

Council Directive 2009/71/EURATOM
Community Framework for the nuclear safety of
nuclear installations

National Report by Malta

Made in connection with Article 9.1

Introduction.....	2
Nuclear installations.....	2
Main use of ionising radiation in Malta.....	2
Applicability of the Directive to Malta.....	2
Structure of this report.	2
Summary.....	2
Article 4. Legislative, regulatory and organisational framework	3
Summary.....	4
4.1a.....	4
4.1b.....	5
4.1c,d.....	5
4.2.....	5
Article 5. Competent regulatory authority	5
5.1.....	6
5.2.....	8
5.3.....	8
Article 6. License Holder	9
Article 7. Expertise and skills in nuclear safety.....	9
Article 8. Information to the Public	10

Introduction.

Nuclear installations.

Malta does not operate, or plan to operate, any form of nuclear installation, as defined by Article 3(1) of the Directive.

The size and the population of the Maltese Islands are such that it is unlikely that there will be any nuclear installations sited within Malta.

The Maltese Government has never taken a position against nuclear power generation.

Main use of ionising radiation in Malta

The use of ionising radiation in Malta is limited to diagnostic and therapeutic medical applications and uses in industry (including non-destructive testing) as well as limited use in research and teaching.

Applicability of the Directive to Malta

In view of the fact that Malta does not have any nuclear installations, as defined in the Directive, not all of the Directive Articles are applicable to it.

Structure of this report.

The format of the report is based on ENSREG Guidelines HLG_p (2012-21)_108 with however most of the information relating to the regulation of ionizing radiation in Malta as opposed to the regulation of nuclear installations.

Summary.

There is 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 the Radiation Protection Board (RPB) which was created by a regulation, namely Legal Notice 44 of 2003.

The Maltese Islands have a small population of approximately 420,000 which means the radiation/nuclear regulatory authority, the RPB, is consequently small as well.

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

The RPB 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 is continuing to develop/update its internal procedures to ensure that all the regulatory tasks are performed as efficiently and effectively as possible.

The RPB is constantly looking to enhance its effectiveness and is currently preparing for the planned IRRS mission in 2015 by completing a thorough self assessment using the IAEA Self-Assessment of Regulatory Infrastructure for Safety (SARIS).

Article 4. Legislative, regulatory and organisational framework

Article 4:

1. Member States shall establish and maintain a national legislative, regulatory and organisational framework (hereinafter referred to as the 'national framework') for nuclear safety of nuclear installations that allocates responsibilities and provides for coordination between relevant state bodies. The national framework shall establish responsibilities for:

(a) the adoption of national nuclear safety requirements. The determination on how they are adopted and through which instrument they are applied rests with the competence of the Member States;

(b) the provision of a system of licensing and prohibition of operation of nuclear installations without a licence;

(c) the provision of a system of nuclear safety supervision;

(d) enforcement actions, including suspension of operation and modification or revocation of a licence.

2. Member States shall ensure that the national framework is maintained and improved when appropriate, taking into account operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and results of safety research, when available and relevant.

Summary

There is no dedicated Radiation/nuclear act in Malta

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)

(<http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10386&l=1>)

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.

Malta issued legal notice 440 of 2007 (Convention on Nuclear Safety Regulations, 2008) (<http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=20432&l=1>) 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. The amended regulation is legal notice 299 of 2011 : Convention on Nuclear Safety Regulations (Amendment) Regulations, 2011.

(<http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=20432&l=1>)

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)

(<http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=25196&l=1>)

was issued.

4.1a

The Radiation Protection Board prepares any legislation in connection with the ionising radiation and nuclear issues.

Once legislation is drafted it goes through a governmental procedure of vetting, which requires that relevant stakeholders are consulted.

Public consultation is also performed through the Occupational Health and Safety Authority website (<http://ohsa.org.mt/Home/Sectors/RadiationProtection.aspx>)

4.1b

Malta does not have any nuclear installations. For the use of ionizing radiation:

The RPB issues authorizations to Radiation Employers for the use of ionizing radiation by virtue of regulation 19 of Legal Notice 44 of 2003.

The use of ionizing radiation by a Radiation Employer without an Authorisation from the RPB is prohibited by Legal Notice 44 of 2003.

4.1c,d

The RPB performs inspections of facilities of Radiation Employers and has the power to take enforcement actions which includes issuing stop orders.

4.2

Malta is currently performing a self assessment (using the IAEA Self-Assessment of Regulatory Infrastructure for Safety (SARIS)).

The use of SARIS and the “full-scope” IRRS mission in 2015 is likely to lead to recommendations to improve the national framework.

