

Convention on Nuclear Safety

National Report by Malta for the 9th Review Meeting

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

Contents

List of Acronyms and Abbreviations	2
Introduction	2
Background	2
Malta's position with respect to nuclear issues.....	3
Usage of ionizing radiation in Malta	3
Applicability of Convention to Malta	3
Summary	4
Regulatory Framework	4
Regulatory Body	4
Emergency Preparedness	5
IRRS missions to Malta	5
Implementation of Challenges and Suggestions from the 7 th Review meeting	7
Article by Article Review	8
Article 7. Legislative and regulatory framework	8
Article 8. Regulatory Body	12
Article 9. Responsibility of the License Holder.....	17
Article 10. Priority to Safety	18
Article 15. Radiation Protection	18
Article 16. Emergency Preparedness	19
Questions from 8 th Review meeting with updated answers	21
General	21
Article 7	22
Article 8	23
Article 10	23
Article 16	24
Annexes.....	27
National Legislation.....	27
Treaties, Conventions & Agreements Malta is party to.....	28
Incident and Trafficking Data Base	28
Code of Conduct on the Safety and Security of Radioactive Sources.....	28

List of Acronyms and Abbreviations

BSS	Basic Safety Standards
EU	European Union
EURDEP	European Radiological Data Exchange Platform
IAEA	International Atomic Energy Agency
IRRS	Integrated Regulatory Review Service
ITDB	IAEA Incident and Trafficking Data Base
RB	Regulatory Body
Commission	Commission for the Protection from Ionising and Non-Ionising Radiation
Convention	Convention on Nuclear Safety

Introduction

Background

Malta became Party to the Convention on Nuclear Safety (hereinafter referred to as the Convention) in 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.

Malta is a member state of the European Union (EU) and therefore is required to comply with the requirements of the Euratom Treaty.

Since the last Seventh Review Meeting Malta has made significant progress in improving its legislative and regulatory framework. Following the IRRS review mission to Malta in 2015 and the follow-up mission in 2020, Malta has issued a new nuclear safety and radiation law as well as regulations falling under this law.

This report gives the status of Malta's response to the challenges and the suggestions that were identified at the Seventh review meeting of the Convention.

This report has included an additional section with updated answers to questions raised by the Maltese report for the Eighth review meeting.

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 any 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 reactor to Malta is Krško Nuclear Power Plant in Slovenia which is 1100 km away.

Usage 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, the following articles: 11, 12, 13, 14, 17, 18 and 19 have not been included in this report in view that as they deal with nuclear installations.

Summary.

Regulatory Framework

Since the last Seventh review meeting, Malta has been working on the findings of the IRRS mission in 2015 and the follow-up IRRS mission of 2020. Malta's focus was initially on the reform of its legislative and regulatory framework and to this end the following new legislative instruments being enacted:

Nuclear Safety and Radiation Protection Act (published 2018)

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

Basic Safety Standards for Ionising Radiation Regulations (published 2018)

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

Nuclear Safety Regulations (published 2018)

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

Management of Radioactive Waste Regulations(published 2019)

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

Commission for the Protection from Ionising and Non-Ionising Radiation Regulations (published 2021)

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

A new regulatory body (RB) was set up in accordance with the Nuclear Safety and Radiation Protection Act called **Commission for the Protection from Ionising and Non-Ionising Radiation** (Commission)

Regulatory Body

The RB for Malta is the Commission for the Protection from Ionising and Non-Ionising Radiation (Commission). The Commission has a Secretariat with four full-time technical staff. The Secretariat is the executive branch of the Commission.



Mission Statement	To allow and regulate the beneficial and justified uses of ionising and non-ionising radiation for the well-being of the population and the environment.
Vision Statement	A culture that allows for the beneficial uses of radiation, safely.

The website of the Commission <https://rpc.gov.mt/>

The Commission is further developing its management system to ensure that all the regulatory tasks are performed as efficiently and effectively as possible.

The Commission is solely funded from central government through the Ministry for Inclusion, Voluntary Organisations and Consumer Rights.

Emergency Preparedness

The national radiological hazard assessment was revised in January 2020 and the national emergency plan was revised (using terminology of GSR Part 7). These were approved in August 2020.

The Commission is working with other governmental entities to include radiological emergency procedures into national Chemical, Biological, Radiological, Nuclear (CBRN) response.

