

MALTA

Maltese National Report for the Sixth 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

List of Acronyms and Abbreviations

ALARA	As low as reasonably achievable
CPD	Civil Protection Department
ECURIE	European Community Urgent Radiological Information Exchange
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
LN	Legal Notice
MEPA	Malta Environment and Planning Authority
OHSA	Occupational Health and Safety Authority
RPB	Radiation Protection Board
TSO	Technical Service Organizations (s)

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Section A: Introduction.

Background

This is the second report Malta has produced for the Joint Convention since it joined the Convention in December 2013.

Malta is a member state of the European Union with a population of approximately 440,400. Malta lies 80 km south of Sicily and has a land mass of just over 316 km²

Malta's use of Radioactive Materials

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 (PET)
- Industrial gauging
- Industrial non-destructive testing (with Ir-192)
- Very limited use in research and teaching.

Malta has a limited number of disused sources in storage, refer to Annex 2

A cyclotron facility for production of medical radionuclides is under construction (as of October 2017)

This report focuses on radioactive waste arising from medical, industrial and research applications of radionuclides.

Malta's Current Regulatory infrastructure

Malta's current regulatory authority is the Radiation Protection Board, (RPB).

The RPB is an inter-ministerial body with representatives from: Health; Environmental; Occupational Health and Safety and Civil Protection agencies.

The RPB was set up in 2003 and has two full time staff members assigned to it (from OHSA) which co-ordinate the work of the RPB. The individual regulatory tasks are then performed by the member agencies of the RPB.

Malta's draft new regulatory infrastructure

Following the Integrated Review Service (IRRS) mission in 2015, a new radiation Act has been drafted and is currently under review by the Government.

The main objective of the draft Act 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.

This draft Act will create a Radiation Protection Commission and its Secretariat to act as the regulatory authority in the areas of nuclear safety and radiation protection.

This draft Act will allow 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.

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 2013 regulations (Legal Notice 186 of 2013) were issued which took into account Malta's obligations to the Joint Convention and the Council Directive 2011/70/Euratom. As required by Legal Notice 186 of 2003 policies and strategies have been 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 will be based upon the following general principles

1. Minimisation of the generation of radioactive waste.
2. Ensuring that there is adequate and suitable conditioning of waste.
3. Development of adequate financing schemes to allow for management of radioactive waste.
4. The setting up of a centralised storage facility.
5. Prohibiting the importation of radioactive waste into Malta.
6. Ensuring Radiation Employers have take-back arrangements with the original suppliers for sealed sources (all suppliers are from overseas).
7. 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, L.N. 48 of 2009) and will seek disposal options for such waste in Malta.
8. Gain control over sources that are out of regulatory control and the recovery of orphan sources
9. The export of radioactive waste if possible
10. Ensuring workers are adequately trained.
11. Participatation in international research activites as appropriate
12. The prime responsibility for radioactive waste resides with the Radiation Employer.
13. To reduce the likelihood of accidents due to, or loss of, radioactive wastes
14. Storage of short lived medical unsealed radioactive sources at Radiation Employer's site.
15. To have an appropriate emergency response systems in place.
16. That radioactive waste shall centrally managed in the long term.
17. To enhance public confidence in relation to the radioactive waste management through public consultation.
18. Shall elaborate on the ways in which the various types of radioactive waste in the country, will be managed during all phases of the radioactive waste life cycle (from cradle to grave);
19. The implementation of waste management options to be proportionate to the waste using a graded approach.
20. Evidence-based and documented decision-making process shall be applied with regard to all stages of the management of radioactive waste
21. The interdependencies between all steps in radioactive waste generation and management shall be taken into account
22. 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. RPB 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 future storage or waste facility.
2. Until such time as storage/disposal facilities are available the RPB to give advice to users who currently hold sources. The RPB strategy will be
 - a. Waste is not to be embedded in any permanent matrix such as lead or concrete.
 - b. Waste to be shielded using the ALARA principle.
 - c. Full documentation to be created for each waste package
3. Any organisation running a central storage facility is to consult with RPB 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 the source.
5. Consideration to be given to the re-conditioning of sources currently conditioned in large concrete blocks.

