# Second National Report by Portugal as Required under Article 14(1) of Council Directive 2011/70/EURATOM

(August 23rd, 2018)

# Regulatory Commission for the Safety of Nuclear Installations



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(August 23<sup>rd</sup>, 2018)

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#### Frequently used Acronyms

ANPC National Civil Protection Authority (Autoridade Nacional de Proteção Civil)

APA Portuguese Environment Agency (Agência Portuguesa do Ambiente)
ARS Regional Health Authorities (Administrações Regionais de Saúde)

COMRSIN Regulatory Commission for the Safety of Nuclear Installations

(Comissão Reguladora para a Segurança das Instalações Nucleares)

CTN Campus Tecnológico e Nuclear

DGEG Directorate-General of Energy and Geology (Direção-Geral de Energia e

Geologia)

DGS Directorate-General of Health (Direção-Geral da Saúde)

DoE/USA Department of Energy of the United States of America

DRE Regional Directorates of Economy (Direções Regionais de Economia)

EIA Environmental Impact Assessment

EU European Union

FCT Foundation for Science and Technology

HEU High Enriched Uranium

HLW High Level Waste

IAEA International Atomic Energy Agency

IAPMEI Agency for Competitiveness and Innovation (Agência para a

Competitividade e Inovação)

ILW Intermediate Level Waste

ITN Nuclear and Technological Institute (Instituto Tecnológico e Nuclear)

IST Instituto Superior Técnico

LEU Low Enriched Uranium

LLW Low Level Waste

MCTES Ministry of Science, Technology and Higher Education (Ministério da

Ciência, Tecnologia e Ensino Superior)

PRR Pavillion for Radioactive Waste (Pavilhão de Resíduos Radioativos)
RPI Portuguese Research Reactor (Reator Português de Investigação)

RW Radioactive Waste

SF Spent Fuel

SGEC Secretaria-Geral da Educação e Ciência

ULisboa University of Lisbon (Universidade de Lisboa)

VSLW Very Short Lived Waste

# Report as Required under Article 14(1) of Council Directive 2011/70/EURATOM

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# A) INTRODUCTION

Directive 2011/70/Euratom, of July 19th, was transposed to the Portuguese legal order by Decree-Law 156/2013, of November 5th, which establishes the framework for the responsible and safe management of spent fuel and radioactive waste. This Decree-Law determines that the Regulatory Commission for the Safety of Nuclear Installations (COMRSIN) is the competent authority to regulate these issues and recognizes the Instituto Superior Técnico (IST) as the public entity for radioactive waste disposal.

Portugal has no nuclear power plants but produces radioactive waste from medical, industrial and research applications of radioactive materials in the form of sealed and unsealed sources, as well as spent fuel from the only existing nuclear reactor in the country, the Portuguese Research Reactor (RPI).

The RPI is a pool-type research reactor (1 MW) operated, since February 2012, by the IST. In February 2012, through Decree-Law 29/2012 of February 9<sup>th</sup>, IST became the successor to and inherited the assets and personnel of the previous operator, the State Laboratory "Instituto Tecnológico Nuclear" (ITN). The former ITN is now called "Campus Tecnológico e Nuclear" (CTN) and constitutes the Campus of IST for nuclear R&D. Throughout this report we use the acronym CTN/IST to denote the Campus of IST. The IST is the Faculty of Engineering that, since July 25<sup>th</sup> 2013, is part of the University of Lisbon (ULisboa) as a result of the merging of two major universities in Lisbon: the University of Lisbon (UL), and the Technical University of Lisbon (UTL).

Portugal has a regulatory body for the safety of nuclear installations, the safety of spent fuel management and the safety of radioactive waste management. Under Decree-Law 30/2012, of February 9<sup>th</sup>, the Regulatory Commission for the Safety of Nuclear Installations (COMRSIN) was created, leading, for the first time in Portugal, to the existence of an independent regulatory body for nuclear safety. Its three Commissioners are appointed for five-year terms by the Prime Minister. In 2013, with the publication of Decree-Law 156/2013 of November 5<sup>th</sup>, the attributions of COMRSIN were broadened to include the regulatory

oversight of the safe management of spent fuel and the safe management of radioactive waste as well as the safe transportation of spent fuel and radioactive waste.

Nevertheless, Portugal does not yet have a single, fully independent regulatory body for radiation protection. As such, the national regulatory infrastructure is still characterized by the existence of various authorities which share competencies in areas such as radiation protection, radioactive waste management, spent fuel management, nuclear safety, transportation of radioactive materials and emergency preparedness and response.

The unification of competences under a single independent regulatory authority is under way. In order to comply with the international obligations imposed by the ratified conventions and European Union (EU) Directives, the legal, technical and scientific competencies currently divided among different institutions is being unified, in order to achieve a higher level of safety.

Presently, the authorities with responsibilities in radiation protection, radioactive waste management, spent fuel, nuclear safety, transportation of radioactive materials, and emergency preparedness and response are the following:

- 1. Regulatory Commission for the Safety of Nuclear Installations (COMRSIN);
- 2. Directorate-General of Health (DGS);
- 3. Instituto Superior Técnico (IST);
- 4. Portuguese Environment Agency (APA);
- 5. Directorate-General of Energy and Geology (DGEG);
- 6. National Civil Protection Authority (ANPC);
- 7. Agency for Competitiveness and Innovation (IPAMEI), as legal successor to the Regional Directorates for Economy (DRE);
- 8. Regional Health Authorities (ARS).

Exemption and clearance levels, as required by Decree-Law 156/2013, have been defined in Ministerial Order 44/2015, of February 20th. This follows the Recommendations of the Group of Experts established under the terms of

Article 31 of the Euratom Treaty – Guidance on general clearance levels for practices (Radiation Protection 122), which were used in the past as reference.

RPI was temporarily shutdown on May 11th, 2016 for maintenance and to allow the operator (IST) to implement the recommendations of the Integrated Safety Assessment of Research Reactors (INSARR) mission that took place in February 2016 at the request of COMRSIN. The executive summary of the INSARR panel was made public at COMRSIN website. On September 14th, 2017, IST has informed COMRSIN that it has proposed to the Government that the RPI be permanently shutdown. IST will submit a decommissioning plan to COMRSIN for approval.

As determined by Decree-Law 156/2013, COMRSIN has prepared the first National Programme for the Implementation of Spent Fuel and Radioactive Waste Management Policy, henceforth abbreviated as National Programme made under the scope of Council Directive 2011/70/EURATOM. A graded approach was followed when defining, developing and implementing solutions that take into consideration the amounts and types of spent fuel and radioactive waste in Portugal and the associated risks. The first National Programme also implements practical solutions from waste generation to disposal endpoints, to avoid undue burdens on future generations. The National Programme underwent Strategic Environmental Evaluation by an independent firm that consulted all relevant stakeholders, including the public. It was submitted to the Government in July 2016 and was approved by the Council of Ministers, Resolution 122/2017 of July 27th, after consultation between different ministries.

The National Programme acknowledges that the Pavilhão de Armazenamento Interino de Resíduos Radioativos (PAIRR) that exists at CTN/IST for over 50 years as an interim facility, has become by law, the sole disposal facility in Portugal for low and intermediate level radioactive waste. The existing facility has been renamed Pavilhão de Resíduos Radioativos (PRR) and has been inspected and licensed by COMRSIN in 2016.

Portugal agrees with the international principles aimed at promoting and enhancing the safety culture for radiological protection, spent fuel management and radioactive waste management. For this reason, Portugal participates in all the related international reporting activities and peer review missions to ensure an international safety culture. The Portuguese Government approved the country's accession to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention) on April 21st 2009, by Decree no. 12/2009. On May 15th 2009, the instrument of ratification was deposited, and the Convention entered into force in the Portuguese legal framework on August 13th 2009.

Portugal has also, under the proposal of COMRSIN, requested an IRRS mission to the International Atomic Energy Agency (IAEA) on May 18<sup>th</sup>, 2018. Preparations are being made with the IAEA to carry out the mission.