IRRS missions to Malta

Malta hosted an IRRS mission in 2015, the full report can be accessed at: <https://rpcems.gov.mt/en/Documents/IRRS%20Report%20Initial%20Mission%202015.pdf>

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.

Malta hosted an IRRS follow-up mission in 2020, the full report can be accessed at: <https://rpcems.gov.mt/en/Documents/IRRS%20Report%20follow%20up%20Mission%202020.pdf>

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

- *“The IRRS team noted that the Maltese Government and the Commission showed a strong commitment to radiation safety.*
- *Since 2015, the Government has enacted a new nuclear safety and radiation protection law, established a new regulatory body and increased the Commission’s budget for regulatory oversight.*
- *Since 2015, the Commission has made good progress in establishing its management system. Since 2015, the Commission has made a number of achievements in the following areas:*
 - *Issue of new regulations in line with the international safety standards;*
 - *Establishing a management system including processes implemented in accordance with a graded approach for the authorization of facilities and activities;*
 - *Establishing processes for drafting, adopting, promoting and amending regulations and guides;*
 - *Establishing a national emergency preparedness and response system.*
- *The Commission is encouraged to continue its efforts to:*
 - *Recruit new staff and develop its Human Resources Plan for staff training and knowledge management;*
 - *Establish means of communication and consultation with interested parties;*
 - *Complete and fully implement its management system;*
 - *Establish procedures for review and assessment for all facilities and activities taking into consideration the graded approach;*
 - *Develop and implement an inspection programme taking into consideration the graded approach.*
- *The IRRS team also offered two new recommendations for the Commission’s consideration:*
 - *Establish, based on a graded approach, the regulatory requirements for emergency preparedness and response for licensees, covering all relevant general, functional and infrastructural elements;*
 - *Ensure that diagnostic reference levels for medical exposures incurred in medical imaging, including image guided interventional procedures are established.”*

Implementation of Challenges and Suggestions from the 7th Review meeting

The challenges identified and suggestion from the 7th review meeting were

Challenge 1: Enabling the new Act and incorporating existing regulations under the new Act. (new)

Action taken: The Nuclear Safety and Radiation Protection Act came into force during 2018 and regulations were issued under the Act.

Challenge 2: Attracting experienced additional employees to the RPB. (new)

Challenge 3: Lack of human resources.

Action taken: Two new Radiation Officers were employed with the Secretariat of the Commission, The Secretariat currently consists of :

- Executive Secretary
- Operations and Quality Manager
- Two Radiation Officers

Suggestion 1: Malta to join to the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency

Action taken: Discussed by Commission but no final decision taken to date.

Article by Article Review

Article 7. Legislative and regulatory framework

Article 7 (1)

7(1) Each Contracting Party shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations.

The below table lists the legislative and regulatory instruments enacted since the last review meeting.

Reference	Title
CAP 585	Nuclear Safety and Radiation Protection Act
SL 585.01	Basic Safety Standards for Ionising Radiation Regulations
SL 585.02	Nuclear Safety Regulations
SL 585.03	Management of Radioactive Waste Regulations Maltese National Radioactive Waste Management Policy
SL 585.04	Commission for the Protection from Ionising and Non-Ionising Radiation Regulations

The complete list of legislative and regulatory instruments is contained within the Annex.

Nuclear Safety and Radiation Protection Act

In 2018 a new law was enacted, entitled the Nuclear Safety and Radiation Protection Act (CAP 585) henceforth referred to as the Act.

The scope of the Act is given in Article 2 of the Act and is reproduced below:

“ (1) *The scope of this Act is to:*

- (a) allow the beneficial and justified uses of ionising and non-ionising radiation;*
- (b) 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;*
- (c) provide for the physical protection of nuclear material;*
- (d) provide a mechanism whereby these objectives are achieved through the establishment of a Radiation Protection Commission and its Secretariat hereinafter referred to as the "Commission" and "Secretariat", to act as the competent national authority in the field of nuclear safety and radiation protection.*

(2) *Notwithstanding the provisions of sub-article (1), this Act shall apply to:*

- (a) the programmed safe management of radioactive waste;*
- (b) conditions for the security of the ionising radiation sources;*

(c) the implementation of the requirements, including but not only, the enactments of any act or regulation, required to give effect to any treaty, convention or protocol related to the ionising radiation, nuclear safety and security related international legal instruments which the Government accedes and ratifies;

(d) equipment, articles and non-nuclear material specified for the reporting of exports and imports according to Article 2(a)(ix) of the Additional Protocol: Provided that this Act shall not apply to activities or practices involving exposures that have been excluded from regulatory control.

