree-Law 222/2008”);
- Decree-Law No. 198/2009, of 26 August, transposing Directive 2006/117/Euratom (hereinafter “Decree-Law 198/2009”); and
- Decree-law No. 279/2009, of 6 October, setting out the legal framework for the opening, modification and functioning of private health units (hereinafter “Decree-Law 279/2009”).

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, starting with Decree-Law No. 37.986, of 27 September 1950, and Decree-Law No. 40.135, of 20 April 1955, which authorised the Minister of Finance to fix export taxes for radioactive materials and their concentrates. Currently, the bulk of the specific regime for the mining and treatment of radioactive ores can be found in Decree-Law 49398/69, Decree-Law 426/83 and in Regulatory-Decree 34/92.

Together, these three laws set out specific provisions broadly relating to licensing, radiological protection of workers, protection and safety of mining and transforming facilities (with a scope going beyond radiological perils).

However, given that there are currently no mining activities in Portugal, this legal framework has been neglected and left unchanged, rendering it largely outdated. It is particularly difficult to reconcile the mining regime, still in force, with the general laws on radiological protection and licensing, requiring the identification of tacit derogations. In any case, it is certain that a large proportion of the radiological protection provisions herein can no longer be considered to be in force. As there are currently no plans to reactivate Portuguese uranium mines, it is unlikely that this legal framework be revisited soon.

The operation and closing of radioactive ore mining or treatment facilities must be authorised (unless radioactivity is below exemption levels). For extraction, a mining concession must be obtained from the Minister of Economy [Article 10(1) of Decree-Law 165/2002]. For the treatment of radioactive ores, a licence must be granted by the respective regional division of the Ministry of Economy [Article 20(a) of Decree-Law 165/2002]. The ITN is responsible for the environmental monitoring in the areas surrounding these facilities [Article 14(o) of Decree-Law 165/2002]. For competencies in other matters, such as radiological protection of workers, the general regime applies.

A special regime, under the responsibility of the Ministries of Economy and Environment, was created to provide for the environmental rehabilitation of areas degraded due to the mining of radioactive ores.

3. Radioactive substances, nuclear fuel and equipment

Any activity which may cause or lead to exposure to ionising radiation or to radioactive contamination in Portugal must be declared to the authorities [Article 8(1) of Decree-Law 165/2002], unless the radioactivity is below exemption levels or is a specifically exempted activity (Decree-Law 140/2005). Some activities, however, are further subject to prior authorisation or licensing. The following activities require an authorisation according to provisions in Regulatory-

Decree 9/90 and Decree-Law 165/2002 (general regime), even though it is debatable whether the latter has not revoked the need for prior authorisation of activities included in the (earlier and hierarchically inferior) regulatory-decree:

- intentional addition of radioactive substances in the manufacture of medical products or import of such products;
- intentional addition of radioactive substances in the manufacture of consumer goods or import or export of such products;
- intentional administration of radioactive substances to persons and, in the case of possible subsequent consequences to humans, to animals, for purposes of diagnostic, treatment or research;
- use of X-ray equipment or of radioactive sources for industrial purposes, processing of products, research or exposure of persons for medical diagnostic or treatment purposes (including accelerators);
- import, manufacture and installation of equipment that produces radiation for scientific, medical or industrial purposes; and
- transport of radioactive material.

The carrying out of these activities by external companies (for the operator) is subject to separate authorisation, under the terms of Regulatory-Decree 29/97.

The competencies for authorisation are as follows:

- ITN: possession, transport, import, sale, rental or any other form of transmission of sealed sources and equipment incorporating sealed sources; transport of radioactive waste and irradiated nuclear fuel;
- DGEG: transport of fresh nuclear fuel;
- DGS: all other activities and equipments subject to prior authorisation.

Generally, the authorisation of these activities and equipments is subject to the presentation, *inter alia*, of a radiological protection plan [Article 35(1) of Regulatory-Decree 9/90]. Unless another deadline is set out in specific provisions, authorities must decide on authorisation requests within 90 days, but this deadline may be extended, subject to due justification [Article 35(2) of Regulatory-Decree 9/90]. Authorisation and licensing procedures entrusted to DGS are subject to fees added to the relevant laws by Decree-Law 215/2008.

The licensing of medical facilities using sources of ionising radiation or equipment incorporating them is subject to a special regime, adopted by Decree-Law 180/2002. This is a detailed regime which includes obligations regarding staff, assessment of radiological safety by an external entity, proof of conformity of equipment, specific authorisation in the case of heavy medical equipment etc. The competent authority is the DGS. Licences must be renewed every five years. Private health units using ionising radiation are further subject to the obligations deriving from Decree-Law 492/99. Once a specific regulation has been adopted for the radiological sector, those provisions will be replaced by the regime established under Decree-Law 279/2009.

