# MALTA

## Maltese National Report for the Seventh Review Meeting of

Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management

On the measures taken by Malta to fulfil the obligations laid down by Article 32

# Contents

# List of Acronyms and Abbreviations

| | |
|---|---|
| ALARA | As low as reasonably achievable |
| BSS | Basic Safety Standards |
| CPD | Civil Protection Department |
| CSF | Centralised Radioactive Waste Storage Facility |
| ECURIE | European Community Urgent Radiological Information Exchange |
| ERA | Environment and Resources Authority |
| EU | European Union |
| EURDEP | European Radiological Data Exchange Platform |
| IAEA | International Atomic Energy Agency |
| IRRS | Integrated Regulatory Review Service |
| ITDB | IAEA Illicit Trafficking Data Base |
| TSO | Technical Service Organizations (s) |

# Section A: Introduction.

## Significant changes since the last review meeting

Malta wishes to report that since the Sixth Review Meeting of the Joint Convention:

- Malta has a new regulatory infrastructure including a new regulatory authority in the field of nuclear safety and radiation protection.
- Malta has an operational centralised radioactive waste storage facility (CSF).
- Most of the disused sources have been transferred to the CSF and that basic volume reduction has been performed on disused sources, including the retrieval of sources which had been encased in concrete blocks.

## Background and Malta's use of Radioactive Materials

This is the third report Malta has produced for the Joint Convention since it acceded to the Convention in December 2013.

Malta is a member state of the European Union with a population of approximately 515,000. Malta lies 80 km south of Sicily and has a land mass of just over 316 $km^2$.

Malta does not have any: nuclear power plants; research reactors; nuclear fuel-cycle activities or any facility producing radioactive material. Consequently, many of the requirements under the Joint Convention therefore do not apply.

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).
- Limited use in research and teaching.

Malta has a limited number of disused sources, most of which are now stored in the CSF which became operational in November 2019.

The cyclotron facility for the production of medical radionuclides that was reported as being under construction in the last Maltese report for the Joint Convention has not been completed.

## Regulatory infrastructure

Since the last review meeting Malta has created a new regulatory infrastructure and to this end has enacted the following law and regulations:

**Nuclear Safety and Radiation Protection Act** CAP585 (published 2018)
https://legislation.mt/eli/cap/585/eng/pdf

**Basic Safety Standards for Ionising Radiation Regulations** SL585.01 (published 2018)
https://legislation.mt/eli/sl/585.1/eng/pdf

**Nuclear Safety Regulations** SL585.02 (published 2018)
https://legislation.mt/eli/sl/585.2/eng/pdf

**Management of Radioactive Waste Regulations** SL585.03(published 2019)
https://legislation.mt/eli/sl/585.30

The Nuclear Safety and Radiation Protection Act (CAP 585) is to ensure the better regulation of the use and safety of ionising radiation and allow for the implementation of requirements of international treaties, conventions or protocols related to ionising radiation and nuclear safety and security. The Act allowed for the consolidation of all existing and anticipated new nuclear safety and radiation protection regulations and will also allow for the regulation of non-ionising radiation.

A new regulatory authority was set up in accordance with the Nuclear Safety and Radiation Protection Act (CAP 585) called **Commission for the Protection from Ionising and Non-Ionising Radiation,** hereinafter referred to as the Commission. The Commission consists of a non-executive chairperson, deputy chairperson and nine expert members representing different aspects such as: environment; occupational health and safety; civil protection; public health; transport …. The executive functions of the Commission are performed by the Commission's Secretariat which has two full time staff members. At the time of writing (October 2020) the Secretariat is in the process of appointing three additional technical officers.

## Malta's Radioactive Waste Management Structure

Malta is committed to managing radioactive waste in line with all relevant international legal instruments including the Joint Convention and European Council Directive on a Community framework for the responsible and safe management of spent fuel and radioactive waste (2011/70/Euratom).

In 2019 the **Management of Radioactive Waste Regulations (**SL585.03) were issued to take into account the new regulatory infrastructure created by the Nuclear Safety and Radiation Protection Act (CAP 595). As required by the waste regulations policies and strategies were developed and are contained within the **National Framework for Radioactive Waste Management.**

## Applicability of Convention to Malta

In view of the fact that Malta does not have any nuclear fuel activities, articles 4 to 10 of the Joint Convention are not applicable.

# Section B: Policies and Practices (Article 32.1 iii, iv, v))

## Radioactive waste management policy (Article 32.1 iii)

The management of radioactive waste in Malta is based upon the following general principles:

1. The prime responsibility for radioactive waste shall reside with the waste producer.
2. Minimisation of the generation of radioactive waste.
3. Ensuring adequate and suitable conditioning of waste.
4. Development of adequate financing schemes to allow for management of radioctive waste.
5. Setting up of a centralised radioactive waste storage facility.
6. Prohibition of the importation of radioactive waste into Malta.
7. Take-back arrangements shall be in place with the original suppliers for sealed sources.
8. Malta will manage any radioactive waste that cannot be sent overseas (in line with Supervision and Control of Shipments of Radioactive Waste and Spent Fuel Regulations, SL 549.51) and will seek disposal options for such waste in Malta.
9. Gain control over sources that are out of regulatory control.
10. Safe recovery of orphan sources.
11. Export of sources for reuse/recycling.
12. All stakeholders shall be adequatly trained.
13. Participatation in international research activites.
14. To reduce the likelihood of accidents due to, or loss of radioactive wastes.
15. Storage of short lived medical unsealed radioactive sources by waste producer.
16. To have appropriate emergency response systems in place.
17. That radioactive waste shall be centrally managed in the long term.
18. To enhance public confidence in relation to the radioactive waste management through public consultation.
19. Shall define how and when the identified goals and requirements will be achieved for the management of radioactive waste.
20. Shall identify the competencies needed for achieving the goals and how they will be provided.
21. Shall elaborate on the ways in which the various types of radioactive waste in the country, including, where appropriate, spent fuel, will be managed during all phases of the radioactive waste life cycle (from cradle to grave);
22. The implementation of waste management options to be proportionate to the waste using a graded approach.
23. Evidence-based and documented decision-making process shall be applied with regard to all stages of the management of radioactive waste.