(3) Without prejudice to the generality of this article the aim of this Act is also to introduce preventive and protective measures of control of detrimental human exposure to non-ionising radiations against known or otherwise anticipated biological effects that have a detrimental effect on mental, physical and, or general well-being of exposed people, either in the short term or long term from any facility or equipment emitting such fields.”

To date four regulations have been published under the Act (refer to next section of this report). The Commission will continue the process of transferring other regulations, enacted before the Act came into force, on radiation and nuclear issues to fall under the Act.

Article 7 (2)(i)

The legislative and regulatory framework shall provide for:

(i) the establishment of applicable national safety requirements and regulations;

To date the following four regulations have been introduced under the Act

- Basic Safety Standards for Ionising Radiation Regulations (BSS Regulations)
- Nuclear Safety Regulations
- Management of Radioactive Waste Regulations
- Commission for the Protection from Ionising and Non-Ionising Radiation Regulations

The complete list of all legislative instruments is given within in the Annex

Basic Safety Standards for Ionising Radiation Regulations

The Basic Safety Standards regulation transposes Malta’s obligation under the EU BSS Directive 2013/59/Euratom

The subject matter and scope of the Basic Safety Standards (BSS) Regulations are given in regulation 2 as:

References

- *Regulation 2 of the BSS Regulations*

Nuclear Safety Regulations

The Nuclear Safety Regulations 585.02 transposes Malta's obligation under the Convention as well as the obligations under the EU nuclear safety directive 2014/87/Euratom.

The Objectives and scope are given in regulations 2 and 3 as:

“2. The objectives of these regulations o:

(a) support the European Union an international effort to achieve and maintain a high level of nuclear safety worldwide through national measures and international co-operation;

(b) to ensure that national arrangements are in place to protect workers, the general public and the environment against potential radiological hazards from nuclear facilities.

3. (1) This regulation:

(a) shall apply to the safety of nuclear facilities;

(b) supplements the Act and Basic Safety Standards for Ionising Radiation Regulations, as regards the nuclear safety of nuclear facilities.”

Management of Radioactive Waste Regulations

The Management of Radioactive Waste Regulations 585.03 transposes Malta's obligation under the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management as well as the obligations under the EU waste directive 2011/70/Euratom.

The scope of the Radioactive Waste Regulations is given in regulation 2 as:

“ (1) The objective of these regulations is to ensure that radioactive waste is managed in a manner that protects human health and the environment now and, in the future, without imposing undue burdens on future generations.

(2) These regulations:

(a) provide the arrangements for safety in radioactive waste management to protect workers and the general public against the dangers arising from ionising radiation;

(b) apply to all stages of: radioactive waste management, from generation to disposal, when the radioactive waste results from civilian activities;

(c) provide for the necessary public information and participation in relation to radioactive waste management while having due regard to security and proprietary information;

(d) bring into effect the provisions of Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste and the International Atomic Energy Agency's Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management; and

(e) provide additional measures, procedures and guidance to those mentioned in Basic Safety Standards for Ionising Radiation Regulations.”

Article 7 (2)(ii)

The legislative and regulatory framework shall provide for:

(ii) a system of licensing with regard to nuclear installations and the prohibition of the operation of a nuclear installation without a licence;

Undertakings are required by the Act and the BSS regulations to notify the Commission to request an authorisation. The authorisation may take the form of a licence or registration.

References:

- *Article 15, 16 of the Act*
- *Regulation 32-39 of BSS Regulations*

Any person who fails to comply with any provisions of the Act or its regulations shall be guilty of an offence.

References

- *Article 21 of the Act*

Article 7 (2)(iii)

The legislative and regulatory framework shall provide for:

(iii) a system of regulatory inspection and assessment of nuclear installations to ascertain compliance with applicable regulations and the terms of licences;

The Act gives the authority to the Secretariat of the Commission to conduct announced and unannounced inspections. The number of physical inspections performed prior to COVID was around 80 per year. During COVID only a limited number of inspections were performed . In the period January to June 2021 49 inspections were performed.

