

Convention on Nuclear Safety

National Report by Malta for the 7th Review Meeting

Made in connection with Article 5 of the Convention on Nuclear Safety

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List of Acronyms and Abbreviations

ECURIE	European Community Urgent Radiological Information Exchange
EU	European Union
EURDEP	European Radiological Data Exchange Platform
GSR	General Safety requirements (IAEA)
IAEA	International Atomic Energy Agency
IRRS	Integrated Regulatory Review Service
ITDB	IAEA Incident and Trafficking Data Base
LN	Legal Notice
RB	Regulatory Body
RPB	Radiation Protection Board

Introduction.

Background

Malta became Party to the Convention on Nuclear Safety (hereinafter referred to as the Convention) on 13th February 2008.

Malta is committed to complying with all relevant international legal instruments in the nuclear field, including the Convention and seeks to continuously improve safety with its available resources.

This report builds upon previous Review Meeting Reports (4th, 5th and 6th reports) and seeks to highlight the progress and challenges faced by Malta.

Since the last Review Meeting, Malta was subject to an Integrated Regulatory Review Service (IRRS) mission in 2015.

Malta's position with respect to nuclear issues

Malta does not operate or plan to operate any form of nuclear installation as defined by the Convention, nor research reactors.

The size and the population of the Maltese Islands are such that it is unlikely that there will be any nuclear facilities (or research reactors) sited within Malta.

The nearest nuclear power reactors are found in main-land Europe, the closest currently being some 1100 km away.

Main use of ionizing radiation in Malta

Malta uses ionizing radiation in medical applications, industrial applications (including non-destructive testing) as well as limited use in research and teaching.

Applicability of Convention to Malta

In view of the fact that Malta does not have any nuclear installations as defined in the Convention, reports made in connection with Maltese obligations to Articles 11, 12, 13, 14, 17, 18, 19 have not been included.

Summary.

Regulatory Framework

Malta's commitments to being a member of the IAEA and the European Union (EU) led to its legislation to be based on the requirements of both the IAEA and the EU.

Since the last Review Meeting, Malta was subject to an IRRS mission in 2015. The IRRS mission made a series of recommendations which are discussed later in this report.

Regulatory Body

The Maltese Islands have a small population of 423,000 which means the radiation/nuclear regulatory body (RB), the Radiation Protection Board, (RPB) is consequently small as well.

The RPB is an inter-ministerial body with representatives from health, environmental and civil protection agencies. The RPB only has two full time staff members which co-ordinate the work of the RPB. The individual regulatory tasks are then performed by the member agencies of the RPB.

The RPB has continued to develop/update its procedures to ensure that all the regulatory tasks are performed as efficiently and effectively as possible. Since the last review meeting new procedures in connection with:

- Radioactive waste management;
- Control of discharges to the environment;
- Transport of radioactive materials;
- Regulatory control of medical establishments,

have been introduced.

Since the last Review Meeting no additional human resources or finance has been made available.

The limited number of staff and the lack of finances pose restrictions on the RPB.

Emergency Preparedness

The national radiological emergency plan, which was approved in August 2010, forms the structure for emergency response. The plan was first used for the Maltese response to the Fukushima accident.

Since the last Review Meeting no emergency exercise was performed.

IRRS mission 2015

Malta was subject to an IRRS mission in 2015, the following modules were applied by the review team:

- Core Questions (GSR Part 1 and GSR Part 3)
- Control of Medical Exposure
- Emergency Preparedness and Response
- Public and Environmental Exposure Control, Waste Management and Decommissioning
- Occupational Radiation Protection
- Safety and Security of Radioactive Sources

The main findings taken from the Executive Summary of the report are:

- “
- *The government of Malta should develop a policy for nuclear and radiation safety to achieve the fundamental safety objective and apply the fundamental safety principles in accordance with national circumstances and with the radiation risks associated with facilities and activities in the country.*
 - *There is a need for a dedicated nuclear and radiation safety Act to regulate those engaged in activities related to ionizing radiation and establish a legal framework for conducting such activities in a manner which protects individuals, workers and the environment.*
 - *A regulatory body should be established in the Act, effectively independent in its decision-making and functionally separate from entities having responsibilities or interests that could unduly influence its decisions.*
 - *The government should make provision for building and maintaining the competence of all parties having responsibilities in relation to safety of facilities and activities and ensure there will be sufficient regulatory staff having the necessary skills and experience to fully implement the regulatory programme for Malta now and into the future.*
 - *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.*
 - *A management system should be implemented by the regulatory body to ensure its regulatory responsibilities are discharged efficiently, effectively, consistently.*
 - *A number of recommendations, of a technical nature with regard to medical exposure, patient protection, occupational radiation protection and other areas, should be expedited, primarily by the regulatory body, to ensure the radiation protection and safety of the public, patients, workers and the environment of Malta.*
- ”