24. The interdependencies between all steps in radioactive waste generation and management shall be taken into account.
25. The use of passive safety features for the long term management of radioactive waste.

## Radioactive waste management practices (Article 32.1 iv)

Waste minimization

1. Commission will only to give clearance for import of radioactive material for justified uses.
2. The replacement of radioactive sources by non-radioactive alternatives if available.
3. Return of disused sealed sources to the overseas supplier.

Waste Conditioning

1. Conditioning to be done in accordance with waste acceptance criteria of storage or waste facilities.
2. Waste is to be transferred to CSF for storage and, if possible, volume reduction is to take place, in addition:
    a. Waste is not to embedded in any permanent matrix such as lead or concrete.
    b. Waste to be shielded using the ALARA principle.
    c. Documentation to be created for each waste package
3. Organisation running the CSF is to consult with Commission before performing any conditioning.
4. Sources that need to be treated as waste are to have their non-active components removed as long as it does not affect the shielding of, or compromising the source.

Financing of radioactive waste management

1. Ensure all stakeholders are aware of their financial obligations in the management of their waste.

Public Participation

1. Seek to keep public fully informed and involved in the long term management of radioactive waste.
2. Public be given the necessary opportunities to participate effectively in the decision-making process regarding radioactive waste management.

Central Radioactive Waste Storage Facility (CSF)

1. CSF facilty is operated by a private company and was issued with a license to operate by the Commission in November 2019.
2. Most disused sources have been transferred to the facilty.
3. Commission will not authorise the indefine storage of disused sources at any other site.
4. Organisation running the CSF takes ownership for all disused/spent radioactive sources within its facilities.
5. Users may be charged for usage of this facility (under the polluter pays principle).

Future Disposal

1. A viable disposable option will be sought before 2044. 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 the campaigns.
2. It is likely that the following options could be considered:
    a. Export of material
    b. Bore Hole Disposal option;
    c. Any other multi-lateral solution as may become available
3. The disposal option will need to take into account the nature of the waste, namely:
    a. Total number of existing sources and possible future acquisitions to waste inventory.
    b. Radionuclides.
    c. Activities.
    d. Physical state of the source, including any possible degratation in the sources.
    e. Site characterisation.

Gaining control over sources that are out of regulatory control

1. On discoverey of source within Malta, the Commission or CPD to be informed. If required radiological emergency plan to initated.
2. Customs to monitor imports at major ports of entry, including all goods entering Malta through the Malta Freeport by Customs Deartment.
3. Customs to monitor a high proportion of goods in trans-shipment through Malta Freeport.
4. Radioactive material discovered at the Malta Freeport to be returned to country of origin.
5. Commission to to decide on targeted areas may be subject to search within Malta.
6. Commission is to run campaigns for collection of sources, including schools, laboratories and lighning rods.
7. Initatives targetted at metal recycling facilities in Malta.

Emergency Plans

1. Commission to ensure that undertakings have emergency plans in place through the authorisation and inspection process.
2. Commission/CPD to initiate the National Radiological Emergency Plan when required.
3. Commission is to keep the radiological emergency plan and the hazard assessment updated (Both updated in 2019).

Orphan Source Recovery

1. Recovery to be performed in line with the National Radiological Emergency Plan which assigns CPD as the lead technical agency
2. On discovery of source the recovery is to be co-ordinated by CPD as the lead technical agency.
3. The Secretariat of the Commision to give CPD advice on recovery operations.
4. Immediate action for Category 1, 2 and 3 sources.
5. National radiological emergency to be initiated by either Commission or CPD

Return of radioactive sealed sources

1. Commission will not authorise the import of new sealed sources unless a declaration is provided by the user for the export of the source at the end of its useful life..

Shipment of Radioactive waste out of Malta

1. Commission to ensure radiation employers are aware of Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations, 2009 (SL 549.51)
2. ERA to Process any applications in consultation with the Secretariat of the Commission.

Imports of Radioactive Waste

1. Commission will not give clearance for import of radioactive waste

Discharges from nuclear medicine departments

1. Discharges to the environment of unsealed nuclear medicine radioactive waste must be under the limits set by a discharge authorisation issued by the Commission pursuant to BSS Regulations (SL585.01), albeit that the undertaking still needs to be store for as long as reasonably achievable
2. Emissions to be subject to radiological assessment following Commission operating procedure.

Education and Training

1. Commission to enforce the requirements stipulated in BSS Regulations (SL585.01) that staff are adequately trained.
2. Commission to facilitate participation in any IAEA training activities in the field of radioactive waste management.

Research

1. Commission to keep abreast of any EU/IAEA activities in this area and to get support for such activities.
2. Commission to seek to get any relevant stakeholders involved in any EU/IAEA training activities.

## Criteria used to define and categorize radioactive waste (Article 32.1 v)

Malta has no formalised categories of waste, radioactive waste is defined in the regulations simply as material for which no further use is foreseen by the user or if the Commission considers that it needs to be considered as waste.

Malta currently has the following types of waste:

- Disused sealed sources in storage.
- Short-lived unsealed sources used in Nuclear medicine.
- Uranium and thorium salts
- Am-241 lightning arrestors

- Am-241 smoke detectors

Details of long-lived material is given in Annex 2

# Section C: Scope of Application.

## Article 3

Further to Article 3 of the Convention:

a. Malta does not have any activities relating to spent fuel management .
b. There is no waste that contains naturally occurring radioactive material apart from some former laboratory uranium and thorium salts in storage.
c. There is no radioactive waste within any military or defence programmes.