References

- *Article 19(1) of the Act*

Article 7 (2)(iv)

The legislative and regulatory framework shall provide for:

(iv) the enforcement of applicable regulations and of the terms of licences, including suspension, modification or revocation.

The Act gives the power of enforcement to the Secretariat of the Commission

References

- Article 19(1) of the Act

Article 8. Regulatory Body

Article 8 (1)

1. Each Contracting Party shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework referred to in Article 7, and provided with adequate authority, competence and financial and human resources to fulfil its assigned responsibilities.

The RB for Malta is the Commission for the Protection from Ionising and Non-Ionising Radiation (Commission), which was set up by virtue of Article 10 of the Act which states:

“(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.

(4) The Commission shall consist of a Non-Executive Chairperson, a Deputy Chairperson, and not more than nine members.

(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.

(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.”

The Commission held a total of 40 meetings in the period October 2018 to end June 2022.

The executive functions of the regulatory body are performed by the Secretariat of the Commission. The Secretariat functions are given in Article 12 of the Act: -

“(1) There shall be set up the Secretariat for the Commission, hereinafter referred to as "the Secretariat", which shall act as the executive of the regulatory authority in the field of nuclear safety and radiation protection.

(2) The Secretariat shall have such functions as may devolve on it under any other law or as may be assigned to in writing by the Minister. In the case that other regulations are in force governing occupational, public and medical exposures, or environmental protection and safety of sources, which in some way address the uses of ionising radiation or non-ionising radiation, or any other substance the use or exposure of which is regulated by this Act, the Secretariat shall recommend to the Commission, if it considers it necessary, to make recommendations to the Minister for the reallocation of the regulatory responsibility to the Secretariat itself or to some other authority as the Secretariat after consultation with the Commission deems fit.

(3) It shall be the function of the Secretariat to:

(a) issue authorizations and grant exemptions concerning the possession and use of radiation sources;

(b) inspect, monitor and assess activities and practices for the purpose of verifying compliance with this Act, applicable regulations and the terms and conditions of authorizations and, or licences;

(c) maintain a national register of radiation sources and a national register of undertakings;

(d) 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;

(e) establish and maintain a national system of accounting for and control of nuclear material and a national system for the registration of licences for nuclear material, and to establish the necessary reporting and record keeping and requirements pursuant to the Safeguards Agreement, and Additional Protocol;

(f) develop the necessary strategies for the implementation of the objectives of the Commission;

(g) advise the Commission on any matter it may refer or on any matter which is considered necessary or expedient; and any such duties as the Commission may assign from time to time;