Following the IRRS mission the RPB developed a concept document for the government on the way to implement the IRRS recommendations. This concept document sought to highlight the need for:

- Government to develop of policy and strategy;
- Creation of a dedicated radiation and nuclear Act;
- Creation of new regulatory body (RB) empowered through the Act;

- An appropriate route of accountability to government, taking into account the issues of effective independence;
- Increase staffing of the RB (to five full-time staff);
- Financial resources to be assigned to the RB;
- Assignment of the regulatory RB as the competent authority for Malta's commitments and obligations internationally in terms of nuclear and radiation safety;
- The necessary agreements, such as memoranda of understandings, with other organizations, nationally and internationally, having commitments and obligations relating to nuclear and radiation safety, including conventions and treaties; and
- A formal management system for the RB.

At the time of writing this report (August 2016) the RPB had forwarded to the government a draft policy and strategy and a dedicated Act and is now waiting for government approval of these.

Article 7. Legislative and regulatory framework

There is no dedicated radiation or nuclear Act in Malta.

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

The scope of LN 44/2003 is to:

1. allow beneficial and justified uses of ionizing radiation
2. provide for adequate protection of people in current and future generations against the harmful effects of ionizing 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.

LN 44/2003 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.

Since the last Review Meeting, no new radiation or nuclear related regulations have been issued.

RPB inspectors have issued stop orders but have not taken any court actions since the last review meeting.

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

Article 8. Regulatory Body

Structure of the Radiation Protection Board

The RB for Malta is currently the RPB.

The RPB was set up as the national competent body for radiation protection and nuclear issues in 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 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 RPB is subordinate to the Prime Minister, not to any particular ministry.