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 Storage Facility

1. Identify private/government entity to set up and run storage facility
2. Facility will need to be authorised by the RPB Once central facility is available users are to transfer disused sources to it.
3. RPB will not authorise (in terms of regulation 19 of Legal notice 44 of 2003) the storage of disused sources on site once central facility is operational.
4. Organisation running the central storage facility is to take 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 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 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 degradation in the sources.
 - e. That some sources have been conditioned previously in large concrete blocks
 - f. Site characterisation

Gaining control over sources that are out of regulatory control

1. On discovery of source within Malta, the Radiation Protection Section at OHSA or CPD to be informed. If required radiological emergency plan to be initiated.
2. Customs to monitor imports at major ports of entry, including all goods entering Malta through the Malta Freeport by Customs Department.
3. Customs to monitor a high proportion of goods in trans-shipment through Malta Freeport.
4. Radioactive material discovered in trans-shipment at the Malta Freeport to be returned to country of origin
5. RPB to decide on targeted areas may be subject to search within Malta.
6. Once central storage facility becomes available, the RPB is to run campaigns for collection of sources, including schools, laboratories and lightning rods.
7. Initiatives targeted at metal recycling facilities in Malta

Emergency Plans

1. RPB to ensure that radiation employers have emergency plans in place through the authorisation and inspection process.
2. RPB/CPD to initiate the National Radiological Emergency Plan when required
3. RPB is to keep the radiological emergency plan and the threat assessment updated

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 Radiation Protection Section at OHSA 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 RPB or CPD

Return of radioactive sealed sources

1. RPB will not authorise the import of new 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. Until such time as a disposal option becomes available in Malta, RPB will encourage Radiation Employers to explore the possibility of exporting radioactive waste.
2. RPB to ensure radiation employers are aware of Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations, 2009 (LN 48 of 2009)
3. MEPA to Process any applications made in connection with LN 48 of 2009 in consultation with the Radiation Protection Section at OHSa

Imports of Radioactive Waste

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

Discharges from nuclear medicine departments

1. Unsealed nuclear medicine radioactive waste is to be stored for as long as reasonably achievable and emissions to the environment must be under a discharge authorisation issued by the RPB pursuant to LN44/2003.
2. Emissions to be subject to radiological assessment following RPB operating procedure.

Education and Training

1. RPB to enforce the requirements stipulated in LN 44/2003 that their staff have adequately trained.
2. RPB to facilitate participation in any IAEA training activities in the field of radioactive waste management.

Research

1. RPB to keep abreast of any EU/IAEA activities in this area and to get support for such activities.
2. RPB 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 however radioactive waste is defined s by Legal Notice 44 of 2003 as:

means a material of whatever physical form, remaining from practices and work activities or interventions, for which no further use is foreseen at present and which (i)

contains or is contaminated with radioactive substances having activity or activity concentration higher than the relevant level of exemption from regulatory control, and (ii) exposure to which is not excluded from these regulations;

Malta currently has the following types of waste:

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

Details of material is given in Annex 2

Section C: Scope of Application.

- a. Malta does not handle spent nuclear fuel
- 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 iii)

Malta does not have a centralised waste management facility (Art 32 2 iii)

Article 32(2 iv)

Disused sources in storage given in Annex 2

Section E. Legislative and Regulatory System

Article 18: Implementing Measures

There is currently no dedicated radiation/nuclear act in Malta, regulations have been enacted under several different Acts, namely: Enabling Powers Act of the Prime Minister; Health Act; Civil Protection Act; Environmental Act).

The regulatory authority for Malta is currently the Radiation Protection Board (RPB) which was created by a regulation, namely Legal Notice 44 of 2003 under Enabling Powers Act of the Prime Minister.

Article 19: Legislative and regulatory framework

The regulatory system governing the safety of potential nuclear installations in Malta is included within the Nuclear Safety and Radiation Protection Regulations 2003 (Legal Notice 44 of 2003, published in January 2003)

The scope of Legal Notice 44 of 2003 is to:

1. allow beneficial and justified uses of ionising radiation
2. provide for adequate protection of people in current and future generations against the harmful effects of ionising radiation and for the safety of radiation sources
3. provide for the physical protection of nuclear material
4. provide a mechanism whereby these objectives are achieved through the establishment of a Radiation Protection Board to act as the competent national authority, by co-ordinating the activities of the regulatory authorities in the field of nuclear safety and radiation protection.

Legal Notice 44 of 2003 makes provision for nuclear fuel activities. Any radiation employer who intended to operate any nuclear facility in Malta would be subject to the requirement for authorisation under regulation 19.

To allow Malta to bring in the provisions of Council Directive 2011/70/EURATOM (Community framework for the responsible and safe management of spent fuel and radioactive waste) and to ratify the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive, Legal Notice 186 of 2013 (Management of Radioactive waste regulations, 2013) was issued.