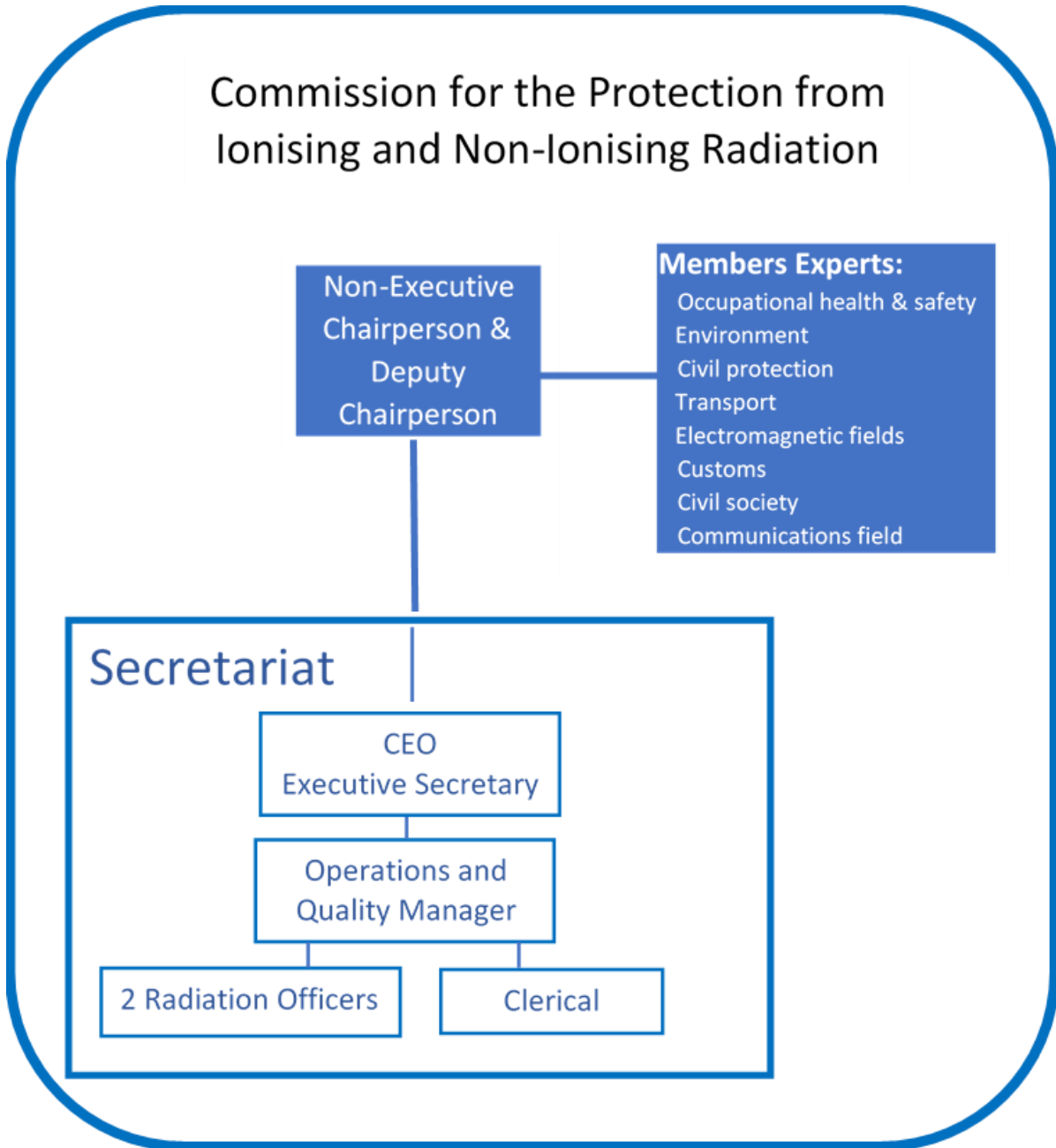
(h) provide technical advice to the Minister or other governmental entities; and

(i) conduct any other functions that are deemed necessary by the Commission, to protect people and the environment of Malta.

(4) Without prejudice to the other provisions of this Act and to any regulations made thereunder, the Secretariat shall, following consultation with the Commission, adopt rules of procedure which shall regulate every stage of its operations.

(5) The Secretariat shall be responsible for keeping the proceedings referred to in article 12(3) and also a register wherein the findings and rulings of the Secretariat shall be entered.”

The Commission organogram is shown below.



The Chairpersons and the member experts discuss the establishment of policies and strategies to be followed by the Secretariat. The Chairpersons and the member experts of the Commission meet frequently. The Commission also has set up separate working groups on the following:

- Legal personality of the Commission
- Radon
- Approval criteria for Medical Physics Experts and Radiation Protection Experts
- Diagnostic reference levels for medical exposures
- Education and training
- Environmental monitoring for radioactivity

The Commission has employed the following full-time staff for the Secretariat:

- Executive Secretary
- Operations and Quality Manager
- 2 Radiation Officers

The Secretariat continues to work on the development of its management system and has acquired the latest version of the RAIS software.

Article 8 (2)

2. Each Contracting Party shall take the appropriate steps to ensure an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy.

The Act created Commission as an effectively independent regulatory body that has functional separation from entities having responsibilities or interests that could unduly influence its decision-making.

The Commission independence is guaranteed in that:

(a) Commission position in government structure

The definition of the Minister given in the Act states that the Minister must not have any responsibilities with regard to the use of ionising radiation.

References

- *Article 3 definition of Minister of the Act*

The Commission currently falls under the Ministry for Inclusion, Voluntary Organisations and Consumer Rights (<https://inclusion.gov.mt/?lang=en>) which does not have any responsibilities with regard to the use of ionising radiation.

(b) Independence of members of Commission

The Minister appoints the Chairperson, Deputy Chairperson, Executive Secretary and members of the Commission.

The Act states that no members of the Commission shall be responsible for the use of any form of ionising radiation.

