IAEA-NS-IRRS-2026/05
ORIGINAL: English

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

The Republic of Malta

Mosta, Malta

25 May - 3 June 2026

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA

Integrated
Regulatory
Review Service

IRRS

Integrated
Regulatory
Review Service

IAEA | IRRS

REPORT OF THE
INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION
TO
MALTA



Integrated Regulatory Review Service

IAEA | IRRS

REPORT OF THE INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO MALTA

Mission dates:	*24 May - 3 June 2026*
Regulatory body visited:	*Commission for the Protection from Ionising and Non-Ionising Radiation*
Location:	*Mosta, Malta*
Regulated facilities, activities, and exposure situations in the mission scope:	*Radiation sources facilities and activities, waste management facilities, decommissioning activities, transport, emergency preparedness and response, occupational exposure, medical exposure, public exposure, interface with nuclear security*
Organized by:	*IAEA*

IRRS TEAM	
Ms Eleftheria Carinou (Greece)	Team leader
Mr Faradally Ollite (Mauritius)	Reviewer
Mr Phiphat Phruksarojanakun (Thailand)	Reviewer
Mr Pedro Rosário (Portugal)	Reviewer
Mr Walter Truppa (Argentina)	Reviewer
Ms Houda Idihia (Morocco)	Reviewer
Mr Manuel Recio (IAEA/NSRW)	Team Coordinator
Ms Baan Fischer (IAEA/NSRW)	Administrative Assistant

IAEA-2026/05

The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

CONTENTS

EXECUTIVE SUMMARY 1

I. INTRODUCTION 4

II. OBJECTIVE AND SCOPE 5

III. BASIS FOR THE REVIEW 6

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT 8

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY 8

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY 9

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE 10

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS 12

1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK 13

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS 13

1.7. PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL 14

1.8. COMPETENCE FOR SAFETY 16

1.9. PROVISION OF TECHNICAL SERVICES 17

1.10. SUMMARY 17

2. THE GLOBAL SAFETY REGIME 19

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION 19

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE 20

2.3. SUMMARY 20

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY 22

3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES 22

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS 23

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY 24

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS 25

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES 26

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL 26

3.7. SAFETY RELATED RECORDS 27

S3 27

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES 27

3.9. SUMMARY 29

4. MANAGEMENT OF THE REGULATORY BODY 30

4.1 RESPONSIBILITY AND LEADERSHIP FOR SAFETY 30

4.2. THE MANAGEMENT SYSTEM 30

4.3. MEASUREMENT, ASSESSMENT AND IMPROVEMENT 31
4.4. SUMMARY 32
5. AUTHORIZATION 33
5.1. GENERIC ISSUES 33
5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES 35
5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES 35
5.4. AUTHORIZATION OF DECOMMISSIONING OF FACILITIES 36
5.5. AUTHORIZATION OF TRANSPORT 37
5.6. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE 37
5.7. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE 39
5.8. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE 39
5.9. SUMMARY 41
6. REVIEW AND ASSESSMENT 42
6.1. GENERIC ISSUES 42
6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES 43
6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES 43
6.4. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES 43
6.5. REVIEW AND ASSESSMENT FOR TRANSPORT 44
6.6. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE 44
6.7. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE 44
6.8. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE 45
6.9. SUMMARY 45
7. INSPECTION 46
7.1. GENERIC ISSUES 46
7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES 46
7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES 47
7.4. INSPECTION OF DECOMMISSIONING ACTIVITIES 47
7.5. INSPECTION OF TRANSPORT 47
7.6. INSPECTION OF OCCUPATIONAL EXPOSURE 48
7.7. INSPECTION OF MEDICAL EXPOSURE 49
7.8. INSPECTION OF PUBLIC EXPOSURE 49
7.9. SUMMARY 49
8. ENFORCEMENT 50
8.1. ENFORCEMENT POLICY AND PROCESS 50
8.2. ENFORCEMENT IMPLEMENTATIONS 51
8.3. SUMMARY 52
9. REGULATIONS AND GUIDES 53
9.1. GENERIC ISSUES 53
9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES 53
9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES 53
9.4. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES 54

9.5. REGULATIONS AND GUIDES FOR TRANSPORT 54
9.6. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE 54
9.7. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE 55
9.8. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE 56
9.9. SUMMARY 57
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS 58
10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS 58
10.2. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS 58
10.3. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS 58
10.4. ROLES OF THE REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY 59
10.5. SUMMARY 61
11. INTERFACE WITH NUCLEAR SECURITY 62
11.1. LEGAL BASIS 62
11.2. REGULATORY OVERSIGHT ACTIVITIES 62
11.3. INTERFACE AMONG AUTHORITIES 63
11.4. SUMMARY 63
12. POLICY DISCUSSIONS AND MEETING WITH PERMANENT SECRETARY 65
12.1. CHALLENGES IN MAINTAINING AND ENHANCING REGULATORY EFFECTIVENESS AND COMPETENCE IN STATES WITH SMALL POPULATIONS. 65
APPENDIX I – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP) 66
APPENDIX II – LIST OF PARTICIPANTS 72
GROUP PHOTO 73
APPENDIX III – LIST OF IRRS REVIEWERS AND COUNTERPARTS 74
APPENDIX IV – MISSION SCHEDULE 75
APPENDIX V – SITE VISITS 82
APPENDIX VI – ORGANIZATIONAL CHART OF RPC 83
APPENDIX VII – MALTA'S REFERENCE MATERIAL USED FOR THE REVIEW 84
APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW 87

EXECUTIVE SUMMARY

At the request of the Government of Malta, an international team of senior nuclear and radiation safety experts met with representatives of the Commission for the Protection from Ionising and Non-Ionising Radiation (RPC) from 25 May to 3 June 2026 to conduct an Integrated Regulatory Review Service (IRRS) initial mission. The mission was conducted at the RPC's headquarters in Mosta, Malta. The mission represented the second full scope IRRS mission hosted by Malta. The first initial mission was conducted from 22 February to 3 March 2015 and the IRRS follow up mission from 8 to 12 March 2020.

The purpose of the mission was to conduct a peer review of Malta's legal and regulatory framework for radiation safety, radioactive waste management, transport safety, emergency preparedness and response and the interface between safety and nuclear security. The review was carried out against the IAEA safety standards and the Code of Conduct on the Safety and Security of Radioactive Sources. The mission also provided opportunities for the exchange of information and experience between the IRRS team members and their Maltese counterparts in the areas covered by the review.

The IRRS team consisted of six experts from six IAEA Member States and two IAEA staff members. The Maltese counterparts included the management and staff of the RPC Secretariat. The opening meeting was attended by the Permanent Secretary for Equality, Reforms and Social Dialogue of the Office of the Prime Minister, members of the RPC Board, and the management and staff of the RPC Executive Secretariat.

The IRRS team reviewed the core modules covering: responsibilities and functions of the Government; the global nuclear safety regime; responsibilities and functions of the regulatory body; management system; regulatory activities within the scope of the RPC's responsibilities, including authorization, review and assessment, inspection, and enforcement; development and content of regulations and guides; and emergency preparedness and response and the safety and nuclear security interface.

In preparation for the mission, Malta conducted a self-assessment and developed a preliminary action plan to address areas identified for improvement. The results of the self-assessment and supporting documentation were provided to the IRRS team as Advance Reference Material (ARM) prior to the mission. During the mission, the IRRS team carried out a systematic review of all topics covered in the ARM. The team recognized the extensive preparation and assessment work undertaken by the RPC, as well as the dedication and professionalism of its staff.

The IRRS team conducted interviews and discussions with RPC staff. The team also carried out site visits and observed regulatory inspection activities at the Sir Anthony Mamo Oncology Centre (SAMOC) Mater Dei Hospital and at the Central Storage Facility (CSF) for disused sealed radioactive sources and radioactive waste. During these visits, the IRRS team held discussions with the management and staff of the operating organizations.

The mission also included discussions on the policy issue: "Challenges in maintaining and enhancing regulatory effectiveness and competence in States with small populations." Members of the IRRS team and representatives of the RPC exchanged views and shared regulatory experience on this topic.

The constructive engagement of the RPC throughout the peer review process enabled the IRRS team to gain a broad understanding of Malta's regulatory framework. The IRRS team recognized the RPC's commitment to the continuous improvement of safety and to the protection of people and the environment. This commitment was demonstrated through the establishment of a full-scope integrated management system subject to continual improvement, efforts to address shortages of qualified staff through the recruitment of experienced radiation specialists from abroad, and the invitation of a second initial IRRS mission to support the further enhancement of Malta's regulatory framework.

The IRRS team also identified areas of good performances, including:

1. The strong and constructive interaction between the RPC, its Secretariat, and the Ministry responsible for the RPC in supporting the development and implementation of Malta's national infrastructure for radiation safety and nuclear security. The close cooperation and regular communication between the RPC and the Government facilitate timely decision-making, coordinated policy development, and effective support for legislative and regulatory improvements.
2. The multidisciplinary composition of the RPC, which enhances strategic leadership, supports informed decision-making, and contributes to the effectiveness and robustness of the regulatory framework for radiation safety and nuclear security.
3. The comprehensive criteria established by the RPC for the recognition of radiation protection experts and medical physics experts, including competence-based recognition, a structured assessment process, and a continuing professional development points system.

In the spirit of continuous improvement, the IRRS mission report includes recommendations and suggestions intended to support the further enhancement of Malta's regulatory infrastructure for radiation safety.

The IRRS team considers that Malta's should establish a national policy and strategy for safety that provides a clear pathway for progressively addressing the challenges associated with establishing and sustaining a resilient regulatory infrastructure, taking into account the current use of radiation sources in the country and foreseeable developments.

In addition, the IRRS team concluded that the following actions, if addressed by the Government, the RPC and other relevant stakeholders, as appropriate, could further enhance the effectiveness of the regulatory system:

The Government should:

- Strengthen arrangements for staffing and competence development of the RPC, based on a comprehensive human resources plan, to ensure that it maintains sufficient in-house expertise and effective independence in carrying out its regulatory functions;
- Ensure that the RPC is not assigned with responsibilities that will compromise its effective independence, in particular with regard to the funding, management and operation of the CSF; and
- Establish, as part of its national policy and strategy for safety, a policy and strategy for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.

The RPC should:

- Strengthen its human resources planning through a comprehensive competence analysis to ensure that it has sufficient staff with the necessary knowledge, skills and abilities to perform all assigned regulatory functions, including in anticipation of future needs;
- Establish effective arrangements including a communication strategy for informing and consulting interested parties and the public on radiation risks associated with facilities and activities, as well as on its regulatory processes and decisions; and
- Issue guidance for applicants on the process of authorization and the format and content of the documents to be submitted in support of the different types of authorizations and, where applicable, authorization stages, including for the renewal and modifications of the authorizations.

A full list of recommendations and suggestions can be found in the IRRS mission report

The IRRS team acknowledged that several recommendations and suggestions included in the report had already been identified in the preliminary action plan developed by the RPC during the self-assessment conducted in preparation for the mission.

The IRRS team expressed its appreciation for the full support and cooperation provided by the RPC and all participating organizations during the mission. The peer review of all aspects within the scope of the mission was conducted in a constructive, open and transparent manner throughout.

The IAEA issued a press release upon conclusion of the mission.

I. INTRODUCTION

At the request of the Government of Malta, an international team of senior safety experts met representatives of the Commission for the Protection from Ionising and Non-Ionising Radiation (RPC) from 25 May to 3 June 2026 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Maltese governmental, legal and regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Malta on 5 January 2024. A preparatory mission was conducted from 4 to 5 December 2025 at the RPC Headquarters in Mosta to discuss the purpose, objectives, and detailed preparations of the review in connection with regulated facilities and activities in Malta and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS team consisted of six senior regulatory experts from six IAEA Member States, and two IAEA staff members. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; radiation sources; radioactive waste management facilities; transport of radioactive material; decommissioning; occupational exposure; control of medical exposure and public exposure control; and interfaces with nuclear security. In addition, the following policy issue was discussed: *"Challenges in maintaining and enhancing regulatory effectiveness and competence in states with small populations"*.

The RPC conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of Malta self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission, the IRRS team performed a systematic review of all topics within the agreed scope through review of the Malta advance reference material, conduct of interviews with management and staff of the RPC and direct observation of two regulatory inspections performed by the RPC at two regulated facilities. Meetings with members of the RPC Board (which consists of the Chairperson and the Expert Members) and with the Permanent Secretary Office of the Prime Minister – Equality, Reforms and Social Dialogue – were also organized.

All through the mission the IRRS team received excellent support and cooperation from the RPC.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Malta's radiation and nuclear safety, governmental, legal and regulatory framework and activities against the relevant IAEA safety standards to report on the effectiveness of the regulatory system and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Malta. It is expected this IRRS mission will facilitate regulatory improvements in Malta and other Member States, utilising the knowledge gained and experiences shared between the RPC and IRRS reviewers and the evaluation of the Maltese regulatory framework for radiation safety, including its good practices.

