MALTA

Report for the 10th Review Meeting of the Convention on Nuclear Safety

Convention on Nuclear Safety

10th Malta National Report, 2025

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LIST OF ABBREVIATIONS

Term	Meaning, definition
ALARA	As low as reasonably achievable
ARTEMIS	Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation
CNS	Convention on Nuclear Safety
Commission	Commission for the Protection from Ionising and Non-Ionising Radiation
CSF	Centralised Storage Facility
CP	Contacting Party
CPD	Civil Protection Department
CAP585	Nuclear Safety and Radiation Protection Act
ERA	Environmental and Resources Authority
EU	European Union
IAEA	International Atomic Energy Agency
IRRS	Integrated Regulatory Review Service
ITDB	IAEA Incident and Trafficking Data Base
NR	National Report
RPB	Radiation Protection Board (previous regulatory body)
RM	Review Meeting
SL	Subsidiary Legislations
SL585.01	Basic Safety Standards for Ionising Radiation Regulations

INTRODUCTION

Malta became a Contacting Party (CP) to the Convention on Nuclear Safety (CNS) in 2008.

Malta does not have any nuclear power plants, research reactors, nuclear fuel-cycle activities, or any facility producing radioactive material.

Malta does not have plans for any Nuclear Programme. Consequently, the CNS requirements regarding nuclear facilities do not apply.

In this regard, Malta is a Category 4 Contracting Party.

Even if Malta does not have any "nuclear installations" according to the definition of the CNS, the term "nuclear facilities" is for practical purposes used in this NR and hence refers to use and storage facilities for radioactive materials.

In this regard, Malta as a CP voluntary reports under articles 7, 8, 9, 10, 15, and 16.3 of CNS.

Articles 11, 12, 13, 14, 17, 18, and 19 of CNS have not been included in this NR as they deal with nuclear installations.

This NR is fulfilling Malta's obligations under Article 5 of the Convention on Nuclear Safety (CNS).

The Commission for the Protection from Ionising and Non-Ionising Radiation (Commission) authored this NR.

This report closely follows the form and structure established by the CPs to the Convention, pursuant to the article 22 and the International Atomic Energy Agency (IAEA) document INFCIRC/572/Rev.8, *Guidelines regarding National Reports under the Convention on Nuclear Safety, dated 6th of March 2025*, and recommendations that have been provided by IAEA in the *General Instructions Related to Report Content, dated 31st of March 2025*.

There have not been any major safety issues since the last NR.

Malta's NRs are available on the Commission website: https://rpc.gov.mt/reports/.

All information and data used in this NR are as of 22nd August 2025.

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SUMMARY

Responses to Applicable Challenges and Suggestions:

Malta has fully addressed the Challenges, Suggestions, and Good Practice from previous 7th, 8th, 9th Review Meetings (RMs) with the exception of:

Suggestion 1 from 7th, 8th 9th RMs (Article 7): Malta is to join the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

The Commission has previously discussed with the Ministry of Foreign Affairs the ratifications of the below conventions but, to date, they have not been ratified:

Convention on Early Notification of a Nuclear Accident
Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

Challenge 2 from 7th RM (Article 8): Attracting experienced additional employees to the RP.

The Commission (which replaced the RPB) consists of Board and a Secretariat to perform executive functions of the Commission. The Board consists of a non-executive Chairperson, Deputy Chairperson and nine expert members. The Secretariat consists of an Executive Secretary, Operations and Quality Manager and currently three Radiation Officers.

The human resources plan must be reviewed annually (taking into consideration the next 3 years). If there is a need for new staff, the Executive Secretary should establish a case for such recruitment. The case will be taken before the Commission for approval. Academic and experience requirements for personnel working at Secretariat are specified in the job-descriptions for the different grades.

Attracting experienced staff has always been, and probably will remain, an issue in a small country such as Malta. A better salary structure was recently introduced which should make it more attractive for prospective employees. Since the last review meeting the number of staff was increased to five, including one highly experienced person from overseas.

Challenge 3 from 7th RM (Article 8): Lack of human resources.

The executive functions in nuclear and radiation safety fields are performed by the Commission's Secretariat which has five full time staff members: Executive Secretary, Operation and Quality Manager and three Radiation Officers.

Taking into account the small amount of radioactive material in use and in storage, the Commission, currently has sufficient human resources to perform its regulatory function under the obligations of CNS but extra new staff are required to ensure continuity of regulatory control in the long-term.

Challenge 4 from 9th RM (Article 8): The Contracting Party should fill the authorized positions in the regulatory body and continue to focus on staff development to build capacity.

The Government approved new staffing positions in the Secretariat for 2025-2028. The Commission is in the process of seeking to fill the positions.

A significant challenge in that the most senior staff have reached or will soon reach retirement age.

Responses to Good performances:

Area of Good Performance from the 8th and 9th RM, 2023: In the framework of technical cooperation with the IAEA, the Commission set up a fully operational Maltese environmental gamma spectrometry radioanalytical laboratory for routine radiological monitoring of food and environmental.

The intention of the laboratory is to provide analysis for the National Radioactivity Monitoring Programme as well as to provide analysis in the event of a radiological emergency affecting Malta.