In light of the above, the Portuguese National Report focuses on valid contracts for reshipment of spent fuel (SF) from the aforementioned research reactor, as well as on the safety of the management of radioactive waste (RW) from research, medical and industrial applications. This report also provides information on the status of the national regulatory infrastructure and the National Programme for the safe management of spent fuel and radioactive waste. As foreseen in article 14(1) of Directive 2011/70/Euratom, of July 19<sup>th</sup>, the present report follows the national report submitted to the Sixth Review Meeting of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

### **B) SUMMARY**

The present report by Portugal describes the major changes that have taken place as a result of the transposition of Council Directive 2011/70/EURATOM into the Portuguese legal framework through Decree-Law 156/2013. These changes took place, not only at the level of the attributions of the regulatory authority for the safety of nuclear installations, COMRSIN, but also in what concerns the requirements that public and private entities that are licensed to use radioactive materials have to comply with, in order to get a license for managing and/or storing radioactive waste.

The present legal framework set up COMRSIN as the sole regulatory body in charge for licensing, inspecting and regulating the safety of spent fuel management and the safety of radioactive waste management and its installations, as well as the responsibility to apply exclusion levels to radioactive materials, as well as apply clearance levels for radioactive waste, and authorizing the transportation of radioactive waste and spent fuel in, into and through Portugal.

All public and private entities that use radioactive materials are required to follow the procedures for the disposal of radioactive waste, are subject to fines if they do not, cannot manage or store radioactive waste without a valid license issued by COMRSIN, and the license holder has the prime responsibility for the safety of spent fuel and radioactive waste management facilities and/or activities.

The new National Programme for the safe management of spent fuel and radioactive waste has been proposed by COMRSIN and was approved by the Council of Ministers, Resolution 122/2017 of July 27<sup>th</sup>, after consultation between different ministries and after undergoing a Strategic Environmental Assessment procedure with public consultation.

As foreseen in article 14(1) of Directive 2011/70/Euratom, of July 19th, the present report follows the national report submitted to the Sixth Review Meeting of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

# C) REPORTING ARTICLE BY ARTICLE

### C.1) Article 2: SCOPE OF APPLICATION

Decree-Law 156/2013, which transposes the Directive 2011/70/EURATOM, has foreseen in its article 2 the same scope of application as the article 2 of the Directive. Any subsequent differences were introduced in the Portuguese law.

### (i) Spent fuel management

There is one civilian research reactor in (RPI) that produces spent fuel, presently shutdown while a decommissioning plan is prepared. Nevertheless, all prior spent fuel from the RPI has been returned to the USA, under the Agreement established between Portugal and the USA.

Given the recent decision from the operator IST to propose the permanent shutdown of the RPI, the current LEU fuel is eligible for return to the USA before May 12th, 2019, as its irradiation was stopped prior to May 12th, 2016. The operator will keep this fuel in the rector pool until it is shipped to the USA or to another country for reprocessing. No other storage facility is foreseen for spent fuel.

### (ii) Radioactive waste management

Radioactive waste resulting from medical, industrial and research applications, including associated discharges and disused sealed sources are also part of the scope of the National Program. Although authorized discharges were not included in the scope of application of Directive 2011/70/EURATOM, the facilities for decay of solid or liquid RW for more than 30 days are subject to specific licensing by COMRSIN. If such storage does not extend 30 days, it is covered under the license for the practice issued by the Directorate-General of Health.

# C.2) Article 4: GENERAL PRINCIPLES

### i) Spent Fuel Management Policy

In the context of international initiatives to enhance non-proliferation measures, safeguards and nuclear security and to combat nuclear terrorism, Portugal declared its interest in participating in the "United States Foreign Research Reactor Spent Nuclear Fuel Acceptance Program" of the Department of Energy of the United States of America (DoE/USA). The Portuguese Government committed to abandoning the use of highly enriched uranium (HEU) by 12th May 2006 (deadline that shifted to 31st May 2007) and to return all HEU fuel, fresh and spent, before 12th May 2009.

The current LEU fuel at RPI was obtained from the USA within the scope of a tripartite agreement Portugal-USA-IAEA and can be returned to the country of origin. Although this is the preferred option under the National Program, the possibility that the spent fuel might be reprocessed in another country was also considered, should the USA not receive it. If the fuel would sent to a reprocessing plant abroad, radioactive waste would be returned to Portugal, most likely in the form of vitrified intermediate level waste (ILW), packed in appropriate containers that could be stored in a surface facility.

At present, there is no spent fuel at IST or anywhere in Portugal. IST does not undertake any activities concerning handling or storage of spent fuel, other than interim storage in the pool of the RPI before shipment to the USA.

As previously provided for in Ministerial Order 10A/MCT/96, and presently required by articles 17, 18(3) and 7(1) of Decree-Law 262/2012, of December 17<sup>th</sup>, and by article 16 of Decree-Law 156/2013, the license holder of the reactor must maintain a register with all relevant information, namely concerning transfers and storage of spent fuel elements. This is complemented by article 14(3) of Decree-Law 156/2013, which requires IST to draft an inventory of spent fuel and radioactive waste existing at CTN/IST and submitting it to COMRSIN by January 31<sup>st</sup>, each year.

An Integrated Safety Assessment of Research Reactors (INSARR) mission took place in February 2016 at the request of COMRSIN. The executive summary of the INSARR panel was made public at COMRSIN website. On September 14th, 2017, IST has informed COMRSIN that it has proposed to the Government that

the RPI be permanently shutdown. IST will submit a decommissioning plan to COMRSIN for approval.

### ii) Spent Fuel Management Practices

In the past, all spent fuel from the operation of the RPI was stored in the reactor's pool until the shipment to the USA.

Given the recent decision from the operator IST to propose the permanent shutdown of the RPI, the current LEU fuel is eligible for return to the USA before May 12th, 2019, as its irradiation was stopped prior to May 12th, 2016. The operator will keep the spent fuel in the pool until it is shipped to the USA or to another country for reprocessing. No other storage facility is foreseen for spent fuel.

### iii) Radioactive Waste Management Policy

Since the publication of Decree-Law 156/2013 of November 5<sup>th</sup>, there is a defined policy on radioactive waste management in Portugal based on fundamental principles.

Regarding spent fuel management and radioactive waste management, the National Programme was proposed by COMRSIN and approved by the Government after undergoing Strategic Environmental Evaluation, as required by paragraph 1(a) of article 3 of Decree-Law 232/2007, of June 15th, modified by Decree-Law 58/2011, of May 4th, that transposes Directives 2001/42/CE of the European Parliament and Council, of June 27th, and 2003/35/CE of the European Parliament and Council, of May 26th. This new policy resulted from the transposition of EU Directive 2011/70/Euratom, of July 19th, into Portuguese Law and meets the requirements of the International Safety Standards.

Under article 14 of Decree-Law 156/2013, IST is responsible for the collection, segregation, conditioning and storage of solid and liquid low level (LLW) and intermediate level (ILW) radioactive waste produced in the country. IST is the operator of a radioactive waste management facility named *Pavilhão de Resíduos Radioactivos* (PRR), which is at present the only national facility for the disposal of radioactive waste in Portugal. It is located in the same CTN/IST campus where the RPI is located and, since the early fifties, has always been

considered an interim solution for the disposal of low and intermediate level radioactive waste. Nevertheless, in the absence of an alternate site, PRR will continue in operation, given the volume of radioactive waste in Portugal. COMRSIN has licensed the PRR, provided that IST implements a few additional security and safety measures, and has set a limit for the total amount of activity that may be stored in the PRR; when 1/3 of this activity limit is exceeded, IST should request an appropriated international peer review of the facility.

IST, under the regulatory oversight of COMRSIN, is responsible for the safe management of all RW stored in its disposal facility.

Concerning medical applications in general, and nuclear medicine in particular, Decree-Law 180/2002 of August 8th establishes that solid and liquid radioactive waste with a very short half-life (VSLW) may be stored on site until it decays or is subject to authorized discharge. Article 9 of Decree-Law 156/2013 requires also that any activity associated with the management of radioactive waste and the associated installations for storage also be licensed by COMRSIN, unless the waste is stored for authorized discharge or otherwise stored for less than 30 days before disposal.

Producers of radioactive waste also have the obligation to provide COMRSIN, before January 31<sup>st</sup> each year, with a report detailing the type and volume of radioactive waste they produced in the previous year, as well as their location and foreseeable destination (article 8(4) of Decree-Law 156/2013; see also, in what concerns nuclear facilities, article 31 of Decree-Law 262/2012).

