

# **Maltese Report on the Implementation of Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community Framework for the Responsible and Safe Management of Spent Fuel and Radioactive Waste**

## **Contents**

List of Acronyms and Abbreviations .....	3
A. Introduction .....	4
Commitment to safe management of radioactive waste and spent fuel .....	4
Legislation and regulatory body .....	4
Current and potential sources of radioactive waste .....	4
Disposal and Storage.....	5
Report Preparation .....	5
B. Recent Developments.....	5
C. Scope and Inventory (ARTICLE 2, ARTICLE 12.1 (C), ARTICLE 14.2 (B)).....	6
Article 2 .....	6
Waste Definitions.....	6
Description of waste .....	7
Article 12.1(c) &14.2(b).....	7
Current inventory.....	7
Future Prospects for increase in waste inventory .....	8
D. General Principles (Article 4) .....	8
Overview .....	8
Article 4.1 .....	9
Article 4.2 .....	9
Article 4.3 .....	9
Article 4.4 .....	10
E. National Framework (Article 5).....	10
Overview .....	10
Article 5.1a .....	12
Article 5.1b.....	12
Article 5.1c .....	12
Article 5.1d.....	12
Article 5.1e.....	13
Article 5.1f.....	13

Article 5.1g .....	13
Article 5.1h .....	13
F. Competent Regulatory Authority (Article 6) .....	14
Overview .....	14
Article 6.1 .....	15
Article 6.2 .....	15
Article 6.3 .....	16
G. Licence holders (Article 7) .....	16
Overview .....	16
Article 7.1 .....	16
Article 7.2 .....	17
Article 7.3 .....	17
Article 7.4 .....	17
Article 7.5 .....	17
H. Expertise and skills (Article 8) .....	18
I. Financial resources (Article 9) .....	18
J. Transparency (Article 10) .....	19
Article 10.1 .....	19
Article 10.2 .....	20
K Implementation of the National Programme (Articles 11 & 12) .....	20
Article 11.1 .....	20
Article 11.2 .....	20
Article 12 .....	20
Overall objectives of Radioactive Waste Management Programme (RWMP) .....	21
Key Performance Indicators of -RWMP .....	22
Policies and Strategies within the RWMP .....	26
Financing of radioactive waste management .....	26
Waste minimisation .....	26
Waste Conditioning .....	26
Central Storage Facility .....	27
Future Disposal .....	27
Gaining control over sources that are out of regulatory control .....	28
Emergency Plans .....	29
Orphan Source Recovery .....	29
Return of radioactive sealed sources .....	29
Shipment of Radioactive waste out of Malta .....	30

Imports of Waste .....	30
Discharges from nuclear medicine departments.....	30
Education and Training .....	30
Research.....	31
Public Participation .....	31
L. Peer Reviews and Self-Assessments (Article 14.3).....	31
M. Future to Improve Safe and Responsible Management of Spent Fuel and Radioactive Waste.....	32
Annex 1: Maltese Legislation .....	32

### **List of Acronyms and Abbreviations**

ALARA	As low as reasonably achievable
ARTEMIS	Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation
BSS	Basic Safety Standards
CPD	Civil Protection Department
EU	European Union
IAEA	International Atomic Energy Agency
IRRS	Integrated Regulatory Review Service
RPB	Radiation Protection Board
RPC	Commission for the Protection from Ionising and non ionising Radiation
RWMP	Radioactive Waste Management Programme
SL	Subsidiary Legislation

## **A. Introduction**

### **Commitment to safe management of radioactive waste and spent fuel**

Malta fully supports efforts for the safe management of radioactive waste and spent fuel within Member States, and the wider international community.

Malta is committed to ensure that all radioactive material currently in Malta is managed in a safe and secure manner and that the long-term goal is the ultimate disposal or re-use of this material.

Malta is further committed to managing radioactive waste in line with all relevant international legal instruments including the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (referred to hereinafter as “Joint Convention”) and the Council Directive 2011/70/EURATOM of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste (referred to hereinafter as the “Directive”).

### **Legislation and regulatory body**

The Directive was transposed into Maltese legislation by virtue of the Management of Radioactive Waste Regulations (SL 585.03) (referred to hereinafter as the “Waste Regulations”), under the Nuclear Safety and Radiation Protection Act (Cap 585) (referred to hereinafter as the “Act”). The Maltese policies and strategies for the management of radioactive waste are contained in the Radioactive Waste Management Programme (RWMP).

The regulatory body is called the Commission for the Protection from ionising and non ionising Radiation (RPC) was set up by virtue of the Act in 2018.

The RPC took over the regulatory responsibilities of the Radiation Protection Board (RPB) in 2018.

The Act, Waste Regulation, RPC and the RWMP form part of the National Framework for Radioactive Waste Management.

### **Current and potential sources of radioactive waste**

Malta does not have any nuclear power plants; research reactors; nuclear fuel-cycle activities or any facility producing radioactive material.

The use of radioactive material in Malta is limited to the following applications:

- Diagnostic and therapeutic nuclear medicine, including Positron Emission Tomography;
- Industrial gauging;
- Industrial non-destructive testing (with Ir-192);
- Very limited use in research and teaching.

Malta also has some sealed sources from past industrial applications as well as Am-241 lightning rods and Uranium and Thorium salts.

Malta has a limited number of disused sources in storage, mostly in a licenced central storage facility. The total unconditioned volume is approximately 1.5M<sup>3</sup>. This material is classed as intermediate, low level and very low-level waste using the IAEA GSG-1 classification.

## Disposal and Storage

Malta does not have any disposal facilities within the Maltese Islands.

Malta has set up a centralised storage facility where radioactive material is stored until a disposal route is identified.

## Report Preparation

This report was prepared by the RPC.

Article 15(2) of the Directive exempts Malta from obligations in respect of the transposition of those provisions in the Directive relating to spent fuel.

Article 14 sets out the reporting requirements to the Commission on the implementation of the Directive. This report is submitted in compliance with both the notification and reporting requirements of the Directive.

The structure of this report follows the ENSREG Guidelines for Member States reporting on Article 14.1 of Council Directive 2011/70/Euratom (January 2018).

## **B. Recent Developments**

Since the last Maltese Directive implementation report the major developments are:

- a) Revised radioactive waste management regulations issued in June 2019 along with National Framework.
- b) Centralised waste storage facility, operated by a private company, became operational once it was licenced by the RPC in November 2019.
- c) Malta had its follow-up IRRS Mission in March 2020.
- d) A new regulation to giving clearer legal personality for the RPC was issued in June 2021 entitled: Commission for The Protection from Ionising and Non-Ionising Radiation Regulations (SL 585.04).
- e) Planning and Preparation for ARTEMIS mission to be held in 2022 has commenced.
- f) Planning for international experts to come to Malta in 2023 to advise on disposal options is underway through a proposed national technical cooperation project with the IAEA.
- g) Recruitment of extra staff is underway, one new member of staff to join the RPC in October 2021.