2023 was the first full year of the Commission's laboratory performing gamma spectrometry of analysis of food, water, feed, and environmental samples. 77 of gamma spectrometry analysis performed in 2023, and 49 in 2024.

An Intercomparison exercise was started in 2023 to compare air filter, soil, sea, and water results between the Commission's laboratory and an overseas laboratory in Greece.

In 2024, the laboratory took part in the IAEA Intercomparison Worldwide Proficiency Test Exercise IAEA-TERC-2024-01, which is designed to monitor and demonstrate performance and analytical capabilities of different radioanalytical laboratories. The exercise consisted of different sample media including water, bauxite, sediment, and simulated contaminated surface samples.

The Commission's laboratory performed the analysis of gamma emitting man-made and natural radionuclides using gamma spectrometry. 69% of the results produced by the Commission's laboratory were consistent with the actual results.

Through an IAEA technical cooperation project, the Commission's laboratory is planning to start some beta/alpha liquid scintillation analysis.

The Commission gives high importance to maintaining an operational laboratory and to this end a substantial amount of time is dedicated by one of the Radiation Officers.

Summary of other Significant Changes Since Previous Report

Further to the challenge from the 7th RM with regard to Malta's legislation and regulatory infrastructure Malta enacted a dedicated Act and promulgated the necessary regulations in particular:

1. Malta has enacted the following new legislative, regulations and guidance that are given in the *Annex A.*
2. A new regulatory body, the Commission for the Protection from Ionising and Non-Ionising Radiation (Commission), was set up in 2018 accordingly to the new Nuclear Safety and Radiation Protection Act (CAP585).
3. 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 the central government through the Office of the Prime Minister - Ministry for Equality, Reforms and Social Dialogue.
4. The national radiological hazard assessment was performed in January 2020, and the national emergency plan were revised and approved in August 2020.
5. The Commission communicates with other governmental entities to include its radiological emergency procedures into the national Chemical, Biological, Radiological, Nuclear response (CBRN).
6. The Commission sent all the necessary reports on the nuclear material accountancy to the European Commission as required under the trilateral EU/IAEA nuclear safeguards agreements (INFCIRC 193).
7. Malta hosted an IAEA IRRS mission in 2015. This mission led to 42 recommendations and 7 suggestions. Following the IRRS review, a new nuclear safety and radiation protection law

was enacted as well as several regulations falling under this law. A list of these legal instruments is given in the *Annex A.*

8. Malta hosted an IRRS follow-up mission in 2020, where many of the recommendations from the 2015 mission and suggestions were closed. The follow-up mission report had 3 open recommendations and 3 open suggestions as well as 2 new recommendations.
9. Malta hosted an Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation (ARTEMIS) Mission in 2022 which produced 8 recommendations and 4 suggestions. Work on IRRS and ARTEMIS findings is ongoing.
10. Currently, the Commission is at the final preparation stage of the next IRRS mission that is going to hold in May-June 2026.

In total, 3 Challenges related to staffing and 1 Suggestion relating to joining conventions from the 7th, 8th, and 9th RMs have not been completely closed.

PART B LEGISLATION AND REGULATION

Articles 7: Legislative and regulatory framework

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

2. The legislative and regulatory framework shall provide for:

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

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

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

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

Summary Statement for Article 7

Malta is a Category 4 of CP. However, it is voluntary reporting on its fulfilment of Article 7.

7.1 Establishing and Maintaining a Legislative and Regulatory Framework

All nuclear activities are regulated by the Nuclear Safety and Radiation Protection Act (CAP585)**,** published in May 2018.

The main subsidiary legislation (SL) is the Basic Safety Standards for Ionising Radiation Regulations (SL585.01) and for nuclear safety is the Nuclear Safety Regulations (SL585.02).

Malta has established a legislative and regulatory framework for nuclear safety and radiation protection based on the legal documents are given in *Annex A.*

For further information on legislation related to nuclear safety and radiation protection, see Article 15 Radiation Protection.

7.2 Provisions of the Legislative and Regulatory Framework

Nuclear Safety and Radiation Protection Act (CAP585)

CAP585 is to ensure 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.

CAP585 assigns the responsibility, to the Commission to be the regulatory body for radiation protection from ionising radiation, and related activities and practices required to be under regulatory control.

The main provisions of the CAP585 include the following:

- Principles of protection and dose limitation.
- Notification, authorisation, inspection, enforcement provisions.
- Regulatory control of radiation sources, radiation protection provisions.

- Emergency response.
- Provisions for transport, export and import of radioactive material.
- Management with radioactive waste.
- Safeguards, nuclear security, including physical protection and prevention of illicit trafficking.

Basic Safety Standards for Ionising Radiation Regulations (SL585.01)

SL585.01 is the key SL adopted in 2018 and with amendments made in 2020 and 2022, that includes regulations of:

- Radiation protection (optimisation, dose limitation, principals of radiation protection, training and information).
- Justification of practices and regulatory control of radiation sources (notification, exemption from notification, registration, licensing, authorisation, clearance and exemption from regulatory control).
- Control of occupational exposures (responsibilities, classification of workplace areas and monitoring, dose records, emergency occupation exposure and radon on workplace).
- Control of medical exposures (justification, optimisation, responsibilities, radiation protection measures, accidental and unintended exposures).
- Emergency exposure situations and existing exposure situations.
- Responsibilities of undertakings, recognition of technical services providers and experts, orphan sources and significant events, system of enforcement.