The key objectives of this mission were to enhance the national legal, governmental and regulatory framework for radiation safety, and national arrangements for emergency preparedness and response through:

- providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;
- providing the host country (regulatory body and the government) with a review of its regulatory technical and policy issues;
- providing the host country (regulatory body and the government) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;
- promoting the sharing of experience and exchange of lessons learned among senior regulators;
- providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;
- providing the host country with recommendations and suggestions for improvement;
- providing other states with information regarding good practices identified in the course of the review;
- providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);
- contributing to the harmonization of regulatory approaches among states;
- promoting the application of IAEA Safety Requirements; and
- providing feedback on the use and application of IAEA safety standards.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IRRS TEAM

At the request of the Government of Malta, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 4 to 5 December 2025. The preparatory meeting was carried out by the appointed Team Leader Ms Elefteria Carinou and the IAEA Team Coordinator, Mr Manuel Recio.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of Malta represented by Mr Paul Brezja, Executive Secretary of the RPC, other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- radioactive waste management facilities;
- radiation sources facilities and activities;
- decommissioning;
- transport of radioactive materials;
- occupational exposure;
- medical exposure;
- public exposure; and
- emergency preparedness and response.

Mr Paul Brezja made presentations on the national context, and the status of the preparation of the self-assessment.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Malta from 25 May to 3 June 2026.

The proposed composition of the IRRS team was discussed and tentatively confirmed. Logistics including meeting and workplaces, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The Maltese Liaison Officer for the IRRS mission was confirmed as Mr Paul Brezja.

The advance reference material (ARM) for the review was provided at the end of March 2026. In preparation for the mission, the IAEA review team members reviewed Malta's advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

The relevant IAEA safety standards, the Code of Conduct on the Safety and Security of Radioactive Sources and the supplementary Guidance on the Management of Disused Radioactive Sources were used as the review criteria. The complete list of IAEA publications used as the references for this mission is provided in Appendix VIII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 24 May 2026 in Malta, directed by the IRRS team Leader and the IRRS Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officer and Deputy Liaison Officer, Mr. Joseph Cremona, were present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday, 25 May 2026, with the participation of Mr Carlos Tabone, Office of the Prime Minister, Permanent Secretary for Equality, Reforms and Social Dialogue, and Members of the Board, senior management and staff of the RPC. Opening remarks were made by Prof. Lourdes Farrugia, Chairperson of the RPC, and by Mr Carlos Tabone. Ms Eleftheria Carinou, IRRS Team Leader, gave opening comments, and Mr Paul Brezja gave an overview of Malta's context, including the regulatory framework in Malta, the activities, and the action plan prepared as a result of the pre-mission self-assessment. Mr Manuel Recio, IAEA Team Coordinator, expressed appreciation for requesting the IRRS mission and presented the programme of work and agenda.

During the IRRS mission, a review was conducted for all areas within the agreed scope with the objective of providing Malta and the RPC with recommendations and suggestions for improvement and where appropriate, identifying good practice. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

In addition to the review, a policy issue discussion was conducted to share views, experience and lessons learned between Malta and the IRRS team on selected policy issues was organized on "*Challenges in maintaining and enhancing regulatory effectiveness and competence in States with small population"*.

The IRRS team performed its review according to the mission programme given in Appendix IV.

The IRRS exit meeting was held on Wednesday, 3 June 2026. The opening remarks at the exit meeting were presented by Prof. Lourdes Farrugia, Chairperson of the RPC, and were followed by the presentation of the results of the mission by the IRRS team Leader Ms Eleftheria Carinou. Ms Ilona Callus, the Director General, Support Services, from the Office of the Prime Minister was representing the Government. Closing remarks were made by Mr Hilaire Mansoux, IAEA, Section Head Regulatory Infrastructure & Transport Safety, Division of Radiation, Transport and Waste Safety, IAEA.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Malta is committed to radiation safety and has incorporated many elements relating to its national policy and strategy for safety within the provisions of the Nuclear Safety and Radiation Protection Act (hereinafter referred to as "CAP.585"). However, Malta has recognised the need to establish a separate overarching national policy and strategy document that consolidates long-term national objectives and strategic directions for safety.

Malta is currently reviewing and finalising its draft national policy and strategy for safety, which is intended to provide clear direction on how the country will achieve the fundamental safety objective and apply the fundamental safety principles in line with national circumstances and the radiation risks associated with present and foreseeable facilities and activities in the country.

The IRRS team met the Permanent Secretary of the Office of the Prime Minister, Equality, Reforms and Social Dialogue to discuss the present situation of Malta's framework for safety. During the meeting, the IRRS team highlighted the importance for the Government of Malta to establish a comprehensive national policy and strategy covering all key elements of the institutional framework needed to ensure radiation safety and was reassured that the review and finalisation of the draft national policy and strategy is in good progress.

The IRRS team was informed that the RPC has been assigned responsibility for the development of the draft national policy and strategy for safety, while clearly recognising that the establishment and adoption of the national policy and strategy for safety remains the responsibility of the Government.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Malta has not yet established a national policy and strategy for safety. The Government is currently reviewing and finalising a draft national policy and strategy for safety intended to address this need.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 1 states that** "*The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamental"*
R1	**Recommendation: The Government should establish and implement a national policy and strategy for safety consistent with the IAEA safety standards, the implementation of which should be subject to a graded approach commensurate with the radiation risks associated with facilities and activities in Malta.**

Meeting with the Permanent Secretary Mr Carlos Tabone, Office of the Prime Minister for Equality, Reforms and Social Dialogue

Tuesday, 26 May 2026 11:00-12:00

Malta: Mr Carlos Tabone, Ms. Michaela Sammut, Ms. Illona Callus, Prof. Lourdes Farrugia and Mr. Paul Brejza.

IRRS Team: Ms Elefteria Carinou, Mr. Faradally Ollite, Mr. Manuel Recio and Ms. Baan Fischer.

The IAEA IRRS team met with the Permanent Secretary explaining that the IRRS peer review mission involves independent experts from member states assessing national systems against international safety standards, with the government retaining ultimate responsibility for safety within a broader regulatory framework that includes an effectively independent regulatory body; for EU Member States, such reviews through EU directives are required every ten years. The topic on the importance of finalizing the high-level national policy and strategy document to ensure long-term safety stability was discussed. Emphasis was put on review and update to the regulatory framework in line with evolving standards and guided by sustained government commitment, including key elements such as competence for safety, sustainability for regulatory infrastructure and emergency preparedness. A key priority is preserving an effective regulatory independence while addressing significant staff turnover by strengthening in-country expertise through a comprehensive human resource development plan with robust competence management to ensure stability. Despite these challenges, Malta's RPC has made notable progress, establishing a strong regulatory framework and an integrated management system to ensure continuity and sustainability. Furthermore, the need to addressing emerging issues related to new technologies and knowledge management is essential and should be considered in preparing to implement forthcoming IRRS mission recommendations through a structured action plan.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

Malta has established a legal and regulatory framework for radiation safety and nuclear security through the enactment of the CAP.585, which entered into force in 2018. The Act establishes the RPC and its Secretariat as the national regulatory authority responsible for nuclear safety, radiation protection, nuclear security, safeguards and related regulatory oversight activities.

CAP.585 establishes the fundamental principles of radiation protection, including justification, optimization and limitation of exposure, and provides for a graded approach in regulatory control. The Act defines the responsibilities and functions of the RPC and of its Secretariat, including authorization, inspection, enforcement, development of regulations, emergency preparedness and response, transport safety, radioactive waste management, safeguards and nuclear security.

CAP.585 provides the Secretariat with authority to issue authorizations, conduct inspections, undertake enforcement actions, and suspend, modify or revoke licences and authorizations where necessary for safety and security. It also establishes the Radiation Protection Appeals Tribunal for appeals against decisions taken by the Secretariat.

The legal framework further includes provisions relating to emergency preparedness and response, environmental monitoring, transport of radioactive material, management of radioactive waste, safeguards implementation and physical protection of radioactive material. The Act also enables the Minister to issue subsidiary legislation and regulations necessary to implement international obligations and regulatory requirements in the field of nuclear safety and radiation protection.

The IRRS team observed that Malta has established a comprehensive primary legal framework covering the main elements of radiation safety and nuclear security and, through secondary legislation, some of the essential pillars of the regulatory framework for safety. However, further development of subsidiary legislation, namely regulations and guides, are needed to support the effective implementation and operationalization of the regulatory framework across all regulated facilities and activities. Further details regarding regulations and guides are provided in Section 9.

The IRRS team acknowledged that certain requirements of the IAEA safety standards are not currently reflected in the Maltese legal and regulatory framework. However, these were not identified as shortcomings, as they are presently not relevant to the facilities and activities within the scope of the country's regulatory programme. It is understood that Malta will closely follow up on national and international development to timely incorporate such requirements into its legal and regulatory framework should they become relevant in the future.

The IRRS team noted the strong and constructive interaction between the RPC, its Secretariat and the Ministry responsible for the RPC (currently the Office of the Prime Minister - Equality, Reforms and Social Dialogue) in supporting the development and implementation of Malta's national infrastructure for radiation safety and nuclear security. The close cooperation and regular communication between the RPC and the Government facilitate timely decision-making, coordinated policy development and effective support for legislative and regulatory improvements. The IRRS team further noted that this interaction supports the allocation of resources and the implementation of national priorities related to radiation safety and security.

The IRRS team identified this cooperative and coordinated approach between the RPC, its Secretariat and the Ministry responsible for the RPC as a **good performance contributing to the continued strengthening of Malta's national safety infrastructure.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

Malta has established the RPC and its Secretariat as the national regulatory authority in the field of radiation safety and nuclear security. CAP.585 defines the functions, powers and responsibilities of the RPC and the Secretariat, including authorization, inspection, enforcement, maintenance of national registers, emergency preparedness and response, safeguards and regulatory oversight of radiation practices and activities.

CAP.585 establishes arrangements intended to support the effective independence of the regulatory body. CAP.585 specifies that the Minister responsible for the Act shall not have under his responsibility any form of ionising or non-ionising radiation facility or source. The Act also provides that members of the RPC shall not be responsible for the use of any form of ionising or non-ionising radiation.

CAP.585 provides for the RPC to be composed of up to nine members each one expert should be an expert in each one the key areas relevant to radiation safety and regulatory oversight, including occupational health and safety, public health, environmental protection, civil protection, transport, customs, electromagnetic fields, civil society and communications. This multidisciplinary composition brings together a broad range of expertise and perspectives that are directly relevant to the regulatory oversight of radiation practices and activities and ensures that the RPC covers all competences needed for effective decision making.

The IRRS team noted that this arrangement facilitates effective consideration of technical, safety, security, environmental, health and societal aspects in regulatory decision-making. It also promotes coordination and information exchange among key national stakeholders and supports the development of integrated and balanced regulatory approaches. The participation of representatives from diverse sectors strengthens the RPC's ability to address emerging issues, contribute to policy development and support the continuous improvement of the national radiation safety infrastructure.

The IRRS team identified the multidisciplinary composition of the RPC as a good performance, as it enhances strategic leadership, supports informed decision-making and contributes to the effectiveness and robustness of the regulatory framework for radiation safety and nuclear security.

The IRRS team was informed that the RPC has been placed under different ministerial portfolios on several occasions in recent years. While these administrative changes have not affected the legal authority of the RPC, they have resulted in the need to repeatedly establish new administrative and reporting arrangements and to familiarize successive ministries with its role, functions and resource needs.

The IRRS team noted that frequent changes in ministerial responsibility may affect continuity in governmental support, strategic planning and long-term resource allocation for the RPC. Greater stability in the governmental arrangements under which the RPC operates would support continuity of oversight, institutional understanding of regulatory needs and the sustained development of the national regulatory infrastructure.

The Secretariat has been assigned broad regulatory powers, including authority to issue authorizations, conduct inspections, carry out enforcement actions and maintain national systems for control of radiation sources and nuclear material. CAP.585 also establishes enforcement powers, inspection authority and an independent appeals mechanism through the Radiation Protection Appeals Tribunal.

CAP.585 requires providing the RPC and its Secretariat with adequate financial and human resources through the national budget to fulfil their regulatory responsibilities. However, the RPC identified challenges related to staffing sustainability, recruitment, succession planning and retention of institutional knowledge. This issue is further discussed in section 3.2. The IRRS team noted that maintaining sufficient in-house technical expertise is important to support the effective independence of the regulatory body and its ability to make informed and objective regulatory decisions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC faces challenges related to staffing sustainability, recruitment, succession planning and retention of institutional knowledge, which may affect its capacity to make independent regulatory decisions. The issue was already identified by Malta and included in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 1 (Rev. 1) para 2.36 (b) states that** " *The government… (b) Shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety; …"*
(2)	**BASIS: GSR Part 1 (Rev.1) Requirement 17 states that** *"The regulatory body shall be effectively independent in the performance of its regulatory functions and shall have functional separation from entities having responsibilities or interests that could unduly influence its decision making."*
R2	**Recommendation: The Government should strengthen arrangements for staffing and competence development of RPC, based on a comprehensive human resources plan, to ensure that it maintains sufficient in-house expertise and effective independence in carrying out its regulatory functions.**

Currently, the Central Storage Facility (CSF) is the only facility in Malta that performs predisposal activities for radioactive waste.