## **C. Scope and Inventory (ARTICLE 2, ARTICLE 12.1 (C), ARTICLE 14.2 (B))**

### Article 2

#### **Article 2-Scope**

1. This Directive shall apply to all stages of:
  - (a) spent fuel management when the spent fuel results from civilian activities;
  - (b) radioactive waste management, from generation to disposal, when the radioactive waste results from civilian activities.
  
2. This Directive shall not apply to:
  - (a) waste from extractive industries which may be radioactive and which falls within the scope of Directive 2006/21/EC;
  - (b) authorised releases.
  
3. Article 4(4) of this Directive shall not apply to:
  - (a) repatriation of disused sealed sources to a supplier or manufacturer;
  - (b) shipment of spent fuel of research reactors to a country where research reactor fuels are supplied or manufactured, taking into account applicable international agreements;
  - (c) the waste and spent fuel of the existing Krško nuclear power plant, when it concerns shipments between Slovenia and Croatia.
  
4. This Directive shall not affect the right of a Member State or an undertaking in that Member State to return radioactive waste after processing to its country of origin where:
  - (a) the radioactive waste is to be shipped to that Member State or undertaking for processing; or
  - (b) other material is to be shipped to that Member State or undertaking with the purpose of recovering the radioactive waste.

This Directive shall not affect the right of a Member State or an undertaking in that Member State to which spent fuel is to be shipped for treatment or reprocessing to return to its country of origin radioactive waste recovered from the treatment or reprocessing operation, or an agreed equivalent.

#### **Waste Definitions**

The Waste Regulation defines radioactive waste as and radioactive waste management as follows:

*"radioactive waste" means radioactive material in gaseous, liquid or solid form for which no further use is foreseen or considered by the Commission.*

*"radioactive waste management" means all activities that relate to handling, pre-treatment, treatment, conditioning, storage, or disposal of radioactive waste, excluding off-site transportation;*

## Description of waste

The current waste inventory includes:

- Waste produced from past industrial and medical applications includes level/density gauging sources, non-destructive testing sources, calibration, and teaching sources.
- Am-241 lightning rods taking down from roofs. (In view that there are still some of these lightning rods in situ, the number that will need to be treated as waste will increase)
- Quantity of Uranium and thorium salts used for research/teaching

## Article 12.1(c) &14.2(b)

### **Article 12 – Contents of national programmes**

1. The national programmes shall set out how the Member States intend to implement their national policies referred to in Article 4 for the responsible and safe management of spent fuel and radioactive waste to secure the aims of this Directive, and shall include all of the following:

(...)

(c) an inventory of all spent fuel and radioactive waste and estimates for future quantities, including those from decommissioning, clearly indicating the location and amount of the radioactive waste and spent fuel in accordance with appropriate classification of the radioactive waste;

### **Article 14- Reporting**

2. On the basis of the Member States' reports, the Commission shall submit to the European Parliament and the Council the following:

(...)

(b) an inventory of radioactive waste and spent fuel present in the Community's territory and the future prospects.

## **Current inventory**

This material is classed as intermediate, low level and very low-level waste using the IAEA GSG-1 classification.

Total unconditioned volume of waste circa 1.5M<sup>3</sup>.

The origin of the bulk of the activity of the waste is past medical and industrial applications. Other waste includes Am-241 lightning rods and some uranium and thorium salts (reported under safeguards).

## Summary of the national inventory of radioactive waste

	Number of sources				Total Activity (GBq)
	>1.01 GBq	1 GBq -1MBq	<1MBq	Unknown Activity	
Cs-137	4	1	0	1	77.5
Am-241	1	62	7		21.4
Ra-226			3	1	0.001
Co-60			8		0.001
Pu-239			1		0.001
Uranium and thorium salts	2.4 kg				

### Future Prospects for increase in waste inventory

Apart from an increase in the number of lightning Am-241 lightning rods Malta does not anticipate a significant increase in the waste inventory.

There is a requirement that undertakings return any sealed long-lived sources, that they acquire, back to the overseas supplier.

## **D. General Principles (Article 4)**

### Overview

Malta's management of radioactive waste seeks to avoid the imposition of undue burdens on future generations and to ensure the protection of workers and the public.

One of Malta's policies was the setting up a of central storage facility, this became operational in November 2019 and will be used for storage prior to export or disposal.

Malta has a limited amount of material (circa 1.5M<sup>3</sup>, unconditioned volume) which may need to be treated as waste. This small amount of material poses challenges in setting up a cost-effective disposal solution within Malta. Because of the small volume, Malta will continue to seek the repatriation/recycling of sources currently in store.



## Article 4.1

*Member States shall establish and maintain national policies on spent fuel and radioactive waste management. Without prejudice to Article 2(3), each Member State shall have ultimate responsibility for management of the spent fuel and radioactive waste generated in it.*

Regulation 5(3) of the Waste Regulations requires that the RWMP includes policies and strategies for the management of radioactive waste. The policies reflect priorities, circumstances, structures, and available human and financial resources whilst the strategies will implement the policies.

The RWMP falls under the responsibility of the RPC.

## Article 4.2

*Where radioactive waste or spent fuel is shipped for processing or reprocessing to a Member State or a third country, the ultimate responsibility for the safe and responsible disposal of those materials, including any waste as a by-product, shall remain with the Member State or third country from which the radioactive material was shipped.*

Regulation 5(6) of the Waste Regulations provides that in the event that radioactive waste is sent overseas for processing, the ultimate responsibility for the safe and responsible disposal of those materials will remain in Malta or the other country from which the radioactive material was shipped.

## Article 4.3

*National policies shall be based on all of the following principles:*

- (a) the generation of radioactive waste shall be kept to the minimum which is reasonably practicable, both in terms of activity and volume, by means of appropriate design measures and of operating and decommissioning practices, including the recycling and reuse of materials;*
- (b) the interdependencies between all steps in spent fuel and radioactive waste generation and management shall be taken into account;*
- (c) spent fuel and radioactive waste shall be safely managed, including in the long term with passive safety features;*
- (d) implementation of measures shall follow a graded approach;*
- (e) the costs for the management of spent fuel and radioactive waste shall be borne by those who generated those materials;*
- (f) an evidence-based and documented decision-making process shall be applied with regard to all stages of the management of spent fuel and radioactive waste.*

Regulation 6(1-6) of the Waste Regulations, incorporates these principles.

## Article 4.4

*Radioactive waste shall be disposed of in the Member State in which it was generated, unless at the time of shipment an agreement, taking into account the criteria established by the Commission in accordance with Article 16(2) of Directive 2006/117/Euratom, has entered into force between the Member State concerned and another Member State or a third country to use a disposal facility in one of them.*

*Prior to a shipment to a third country, the exporting Member State shall inform the Commission of the content of any such agreement and take reasonable measures to be assured that:*

*(a) the country of destination has concluded an agreement with the Community covering spent fuel and radioactive waste management or is a party to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management ('the Joint Convention');*

*(b) the country of destination has radioactive waste management and disposal programmes with objectives representing a high level of safety equivalent to those established by this Directive; and*

*(c) the disposal facility in the country of destination is authorised for the radioactive waste to be shipped, is operating prior to the shipment, and is managed in accordance with the requirements set down in the radioactive waste management and disposal programme of that country of destination*

Regulation 6(7) of the Waste Regulations requires that any radioactive waste shall be disposed of in the Member State in which it was generated, unless at the time of shipment an agreement, taking into account the Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations, (SL 549.51), has entered into force between Malta and another country to use a disposal facility in one of them.