The regime for the licensing of sealed sources, entrusted to ITN, is set out in Decree-Law 38/2007.

4. Nuclear installations

Portugal is party to the following main treaties relating to nuclear safety:

- 1994 Convention on Nuclear Safety;
- 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- 1991 Espoo Convention on Environmental Impact Assessment in a Transboundary Context;
- 1998 Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters; and
- Portuguese-Spanish agreement on co-operation in relation to nuclear facilities at the border (1980).

a) Licensing and inspection, including nuclear safety

Although the competencies relating to the licensing of nuclear installations, i.e. nuclear fuel cycle facilities, have been relatively recently (re-)assigned to DGEG (by Decree-Law 165/2002), the remaining legal framework relating to the licensing of these facilities is very old and has never been revised. It should be noted that ITN's nuclear research reactor is the only nuclear installation currently in operation in Portugal and that no new installations have been seriously proposed; consequently, it has not been deemed necessary to update this legal framework.

Hence, the legal framework for nuclear power plants and other nuclear fuel cycle facilities can be found, to a large extent, in Decree-Law No. 49398/69 and in Decree 487/72. Although licensing is entrusted to DGEG, supervision and enforcement in what concerns nuclear law is entrusted to ITN. This rather old legal framework will not be described in more detail because pragmatically it would have to be completely overhauled if the construction of any new nuclear facility were proposed.

Environmental impact assessments, under the auspices of APA, are mandatory for all nuclear fuel cycle facilities, in accordance with Decree-Law No. 69/2000, of 3 May (as revised).

b) Protection of the environment against radiation effects

Environmental protection is governed primarily by Law No. 11/87, of 7 April (last amended by Law No. 13/2002, of 19 February), which *inter alia* prohibits the release or introduction of radioactive substances, in any way, into Portuguese waters, soil, subsoil or atmosphere. Aside from the general interdiction, this is fundamentally a basic framework setting out a programme for further legal development.

In this respect, the aforementioned regime on mandatory environmental impact assessments (Decree-Law No. 69/2000, of 3 May, as revised) should also be considered.

APA is the national authority responsible for guaranteeing the protection of the environment from contamination by sources of ionising radiation.

c) Emergency response

Portugal is party to the following main treaties relating to emergency response:

- 1986 Convention on Early Notification of a Nuclear Accident; and

- 1986 Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency.

The core of the national legal framework relating to emergency response is to be found in Decree-Law No. 36/95 and in Decree-Law No. 174/2002.

The framework concerning information to the general public relating to radiological emergencies is set out in transposition of Directive 89/618/Euratom, and is in conformity thereto. The required preventive information should always be publicly available and be provided to the population which may be affected in the case of a radiological emergency every three years, as well as whenever it is significantly revised. Specific information is to be provided to persons which may be involved in the reaction to a radiological emergency. As for reactive information, it is divided into "pre-alarm" and "emergency" situations.

ANPC – and its regional and local branches, depending on the geographical scope of the possible or actual emergency – is responsible for providing the above mentioned information, in co-operation with DGS and the respective technical intervention authority (see below). It is also responsible for transmitting "reactive" information to the European Commission and to any possibly affected states.

Decree-Law No. 174/2002 is primarily aimed at transposing Title IX of Directive 96/29/Euratom, and it is applicable not only to radiological emergencies, *stricto sensu*, but also whenever situations of prolonged exposure to ionising radiation are identified. Reaction to emergencies is to be co-ordinated by ANPC, together with a technical intervention authority, which varies depending on the characteristics of the emergency: (i) DGS for emergencies within radiological facilities; (ii) APA for emergencies with possible external consequences; and (iii) ITN for emergencies during transport or related to sealed or orphan sources.

The same law regulates the drafting and adoption of internal and external radiological emergency plans. The licence holders of radioactive facilities must immediately notify the competent technical intervention authority if a radiological emergency occurs, as well as the ANPC if the population may be affected.

APA is the national contact point for radiological emergencies occurring outside Portugal's borders, maintaining a national network for the detection of abnormal increases in environmental radioactivity. The ANPC is the contact point for radiological emergencies occurring within Portuguese territory or jurisdiction, and requests for assistance from other states should be directed to it.