Under article 6(3)(d) of Decree-Law 156/2013, the National Programme includes an inventory of all spent fuel and radioactive waste in Portugal, including estimates of future amounts, indicating their quantity and location. Article 13(l) further states that COMRSIN must draft an annual inventory of spent fuel and radioactive waste existing in Portugal, keeping it constantly updated.

The regime relating to the use of radioactive sealed sources is set out in Decree-Law 38/2007, of February  $19^{th}$ , which transposes Directive 2003/122/Euratom.

The cost associated to the collection and disposal of radioactive waste by IST, including spent and disused sealed sources, falls on the producer and has been set according to radionuclide, activity, and volume as defined by Ministerial Order no. 891/2015, of February 20th that also regulates the fees charged by COMRSIN for characterizing and authorizing the disposal of radioactive waste, for applying exclusion or clearance levels for radioactive waste, as well as for licensing radioactive waste storage facilities and management practices.

Whenever radioactive waste is encountered and its producer or holder cannot

be identified (orphan sources), IST is responsible for the costs of collecting the radioactive waste, including sealed sources, and storing it in its disposal facility. This guarantees the existence of a public solution for all radioactive waste that is produced in Portuguese territory.

### iv) Radioactive Waste Management Practices

In Portugal, radioactive waste originates mainly from medicine, industry and research activities. Only low level radioactive waste (LLW) and intermediate level radioactive waste (ILW) is produced from activities in these sectors.

Until 2013, solid radioactive waste produced in hospitals, mainly from nuclear medicine services, including gloves, syringes, gowns and other contaminated materials used to be collected by former-ITN. Today, these facilities manage their own radioactive waste according to internal procedures as part of their own Radiation Protection Programme and conditions set in the authorization to carry out the practice. Changes have taken place as a result of the entry into force of Decree-Law 156/2013, whereby the activity associated with the management of radioactive waste and the associated installations for storage needs to be additionally licensed by COMRSIN, unless the waste is stored for authorized discharge or otherwise stored for less than 30 days before disposal.

COMRSIN has already licensed 48 radioactive waste management and storage facilities in hospitals and research centers.

The radioactive liquid effluents generated in hospitals that perform therapy with internment or that are classified as higher risk (based on isotope and annual activity) are sent to retention tanks, where the radioactive liquid is maintained during the decay process. When the radioactive liquid is under the legal levels of authorized discharge, the tanks are opened and the liquid goes to the public sewerage system. Under Article 24(1)(e) of Decree-Law 180/2002, of August 8th, all radioactive waste resulting from medical applications must be registered before disposal and this registry must be kept for 10 years. Technetium-99m generators contribute significantly to the total amount of radioactive waste generated in Nuclear Medicine services. Nevertheless, after the licensing of the local installations by COMRSIN, the generators are allowed to be returned to the manufacturer for recycling after decaying for 13 weeks on site.

Concerning I-125 sources ("seeds") that are leftovers from brachytherapy procedures, two pathways have been established by COMRSIN: a) local storage for 2 years and subsequent disposal at the PRR facility with COMRSIN's authorization; b) local storage for 215 weeks after which they are cleared from regulatory control and may be disposed as nonradioactive waste. During

licensing, COMRSIN evaluates the local storage facility and its staff vis-á-vis safety procedures associated with the management of radioactive iodine seeds and decides which pathway the installation should be licensed to follow. It is also possible that an installation that is offered clearance after 215 weeks, requests instead the disposal to PRR after 2 years.

Sealed sources from industrial and medical applications, as well as from research labs and academia (that have not been returned to the supplier), smoke detectors (containing Ra-226 and Am-241 sources), lightning rods and other contaminated material collected in scrap yards comprises the remaining solid waste that is stored in the CTN/IST campus. The PRR disposal facility also stores radioactive solid and liquid waste contaminated with H-3, C-14 and Ca-45 resulting from research laboratories.

The following types of radioactive waste are stored in the PRR:

- Sealed sources (spent, disused and orphan sources) in storage/custody from medical, industrial and research applications;
- ii. Open sources from medical and research applications that were not disposed of by the operators;
- iii. Equipment (or parts of equipment) containing sealed sources that were used in medical, industrial and research applications;
- iv. Radium historical waste from medical applications;
- v. Depleted uranium previously used as counterweights or as shielding (this material is under IAEA/Euratom safeguards);
- vi. Solid low level radioactive waste with short or medium-lived radionuclides;
- vii. Radioactive liquid waste from research labs containing mainly, H-3, C-14 and Ca-45.

The disused sealed sources regime is to be found, predominantly, in Decree-Law 38/2007, which transposes Directive 2003/122/Euratom. This regime establishes that, for the use of radioactive sealed sources, a license must be obtained from IST prior to its possession, transport and transfer.

All the licenses granted under this regime (ownership, transport, entrance, etc.) contain a description of the licensed material and other relevant information

available, such as volume or mass, activity and specific radionuclide. Additionally, under article 4(5) of the Decree-Law mentioned above, the licensee must pay a deposit for each sealed source. Once the licensee considers that the source is no longer used for the practice for which the authorization has been granted, it should be either returned to the manufacturer or collected by IST. Under article 15 of Decree-Law 156/2013, in the latter case, the licensee must inform COMRSIN, who shall characterize and classify the waste in question and instruct its collection by IST.

Licensees also have to present an annual declaration of the sources in use.

The mechanism created by the deposit presents a two-way advantage: (a) The licensee is encouraged to notify the licensing authority once the source is no longer in use; and (b) Portugal can effectively control the licensed disused sealed sources, preventing the existence of orphan sealed sources. This mechanism also contributes to the implementation of the *Code of Conduct on the Safety and Security of Radioactive Sources*.

### Storage and disposal

All the solid radioactive waste received from private and public entities from across the country is stored at the PRR disposal facility, after appropriate segregation and conditioning is carried out. Liquid waste contaminated with H-3, C-14 and Ca-45 is also stored at the PRR.

The PRR is a surface facility that for many years has been used as an *interim* storage for the disposal of RW in Portugal. IST is responsible for managing all RW in its disposal facility under the regulatory oversight of COMRSIN (Article 14(2) of Decree-Law 156/2013).

In 2015 COMRSIN developed an online platform that serves as a database for all radioactive waste that is stored at the PRR after January 1st 2014. Producers and holders of radioactive waste may submit online requests for the disposal, clearance or exclusion of their radioactive waste. The platform also serves as a database and process management tool for licensing installations that store and manage radioactive waste for more than 30 days. The corresponding authorizations/licenses are issued by COMRSIN after the information has been appropriately scrutinized by its staff. This online platform also allows the estimation of the total activity that is sent for disposal at the PRR. Prior to 2014, IST kept a registration system based on a spreadsheet.

At the moment, there is no other disposal facility for radioactive waste, either LLW or ILW. In order to look for possible disposal sites for this type of waste (surface and near-surface facilities) academic studies have previously been carried out by the former ITN and the Universities of Lisbon, Porto and Évora,

with the support of the Foundation for Science and Technology (FCT). However, these studies were not implemented, but may be useful when the National Programme is reviewed or when the PRR approaches its licensed capacity.

### v) Criteria used to define and categorize radioactive waste

COMRSIN is the Portuguese regulatory authority that has the power to classify radioactive materials as radioactive waste. Ministerial Order 44/2015, of February 20th defines clearance levels, as required by Decree-Law 156/2013. The adopted clearance levels are the ones defined in Annex VII of the recent Council Directive 2013/59/EURATOM. Under article 42 of Decree-Law 156/2013, the exclusion levels are based on the clearance levels published by the aforementioned Ministerial Order.

Categorization of radioactive waste and management options are included in the National Programme, as specified in the International Atomic Energy Agency's standards, and summarized as:

Classification	Very short half-life <100 d	Short half-life <31 yr	Long half-life >31 yr	
Very Low Activity (VLLW)		(PRR	oosal facility /IST) learance after decay	
Low Activity (LLW)	On-site decay  Disposal as  conventional waste	Surface disposal facility (PRR/IST) with possibility of clearance after decay	Surface disposal facility (PRR/IST)	
Intermediate Activity (ILW)		Surface disposal facility (PRR/IST)		
High Activity (HLW)	N.A.	N.A.	N.A.	