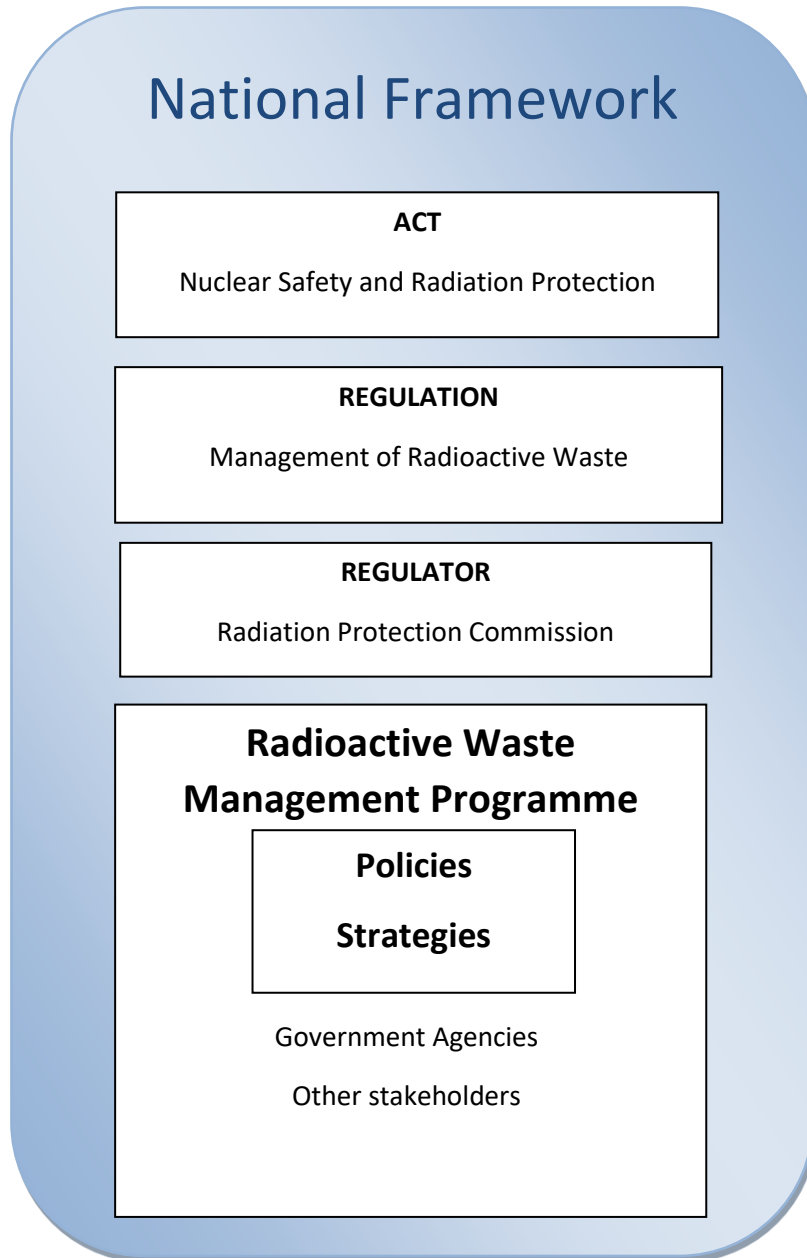
Regulation 15 of the Waste Regulations requires that the RPC informs the European Commission of any waste shipments overseas.

## **E. National Framework (Article 5)**

### Overview

The Waste Regulations take into account Malta's obligations to the Joint Convention and the Directive. As required by the Waste Regulations, policies and strategies have been developed and are contained within the National Framework for Radioactive Waste Management.

The National Framework is shown in the below diagram:



Regulatory control of radioactive material currently in store falls under the regulatory supervision of the RPC by virtue of the Basic Safety Standards for Ionising Radiation Regulations, 2018, SL 585.01 (Hereinafter referred to as BSS Regulations) and the Waste Regulations. The RPC is empowered to licence, inspect, and take enforcement actions at any site that is currently storing radioactive material.

### Article 5.1a

*Member States shall establish ....(a) a national programme for the implementation of spent fuel and radioactive waste management policy*

Regulation 5 of the Waste Regulations establishes the requirement for RWMP.

Following consultation, the RWMP programme was drawn up by the RPC and included policies and strategies.

The policies reflect priorities, circumstances, structures, and available human and financial resources whilst the strategies implement the policies.

### Article 5.1b

*Member States shall establish ...(b) national arrangements for the safety of spent fuel and radioactive waste management. The determination of how those arrangements are to be adopted and through which instrument they are to be applied rests within the competence of the Member States;*

The national arrangements fall under the RPC in view that it is responsible for the Waste Regulations and the RWMP.

### Article 5.1c

*Member States shall establish ...(c) a system of licensing of spent fuel and radioactive waste management activities, facilities or both, including the prohibition of spent fuel or radioactive waste management activities, of the operation of a spent fuel or radioactive waste management facility without a licence or both and, if appropriate, prescribing conditions for further management of the activity, facility or both;*

Regulation 11(1) of the Waste Regulations requires that the RPC ensures that all stages of the waste management programme are subject both to a licence in terms of the Act and applicable regulations made under the Act (most notably BSS Regulations).

### Article 5.1d

*Member States shall establish ...(d) a system of appropriate control, a management system, regulatory inspections, documentation and reporting obligations for radioactive waste and spent fuel management activities, facilities or both, including appropriate measures for the post-closure periods of disposal facilities;*

Regulation 12(e) of the Waste Regulations requires that the RPC provides for a system of appropriate licencing of radioactive waste management activities, including appropriate measures for the post-closure periods of disposal facilities.

## Article 5.1e

*Member States shall establish ... (e) enforcement actions, including the suspension of activities and the modification, expiration or revocation of a licence together with requirements, if appropriate, for alternative solutions that lead to improved safety;*

Regulation 12(f) of the Waste Regulations requires that the RPC performs the necessary enforcement actions.

## Article 5.1f

*Member States shall establish ... (f) the allocation of responsibility to the bodies involved in the different steps of spent fuel and radioactive waste management; in particular, the national framework shall give primary responsibility for the spent fuel and radioactive waste to their generators or, under specific circumstances, to a licence holder to whom this responsibility has been entrusted by competent bodies;*

Regulation 12(b) of the Waste Regulations requires the RPC to advise the Minister on the assignment of responsibilities to various stakeholders.

Regulation 14(1) of the Waste Regulations assigns the prime responsibility for the safety of radioactive waste management facilities and/or activities to the licence holder.

## Article 5.1g

*Member States shall establish ... (g) national requirements for public information and participation;*

Regulation 6(9) of the waste Regulations requires that the policies include the public and workers' involvement in the decision-making process.