5. Trade in nuclear materials and equipment

Except in cases where radioactivity is below exemption levels, the import or export to Portugal of equipments that produce ionising radiation (for scientific, medical or industrial purposes), of medical products or of consumer goods including radioactive substances is subject to prior authorisation by DGS [Article 8(2)(b) and (c) of Decree-Law 165/2002; Article 34(b) of Regulatory-Decree 9/90]. It is forbidden to intentionally add radioactive substances to foodstuffs, toys, personal accessories and to cosmetics, as it is to import or export such products [Article 8(4) of Decree-Law 165/2002].

Manufacturers, importers and suppliers of radioactive materials and equipments producing ionising radiation must ensure that such materials or equipments abide by national safety legislation (certified by DGS), and they can only be sold, rented or subjected to any other form of transaction if accompanied by the conformity certificate from DGS and by written information (in principle, in Portuguese) specifying technical characteristics, associated risks and instructions for proper use and disposal (Article 11 of Regulatory-Decree 9/90).

The legal framework for the control of import and exports of (*inter alia*) dual use items is set out in Decree-Law No. 436/91, of 8 November, regulated by Ministerial Order No. 439/94, of 29 June (approving the list of goods and technologies subject to prior licensing and certification). It is also worth noting Communication No. 83/2003 of the Directorate-General for Customs and Excise. It has been announced that this legal framework is under review; however, no further details are publicly available. Violations of these legal obligations are subject to sanctions under the General Regime of Fiscal Infractions, adopted by Law No. 15/2001, of 5 June, last revised by Decree-Law No. 73/2010, of 21 June.

Since this legal framework has not been changed since the mid-90s, there are significant differences in relation to the EU control regime for dual use items [Regulation (EC) 428/2009], e.g. brokerage is not included, and it is debatable whether transit, transshipment and transfers (ITT) are included. Authorisation is granted by the Directorate-General for Customs and Excise at the Ministry of Finance, and (in the case of military equipment) by the Directorate-General for Armament and Defence Equipment.

Finally, it should be noted that the sale, acquisition, import, transfer, manufacture and possession of radioactive weapons, of weapons susceptible of causing a nuclear explosion or of components meant for the manufacture of such weapons is forbidden by criminal law, and subject to imprisonment for a period of 2 to 12 years (Law No. 5/2006, of 23 February, as revised by Law No. 17/2009, of 6 May).

6. Radiation protection

Portugal is party to the following main treaties relating to radiation protection:

- 1960 ILO Radiation Protection Convention No. 115; and
- 1974 ILO Occupational Cancer Convention No. 139.

The legal framework relating to radiation protection is spread out in different laws, not only due to the usual succession of laws, accompanied by tacit derogations, but also due to the adoption of laws in reaction to the opening or threat of EU infringement proceedings. The national radiation protection regime may be divided into the following areas, according to content: (i) basic provisions on radiation protection; (ii) occupational exposure; (iii) exposure for medical purposes; (iv) professional qualification in radiological protection; (v) service providers; and (vi) environmental monitoring.

It should be noted that Regulatory-Decree No. 34/92 contains a specific regime for radiation protection applicable to uranium mining and associated activities. It is debatable to what extent some of the provisions of that regulatory-decree remain in force. However, the issue is *moot*, as there are no active uranium mining facilities in Portugal.

(i) Basic provisions on radiation protection

The basic regime includes the principles of justification of new practices, optimisation and ALARA (Article 4 of Decree-Law 165/2002). Persons legally responsible for facilities, activities or equipments subject to radiation protection requirements must submit to the competent authority a radiological protection plan, an internal and (if relevant) external emergency plan and must comply with and help authorities during inspections etc. (see Articles 7 to 9 of Regulatory-Decree 9/90).

The regime relating to dose limits (by category of persons), their method of calculation, monitoring, rules for specially authorised exposures, mandatory notification of excess dose and other radiation dose-related issues are regulated in Decree-Law 165/2002, Decree-Law 222/2008 and Regulatory-Decree 9/90. These provisions are, after the adoption of Decree-Law 222/2008, in conformity with EU law. DGS has the vast majority of competencies in this domain, including the power to authorise exceptional exposures.

(ii) Occupational exposure

Occupational exposure to ionising radiation is regulated in the same three legal acts, and further in Decree-Law No. 167/2002. Following the opening of an infringement proceeding by the European Commission, this body of rules now complies with the requirements of Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. Dosimetry must be carried out by companies specifically licensed for that purpose, and results of readings must be periodically communicated to ITN, which keeps the centralised national record. In case of detection of an excessive dose received by a worker, this must be immediately communicated to DGS.