The CSF is operated by a private company under contract from the Government and licensed by RPC. The IRRS team was informed that options for the management and operation of CSF were being considered and that it has been decided that the new contract to that effect will be made through the RPC. The

implementation of this option will lead to RPC having direct responsibilities over the management of the CSF, which compromises its effective independence and capabilities of discharging of its responsibility for regulating the safety of facilities and activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The CSF is currently operated by a private company under contract from the Government. The IRRS team was informed that options for the management and operation of CSF were being considered.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 4, para. 2.9 states that** "*No responsibilities shall be assigned to the regulatory body that might compromise or conflict with its discharging of its responsibility for regulating the safety of facilities and activities.*"
(2)	**BASIS: GSR Part 3 Requirement 2, para. 2.16 states that** *"The government shall ensure that the regulatory body is effectively independent, in making decisions relating to protection and safety, of persons and organizations using or promoting the use of radiation and radioactive material, so that it is free from any undue influence by interested parties and from any conflicts of interest; and shall ensure that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making."*
R3	**Recommendation: The Government should ensure that the RPC is not assigned with responsibilities that will compromise its effective independence, in particular with regard to the funding, management and operation of the CSF.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Maltese legislative and regulatory framework establishes that the prime responsibility for safety rests with the undertaking or authorized person operating facilities conducting activities involving radiation sources along the lifetime of the facilities and the duration of the practices. This responsibility cannot be delegated or transferred, and this includes responsibility for the activities of contractors and sub-contractors whose activities might affect safety and security.

Authorized parties are required to ensure that radiation practices are conducted in accordance with regulatory requirements and that workers, patients, members of the public and the environment are adequately protected from the harmful effects of ionising radiation. The legal and regulatory framework also establishes obligations relating to education and training, radiation monitoring, record keeping, and the reporting of incidents.

The RPC has established regulatory oversight arrangements, including authorization, inspection and enforcement processes, to verify compliance with regulatory requirements. The IRRS team further noted that CAP.585 provides the legal basis for enforcement actions, suspension or revocation of authorizations, and prosecution in cases of non-compliance.

The IRRS team noted, however, that the RPC operates with a relatively small number of staff responsible for a broad range of regulatory functions and oversight activities. Continued attention to staffing sustainability, inspection coverage and consistency of regulatory oversight will support the effective implementation of compliance monitoring and enforcement activities. **This issue is addressed in Recommendation R7 in section 3.3**

1.5. COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

In line with the provisions of the Maltese legal and regulatory framework, the RPC has established cooperation arrangements with several national authorities and organizations, including Customs, the Civil Protection Department, the Police, health authorities and security-related entities.

The IRRS team observed that some operational arrangements and memoranda of understanding have been developed to support the practical implementation of coordination mechanisms and response arrangements. However, the IRRS team noted that these formal cooperation arrangements are not periodically reviewed, and their effectiveness is not systematically assessed to support continuous improvement. This is particularly important for maintaining effective coordination during emergency situations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC has established some formal cooperation arrangements and operational coordination mechanisms with relevant national authorities involved in safety, security and emergency response functions. However, these arrangements are not periodically reviewed, and their effectiveness is not systematically assessed to support continuous improvement. The issue was already identified by Malta and included in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions…"*
(2)	**BASIS: GSR Part 7 Requirement 6 states that** *"arrangements for emergency preparedness and response shall be regularly exercised and reviewed in the light of experience gained and lessons identified."*
S1	**Suggestion: The RPC should consider establishing a process for the periodic review and assessment of formal cooperation arrangements and operational coordination mechanisms with relevant national authorities to ensure their continued effectiveness.**

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

The Maltese legal and regulatory framework includes provisions for protection against unregulated and existing radiation risks. The framework addresses orphan sources, existing exposure situations, emergency exposure situations, environmental monitoring, and the protection of workers, the public and the environment from the harmful effects of ionising radiation.

One area of existing exposure in Malta is radon in dwellings and workplaces. The RPC has conducted radon assessments, the results of which indicate that protective actions are currently not required. However, further assessments and studies are ongoing to support a more comprehensive understanding of radon exposure levels and associated risks within the country. **This issue is addressed in Suggestion S8 in section 9.8**

The RPC has established some operational arrangements and cooperation mechanisms with Customs, Civil Protection Department, Police and other relevant authorities to support detection and response to radiological events. The IRRS team noted that certain practical and informal arrangements, detailed in DOC-038 and OP-067, are in place for the management and secure control of orphan sources. However,

Malta has not yet established a formal national strategy and comprehensive arrangements for the identification, recovery, management and secure control of orphan sources, including for the integration with the arrangements for the preparation and response to radiological emergencies after the detection of an orphan source. Further details are provided in section 10.1.

In accordance with the provisions of the Code of Conduct on the Safety and Security of Radioactive Sources, the responsibility for establishing a national strategy and arrangements for the identification, recovery, management and secure control of orphan sources rests with the Government. The IRRS team noted, however, that in Malta this responsibility has been assigned to the RPC. Therefore, it is the responsibility of the RPC to develop the national strategy and arrangements for the identification, recovery, management and secure control of orphan sources for adoption by the Government and implementation through the provision of the necessary resources and arrangements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Although there are some procedures in place which partly deal with actions to be undertaken upon discovery of an orphan source, a national strategy and arrangements for the identification, recovery, management and secure control of orphan sources are yet to be established.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 9 states that** *"The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization."*
(2)	**BASIS: IAEA CoC para. 8 states** *that "Every State should have in place an effective national legislative and regulatory system of control over the management and protection of radioactive sources. Such a system should:* *(a) place the prime responsibility for the safe management of, and the security of, radioactive sources on the persons being granted the relevant authorizations; (b) minimize the likelihood of a loss of control; (c) include national strategies for gaining or regaining control over orphan sources; (d) provide for rapid response for the purpose of regaining control over orphan sources; (e) foster ongoing communication between the regulatory body and users; (f) provide for measures to reduce the likelihood of malicious acts, including sabotage, consistent with the threat defined by the State; (g) mitigate or minimize the radiological consequences of accidents or malicious acts involving radioactive sources; and (h) provide for its own continuous improvement."*
(3)	**BASIS: IAEA CoC para. 21 states that** *"Every State should ensure that arrangements are in place for the safe management and secure protection of orphan sources."*
R4	**Recommendation: The Government should establish and implement arrangements for the identification, recovery, safe management and secure control of orphan sources.**

1.7. PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL

The Maltese legal and regulatory framework establishes responsibilities relating to the safe management, storage, transport and control of radioactive waste and disused radioactive sources. It requires the RPC and its Secretariat to establish and maintain a national policy and strategy for radioactive waste management.

The framework also establishes responsibilities relating to authorization, regulatory oversight and enforcement associated with radioactive waste management activities.

Radioactive waste generated in Malta consists primarily of disused sealed radioactive sources, radioactive material arising from medical and industrial applications, and small quantities of radioactive waste associated with authorized practices and activities.

Malta has established the CSF for interim storage and management of radioactive waste and disused radioactive sources. The IRRS team further observed that Malta relies on a graded and pragmatic approach appropriate to the national circumstances and the relatively limited inventory of radioactive waste within the country.

The IRRS team observed, however, that long-term arrangements relating to management, financing and final disposition of radioactive waste and disused radioactive sources continue to evolve. Malta relies significantly on interim storage arrangements and external pathways for long-term management or disposal of certain radioactive sources and materials.

The IRRS team was informed that the arrangements associated with the operation and financing of the CSF were presently under consideration. The IRRS team underlined that continued attention should be placed on maintaining effective separation between regulatory responsibilities of the RPC and operational or financial arrangements associated with radioactive waste management activities, so as to avoid potential conflicts of interest and maintain the effective independence of the regulatory body. This issue is further discussed in section 1.3 above.

A decommissioning plan is currently required for nuclear facilities (note: currently there are no nuclear facilities in Malta, but the regulations transpose the provisions of an EU Directive that includes this type of facilities within its scope) and pre-disposal radioactive waste management facilities. However, no equivalent requirement exists for other types of facilities and activities that may require decommissioning or termination, including certain medical and industrial facilities using radioactive material. The legal and regulatory framework also does not require the submission of a final decommissioning report to the RPC for review and approval prior to the conduct of decommissioning activities. This issue is further discussed in section 5.4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are requirements for a decommissioning plan for some facilities and activities, such as predisposal radioactive waste management facilities, but not for all facilities and activities for which decommissioning is relevant. Additionally, there is no requirement for the submission of a final decommissioning report to the RPC for review and approval.	
(1)	**BASIS: GSR Part 6 Requirement 4 states that** *"The government shall establish and maintain a governmental, legal and regulatory framework within which all aspects of decommissioning, including management of the resulting radioactive waste, can be planned and carried out safely. This framework shall include a clear allocation of responsibilities, provision of independent regulatory functions, and requirements in respect of financial assurance for decommissioning."*
(2)	**BASIS: GSR Part 6 Requirement 2 states that** *"A graded approach shall be applied in all aspects of decommissioning in determining the scope and level of detail for any particular facility, consistent with the magnitude of the possible radiation risks arising from the decommissioning"*

(3)	**BASIS: GSR Part 6 Requirement 15, para. 9.1 states that** *"A final decommissioning report shall be prepared by the licensee to demonstrate that the end state of the facility as specified in the approved final decommissioning plan has been reached. This report shall be submitted to the regulatory body for review and approval."*
R5	**Recommendation: The Government should review the legal and regulatory framework to ensure that it provides for the safe decommissioning of all relevant facilities.**

1.8. COMPETENCE FOR SAFETY

The Maltese legal and regulatory framework establishes responsibilities and requirements relating to the education, training, competence and authorization of persons with duties important to radiation safety, including Radiation Protection Officers (RPOs), Radiation Protection Experts (RPEs), Medical Physics Experts (MPEs), practitioners and other professionals involved in radiation practices.

CAP.585 establishes responsibilities for the RPC and its Secretariat to develop policies, regulations and guidance supporting radiation safety and competence development. Subsidiary legislation requires authorized parties to ensure that workers and professionals involved in radiation practices receive appropriate education, information, instruction and training commensurate with their responsibilities and the radiation risks associated with the practices and activities performed.

Malta relies on a limited national pool of specialized radiation protection expertise and, in several technical areas, makes use of external and overseas expertise and technical support services. The IRRS team noted that the RPC has identified challenges relating to the recruitment and retention of qualified personnel, succession planning and the long-term sustainability of competence within the RPC.

The IRRS team was informed that arrangements relating to the implementation of the national training framework required under Regulation 14 of SL585.01 continue to evolve. The IRRS team considers that continued development of the national competence framework and knowledge management arrangements will support long-term sustainability of the national safety infrastructure.

The national training framework currently focuses primarily on radiation protection training. The IRRS team considers it important for the Government to establish a broader national strategy for education and training for competence in safety, aimed at ensuring the availability and long-term sustainability of suitably qualified and experienced personnel necessary for the safe and secure application of nuclear science and technology in Malta.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Malta has not yet established national policy and strategy for education and training for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 11 states that** *"The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities."*
(2)	**BASIS: GSR Part 1 (Rev.1) para. 2.33 states that** *"The government shall ensure that arrangements are made for education and training for building competence in protection and safety and for maintaining competence."*

R6	**Recommendation: The Government should establish, as part of its national policy and strategy for safety, a policy and strategy for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.**

1.9. PROVISION OF TECHNICAL SERVICES

The Maltese legal and regulatory framework establishes responsibilities relating to radiation monitoring, dosimetry, calibration, quality assurance, medical physics, radiation protection expertise and other technical services supporting radiation protection and safety.

The RPC and its Secretariat are responsible for the regulatory oversight of technical services and technical service providers associated with radiation practices and activities.

The IRRS team noted that Malta relies on overseas service providers for specialized technical services, including personal dosimetry and calibration services, due to the limited scale of radiation practices and the relatively small national technical infrastructure.

The IRRS team further observed that arrangements relating to the authorization, oversight and formal recognition of certain technical service providers have not yet been fully established by the RPC. The IRRS team considers that continued strengthening of the framework for the oversight of technical services will support the long-term sustainability, consistency and reliability of technical services important to radiation safety.

1.10. SUMMARY

Malta has significantly strengthened its national framework for radiation safety and nuclear security through the enactment of CAP.585, which establishes the RPC and its Secretariat as the national regulatory authority and provides the legal basis for regulatory oversight of radiation practices and activities. The legal and regulatory framework addresses key areas including authorization, inspection, enforcement, emergency preparedness and response, radioactive waste management, transport safety, safeguards and protection against existing and unregulated radiation risks.

The IRRS team emphasized that continued attention should be given to maintaining a clear separation between the regulatory responsibilities of the RPC and any other functions that could give rise to conflicts of interest or compromise its effective independence.

The IRRS team identified the multidisciplinary composition of the RPC as a **good performance,** as it enhances strategic leadership, supports informed decision-making and contributes to the effectiveness and robustness of the regulatory framework for radiation safety and nuclear security.

Malta has established the main elements of a framework for safety broadly consistent with the IAEA safety standards. The Government is also progressing the development of a national policy and strategy for safety, and the IRRS team noted the strong and constructive interaction between the RPC, its Secretariat and the current Ministry responsible for the RPC in supporting the continued development of the national safety infrastructure.

The IRRS team identified this cooperative and coordinated approach between the RPC, its Secretariat and the Ministry responsible for the RPC as a **good performance** contributing to the continued strengthening of Malta's national safety infrastructure.

Malta applies a graded and pragmatic approach commensurate with the national circumstances and the relatively limited scale of radiation practices and radioactive waste management activities within the country. Cooperation arrangements have also been established with relevant national authorities to support emergency preparedness and response, transport safety, orphan source detection and other regulatory functions.