## Article 5.1h

*Member States shall establish ... (h) the financing scheme(s) for spent fuel and radioactive waste management in accordance with Article 9.*

Regulation 7 of the Waste Regulations requires that the RPC provides the Minister with estimates of the costing of the radioactive waste management programme. The estimates shall include an assessment of the national programme costs and the underlying basis and hypotheses for that assessment, which must include a profile over time.

The RPC has provided the Minister with the initial estimated costs for:

- Export of waste
- Annual cost for storage of waste within central facility
- Geological disposal using bore-hole technology.

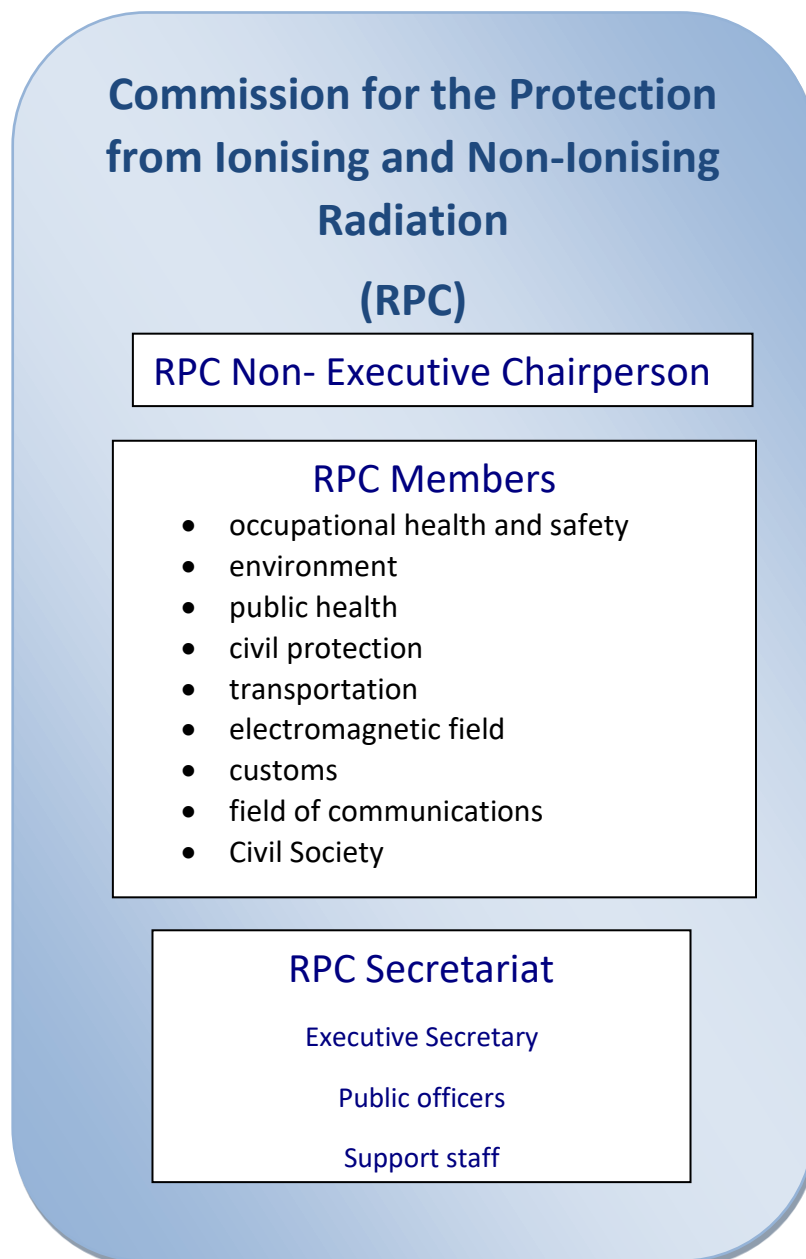
The RPC is due to provide the Minister with disposal options and costings at the end of 2023 following the advice received from experts contracted through a proposed IAEA national technical cooperation project.

## **F. Competent Regulatory Authority (Article 6)**

### Overview

Malta's regulatory authority is the RPC. The RPC was set up as the national competent body for radiation protection and nuclear issues by the Act.

The internal structure of the RPC is shown diagrammatically below:



The RPC was set up in 2018 and has two full-time staff members assigned to it in its Secretariat which co-ordinates the regulatory responsibilities.

The RPC falls under the Ministry of Tourism and Consumer Protection.

The Functions of the RPC are the following:

- (a) Develop policies and strategies to be followed by the Secretariat, relating to the protection against ionising and non-ionising radiation;*
- (b) Develop regulations relating to the protection against ionising and non-ionising radiation;*
- (c) Act as a body of general review of the Secretariat;*
- (d) Provide advice to the Secretariat when required as to the interpretation of the relevant provision in this Act;*
- (e) Be the national body which gives effect to any decision of the UN Security Council or International Atomic Energy Agency, European Commission or internationally recognised entity or competent authority in the field of nuclear safety and radiation protection;*
- (f) Implement the regulatory requirements of Conventions and other European Union legislation within the scope of this Act;*
- (g) Prescribe the fees to be paid in respect of the issue, validation, renewal, extension or variation of any certificate, licence or other document or the undergoing of any examination or test required by this Act or any regulations, directive or order made thereunder and in respect of any other matters in respect of which it appears to the Commission to be expedient for the purpose of the Act, regulations, directive or order to charge fees.*

## Article 6.1

*Each Member State shall establish and maintain a competent regulatory authority in the field of safety of spent fuel and radioactive waste management.*

The RPC was set up by virtue of Article 10 of the Act to act as the regulatory authority in the field of nuclear safety and radiation protection.

Regulation 12 of the Waste Regulations gives the RPC an overall responsibility for the implementation of these regulations. Regulation 12(3)(f) of the Waste Regulations gives the power to the RPC to enforce the provisions of the regulations.

## Article 6.2

*Member States shall ensure that the competent regulatory authority is functionally separate from any other body or organisation concerned with the promotion or utilisation of nuclear energy or radioactive material, including electricity production and radioisotope applications, or with the management of spent fuel and radioactive waste, in order to ensure effective independence from undue influence on its regulatory function.*

The RPC is functionally separate from any body/entity concerned with the use of radioactive material.

The RPC falls under the portfolio of a ministry which is assigned by virtue of the following definition in the Act:

*"Minister" means the Minister responsible for matters related to and incidental to this Act and such Minister shall not have under his responsibility any form of ionising or non-ionising radiation facility or source;*

To ensure independence of the members of the RPC, Article 10(5) of the Act states:  
“...no members shall be responsible for the use of any form of ionising or non-ionising radiation.”

The separated legal personality of the RPC was strengthened by the publication of Commission for The Protection from Ionising and Non-Ionising Radiation Regulations (SL 585.04) in 2021.

### **Article 6.3**

*Member States shall ensure that the competent regulatory authority is given the legal powers and human and financial resources necessary to fulfil its obligations in connection with the national framework as described in Article 5(1) (b), (c), (d) and (e).*

Article 61 of the Act makes provision for the RPC to be provided with adequate financial and human resources.