# Section D: Inventories and Lists.

## Article 32(2)(i & ii)

Not applicable as there are no spent fuel activities

## Article 32(2)(iii)

Malta does not have a disposal facility but has one storage facility, the pertinent details of which are:

- A centralised radioactive waste storage facility (CSF), located in the south of the island was has been set up by a private company and was issued with a licence by the Commission in November 2019.
    - The storage facility is not designed for the indefinite storage in time of the radioactive material. In accordance with the Radioactive Waste Management Programme the Government is to seek a disposal/recycling option by 2044 and is due to take a decision on viability of disposal options by the end of 2023.
    - The CSF performs basic volume reduction techniques, segregates the material according to the radionuclide and stores the material in appropriately shielded containers within a specially adapted 20 foot ISO shipping container.
    - The company receives funding from central government and charges users for the collection and storage of radioactive material.

## Article 32(2)(iv)

Disused sources in storage at the facility is sown below

| **Cs-137** | | | |
|---|---|---|---|
| Original use | Number of sources | Activity of individual sources | Total Activity |
| NDT | 1 | 37.8 GBq | 37.8 GBq |
| Humbolt source | 1 | 370 MBq | 370 MBq |
| Liquid level gauge | 4 | 10 MBq | 40 MBq |
| | | | |
| NDT (Army) | 1 | Not known as not fully dismantled | |
| NDT (Shipyard) | 1 | Not known as not fully dismantled | |
| Total Cs-137 activity excluding two NDT sources not as yet fully dismantled | | | **38.2GBq** |

| **Am-241** | | | |
|---|---|---|---|
| Original use | Number of sources | Activity of individual sources | Total Activity |
| Humbolt source | 1 | 1.48 GBq | 1.48 GBq |
| Liquid level gauge | 5 | 1.67 GBq | 8.33 GBq |
| Lightning rod - pellet source | 12 | 35 MBq | 0.42 GBq |
| Lightning rod - foil source | 113 | 23 MBq | 2.60 GBq |
| Smoke Detectors | 88 | 37 kBq | 3.26 MBq |
| Total activity | | | **12.83 GBq** |

# Section E. Legislative and Regulatory System

## Article 18: Implementing Measures

Obligations pertaining to this Convention are met through the legislative framework that consists of the Nuclear Safety and Radiation Protection Act (CAP 585) and regulations made under this Act.

Regulation 2(2)(d) of the Management of Radioactive Waste Regulations (SL585.03) specifically has within its scope to bring into effect the provisions of the Convention.

The Commission as the regulatory authority is to bring into effect the provisions of the Act and the Regulations.

## Article 19: Legislative and regulatory framework

The framework for radioactive waste management is contained in the *National Framework*.

The National Framework consists of

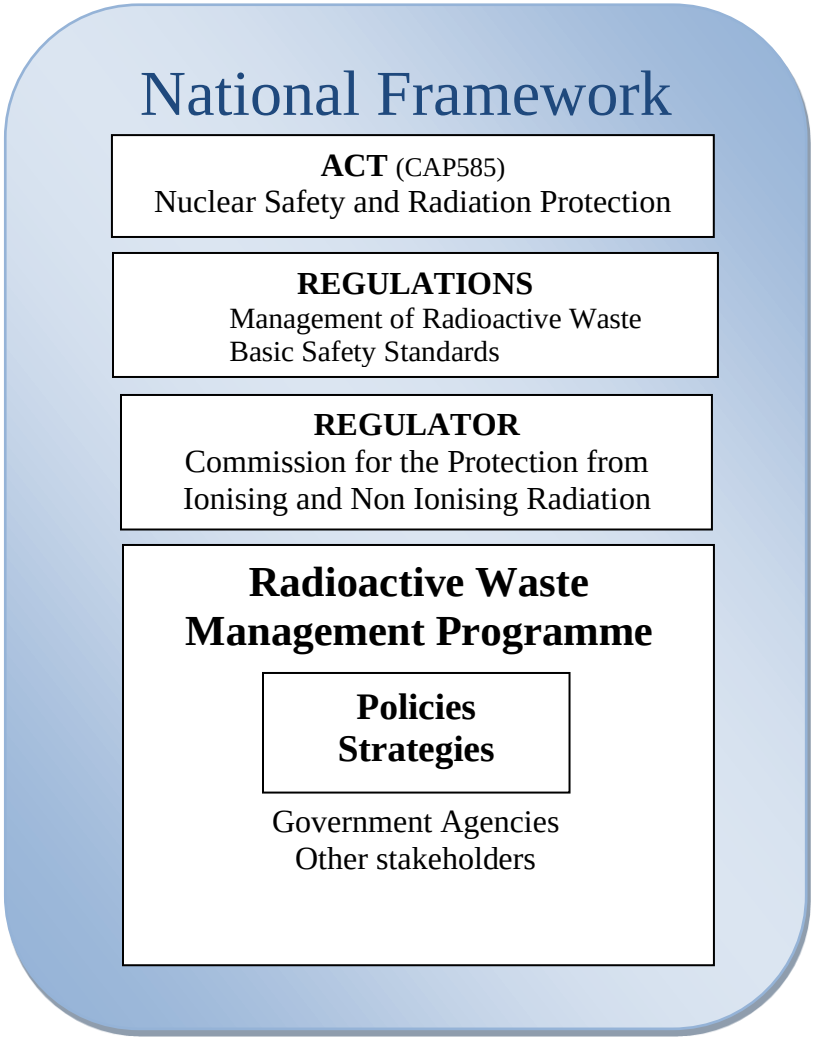
**Act :-** Nuclear Safety and Radiation Protection Act (CAP 585)

**Regulations**:- Management of Radioactive Waste Regulations (SL 585.03)
BSS Regulations (SL 585.01)

**Regulator**:- Commission

**Radioactive Waste Management Programme:-** This is required by the Management of Radioactive Waste Regulation (SL 585.03) and contains policies and strategies and elaborates on the responsibilities of the various stakeholders.