Outside workers are subject to a specific and more outdated regime, set out in Regulatory-Decree No. 29/97. Decree-Law No. 29/94, of 29 July, last revised by Decree-Law No. 109/2000 [Article 5(4)(i)], requires companies with more than 50 workers to keep internal medical services.

(iii) Exposure for medical purposes

Decree-Law No. 180/2002 regulates the protection of persons (patients, research subjects, professionals and the general public) in the context of the use of ionising radiation for medical purposes. It is a rather detailed regime, which should be read together with the provisions of Decree-Law No. 492/99 (although the latter is applicable only to private health units). In the scope of this decree-law, all relevant competencies are distributed exclusively within the Ministry of Health, and assigned almost entirely to DGS.

(iv) Professional qualification in radiological protection

Although the issue had been previously regulated, the incomplete and uncertain terms of the previously existing rules led to the adoption of Decree-Law No. 222/2008 – a new regime on the recognition of professional qualification of experts in radiological protection, and on their tasks. This legislation distinguishes between (in decreasing degree of required expertise and training in radiological protection): “qualified expert”, “qualified technician” and “operating technician”. However, several doubts have arisen as to the precise manner in which this new regime is to be articulated with previously existing obligations. It should be noted that the current legal framework does not explicitly require the presence of experts qualified in radiological protection at radiological facilities.

(v) Service providers

The exercise of certain services in the area of radiological protection, by public or private persons, has been subject to mandatory licensing under Decree-Law No. 167/2002 (except for companies from other member states there authorised to carry out such activities), specifically: studies on radiological protection conditions at radiological facilities (required for licensing procedures), technical assistance in radio-diagnostics, dosimetry, and training in radiological protection. The renewable five year licences are awarded by DGS, subject to a favourable opinion by ITN.

(vi) Environmental monitoring

In parallel with the national network managed by APA aimed at the detection of abnormal increases in environmental radioactivity, ITN has been entrusted with the periodical monitoring of radioactive substances in the environment (air, soil, waters, vegetation and foodstuffs), through a sampling method, in accordance with Decree-Law No. 138/2005. Results of measurements are communicated to the European Commission.

Finally, the regime concerning the control of instruments for the measurement of ionising radiation, and associated complementary devices, has been set out in Ministerial Order No. 1106/2009, of 24 September, allocating the respective competencies to ITN.

7. Radioactive waste management

Portugal is party to the following conventions relevant in the fields of radioactive waste management:

- 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter;
- 1992 OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic;
- 1997 Joint Convention on the Safety of Spent Nuclear Fuel Management and the Safety of Radioactive Waste Management; and
- 2000 Cotonou Agreement.

The legal framework relating to radioactive waste is extremely incomplete, something which is partly explained by the reality of radioactive waste production in Portugal. It should be noted that the irradiated nuclear fuel used in the Portuguese Research Reactor, at ITN, is periodically shipped back to the United States of America.

The release or introduction of radioactive waste into Portuguese waters, soil, subsoil or atmosphere is forbidden [Article 26(1) of Law No. 11/87, of 7 April]. Under national law, any activity for the elimination or storage of radioactive waste must be planned so as to avoid or reduce as much as possible the consequences of the environmental dispersal of radiation, both in case of normal functioning and in case of emergencies (Article 44 of Regulatory-Decree No. 9/90).

As a general rule, and given the limited amount and types of radioactive waste produced in Portugal, it was decided that ITN would collect and temporarily store all solid radioactive waste produced on Portuguese territory [Article 14(j) of Decree-Law 165/2002]. The same applies, naturally, in the case of detection of orphan sources [Article 11(3) and (4) of Decree-Law 38/2007].

Radioactive waste produced in hospitals is subject to a specific legal framework, set out in Decree-Law No. 180/2002 (Articles 55, 71 and 79) and in Order No. 242/96, of 5 July, requiring separation and temporary storage of liquid waste to ensure decline of activity before disposal.

Finally, there are specific provisions – now *lettre morte* – concerning the disposal of radioactive waste resulting from uranium mining and related activities (see Regulatory-Decree No. 34/92).

8. Non-proliferation and physical protection

Portugal is party to the following main treaties relevant in the fields of non-proliferation and physical protection:

- 1957 Nuclear Energy Security Control Convention;
- 1959 Antarctic Treaty;
- 1965 Safeguards Agreement between Portugal, the USA and the IAEA;
- 1967 Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, including the Moon and Other Celestial Bodies (Outer Space Treaty);

- 1968 Treaty on the Non-Proliferation of Nuclear Weapons, including a safeguards agreement (7 August 1978) and an additional protocol to the safeguards agreement (22 September 1998);
- 1971 Seabed Arms Control Treaty;
- 1973 Agreement between the Euratom Community, its member states and the IAEA concerning the NPT Treaty;
- 1979 Convention on the Physical Protection of Nuclear Material;
- 1996 Comprehensive Nuclear-Test-Ban Treaty (not yet in force);

Portugal also participates in the Nuclear Suppliers Group, the Zangger Committee, the Proliferation Security Initiative and the Megaports initiative.