References

- *Article 10(5), 10(6) 13(1) of the Act*

(c) Financial independence of Commission

Financial independence is guaranteed by Article 61 of the Act:

“ (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.”

Article 9. Responsibility of the License Holder

Each Contracting Party shall ensure that prime responsibility for the safety of a nuclear installation rests with the holder of the relevant licence and shall take the appropriate steps to ensure that each such licence holder meets its responsibility.

Both the Act and the BSS regulations place the prime responsibility for the safety and security of ionising and non-ionising radiation sources with the undertaking:

References

- *Article 5 of the Act*
- *Regulation 5(3) of BSS Regulations*

Article 10. Priority to Safety

Each Contracting Party shall take the appropriate steps to ensure that all organizations engaged in activities directly related to nuclear installations shall establish policies that give due priority to nuclear safety.

The principle that the undertaking has the prime responsibility for safety and security is given in the Act.

References

- *Article 5 and 18 of the Act*
- *Regulation 5(3) of BSS Regulations*

Further obligations of the undertaking with regard to implementing a radiation protection programme and ensuring adequate training is given in Article 25 of the Act

“(1) All undertakings shall implement an appropriate radiation protection programme.

(2) Undertakings shall ensure that only workers who have undergone adequate radiation protection training, including the use of related equipment used in the course of their employment, shall carry out work with radiation sources or in radiation environments.”

Article 15. Radiation Protection

Each Contracting Party shall take the appropriate steps to ensure that in all operational states the radiation exposure to the workers and the public caused by a nuclear installation shall be kept as low as reasonably achievable and that no individual shall be exposed to radiation doses which exceed prescribed national dose limits.

Dose constraints and dose limits for workers and the public are specified in the BSS regulations. The undertaking has the responsibility to ensure compliance with dose constraints and dose limits.

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

References

- *Regulation 6-13 of BSS Regulations*

Article 16. Emergency Preparedness

1. Each Contracting Party shall take the appropriate steps to ensure that there are on-site and off-site emergency plans that are routinely tested for nuclear installations and cover the activities to be carried out in the event of an emergency

For any new nuclear installation, such plans shall be prepared and tested before it commences operation above a low power level agreed by the regulatory body.

2. Each Contracting Party shall take the appropriate steps to ensure that, insofar as they are likely to be affected by a radiological emergency, its own population and the competent authorities of the States in the vicinity of the nuclear installation are provided with appropriate information for emergency planning and response.

3. Contracting Parties which do not have a nuclear installation on their territory, insofar as they are likely to be affected in the event of a radiological emergency at a nuclear installation in the vicinity, shall take the appropriate steps for the preparation and testing of emergency plans for their territory that cover the activities to be carried out in the event of such an emergency.

National Plan

Article 31 of the Act requires that the Secretariat maintains a national radiological emergency plan. Article 31 states:

“ A national emergency plan for responding to potential nuclear or radiological emergencies shall be developed and maintained by the Secretariat in conjunction with the Commission and approved by the Minister, after consultation with the Commission and other Ministers, if the Minister believes that their consultation is necessary to fulfil his functions under this Act.”

Malta updated its national radiological emergency plan in August 2020. The emergency plan was completed following a hazard assessment in January 2020.

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.

- 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 yet.

Resources available for emergency response

The 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.

On-site Plans

Article 30 of the Act requires undertakings to have in place onsite emergency procedures.

“No licence to conduct an activity or practice, operate a facility, or possess or use a source may be granted unless and until an appropriate emergency preparedness and response plan has been developed by the applicant and reviewed by the Secretariat.”

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 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.

In the event of a radiological emergency the public would receive information from the Commission

Questions from 8th Review meeting with updated answers

This section includes the questions raised in response to the Maltese report for the 8th Review meeting along with answers updated as of July 2022.

General

Question from Jordon following the 8th Review meeting report

“There is no mention about the management of radioactive waste resulted from ionizing radiation application , just there is a regulation to regulate these activities without determine if there is a facility inside the country or not.”

Answer to question as of July 2022:

Malta has small limited amount of radioactive material that needs to be managed as waste. Malta has a centralised radioactive waste storage facility which is licensed by the Commission. Malta does not have a radioactive waste disposal facility.

The Scope of the Management of Radioactive Waste Regulations is given on page 9 of the report for the 9th Review Meeting.