A diagrammatic representation of the framework :



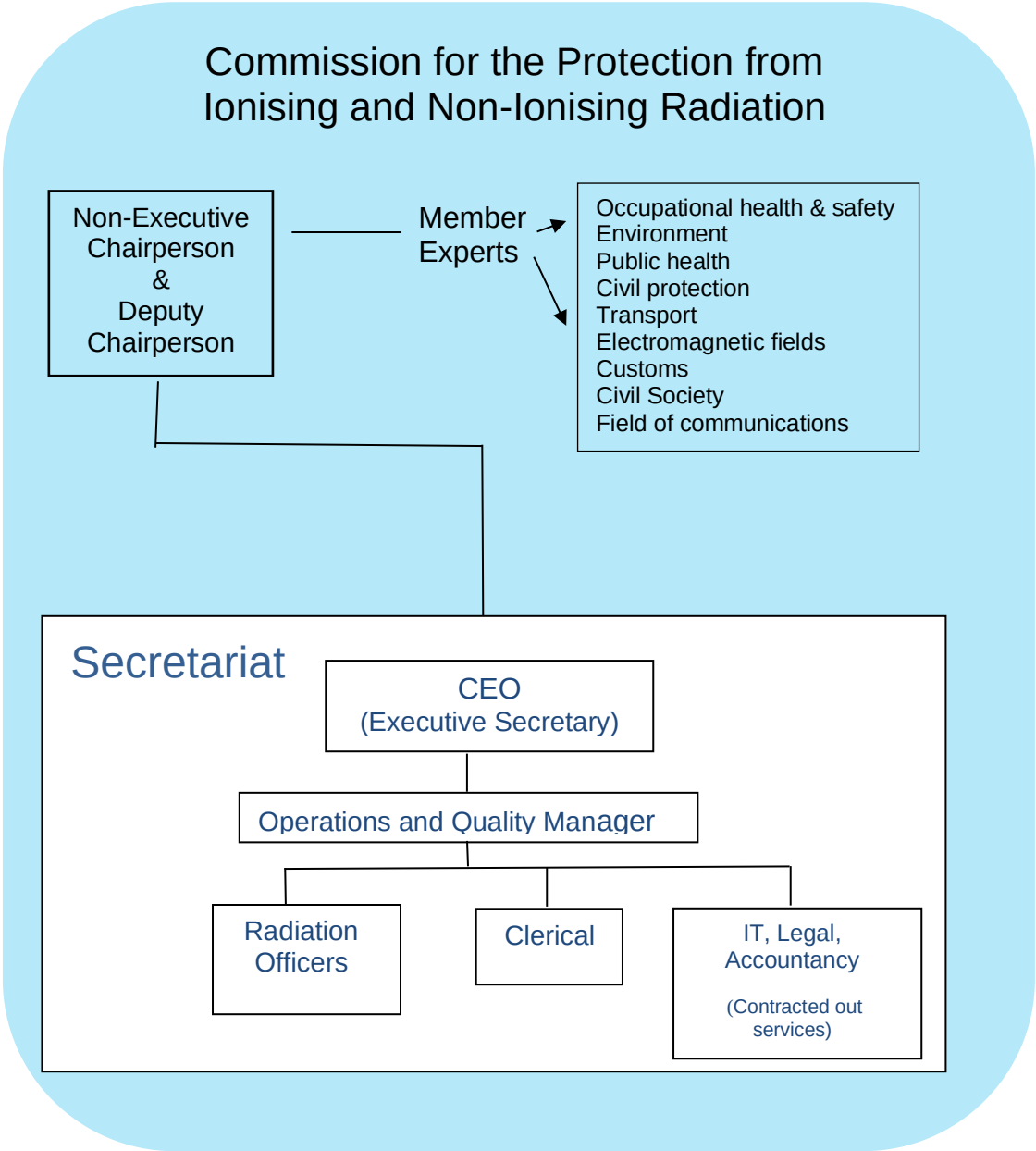
The framework provides for the requirements for licensing, inspection, enforcement is through the Basic Safety Standards Regulations for Ionising radiation regulations (SL 585.01). The framework also assigns responsibilities,

## Article 20: Regulatory Body

Structure of the Commission

The Act has provisions for the creation of the Commission for the Protection from Ionising and Non-Ionising Radiation as an independent regulatory body that has functional separation from entities having responsibilities or interests that could unduly influence its decisions.

The organogram of the Commission is



The Commission was appointed by the Government in October 2018 and since then the appointed expert members have held formal meetings once a month on average.

The independence of the Commission is guaranteed in that:

The Act (CAP585) refers to the Minister as:

> *"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;*

Article 10(5) of the Act (CAP585) states that is the Minister who appoints the members of the Commission and this Article states that no members shall be responsible for the use of any form of ionising radiation.

> *(5) The Minister shall appoint members, as expert members in the Commission, for a period of three years and such period may be extended for further periods of three years each. The Commission shall be composed as follows:*
>
> *(a) one member with regard to occupational health and safety issues;*
> *(b) one member with regard to environment issues;*
> *(c) one member with regard to the public health issues;*
> *(d) one member with regard to the civil protection issues;*
> *(e) one member with regard to transportation issues;*
> *(f) one member with regard to the electromagnetic field issues;*
> *(g) one member with regard to customs issues;*
> *(h) one member representing civil society; and*
> *(i) one member representing the field of communications:*
>
> *Provided that the Minister may change the composition of the Commission so as to reflect the regulatory exigencies developing from time to time, provided that no members shall be responsible for the use of any form of ionising or non-ionising radiation.*
>
> *Members of the Commission shall be allowed to be represented by a replacement at meetings of the Commission and any such replacements shall have voting rights.*
>
> *The Executive Secretary shall attend all meetings of the Commission but shall not have voting rights.*

Article 10(6) of the Act (CAP585) states it is for the Minister to appoint the Chairperson and the Deputy Chairperson

> *(6) The Chairperson and the Deputy Chairperson shall be appointed by the Minister for a period of three years and such period may be extended for further periods of three years each:*
>
> *Provided that where the Chairperson is absent from Malta or is otherwise temporarily unable to perform the functions of that office, all duties and functions of the Chairperson shall be assumed by the Deputy Chairperson.*