The national legal framework relating to non-proliferation, physical protection and nuclear security in general is rather incomplete.

The Physical Protection Convention has been implemented by Decree-Law No. 375/90 which was subsequently amended in order to take into account succession between government bodies, this regime designates the Portuguese Environmental Agency as the contact point and national authority for the exercise of the respective competencies, including the authorisation of the activities subject to prior authorisation under the convention. In what concerns transport by road, the legal framework set out by Decree-Law 41-A/2010, of 29 April, also contains provisions relating to physical protection of nuclear materials.

The ITN –which is the only entity in Portugal holding materials subject to safeguards – has been appointed the contact point and competent authority to implement the IAEA Safeguards Agreement, in accordance with Decree-Law No. 319/2003. While there may be some legal issues deriving from the fact that this law refers primarily to the additional protocol, it has generally been interpreted as centralising at ITN all the competencies relating to the implementation of the safeguards agreement (an interpretation aided by Article 3 of this decree-law).

Export and import of dual use items is subject to the provisions of Decree No. 439/94, of 29 June, a regime which has not been updated to take into account evolutions of EU law since then.

Finally, one should consider national criminal law provisions relating to the proliferation of nuclear materials – see Law No. 5/2006, of 23 February, as revised by Law No. 17/2009, of 6 May (Articles 2 to 4, 86 and 87 – general regime), Law No. 100/2003, of 15 November (Article 79 – regime relating to military facilities), Law No. 52/2003, of 22 August (Articles 2, 4 and 6 – regime relating to nuclear terrorism), and Articles 272, 273, 275, 277, 285 and 286 of the Criminal Code (general regime).

Other competencies in this domain not yet mentioned are distributed primarily within the Ministry of Foreign Affairs (see Decree-Law No. 204/2006, of 27 October).

A specific authority has been created to follow several matters within this domain – the National Authority for the Purposes of the Comprehensive Nuclear Test Ban Treaty (*Autoridade Nacional para efeitos do Tratado de Proibição Total de Ensaio Nucleares*). This authority was established by the Council of Ministers Resolution No. 102/2001, of 29 August, which has since been revised by Council of Ministers Resolutions No. 26/2002, of 7 March, and 63/2010, of 26 August.

The confidentiality of information obtained under Article 24 of the Euratom Treaty must be maintained in accordance with Article 88 of Council of Ministers Resolution 37/89, of 1 June.

9. Transport

Portugal is party to the following main treaties relevant in the field of transport of radioactive material:

- 1957 ADR Agreement;
- 1960/1974 SOLAS Convention;
- 1964 Agreement between Portugal and the USA concerning the nuclear ship Savannah;
- 1971 Agreement between Portugal and Germany concerning the nuclear ship N/N Otto Hahn;
- 1980 CIV and CIM Uniform Rules, annexed to the International Carriage by Rail Convention;
- 1994 Montego Bay Convention; and
- 2001 INF Code.

Any transport of radioactive material through Portuguese territory or through an area subject to Portuguese jurisdiction must be previously authorised [Article 34(a) of Regulatory-Decree 9/90]. The competence to authorise such transports varies according to the material in question. Thus, the transport:

- of sealed sources and equipment including sealed sources, of radioactive waste and of irradiated nuclear fuel is authorised by the ITN [Decree-Law 165/2002, Article 14(a); Decree-Law 38/2007, Article 4(1); Decree-Law 198/2009, Article 3(1)];
- of fresh nuclear fuel is authorised by the DGEG [Decree-Law 165/2002, Article 13(b); Decree-Law 198/2009, Article 3(1)];
- of all other materials and radioactive sources is authorised by the DGS (Regulatory-Decree 9/90, Article 34).

This being said, ITN is always the authority entrusted with evaluating and controlling safety conditions during the transport of any and all radioactive materials and sources [Decree-Law 165/2002, Article 14(i), Decree-Law 311/98, Article 4(1)(e)].

The safety rules applicable to the transport by road or railway of radioactive materials are currently set out in Decree-Law 41-A/2010, of 29 April.

There are no specific national provisions concerning air transport, but the law explicitly orders the enforcement of applicable international provisions (see Article 9 of Decree-Law 165/2002).