### C.3) Article 5: NATIONAL FRAMEWORK

#### **Implementing measures**

The transposition into the Portuguese legal framework of Council Directive 2011/70/Euratom, of July 19<sup>th</sup>, was carried out by Decree-Law 156/2013 of November 5<sup>th</sup>.

One must also take into account the national transposition, through Decree-Law 38/2007 of February 19<sup>th</sup>, of Council Directive 2003/122/Euratom, which relates to matters involving disused sealed sources.

But many other laws and regulations must also be taken into account, as described below.

### Legislative and regulatory framework

# i) The establishment of applicable national safety requirements and regulations for radiation safety

Portugal has complied with its obligations under EU primary and secondary legislation relating to safety requirements and radiation safety.

Since Portugal's accession to the EU in 1986, a number of legal acts have been adopted, and many have continued to be in force even though some of their content has been derogated by later laws. Consequently, it is only through interpretation and consideration of the ensemble of the relevant legal instruments that one can determine the provisions currently in force. That being said, this situation has not created significant practical difficulties.

The current legislative and regulatory framework relating to safety requirements and radiation safety is made up, essentially, by the following acts, in chronological order:

Decree-Law 426/83, of 7 December	Basic legal framework relating to uranium mining
Decree-Law 348/89, of 12 October	General rules for applications of ionizing radiation and distribution of attributions (applicable only to a small degree, insofar as it has been substantially derogated by subsequent laws)
Regulatory Decree 9/90, of April 19 <sup>th</sup>	Regulates and complements Decree-Law 348/89
Regulatory Decree 34/92, of December 4 <sup>th</sup>	Regulates Decree-Law 426/83, setting out, <i>inter alia</i> , radiological protection rules for uranium mining activities
Decree-Law 36/95, of February 14 <sup>th</sup>	Establishes a system for information to the population relating to radiological emergencies, transposing Directive 89/618/Euratom
Regulatory Decree 29/97, of July 29 <sup>th</sup>	Sets out rules for the protection of external workers intervening in controlled areas, transposing Directive 90/641/Euratom
Decree-Law 165/2002, of July 17 <sup>th</sup>	General principles of radiation protection and distribution of relevant attributions between public bodies
Decree-Law 167/2002, of July 18 <sup>th</sup>	Regulates the licensing, operation and duties of service providers in the field of radiological protection, including radiation protection studies for radiological installations, dosimetry (individual and area monitoring) and training
Decree-Law 174/2002, of July 25 <sup>th</sup>	Regulates preparation and response to radiological emergencies
Decree-Law 180/2002, of August 8th, as revised by Decrees-Law 215/2008, 279/2009 and 72/2011	Transposes Council Directive 97/43/Euratom, on the application of ionizing radiation during medical diagnostics and treatment, including the establishment of licensing and operating requirements for radiotherapy, nuclear medicine and radio-diagnostic facilities
Decree-Law 138/2005, of August 17 <sup>th</sup>	Establishes a system for environmental monitoring of levels of radioactivity in the atmosphere, waters and soil
Decree-Law 140/2005, of August 17 <sup>th</sup>	Regulates exemption levels for the licensing and prior authorization of activities using ionizing radiation
Decree-Law 38/2007, of February 19 <sup>th</sup>	Regulates the licensing and radiation protection rules associated to the use of sealed radioactive sources, transposing Directive 2003/122/Euratom
Decree-Law 222/2008, of November 17 <sup>th</sup>	Complements the transposition of the Basic Safety Standards Directive by revising, inter alia, the dose limits for workers, apprentices, students and members of the public
Decree-Law 227/2008, of November 25 <sup>th</sup>	Transposes article 38 of Council Directive 96/29/Euratom, of 13 May, that requires the establishment of a system of qualified experts and

	tochnicians
Ministerial O	technicians  Sata out the food to be shared for saveral liganging and
Ministerial Order no.	Sets out the fees to be charged for several licensing and
596/2009, of June 5 <sup>th</sup>	authorization procedures related to radiological
D I	protection carried out by DGS
Decree-Law	Sets out rules relating, inter alia, to radiological
145/2009, of June 17 <sup>th</sup>	protection in medical devices and accessories,
	transposing Directive 2007/47/EC
Decree-Law	Sets out rules relating to transfers of spent fuel and
198/2009, of August	radioactive waste, transposing Directive
26 <sup>th</sup>	2006/117/Euratom
Law 102/2009, of	General regime for security and safety in the workplace,
September 10 <sup>th</sup>	including provisions concerning radiological protection
_	of workers
Ministerial Order no.	Adopted the regulation for the metrological control of
1106/2009, of	measuring instruments for ionizing radiation, under
September 24 <sup>th</sup>	Decree-Law no. 291/90, of 20 September
Decree-Law 10/2010,	Legal framework for the management of waste,
of February 4 <sup>th</sup> ,	including radioactive waste, resulting from mining
revised by Decree-Law	operations, transposing Directive 2006/21/EC
31/2013, of February	
22 <sup>nd</sup>	
Order no. 6402/2010,	Awards competencies associated to metrological
of 12 April	control, under Ministerial Order no. 1106/2009, to ITN
Decree-Law 41-	Sets out the rules applicable, <i>inter alia</i> , to radiological
A/2010, of April 29th,	protection during transport of radioactive materials by
last revised by Decree-	land, transposing Directives 2006/90/EC and
Law 19-A/2014, of	2008/68/EC. The last revision transposed Directive
February 7 <sup>th</sup>	2012/45/EU
Decree-Law 29/2012,	Integrates ITN into IST and regulates the transfer of
of February 9th	assets and attributions to the latter (see also Decree-
or rebruary 5	Law 125/2011, of 29 December)
Decree-Law 30/2012,	Created and regulated the functioning of COMRSIN (see
of February 9th	also Ministerial Order no. 4382/2012, of 28 March)
Decree-Law 56/2012,	Regulates the functioning and attributions of APA,
of March 12 <sup>th</sup>	confirming those relating to radiological emergencies
Decree-Law 262/2012,	Regulates the obligations of operators of nuclear
of December 17 <sup>th</sup>	facilities, in furtherance of the regime set out in Decree-
טו שבנכווושפו 1/ייי	Law 30/2012
Decree-Law 70 /2012	Rules restricting the use of certain dangerous
Decree-Law 79/2013,	substances in electronic and electrical equipment,
of June 11 <sup>th</sup> , revised by Decree-Law 119/2014,	including ionizing radiation and establishment of certain
- · · · · · · · · · · · · · · · · · · ·	
of August 6 <sup>th</sup>	Pulse for environmental impact assessment including
Decree-Law 151/2013,	Rules for environmental impact assessment, including
of October 31st, revised	for nuclear facilities, transposing Directive 2011/92/EU
by Decree-Law	
47/2014	Establishes the logal and regulatory framework for the
Decree-Law 156/2013,	Establishes the legal and regulatory framework for the
of November 5 <sup>th</sup>	safe management of spent fuel and radioactive waste,

	transposing Directive 2011/70/Euratom
Law 19/2014, of April	Defines the fundamental basis of environmental policy,
14 <sup>th</sup>	including obligations to assess risk of radioactive
	environmental contamination
Decree-Law 67/2014,	Legal framework for the management of waste from
of May 7 <sup>th</sup>	electrical and electronic equipment, including certain
	equipment that uses or is contaminated by ionizing
	radiation
Decree-Law 127/2014,	Sets out the basic framework for the licensing and
of August 22 <sup>nd</sup>	functioning of private facilities providing healthcare,
	including the use of ionizing radiation
Ministerial Order	Defines exemption and clearance levels for radioactive
44/2015, of February	waste, implementing Decree-Law 156/2013
20 <sup>th</sup>	
Resolution from the	Approves the National Programme for the safe
Council of Ministers	management of spent fuel and radioactive waste
122/2017, of July 27 <sup>th</sup>	
Decree-Law 135/2017,	Ammends Decree-Law 30/2012 and 262/2012,
of October 20 <sup>th</sup>	transposing Directive 2014/87/EURATOM.