SL585.01 is based on the requirements of IAEA Radiation Protection and Safety of Radiation Sources International Basic Safety Standards, GSR Part 3 and the requirements of the EU Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (2013/59/Euratom) and establishes the basic safety standards for the radiation protection of individuals under the occupational, medical and public exposures.

Nuclear Safety Regulations SL585.02

The Nuclear Safety Regulations was initially adopted in 2018 and was subsequently amended in 2020. SL585.02 implements *Council Directive, establishing a community framework for the safety of nuclear installations (2009/71/Euratom),* and the *Convention on Nuclear Safety (CNS).*

There are no nuclear facilities in Malta and there are no plans for them in the future.

Management of radioactive waste regulations SL585.03

SL585.03 were adopted in 2019. This regulation provides for the arrangements for safety in radioactive waste management and apply to all stages of: radioactive waste management, it brings into effect the provisions of *EU Directive 2011/70/Euratom and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (Joint Convention)* and is a part of the national policy that radioactive waste (includes disused sources) is managed in a manner that protects human health and the environment now and in the future, without imposing undue burdens on future generations.

Radioactive Waste Management Programme (as required by SL585.03)

The Radioactive Waste Management Programme was initially created in 2014 and was last updated in 2022. The programme is required by virtue of Regulation 5 of SL585.03 and contains the policies and strategies for the management of radioactive waste.

Commission for the Protection from Ionising and Non-ionising Radiation Regulations (SL585.04)

SL585.04 was adopted in 2021. This regulation further clarifies the distinct legal personality of the Commission and exemption from liability of members and employees of the Commission.

A complete list of Maltese legislation relating to CNS is given in the *Annex A* of the NR.

Further information on the legislation related to nuclear security and radiation protection is given in the Article 15 of this NR.

Incident and Trafficking Data Base

Malta joined the IAEA Incident and Trafficking Data Base (ITDB) in 2009. The Commission acts as the ITDB contact point and distributes information to relevant government entities as well as sending any incident notifications to the IAEA.

Peer Reviews of regulatory infrastructure

As part of its commitments to safety and the EU Malta has invited the following peer reviews:

Infrastructure Appraisal for Malta of Radiation Safety and the Security of Radioactive Sources (RaSSIA) in 2005.

Integrated Regulatory Review Service (IRRS) initial mission 2015.

IRRS follow-up mission 2020.

ARTEMIS in 2014.

All above reports are available at: https://rpc.gov.mt/reports/.

A new IRRS mission is going to be held in the second quarter of 2026.

Ratification of international conventions and legal instruments related to nuclear safety

Malta is a Contracting Party to the following international arrangements:

- Convention on Nuclear Safety, came into force 2008.
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management came into force in 2013.
- Convention on Physical Protection of Nuclear Material came into force in 2003 as well as its amendment, acceptance instrument deposited 2013.
- Agreement between the European Atomic Energy Community, its non-nuclear weapon Member States and the IAEA came into force on 2007 (INFCIRC193, safeguards).

Malta complies with the provisions of the above list of International Conventions and fully participates in the review process, namely:

- Submitting National Reports for the Review Meetings,
- Provides questions to other contracting parties prior to the review meeting,

- Answers questions posed to Malta prior to the review meeting,
- Attends review meetings, participating in country group meetings and in the exchange of questions and responses for clarification of the National Reports.

Malta expressed its commitment to the IAEA Code of Conduct for the Safety and Security of Radioactive Sources in 2004.

Malta has also declared support for the:

IAEA supplementary Guidance on the import and export of radioactive sources to the "Code of Conduct on the Safety and Security of Radioactive Sources" in 2015.

IAEA Supplementary Guidance on the Management on disused radioactive sources, to the "Code of Conduct on the Safety and Security of Radioactive Sources" in 2023.

The Executive Secretary of the Commission acts as the national Point of Contact for facilitating the IAEA Code of Conduct for the Safety and Security of Radioactive Sources, IAEA Guidance on the import and export of radioactive sources, IAEA Guidance on the Management on disused radioactive sources.

The Commission is a member of the following EU groups:

Heads of European Radiological Competent Authorities (HERCA),

European Nuclear Safety Regulators Group (ENSREG).

Malta is a party to the main relevant international conventions (list of ratified conventions is given in the *Annex B* of this NR).

Malta fully participates in the CNS review process and invites international peer views in line with its obligations under *Council Directive 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations*.

7.2 (ii) System of Licensing

Malta is an EU Member State and has been transposed into its own legal system the relevant EU obligations in the field of radiation safety and nuclear security.

The Commission is the regulatory body responsible for regulation of safety and security, and control of radiation sources.

The notification, registration and licensing are a part of the national regulatory control system.