However, the IRRS team identified several areas where further strengthening of the framework for safety is needed taking into consideration current and foreseeable uses of radiation sources in the country. These include the continued development of subsidiary legislation, regulatory guidance and implementation arrangements; strengthening staffing sustainability and competence development within the RPC; periodic assessment of coordination mechanisms; establishment of a national strategy for orphan sources; enhancement of arrangements for decommissioning; and further development of oversight arrangements for technical services and competence management.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Malta is a member of the European Union and complies with its obligations under the Treaty establishing the European Atomic Energy Community (Euratom). By virtue of CAP.585, the RPC is the national body responsible for giving effect to any decision of the United Nations Security Council, the IAEA, the European Commission (EC) or internationally recognized entity or competent authority in the field of nuclear safety and radiation protection, whenever so directed by the Minister. The RPC shall also implement the regulatory requirements resulting from the obligations of the Conventions and other EU legislations within the scope of CAP.585. In addition, the RPC is a member of the Heads of European Radiological Competent Authorities (HERCA) and the European Nuclear Safety Regulators Group (ENSREG), through which it participates in regional regulatory cooperation and keeps abreast of developments in radiation protection and nuclear safety across the EU.

Malta is a contracting party to:

- Convention on Nuclear Safety;
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- Convention on Physical Protection of Nuclear Material and its Amendment;
- Safeguards Trilateral Agreement (INFCIRC/193); and
- Comprehensive Nuclear-Test-Ban Treaty.

Malta has also declared its commitment to the Code of Conduct for the Safety and Security of Radioactive Sources, including its supplementary guidance on import and export and on the management of disused radioactive sources.

In addition to IRRS, Malta has invited international peer reviews, including the Infrastructure Appraisal for Malta of Radiation Safety and the Security of Radioactive Sources (RaSSIA), the Integrated Regulatory Review Service (IRRS) and the Integrated Review Service for Radioactive Waste and Spent Fuel Management, Decommissioning and Remediation (ARTEMIS). Malta uses the findings and recommendations from these missions to improve its regulatory infrastructure. Experienced members of the Secretariat have been called upon by the IAEA to serve as experts and IRRS reviewers, contributing to international regulatory capacity building.

The IRRS team was informed of a positive progress towards the ratification of the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency. The Ministry of Foreign Affairs has informed the RPC that the Ministry is able to proceed with the ratification of both Conventions at the moment. CAP.585 already contains several provisions anticipated these both Conventions, especially regarding emergency planning, international notifications, and cooperation with IAEA and the EC. Therefore, the RPC's main task before ratification would be to strengthen operational readiness, implementing procedures, conducting training and emergency exercises to demonstrate practical preparedness, completing any necessary legal and administrative reviews to confirm compliance with treaty obligations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Malta has not yet acceded or ratified the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency. The issue was already included by Malta in the initial action plan prepared for the mission.	
(1)	**BASIS: SSG-44 Action 63 states that** *"The government should become a party to the relevant international conventions"*
S2	**Suggestion: The Government should consider acceding or ratifying the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

The RPC has mechanisms in place to routinely collect, analyze and share operating and regulatory experience.

The RPC participates in several instruments managed by the EU's institutions and the IAEA which include reporting and sharing information and experience on aspects of its regulatory infrastructures. The RPC acts as the national contact point for the IAEA Incident and Trafficking Database (ITDB), reviewing all incident notifications received and distributing relevant information to stakeholders in Malta. The RPC also participates in ECURIE (European Community Urgent Radiological Information Exchange) and USIE (IAEA Unified System for Information Exchange in Incidents and Emergencies), which provide channels for receiving and sharing information on radiological incidents and emergencies.

The RPC staff participate in IAEA technical cooperation activities and regional training courses, including hosting a course on the transport of radioactive materials organized in cooperation with the IAEA in 2024. Staff have also served as experts and IRRS reviewers in other countries, providing a means of both sharing and gaining regulatory experience internationally. The RPC actively participates and shares its experience in international activities related to the implementation of the Code of Conduct on the safety and security of radioactive sources and its supplementary guidance on the import and export of radioactive sources and management of disused radioactive sources.

The RPC conducts a well-organised and structured weekly staff meeting as its principal mechanism for discussing safety-related issues and experience. These meetings cover a range of topics, from routine inspection findings to training received abroad. Regulatory experiences are regularly collected and shared during these weekly meetings. Given the small number of staff in the RPC, this arrangement is considered systematic and effective as a means of sharing regulatory experience internally, as well as to identify operating and regulatory experience worth to share with other countries on bilateral basis or through international instruments. The IRRS Team encourages the RPC to continue improving its current practice to better be in line with the DS547 on Regulatory Experience Feedback Management recently approved by the IAEA Commission on safety standards, which will soon be published by the IAEA.

2.3. SUMMARY

Malta complies with its obligations under the Euratom Treaty and has also entered into a range of international obligations and arrangements. Positive progress has been made towards the ratification of the

Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, with the RPC actively developing the necessary implementing regulations in preparation for formal ratification.

Malta has a proven record of sharing its regulatory experience through peer reviews and participation in EU and IAEA fora. Given the size of the organisation, the well-structured and documented weekly staff meetings of the Secretariat provide an effective mechanism for collecting and analysing operating and regulatory experience as well as for making decisions regarding sharing the experience internally, with other local entities and, where appropriate, with other regulatory bodies and international organizations.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

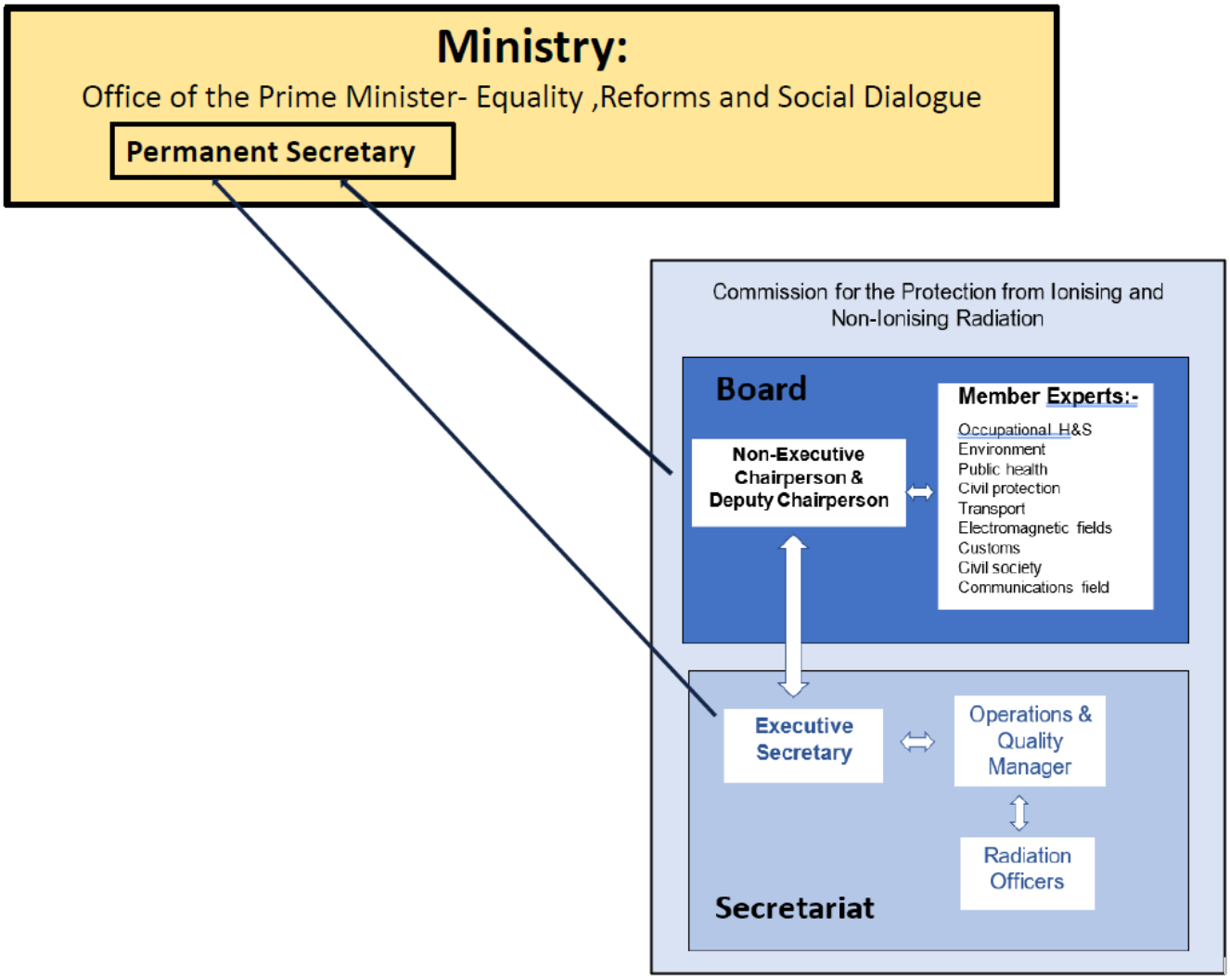
Malta has established the RPC along with its Secretariat as the national regulatory body responsible for radiation safety and nuclear security under CAP.585. The Act defines the functions, powers and responsibilities of the RPC and its Secretariat, including authorization, inspection, enforcement, emergency preparedness and response, safeguards, and regulatory oversight of radiation practices and activities.

The organizational structure of the RPC consists of a Board supported by a Secretariat that is responsible for the implementation of the regulatory programme and the conduct of day-to-day regulatory activities. The Board consists of a Non-Executive Chairperson, a Deputy Chairperson and up to nine members appointed by the Minister (See diagram below). The composition of the Board includes representation from key areas relevant to radiation safety and regulatory oversight, including occupational health and safety, environment, public health, civil protection, transport, electromagnetic fields, customs, civil society and communications. The RPC has also established subcommittees and cooperation arrangements to support activities in specialized technical areas.

The RPC applies a graded and pragmatic approach to regulation appropriate to the relatively limited scale and complexity of radiation practices and activities conducted in Malta. The IRRS team observed that the Secretariat performs a broad range of regulatory functions with a relatively small number of staff.

CAP.585 requires the Government to provide the RPC and its Secretariat with adequate financial and human resources to fulfil their regulatory responsibilities. The IRRS team noted that the RPC has identified challenges relating to staffing sustainability, recruitment and retention of qualified personnel, succession planning and preservation of institutional knowledge. The review team further observed that several specialized regulatory and technical functions rely on a limited number of experienced personnel and external technical support arrangements.

The IRRS team considers that continued attention to organizational resilience, workload management, succession planning and long-term resource allocation will support the sustainable implementation of the regulatory programme.



Organisational Structure of RPC

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

Malta has established legislative provisions intended to ensure the effective independence of the RPC in the performance of its regulatory functions through the CAP.585.

CAP.585 specifies that the Minister responsible for the RPC shall not have under his responsibility any form of ionising or non-ionising radiation facility or source, and that members of the Commission shall not be responsible for the use of any form of ionising or non-ionising radiation. These provisions support organizational separation between the regulatory body and entities having responsibilities or interests relating to radiation practices and activities.

CAP.585 establishes the authority of the RPC and its Secretariat to perform regulatory functions including authorization, inspection, enforcement and development of regulations and guidance. The legal framework establishes an independent appeals mechanism through the Radiation Protection Appeals Tribunal.

The RPC has established internal policies requiring Secretariat staff to declare any actual or potential conflicts of interest that may arise in the performance of their regulatory duties that can compromise the effective independence of the organization.

The RPC operates with a relatively small Secretariat responsible for a broad range of regulatory functions and activities. The IRRS team noted that the RPC makes use of subcommittees and external technical expertise to support the performance of specialized regulatory and technical functions.

The reliance of the RPC on external organizations, consultants, and other governmental entities for technical support in the discharge of certain regulatory functions, may compromise its ability to make informed and objective regulatory decisions, if there is not sufficient competence within the RPC. Further details are provided in section 1.3.

The IRRS team considers that continued attention be given, so that the RPC is not assigned with any such responsibilities that could create actual or perceived conflicts of interest or compromise its objectivity in the performance of its regulatory functions.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The responsibilities and functions of the RPC and its Secretariat, including authorization, inspection, enforcement, emergency preparedness and response, safeguards, and regulatory oversight of radiation practices and activities, are established under CAP.585.

The RPC currently operates with a Secretariat composed of six staff members and faces significant challenges in fulfilling its broad range of regulatory responsibilities with the existing staffing level. The RPC has developed a basic human resources plan. However, the IRRS team noted that the plan is not supported by a comprehensive analysis of staffing needs, workload and competency requirements necessary to perform all assigned regulatory functions effectively and sustainably.

The IRRS team further noted that the RPC has identified challenges relating to the recruitment and retention of qualified personnel, succession planning and the long-term sustainability of competence within the organization. In particular, two senior staff members possessing significant managerial, leadership and technical expertise are expected to retire in the near future. The IRRS team observed that this may affect continuity, institutional knowledge retention and the effective implementation of the regulatory programme if not adequately addressed in advance.