## **G. Licence holders (Article 7)**

### **Overview**

Malta has a centralised storage facility and this facility that was first issued a by the RPC in November 2019.

### **Article 7.1**

*Member States shall ensure that the prime responsibility for the safety of spent fuel and radioactive waste management facilities and/or activities rest with the licence holder. That responsibility cannot be delegated.*

Regulation 14(1) of the Waste Regulations hold the licence holder primarily responsible for the safety of radioactive waste management facilities and/or activities.



## Article 7.2

*Member States shall ensure that the national framework in place require licence holders, under the regulatory control of the competent regulatory authority, to regularly assess, verify and continuously improve, as far as is reasonably achievable, the safety of the radioactive waste and spent fuel management facility or activity in a systematic and verifiable manner. This shall be achieved through an appropriate safety assessment, other arguments and evidence.*

Regulation 14(2) of the Waste Regulations requires this to be done by the licence holders.

## Article 7.3

*As part of the licensing of a facility or activity the safety demonstration shall cover the development and operation of an activity and the development, operation and decommissioning of a facility or closure of a disposal facility as well as the post- closure phase of a disposal facility. The extent of the safety demonstration shall be commensurate with the complexity of the operation and the magnitude of the hazards associated with the radioactive waste and spent fuel, and the facility or activity. The licensing process shall contribute to safety in the facility or activity during normal operating conditions, anticipated operational occurrences and design basis accidents It shall provide the required assurance of safety in the facility or activity. Measures shall be in place to prevent accidents and mitigate the consequences of accidents, including verification of physical barriers and the licence holder's administrative protection procedures that would have to fail before workers and the general public would be significantly affected by ionising radiation. That approach shall identify and reduce uncertainties.*

The responsibility for this falls under the RPC in its role of enforcing Regulation 14(3) of the Waste Regulations.

## Article 7.4

*Member States shall ensure that the national framework require licence holders to establish and implement integrated management systems, including quality assurance, which give due priority to safety and are regularly verified by the competent regulatory authority.*

The responsibility for this falls under the RPC in its role of enforcing Regulation 14(4) of the Waste Regulations.

## Article 7.5

*Member States shall ensure that the national framework require licence holders to provide for and maintain adequate financial and human resources to fulfil their obligations with respect to the safety of spent fuel and radioactive waste management as laid down in paragraphs 1 to 4.*

The responsibility for this falls upon the license holder by virtue of Regulation 14(5) of the Waste Regulations.

## H. Expertise and skills (Article 8)

*Member States shall ensure that the national framework require all parties to make arrangements for education and training for their staff, as well as research and development activities to cover the needs of the national programme for spent fuel and radioactive waste management in order to obtain, maintain and to further develop necessary expertise and skills.*

Article 25 of the Act and Regulation 14 of the BSS regulations require licence holders to ensure that only workers who have undergone adequate radiation protection training, shall carry out work with radiation sources or in radiation environments.

Regulation 13(1) of the Waste Regulations requires that members of its Secretariat have sufficient understanding of the safety and security aspects related to the management of radioactive waste. In particular, the Commission shall ensure that members of the Secretariat have participated in ongoing training.

Regulation 13(2) of the Waste Regulations require that during the licensing process, the RPC shall require that arrangements for education and training have been undertaken by potential license holders.

## I. Financial resources (Article 9)

*Member States shall ensure that the national framework require that adequate financial resources be available when needed for the implementation of national programmes referred to in Article 11, especially for the management of spent fuel and radioactive waste, taking due account of the responsibility of spent fuel and radioactive waste generators.*

	Option	Notes	Cost breakdown	Total 10-year cost
1	Storage and conditioning by private sector company, followed by export	<ol style="list-style-type: none"> <li>There is competency in the private sector to store and condition material.</li> <li>20-foot ISO storage container and waste handling/shielded provided to operator.</li> <li>As storage is not the final solution, waste will still need to be exported at a later date.</li> <li>Currently there is no known overseas entity which will be willing to accept all radioactive material. Export options may be available for Am-241 lightning rod sources and other Am-241 sources</li> </ol>	<p>€35000 annually. (This includes waste preparation and site rent)</p> <p><u>Export Estimate for Am-241</u></p> <p>€82800 (€69,000 +20%) additional 20% is an assumed margin private operator would take)</p> <p>If not, all waste is exportable, then the annual cost keeps recurring.</p>	<p>First year €35,000</p> <p>Subsequent years until export €35,000</p> <p>Export €82,800</p> <p>Total 10-year Cost include export in 10 year</p> <p style="border: 1px solid black; display: inline-block; padding: 2px;">€432,800</p>
2	Bore Hole disposal	<ol style="list-style-type: none"> <li>High cost, considering limited inventory of waste.</li> </ol>	<p><u>Waste preparation by contractor @ €80/hour</u></p> <p>4 wks. = 160hrs</p>	<p>Waste deposited in bore hole after 10 years</p>

(IAEA methodology)	<ol style="list-style-type: none"> <li>2. Environmental assessments and site location would require extensive work.</li> <li>3. Would provide for final solution within Malta.</li> <li>4. Final Solution</li> </ol>	<p>€12,800</p> <p>10 Subsequent years 12x4hrs=48hrs Cost= €3840/year</p> <p>10-year cost €38,400</p> <p>Bore hole disposal estimate 1 million dollars (€850,000) <a href="https://www.iaea.org/OurWork/ST/NE/NEFW/Technical-Areas/WTS/BOSS-main.html">https://www.iaea.org/OurWork/ST/NE/NEFW/Technical-Areas/WTS/BOSS-main.html</a></p>	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> <p>€901,200</p> </div>
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Regulation 7 of the Waste Regulations require that the RPC to provide the Minister with estimates of the costing of the radioactive waste management programme.

The costs for achieving the other KPIs will be met from the operational budget of the RPC.

Regulation 8(1) of the Waste Regulations requires that licence holders to be responsible for their radioactive waste. Through the polluter pays principle, licence holders are responsible for all financing of the management of their waste.

Regulation 14(5) of the Waste Regulations requires that license holders provide for and maintain adequate financial and human resources to fulfil their obligations with respect to the safety of radioactive waste management.

Funding of the RPC is guaranteed by Article 61 of the Act from the national budget.

## **J. Transparency (Article 10)**

### **Article 10.1**

*Member States shall ensure that necessary information on the management of spent fuel and radioactive waste be made available to workers and the general public. This obligation includes ensuring that the competent regulatory authority inform the public in the fields of its competence. Information shall be made available to the public in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.*

Regulation 6(9) of the Waste Regulations requires that there is a policy that ensures the public and workers' involvement in decision-making process.

## Article 10.2

*Member States shall ensure that the public be given the necessary opportunities to participate effectively in the decision-making process regarding spent fuel and radioactive waste management in accordance with national legislation and international obligations.*

Regulation 6(9) of the Waste Regulations requires that there is a policy that ensures that the public be given the necessary opportunities to participate effectively in the decision-making process regarding radioactive waste management.

Any new regulations governing radioactive waste management as well as the RWMP will go out for consultation.