# ii) A system of licensing of spent fuel and radioactive waste management activities

The licensing of spent fuel and radioactive waste management activities in Portugal is presently governed by Decree-Law 156/2013 of November 5<sup>th</sup>. This regime applies: (a) to all phases of the management of spent fuel arising from civilian activities; (b) to all phases of the management of radioactive waste arising from civilian activities, from their production to their disposal; and (c) to facilities for the management of spent fuel and of radioactive waste.

Article 9 of Decree-Law 156/2013 subjects these activities, in all phases (from choice of siting to decommissioning), to mandatory licensing, to be granted by COMRSIN, except in the case of authorized discharges, the storage of radioactive waste for a period not exceeding 30 days before disposal, and radioactive waste management activities associated to interventions in the context of radiological emergencies. Storage carried out over shorter periods is covered by the license issued for the underlying practice.

Article 11 of Decree-law 156/2013 also subjects the transport of spent fuel and radioactive waste from, to and through Portugal to prior authorization by COMRSIN, which is also responsible for evaluating and inspecting the safety condition of such transports. These provisions have partly derogated from, but are still complemented by Decree-Law 198/2009, of August 26<sup>th</sup>.

Excluded from the above mentioned regime are authorized radioactive discharges, gaseous, liquid or solid form, and the management of radioactive waste arising from mining operations. The latter is governed by the general regime provided for in Decree-Law 10/2010, of February 4<sup>th</sup>, revised by Decree-Law 31/2013, of February 22<sup>nd</sup>. Prior licensing of such installations is mandatory and must be obtained from the Directorate-General for Energy and Geology, after consulting several entities (COMRSIN is not included in the consultation procedure). It should, however, be noted that no such operation is currently active in Portugal. Consequently, no further details shall be provided regarding this regime, as it is of no practical relevance.

# iii) A system of prohibition of the operation of a spent fuel or radioactive waste management facility without a license

The operation of a spent fuel or radioactive waste management facility without a license is prohibited by the legislation mentioned in the previous heading. Infringements to this prohibition, in accordance with article 47(1) of Decree-Law 156/2013, are subject to fines of up to EUR 45.000.

One should also take into account general prohibitions of carrying out activities implying the use or potential exposure to ionizing radiation without prior authorization of the competent authority - see article 8 of Decree-Law 165/2002 - and the rules that requires a prior license by COMRSIN for the operation of a nuclear facility - see article 11 of Decree-Law 30/2012 (complemented by Decree-Law 262/2012).

# iv) A system of appropriate institutional control, regulatory inspection, documentation and reporting

COMRSIN is responsible for controlling and inspecting, as well as receiving all relevant documentation and notifications associated to the management of spent fuel and radioactive waste and to its transport to, from and throughout Portugal - see, e.g., articles 45, 11(2), 13(b) and (c) of Decree-Law 156/2013. Its inspections must be systematic and be supported on a predetermined internal plan for periodical assessment.

All information and evaluations relevant to the safety of spent fuel and radioactive waste management activities and facilities must be recorded and kept permanently updated by the respective operator and be made available to COMRSIN; the operator must also demonstrate compliance with applicable

norms whenever this is requested by COMRSIN. This information must be kept until it is shown that it has become obsolete or must be replaced (see articles 16 and 29(3) of Decree-Law 156/2013). Similar record keeping obligations are imposed on operators of nuclear facilities by article 6 of Decree-Law 262/2012 and, in the case of holders of sealed sources, by article 6 of Decree-Law 38/2007.

Article 30 of Decree-Law 156/2013 provides a specific framework for regulatory inspection by COMRSIN and stipulates that these interventions must aim at promoting safety by taking into account, *inter alia*, technological developments, research and development, new international rules and recommendations, etc. COMRSIN is tasked, by article 31, with the adoption of a regulation to provide further specifications on how regulatory inspections are carried out. Safety inspections prior to licensing are foreseen and governed specifically by article 34 of Decree-Law 156/2013. This regime is complemented by the verification provisions set out for nuclear facilities in Decree-Law 262/2012, *maxim* articles 30 to 33.

Operators are subject to a general duty of cooperation with COMRSIN, including a duty to allow full access to facilities for inspection and evaluation, at any moment, with no prior warning required (see article 17 of Decree-Law 156/2013, article 7 of Decree-Law 262/2012 and article 13 of Decree-Law 30/2012).

This framework is complemented by the already mentioned provisions that provide for the keeping of an updated inventory of radioactive waste and spent fuel existing in Portugal.

COMRSIN is generally empowered to request technical assistance from other public bodies, or even from private entities, in order to adequately pursue its tasks (see article 7 of Decree-Law 30/2012).

# v) The enforcement of applicable regulations and of the terms of the licenses

Aside from what has already been described in the previous heading, COMRSIN is empowered to act in furtherance of a high level of radiological protection, promoting the continuous improvement of safety at facilities and in management activities. It may inspect, order corrective measures and set timelines for compliance, change, suspend or revoke licenses, alter operating conditions, order the temporary or definitive closure of facilities, and order any other urgent provisional measure, to the extent that such measures are necessary to ensure the radiological protection of workers, the public and the environment as well as to reduce risks. Any corrective measures ordered must

be followed up with subsequent inspections. In this regard, see articles 13(b) and (c), 30(5), 38 and 46 of Decree-Law 156/2013. See also, for nuclear facilities, article 34 of Decree-Law 262/2012.

Fines for violations detected by COMRSIN, are imposed by the member of Government responsible for the sector of activity in question (e.g., the Minister of Science, Technology and Higher Education, in what concerns the RPI). The applicable fine could be as high as 74 819,68 Eur.

# vi) A clear allocation of responsibilities to the bodies involved in the different steps of spent fuel and radioactive waste management

Responsibilities are clearly allocated between the operator and the relevant public authorities by the above mentioned provisions of Decree-Law 156/2013.

The operator is made primarily and fully responsible for the safety of spent fuel or radioactive waste management or facilities by articles 3(r), 7, 8, 10 and 11(3) and (4) thereof. The responsibility cannot be delegated or transferred. See also, for nuclear facilities, the same principle expressed in articles 4 and 5 of Decree-Law 262/2012 and article 12 of Decree-Law 30/2012. In what concerns sealed sources that are no longer to be used, the obligations of their holders are laid out in articles 5(1)(e) and 10 of Decree-Law 38/2007 (as implicitly revised by Decree Law 156/2013).

In accordance with article 4(2) of Decree-Law 156/2013, the State is ultimately responsible for the management of spent fuel and radioactive waste generated on Portuguese territory.

COMRSIN is responsible for licensing, inspection and enforcement as mentioned above. Aside from the provisions that have been mentioned above, one should further consider its general mission, as set out in articles 4 and 8 of Decree-Law 30/2012.

IST is given the responsibility for the collection, storage and disposal of all solid or liquid (non-exempt) radioactive waste produced or found on national territory (see article 14 of Decree-Law 156/2013). IST is also the operator of the radioactive waste disposal facility.

# C.4) Article 6: REGULATORY BODY

In what concerns radioactive waste and spent fuel COMRSIN is the Portuguese regulatory body.

Presently, under article 13 of Decree-Law 156/2013 and article 8 of Decree-Law 30/2012, COMRSIN is responsible for:

- i. Licensing, evaluating, monitoring and inspecting facilities and activities relating to the management of spent fuel and radioactive waste (encompassing all phases, from initial choice of siting to decommissioning);
- ii. Authorizing and inspecting transports of spent fuel and radioactive waste in Portugal;
- iii. Characterizing and classifying radioactive materials as radioactive waste;
- iv. Applying clearance levels, on a case by case basis;
- v. Ordering the collection of radioactive waste for storage and disposal;
- vi. Authorizing the disposal of radioactive waste;
- vii. Imposing fines for infringements of rules relating to licensing or safety (through the relevant member of Government), suspending or canceling licenses and ordering provisional measures;
- viii. Preparing and continuously updating an inventory of radioactive waste on national territory;
  - ix. Cooperating with the relevant bodies for the drafting of education and training plans;
  - x. Making available to workers and the general public the necessary information concerning the management of spent fuel and radioactive waste;
  - xi. Drafting and proposing to the Government legislation in this domain, as well as approving regulations whenever empowered to do so by law; and
- xii. Cooperating with the relevant authorities and international organizations, validating data relating to spent fuel and radioactive waste to be communicated to international organizations (except in the case of radiological emergencies), taking part in the preparation of international agreements within this domain.