The IRRS team noted that continued attention should be given to structured knowledge transfer and the implementation of systematic training and competence development programmes to ensure that newly recruited staff acquire the technical, regulatory and managerial competencies necessary to effectively perform their functions. This includes the development of individual training plans, mentoring arrangements, participation in international training activities and progressive on-the-job experience across the different regulatory areas.

The IRRS team observed that the RPC has established arrangements for education, training and competence development of its staff and, within its limited resources, makes effective use of international cooperation activities, technical meetings and training programmes to support competence development in specialized technical areas.

The IRRS team considers that there is a need for a comprehensive human resources and succession planning strategy based on a systematic assessment of staffing needs, workload, core competencies and future regulatory demands. Such a strategy would support long-term organizational resilience, preservation of institutional knowledge, sustainability of technical competence and the effective and independent implementation of the regulatory programme.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC human resources plan is not supported by a comprehensive competence analysis to determine the staffing levels and competencies necessary to perform all assigned regulatory functions.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18, para 4.11 states that** "*The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 18, para 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
R7	**Recommendation: The RPC should strengthen its human resources planning through a comprehensive competence analysis to ensure that it has sufficient staff with the necessary knowledge, skills and abilities to perform all assigned regulatory functions, including in anticipation of future needs.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

The RPC makes use of subcommittees and external technical expertise to support the performance of specialized regulatory and technical functions. CAP.585 establishes the legal authority of the RPC and its Secretariat to obtain the technical support and expertise necessary for the implementation of the regulatory programme.

Malta relies on a limited national pool of specialized radiation protection expertise and therefore makes use of external experts, overseas technical support organizations and advisory arrangements in several technical areas, including personal dosimetry, calibration of radiation detection equipment and other specialized radiation protection services.

The IRRS team noted that several important technical functions rely on external and overseas support arrangements. The review team recognized that this approach is understandable in view of Malta's relatively small size, the limited scale of radiation practices and the limited availability of specialized expertise within the country.

The IRRS team considers that continued attention to formal oversight arrangements, competence management and the avoidance of potential conflicts of interest is important to support the effective independence of the RPC and the objectivity of regulatory decision-making.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

The RPC maintains regular interaction with authorized parties through authorization and licensing processes, inspections, regulatory consultations, follow-up of regulatory issues and communication on radiation protection and safety matters. These interactions support regulatory oversight and facilitate communication regarding compliance with regulatory requirements and implementation of safety measures.

The RPC provides guidance and information to authorized parties on regulatory requirements, radiation protection obligations and the implementation of applicable safety and security measures. The IRRS team noted that the RPC makes use of its website as the primary platform for communication and dissemination of regulatory information, guidance documents and relevant notifications to authorized parties and the public.

The IRRS team also noted that arrangements are in place for the submission and handling of complaints and regulatory concerns. However, it was observed that there are currently no formalized arrangements for the systematic collection, review and consideration of suggestions and feedback received from authorized parties and other stakeholders, or for evaluating how such feedback may contribute to the improvement of regulatory guidance, communication and regulatory processes.

The IRRS team considers that establishing more formal stakeholder feedback mechanisms would support transparency, continuous improvement and enhanced communication between the regulatory body and authorized parties.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

The RPC applies a graded approach to regulatory oversight, taking into account the scale and complexity of radiation practices and activities and the associated radiation risks. Regulatory control is implemented through authorization processes, inspection activities, enforcement actions and the follow-up of corrective measures.

The relatively small number of authorized facilities and activities in Malta facilitates close interaction between the RPC and authorized parties and supports continuity and familiarity in regulatory oversight. The IRRS team noted that the RPC has established documented procedures and operational arrangements intended to support consistency, transparency and traceability in regulatory decision-making and regulatory actions.

The RPC performs a broad range of regulatory and technical functions with a relatively small Secretariat and relies on a limited number of experienced personnel for several key regulatory activities. The IRRS team noted that limitations in staffing resources and the concentration of technical expertise within a small number of individuals may affect the long-term stability, consistency and resilience of regulatory control, particularly in the event of staff turnover or increased regulatory demands.

The IRRS team considers that continued attention to staffing sustainability, competence development, internal review arrangements, harmonization of regulatory decisions and the long-term robustness of regulatory information and knowledge management systems will support the stability, consistency and effectiveness of regulatory control.

3.7. SAFETY RELATED RECORDS

The RPC maintains regulatory records and national registers relating to radiation sources, authorizations, inspections, enforcement activities and radioactive waste management in accordance with CAP.585 and its subsidiary legislation.

The RPC has established arrangements for the collection, maintenance and retention of safety-related information necessary to support regulatory oversight activities and the control of radiation practices and radiation sources. The IRRS team observed that regulatory records are currently maintained in electronic form through separate spreadsheet files stored on a cloud-based system.

The IRRS team noted that maintaining records in separate spreadsheet files may limit the accessibility, traceability, consistency and ease of retrieval of regulatory information, particularly as the volume and complexity of regulatory data continue to increase. The IRRS team further noted that the RPC identified potential risks associated with data integrity and long-term reliability of the current system, including the possibility of accidental corruption or loss of information.

The IRRS team considers that it is important for the RPC to continue reviewing the centralization of its safety-related records and to assess the implementation of an appropriate integrated information management system for the establishment, maintenance, control, protection and retrieval of regulatory records. Such arrangements would support timely access to accurate, comprehensive and up-to-date regulatory information and would enhance the efficiency, continuity and robustness of regulatory oversight activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC maintains safety-related records in separate spreadsheet files which may limit the accessibility, traceability and ease of retrieval of regulatory information. The issue was already identified by Malta and included in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 35 states that** *"The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities."*
(2)	**BASIS: GS-G-3.1. 6.38 states that** *"Records should be readable, complete, identifiable and easily retrievable."*
S3	**Suggestion: The RPC should consider improving its information management system for its safety related records to enhance accessibility, traceability and ease of retrieval of regulatory information.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

CAP.585 provides the legal basis for the RPC to communicate and consult with authorized parties, governmental authorities, emergency response organizations and members of the public on matters relating to radiation safety and nuclear security.

The RPC communicates with interested parties through authorization and inspection processes, guidance documents, consultations, public information activities and coordination meetings with national authorities

and stakeholders. The IRRS team noted that the RPC also conducts consultations with interested parties during the development of regulations and guidance documents, which supports transparency and stakeholder involvement in the regulatory process.

The RPC makes use of its website as the principal platform for communicating regulatory information, guidance, notifications and other information relevant to authorized parties and the public. The IRRS team believes that, however, that opportunities exist to further expand and diversify communication channels and outreach activities to enhance engagement with interested parties and improve public awareness of radiation safety issues and regulatory activities.

The IRRS team also observed that the RPC has not yet established a formal communication strategy with clearly defined objectives, responsibilities and arrangements for communication and consultation activities. In addition, arrangements for systematically informing and consulting interested parties and the public regarding potential radiation risks associated with facilities and activities are not yet formally established. The IRRS team further noted that mechanisms for the periodic evaluation of the effectiveness of stakeholder communication and consultation processes have not yet been formally established.

The IRRS team noted the constructive and effective communication between the RPC and the Office of the Prime Minister, Equality, Reforms and Social Dialogue, which has supported the continued strengthening and development of the national regulatory infrastructure for radiation safety and nuclear security.

The IRRS team considers that continued attention to communication strategies, stakeholder engagement arrangements and the long-term sustainability of communication activities will support transparency, public confidence and the effective implementation of the regulatory framework.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC has not yet established effective arrangements, including a communication strategy for informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 36 states that "***The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."*
(2)	**BASIS: GSG-6 para 4.3 states that** *"A communication strategy appropriate for the role and functions of the regulatory body should be developed and implemented.".*
(3)	**BASIS: GSG-6 para 4.4 states that** *"Clear responsibilities for communication and consultation activities should be established within the regulatory body"*
R8	**Recommendation: The RPC should establish arrangements including a communication strategy for informing and consulting interested parties and the public on radiation risks associated with facilities and activities, as well as on its regulatory processes and decisions.**

3.9. SUMMARY

Malta has established the RPC and its Secretariat as the national regulatory body responsible for radiation safety and nuclear security under CAP.585. The legal and regulatory framework clearly defines the responsibilities and functions of the regulatory body, including authorization, inspection, enforcement, emergency preparedness and response, safeguards, communication and regulatory oversight of radiation practices and activities.

The RPC applies a graded and pragmatic approach to regulatory oversight appropriate to the relatively limited scale and complexity of radiation practices and activities in Malta. The IRRS team noted the constructive interaction between the RPC, authorized parties, national authorities, advisory bodies and the Office of the Prime Minister, Equality, Reforms and Social Dialogue, which supports coordination, regulatory oversight and the continued development of the national regulatory infrastructure.

The IRRS team further noted that the RPC has established arrangements relating to regulatory control, stakeholder communication, competence development, safety-related records and the use of advisory and technical support organizations. Malta also makes effective use of international cooperation activities and overseas technical support arrangements to supplement its limited national technical expertise.

However, the IRRS team identified several areas where further strengthening of regulatory arrangements would support the long-term sustainability, consistency and effectiveness of regulatory oversight. These include strengthening human resources and succession planning; maintaining sufficient in-house technical expertise to support effective independence; further developing stakeholder communication and feedback mechanisms; improving the management and centralization of safety-related records; and enhancing arrangements for oversight of external technical support services and communication with interested parties.

The IRRS team considers that continued attention to staffing sustainability, competence management, knowledge transfer, communication strategies, information management systems and organizational resilience will support the effective, independent and sustainable implementation of the regulatory programme.

4. MANAGEMENT OF THE REGULATORY BODY

4.1 RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The RPC has established an Integrated Management System (IMS) that defines responsibilities, authorities and organizational arrangements for the implementation of its regulatory functions and activities. The management system supports the coordination and oversight of authorization, inspection, enforcement, emergency preparedness and response, radioactive waste management and supporting administrative processes.

The IRRS team observed that leadership responsibilities and interfaces between the RPC and its Secretariat are defined within the management system documentation and associated operational arrangements. The management system also provides a framework for communication, coordination and accountability in the performance of regulatory activities.

The IRRS team noted that the Executive Secretary of the RPC holds regular meetings with Secretariat staff to discuss issues relating to safety, regulatory activities and organizational priorities. These meetings support the communication of safety objectives, monitoring of regulatory activities and understanding of safety responsibilities throughout the organization.

The IRRS team observed that management promotes an open communication and reporting culture within the RPC, encouraging staff interaction, discussion of regulatory issues and the reporting of concerns relevant to safety and regulatory effectiveness. It also observed that management and staff demonstrate a clear awareness of their respective safety responsibilities and maintain close cooperation in the implementation of regulatory oversight activities.

4.2. THE MANAGEMENT SYSTEM

The RPC has established and implemented an IMS to support the performance of its regulatory responsibilities and activities. The IMS provides the framework for the management of regulatory, technical and administrative processes associated with authorization, inspection, enforcement, emergency preparedness and response, review and assessment, environmental monitoring, radioactive waste management and supporting organizational functions.

The IMS includes documented policies, procedures, operational instructions and administrative arrangements intended to support consistency, traceability and effectiveness in the implementation of regulatory activities. The IMS further incorporates documented processes and organizational arrangements intended to ensure that safety considerations are systematically integrated into regulatory decision-making and the conduct of regulatory oversight activities.

The IRRS team observed that the RPC has applied a graded and pragmatic approach in the development and implementation of the IMS, commensurate with the relatively limited scale and complexity of radiation practices and activities conducted in Malta. The IRRS team noted that the relatively small organizational structure of the RPC facilitates direct communication between management and staff and supports timely follow-up of identified issues, corrective actions and organizational improvements.

The RPC has made commendable efforts in developing a comprehensive management system. However, the IRRS team has noted that some processes and procedures relating to assigned regulatory functions, such as enforcement procedures and internal guidance to perform the review and assessment of certain aspects

of the documentation supporting the authorizations, are not yet formally documented within the IMS. The continued development and consolidation of the management system will further support the stability, consistency and effectiveness of regulatory control and the sustainable implementation of the regulatory programme.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC management system needs to have additional processes and procedures to cover all its regulatory functions.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 19 states that** *"The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement"*
(2)	**BASIS: GSR Part 1 (Rev. 1) para 4.16 states that** *"The management system shall maintain the efficiency and effectiveness of the regulatory body in discharging its responsibilities and performing its functions."*
S4	**Suggestion: The RPC should consider further developing its management system to cover all its regulatory functions.**

4.3. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The IRRS team observed that the Integrated Management System (IMS) is not yet being monitored, systematically reviewed and assessed to evaluate its effectiveness and support continuous improvement. Formal arrangements for periodic internal reviews, independent assessments and management reviews have not yet been fully established. In addition, measurable performance indicators for monitoring the effectiveness of regulatory and management processes have not yet been developed.

The IRRS team further observed that strengthening arrangements for process integration, implementation of the graded approach, internal coordination and interface management would further support the effectiveness and consistency of the management system.