The formal written notification must be submitted to the Commission by the user at least thirty days before the commencing of a practice.

The user shall submit, as established in Regulation 38 of SL585.01, to the Commission all relevant information about the practice or work activity which may be considered necessary by the Commission, and which shall include documents stated in the 8th Schedule of SL585.01, such as:

- Responsibilities and organisational arrangements for protection and safety.
- Staff competences, including information and training.
- Design features of the facility and of radiation sources.
- Anticipated occupational and public exposures in normal operation.

- Safety assessment of the activities and the facility.
- Emergency response procedures.
- Maintenance, testing, inspection and servicing to ensure that the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime.
- Management of radioactive waste and arrangements for the disposal of such waste, in accordance with applicable regulatory requirements.
- Management of disused sources.
- Quality assurance programmes.

Prior to authorizations of facilities and activities an inspection is carried out and information according to the standard check list must be provided.

The Commission has sufficient authority to issue authorizations and to grant exemptions concerning the possession and use of radiation sources.

In 2024 total of 48 licences were issued/reissued with 32 new licences being issued for the first time whilst 16 licences were renewed. In comparison in 2023 a total 8 licences were issued/reissued with one new licence being issued for the first time whilst 7 licences were renewed.

A breakdown of the licenses issued in 2024 per application is shown in the below table:

Application	**Licences issued in 2023**	**Licences issued in 2024**	**Licences issued up to 22nd August 2025**
Medical	3	14	9
Veterinary clinics	-	26	-
Industrial (non-destructive testing)	1	1	3
Industrial (low risk)	-	6	22
CSF	1	1	1
Total	**5**	**48**	**35**

7.2 (iii) System of Regulatory Inspection and Assessment

The Commission carries out inspections of facilities and activities to verify if the authorized party is following the legislation and regulatory requirements.

The Commission conducts both announced and unannounced inspections.

The regulatory inspections are conducted at all the stages of the lifetime of the radioactive sources. The Commission has a right to inspect the applicants for licensing and activities with radiation sources, disused sources and other facilities using radioactive material.

The legal basis for inspections (announced and unannounced) is set up in CAP585.

Inspections are planned and conducted in compliance with the principle of graded approach, to ensure a more efficient use of financial and human resources and to target inspections at activity areas which, when related to radiation protection and physical security, pose a higher potential risk to employees of the license holders, the public and the environment.

Periodicity of inspections is established taking into account the categorization of users, considering results of previous inspections and essential events, which has influence on undertaking activities.

The findings of an inspection are provided to the undertaking in an inspection report. If violations of regulatory requirements are identified during the inspection, the enforcement actions are applied in accordance with the established procedure.

Any corrective actions that the undertaking has to take, shall be performed within the time frames set up by the Commission.

The Commission follows the implementation of any corrective actions. If further incompliances with legislation is identified the undertaking shall be subject to further enforcement actions unless justifying that the corresponding actions are not necessary.

A graded approach is being applied to inspections, with the higher risk applications being inspected more frequently.

The number of inspections which have been performed from 2023 -2025 is given in the table below:

Application	**Inspections in 2023**	**Inspections in 2024**	**Inspections in 2025 (till 22nd August)**
Medical	96	33	21
Industry	5	42	36
CSF	0	0	2
Other	3	4	2
Total	**104**	**79**	**61**

7.2 (iv) Enforcement

Regulatory control is a form of control or regulation applied to human activities for the enforcement of radiation protection requirements.

CAP585 and CAP585.01 provide enforcement powers to Commission. Through different sections of the legislation, these acts empower Commission to amend or revoke an operation permit, shutdown of facility or stop an activity, require further information to be provided.

In performing the state regulatory functions, the Commission applies enforcement actions in the manner set out in the Article 19 of the CAP585.

For cases representing an immediate safety or security hazard, the Commission requires the person or entity subject to enforcement action to suspend its activities, or parts thereof until the situation has been corrected. In such cases, the Commission may also suspend, revoke or modify the terms and conditions of the licence.

In cases of persistent or extremely serious non-compliance with or violation of the terms and conditions of an authorization or a licence or in cases of significant release of radioactive material into the environment, the Commission may revoke the authorization or licence and require the licensee to remedy any unsafe condition.

No person may threaten, insult, molest or disturb inspectors in the performance of their duties, or knowingly give an officer false information, or break or tamper with any seal made, or with any monitoring equipment installed, put up or left by an officer in a workplace or, in the case of personal monitoring equipment, on a worker.

Any radiation officer of the Commission may give an order, verbally or in writing, and every person shall obey such order forthwith until such time as it is revoked by the Commission or the Appeals Tribunal.

Provided that the person who receives the order, whether such person is a worker or an undertaking, may defend himself from the charge of having disobeyed the order if he proves that compliance with the order would have constituted a violation under CAP585.

Provided further that any order given verbally shall be confirmed in writing and served upon the person to whom it was given within three working days.

System of enforcement established in the Section 7 of CAP585.

The Commission has the power to require any individual or legal person to take action to remedy deficiencies and prevent their recurrence as states in the stop order, or to withdraw, where appropriate, authorisation when the results of a regulatory inspection or another regulatory assessment indicate that the exposure situation is not in compliance with the regulations.