## **K Implementation of the National Programme (Articles 11 & 12)**

### Article 11.1

*Each Member State shall ensure the implementation of its national programme for the management of spent fuel and radioactive waste ('national programme'), covering all types of spent fuel and radioactive waste under its jurisdiction and all stages of spent fuel and radioactive waste management from generation to disposal.*

As required by the Waste Regulations, the RWMP consists of policies and strategies.

Regulation 2(3) of the Waste Regulations provides for all stages of the life cycle of radioactive material from its import to ultimate export or disposal.

### Article 11.2

*Each Member State shall regularly review and update its national programme, taking into account technical and scientific progress as appropriate as well as recommendations, lessons learned and good practices from peer reviews*

The RPC is responsible for the review of the RWMP by virtue of Regulation 12(h) of said Regulations.

## Article 12

### *Article 12.1*

*The national programmes shall set out how the Member States intend to implement their national policies referred to in Article 4 for the responsible and safe management of spent fuel and radioactive waste to secure the aims of this Directive, and shall include all of the following:*

- (a) the overall objectives of the Member State's national policy in respect of spent fuel and radioactive waste management;*
- (b) the significant milestones and clear timeframes for the achievement of those milestones in light of the overarching objectives of the national programme;*
- (c) an inventory of all spent fuel and radioactive waste and estimates for future quantities, including those from decommissioning, clearly indicating the location and amount of the radioactive waste and spent fuel in accordance with appropriate classification of the radioactive waste;*
- (d) the concepts or plans and technical solutions for spent fuel and radioactive waste management from generation to disposal;*
- (e) the concepts or plans for the post-closure period of a disposal facility's lifetime, including the period during which appropriate controls are retained and the means to be employed to preserve knowledge of that facility in the longer term;*
- (f) the research, development and demonstration activities that are needed in order to implement solutions for the management of spent fuel and radioactive waste;*
- (g) the responsibility for the implementation of the national programme and the key performance indicators to monitor progress towards implementation;*
- (h) an assessment of the national programme costs and the underlying basis and hypotheses for that assessment, which must include a profile over time;*
- (i) the financing scheme(s) in force;*
- (j) a transparency policy or process as referred to in Article 10;*
- (k) if any, the agreement(s) concluded with a Member State or a third country on management of spent fuel or radioactive waste, including on the use of disposal facilities.*

*Article 12.2*

*The national programme together with the national policy may be contained in a single document or in a number of documents.*

## Overall objectives of Radioactive Waste Management Programme (RWMP)

The overall objectives of the RWMP are to:

- Gather together all existing radioactive material is suitably conditioned and stored in one location managed by an entity licensed by the RPC;
- Development of adequate financing schemes to allow for management of radioactive waste;
- Take steps to ensure no new material enters the radioactive waste stream;
- Have plans in place to locate existing radioactive material that is not under regulatory control;
- Have plans to respond to discovery of radioactive material;
- Seek to get material returned overseas back to the supplier or sent for recycling;
- Dispose of any remaining material in Malta or exported if feasible.
- To enhance public confidence in relation to the radioactive waste management through public consultation;

- To decay storage of short lived radionuclides;
- To ensure workers are adequately trained;
- To participate in international research activities as appropriate.

### Key Performance Indicators of -RWMP

<b>Policy</b>	<b>Action</b>	<b>KPI</b>	<b>Status</b>
Financing of radioactive waste management	Funding for RPC	Sufficient funds being allocated on annual basis	Funds allocated annually for to the RPC
	Funding for central storage facility	Central government funding storage facility	Funds provided annually from central government to the entity running the facility
	Funding for disposal	Funding estimate for disposal to be prepared	The Government to be presented with disposal options and costings at the end of 2023
Waste minimisation	RPC to only allow justified use of radioactive material to minimise the number of sources that could potentially enter the waste stream	RPC follows the authorisation procedures that require all use of radioactive material is justified	RPC maintains national inventory of all radioactive material
	To maintain over-sight of the waste in the central storage facility	RPC has up-to-date records of waste in store	Under the conditions of the licence for the central waste store the RPC is to be notified each time a waste consignment is received by licence holder.
			RPC maintain an up-to-date inventory of radioactive waste

Waste Conditioning	Volume reduction	RPC to issue licence conditions in connection with the conditioning. Any Conditioning is to allow for future disposal options produce a waste package acceptable for handling, storage, transport, disposal.	Licensed operator of the waste storage facility is required, under the conditions of the license, to maintain a site inventory and the RPC is to be notified each time a waste consignment is received	
		Supervision of Volume reduction	Majority of sources underwent volume reduction in December 2019. Remaining sources to undergo volume reduction by end 2021	
	Provision of training	Training provided	Training from the IAEA in volume reduction of Maltese sources received in December 2019.	
			Training planned through IAEA national technical cooperation project in 2023	
	Central Storage Facility	Setting up of central storage facility	Site for storage facility to be identified by mid-2019	Site and company to run the facility identified in 2019
			Acquisition of specialist equipment for waste management along with 20-foot ISO container by January 2019	Equipment delivered
Specialist advice on setting up storage facility end 2019			Advice received through IAEA national technical cooperation project	
Central store to be licenced by end 2019			Licenced in 2019 by RPC	
Transfer of sources to central storage facility		Transfer sources to centralised store by end 2020	Most sources transferred by mid-2021	

Future Disposal	Government to decide on disposal method	RPC presents the Government with disposal options by end of 2023 based on expert advice received	RPC has proposal for national technical cooperation project with the IAEA for expert advice to be provided in 2023
Gaining control over sources that are out of regulatory control	Review of relevant Standard operating procedures	Emergency plan and Customs SOP to be reviewed	Plans reviewed
	Campaign to regain control of sources	Campaign for Am-241 lightning rods still in situ	Identification of radioactive lightning rods in situ ongoing by RPC, campaign by end 2022.
Emergency Plans	Review of emergency plans	All sites holding waste to have had their on-site emergency plans reviewed by RPC	Licensee of the national radioactive store emergency plan reviewed in November 2019 when licensee applied for license
		Emergency plan reviewed	National radiological emergency documents reviewed by RPC in 2020
	Testing of plan through exercise	National emergency plan exercise	Exercise planned in 2021
Orphan Source Recovery	Review of emergency plans	All sites holding waste to have had their on-site emergency plans reviewed by RPC	To be performed when sites are inspected
	Testing of plan through exercise	Emergency plan exercise	Exercise planned in 2021
Return of radioactive sealed sources	Preventing new sources from entering the waste stream	All new sealed sources have agreement for their export at the end of their use in Malta.	RPC will not authorise the importation of any new sealed source unless there is an agreement for their export at the end of their use.
	Exploring possibilities for the export of existing sources	Export repatriation/recycling of sources currently in store	RPC will investigate the possibilities of export of radioactive material that is no longer in use