Financial independence is guaranteed by Article 61 of the Act (CAP585):

*61. (1) The Commission and the Secretariat shall be provided with adequate financial and human resources, through the national budget, to fulfil their responsibilities under this Act and applicable regulations.*

*(2) The Commission may charge fees pursuant to article 10(2)(g):*

*Provided that any fees or fines collected by the Secretariat shall be paid to the Ministry for Finance.*

*(3) The Minister responsible for Finance may, after consultation with the Minister, make advances to the Commission of such sums as the Minister responsible for Finance may agree to be required by the Commission for carrying out any of its functions under this Act, and may make such advances on such terms and conditions as the Minister responsible for Finance may, after consultation as aforesaid, deem appropriate. Any such advance may be made by the Minister responsible for Finance out of the Consolidated Fund, and without further appropriation other than this Act, by warrant, authorising the Accountant General to make such advance.*

*(4) The Commission shall be responsible for developing its own budget and for presenting it to the Minister for approval.*

*(5) The Commission shall cause to be prepared, at the end of every financial year, a financial report recording the income and expenditure of the Commission and the Secretariat and the projected estimates of the income and expenditure of Commission and the Secretariat for the next following financial year: Provided that the estimates of the Commission for the first financial year of the Commission shall be prepared and adopted within such time as Minister may, by notice in writing to the Commission, specify.*

## Legislative and regulatory framework

A complete list of Maltese legislation relating to radiation protection/nuclear issues along with the list of conventions/agreements is attached Annex 1.

## Functions of the Commission

The functions of the Commission are given in Article 10 of the Act (CAP585):

***10.*** *(1) There shall be set up a Commission for the protection from ionising and non-ionising radiation, hereinafter referred to as "the Commission", which shall act as the regulatory authority in the field of nuclear safety and radiation protection. The Commission shall have such functions in respect of its structures as are set out in this Act and such other functions as may devolve upon it under any other law, or as may be assigned to it by the Minister.*

*(2) It shall be the function of the Commission to:*

*(a) draw up and establish policies and strategies in consultation with the Minister to be followed by the Secretariat, relating to the protection against ionising and non-ionising radiation and other concerns addressed by the Act;*

*(b) co-ordinate the preparation of regulations governing any issues made in connection with this Act;*

*(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 whenever so directed by the Minister;*

*(f) implement the regulatory requirements of Conventions and other EU legislation within the scope of this Act:*

*Provided that the Commission shall regulate its own procedures upon consultation with the Secretariat and the Minister on all matters related to its functions on matters regulated by 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:*

*Provided that the Commission may appoint for this purpose, committees or sub-committees and it may co-opt on such committees or sub-committees competent persons from outside its membership, who in the opinion of the Commission, have professional or expert knowledge on any matter dealt with under this Act; so however that the co-opted members shall not have a vote on any matter before a committee or sub-committee.*

*(3) Without prejudice to the generality of this article, the Commission may undertake such other activity it may deem necessary or expedient for the purposes of its functions and objectives under this Act.*

*(a) draw up and establish policies and strategies in consultation with the Minister to be followed by the Secretariat, relating to the protection against ionising and non-ionising radiation and other concerns addressed by the Act;*
*(b) co-ordinate the preparation of regulations governing any issues made in connection with this Act;*
*(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 whenever so directed by the Minister;*
*(f) implement the regulatory requirements of Conventions and other EU legislation within the scope of this Act:*

*Provided that the Commission shall regulate its own procedures upon consultation with the Secretariat and the Minister on all matters related to its functions on matters regulated by 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:*

*Provided that the Commission may appoint for this purpose, committees or sub-committees and it may co-opt on such committees or sub-committees competent persons from outside its membership, who in the opinion of the Commission, have professional or expert knowledge on any matter dealt with under this Act; so however that the co-opted members shall not have a vote on any matter before a committee or sub-committee.*

*(3) Without prejudice to the generality of this article, the Commission may undertake such other activity it may deem necessary or expedient for the purposes of its functions and objectives under this Act.*

Commission Procedures

A Management System has been developed using Microsoft Excel and is based on the management system of the Icelandic Radiation Safety Authority.

The Management system is divided into 11 elements as follows:

- Workings of the Commission
- Management of the Secretariat
- Finance
- Document Management
- Staff
- Computer System
- Education
- Authorisation and Inspections
- Dose & Environmental Monitoring
- Emergency Preparedness
- Others

Each element has its own procedures. All procedures have supporting documentation, including instructions, checklists, documents, standard forms, and standard letters or email texts. All the supporting documentation is hyperlinked in order to facilitate the use for staff.

Work on the further development of the management system is on-going.

The management system is in use by the staff of the Secretariat.

Inspections

Announced and unannounced inspections of sites that use ionising radiation (some 200 sites in total) are performed mainly by the staff of the Secretariat. The average number of regulatory site visits averaged at approximately 50 per year pre-COVID-19.

Authorisations (licenses)

The Commission issues licenses to for medical exposure applications (excluding dental) higher risk industrial, and the CSF.

Technical Service Organizations (TSOs)

Owing to the small size of Malta, technical services normally need to be provided from overseas TSOs, for such services as:

- Personal Dosimetry
- Monitor Calibration
- Laboratory analysis of food/environmental samples.

# Section F: Other General Safety Provisions.

## Article 21: Responsibilities of the license holder

In general terms under Maltese legislation, for the use of ionising radiation the *undertaking* has the prime responsibility for safety. The undertaking must justify, optimize and ensure dose limitation is performed, taking actions in order to protect the workers, the patients, the public and the environment from risks arising from the use of ionising radiation.