Summary of Responses to Applicable Challenges and Suggestions

No challenges or suggestions received from previous RMs with regard to enforcement.

Article 8: Regulatory Body

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.*
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.*

Summary Statement for Article

Malta is a Category 4 CP. However, Malta is voluntarily reporting on its fulfilment of Article 8.

Malta has a sole regulatory body on nuclear safety and radiation protection matters (Commission), and its functions are defined in Articles 10, 12 of CAP585.

8.1 Establishment of the Regulatory Body

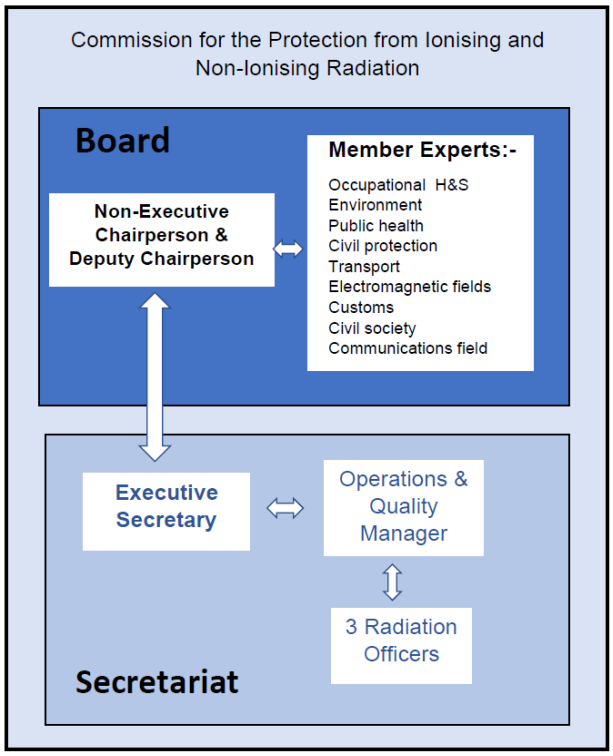
CAP585 created the Commission as the sole regulatory body on nuclear safety and radiation protection matters and defined its functions.

Whilst the Commission was established in 2018, it should be noted that all regulatory functions were transferred from the RPB (established in 2004).

The function of the Commission is to carry out regulatory control of facilities and activities with sources of ionising radiation and to protect the public and the environment from harmful effects of ionising radiation. Its responsibilities cover all activities and practices with radiation sources and other radioactive material (radioactive waste, disused sources, nuclear material, contaminated material).

The Commission consists of Board and a Secretariat to perform executive functions of the Commission. The Board consists of a non-executive chairperson, deputy chairperson and nine expert members. The Secretariat consists of an Executive Secretary, Operations and quality manager and currently three Radiation Officers.

The composition of the Commission in line with regulatory framework established in Part III (Article 10 to 13) of CAP585 is shown in the figure below.



The function of the Commission is to carry out state regulation and supervision of safety facilities and activities with sources of ionising radiation in order to protect the public and the environment from harmful effects of ionising radiation.

8.2 Status of the Regulatory Body

The Commission falls under the portfolio of the Parliamentary Secretariat for Equality, Reforms, and Social Dialogue within the Office of the Prime Minister .

Financial independence is guaranteed by Article 61 of the CAP585.

The Commission demonstrates its continuing commitment to fulfil Malta's European and international regulatory obligations.

In accordance with Article 10 (2) of CAP585, the Commission can establish sub-committees. Currently there are four sub-committees available, each comprising expert members from the Commission Board, Executive Secretary and, if needed, invited external experts.

The choice of these experts was primarily based on the specific policies each sub-committee has been tasked with addressing. These sub-committees met as often as required and together with members of the Secretariat they drafted policies addressing obligations, strategies, and documentation related to radon monitoring, training, environmental monitoring, and non-ionising radiation.

The sole revenue for the Commission is from central Government pursuant to 61(1) of CAP585. Whereas the Commission may charge fees pursuant to Article 61(2) of CAP585, but any fees or fines collected will go to the Ministry of Finance and not the Commission.

The Commission continues to recognise that although the Secretariat currently has sufficient human resources to fully comply with its legal obligations under CAP585, the Commission is doing all in its

powers to increase the staffing of the Secretariat taking into consideration the retirement of some of the staff.

With reference to the Commission procedures, a management system has been developed. Work on the further development of the management system is on-going.

Summary of Responses to Applicable Challenges and Suggestions

Challenge 2 from 7th RM (Article 8): Attracting experienced additional employees to the RPB – is on-going.

The human resources plan must be reviewed annually (taking into consideration the next 3 years). If there is a need for new staff, the Executive Secretary should establish a case for such recruitment. The case will be taken before the Commission for approval. Academic and experience requirements for personnel working at Secretariat are specified in the job-descriptions for the different grades.

Attracting experienced staff has always been, and probably will remain, an issue in a small country such as Malta. A better salary structure was recently introduced which should make it more attractive for prospective employees. Since the last review meeting the number of staff was increased to five, including one highly experienced person from overseas.