Malta reports on radioactive waste management under the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. Reports are available: <https://rpc.gov.mt/en/Pages/Reports.aspx>

Question from Jordon following the 8th Review meeting report

“Determine the period needed to recruitment a new employees, because there is a lack of human resources and even though there is 2-full time personnel existing in the radiation protection section, it is necessary to provide a qualifies staff in case of one of the existing employee leave the work in radiation protection section and other sections?”

Answer to question as of July 2022:

The Government is aware of the need for the employment of extra staff for the Secretariat of the Commission. Two Radiation Officers have been

employed: one in October 2021, one in March 2022. The new recruits are undergoing in-house and overseas training.

Question from UK following the 8th Review meeting report

“During the 7th Convention meeting a challenge was identified for Malta to employ additional experienced employees to the regulatory body. The report states that a human resources plan has been drawn up but does not provide details. Please provide further details of this human resources plan.”

Answer to question as of July 2022:

The Government is aware of the need for the employment of extra staff for the Secretariat of the Commission. Two Radiation Officers have been employed: one in October 2021, one in March 2022. The new recruits are undergoing in-house and overseas training.

Article 7

Question from USA following the 8th Review meeting report

“Has Malta experienced any challenges or identified any lessons-learned as a result of the implementation of the legislative and regulatory changes made since 2018?”

Answer to question as of July 2022:

The main challenge has been that the legislative review, along with the IRRS process, created a greater workload for the staff of the Secretariat of the Commission.

The lack of human resources of the Commission has been acknowledged by the Government and as a consequence two Radiation Officers have been employed.

Question from USA following the 8th Review meeting report

“The United States commends Malta on the significant progress made in reforming its legislative and regulatory framework since the previous meeting.”

Answer to question as of July 2022:

We thank the United States for their comment. The effort put into the legislative review is certainly worth it as we have ended up with an independent regulatory body and better regulations.

Article 8

Question from Jordan following the 8th Review meeting report

“What are the responsibilities of Clerical?”

Answer to question as of July 2022:

Currently there is no staff dedicated to clerical issues. The Clerical staff, when engaged, will carry out the daily non-technical administrative responsibilities, such as answering phones, taking messages, handling mail and scheduling appointments, scanning, making copies, data entry. Filing etc., office reception. Currently this is being done by existing staff

Question from Jordan following the 8th Review meeting report

“Could you please give examples about non-ionizing radiation applications?”

Answer to question as of July 2022:

The Commission body is tasked with the regulation of both ionizing and non-ionizing radiation. As is the case in other countries there are varied uses of non-ionising radiation in Malta. Non-ionizing radiation falls outside the scope of this Convention report.

Article 10

Question from Slovakia following the 8th Review meeting report

“How is the safety culture applied at the Regulatory Body?”

Answer to question as of July 2022:

The Commission is committed within its management system to foster a safety culture and behavioural expectations mainly by encouraging staff to have a questioning attitude and discourage complacency when it comes to safety related issues.

From the management system the Commission is bound to:

- (a) Actively seek information on performance of its staff within their area of responsibility and demonstrating commitment to improving performance;
- (b) Development of individual and institutional values and expectations;
- (c) Ensuring that staff actions serve to encourage the reporting of safety related problems, to develop questioning and learning attitudes, and to correct acts or conditions that are averse to safety
- (d) Shall encourage and support all individuals in achieving safety goals and performing their tasks safely;
- (e) Shall engage all individuals in enhancing safety performance;

To aid reaching these safety culture goals:

- Weekly planning meeting (of all members of staff) agenda carries safety issues as the first item for discussion;
- Every 3 months there is one on one performance review between staff and the senior management.

Article16

Question from Slovakia following the 8th Review meeting report

“Regarding the national emergency plan of Malta, how often exercises at national level are conducted?”

Answer to question as of July 2022:

There have been no recent national level exercises.

Question from UK following the 8th Review meeting report

“The report discusses the legal dose limits for Malta as defined in regulations and compliance with these. However no discussion is made of reducing doses as low as reasonably achievable. Please provide details of how Malta ensures that radiation doses are kept as low as reasonably achievable.”

Answer to question as of July 2022:

The question does not appear to be directly related directly to Article 16 of the Convention.

There is the general requirement for the optimisation in that Article 7 of the Act as well as regulation 5(1)(b) of the BSS requires that doses are kept as low as is reasonably achievable.