As for maritime transport, it is governed by a seemingly incomplete body of rules, included in: Decree-Law No. 265/72, of 31 July [e.g. Articles 128(f) and (g)]; the Regulations of the different maritime ports [e.g. Ministerial Order 206/91, Articles 21(8), 52 and 58(6)]; Decree-Law No. 106/2004, of 8 May; and Decree-Law No. 180/2004, of 27 July [as subsequently revised; e.g. Article 3(a)(xi)].

The transport of sealed sources and of radioactive waste is subject to special regimes. The first is set out in Decree-Law 38/2007. The second is set out in Decree-Law 198/2009, which transposes Directive 2006/117/Euratom, the content being therefore identical thereto.

For the transport of uranium ore and concentrate, one should also take into account Article 68 of Regulatory-Decree 34/92.

The transport of radiopharmaceuticals and associated products should take into account the provisions of Decree-Law No. 176/2006. Article 130 renders applicable in the internal legal order IAEA rules relating to packaging and labelling of such products.

Finally, there is also specific legislation concerning nuclear ships. The entry of nuclear warships in Portuguese waters and ports must be authorised by the Minister of Defence, in accordance with Decree No. 267/72, of 1 August (see also Ministerial Order No. 16650/2006). The entry of civilian nuclear ships is authorised by the same Minister, but under the terms of Decree-Law No. 45672, of 22 April 1964. This law also foresees the consultation of an inter-ministerial committee (Permanent Commission for Nuclear Ships). The remaining competences aimed at guaranteeing the safety of nuclear ships during their stay in Portuguese waters or ports are assigned to ITN and the Directorate-General of the Maritime Authority. These legal frameworks are largely outdated and must be interpreted in light of subsequent redistributions of competences.

10. Nuclear third party liability

Portugal is only party to two conventions in the field of nuclear third party liability:

- 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy (not yet ratified amendment Protocol of 2004); and
- 1962 Convention on the Liability of Operators of Nuclear Ships.

The national legal framework concerning nuclear third party liability is incomplete. The Paris Convention has never been implemented into national law, and indeed the current general rules explicitly contradict that convention.

The general rule (Article 10 of Decree-Law No. 348/89) is that the operator or person responsible for facilities, equipments or materials producing ionising radiation, and using them "in its own interest", is liable for damages caused to third parties. However, the operator can exclude its liability by demonstrating that, at the time of the facts leading to the damages, the facility, equipment or material in question was functioning and used in accordance with technical rules in force and was perfectly maintained. Liability may also be excluded if the operator demonstrates that the damages are a result of *force majeure*.

With regard to insurance, the general regime (applicable only to private persons) requires mandatory third party insurance for any operator or person responsible for such a facility, equipment or material (Article 11 of Decree-Law 348/89). The precise terms for this insurance and liability should have been regulated, however, the required regulatory-decree has, so far, not been approved.

This general regime has been complemented by some special provisions applicable to specific types of activities or sources of ionising radiation.

Liability relating to damages caused by sealed sources and equipments incorporating sealed sources is subject to special regulation. In this case, strict liability has been imposed, and the regime covers damages to the environment, persons and property (Article 16 of Decree-Law No. 38/2007). Insurance is only mandatory for sources whose accumulated nominal activity exceeds 1 GBq. In such cases, insurance must be made in the value of EUR 100 000, for sources under 10 GBq; EUR 250 000, for sources between 10 GBq and 1 TBq; and EUR 500 000 for sources exceeding 1 TBq.

The other example is liability during transport of radioactive waste and irradiated nuclear fuel – see Articles 18 and 19 of Decree-Law No. 198/2009. In this case, the regime is less complete as it is more focused on the insurance contract, rather than the liability of the operator.

In the case of medical facilities using ionising radiation, it has been explicitly foreseen that the liability of the licence holder is only terminated when all materials and equipments have been removed from the facility and the latter has been decontaminated [when required – see Article 35(2) of Decree-Law 180/2002].

Finally, companies providing services in the area of radiological protection are also subject to mandatory (full or partial) third party insurance (Article 17 of Decree-Law 167/2002).

II. Institutional framework

As mentioned in Part I of this study, competencies in the nuclear area in Portugal are currently shared between more 50 different bodies, with the bulk of competencies being assigned to bodies within the Ministry of Economic Affairs and Innovation, the Ministry of Health, the Ministry for Environment and Territorial Planning and the Ministry for Science, Technology and Higher Education.

1. Regulatory and supervisory authorities

a) Ministry of Health

The Ministry of Health holds the largest proportion of nuclear-related competencies, *lato sensu*, in Portugal. Most of these competencies are entrusted to the Directorate-General for Health (*Direcção-Geral da Saúde* – DGS).