The IRRS team considers that establishing systematic arrangements for performance monitoring, internal assessment, and continuous improvement of the IMS would support the effective and sustainable implementation of the RPC's regulatory functions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC management system is not being systematically reviewed and updated, and arrangements for the periodic evaluation of its effectiveness have not yet been fully established.	
(1)	**GSR Part 1 (Rev.1) Requirement 19 states that** "*The regulatory body shall establish, implement, assess and improve a management system that is aligned with its safety goals and contributes to their achievement."*
(2)	**GSR Part 2 Requirement 14 states that** *"The effectiveness of the management system shall be measured, assessed and improved."*

R9	**Recommendation: The RPC should establish and implement arrangements for the periodic review, assessment and continuous improvement of its management system, including evaluation of its effectiveness.**

4.4. SUMMARY

The RPC has established and implemented an Integrated Management System (IMS) to support the performance of its regulatory responsibilities and activities. The IMS provides a framework for the management of regulatory, technical and administrative processes associated with authorization, inspection, enforcement, emergency preparedness and response, review and assessment, environmental monitoring, radioactive waste management and supporting organizational functions. The IRRS team noted that the management system supports coordination, communication and accountability in the implementation of regulatory activities.

The IRRS team observed that the RPC has made commendable efforts in developing a comprehensive management system and has applied a graded and pragmatic approach in its implementation, commensurate with the relatively limited scale and complexity of radiation practices and activities in Malta.

However, the IRRS team identified several areas where further strengthening of the management system would support the long-term effectiveness, consistency and sustainability of regulatory activities. The IRRS team considers that continued development, assessment and improvement of the IMS will support the effective, consistent and sustainable implementation of the RPC's regulatory functions.

5. AUTHORIZATION

5.1. GENERIC ISSUES

Under Maltese legislation (CAP.585), notification and as appropriate authorization are required for the operation of facilities involving non-exempted radiation sources and the conduct of activities involving such radiation sources. SL585.01 determines which practices are exempted from regulatory control.

For practices that are subject to authorization, the RPC may apply either registration or licensing. However, the form of authorization by registration is not currently being implemented by the RPC, as no relevant processes have been established to that end.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Although the regulations establish the concept of registration as a form of authorization, registration is not applied in practice by RPC. No processes have been established by the RPC for the implementation of registration.	
(1)	**BASIS: GSR Part 3 Requirement 7 para. 3.8 states that** *"Any person or organization intending to carry out any of the actions specified in para. 3.5 shall, unless notification alone is sufficient, apply to the regulatory body for authorization, which shall take the form of either registration or licensing."*
(2)	**BASIS: GSR Part 3 Requirement 3 para. 2.31. states that** *"The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation.***"**
S5	**Suggestion: The RPC should consider establishing processes for using registration as a form of authorization, taking into account a graded approach.**

For license applications, SL585.01 determines that the following information should be provided to the RPC:

- 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 procedures;
- Maintenance, testing, inspection and servicing so as 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.

While these requirements are established for a license application, the RPC has not yet developed guidance for applicants on the content and format, addressing all types of authorizations. This applies to other types of applications, such as renewal or modification of authorizations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The regulations define the requirements for licensing applications. However, the RPC has not yet established guidance for applicants across all types of authorizations, on the format and content of the documents to be submitted, including in the case of modifications and renewal.	
(1)	**BASIS: GSR Part 1 rev 1 Requirement 24, para. 4.34 states that** *"The regulatory body shall issue guidance on the format and content of the documents to be submitted by the applicant in support of an application for an authorization."*
R10	**Recommendation: The RPC should issue guidance for applicants on the process of authorization and the format and content of the documents to be submitted in support of the different types of authorizations and, where applicable, authorization stages, including for the renewal and modifications of the authorizations.**

During the authorization phase, the RPC conducts an inspection to confirm that the information supplied complies with the applicable regulations. This is described in further detail in section 7.1.

The licence that is issued includes all the equipment authorized within the practice, any conditions that may have been established, and the expiry date. The duration of the authorization varies according to the type of practice, ranging from 1 (e.g. for practices involving high activity sealed sources) to 4 years (e.g. for dental intraoral radiography equipment), based on a graded approach.

The authorisation documents are signed by the Executive Secretary, and the corresponding records are maintained by the RPC, i.e. hard copies are scanned and entered into the electronic filing system, in the appropriate facility's file.

The RPC is empowered to include specific conditions in the authorization, when appropriate, to impose appropriate restrictions.

When modifications to the authorization are requested by the authorized party, a new licence is re-issued. The modifications that require notification to the RPC are:

- Changes in the radiation sources;
- Changes in the legally responsible person;
- Replacement of significant parts of radiation equipment;
- Decommissioning of equipment, to ensure proper dismantling, removal of sources;
- Transfer of any radioactive material to another facility;
- When a sealed source becomes disused and is placed in storage at the facility;
- Changes in any methods of management of radioactive waste.

- Any other material changes within a facility.

If a facility needs to discharge radioactive materials to the environment, specific conditions are included in a separate licence, as detailed in section 5.8.

The authorized party is required to notify the RPC at least one month prior to the expiry of their authorisation. The IRRS team was informed that, even if the authorized parties do not submit the request for renewal of authorisation, the RPC arranges for an inspection prior to the expiry and re-issues the licence if the authorized party intends to continue to carry out the activity, and if compliance with the regulations has been demonstrated.

The applicants and authorized parties may appeal decisions of the RPC, where a two-tier process is followed. For minor issues, the Executive Secretary of the RPC may evaluate the grievance, make a decision and inform the applicant. For other issues, process involves taking the matter to the attention of the President of the Appeals Tribunal, who decides. This issue is discussed in detail in section 8.2.

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Under the SL 585.03, facilities and activities for management of radioactive waste require a license from the RPC for all the phases of their life cycle, i.e. siting, design, construction, commissioning, operation, decommissioning or closure.

Prime responsibility for safety in the management of radioactive waste rests with the licensee, who is also responsible for regularly assessing and continuously improving the safety of their activities, preparing a safety demonstration that covers the development, operation and decommissioning of the facilities and activities, establishing and implementing an integrated management system that assigns due priority to safety, and maintaining adequate human and financial resources to fulfil their obligations with regard to safety.

While the RPC has established internal documents to conduct the review and assessment of license applications for predisposal waste management facilities, there is no guidance for applicants on the format and contents of the applications. The RPC informs the applicants after the application has been received and reviewed and may request any additional information required to complete the review of the application. **This issue is addressed in Recommendation R10 in section 5.1.**

Currently, the CSF is the only facility in Malta that performs predisposal activities for radioactive waste.

The CSF is operated by a private company under contract with the Government. Past contracts with the private company have been with the Ministry responsible for the RPC. This issue is highlighted in further detail in section 1.7.

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Under Maltese legislation, notification and as appropriate authorization are required for the operation of facilities involving non-exempted radiation sources and the conduct of activities involving such radiation sources require authorization. The list of activities which are subject to registration or licensing, is established in the regulation.

Applicants are required to submit documentation demonstrating that appropriate safety measures are in place in support of their application for authorization. Although the regulations specify the information

required for licensing, no requirements are in place regarding registration, and no additional guidance is provided on the expected format or content of the documents to be submitted by the applicant for specific types of facilities or activities. **This issue is addressed in Recommendation R10 in section 5.1.**

Currently, no registrations have been issued, and most facilities and activities are subject to licensing, with the exception of dental clinics, which have received permission for the use of dental equipment via email correspondence, without authorization documents being issued. The IRRS team was informed that the RPC inspection programme for 2026–2030 includes the inspection of 125 dental clinics, in order to issue formal authorization documents.

Authorizations issued by the RPC are granted for a specified validity period and are subject to established regulatory provisions for their amendment, renewal, suspension, or revocation. The process of authorization is governed by a dedicated procedure; however, this procedure does not currently address the specific steps related to amendment, renewal, suspension, or revocation of authorizations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: While provisions for the amendment, renewal, suspension and revocation of authorizations exist in the legislation, the RPC has not established procedures to implement these provisions.	
(1)	**BASIS: GSR Part 1 (Rev. 1) para. 4.37 states that "**Any subsequent amendment, renewal, suspension or revocation of the authorization for a facility or an activity shall be undertaken in accordance with a clearly specified and established procedure, and shall make provision for the timely submission of applications for the renewal or amendment of the authorization"
S6	**Suggestion: The RPC should consider establishing a procedure for the amendment, renewal, suspension or revocation of authorizations for facilities or activities.**

The RPC authorizes import and export of radioactive sources. Malta is not a manufacturer of radioactive sources and currently does not possess any Category 1 radioactive sources. A category 2 radioactive source is currently in the process of being imported for use in brachytherapy. However, the IRRS team encourages the RPC to further revise authorization procedures taking into account the provisions of the Guidance on the Import and Export of category 1 and 2 Radioactive Sources, including the request for consent and notification.

5.4. AUTHORIZATION OF DECOMMISSIONING OF FACILITIES

At the time of the IRRS Mission, there are no facilities undergoing decommissioning in Malta.

SL585.03 establishes that decommissioning activities for radioactive waste management facilities are subject to licensing by the RPC. This subsidiary legislation also establishes that authorized parties of these facilities are required to provide and maintain adequate financial and human resources to fulfil their obligations with respect to the safety of radioactive waste management, through all phases of the facility's

life cycle, including decommissioning. Predisposal waste management facilities are required to submit a decommissioning plan as part of the authorization process, that addresses:

- A detailed explanation of funding arrangements for decommissioning;
- Provisions for preparing for decommissioning during the operational phase, including the maintenance of records that will support future decommissioning planning;
- A description of the decommissioning process, covering methods for decontamination, dismantling, and demolition;
- The management of radioactive materials generated during decommissioning, including waste inventory, minimization strategies, and disposal plans;
- Post-decommissioning activities, such as conducting a final radiological survey and implementing environmental remediation measures for the site.

The regulations establish that the decommissioning plan is to be periodically reviewed and updated to accommodate changes in the facility, the regulatory framework, or advancements in technology. However, it does not require the licensee to submit a final decommissioning report to the RPC upon completion of decommissioning activities. Instead, the RPC plans to perform an on-site inspection to verify that radioactive material has been removed and no residual contamination is present before terminating the licence. This approach does not ensure that the licensee formally demonstrates fulfilment of all decommissioning obligations prior to the termination of the authorization. **This issue is addressed in Recommendation R5 in section 1.7.**

For other types of facilities that may require decommissioning, such as certain medical and industrial facilities involving radioactive material, neither a decommissioning plan nor a final report is required by the regulations. Instead, the entire procedure is handled within the process for terminating the authorization for the facility or activity. In such cases, similarly, the RPC performs an inspection, before terminating an authorization for the facility or activity and releasing it from regulatory control, to ensure that all radioactive material has been removed and that no residual contamination is present. **This issue is addressed in Recommendation R5 in section 1.7.**

5.5. AUTHORIZATION OF TRANSPORT

The regulatory framework for the transport of radioactive material in Malta is established under CAP.585, which formally adopts the requirements and mechanisms of the IAEA safety standards SSR-6 (Rev 2). The authorization of carriers and the validation of foreign package designs are performed through specific licensing procedures such as OP-025.

Personnel involved in the transport of radioactive material must complete a 4-hour training course and examination for drivers, to obtain a Class 7 license. The applicants for a transport license submit dose assessments for the drivers based on the workload. Currently, national transport is limited to radiopharmaceuticals and a single NDT source. As there is no manufacturer for packages in Malta the RPC relies on international certificate validation for the package design.

5.6. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

Regulations empower the RPC to recognize technical service providers and to establish criteria for such recognition in order to ensure the availability and continuity of the expertise required to support regulated

activities. However, no specific requirements have been established to date for personal dosimetry and calibration of equipment service providers.

As a result, no personal dosimetry or calibration service providers have been recognized by RPC. Licensees are required to ensure external individual surveillance through services approved by a European Union Member State or accredited to ISO 17025. Internal individual dosimetry is not implemented, and all calibration of equipment is performed by ISO accredited foreign services.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC has the authority to approve technical service providers. However, no specific requirements have been established for implementing this provision, including for personal dosimetry and calibration of equipment service providers. The issue was already included by Malta in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 1 para. 2.41 states that**: *"Technical services do not necessarily have to be provided by the government. However, if no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services. The regulatory body shall authorize technical services that may have significance for safety, as appropriate."*
S7	**Suggestion: The RPC should consider establishing specific requirements and criteria for the authorization of technical service providers that may have significance for safety, including providers of personal dosimetry and calibration services.**

The RPC developed a structured system for the Recognition of Radiation Protection Experts (RPEs) that defines the following:

- Competence-Based Recognition: Recognition is based on academic qualifications, practical experience, technical competence, understanding of radiation protection principles, and ability to perform specific duties and responsibilities.
- Structured Assessment Process: The RPC applies a formal review and assessment process including review of qualifications, training records, professional experience, competence portfolio. Recognition may be granted for specific areas of practice or refused where competence is insufficient. Re-certification is required every 5 years.
- Continuous Professional Development point system (tool): Recognized experts are expected to maintain competence through continuous training, professional development, and periodic renewal of recognition.

Criteria for the recognition of RPEs, guidance for applicants, a list of recognized RPEs, and regular updates are available on the RPC website. Since 2018, 19 RPEs with medical, industrial and other areas of expertise have been recognized by RPC.

Through this approach, the RPC has established a comprehensive approach for the recognition of RPEs. **This is considered by the IRRS team as an area of good performance**.

The regulations do not require Radiation Protection Officers (RPOs) to be recognized by the RPC. However, to assist licensees in the designation of suitably qualified RPOs, the RPC has issued guidance on "the designation of Radiation Protection Officers by undertaking" which clarifies their roles and tasks, as well as the required education, training and prior work experience.