With regard to the management of radioactive waste Regulation 14 of the Management of Radioactive Waste Regulations (SL 585.03) states:

> ***14.*** *(1) The prime responsibility for the safety of radioactive waste management facilities and/or activities rests with the licence holder.*
>
> *(2) Licence holders shall:*
> *(a) regularly assess, verify and continuously improve, as far as is reasonably achievable, the safety of the radioactive waste management facility or activity in a systematic and verifiable manner. This shall be achieved through an appropriate safety assessment, other arguments and evidence;*
>
> *(b) 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 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;*

*(c) establish and implement integrated management systems, including quality assurance, which give due priority for overall management of radioactive waste to safety and are regularly verified by the Commission; and*

*(d) provide for and maintain adequate financial and human resources to fulfil their obligations with respect to the safety of radioactive waste management.*

In the case where there is no identified licence holder Regulation 9 of the Management of Radioactive Waste Regulations (SL 585.03) states:

***9.*** *If there is no licence holder for a source or other responsible party, the responsibility for the source rests with the government of Malta.*

## Article 22: Human and financial resources

Following the Commission procedure "Notification and Authorization for Waste or Storage Facility (Op-50)" Operators during the review and assessment process, shall confirm that the undertaking:

- Has staff that are trained, qualified and competent, and, where applicable, licensed by the regulatory body.
- Has considered that there is a mechanism to provide and ensure adequate financial resources to discharge its responsibilities.

## Article 23: Quality assurance

The Commission's quality assurance programme is contained within its management system.

There is a specific procedure within the management system on the "Notification and Authorization for Waste or Storage Facility" it includes sections on requirements for long-term dedicated storage facility.

Undertakings are required to by the BSS Regulations (SL 585.01) to have Radiation Protection Programme in place.

## Article 24: Operational radiation protection

Radiation exposure of workers and the public

Undertakings are required to optimize the doses to workers and the public by virtue of BSS Regulations (SL 585.01).

To protect the environment the Commission has a specific operating procedure for the control of radioactive discharges from nuclear medicine establishments.

Environmental Monitoring in Malta

The Commission has a specific operating procedure for radiation/radioactivity monitoring of:

- Food,
- Milk
- Drinking water,
- Sea water
- Soil
- Ambient gamma dose rate,
- Air-particulates collected through high volume air sampler

## Article 25: Emergency preparedness

**National Plan**

The Commission has a national radiological emergency plan. The emergency plan was completed following a radiological emergency hazard assessment .

The scope of the hazard assessment document is to identify the radiological threats in the event of an incident that would require the radiological emergency procedures to be activated.

In line with GSR Part 7:

- Malta only has threat emergency preparedness categories IV and V activities.
- The only emergency class in Malta is "*Other nuclear or radiological emergency*"

The scope of the radiological emergency plan document is to:

- Provide a framework for the operation of the activities by government entities to mitigate the effects of the risks identified in threat assessment document
- Outline the government entities likely to be involved and their responsibilities.
- Place responsibilities on each government agency involved in the plan to develop its own procedures

The review of the medical response capabilities in the event of a radiological emergency is under-way but has not been completed.

Resources available for emergency response

Civil Protection Department is fully equipped with field equipment and has undergone training in radiological response with the assistance of the IAEA

The Accident and Emergency Department in the main hospital in Malta, has basic monitoring equipment. An operating procedure for the Accident and Emergency Department as well as training plan for hospital staff is being drafted, implementation of the plan and training has been delayed due to COVID-19.

Testing of emergency procedures

In January 2017 the Maltese response to the detection of a high dose-rate Cs-137 source discovered at Malta Freeport was tested.

Malta Freeport is a major container handling port focused on the 'hub' concept, whereby cargo is discharged from large mother vessels and relayed to a network of regional ports by regular and frequent feeder vessels. Around 96 per cent of Malta Freeport's container traffic is transhipment business. Currently the Freeport handles about 3 million container movements per year with a large proportion of them being subject to screening with portal monitors fitted with gamma and neutron detection capability.

Emergency monitoring

Data capture from the Maltese gamma dose environmental monitor is managed by ERA and is sent on an hourly basis to the Civil Protection Department 24 hour response centre and to European Radiological Data Exchange Platform (EURDEP) system. In the event of a nuclear incident in Europe, Malta would access EURDEP real-time data.

Exchange of information

Malta participates in the European Community Urgent Radiological Information Exchange (ECURIE) system and participates in ECURIE exercises.

In the event of a radiological emergency the public would receive information from the Director of the Civil Protection Department.

## On-site Plans

Undertakings in terms of Maltese regulations are obliged to have in place on-site emergency procedures.

The procedure within the management system of the Commission on the "Notification and Authorization for Waste or Storage Facility (Op-50)" requires undertakings to consider emergency preparedness issues.

## Article 26: Decommissioning

Malta does not have any current or past nuclear facility that needs/needed decommissioning.

# Section G: Safety of Spent Fuel Management.

Not applicable for Malta

# Section H: Safety of Radioactive Waste Management.

## Article 11: General safety requirements

General requirements laid down Management of Radioactive Waste Regulations (SL 585.03)

Policies and strategies have been developed and are contained within the National Framework for Radioactive Waste Management, refer to section B of this report

## Article 12: Existing facilities and past practices

Sealed sources in long term storage

Disused sources listed in Section D were moved to the CSF in 2019-2020. The facility is licensed and subject to inspections from the Commission.

Disused sources not as yet transferred to the CSF are shown in the below table

| Original use | Radionuclide | Amount / Number of individual sources | Activity of individual sources | Total Activity | Notes |
|---|---|---|---|---|---|
| Laboratory analytical | Uranium and thorium salts | 2.23kg uranium salts 0.125kg thorium salts | | | In storage at one government site. Material declared under safeguards |
| Calibration | Ra-226 | 1 | Activity unknown | | Part of equipment used for dosemeter probe |
| School sources | Ra-226 | 3 | 0.185 MBq | 0.56MBq | Data from survey performed in 2016 of schools |
| | Sr-90 | 8 | 0.185 MBq | 1.48MBq | |
| | Co-60 | 8 | 0.185 MBq | 1.48MBq | |
| | Am-241 | 7 | 0.185 MBq | 1.30MBq | |
| | Pu-239 | 1 | 0.185 MBq | 0.19MBq | |

The sources in the above table are subject to regulatory inspections from the Commission.