The level of regulatory compliance is assessed by the Commission during inspections and review of the annual occupational dose records that are submitted to the Commission.

Question from Mexico following the 8th Review meeting report

“Has the staff of the regulatory body of Malta participated in the exercises and drills of Nuclear and / or Radiological Emergency Plans of neighbouring countries?”

Answer to question as of July 2022:

Malta is an island with the nearest NPP over 1000km away.
Malta has not participated in any exercises or drills in other countries.

Question from Mexico following the 8th Review meeting report

*“In the event of a Radiological Emergency in Europe:
a. Does the Maltese government have the technological and human resources to measure the concentration of radionuclides in the environment, and with them to estimate the internal and external dose in the population?*

b. Are their specific actions to be carried out according to the National Radiological Emergency Plan?”

Answer to question as of July 2022:

(a) Malta has real time capabilities for measuring low volume air particulate samples. Through Malta’s environmental monitoring plan, Malta collects high volume air particulate samples, food, water, milk, soil and seawater but these need to be sent overseas for analysis.

(b) The National Radiological Emergency Plan makes provision for increased monitoring of the environment in emergency situations.

Question from Mexico following the 8th Review meeting report

“In the hypothetical event of a Radiological Emergency in Europe, at the nearest nuclear power plant or another, does the Maltese government have technical analyses to estimate the radiological consequences in the country?”

Answer to question as of July 2022:

Malta is an island with the nearest NPP over 1000km away .

Malta has limited capability to make detailed assessments and therefore would likely need assistance in detailed analysis on the radiological consequences.

Annexes

National Legislation

Reference	Date	Title
S.L. 365.11	23-Jul-2001	Comprehensive Nuclear-Test Ban Treaty Regulations. https://legislation.mt/eli/sl/365.11/eng/pdf
S.L. 365.15	28-Jan-2003	Nuclear Safety and Radiation Protection Regulations, 2003 https://legislation.mt/eli/sl/365.15/eng/pdf
S.L.117.14	30-Apr-2004	Importation Control Regulations, 2004 https://legislation.mt/eli/sl/117.14/eng/pdf
S.L. 365.12	20-Sep-2004	Dual-use Items (Export Control) Regulations, 2004 https://legislation.mt/eli/sl/365.12/eng/pdf
S.L. 365.20	10-Jul-2007	Treaty on the Non-Proliferation of Nuclear Weapons (Euratom Safeguards and Additional Protocol) Regulations, 2007 https://legislation.mt/eli/sl/365.20/eng/pdf
S.L. 549.51	13-Feb-2009	Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations, 2009 https://legislation.mt/eli/sl/549.51/eng/pdf
CAP 585	25-May-2018	Nuclear Safety and Radiation Protection Act https://legislation.mt/eli/cap/585/eng
S.L. 585.01	3-Jul-2018	Basic Safety Standards for Ionising Radiation Regulations https://legislation.mt/eli/sl/585.1/eng
S.L. 585.02	15-July-2018	Nuclear Safety Regulations. https://legislation.mt/eli/sl/585.2/eng
S.L. 585.03	18-Jun-2018 14-Jun-2022	Management of Radioactive Waste Regulations https://legislation.mt/eli/sl/585.3/eng Radioactive Waste Management Programme https://rpc.gov.mt/en/Documents/Doc%20058_001%20Rad%20Waste%20Man%20Prog.pdf
S.L. 585.04	11-Jun-2021	Commission for the Protection from Ionising and Non-Ionising Radiation Regulations https://legislation.mt/eli/sl/585.4/eng

Treaties, Conventions & Agreements Malta is party to

Title	
Comprehensive Nuclear-Test Ban Treaty	Ratification 23-Jul-2001
Convention on the Physical Protection of Nuclear Material	Entry into force 15 Nov 2003
Euratom Treaty	Entry into force 1 May 2004
Amendment to the Convention on the Physical Protection of Nuclear Material	Acceptance 16-Dec-2013
Agreement between the European Atomic Energy Community, its non-nuclear weapon Member States and the IAEA	Entry into force 1-Jul-2007
Convention on Nuclear Safety	Entry into force 13-Feb-2008
Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management	Entry into force 15-Dec-2013

Incident and Trafficking Data Base

Malta joined the IAEA Incident and Trafficking Data Base in 2009

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

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