Malta issued legal notice 440 of 2007 (Convention on Nuclear Safety Regulations, 2008)) to enable it to ratify the Convention of Nuclear Safety. This regulation was subsequently amended to allow Malta to transpose Council Directive 2011/70/EURATOM. by legal notice 299 of 2011. This regulation was subsequently further amended to allow Malta to transpose Council Directive 2014/87/EURATOM by legal notice 214 of 2017.

Malta issued Control and Security of High-Activity Radioactive and Orphan Sources Regulations, Legal notice 13 of 2006. These regulations implement the requirements of Council Directive on control of high-activity sealed radioactive sources and orphan sources 2003/122/Euratom and the International Atomic Energy Agency's Code of Conduct on the Safety and Security of Radioactive Sources. Malta has two in use that fall under these regulations.

Article 20: Regulatory Body

Structure of the Radiation Protection Board

The RPB was set up as the national competent body for radiation protection and nuclear issues by a regulation, namely Legal Notice 44 of 2003.

The RPB is made up from representatives of four different governmental organizations.

Two full-time personnel in the Radiation Protection Section within the Occupational Health and Safety Authority co-ordinate the work of the RPB.

The internal structure of the RPB is show diagrammatically in the below figure 1.

Structure of Maltese Radiation Protection Board

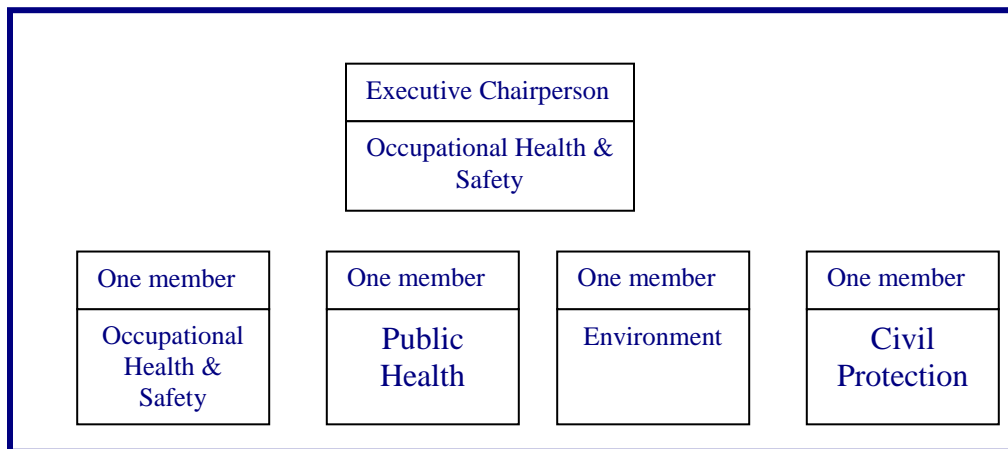


Figure 1. Internal structure of the Radiation Protection Board.

The position of the RPB within the governmental structures in Malta is shown below in figure 2

Position of the RPB within the administrative set-up in Malta:

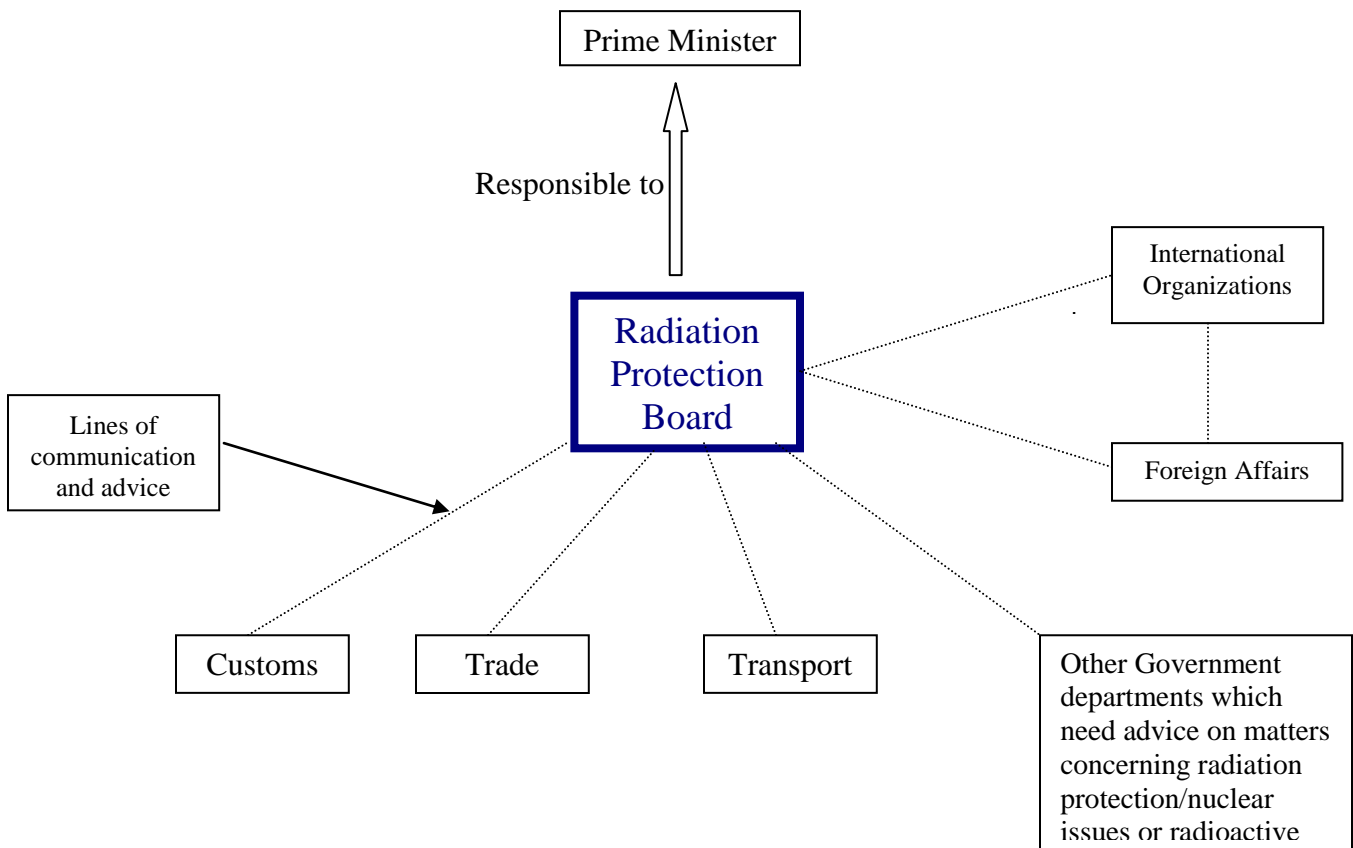


Figure 2. Position of the RPB within the governmental structures

The RPB is subordinate to the Prime Minister, not to any particular ministry.

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 Radiation Protection Board

The main functions of the RPB as defined by LN 44/2003 regulations as:

- a) take the necessary measures to improve the co-operation and co-ordination of the government bodies which have responsibility for issues related to occupational health and safety,

environment, public health, and civil protection amongst themselves and with other interested parties;

- b) tender advice to the government on allocation of responsibilities in the field of nuclear safety and radiation protection when these are unclear or unresolved;
- c) co-ordinate the preparation of regulations governing notification, authorization of practices, work activities, radiation sources and establishing radiation protection and safety requirements;
- d) define criteria for exclusion, exemption and clearance from regulatory requirements;
- e) receive notifications, and issue authorizations and grant exemptions concerning the possession and use of radiation sources, subject to any condition that may be required in the opinion of the Board and to revoke at any time any such authorizations if the Board feels that the required standards or levels of safety are not being complied with;
- f) coordinate and conduct inspections and enforcement actions to assess radiation safety conditions and compliance with applicable regulatory and authorization requirements and to protect the health and safety of workers and the public;
- g) compile a national register of practices, work activities and sources;
- h) gather the required data to enable an assessment of total exposure from all practices and work activities in Malta and including the distribution of the individual occupational and public exposures for each type of practice, and to enable the setting up of a National Register for Occupational Exposure to Ionising Radiation;
- i) initiate surveys on background radiation and radioactive contamination of all environmental media;
- j) approve the capacity of persons to act as approved dosimetric services and qualified radiation experts for radiation employers;
- k) Co-operate with other Regulatory Authorities abroad on relevant issues and fulfil international obligations of which Malta is a signatory.

Radiation Protection Board Procedures

The RPB is in a process of further developing its operational procedures.

The Operating Procedures are designed to ensure:

- That all RPB activities are coordinated and transparent and proportionate
- Avoidance of duplication of activities
- Identify the responsibilities of the member agencies of the RPB and other governmental entities

Approved procedures that are currently in place are:

- General Operating Procedures of the functioning of the RPB
- Emergency Response
- Environmental Monitoring
- Safeguards Reporting
- ITDB Reporting
- Medical Regulation Enforcement
- Control of radioactive discharges
- Radioactive Waste Management

Working of the RPB

On average the RPB holds 3-4 formal meetings per year with the core activities performed by two persons employed by OHSA.