Article 5. Competent regulatory authority

Article 5:

- 1. Member States shall establish and maintain a competent regulatory authority in the field of nuclear safety of nuclear installations.*
- 2. Member States shall ensure that the competent regulatory authority is functionally separate from any other body or organisation concerned with the promotion, or utilisation of nuclear energy, including electricity production, in order to ensure effective independence from undue influence in its regulatory decision making.*
- 3. Member States shall ensure that the competent regulatory authority is given the legal powers and human and financial resources necessary to fulfil its obligations in connection with the national framework described in Article 4(1) with due priority to safety. This includes the powers and resources to:*
 - (a) require the licence holder to comply with national nuclear safety requirements and the terms of the relevant licence;*

- (b) require demonstration of this compliance, including the requirements under paragraphs 2 to 5 of Article 6;
- (c) verify this compliance through regulatory assessments and inspections; and
- (d) carry out regulatory enforcement actions, including suspending the operation of nuclear installation in accordance with conditions defined by the national framework referred to in Article 4(1).

5.1

The RPB was set up as the national competent body for radiation protection and nuclear issues and was set up 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 structure of the RPB is show diagrammatically in the below figure 1.

Structure of Maltese Radiation Protection Board

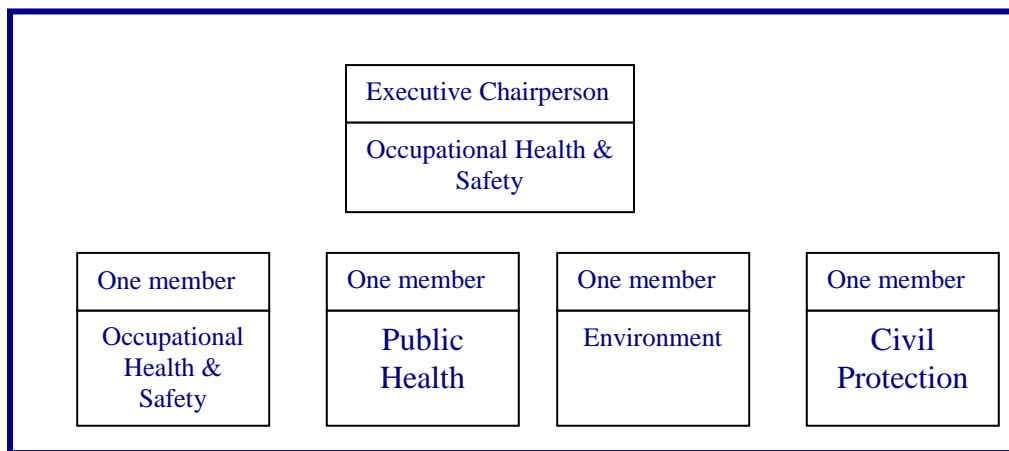


Figure 1. Internal structure of the Radiation Protection Board.

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

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

Radiation Protection Board Procedures

The RPB is in a process of creating and reviewing its operational 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
- Medical Regulation Enforcement

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 100 per year over the past three years.