DGS is generally in charge of ensuring the protection of persons against the dangers of ionising radiation and holds a large range of competencies mentioned throughout this study. It holds the licensing and authorisation competencies relating to: (i) all practices, facilities and equipments utilising ionising radiation, if the competence in question has not been assigned to another body; and (ii) public and private services providers in the field of radiological protection and training. It keeps the national registry of persons holding equipment that produce or use ionising radiation, inspects and enforces rules on the radiological protection of workers, approves most radiological emergency plans, etc.

Regional Health Authorities (*Administrações Regionais da Saúde* – ARS) supervise the functioning of medical facilities and play a role in the licensing of private health units using ionising radiation. The supervisory function is carried out together with Technical Assessment Commissions (*Comissões de Verificação Técnica*), supposedly set up by each ARS.

The Health Regulatory Authority (*Entidade Reguladora da Saúde* – ERS) holds competencies relating to the licensing and supervision of private health units using ionising radiation, but arguably not including the enforcement of radiological protection laws.

INFARMED (*Autoridade Nacional do Medicamento e Produtos da Saúde*) implements and supervises the functioning of the legal framework relating to radiopharmaceutical products.

b) Ministry of Science, Technology and Higher Education

The competencies of the Ministry of Science, Technology and Higher Education in the nuclear field are concentrated at the Nuclear and Technological Institute (*Instituto Tecnológico e Nuclear* – ITN),

established by Decree-Law No. 324-A/94, of 30 December (which governs, *inter alia*, its structure and financing), to replace the Nuclear Energy and Engineering Institute.

ITN is the national body with the second largest set of competencies in the nuclear field after DGS. It is the licensing authority for sealed sources and equipment, including sealed sources, and for the transport of radioactive waste and irradiated nuclear fuel. It supervises facilities and equipments using ionising radiation for research or training. It calibrates ionising radiation measurement instruments, sets the conditions for the approval of facilities aimed at the irradiation of foodstuffs, collects and stores all national solid radioactive waste, keeps the national registry of professional exposure to radiation, etc.

Additionally, ITN issues opinions and provides technical assistance to all other national regulatory bodies in the exercise of their competencies in the nuclear field. Thus, some licensing procedures carried out by DGS require a mandatory opinion by ITN, while others do not require such an opinion, but ITN's assistance is still requested, as the only national body with the technical expertise required to assess the radiological safety of complex equipments and facilities.

ITN also carries out research and training in this field and it represents Portugal at the European and international levels in a large range of nuclear-related issues. It should be noted that, as a result of this framework of competencies and of the fact that ITN operates the only (research) nuclear reactor in Portugal, it is often put into the position of regulating or inspecting itself.

c) Ministry of Economy and Innovation

The Ministry of Economy and Innovation, through the Directorate-General of Energy and Geology (*Direcção-Geral de Energia e Geologia* – DGEG), has essentially retained competencies in the licensing of uranium mining, nuclear reactors and some associated activities.

DGEG: (i) licenses nuclear fuel cycle facilities and is (theoretically) responsible for the inspection of nuclear power plants in what concerns nuclear safety; (ii) authorises transports of fresh nuclear fuel; and (iii) holds several competencies relating to uranium mining facilities. In practice, DGEG's role in the nuclear sector today is mostly limited to the licensing of the existing research reactor.

The regional directorates of the Ministry of Economy and Innovation (*Direcções Regionais de Economia* – DREs) play a role in the licensing of uranium mining facilities and are responsible for the enforcement of nuclear law in relation to industrial facilities.

The Authority for Working Conditions (*Autoridade para as Condições de Trabalho* – ACT) plays an accessory role in promoting the safety of workers, including the possible monitoring and statistical evaluation of exposure to ionising radiation.

d) Ministry of Environment and Territorial Planning

The Ministry of Environment and Territorial Planning currently holds competencies almost exclusively associated to the protection of the environment from ionising radiation, almost all of which are concentrated at the Portuguese Environmental Agency (*Agência Portuguesa do Ambiente* – APA).