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

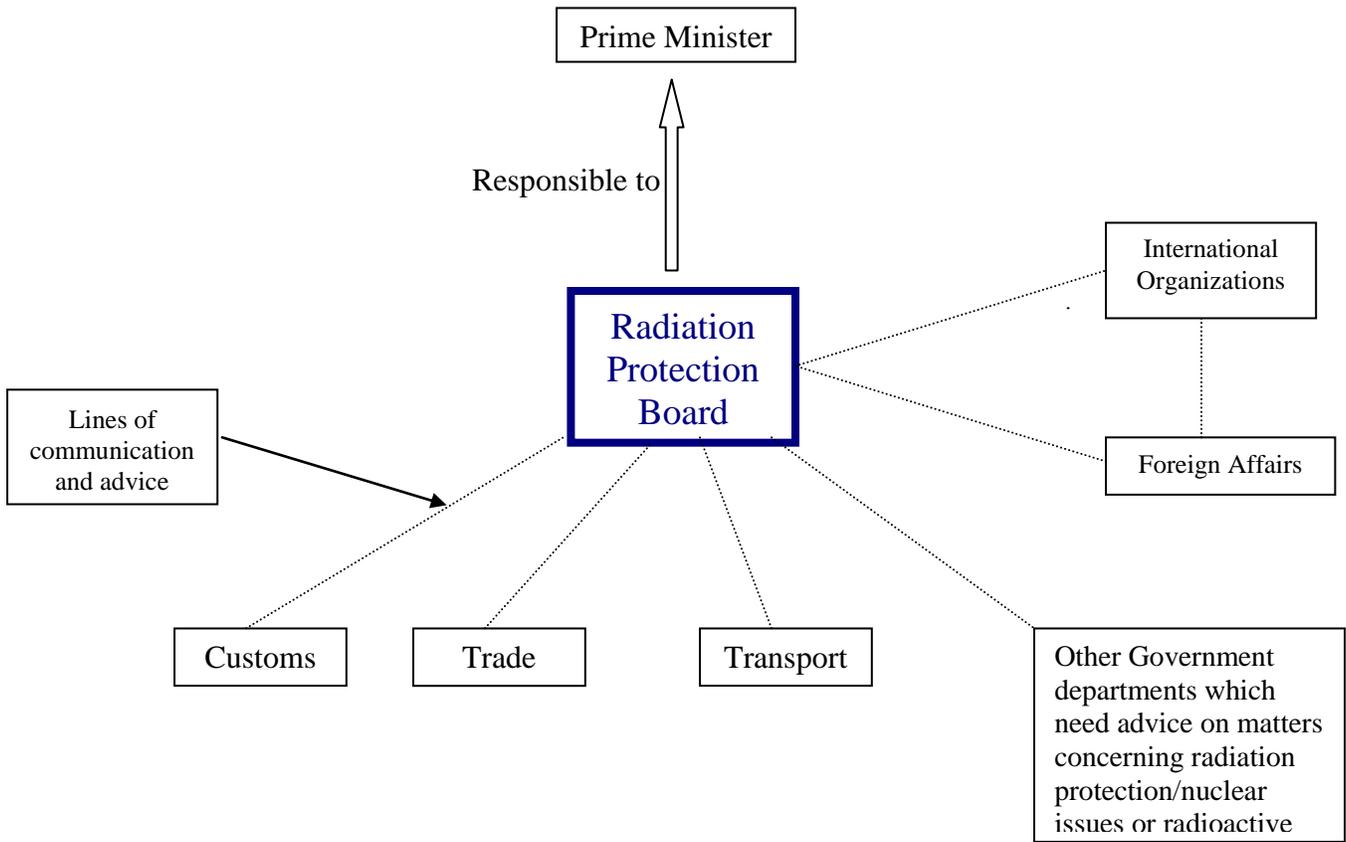


Figure 2. Position of the RPB within the governmental structures

Functions of the Radiation Protection Board

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

- 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

Following the previous Review Meetings the RPB continues the process of reviewing its operations and is in the process of creating/reviewing its operating procedures.

The objectives of these operating procedures are to further RPB's aims of achieving high levels of protection for people and the environment from ionising radiation.

In particular these 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
- Management of radioactive waste
- Control of discharges to the environment
- Transport of radioactive materials
- Regulatory control of medical establishments

Staffing of the Radiation Protection Board

Currently the core activities of the RPB are performed by two persons. Many activities are delegated to other governmental entities such as Health Ministry, the Environment and Resources Authority (falling under the responsibility of the Ministry for Sustainable Development the Environment and Climate Change) and the Civil Protection Department.

There has been no change in the staffing level (two full-time persons) of the RPB since it was created thirteen years ago.

Inspections

Announced and unannounced inspections of sites that use ionizing radiation (some 210 sites in total) are performed mainly by the core staff of the RPB. The average number of regulatory site visits averaged at approximately 85 per year over the past three years.

Since the last review meeting all medical establishments (excluding dentists) were subject to an inspection campaign and have all been issued with licenses.

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.

Monitoring of imported goods and trans-shipment goods

RPB collaborates with the Customs Department in the operation of radiation portal monitoring at the ports.

Through this monitoring several consignments of contaminated scrap metal and finished goods have been detected. The contaminated items were returned to the country of origin.

Article 9. Responsibility of the License Holder

Under Maltese legislation, the radiation employer is responsible for justification, optimization and dose limitation and taking actions in order to protect the workers, the patients, the public and the environment from risks arising from the use of ionizing radiation.

Article 10. Priority to Safety

Maltese legislation requires that radiation employers:

- Perform and update as required a radiological risk assessment.
- Seek appropriate advice as required from qualified experts.
- Have written rules in place, and ensure that these rules are adhered to.

Article 15. Radiation Protection

Maltese legislation requires that radiation doses are kept as low as is reasonably achievable.

Malta has defined national dose limits for workers and the general public as well as emergency worker guidance levels which follow the existing European Union Directive 96/29/Euratom

In the event of an emergency in Malta, the generic intervention/action levels are given in the RPB emergency operating procedures.

Article 16. Emergency Preparedness

On-site Plans

Radiation employers in terms of Maltese regulations are obliged to have in place onsite emergency procedures.

National Plan

Malta has a national radiological emergency plan. The emergency plan was completed following a radiological emergency threat assessment (using IAEA methodology).

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 has not been completed.

Resources available for emergency response

Civil Protection Department is fully equipped with field equipment and has undergone both initial training in radiological response with the assistance of the IAEA and also has undergone further training in this area as part of the national radiological, biological chemical response plan.

The Accident and Emergency Department in the main hospital in Malta, has since the last Review Meeting, been equipped with basic monitoring equipment.

Testing of emergency procedures

The last time the plan was used was in December 2013 during the recovery of buried radioactive source.

Emergency monitoring

Data capture from the Maltese gamma dose environmental monitor is managed by the Environment and Resources Authority and is sent on an hourly basis to the Civil Protection Department 24 hour response centre and to the 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.

Annex 1

Legislative

Legal Notice Number	Publication Date	Title
LN 156/2001	23-Jul-2001	Comprehensive Nuclear-Test Ban Treaty Regulations. http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=18795&l=1
LN 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
LN 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
LN 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
LN 242/2004	30-Apr-2004	Importation Control Regulations, 2004 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=16612&l=1
LN 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
LN 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
LN182/2007	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
LN 440/2007	28-Dec-2007	Convention on Nuclear Safety Regulations, 2008 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=20432&l=1
LN 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
LN 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
LN 353/2012	19-Oct-2012	<u>Medical Exposure (Ionising Radiation) Regulations, 2013</u> http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=23969&l=1
LN 186/2013	16-Jul-2013	Management of Radioactive Waste Regulations, 2013 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=12065&l=1
LN 187/2013	16-July-2013	Nuclear Safety and Radiation Protection (Amendment) Regulations, 2013 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=25197&l=1

Conventions/agreements

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

Illicit Trafficking Data Base

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

Declarations

Support Code of Conduct on the Safety and Security of Radioactive Sources.