Shipment of Radioactive waste out of Malta	Explore possibilities for the export of existing sources	Export possibilities for radioactive waste sources have been explored.	RPC will investigate the possibilities of export of radioactive material that is no longer in use
Imports of Waste	Prevention of the importation of waste	No waste imported	RPC will not authorise the importation of any radioactive waste
Discharges from nuclear medicine departments	Review of discharges from individual nuclear medicine departments	Each nuclear medicine department to have produced annual discharge figures	Both nuclear medicine organisations are required by their license conditions to send annual discharge figures to the RPC by the end of each January of the following year.
	National discharge figures for discharges from nuclear medicine departments to be collated	RPC to produce annual discharge figures from nuclear medicine departments in Malta	RPC to collate annual figures for Malta each year.
Education and Training	Having adequately trained staff involved in waste management	Training staff involved in handling, storage, and disposal and to maintain on-going training	RPC and personnel from company who manage centralised waste storage facility received training from the IAEA in volume reduction of Maltese sources received in December 2019.
			Proposal for RPC staff training through IAEA national technical cooperation project in 2023.
	Over-sight of undertakings training	RPC to have reviewed training for organisations using radioactive material	RPC reviews training through the authorisation and inspection processes.
Research	To participate in research relevant to Malta	RPC to keep abreast of any EU/IAEA activities in this area and to get support for such activities	RPC to participate in relevant IAEA/EU meetings as and when they are held.

## Policies and Strategies within the RWMP

### **Financing of radioactive waste management**

Policy	<ol style="list-style-type: none"><li>1. To ensure that sufficient funds are available for the management of radioactive waste.</li><li>2. The owner of the waste will be responsible for the financing of its management.</li><li>3. An assessment of the national programme costs and the underlying basis and hypotheses for that assessment, which must include a profile over time.</li></ol>
Strategy	<ol style="list-style-type: none"><li>1. RPC to produce various budget estimates for different storage and disposal scenarios. The budget estimates are to include various costs for the whole programme over time.</li><li>2. The government shall decide on how the programme shall be financed over time. No funding for radioactive waste management is to come from budget allocated to the RPC.</li></ol>

### **Waste minimisation**

Policy	<ol style="list-style-type: none"><li>1. To have the minimum number of sources that need to be treated as radioactive waste.</li><li>2. To ensure that the physical volume of waste is kept small as is safely achievable.</li></ol>
Strategy	<ol style="list-style-type: none"><li>1. RPC only to give clearance for import of radioactive material for justified uses.</li><li>2. The replacement of radioactive sources by non-radioactive alternatives if available.</li><li>3. Return of disused sealed sources to the overseas supplier.</li></ol>

### **Waste Conditioning**

Policy	<ol style="list-style-type: none"><li>1. Any Conditioning is to allow for future disposal options produce a waste package acceptable for handling, storage, transport, disposal.</li></ol>
Strategy	<ol style="list-style-type: none"><li>1. Conditioning to be done in accordance with waste acceptance criteria of future storage or waste facility.</li><li>2. Until storage/disposal facilities are available the RPC is to give advice to users who currently hold sources. The RPC strategy will be:<ul style="list-style-type: none"><li>• Waste is not to be embedded in any permanent matrix such as lead or concrete.</li><li>• Waste to be shielded using the ALARA principle.</li><li>• Full documentation to be created for each waste package.</li></ul></li></ol>

	3. Any organisation running a central storage facility is to get RPC approval before performing any conditioning.
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### Central Storage Facility

Policy	<ol style="list-style-type: none"> <li>1. Until such time a disposal option is available, a central storage facility is to be set up.</li> <li>2. Long-lived Sources will be stored in one central storage facility.</li> <li>3. Central store will have a planned operating life of at least fifty years.</li> </ol>
Strategy	<ol style="list-style-type: none"> <li>1. RPC to obtain equipment for storage facility to include: <ol style="list-style-type: none"> <li>a) 20 foot ISO storage container</li> <li>b) Type A storage container and capsules designed for transport and storage</li> <li>c) Lead shielding bricks</li> </ol> </li> <li>2. RPC to present to the Government options for the setting up of storage room with costings and options to include: <ol style="list-style-type: none"> <li>a) General governmental waste agency to take responsibility for the management of the store consisting of 20 foot ISO container and sub-contract TSO for radiation protection aspects including conditioning of waste</li> <li>b) Private organisation takes on the responsibility for the management of the store at his own facility.</li> <li>c) Private organisation takes on the responsibility for the management of the store at the government site.</li> </ol> </li> <li>3. Government identifies private/government entity to be set up and run storage facility.</li> <li>4. Government to set any fees to be charged for the use of the store.</li> <li>5. Facility and any TSOs to be licenced by RPC and will fall under all appropriate Maltese regulations including, but not limited to the Waste Regulations and the BSS Regulations.</li> <li>6. Once a central facility is operational, users are to transfer disused sources there to.</li> <li>7. RPC will not authorise the storage of disused sources on site once central facility is operational.</li> <li>8. The organisation running the central storage facility is to take ownership for all disused/spent radioactive sources within its facilities.</li> </ol>

### Future Disposal

Policy	<ol style="list-style-type: none"> <li>1. Indefinite storage is not an option, the goal is to seek a viable disposal option for radioactive waste.</li> <li>2. Disposal is seen as the final solution for the management of long lived (&gt; 30 years) radioactive waste.</li> </ol>
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	<ol style="list-style-type: none"> <li>3. Prior to a viable disposal option being found, long lived waste is to be stored in a central location.</li> <li>4. Any Maltese disposal option must consider the environmental aspects. A complete environmental risk assessment must be performed.</li> <li>5. In view of the fact that no disposal option has been identified, at the moment a disposal option will be sought before thirty years have elapsed (2044).</li> <li>6. In the event that a disposal facility is set up in Malta, the concepts or plans for the post-closure period of a disposal facility's lifetime, including the period during which appropriate controls are retained and the means to be employed to preserve knowledge of that facility in the longer term are to be considered.</li> </ol>
Strategy	<ol style="list-style-type: none"> <li>1. A viable disposal option will be sought before thirty years have elapsed. The permanent solution (i.e. disposal) will take into account the current inventory and sources recovered due to detection at the ports and sources recovered due to campaigns.</li> <li>2. It is likely that the following options could be considered: <ul style="list-style-type: none"> <li>• Export of material</li> <li>• Bore Hole Disposal option</li> <li>• Any other multi-lateral solution as may become available.</li> </ul> </li> <li>3. The disposal option will need to take into account the nature of the waste, namely: <ul style="list-style-type: none"> <li>• Total number of existing sources and possible future acquisitions to waste inventory</li> <li>• Radionuclides</li> <li>• Activities</li> <li>• Physical state of the source, including any possible degradation in the sources.</li> <li>• Site characterisation</li> </ul> </li> </ol>

### **Gaining control over sources that are out of regulatory control**

Policy	<ol style="list-style-type: none"> <li>1. To bring into regulatory control any sources that are discovered.</li> <li>2. To develop a source recovery plan.</li> <li>3. To aim to detect radioactive material in trans-shipment through Malta.</li> <li>4. Any material discovered in trans-shipment to be returned to the country of origin.</li> </ol>
Strategy	<ol style="list-style-type: none"> <li>1. Upon the discovery of a source within Malta, the RPC or CPD are to be informed. If required, a radiological emergency plan is to be initiated.</li> <li>2. Customs to monitor imports at major ports of entry, including all goods entering Malta through the Malta Freeport by Customs Department.</li> <li>3. Customs to monitor a high proportion of goods in trans-shipment through the Malta Freeport.</li> </ol>