Occupational Health Services must be approved by the RPC. Any person who is registered on the Specialist Accreditation Register of the Medical Council as a Medical Practitioner in Occupational Medicine and has undertaken further education in ionizing radiation can apply to provide an Occupational Health Service in Malta. Currently, no occupational Health Service dedicated to radiation protection is available in Malta. The regulations require occupational health surveillance only for category A workers, and no category A workers have currently been classified in the country.

5.7. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

The RPC issues approval certificates for MPEs for a validity period of up to five years per specialty covering radiotherapy, nuclear medicine, diagnostic and interventional radiology. MPEs need to be registered with the Council for Professions Complementary to Medicine in Malta as Medical Physicists, have a minimum of two years of recent work experience in their respective specialty and documented Continuing Professional Development. Re-certification is required every five years, with 48 months of work experience and documented Continuing Professional Development.

Criteria of the recognition of Medical Physics Experts (MPEs), guidance for applicants and a list of recognized Experts as well as regular updates are available on the RPC website. Currently, 16 MPEs with expertise in diagnostic radiology, radiotherapy, or nuclear medicine have been recognized by RPC. Through this approach, the RPC has established a comprehensive approach for the recognition of MPEs. **This is considered by the IRRS team as an area of good performance**.

5.8. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

Dose limits for the public are in line with GSR Part 3. When applying for an authorization, the applicant must present a safety assessment that takes into account the exposure of members of the public in normal operation. This assessment must demonstrate that the activity complies with the dose constraint for members of the public of 0.25 mSv per year from any practice.

When an authorization is granted for activities that involve discharges to the environment, the RPC establishes discharge conditions for liquid and solid materials being released to the environment. For the release of liquid discharges, the RPC establishes the limit based on an assessment of the dose to the public from ingestion, ensuring compliance with the dose constraint. Solid materials may be cleared if their activity concentration is lower than the values established in SL 585.01. For radionuclides not listed in the regulations, the RPC may adopt the use the values included in GSR Part 3.

Under the National Radioactivity Monitoring Programme, the RPC, together with Environment and Resources Authority and the Environmental Health Directorate and the Animal Health and Welfare Directorate, carries out measurements of radioactivity in samples collected periodically from several environmental compartments, e.g. air particulates, sea water, water for human consumption, soil, mixed diet meals, milk, feedstuffs. While the RPC provides measurements to European Union networks, it does not present its findings directly to the public in Malta.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC provides environmental monitoring data to European Union networks but does not make this data available to the public locally in a timely manner. The issue was already included by Malta in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 3 Requirement 32, para. 3.136 states that** *"The regulatory body shall publish or shall make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure."*
R11	**Recommendation: The RPC should publish or make available on request, as appropriate, the results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure, as well as other relevant information.**

SL585.01 requires that authorized parties perform environmental monitoring, as appropriate, in connection with their practices. However, there are no provisions to ensure the results should be made available to the public.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no provisions to ensure the results of authorized parties' environmental monitoring programmes are made available to the public.	
(1)	**BASIS: GSR Part 3 Requirement 32, para. 3.137(h) states that** *"Registrants and licensees shall, as appropriate: (...)* *h) Publish or make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure."*
R12	**Recommendation: The RPC should establish provisions to ensure that authorized parties are required to publish or make available on request, as appropriate, the results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure.**

With regards to consumer products, SL585.01 establishes that an authorization, in the form of a license is required for the deliberate addition of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products, and the import of such products. The IRRS Team was informed that such activities are not currently carried out in the country and therefore the RPC has not yet established guidance for applicants regarding the scope and contents of the applications. The IRRS team encourages the RPC to develop new procedures as and when required.

5.9. SUMMARY

Malta has established a comprehensive system for the authorization of facilities and activities. The RPC could enhance the functionality of this authorization system by establishing practical arrangements for registration, in accordance with a graded approach, allowing for more efficient use of the RPC's resources.

Additionally, improvements are needed in the following areas: providing guidance for applicants on the contents and format for applications for authorizations, establishing a procedure for the renewal and amendment of authorizations, establishing requirements for the approval of technical services, and improving the provision of information to the public by publishing the results of the environmental monitoring programme.

The RPC has established comprehensive criteria for the recognition of RPEs and MPEs that takes into account a competence-based recognition, a structured assessment process, and a continuous professional development points system. This was considered by the IRRS team as an area of good performance.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

The RPC ensures that facilities, activities and exposure situations are in compliance with the requirements and authorization conditions. This function is grounded in CAP.585, which provides that the RPC may issue authorizations that must be subject to an appropriate review and assessment before being issued.

The RPC has developed an internal operating procedure to guide the review and assessment process. This procedure covers common elements of the review and assessment for all types of practices in the country, namely, radiotherapy, nuclear medicine, X-ray imaging in radiology, industrial radiography, nuclear gauges, and X-ray used in inspection. The procedure is applied in accordance with a graded approach and also addresses the security of radioactive sources.

The competence of individuals responsible for the safety of the facility is assessed during the review of the application. The RPC verifies that relevant personnel hold the necessary radiation protection qualifications and training.

To support the review and assessment process, the RPC has initiated the development of review and assessment checklists for all practices. The IRRS team noted that, at the time of the mission, only one such checklist, for brachytherapy, has been finalised.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC has developed an internal operating procedure for the review and assessment process and has only one specific checklist for the review and assessment of brachytherapy. Specific criteria and checklists for the review and assessment of other facilities and activities have not yet been developed. The issue was already included by Malta in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 22, para 4.26 states that "***The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which its requirements, judgements and decisions are based."*
(2)	**BASIS: GSR Part 1 (Rev. 1) Requirement 26; para 4.41 states that** *"Technical and other documents submitted by the applicant shall be reviewed and assessed by the regulatory body to determine whether the facility or activity complies with the relevant objectives, principles and associated criteria for safety"*
R13	**Recommendation: The RPC should establish criteria and develop checklists for conducting the review and assessment of all types of facilities and activities in accordance with a graded approach.**

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

Regulations establish that authorized parties shall perform safety assessments in support of a license application, and to review and update them as required. The safety assessment is an integral part of the safety case for the CSF.

The RPC has established internal guidance for reviewing and assessing licensing applications for predisposal waste management facilities. This guidance provide direction to the RPC to review and assess the topics covered in the safety case in a systematic and consistent manner. Review and assessment are carried out based on the information submitted in the safety case and periodically updated in line with the renewal process for the license. It also takes into account information collected during the inspections that are performed at the facility.

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The RPC applies a graded approach to the review and assessment of practices with radiation sources, in accordance with internal procedures that classify practices into four categories: sealed sources, unsealed sources, X-ray producing equipment and other practices. To support this process, the RPC has initiated the development of checklists. Currently, only one checklist covering brachytherapy had been finalised. **This issue is addressed in Recommendation R13 in section 6.1.**

The review and assessment process includes inspections that are undertaken to confirm compliance with the applicable safety and regulatory requirements, including in the case of amendment, renewal, suspension, or revocation of authorizations

All information related to the authorization and inspection of facilities and activities is maintained in dedicated shared folders for each facility, ensuring access to all relevant documents and complete regulatory history during the review and assessment process. The basis for the decisions to grant licenses is not recorded in a structured form that consolidates the review performed. **This issue is addressed in Suggestion S4 in section 4.2.**

6.4. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

Malta has no facilities undergoing decommissioning. During the review and assessment of an application for decommissioning for predisposal waste management facilities, the RPC will review the necessary information on any required decommissioning activities. However, internal processes have not yet been established. **This issue is addressed in Recommendation R13 in section 6.1.**

Moreover, for other facilities that may require decommissioning, there are no requirements for the facilities to prepare a decommissioning plan and there is no guidance for RPC staff to conduct the review and assessment of the decommissioning plan. **This issue is addressed in Recommendation R5 in section 1.7.**

6.5. REVIEW AND ASSESSMENT FOR TRANSPORT

The review and assessment of the transport of radioactive material is carried out by the RPC using the established procedures in compliance with IAEA safety standards **SSR-6 (Rev. 2).** Through this process, the RPC verifies that the applicant possesses the necessary basic equipment and competences to carry out transport of Class 7 material on Maltese roads. However, RPC has not established an internal procedure for the review of the emergency procedures during transport. **This issue is addressed in Recommendation R17 in section 10.3**.

6.6. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

The review and assessment of occupational exposure during the notification and authorization process is carried out by the RPC, taking into account aspects such as the safety assessment, the use of dose constraints for occupational exposure, the assignment of responsibilities within the authorized party, the designation of RPOs, and the availability of RPEs to provide advice on occupational and public exposures. The assessment of documentation is usually complemented by an on-site inspection of the facility.

The authorized party, for the purposes of monitoring and surveillance, based on the safety assessment, classifies the occupationally exposed workers into “category A” or “category B”. Both category A and B workers are individually monitored. Doses received by category A and B for workers are reported to the National Dose Registry maintained by the RPC.

For the aircrew members liable to receive an effective dose greater than 1 mSv/year from exposure to cosmic radiation, employers are required to assess occupational exposure and take adequate measures regarding dose optimization and information to workers. A reference level of 6 mSv/year has been established. However, no national methodology has been established yet for dose assessment. In practice, airline companies use different calculation platforms to estimate exposures, typically based on flight routes and altitude. The IRRS Team encourages the RPC to develop guidance on the national methodology for the assessment of occupational doses to air crew.

In 2025, 59 airline companies registered in Malta reported the aircrew doses to the RPC. These doses were reviewed and then recorded.

6.7. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

As part of the review and assessment of an application for authorization of a medical facility or activity, the RPC evaluates relevant requirements related to medical exposure, including, allocation of responsibilities, information on medical radiological equipment, information on measuring instruments for quality control, justification and optimization procedures, provisions of information to patients, procedures for minimizing unintended or accidental medical exposure.

For medical radiological equipment, an acceptance test report is submitted to the RPC for review, and the legally responsible person for the practice is required to issue a declaration confirming that the equipment is fit for clinical use.

The information submitted regarding the competence and training of health professionals are verified through the process for the recognition of MPEs, as well as the professional experience of practitioners and persons performing the practical aspects of medical exposures.

Authorized parties are required to notify the RPC of any accidental or unintended exposure involving medical exposure that meets the criteria defined in the regulations, and to submit an incident report. The RPC conducts inspections/interviews as part of the investigation into the incident and issues a report documenting the investigation of the findings, as well as any corrective actions to be implemented or additional documents to be provided.

6.8. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

When issuing the license, the RPC includes conditions to ensure that the authorized party submits, on an annual basis, information on the total radioactivity discharged to the environment and an estimate of doses to individuals from the discharges. The RPC reviews this discharge information to ensure that the discharges are in compliance with its discharge authorisation.

The only facility in Malta that performs discharges to the environment is a nuclear medicine department, with conditions established in its respective license.

The IRRS Team was informed that consumer products containing radioactive substances are not currently manufactured in the country. Nevertheless, the RPC has not yet established internal processes to address review and assessment of such applications. The IRRS team encourages the RPC to develop new procedures as and when required.

6.9. SUMMARY

The RPC has established a regulatory basis for review and assessment, supported by an internal operating procedure that captures common elements of the process across all regulated practices and explicitly requires application of a graded approach. However, specific evaluation criteria should be developed for each facility type and activity to bring it in line with IAEA safety standards.

The review and assessment of occupational exposure is well-structured, encompassing safety assessments, dose constraint verification, designation of radiation protection roles, individual dose monitoring for all exposed workers and dose evaluation for aircrew members.

The review and assessment of medical exposure is comprehensive, covering competence verification, equipment acceptance testing, and incident follow-up.

The RPC also effectively reviews annual discharge information from the only facility performing environmental discharges to verify compliance with applicable dose constraints.

7. INSPECTION

7.1. GENERIC ISSUES

The RPC is empowered through CAP.585 to perform inspections on the facilities and activities that it regulates. Internal procedures have been established to carry out the inspections. The RPC conducts both planned and reactive inspections. Inspections may be announced or unannounced.

The established procedures consider different frequencies for inspections, ranging from 1 year to 4 years, according to the type of facility or activity, taking into account a graded approach. Planned inspections are linked with the process for renewal of authorizations.

Planned inspections are performed at different points over the facility's life cycle:

- Initial or pre-operational inspections are carried out prior to a practice commencing radiation use;
- Routine inspections are performed periodically throughout the validity of the authorization and when a facility's authorization is about to expire.
- On cessation of activities, to confirm that radiation sources have been removed and no residual contamination is present at the facility.

The IRRS team was informed that the RPC has established a 4-year programme for planned inspections, based on licence expiry dates.

Reactive inspections are also conducted in response to incidents, complaints, or non-compliance reports.
The RPC procedures establish that inspections are generally performed by at least two inspectors. One inspector will take the lead and will coordinate the preparations for the inspection. In preparation for the inspection, the inspectors review all the necessary information, including the authorized party's authorisation and any issues that were outstanding from the previous inspection. Equipment to be used in the inspection is also selected and verified in the preparatory stage. The inspections are performed according to pre-prepared checklists that are tailored to the authorized party.

After the inspection, the authorized party is informed of the findings and a report is sent, detailing any non-compliances, any corrective actions needed, and the amount of time they should be completed in.
In the case that serious non compliances are noted during an inspection, a verbal stop order may be issued by the inspector, followed by a written order sent to site management within 48 hours.