Unsealed radioactive material

The main use of unsealed sources in Malta is in diagnostic and therapeutic nuclear medicine. There are currently three nuclear medicine sites, two of which with positron emission tomography technology, and one site performing therapeutic techniques for thyroid disorders.

All the above sites have delay storage tanks and are required to take steps to ensure that the ALARA principal is applied to their radioactive discharges to the environment.

Each site is set limits on the activity levels they can discharge through a Commission licence issued under BSS Regulations (SL 585.01).

To enable discharge limits to be determined in terms of activity per radionuclide that will ensure discharges are in compliance with the generic dose constraint of an effective dose, applicable to a single practice or work activity and to the mean dose among individuals of the critical group of the public, shall be 0.25 mSv/y as given in Regulation 12 of the BSS Regulations (SL 585.01)

The Commission issues annual authorisation for the accumulation and disposal of Radioactive Waste.

The Radiation employer is required to

- Apply the ALARA principal in any discharges.
- Comply with all conditions of Authorisation to Accumulate and Discharge Radioactive Waste.
- Set up a suitable monitoring programme for the waste
- Send annual returns of all discharges to the Commission

## Article 13: Siting of proposed facilities

The CSF consists of a modified 20 foot ISO container.

In the review and assessment of the proposed storage facility the Commission considered

- The site related factors that could effect the safety and security of the facility
- The external dose rates and the contamination risks.
- Owing to the low risks involved with the facility and the location of the facility no specific information was given to the public.

## Article 14: Design and construction of facilities

The design of the CSF has limited impacts on workers and the population at large. The small inventory of radioactive sources are kept in heavily shielded containers within the 20 foot ISO container.

The storage facility is not designed for the indefinite storage in time of the radioactive material. In accordance with the Radioactive Waste Management Programme the Government is to seek a disposal/recycling option by 2044 and is due to take a decision on viability of disposal options by the end of 2023.

## Article 15: Assessment of the safety of facilities

As part of the licensing process for the CSF the operator (undertaking) had to provide the Commission with safety and environmental assessments for the proposed facility.

## Article 16: Operation of facilities

Malta's only waste management facility is the CSF.

The Commission issued a licence to the facility in 2019 based inspections and on the documentation provided by the company which included:

- Safety assessment
- Environmental assessment
- Radiation Protection Programme
- Emergency Procedures
- Maintenance program
- Method statements for characterisation and segregation of disused sources
- Procedures for:
    - Preparation of cemented drums
    - Dismantling of smoke detectors
    - Dismantling of lightning rods

## Article 17: Institutional measures after closure

The CSF is designed for the interim storage of radioactive material prior to its recycling or disposal.

At the end of the working life of the facility all radioactive material will be removed.

# Section I: Transboundary movement (Article 27).

Maltese Customs performs gamma and neutron monitoring on a large percentage of shipping containers in trans-shipment and all containers entering through Malta Freeport.

This monitoring has led to the detection of contaminated scrap metal and finished metal goods.

The Commission and the Customs Department use a standard operating procedure drawn up between them to deal with the detection of radioactive material at Maltese ports. These procedures include:

- Arrangements to send the items back to the country of origin in compliance with international transport regulations.
- The regulatory authority of the country of origin is informed of the return shipment.
- Notification to the ITDB.

# Section J: Disused sealed sources (Article 28).

## National Legislation

The management of disused sealed sources falls under two regulations, namely:

- Management of Radioactive Waste Regulations (SL 585.03).
- BSS Regulations (SL 585.01), in particular regulations 112 to 120.

## Strategy

As required by Management of Radioactive Waste Regulations policies and strategies have been developed and are contained within the National Framework for Radioactive Waste Management.

All Sources that are either in the CSF or at other locations are subject to Commission inspections.

The National Framework for Radioactive Waste Management envisages:

1. Take back arrangements by the supplier when new sources are purchased.
2. The setting up of CSF for existing sources.
3. The export of sources whenever possible.
4. Exploring disposal option within Malta.

## Status of Sources

The list of sources are given in Annex 2

Since the last Review meeting most of the sources have been transferred to the CSF.

The sources which had previously been encased from in concrete have been removed from the concrete

Also since the last review meeting more Am-241 lightning rods have been brought under regulatory control.

# Section K: General efforts to improve safety.

## Maltese Actions in connection with challenges identified in the 6th Review meeting

The actions taken with respect to the three challenges that were identified at the last Review Meeting are as follows:

**Challenge 1-** Complete implementation of newly introduces regulatory regime, including the management system.

Actions:

- The Act and the key regulations have been enacted 2018-2019.
- The management system is at an advanced stage of development, pending work on the management system includes mostly procedures and supporting documents for certain administrative procedures relating to Commission staffing and premises.

**Challenge 2-** Ensure adequate and appropriate training is provided to staff (and their replacements) to fulfil the responsibilities of the Radiation Protection Board

Actions:

- Call for three officers issued in 2020, one to two positions expected to be filled by the end of 2020
- Training plan developed as part of management system.

**Challenge 3**- Investigate options for the disposal of radioactive waste on Malta to supersede the function of the centralized storage facility.

Actions:

- Commission working to provide the Government disposal options by mid 2023 in order that the Government can take decision by end 2023.

- Malta is seeking to get expert advice through a proposed national technical cooperation project with the IAEA in 2022-2023

## Maltese Integrated Regulatory Review Service (IRRS) Mission

Malta was subject to an IRRS Mission in 2015. Following this mission and the follow-up mission performed in March 2020 Malta worked on implementing the IRRS recommendations and suggestions.