	<ol style="list-style-type: none"> <li>4. Radioactive material discovered in trans-shipment to be returned to the country of origin.</li> <li>5. RPC to decide on targeted areas may be subject to search within Malta.</li> <li>6. Once a central storage facility is made available, campaigns for the collection of sources, including schools and laboratories lightning rods will be undertaken.</li> <li>7. Initiatives targetted at metal recycling facilities in Malta.</li> </ol>
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### **Emergency Plans**

Policy	<ol style="list-style-type: none"> <li>1. Radiation employers shall have their own appropriate plans to deal with the safety and security of any material in use or in storage.</li> <li>2. RPC/CPD to have the ability to respond as required.</li> </ol>
Strategy	<ol style="list-style-type: none"> <li>1. RPC to ensure that radiation employers have emergency plans in place through the authorisation and inspection process.</li> <li>2. RPC/CPD to initiate the National Radiological Emergency Plan when required.</li> <li>3. RPC to keep the radiological emergency plan and the threat assessment updated.</li> </ol>

### **Orphan Source Recovery**

Policy	<ol style="list-style-type: none"> <li>1. Recovery performed by trained personnel in a controlled manner paying due consideration to the radiation safety issues of workers and the public.</li> </ol>
Strategy	<ol style="list-style-type: none"> <li>1. Recovery to be performed in line with the National Radiological Emergency Plan which assigns CPD as the lead technical agency.</li> <li>2. Upon the discovery of a source, the recovery is to be co-ordinated by the CPD as the lead technical agency.</li> <li>3. The Office of the Executive Chairperson within the RPC is to give CPD advice on recovery operations.</li> <li>4. Immediate action for Category 1, 2 and 3 sources.</li> <li>5. National radiological emergency to be initiated by either RPC or CPD.</li> </ol>

### **Return of radioactive sealed sources**

Policy	<ol style="list-style-type: none"> <li>1. Attempts to be made to send any existing disused sources overseas for reuse/recycling.</li> <li>2. New sealed sources to be returned to supplier once these become disused .</li> <li>3. Any transport operation to be fully compliant with applicable transport regulations.</li> </ol>
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Strategy	1. RPC will not authorise the import of new sources unless a declaration is provided by the user for the export of the source.
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### Shipment of Radioactive waste out of Malta

Policy	<ol style="list-style-type: none"> <li>1. Export of radioactive waste will be encouraged.</li> <li>2. Any export of radioactive waste to be done in conformity with the Supervision and Control of Shipments of Radioactive Waste and Spent Fuel Regulations,(SL 549.51).</li> </ol>
Strategy	<ol style="list-style-type: none"> <li>1. Until such time as a disposal option becomes available in Malta, RPC will encourage Radiation Employers to explore the possibility of exporting radioactive waste.</li> <li>2. RPC to ensure that radiation employers are aware of SL 549.51. The Environmental Protection Agency (EPA) to process any applications made in connection with SL 549.51.</li> </ol>

### Imports of Waste

Policy	1. Malta will not accept radioactive waste to be imported into Malta for any purpose.
Strategy	1. RPC will not give clearance for import.

### Discharges from nuclear medicine departments

Policy	1. Unsealed nuclear medicine emissions to the environment will be kept as low as reasonably achievable taking into account economic and social factors.
Strategy	<ol style="list-style-type: none"> <li>1. Unsealed nuclear medicine sources to be stored for as long as reasonably achievable and emissions to the environment must be under a discharge authorisation issued by the RPC pursuant to the BSS Regulations.</li> <li>2. Emissions to be subject to a radiological assessment following the RPB/RPC operating procedure.</li> </ol>

### Education and Training

Policy	1. Persons involved in the handling, transport, storage and possible future disposal shall be sufficiently trained.
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Strategy	<ol style="list-style-type: none"> <li>1. RPC to enforce the requirements upon adoption of Regulation 13 of the Waste Regulations, namely that their staff have been adequately trained.</li> <li>2. RPC to facilitate participation in any International Atomic Energy Agency (IAEA) training activities in the field of radioactive waste management.</li> </ol>
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### Research

Policy	<ol style="list-style-type: none"> <li>1. Malta will support and participate if possible in any international research initiatives in the management of radioactive waste.</li> </ol>
Strategy	<ol style="list-style-type: none"> <li>1. RPC to keep abreast of any EU/IAEA activities in this area and to get support for such activities.</li> <li>2. RPC to seek to involve any relevant stakeholders in any EU/IAEA training activities.</li> </ol>

### Public Participation

Policy	<ol style="list-style-type: none"> <li>1. Seek to keep the public fully informed and involved in the long-term management of radioactive waste.</li> <li>2. Public to be given the necessary opportunities to participate effectively in the decision-making process regarding radioactive waste management.</li> </ol>
Strategy	<ol style="list-style-type: none"> <li>1. This programme and any revisions to go out for public consultation.</li> <li>2. RPC to make available to the public, the National Report for the Joint Convention and any other reports made in connection with key performance indicators.</li> </ol>

## **L. Peer Reviews and Self-Assessments (Article 14.3)**

3. Member States shall periodically, and at least every 10 years, arrange for self-assessments of their national framework, competent regulatory authority, national programme and its implementation, and invite international peer review of their national framework, competent regulatory authority and/or national programme with the aim of ensuring that high safety standards are achieved in the safe management of spent fuel and radioactive waste. The outcomes of any peer review shall be reported to the Commission and the other Member States, and may be made available to the public where there is no conflict with security and proprietary information.

Malta has started its preparations for an ARTEMIS mission to be held towards the end of 2022.

## **M. Future to Improve Safe and Responsible Management of Spent Fuel and Radioactive Waste**

The near-term plans to improve radioactive waste management include:

- a) International peer review via an ARTEMIS mission in 2022.
- b) Recruitment of more staff for the RPC.
- c) Receiving international expert advice on disposal options in 2023 through a proposed IAEA national technical cooperation project.
- d) Government decision on disposal options post 2023 considering the advice from international experts.

### **Annex 1: Maltese Legislation**

Nuclear Safety and Radiation Protection Act (Cap. 585 of the Laws of Malta)

<https://legislation.mt/eli/cap/585/eng>

Basic Safety Standards for Ionising Radiation Regulations (SL 585.01)

<https://legislation.mt/eli/sl/585.1/eng>

Nuclear Safety Regulations (SL 585.02)

<https://legislation.mt/eli/sl/585.2/eng>

Management of Radioactive Waste Regulations (SL 585.03)

<https://legislation.mt/eli/sl/585.3/eng>

Commission for The Protection from Ionising and Non-Ionising Radiation Regulations (SL 585.04)

<https://legislation.mt/eli/sl/585.4/eng>

Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations (SL 549.51)

<https://legislation.mt/eli/ln/2009/48/eng>