Challenge 3 from 7th RM (Article 8): Lack of human resources – is on-going.

The executive functions in nuclear and radiation safety fields are performed by the Commission's Secretariat which has five full-time staff members: Executive Secretary, Operational Manager, and three Radiation Officers. Taking into account the small amount of radioactive source in use and in storage, the Commission has sufficient human resources to perform its regulatory function under the obligations of CNS, but extra new staff are required to ensure continuity of regulatory control in the long-term.

Challenge 4 from 9th RM (Article 8): The Contracting Party should fill the authorized positions in the regulatory body and continue to focus on staff development to build capacity – is on-going.

The human resources plan has been approved by the Commission and reviewed. The Commission's Secretariat actively participated in training events and to this end ran a total of nine workshops in 2024 on regulatory issues.

Summary of other Significant Changes Since Previous Report

In addition to work summarized above to address the Challenges, during the reporting period, Malta has made the following improvement: subscribed to the commitments of the IAEA Supplementary Guidance on the Management on disused radioactive sources, to the "Code of Conduct on the Safety and Security of Radioactive Sources", commitment letter dated 2023.

Malta has no significant changes to highlight under Article 8 during the reporting period, other than the work already summarized above to address the Challenges.

Future Focus

Malta has identified the following issue as an area that demands future effort, which is to formalize the process for determination of the staffing needs/competencies for the Secretariat. A procedure for the development of the 3-year human resource plan should be developed. There is a significant challenge in that the most senior staff have reached or will soon reach retirement age.

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.

Summary Statement for Article

Malta is a Category 4 CP however it is voluntarily reporting on its fulfilment of Article 9.

Prime responsibility for safety

In general terms, under Maltese legislation, an undertaking using ionising radiation has the prime responsibility for safety and security.

Definition stated in the article 3 of CAP585 and the article 4 of SL585.01 states: "undertaking" means a natural or legal person who has legal responsibility under national law for carrying out a practice, or for a radiation, whether ionising, or non-ionising source (including cases where the owner or holder of a radiation source does not conduct related human activities).

The undertaking must justify, optimize and ensure dose limitation is performed, taking actions in order to protect the workers, member of the public and the environment from risks arising from the use of ionising radiation.

Article 5 of CAP585 and sub-article 5 (3) of SL585.01 clearly state that the prime responsibility for the safety and security of ionising radiation sources rests with the undertaking.

Sub-article 5 (3) of SL585.01 also states that *"Provided that the prime responsibility for safety and security rests with the licence holder. That responsibility cannot be delegated and includes responsibility for the activities of contractors and sub-contractors whose activities might affect safety and security."*

Regulation 14 of the SL585.03 deals specifically with the responsibilities of the undertaking with regards to the management of radioactive waste.

Inspection checklists for each practice with ionising radiation include questions how these requirements have been implemented and documented in the radiation protection programme of an undertaking.

In the case of emergency situation (on or outside Maltese territory), the Commission's responsibilities are assigned in Section 2 Emergency exposure situations of SL585.01, and are also established in the National radiological emergency plan referred to in Article 31 of the CAP585.

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 (article 30 of CAP585).

Information to members of the public about health protection measures to be applied and the steps to be taken in the event of an emergency are established in Regulations 93, and 94, and the Eleventh Schedule of SL585.01.

Summary of Significant Changes Since Previous Report

During the reporting period, Malta has no significant changes to highlight under Article 9.

PART C: GENERAL SAFETY CONSIDERATIONS

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.

Summary Statement for Article

Malta is a Category 4 CP; however, it is voluntarily reporting on its fulfilment of Article 10.

Malta has no nuclear facility in operation or in plan.

Main Requirements and Administrative Arrangements

The general requirement for the responsibility of the undertaking to take prime responsibility is stated in Article 5 of CAP585 and Article 5 of SL585.01 in particular:

"The prime responsibility for the safety and security of ionising radiation sources rests with the undertaking: Provided that the prime responsibility for safety and security rests with the licence holder. That responsibility cannot be delegated and includes responsibility for the activities of contractors and sub-contractors whose activities might affect safety and security".

The prime responsibility regarding waste is given in Article 37 of CAP585 which states:

"The prime responsibility for ensuring the safety and security of radioactive waste inside or outside a radioactive waste facility throughout its life rests with the holder of the relevant authorization or licence:

Provided that the responsibility for ensuring the safety and security of radioactive waste for which no undertaking or entity can be determined shall rest with the relevant body governing matters related to the disposal of radioactive waste".

The undertaking is defined in Article 3 of CAP585 and the Regulation 4 of SL585.01 as:

"undertaking" means a natural or legal person who has legal responsibility under national law for carrying out a practice, or for a radiation, whether ionising, or non-ionising source (including cases where the owner or holder of a radiation source does not conduct related human activities)"

The legal provision that requires persons to comply with CAP585 and its regulations is Article 21 of CAP585 which states that any person who fails to comply with any of the provisions of the Act or its regulations shall be guilty of an offence.