Inspections

Announced and unannounced inspections of sites that use ionising radiation (some 200 sites in total) are performed mainly by the core staff of the RPB. The average number of regulatory site visits averaged at approximately 75 per year over the past three years.

Authorisations (licenses)

The RPB is in the process of issuing authorizations (in terms of regulation 19 of LN 44 of 2003) to Radiation Employers. The duration of the authorization varies from 1 to 4 years.

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

Under Maltese legislation, for the use of ionising radiation the Radiation Employer has the prime responsibility for safety. The Radiation Employer 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.

The Radiation employer is required to seek advice from a Qualified Expert (as defined by LN 44 of 2003)

Article 22: Human and financial resources

Financing of the Radiation Protection Board

There is no separate budget for the RPB, the funding for RPB activities comes from the member entities of the RPB.

Staffing of the Radiation Protection Board

There is no staff employed by the RPB, the core activities are performed by two persons employed by OHSA.

Other activities are delegated to other governmental entities such as Health Ministry, Environment Ministry and the Civil Protection Department.

Article 23: Quality assurance

The RPB is in a process of developing a management system for the RPB. To date the RPB has a set of operational procedures as described under Article 20.

Article 24: Operational radiation protection

Radiation exposure of workers and the public

Radiation Employers are required to optimize the doses to workers and the public by virtue of LN 44 of 2003.

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

Environmental Monitoring in Malta

The RPB 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

Malta only has threat category IV and V activities (as defined by GS-R-2).

On-site Plans

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

National Plan

The RPB has a national radiological emergency plan. The emergency plan was completed following a radiological emergency threat assessment (refer to GS-R-2).

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

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.

Testing of emergency procedures

In January 2017 The RPB and the Customs Department practised their responses to the detection of a high dose-rate Cs-137 source discovered at Malta Freeport.

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 transshipment 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 the Malta Environment and Planning Authority 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.

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 Legal Notice 186 of 2013

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 are currently in secure storage on the sites of Radiation Employers. These sources are subject to RPB inspections.

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 PET 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 RPB Authorisation issued under Legal Notice 44 of 2003

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 Schedule 3 of Legal Notice 44 of 2003.

The RPB 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 RPB

Article 13: Siting of proposed facilities

There is currently no centralized storage or disposal facility in Malta. The manner in which sealed source and unsealed sources is described in report on Article 12.

Article 14: Design and construction of facilities

To date no centralized storage/disposal facility has been identified. The National Framework for Radioactive Waste Management envisages that a central storage facility.

A possible site has been identified

Article 15: Assessment of the safety of facilities

Any future storage facility would need to authorized by the RPB.

Article 16: Operation of facilities

No such facility currently exists.

Article 17: Institutional measures after closure

No such facility currently exists.

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:

Date	Commodity	Radioisotope(s)	Max surface dose rate of shipping container (μSvh^{-1})
November 2016	Stainless steel scrap	Am-241	3.8
July 2016	Aluminum scrap	Th-232, Ra-226	0.1
March 2015	Stainless steel scrap	Ra-226	38
August 2013	Stainless steel finished goods (kettles)	Co-60	3.6
March 2013	Submersible pumps	Co-60	21
January 2013	Industrial food processing equipment – stainless steel	Co-60	4

The RPB 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 are to be made 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).

The list of sources are given in Annex 2

Status of Sources

Industrial NDT

- Two Cs-137 Non destructive testing sources encased in concrete (approximately 20 years ago) stored on private industrial site.
- One Cs-137 Non destructive testing source stored on government site

Liquid level indicators

- One Cs-137 encased in concrete (approximately 20 years ago) stored on private industrial site
- One Cs-137
- Five Am-241 stored at one private industrial site

Industrial portal density/moisture gauge.

- One Cs-137 Am-241 gauge in storage at government site

Medical

- One Ra-226 formally used for calibration purposes currently stored on government hospital site.

Lightning rods (Am-241)

- Eight currently in storage, at various governmental and private sites, many still in situ.
- Number of lightning rods in situ as yet not determined. No resources have currently been set aside to find out the number of lightning rods in situ.

School teaching sources

- Survey performed to ascertain total number of such sources in 2016.

Legal and Strategy

Refer to article 19.