This year the IRRS follow-up team concluded *"the Maltese Government showed a strong commitment to radiation safety and that most of the recommendations and suggestions identified in 2015 had been addressed"*

The IRRS reports 2015 and follow-up of 2020 are available at:

https://www.iaea.org/sites/default/files/documents/review-missions/irrs_report_malta_26may2015.pdf

https://www.iaea.org/sites/default/files/documents/review-missions/irrs_malta_fu_2020.pdf

## Radiation Safety Information Management system (RASIMS)

Malta in 2019-2020 completed five of the six RASIMS questions sets

# Annex 1 – Legal – Conventions – ITDB – Declarations

## Legislative

| Reference | Date | Title |
|---|---|---|
| SL 365.11<br>LN 156/2001 | 23-Jul-2001 | Comprehensive Nuclear-Test Ban Treaty Regulations.<br>https://legislation.mt/eli/sl/365.11/eng/pdf |
| SL 365.15<br>LN 44/2003 | 28-Jan-2003 | Nuclear Safety and Radiation Protection Regulations, 2003<br>https://legislation.mt/eli/sl/365.15/eng/pdf |
| SL117.14<br>LN 242/2004 | 30-Apr-2004 | Importation Control Regulations, 2004<br>https://legislation.mt/eli/sl/117.14/eng/pdf |
| SL 365.12<br>LN 416/2004 | 20-Sep-2004 | Dual–use Items (Export Control) Regulations, 2004<br>https://legislation.mt/eli/sl/365.12/eng/pdf |
| SL 365.20<br>LN 182/2007 | 10-Jul-2007 | Treaty on the Non-Proliferation of Nuclear Weapons (Euratom Safeguards and Additional Protocol) Regulations, 2007<br>https://legislation.mt/eli/sl/365.20/eng/pdf |
| SL 549.51<br>LN 48/2009 | 13-Feb-2009 | Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations, 2009<br>https://legislation.mt/eli/sl/549.51/eng/pdf |
| CAP 585 | 25-May-2018 | **Nuclear Safety and Radiation Protection Act**<br>https://legislation.mt/eli/cap/585/eng/pdf |
| SL 585.01<br>LN 210/2018 | 3-Jul-2018 | **Basic Safety Standards for Ionising Radiation Regulations**<br>https://legislation.mt/eli/sl/585.1/eng/pdf |
| SL 585.02<br>LN 323/2018 | 15-July-2018 | **Nuclear Safety Regulations**<br>https://legislation.mt/eli/sl/585.2/eng/pdf |
| SL 585.03<br>LN 123/2019 | 18-Jun-2019 | **Management of Radioactive Waste Regulations**<br>https://legislation.mt/eli/sl/585.30/eng/pdf<br>Maltese National Radioactive Waste Management Policy |
| | | Council Regulation (Euratom) 1493/93 on shipments of radioactive substances between States<br>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31993R1493&from=EN |

## Conventions/agreements

| Title | | Legal Notice Number |
|---|---|---|
| Comprehensive Nuclear-Test Ban Treaty | Ratification 23-Jul-2001 | SL 365.11 |
| Convention on the Physical Protection of Nuclear Material | Entry into force 15 Nov 2003 | SL 365.15 |
| Amendment to the Convention on the Physical Protection of Nuclear Material | Acceptance 16-Dec-2013 | SL 365.15 |
| Agreement between the European Atomic Energy Community, its non nuclear weapon Member States and the IAEA | Entry into force 1-Jul-2007 | SL 365.20 |
| Convention on Nuclear Safety | Entry into force 13-Feb-2008 | SL 585.02 |
| Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management | Entry into force 15-Dec-2013 | SL 585.03 |
| Treaty on the Prohibition of Nuclear Weapons | Ratification 21-Sp-2020 | |

## Illicit Trafficking Data Base

Malta joined the IAEA Illicit Trafficking Data Base on 13th May 2009

## Declarations

March 2004
Malta declared its support Code of Conduct on the Safety and Security of Radioactive Sources.

April 2015
Malta declared support Code of Conduct on the Safety and Security of Radioactive Sources, and supplementary Guidance on the Import and Export of Radioactive Sources

# Annex 2 - Disused sources

## Disused sources in the CSF

| **Cs-137** | | | |
|---|---|---|---|
| Original use | Number of sources | Activity of individual sources | Total Activity |
| NDT | 1 | 37.8 GBq (2018) | 37.8 GBq |
| Humbolt | 1 | 370 MBq | 370 MBq |
| Liquid level gauge | 4 | 10 MBq | 40 MBq |
| | | | |
| NDT (Army) | 1 | Not known as not fully dismantled | |
| NDT (Shipyard) | 1 | Not known as not fully dismantled | |
| Total Cs-137 activity excluding two NDT sources not as yet fully dismantled | | | **38.2GBq** |

| **Am-241** | | | |
|---|---|---|---|
| Original use | Number of sources | Activity of individual sources | Total Activity |
| Humbolt | 1 | 1.48 GBq | 1.48 GBq |
| Liquid level gauge | 5 | 1.67 GBq | 8.33 GBq |
| Lightning rod - pellet source | 12 | 35 MBq | 0.42 GBq |
| Lightning rod - foil source | 113 | 23 MBq | 2.60 GBq |
| Smoke Detectors | 88 | 37 kBq | 3.26 MBq |
| Total activity | | | **12.83 GBq** |

## Disused sources not as yet transferred to the CSF

| Original use | Radionuclide | Amount / Number of individual sources | Activity of individual sources | Total Activity | Notes |
|---|---|---|---|---|---|
| Laboratory analytical | Uranium and thorium salts | 2.23kg uranium salts 0.125kg thorium salts | | | In storage at one government site. Material declared under safeguards |
| Calibration | Ra-226 | 1 | Activity unknown | | Part of equipment used for dosemeter probe |
| School sources | Ra-226 | 3 | 0.185 MBq | 0.56MBq | Data from survey performed in 2016 of schools |
| | Sr-90 | 8 | 0.185 MBq | 1.48MBq | |
| | Co-60 | 8 | 0.185 MBq | 1.48MBq | |
| | Am-241 | 7 | 0.185 MBq | 1.30MBq | |
| | Pu-239 | 1 | 0.185 MBq | 0.19MBq | |