An undertaking should:

- include into accounting the nuclear materials used in the operation and exercise their control in such a manner as to ensure performance of the obligations of Malta regarding the safeguards of the IAEA and the European Atomic Energy Community (EURATOM),
- investigate radiological accidents in the manner, prescribed by the CAP585 and CAP585.01,
- carry out and submit to the Commission a safety assessment,
- prepare an emergency procedure.

In addition, holders of licences according to the national legal requirements shall:

- have the material, financial, and human resources that are sufficient for involvement in the licensed activity in compliance with the regulations,
- ensure high level of safety culture and competence of the organisation and its workers,
- develop an organisational structure which would ensure the fulfilment of radiation safety policy,
- ensure radiation protection of staff and members from public,
- ensure quality of the licensed activity, proper management of documentation, its storage during all lifetime of radiation installation, renewal in time, and approval by Commission when it is necessary,
- be responsible for the radiation protection even if the validity of the licence is suspended or it is revoked,
- monitor emissions of radionuclides into the environment in a systematic manner (waste storage facility and medical cyclotron), apply principles of "defence-in-depth" and the ALARA.

Implementation, Regulatory Review and Control

The regulatory control regime is based on the principles of justification, optimisation, and dose limitation.

Regulatory control provides through the notification, registration/licensing, inspection process, and based on the graded approach.

Further obligations of the undertaking with regard to implementing a radiation protection programme and ensuring adequate training is given in Article 25 of the CAP585.

Summary of Significant Changes Since Previous Report

During the reporting period, Malta has no significant changes to highlight under Article 10.

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.

Summary Statement for Article

Malta is a Category 4 CP however it is voluntarily reporting on its fulfilment of Article 15.

Protection of the public, workers, and the environment against the possible radiation impact is regulated by the CAP585 and regulations are given in Annex A.

The basic standards and safety requirements for occupational and public exposure (including dose limits) are established in SL585.01.

These regulations set out the requirements for radiation protection of workers and the public and they are in compliance with the General Safety Requirements GSR Part 3 and the Basic Safety Standards Directive (2021/59/Euratom).

In accordance with the requirements of SL585.01, the undertaking has to establish a Radiation Protection Program in order to ensure adequate protection of workers and the public.

The following items should be included in the Radiation Protection Program:

- organizational arrangements for radiation protection (responsibilities and functions of radiation protection expert, radiation protection officer, local rules and procedures).
- classification of working areas and access control.
- arrangements for individual and workplace monitoring.
- individual protective equipment
- implementation of engineered controls (if its applicable)
- ALARA programme and programme of health surveillance
- radiation protection training of workers and instructors.

According to the SL585.01 the dose limits for the occupational exposure, apprentices and students, and members of public are presented in the table below:

	Dose limit for occupational exposure, mSv	Dose limits for apprentices and students, mSv		Dose limits for members of the public, mSv
		Aged between 16 and 18 years	Aged 18 years or over	
Annual effective dose	20[1]	6	20[1]	1
Annual equivalent dose for the lens of the eye	20[2]	15	20[2]	15
Annual equivalent dose for the skin	500[3]	150[3]	500[3]	50[3]
Annual equivalent dose for extremities	500	150	500	-

[1] In special circumstances, a higher effective dose of up to 50 mSv in a single year may be authorized by the Commission provided that the average annual dose over any five consecutive years, including the years for which the limit has been exceeded, does not exceed 20 mSv.
[2] 100 mSv in any five consecutive years subject to a maximum equivalent dose of 50 mSv in a single year.
[3] Annual equivalent dose limits shall apply to the dose averaged over any area of 1 cm2, regardless of the area exposed.

Dose constraints and dose limits for workers and the public are specified in the SL585.01. The undertaking has the responsibility to ensure compliance with dose constraints and dose limits.

System of radiation protection, established in the regulations 5 to 13 of the SL585.01, includes optimisation, dose limitation and reference levels in the emergency or existing situations.

Summary of Significant Changes Since Previous Report

Malta has no significant changes to highlight under Article 15 during the reporting period.

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.*

Summary Statement for Article

Malta is a Category 4 CP and is reporting on its fulfilment of its obligation under sub-article 6.3.

16.1 Emergency Plans

Sub-Article 16.1 does not apply to Malta, as a Category 4 CP.

16.2 Information of the Public and Neighboring States

Sub-Article 16.2 does not apply to Malta, as a Category 4 CP.

16.3 Emergency Preparedness for Contracting Parties Without Nuclear Installations

Article 31 of CAP585 requires the Secretariat in conjunction with the Commission to develop and maintain a National Emergency Plan. The National Emergency Plan has to be developed by the Commission and approved by the Minister.

Regulation 89 of the SL585.01 builds upon article 31 of the CAP585 and additionally requires the development of a National Radiological Hazard Assessment.

The National Radiological Hazard Assessment was developed prior to the National Radiological Emergency Plan and assessed the potential radiological and nuclear hazards and potential consequences of an emergency as well as possible mitigation measures in Malta in order to provide a basis for establishing graded approach to arrangements for preparedness and a response for a nuclear or radiological emergency.

The hazards identified are grouped in accordance with the emergency preparedness categories which are in line with IAEA Safety Standard: Preparedness and Response for Nuclear or Radiological Emergency, GSR Part 7.