As required by Legal Notice 186 of 2003 policies and strategies have been developed and are contained within the National Framework for Radioactive Waste Management.

Sources are currently stored at various governmental and private facilities and are subject to RPB inspection.

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 centralised storage facility for existing sources
3. The export of sources whenever possible
4. Exploring disposal option within Malta.

Section K: General efforts to improve safety.

Article 16: Maltese Integrated Regulatory Review Service (IRRS) Mission

Implementation of 2015 IRRS recommendations

Following the IRRS mission in 2015, Malta has been working on implementing the recommendations. At the time of writing this report (October 2017) a draft new law has been prepared and is due to be presented to the House of Representatives.

The IRRS report is available at:

<http://www-ns.iaea.org/actionplan/missions.asp?mt=IRRS&my=2015&cn=Malta&ms=Completed&func=search&submit.x=12&submit.y=12>

The table of recommendations and suggestions is included as Annex 3

Annex 1 – Legal – Conventions – ITDB – Declarations

Legislative

Legal Notice Number	Publication Date	Title
156/2001	23-Jul-2001	Comprehensive Nuclear-Test Ban Treaty Regulations. http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=18795&l=1
245/2002	30-Aug-2002	Radiological Emergency (Information to the Public) Regulations, 2002 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=18085&l=1
44/2003	28-Jan-2003	Nuclear Safety and Radiation Protection Regulations, 2003 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=18319&l=1
173/2004	20-Apr-2004	Nuclear Safety and Radiation Protection (Amendment) Regulations, 2004 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=17735&l=1
242/2004	30-Apr-2004	Importation Control Regulations, 2004 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=16612&l=1
416/2004	20-Sep-2004	Dual-use Items (Export Control) Regulations, 2004 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=16695&l=1
13/2006	13-Jan-2006	Control and Security of High-Activity Radioactive and Orphan Sources Regulations, 2006 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=19023&l=1
182/2007	10-Jul-2007	Treaty on the Non-Proliferation of Nuclear Weapons (Euratom Safeguards and Additional Protocol) Regulations, 2007 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=19527&l=1
440/2007	28-Dec-2007	Convention on Nuclear Safety Regulations, 2008 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=20432&l=1
48/2009	13-Feb-2009	Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations, 2009 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=19982&l=1
299/2011	22-Jul-2011	Convention on Nuclear Safety Regulations (Amendment) Regulations, 2011 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=22430&l=1
353/2012	19-Oct-2012	Medical Exposure (Ionising Radiation) Regulations, 2013 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=23969&l=1
186/2013	16-Jul-2013	Management of Radioactive Waste Regulations, 2013 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=12065&l=1
187/2013	16-Jul-2013	Nuclear Safety and Radiation Protection (Amendment) Regulations, 2013 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=25197&l=1
214/2017	15-Aug-2017	Convention on Nuclear Safety Regulations (Amendment) Regulations, 2017 http://justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=28626&l=1
-	-	Council Regulation (Euratom) 1493/93 on shipments of radioactive substances between States http://ec.europa.eu/energy/nuclear/radiation_protection/doc/radioactive_sources/regulation_1493_93.pdf

Conventions/agreements

Title		Legal Notice Number
Comprehensive Nuclear-Test Ban Treaty	Ratification 23-Jul-2001	LN 156/2001
Convention on the Physical Protection of Nuclear Material	Entry into force 15 Nov 2003	LN 44/2003
Amendment to the Convention on the Physical Protection of Nuclear Material	Acceptance 16-Dec-2013	LN 187/2013
Agreement between the European Atomic Energy Community, its non nuclear weapon Member States and the IAEA	Entry into force 1-Jul-2007	LN182/2007
Convention on Nuclear Safety	Entry into force 13-Feb-2008	LN 440/2007
Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management	Entry into force 15-Dec-2013	LN 186/2013