IST is entrusted with collecting and disposing all solid or liquid radioactive waste produced or found in Portugal (above exemption levels). IST is also responsible for the subsequent safe management of radioactive waste, under the supervision of COMRSIN, and for drafting an inventory thereof to be provided to COMRSIN - article 14 of Decree-Law 156/2013.

Radiological emergencies are regulated separately by Decree-Law 36/95, and by Decree-Law 174/2002. For further on this, see section C.5.

As for compliance with the requirement that the regulatory body be "provided with adequate authority, competence, financial and human resources to fulfill its assigned responsibilities" the relevant national provisions are primarily to be found in Decree-Law 30/2012.

COMRSIN does not have a separate legal personality (which accounts, *inter alia*, for why it cannot impose fines itself). It functions with the logistical, administrative and legal support of the Secretariat-General of Education and Science (SGEC).

COMRSIN is governed by three Commissioners, appointed by the Prime Minister for five year renewable terms, chosen on the basis of academic, scientific and technical merit. Commissioners receive no remuneration for their functions, but are entitled to be refunded for associated travel and other expenses. COMRSIN has no staff of its own but may use its budget (allocated through SGEC) to hire the services necessary to accomplish its tasks. Furthermore, it is empowered to request the cooperation of experts from public and, on a subsidiary basis, from private entities, and through this mechanism it may count on the presence of workers assigned from other public bodies. Since 2016 COMRSIN has collected about 36.000,00 € in license fees that add up to the State allocated budget.

At present COMRSIN has, in addition to the three commissioners, a full time administrative adjunct, and two part-time collaborators: one is a legal adviser in nuclear law and the other is a physicist. COMRSIN is expected to be reorganized in the course of the legal revisions that are currently under way.

As for compliance with the requirement that there be "effective independence of the regulatory functions from other functions where organizations are involved in both spent fuel or radioactive waste management and in their regulation", article 4(2) of Decree-Law 30/2012 provides that COMRSIN is an independent entity, functionally separate from any entity or organization related to the promotion or use of nuclear energy, including the production of electricity, and that it decides its activities and exercises its regulatory and supervision powers in an independent manner. Although COMRSIN is logistically dependent on SGEC, that functions under the same umbrella of IST, the Ministry of Science, Technology and Higher Education, it should be noted that the Commissioners are appointed directly by the Prime-Minister. There are no specific provisions for the removal of Commissioners from office, general civil service rules applying thereto.

### C.5) Article 7: LICENSE HOLDERS

COMRSIN is entrusted with supervising and guaranteeing that license holders abide by their responsibilities, as described throughout this report. Nevertheless, article 52 of Decree-Law 156/2013 established a moratorium of two years, ending on November 5<sup>th</sup> 2015, for producers of RW to adjust to the present legislation and prepare themselves to get a license for the activity and installations where they manage and store RW for more than 30 days.

COMRSIN has prepared a practical guidance document that contains a set of guidelines to be followed by private and public institutions that produce, manage and/or store radioactive waste. These guidelines follow IAEA safety standards and make specific recommendations on how to manage and store RW. These guidelines include requirements for licensing RW management activities and storage facilities for RW.

The document is on COMRSIN website:

#### http://www.comrsin.pt/index.php/pt/gestao-segura-residuos.

All licensees authorized by DGS to carry out practices that use radioactive materials have been informed of this document by COMRSIN and DGS.

IST presented the elements for licensing the disposal facility that exists in the Portuguese territory, *Pavilhão de Resíduos Radioativos*. A license for the PRR was issued by COMRSIN in April 2016 with several conditions, which are being implemented by the operator on time. COMRSIN is closely following the implementation of the license conditions by the operator.

COMRSIN has licensed 48 installations in medical and research sectors, in addition to the PRR, all following international best practices, IAEA safety standards and national legislation, namely Decree Law 156/2013.

National legislation ensures that the prime responsibility for the safety of spent fuel and radioactive waste management rests with the holder of the relevant license, as provided for in articles 3(r), 7, 8, 10 and 11(3) and (4) of Decree-Law 156/2013, articles 4 and 5 of Decree-Law 262/2012 and article 12 of Decree-Law 30/2012. The same principle is also expressed, for sealed sources, in articles 5(1)(e) and 10 of Decree-Law 38/2007 and, for transport, in article 11(3) and (4) of Decree-Law 156/2013 and article 18 of Decree-Law 198/2009.

#### **General safety requirements**

The national legal framework ensures that, at all stages of radioactive waste management individuals, society and the environment are adequately

protected against radiological and other hazards.

### Specifically:

- i. Criticality and removal of residual heat during radioactive waste management are not directly addressed by specific provisions, but control of these factors is a necessary corollary of several provisions (see, e.g., articles 4(c) and (e), 21, 22, 28 and 29 of Decree-Law 156/2013, and articles 12, 16, 17, 18(2)(h) and 26 to 29 of Decree-Law 262/2012);
- ii. Generation of radioactive waste must be kept to the minimum practicable, both in terms of volume and activity levels, as provided for in article 4(1)(a) of Decree-Law 156/2013;
- iii. Interdependencies among the different steps in radioactive waste management must be taken into account, under article 4(1)(b) of Decree-Law 156/2013;
- iv. National protective methods for individuals, society and the environment, that are rooted in EU Directives and internationally endorsed criteria and standards, are provided for by the ensemble of the nuclear safety and radiological protection provisions described throughout this report;
- v. While there are no provisions explicitly requiring the consideration of biological, chemical and other associated hazards, such considerations are necessarily a corollary of the general safety provisions mentioned above; and
- vi. As for burdens imposed on future generations, article 4(1)(d) of Decree-Law 156/2013 requires that any such burdens be minimized.

### Existing facilities and past activities

The legal framework for spent fuel and radioactive waste management and facilities, provided for in Decree-Law 156/2013, is applicable to existing facilities and activities.

A transitional regime was foreseen according to which, within two years of the publication of this law, operators had to take adequate measures to revise:

- i. The safety of the activity/facility in question and, if necessary, to carry out all reasonably possible improvements thereto;
- ii. The results of past practices, so as to determine whether any intervention is needed for reasons of radiation protection, bearing in

mind that the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including the social costs, of the intervention;

Once the above mentioned deadline expired, COMRSIN had to inspect and certify the safety conditions of facilities, issuing a new license or ordering the adoption of corrective measures.

IST presented the elements for licensing the disposal facility that exists in the Portuguese territory, *Pavilhão de Resíduos Radioativos*. A license for the PRR was issued by COMRSIN in April 2016 with several conditions, which are being implemented by the operator on time. COMRSIN is closely following the implementation of the license conditions by the operator.

COMRSIN has licensed 48 installations in medical and research sectors, in addition to the PRR, all following international best practices, IAEA safety standards and national legislation, namely Decree Law 156/2013.

### Siting of proposed facilities

The choice of siting of proposed facilities is subject to approval by COMRSIN as part of the licensing procedure (articles 9(1) and 13(b) of Decree-law 156/2013).

Under article 21 of Decree-Law 156/2013, any project to create a new spent fuel or radioactive waste management facility must:

- (a) Assess all relevant factors relating to the siting of the facility which may affect its safety throughout its lifespan;
- (b) Assess the probable impact on the safety of persons and the environment, in accordance with Environmental Impact Assessment (EIA) procedure laid out in Decree-Law 151-B/2013, of October 31<sup>st</sup>, revised by Decree-Law 47/2014 (which transposes Directive 2011/92/EU).

Choices made at this phase must take into account potential radiological consequences for workers, the general public and the environment, so as to ensure compliance with dose limits set out in Decree-Law 222/2008 and with the ALARA principle.

Consultation of potentially affected contracting parties is guaranteed by the already mentioned national provisions that transpose the EU's Environmental Impact Assessment Regime. Additionally, article 21(3) of Decree-law 156/2013

requires the Portuguese State to take all adequate measures to guarantee that any new facilities shall not have unacceptable effects on neighboring States.