APA: (i) operates the national alert network for the continuing monitoring of abnormal increases in environmental radioactivity; (ii) is the national contact point for cross-border radiological emergencies; (iii) plays an advisory role in relation to external radiological emergency plans and is the technical authority in the case of actual emergencies with consequences beyond the respective facility or activity; (iv) is the licensing authority under the regime for the physical protection of nuclear materials; (v) is responsible for managing national environmental impact assessments (EIA) and is the contact point for foreign EIAs etc.

e) Other authorities

The purpose of this study is not to give an exhaustive list of the public bodies holding competencies relevant to the nuclear field, however, the following ones should still be mentioned briefly:

- National Authority for Civil Protection (*Autoridade Nacional de Protecção Civil – ANPC*): contact point for the notification of national radiological emergencies; co-ordinates the development of external radiological emergency plans and the reaction to any such emergencies (including information to the population);
- Directorate-General of the Maritime Authority (*Direcção-Geral da Autoridade Marítima – DGAM*): holds competencies relating to visits of nuclear ships to Portuguese waters or ports;
- Portuguese Institute of Accreditation (*Instituto Português da Acreditação – IPAC*): responsible for the accreditation of service providers in the field of radiological protection;
- Food and Economic Safety Authority (*Autoridade de Segurança Alimentar e Económica – ASAE*): responsible for the enforcement of provisions relating to the use of ionising radiation in foodstuffs.

2. Advisory bodies

a) Independent Commission for Radiological Protection and Nuclear Safety (CIPRSN)

The Independent Commission for Radiological Protection and Nuclear Safety (*Comissão Independente para a Protecção Radiológica e Segurança Nuclear – CIPRSN*) was created by Decree-Law No. 139/2005, as a successor to the *Comissão para a Protecção Radiológica e Segurança Nuclear*, and partly as a reply to international criticism regarding the absence of an independent regulatory authority.

It is made up of five members, appointed by the Prime Minister for non-remunerated mandates of five years, which cannot be removed except for extraordinary circumstances. There are no provisions for budget or staff (even though existing civil servants can be assigned to work at CIPRSN), and technical support should be provided by ITN.

CIPRSN has been entrusted, in essence, with: (i) proposing legislation relating to radiological protection and nuclear safety; (ii) assessing the enforcement of nuclear law in Portugal, in light of international best practices and proposing appropriate courses of action; (iii) recommending the carrying out of inspections and any tasks suitable to the protection of workers and the population against the dangers of ionising radiation; (iv) validating data in this sector to be transmitted to European or international bodies; (v) keeping track of international developments in radiological protection and nuclear safety and informing the government thereof; and (vi) co-operating with the activities of other bodies in the nuclear sector.

b) National Radiation Protection Commission (CNPCR)

The National Radiation Protection Commission (*Comissão Nacional de Protecção contra Radiações – CNPCR*) was originally set up within DGS by Decree-Law No. 348/89 (Section 4). Decree-Law No. 165/2002 granted additional competencies to the Commission. It is an inter-ministerial advisory body, made up of representatives of the following:

- DGS, presiding;
- specialists in nuclear medicine, radiology, radiotherapy and dermatology from departments of the College of Physicians;
- College of Dentists;

- ITN;
- Authority for Working Conditions;
- DGEG.

The CNPCR issues opinions and recommendations on a variety of subjects, including specific licensing procedures, described primarily in Articles 5 and 6 of Decree-Law 348/89, as revised by Article 22 of Decree-Law 165/2002.

c) National Commission for Radiological Emergencies (CNER)

Articles 23 and 24 of Decree-Law No. 165/02 established the National Commission for Radiological Emergencies (*Comissão Nacional para Emergências Radiológicas* – CNER). It is an inter-ministerial advisory body made up of representatives of the following bodies:

- ANPC, presiding;
- DGS;
- National Institute for Medical Emergencies;
- APA;
- Meteorology Institute;
- Commission for the Planning of Agriculture, Fisheries and Emergency Food ;
- ITN;
- DGEG.

The CNER issues opinions on external radiological emergency plans and advises the ANPC on the preparation and response to national radiological emergencies

d) Other advisory bodies

Other advisory bodies, of lesser relevance, to be taken into account are:

- the National Technical Commission for Ionising Radiation, Ultra-Sounds and Magnetic Fields: set up by Article 10 of Decree-Law No. 492/99, exercises advisory functions in the scope of the regime for the licensing of private health units working with these technologies;
- the Commission for Nuclear Fuel and Power Plants: set up by Ministerial Order 23527, of 9 August 1968, this Commission no longer functions, although it has never been formally terminated; and
- the National Commission for Nuclear Ships: set up by Decree-Law No. 45672, of 22 April 1964, it may function if summoned by the Ministry of National Defence.

3. Public and semi-public agencies

None of the main bodies holding regulatory competencies in this domain can accurately be qualified as public or semi-public agencies, given their reduced degree of independence (subject to ministerial supervision and direction).

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NUCLEAR ENERGY AGENCY

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 29 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, Poland, 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 program 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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