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 in storage

Original use	Radionuclide	Number	Max Activity	Total activity	Notes
Industrial NDT	Cs-137	2	Not known	Not known	Sources in storage on private industrial site. Both of them encased in separate 1M ³ concrete blocks (about 20 years ago)
Industrial NDT	Cs-137	1	Not known	Not known	Source within its projector, in storage on government site
Liquid level indicators	Cs-137	2	Not known	Not known	Both in storage on private industrial site, one encased in 1M ³ concrete block (about 20 years ago)
Liquid level indicators	Am-241	5	1.665GBq	8.3GBq	Sources in storage on private drinks bottling site
Medical	Ra-226	1	Not known	Not known	Source in store at government hospital
Industrial portal density/moisture gauge	Am-241	1	370 MBq	370MBq	Troxler Portable density gauge, unused for several years
	Cs137	1	1.48GBq	1.48GBq	
Lightning Rod	Am-241	8	Not known	Not known	Two in storage at government site , one in storage at private site
Lightning rods in situ	Am-241	unknown	Not known	Not known	
Laboratory analytical	Uranium and thorium salts	2.23kg uranium salts 0.125kg thorium salts			In storage at one government site. Material declared under safeguards
School sources	Ra-226	3	0.185 MBq	0.555MBq	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	1.295MBq	
	Pu-239	1	0.185 MBq	0.185MBq	

Annex 3 – IRRS recommendations of their 2015 mission

Task		Action	
Ref No	Description	Ref No of IRRS/	Description
G1	Governmental Policy and Strategy	R1	The government should establish a national policy and strategy for safety, taking into account current and future risks associated with radiation facilities and activities in Malta. Implementation of the policy should be subject to a graded approach.
G2	Development of Dedicated Nuclear and Radiation Act	R2	Government should establish a dedicated nuclear and radiation safety Act. The Act should regulate the conduct of legal or natural persons engaged in activities related to fissionable materials, ionizing radiation and exposure to natural sources of radiation and provide a legal framework for conducting activities related to nuclear energy and ionizing radiation in a manner which protects individuals, property and the environment.
		R3	The government should ensure that the nuclear and radiation safety Act includes provisions to establish an effectively independent regulatory body functionally separated from entities having responsibilities or interests that could unduly influence its decision-making.
		R4	Government should, in the legal framework for safety, stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities, make provision for adequate arrangements for the regulatory body to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities and provide for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties.
		R5	The Government should provide resources that enable active participation in international cooperation activities for safety such as sharing of regulatory experience and participation in IAEA safety review missions.
G3	Regulatory Body Staffing	R6	The government should ensure the regulatory body employs a sufficient number of staff in accordance with the extent, scope and complexity of the regulatory programme for radiation safety.
G4	Regulatory Body Competences	R4	Government should, in the legal framework for safety, stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities, make provision for adequate arrangements for the regulatory body to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities and provide for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties.
		R5	The Government should provide resources that enable active participation in international cooperation activities for safety such as sharing of regulatory experience and participation in IAEA safety review missions.
		S2	The government should consider in the short term, prioritising measures to ensure knowledge and experience is shared between senior members and new recruits and in the long-term to maintain staff having the competences and experience necessary for effective current and future regulatory oversight of all facilities and activities in Malta, together with Malta's responsibilities for, and contribution to nuclear and radiation safety internationally.

G5	Regulations and Guides	R16	The government should establish within the legal framework for radiation safety, processes for establishing or adopting, promoting and amending regulations and guides, including consultation, with account taken of internationally agreed standards and the feedback of relevant experience.
G6	Maltese participation in International agreements	S1	Government should consider ratification of the conventions on Early Notification and Assistance and making a political commitment to the Guidance on Import and Export of Radioactive Sources.
RB1	Management System of the Regulatory Body	R10	The regulatory body should adopt or develop a management system compatible with international requirements and appropriate to its size and the scope and extent of its regulatory functions and activities.
		R7	The regulatory body should establish formal and informal mechanisms of communication with authorised parties on all safety related issues.
		R8	The regulatory body should extend its national registers to include records of the occupational exposure history of each worker.
		R9	The regulatory body should promote the establishment of appropriate means of informing and consulting interested parties and the public about possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.
		R11	The regulatory body should establish a process that allows the authorized party to appeal against a regulatory decision relating to an authorization for a facility or an activity or a condition attached to an authorization.
		R12	The regulatory body should establish a process in accordance with a graded approach, for all facilities and activities subject to authorization according to GSR Part 1 and GSR Part 3. The requirements for authorization should include the detailed specification of all radiation sources / devices associated with the facility / activity.
		R13	The regulatory body should develop procedures for review and assessment for all facilities and activities. Review and assessment should be performed in accordance with a graded approach.
		R14	The regulatory body should develop and implement a programme of inspections that confirms compliance with regulatory requirements and specifies the types of regulatory inspection, the frequency of inspections and utilizes a graded approach.
		R15	The regulatory body should implement a process that follows specified procedures to ensure the stability and the consistency of regulatory control and to prevent subjectivity in decision.
			S3
	AR M 4	RPB to develop formal communications with relevant governmental agencies through MoUs	
RB2	Emergency preparedness	R17	The regulatory body should develop, in cooperation with the authorities responsible for the food, health and agriculture, legally binding optimized