It should also be noted that Portugal has signed an international agreement with Spain (Portuguese-Spanish Agreement on Cooperation relating to the Safety of Bordering Nuclear Facilities, 1980). Even if no facilities are actually covered by the scope of this agreement (limited to nuclear installations located no more than 30km from the border), it has nonetheless served as a basis for cooperation between the two countries in this domain. A new Protocol between the Consejo de Seguridad Nuclear (CSN) in Spain, and APA, IST and ANPC has been signed on July the 30st 2015, relating to emergencies and preparedness consultation and cooperation in the event of nuclear and radiological accidents.

Information on the safety of a such facility must be made available to members of the public, both by the operator and by COMRSIN, as provided for in articles 4(1)(j) and 13(e) of Decree-Law 156/2013, and in article 15 of Decree-Law 30/2012 (aside from consultation procedures deriving from the general rules on EIA procedures). A specific framework for information of the public relating to radiological emergencies is set out in Decree-Law 36/95.

### Design and construction of facilities

Under article 22 of Decree-Law 156/2013:

- i. The design and construction of spent fuel and radioactive waste management facilities must include suitable measures to limit possible radiological impacts on individuals, society and the environment, including those from discharges or uncontrolled releases:
- ii. At the design stage, prior planning and, if necessary, technical provisions relating to decommissioning must be taken into account;
- iii. The technologies incorporated in the design and construction of a radioactive waste management facility must be supported by relevant experience, testing or analysis.

There are currently no proposals for the design or construction of new spent fuel or radioactive waste management facilities in Portugal, beyond small storage facilities where radioactive waste may be stored for more than 30 days that are also subject to licensing and inspection by COMRSIN.

### **Operation of facilities**

The national legal framework provides for the safe operation of spent fuel and radioactive waste management facilities.

Licenses are only granted to operators upon demonstration of compliance with safety requirements, relating to all stages of the lifespan of the facility, including a final inspection prior to initiation of operations, as provided for, e.g., in articles 9(1), 23 and 34 of Decree-Law 156/2013.

A management system, including operational limits and conditions, must be developed and revised, as appropriate, in accordance with articles 28 and 29 of Decree-Law 156/2013.

The operation of the facility must be able to rely on support from suitable human resources, as described below.

Procedures for characterization of radioactive waste, under the responsibility of COMRSIN, are set out in articles 13(h) and (j) and 15(2) of Decree-Law 156/2013. Aside from provisions relating to exempted materials and liquid waste which may be stored temporarily before discharge (*maxim* in medical facilities), provisions on the segregation of radioactive waste are included in the National Programme.

Incidents, significant to safety, must be reported in a timely manner by the holder of the license to the regulatory body and to other relevant authorities, as described above.

In addition to other provisions already mentioned in this report, article 20 of Decree-Law 156/2013 requires operators to grant workers and the general public all relevant information regarding the management of spent fuel and radioactive waste, complying with international obligations. These transparency requirements are subject to exceptions in the name of national security and confidentiality required by other legal provisions.

Operators must periodically revise the safety of the facility, subject to supervision by COMRSIN, which requires the existence of a methodology to collect and analyze relevant operating experience, which can allow for the assessment and the determination of the necessary corrective measures (see, e.g., article 30 of Decree-Law 156/2013).

#### Institutional measures after closure

As provided for in articles 3(i) and 23(1) of Decree-Law 156/2013, the closing of a spent fuel or radioactive waste management facility must guarantee the adoption of any potentially necessary technical interventions or works to ensure long lasting safety. The initial project of any such facility must already take this issue into account, foreseeing possible evolutions of conditions of the site after closure (article 21(1)(b)).

The National Programme approved by the Council of Ministers addresses the issue of closure, including the time during which adequate controls must be maintained, indicating the means to be used so as to preserve knowledge and information about the facility on the very long term (article 6(3)(g) of Decree-Law 156/2013).

Institutional measures after closure of the PRR are not yet foreseen.

### **Quality Assurance**

Articles 28 to 31 of Decree-Law 156/2013 set up a management system for spent fuel and radioactive waste which ensures that appropriate quality assurance programs concerning the safety of spent fuel and radioactive waste management are established and implemented.

Under article 28, this management system encompasses all provisions relating to the organization, distribution of responsibilities, resources, procedures and assurances for the safe management of such facilities, including the disposal of radioactive waste. This system must be built having safety as its first priority and should also include provisions relating to the prevention of incidents and the reduction of their potential consequences (the components of these systems are further specified in article 29).

The system must be presented by the operator to COMRSIN for approval during the licensing procedure. Any subsequent change must also be approved by COMRSIN. Quality assurance is further provided for through supervision and inspections by COMRSIN, as foreseen in articles 30 and 31. The regulator must not only confirm compliance with legal provisions and previously communicated management systems, but also ensure that the existing level of safety is in accordance with international rules and best practices, identifying opportunities for improvement whenever reasonably possible.

#### **Operational radiation protection**

The national legislative and regulatory framework already described above

transposes the relevant EU Directives relating to radiological protection.

The most relevant provisions are briefly described below:

- i. ALARA principle for exposure of workers and the public and for discharges: article 4(3) of Decree-Law 165/2002 and articles 4(1)(d) and 21(2) of Decree-Law 156/2013;
- ii. Radiation dose limits: article 4(4) and (5) of Decree-Law 165/2002, articles 4 to 8 and 11 of Decree-Law 222/2008 and articles 21(2) and 29(5) of Decree-Law 156/2013;
- iii. Measures to prevent unplanned and uncontrolled releases of radioactive materials into the environment: these measures derive from the ensemble of safety, licensing, supervision and inspection provisions described through this report (see, e.g., article 4(1)(c) of Decree-Law 156/2013);
- iv. Measures to ensure that, in the event of an unplanned or uncontrolled release of radioactivity into the environment, appropriate corrective measures are implemented to control the release and mitigate its effects: see description of emergency preparedness provisions (*infra*, reporting under article 25); see also articles 22(a) and 28(2) of Decree-Law 156/2013.

### **Emergency and preparedness**

In addition to provisions specifically applicable to spent fuel and radioactive waste, included in Decree-Law 156/2013, the national general legal framework relating to radiological emergencies, also applicable to spent fuel and radioactive waste management and facilities, is to be found in Decree-Law 36/95 (establishing a system for information to the population relating to radiological emergencies) and in Decree-Law 174/2002 (establishing rules for preparation and response to radiological emergencies and distributing attributions between public authorities), which ensure the transposition of the relevant provisions of EU Directives. Furthermore, in what concerns transboundary events, the ANPC has been designated the national contact point for notification of international radiological emergencies occurred on Portuguese territory or under Portuguese jurisdiction and APA has been designated the contact point to receive notifications of radiological emergencies occurred abroad (articles 18 and 19 of Decree-Law 165/2002; article 6 of Decree-Law 174/2002).

These general rules assign competencies to different public bodies, depending on the specific characteristics of the radiological emergency in question. Thus, while the ANPC (or, in the autonomous regions of Madeira and Azores, the regional civil protection authorities) will always coordinate response, it relies heavily on advisement of three Technical Authorities for Intervention: (a) APA,

whenever the emergency places the population or the environment at risk; (b) IST, for emergencies occurring during transport or associated to sealed or orphan sources; (c) DGS, for emergencies within facilities. In any other cases, the Minister of Internal Affairs designates the coordinating authority.

Operators of spent fuel or waste management facilities must develop an internal emergency plan and, if the activity in question involves a risk of contamination outside the facility, an external emergency plan (see articles 25 and 26 of Decree-Law 156/2013). Internal plans must foresee all scenarios and necessary reactions and be approved by COMRSIN. Internal emergency plans developed for new facilities must be tested before the facility goes into operation, and such plans must be further tested every 3 years, at most, in simulations of different scenarios (including external contamination). Workers must be duly informed of the details of the internal emergency plan.

Any emergency associated to spent fuel or radioactive waste facilities or management activities must be immediately notified to COMRSIN, to the authority responsible for interventions (as described above) and to the civil protection authorities, and internal emergency plans must clearly allocate responsibilities for such notifications.

External emergency plans are prepared by the civil protection authorities, and operators are obliged to supply them with all relevant information (updating this information whenever necessary) and to cooperate in the development of these plans. COMRSIN also cooperates in the drafting of national radiological emergency plans (article 13(g) of Decree-Law 156/2013).