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

Currently, both above documents are under review.

The scope of the National Radiological Emergency Plan is the following:

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,

to outline the government entities likely to be involved and their responsibilities,

to place responsibilities on each government agency involved in the plan to develop its own procedures,

to make available resources for emergency response, fully equipped with field equipment and has undergone training in radiological response with the assistance of the IAEA.

The Radiological Emergency Plan includes the responsibilities of:

Civil Protection Department (CPD),

Health Care Services and Environmental Health Directorate,

Environment and Resources Authority (ERA), and other governmental agencies such as Malta Police, Armed Forces of Malta, Department of Information.

At licensee level, the user shall establish and maintain local emergency plans commensurate with the hazards associated with the radioactive material in use or storage, and report incidents significant to safety in a timely manner to the Commission and other interested parties.

As established in the Regulation 91 of SL585.01, in case of radiation incident or accident the Commission is responsible for:

- coordination of response activity of the CPD to organize the appropriate protective measures.
- coordination of the recovery of any radioactive material.
- advice on the termination of nuclear or radiological emergency and the transition to normal activities.
- assess and record the consequences of the emergency and of the effectiveness of the protective measures.

Regulation 93 of SL585.01 requires the Secretariat to ensure that the members of the public likely to be affected in the event of an emergency are given information about the health protection measures applicable to them and about the action they should take in the event of such an emergency.

Regulation 94 of SL585.01 requires the Secretariat together with CPD to ensure that the members of the public affected are informed without delay about the facts of the emergency, the steps to be taken and, as appropriate, the health protection measures applicable to these members of the public.

Regulation 122 of SL585.01 focuses on the national emergency management systems that are required. The Commission should collaborate with the CPD to develop the national hazard assessment document that identifies the risks that may lead to a radiological emergency and the national radiological emergency plan.

The SL585.01 also include 2 schedules, Tenth and Eleventh Schedules which provide more information on emergency exposure situations.

The Tenth Schedule of the SL.585.01 provides the elements that shall be incorporated into the undertakings' emergency management systems, as well as in the emergency response plans.

The Eleventh Schedule of the SL585.01 includes elements for the information supplied to members of public about health protection measures to be applied and steps to be taken in the event of an emergency.

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 was drafted but not implemented.

The Commission participates in both European Community Urgent Radiological Information Exchange (ECURIE) and Unified System for Information Exchange in Incidents and Emergencies (USIE) desk-top exercises.

The staff within the Secretariat go through internal training exercises for scenarios, such as discovery of radioactive source at Freeport or other location.

Currently the Malta Freeport handles about 3 million container movements per year with a large proportion (approx. 75%) of them being subject to screening with portal monitors fitted with gamma and neutron detection capability.

The Commission remains committed to coordinate the environmental monitoring programme in Malta. This programme monitors radioactivity in the environment from the sampling of air particulates, seawater, and soil by the ERA, and the drinking water, milk, and food by the Environmental Health within the Department for Health Regulation, following a National Environmental Monitoring Plan. These results are transmitted on an annual basis to the EU Database of radioactivity monitoring results (REMdb).

ERA's gamma dose monitoring stations have their data transmitted directly to the EU and are included in the European dose rate map: https://remap.jrc.ec.europa.eu/Simple.aspx.

The distance from Malta to nearest nuclear installation consists of at least 1000 km. In the event of a nuclear incident, Malta would access REMdb on real-time data.

Summary of Significant Changes Since Previous Report

Malta has no significant changes to highlight under Article 16 during the reporting period.

Future Focus

Malta has identified the following issue involving as an area that demands future effort to join and ratified the *Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency*.

ANNEXES:

Annex A. National Legislation

The following legislation are given on https://rpc.gov.mt/laws-and-regulations/:

1. Nuclear Safety and Radiation Protection Act, CAP585, published 2018.
2. Basic Safety Standards for Ionising Radiation Regulations SL585.01 (initially published in 2018 and amended in 2020 and 2022).
3. Nuclear Safety Regulations SL585.02 (published in 2018).
4. Management of Radioactive Waste Regulations SL585.03 (published in 2019).
5. Commission for the Protection from Ionising and Non-Ionising Radiation Regulations SL585.04 (published in 2021).
6. Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) SL549.51 (published in 2009).

Annex B. List of Conventions

Malta is a Contracting Party to the following international arrangements:

1. Convention on Nuclear Safety came into force 2008
2. Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management came into force in 2013
3. Convention on Physical Protection of Nuclear Material came into force in 2003 as well as its amendment, acceptance instrument deposited 2013
4. Agreement between the European Atomic Energy Community, its non-nuclear weapon Member States and the IAEA came into force on 2007 (INFCIRC193, safeguards)

Annex C. Reference Material

The following peer reviews reports are given at: https://rpc.gov.mt/reports/:

1. Integrated Regulatory Review Service (IRRS) initial mission, 2015.
2. IRRS follow-up mission, 2020.
3. Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation (ARTEMIS), 2014.
4. CNS reports.
5. Joint Convention reports.
6. Maltese Report on the Implementation 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.