			national intervention levels, in accordance with the international standards.
		R18	The government should through legislation assign responsibilities and functions to the regulatory body for its role in recovery work and the transition to normal activities.
		R19	The regulatory body should strengthen its regulatory control of the licensees' emergency planning for category I, II, III facilities and should verify the appropriateness and affectivity of these plans.
		R20	The regulatory body should develop regulatory requirements for EPR quality assurance programme to be established and maintained by the licensees.
		S4	The regulatory body, together with its national counterparts within the national Emergency Framework, should consider regular reviewing and updating the hazard assessment in its RPB-OP-S-Emergency Threat Assessment document and revise the National Radiological emergency plan accordingly.
		S5	The regulatory body should consider modifying its emergency classification system to be consistent with the classification given in GS-R-2.
		S6	The regulatory body should consider revising the national radiation emergency preparedness and response planning document (RPB-OP-S-Emergency Framework-2010-1) to make it consistent with the national regulations and the international standards.
		S7	The regulatory body should consider working towards the development of the standard operating procedures for medical response, in radiological emergency situations as well as establishing the relevant training programme for medical professionals.
RB3	Medical Exposure Control	R21	The government should ensure that relevant parties are authorized to assume their roles and responsibilities and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients who have undergone therapeutic procedures using unsealed sources or patients who still retain implanted sealed sources.
		R22	The regulatory body should regulate asymptomatic exposures.
		R23	The regulatory body should ensure through regulations that patients or their legal representatives are informed of the expected diagnostic or therapeutic benefits of the radiological procedure as well as of the radiation risks.
		R24	The regulatory body should amend regulations to include a requirement that an appropriately specialized medical physicist be involved in interventional radiology or therapeutic procedures.
		R25	The regulatory body should amend the regulations to include a requirement that radiation employers should ensure that sufficient medical personnel and paramedical personnel are available.
		R26	The regulatory body should revise the regulations on dosimetry and calibration of equipment as well as responsibilities of medical physicists to be in line with the GSR Part 3.
		R27	The regulatory body should add a requirement into regulations for registrants and licensees to ensure that signs in appropriate languages are placed in appropriate places to request female patients who are to undergo a radiological procedure to notify the possible pregnancy or in case of nuclear medicine procedure breast feeding.

		R28	The regulatory body should add a requirement in regulations such that patients or their legal representatives are required to be informed of unintended exposures.
		R29	The regulatory body should revise regulations such that the concept of periodical radiological reviews / clinical audits would be included. The review should be performed by the radiological medical practitioners in cooperation with the medical radiation technologists and the medical physicists.
RB4	Occupational Exposure Control	R30	The government or the regulatory body should establish compliance with the relevant dose limits specified in Schedule III for occupational exposure of GSR Part 3.
		R31	The regulatory body should add a requirement in regulations such that people under the age of 16 could not be exposed to occupational exposure.
		R32	The government should ensure that regulations clearly set out requirements for the documentation of arrangements for radiological protection and also the recording of non-compliances.
		R33	The government should ensure that radiation employers provide training in protection and safety, as well as periodic retraining as required to ensure the necessary level of competence.
		R34	The regulatory body should ensure that radiation protection of workers performing activities in radiological areas not under control of their own employer is assured through the necessary cooperation between the parties, with appropriate allocation of responsibilities clearly documented.
		R35	The regulatory body should issue requirements applicable to workers, on the proper use of monitoring equipment and that workers should make available to the employer information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others.
		R36	The regulatory body should address through regulations the frequency and type of workplace monitoring as well as requirements for specific monitoring in case of intake of radionuclides.
		R37	The regulatory body should require that radiation employers establish the relevant investigation level and the procedures to be followed in the event that any such level is exceeded.
		R38	The regulatory body should require that radiation employers as appropriate designate a Radiation Protection Officer in accordance with criteria determined by the regulatory body for their designation, roles and responsibilities.
		R39	The regulatory body should add requirements in regulations about the contents of records of both for individual and workplace monitoring
RB5	Environmental Protection	R40	The regulatory body should implement a procedure for approval of discharge limits in compliance with relevant requirements in GSR Part 3.
		R41	The regulatory body should establish in Maltese regulations criteria for clearance.
		R42	The regulatory body should require that radiation employers make the results of environmental monitoring programmes and assessments of doses from public exposure available at specified intervals and should publish all such results.