#### **Decommissioning**

The national legal framework ensures the safety of the decommissioning of a nuclear facility. Decree-Law 156/2013 (articles 6(3)(f) and (g), 22(b), 23(1), 27, 32(1)(k), 47(2)(a)), in what concerns spent fuel and radioactive waste management facilities, and Decree-Law 262/2012 (article 14), in what concerns new nuclear facilities, require that the future decommissioning be taken into account in the design and construction of facilities and that there be a plan for adequate financial resources as a precondition to licensing. Fines are foreseen for failure to provide for such resources. The evaluation of a facility's safety by COMRSIN shall include the provisions made for decommissioning and for the phase, that follows decommissioning.

The National Programme for spent fuel and radioactive waste management, includes further details on the concepts, plans and technical solutions for decommissioning of facilities and for the necessary supervision and control after decommissioning.

No facilities in Portugal are currently being decommissioned. No specific decommissioning strategy has yet been defined for the RPI or PRR. However, both decommissioning plans will require approval by COMRSIN.

### **C.6) Article 8: EXPERTISE AND SKILLS**

Under the existing legal framework (*maxime* articles 19 and 24 of Decree-Law 156/2013 and article 12(5) of Decree-Law 30/2012), any entity taking part in the management of spent fuel or radioactive waste must have at its disposal enough workers, with adequate qualifications and training to pursue the activities in question. Such entities must also develop an appropriate program of research and development that conforms with the objectives set out in the National Program, so as to ensure the continued existence of qualified human resources. A systematic and duly documented HR policy must be developed, having in mind these long term goals.

### C.7) Article 9: FINANCIAL RESOURCES

Operators must demonstrate that they have sufficient financial resources to ensure the safety of the activities and facilities for the management of spent fuel and radioactive waste. A plan for adequate financial resources must be presented as a precondition to licensing. Fines may be imposed for failure to provide for such resources (see, e.g., articles 19(3), 32(1)(k) and 47(2)(a) of Decree-Law 156/2013, and article 12(5) of Decree-Law 30/2012). These provisions apply to the entire lifespan of facilities and activities.

In what concerns human and financial resources available to COMRSIN, please see reporting under article 6 in section C.4.

# C.8) Article 10: TRANSPARENCY

In addition to other provisions already mentioned in this report, article 20 of Decree-Law 156/2013 requires operators to grant workers and the general public all relevant information regarding the management of spent fuel and radioactive waste, complying with international obligations. These transparency requirements are subject to exceptions in the name of national security and confidentiality required by other legal provisions.

Likewise the general public should be granted the possibility to participate, though public consultation, in the decision making process involving the management of SF and RW according to national legislation and international obligations, provided the safety and confidentiality of the information is safeguarded.

Reports presented by COMRSIN to international institutions are publicly available on its website.

### C.9) Article 11&12: NATIONAL PROGRAM

As determined by Decree-Law 156/2013, COMRSIN has prepared the first National Programme for the Implementation of Spent Fuel and Radioactive Waste Management Policy, made under the scope of Council Directive 2011/70/EURATOM.

A graded approach was followed when defining, developing and implementing solutions that take into consideration the amounts and types of spent fuel and radioactive waste in Portugal and the associated risks.

The first National Programme also implements practical solutions from waste generation to disposal endpoints, to avoid undue burdens on future generations.

The National Programme underwent Strategic Environmental Evaluation by an independent firm that consulted all relevant stakeholders, including the public. It was submitted to the Government in July 2016 and was approved by the Council of Ministers, Resolution 122/2017 of July 27th, after consultation between different ministries.

# D) ANNEXES

# **Annex I: INVENTORY OF RADIOACTIVE WASTE**

2009								
Sealed sources (no.)	Smoke detectors (no.)	Lightning rods (no.)	Medical and research waste (m³)	Tc-99m generators (no.)	Others* (no.)	Scrap metal (weight)	Depleted uranium (weight)	
78	11315	24	24.5	276	26	4000 kg	20 kg (12+8)	

Source: IST

2010							
Sealed sources (no.)	Smoke detectors (no.)	Lightning rods (no.)	Medical and research waste (m <sup>3</sup> )	Tc-99m generator s (no.)	Others * (no.)	Scrap metal (weight)	Depleted uranium (weight)
112	5004	27	19.75	529	57	2 big bags (c. 1t) + 1 drum 220 l	-

Source: IST

2011								
Sealed	Smoke	Lightning	Medical	Tc-99m	Others	Scrap	Depleted	
sources	detectors	rods	and	generator	* (no.)	metal	uranium	
(no.)	(no.)	(no.)	research	s (no.)		(weight)	(weight)	
			waste (m³)					
62	1721	6	20	365	19	827 kg	-	
						(cash		
						machine		
						s)		

Source: IST

2012

<sup>\*</sup> Old electronic valves and iodine seeds

Sealed sources (no.)	Smoke detectors (no.)	Lightning rods (no.)	Medical and research waste	Tc-99m generator s (no.)	Others	Scrap metal (weight)	Depleted uranium (weight)
69	10726	28	2.8 m <sup>3</sup> + 3052 kg	773	2 old electro nic valves + 1968 kg of iodine seeds packag es and NORM waste	8261	178.5

Source: IST

2013							
Sealed sources (no.)	Smoke detectors (no.)	Lightning rods (no.)	Medical and research waste (m³)	Tc-99m generator s (no.)	Others	Scrap metal (weight)	Depleted uranium (weight)
68	3657	16	4.8 m <sup>3</sup> + 1787 kg	128	104.5 kg of iodine seeds packag es	1292	149.3

Source: IST

From 2014 onwards, the information listed is recovered from COMRSIN's online platform.

2014

Iodine seeds (n)	Smoke detectors (n)	Other (n)	Tc-99m generators (n)	Sealed sources (n)	Lightning rods (n)	Uranium and thorium salts (n)
393	3136	130	76	74	10	3
	33.5 TBq					

Source: COMRSIN

2015

Iodine seeds (n)	Smoke detectors (n)	Other (n)	Tc-99m generators (n)	Sealed sources (n)	Lightning rods (n)	Uranium and thorium salts (n)
17469	1469	265	263	31	19	15
	0,0727 TBq					

Source: COMRSIN

2016

Iodine seeds (n)	Smoke detectors (n)	Other (n)	Tc-99m generators (n)	Sealed sources	Lightning rods (n)	Uranium and thorium salts (n)
5877	1525	193	27	70	17	18
Estimated total activity sent to disposal (all radionuclides)						0,0493 TBq

Source: COMRSIN

2017

Iodine seeds (n)	Smoke detectors (n)	Other (n)	Tc-99m generators (n)	Sealed sources	Lightning rods (n)	Uranium and thorium salts (n)
-	1575	148	-	67	17	15
Estimated total activity sent to disposal (all radionuclides)						16,29 TBq

Source: COMRSIN

2018 (as of August 23<sup>rd</sup>)

Iodine seeds (n)	Smoke detectors (n)	Other (n)	Tc-99m generators (n)	Sealed sources	Lightning rods (n)	Uranium and thorium salts (n)
-	571	2075 (includes 2000 items of laboratory- generated waste containing H-3, with an individual mass of 2 g each)	-	53	5	118
Estimated total activity sent to disposal (all radionuclides)						0.0256 TBq

Source: COMRSIN

# **Annex II: OVERVIEW MATRIX**

Overview matrix chart of Spent Fuel and Radioactive Waste Management (as presented for the purpose of the  $6^{th}$  Review Meeting of the Joint Convention).

Type of Liability	Long Term Management	Funding Liabilities	Current Practice	Planned Facilities
	Policy		/Facilities	
Spent Fuel	Return to supplier	State funds	Operating pool	None
Nuclear Fuel	N.A.	N.A.	N.A.	N.A.
Cycle Waste				
Application Waste	National disposal facility at PRR	State funds and fees collected from waste producers	On-site temporary storage Waste sorting and conditioning Waste minimization policy under the National Programme	None
Decommissioning Under discussion		State funds	Under discussion	Under discussion
Disused Sealed Sources	Return to supplier as disused source Classification as radioactive waste, followed by disposal at PRR facility	State funds	Return to supplier as disused source Classification as radioactive waste, followed by disposal at PRR facility	None