5.2

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

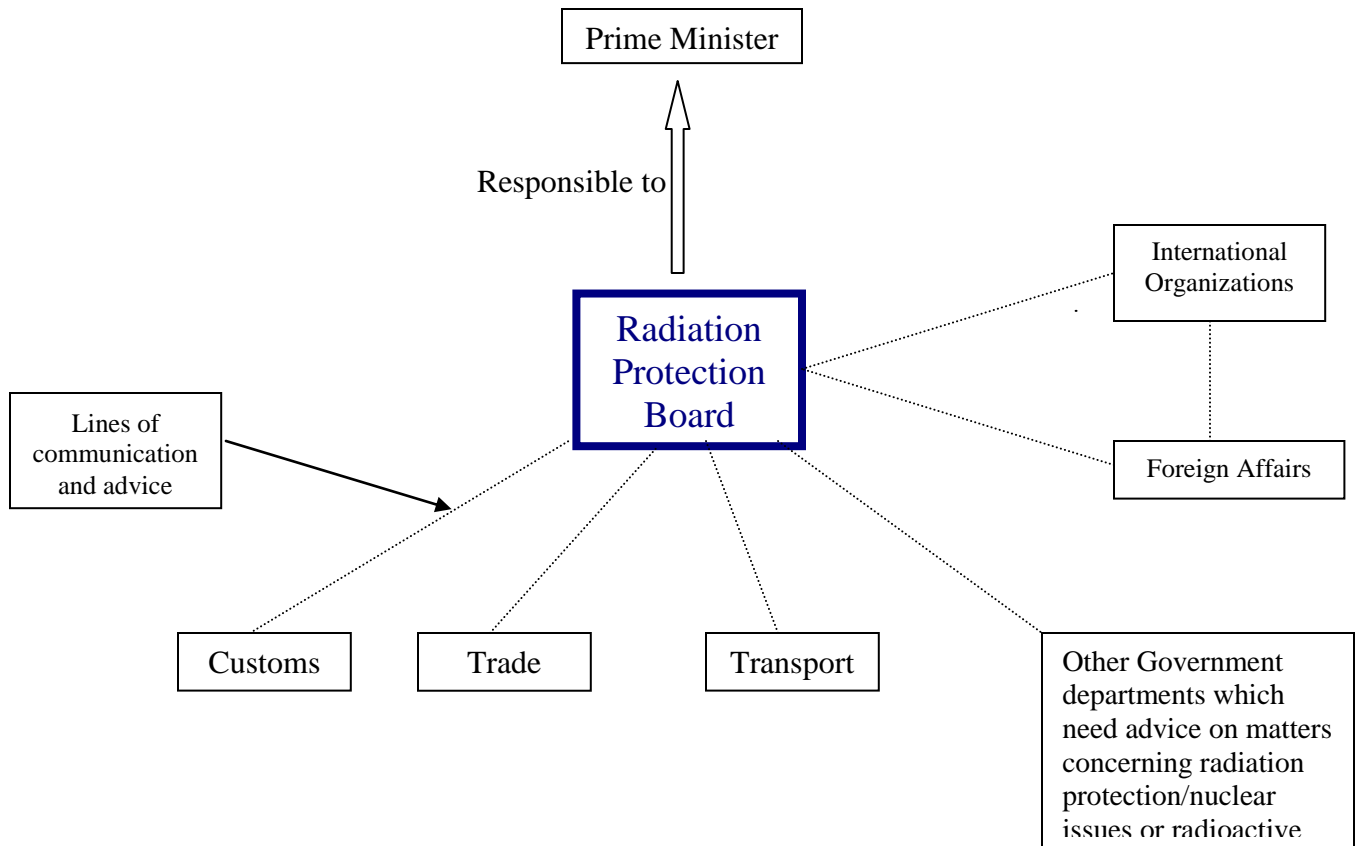


Figure 2. Position of the RPB within the governmental structures

5.3

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

Currently the core activities of the RPB are performed by just two persons. Many activities are delegated to other governmental entities such as Health Ministry, Environment Ministry and the Civil Protection Department.

Technical Service Organizations (TSOs)

Owing to the small size of Malta , TSOs from overseas are used for such services as

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

Article 6. License Holder

Article 6:

- 1. Member States shall ensure that the prime responsibility for nuclear safety of a nuclear installation rests with the licence holder. This responsibility cannot be delegated.*
- 2. Member States shall ensure that the national framework in place requires licence holders, under the supervision of the competent regulatory authority, to regularly assess and verify, and continuously improve, as far as reasonably achievable, the nuclear safety of their nuclear installations in a systematic and verifiable manner.*
- 3. The assessments referred to in paragraph 2 shall include verification that measures are in place for prevention of accidents and mitigation of consequences of accidents, including verification of the physical barriers and licence holder's administrative procedures of protection that would have to fail before workers and the general public would be significantly affected by ionizing radiations.*
- 4. Member States shall ensure that the national framework in place requires licence holders to establish and implement management systems which give due priority to nuclear safety and are regularly verified by the competent regulatory authority.*
- 5. Member States shall ensure that the national framework in place requires licence holders to provide for and maintain adequate financial and human resources to fulfil their obligations with respect to nuclear safety of a nuclear installation, laid down in paragraphs 1 to 4.*

Malta does not have any nuclear installation license holders.

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.

Article 7. Expertise and skills in nuclear safety

Article 7:

Member States shall ensure that the national framework in place requires arrangements for education and training to be made by all parties for their staff having responsibilities relating to the nuclear safety of nuclear installations in order to maintain and to further develop expertise and skills in nuclear safety.

The below information is in connection with the use of ionising radiation as opposed to nuclear installations

Radiation Employers

Radiation employers have a duty under regulation 29 of Legal Notice 44 of 2003 requires that “*exposed workers, apprentices and students who, in the course of their work or studies are obliged to use sources, are given suitable and sufficient information, instruction and training*”

RPB

There is no system in place yet

Article 8. Information to the Public

Article 8:

Member States shall ensure that information in relation to the regulation of nuclear safety is made available to the workers and the general public. This obligation includes ensuring that the competent regulatory authority informs the public in the fields of its competence. Information shall be made available to the public in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.

All of the following is available in the English Language

General information on ionising radiation is made available on the Radiation Section of the Occupational Health and Safety Authority web-site. <http://ohsa.org.mt/Home/Sectors/RadiationProtection.aspx>. This location is also used for posting documents for public consultation.

Annual information on the activities can also be located within the Occupational Health and Safety Authority Activity Reports (<http://ohsa.org.mt/Home/UsefulInformation/Reports.aspx>)

Radiation Protection/Nuclear Legal Notices can also be found on the OHSa website (<http://ohsa.org.mt/Home/Legal/RadiationProtectionLegalNotices.aspx>)

In the event of a radiological emergency information to the public would be provided by the Civil Protection Department as required by legal notice 245 of 2002 Radiological Emergency (Information to the Public) Regulations, 2002
<http://docs.justice.gov.mt/lom/Legislation/English/SubLeg/411/02.pdf>