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

Predisposal waste management facilities and activities are inspected by the RPC on a yearly basis. Inspections are performed following the procedures outlined in section 7.1.

The IRRS team observed a planned inspection conducted by the RPC at the CSF, a radioactive waste management facility. The IRRS team observed that the inspectors prepared the inspection in advance, by reviewing various documents related to the facility. The inspection started with an entrance meeting, where inspectors informed the authorized party of the scope and purpose of the inspection, and requested relevant

documentation to be presented for review. During the walkdown of the facility, the RPC inspectors verified some of the radioactive sources stored and the status of their conditioning.

The inspectors conducted themselves professionally, and showed a high level of proficiency, carrying out measurements with their own equipment. At the end of the inspection, the inspectors informed the authorized party of the findings of the inspection, as well as the next steps to be followed.

After the inspection, the IRRS team discussed with the representative of the authorized party and was informed that they have a cordial and productive relationship with the RPC, highlighting their constant readiness to support any needs they may have. The representative emphasised the importance of the RPC continuing to be able to perform its regulatory oversight, which they consider an important contribution to the safety of activities.

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Inspections of facilities and activities involving radiation sources are conducted in accordance with a graded approach, as established in the internal procedure. In practice, the frequency of inspections is generally aligned with the period of validity of the authorization.

Inspections are always performed by at least two officers, with one designated as the lead inspector. Inspections are conducted in accordance with inspection procedure, supported by specific checklists tailored to the different types of facilities, and practices, such as radiotherapy, nuclear medicine, medical X-ray, etc. After the inspection, the completed checklist is retained in the facility's file. The inspection report is sent to the licensee including the results of the inspection, detailing any areas of non-compliance, specifying the corrective actions to be implemented, and indicates the timeframe within which the facility required to address them.

The IRRS team was informed that during 2025, the RPC inspected 108 facilities and activities involving radiation sources. The four-year inspection programme for the period 2026-2030, includes a total of 454 planned inspections. The programme is subject to review on an annual basis taking into account regulatory priorities and needs.

7.4. INSPECTION OF DECOMMISSIONING ACTIVITIES

Currently, no facilities in Malta are undergoing decommissioning. Therefore, the RPC has not established a system for inspection of such activities. **This issue is addressed in Suggestion S4 in section 4.2.**

7.5. INSPECTION OF TRANSPORT

Inspections of carriers transporting radioactive material are performed by the RPC. Transport inspections cover all relevant aspects of the transport operation, including the condition of vehicles and packages, marking and labelling, compliance with radiation protection and training requirements, emergency response arrangements, written instructions, radiation protection programmes and security measures. Dose rate measurements on the surface of packages are also carried out as part of the inspection.

Any non-compliances identified during the inspection, together with the required corrective actions and associated timelines, are communicated to the licensee in a written inspection report.

The RPC has established an inspection programme for transport activities; however, this programme does not include on-site inspections of domestic carriers during physical transport operations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC has included transport activities in its inspection programme. However, the current programme does not include inspections carried out during physical transport activities.	
(1)	**BASIS: SSR-6 (Rev. 2), para. 302 states** *A radiation protection programme shall be established for the transport of radioactive material. The nature and extent of the measures to be employed in the programme shall be related to the magnitude and likelihood of radiation exposure. The programme shall incorporate the requirements of paras 301, 303–305, 311 and 562. Programme documents shall be available, on request, for inspection by the relevant competent authority*
(2)	**BASIS: GSR Part 3, para. 1.11 states** *that the regulatory body is responsible for carrying out its statutory functions, specifically the authorization and inspection of facilities and activities*
S8	**Suggestion: The RPC should consider expanding its inspection programme for the transport of radioactive material to include inspections carried out during physical transport activities.**

7.6. INSPECTION OF OCCUPATIONAL EXPOSURE

The RPC ensures that authorized parties comply with occupational exposure requirements by conducting inspections. Inspections related to occupational exposure are carried out by the RPC in accordance with the procedures outlined in Section 7.1.

Before any inspection is conducted, including pre-authorization inspections, the radiation protection programme (RPP) and any available occupational dose records are reviewed. During inspections, the RPC uses a checklist to verify that the safety assessment and the RPP are available and up to date, and that they include appropriate procedures and arrangements for:

- monitoring workers' exposure;
- providing education and training in radiation protection and safety;
- carrying out individual and/or workplace monitoring, as applicable; and
- ensuring that monitoring results are properly recorded and retained.

7.7. INSPECTION OF MEDICAL EXPOSURE

During inspections conducted by the RPC, requirements regarding medical exposures are part of the aspects verified during inspections of medical facilities and activities. The RPC ensures compliance with medical exposure requirements during facility inspections by following a structured approach based on detailed checklists for each medical practice (Dental, Medical X-ray, Nuclear Medicine, Radiotherapy).

These checklists make reference to each of the medical exposure regulatory requirements to be checked during inspections, including approval of persons involved in medical exposures, use of diagnostic reference levels, use of dose constraints for comforters and carers, testing of medical radiological equipment, radiation protection of pregnant and breastfeeding patients and release of patients following radionuclide therapy.

The IRRS team observed a planned and announced inspection conducted by RPC at the Sir Anthony Mamo Oncology Centre (SAMOC) at Mater Dei Hospital. The observed inspection was carried out to verify compliance with the applicable safety and regulatory requirements prior to authorization for the import of a sealed radioactive source for a new brachytherapy unit. During the entrance meeting, hospital representatives were informed of the scope and objectives of the inspection.

The inspection was carried out according to RPC's inspection procedure. A structured checklist was used for the conduct of the inspection, covering specific thematic areas. At the end of the inspection, the RPC inspectors verbally presented the findings to the representatives of the facility, highlighting the main observations and areas requiring attention.

After the inspection, the IRRS team interviewed the hospital representatives who emphasized the close and collaborative working relationship with the RPC. They noted that RPC is readily accessible and responsive to queries regarding regulatory requirements, inspection or authorization processes, which promotes effective communication and facilitates regulatory compliance.

7.8. INSPECTION OF PUBLIC EXPOSURE

The RPC has included the requirements for the protection of the public in its inspection procedures and checklists, including the estimation of doses to the public and their compliance with the dose constraints.

The RPC inspects facilities during the construction phase to confirm that any shielding installed is in line with the safety assessment. If required, the RPC measures doses in or around the property to monitor potential public exposures.

For authorized parties that perform discharges to the environment, the RPC requires the submission, on a yearly basis, of a report detailing the total radioactivity discharged to the environment. The RPC verifies the compliance with the dose constraint for the public due to these discharges.

7.9. SUMMARY

The RPC has established a comprehensive inspection programme for facilities and activities. This inspection programme is closely linked with the authorisation process.

RPC's inspection programme needs to be expanded to include inspections during physical transport activities.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

The RPC and its Secretariat are empowered under the CAP.585 to conduct inspections, investigate non-compliances, issue directives and undertake enforcement actions relating to radiation practices and activities. The legal framework establishes enforcement powers including the suspension, modification or revocation of authorizations, issuance of enforcement notices, administrative sanctions and prosecution in cases of non-compliance with regulatory requirements.

The IRRS team noted that the RPC has established an enforcement policy and supporting enforcement guidance documents that outline a graded approach to enforcement and categorize non-compliances according to their significance and potential safety impact. The enforcement arrangements identify different enforcement actions, including warning letters, stop orders, revocation of authorizations, sealing of non-compliant equipment, administrative fines and prosecution for serious breaches of regulations. The policy also establishes timelines for corrective actions commensurate with the severity of the identified non-compliance.

The IRRS team further observed that the RPC applies a graded and pragmatic approach to regulatory oversight and enforcement activities, taking into account the radiation risks, the significance of the non-compliance and the potential consequences to workers, patients, members of the public and the environment. Enforcement actions may arise from inspections, incident investigations, complaints, failure to provide regulatory information, or information received from national or international organizations.

The IRRS team also noted that the RPC has developed standard templates and operational guidance to support implementation of enforcement actions, including enforcement orders and stop orders. However, The RPC has not yet established the administrative fines provided by CAP.585 that shall be applicable for non-compliances, thereby limiting the use of this particular administrative action.

The IRRS team observed that although an enforcement policy and related guidance documents have been established, arrangements for the practical implementation of the enforcement process is not yet established. In particular, there is a need for further consolidation and formalization of enforcement procedures to ensure consistency, transparency, documentation and systematic follow-up of enforcement actions and corrective measures.

The IRRS team considers that continued development and implementation of comprehensive enforcement procedures will support the effective, consistent and transparent application of regulatory enforcement activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC has established an enforcement policy. However, not all the enforcement processes and procedures have been established.	
(1)	**BASIS: GSR Part 1 (Rev.1) para. 4.63 states that** *"The enforcement process shall be specified by the regulatory body."*

(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 31, para. 4.60 states that** *"… the regulatory body shall confirm that the authorized party has effectively implemented any necessary corrective actions*."
S9	**Suggestion: The RPC should consider further developing its enforcement processes and procedures.**

8.2. ENFORCEMENT IMPLEMENTATIONS

The IRRS team noted that the RPC has undertaken limited enforcement actions mainly to issuing stop orders, reflecting the relatively small scale and complexity of radiation practices and activities within Malta.

As highlighted in Section 8.1, although the RPC has established an enforcement policy and supporting guidance documents, comprehensive processes and procedures for the consistent, transparent and effective implementation of enforcement activities have not yet been fully developed and implemented.

The IRRS team further noted that, although CAP.585 establishes an appeals mechanism through the Radiation Protection Appeals Tribunal, the mechanism has not yet been operationalized in practice. Implementing procedures and guidance for the operation of the appeals process, including timelines and administrative arrangements for the submission, handling and resolution of appeals, have not yet been formally established.

The IRRS team also observed that information relating to appeal rights and appeal procedures is not systematically incorporated into enforcement documentation or routinely communicated to authorized parties. In addition, the appeals mechanism has not yet been tested or exercised in practice.

The IRRS team considers that continued development and implementation of enforcement and appeals procedures would support consistency, transparency, legal clarity and the effective implementation of regulatory enforcement activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Although the legal framework establishes an appeal mechanism for decisions of the RPC, the implementing procedures and guidance for the practical operation of the appeals process are yet to be established. The issue was already identified by Malta and included in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 1 (Rev 1) para 2.5 (i) states that "***The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:…(11) Provision for appeals against decisions of the regulatory body;…"*
(2)	**BASIS: GSR Part 1 (Rev 1) para 4.32 states that "***The regulatory body shall establish a process that allows the authorized party to appeal against a regulatory decision relating to an authorization for a facility or an activity or a condition attached to an authorization"*
R14	**Recommendation: The Government should establish and implement procedures and guidance for the practical operation of the appeals process for regulatory and enforcement decisions.**

8.3. SUMMARY

Malta has established a legal basis for regulatory enforcement under CAP.585, including provisions for inspections, enforcement actions, suspension or revocation of authorizations and prosecution in cases of non-compliance with regulatory requirements. The legal framework also establishes an appeals mechanism through the Radiation Protection Appeals Tribunal.

The RPC applies a graded and pragmatic approach to enforcement activities commensurate with the relatively limited scale and complexity of radiation practices and activities in Malta. The IRRS team noted that the RPC has established an enforcement policy and supporting guidance documents intended to support regulatory enforcement activities.

However, the IRRS team identified several areas where further strengthening of enforcement arrangements would support the consistency, transparency and effectiveness of regulatory oversight. These include the continued development and implementation of comprehensive enforcement procedures, systematic follow-up and documentation of enforcement actions, and the operationalization of the appeals mechanism established under the legal framework.

The IRRS team considers that continued development of enforcement and appeals arrangements will support the effective, consistent and transparent implementation of regulatory enforcement activities.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The RPC is responsible for drafting regulations under CAP.585, which are subsequently submitted to the Minister responsible for the RPC for approval. Public consultation is carried out in line with governmental procedures. Furthermore, CAP.585 empowers the RPC to issue guidelines.

The RPC has also established, within its IMS, a process for the development of regulations and supporting guidance documents, ensuring consistency with national legislation and international standards. However, the procedures for the review of regulations and guides are not addressed neither in the regulations nor in the IMS. **This issue has been addressed in Suggestion S4 in section 4.2.**

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

SL 585.03 establishes the requirements applicable to predisposal waste management facilities. There are requirements for the minimisation of activity and volume of radioactive waste produced, and for consideration of the options to recycle and reuse of radioactive materials, for the use of passive safety features for the long term management of radioactive waste, for the need to consider the interdependencies between all steps in radioactive waste generation and management, including the need for the appropriate conditioning, for consideration of funding of radioactive waste management activities in the long term.

In addition, a Radioactive Waste Management Programme with the general principles under which such activities are carried out in the country has been established. The National Programme establishes the roles and responsibilities of all parties involved in radioactive waste management. It determines that the prime responsibility for radioactive waste management resides with the principal party generating the waste.

The RPC has produced internal guidance documents for the review of applications for predisposal waste management facilities and activities, that describe the content of the corresponding safety case and safety assessment, including the establishment of appropriate waste acceptance criteria. There is, however, a need to reflect these arrangements in guidance for applicants of authorizations of such facilities and activities. **This issue is addressed in Recommendation R10 in section 5.1.**

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The legal and regulatory framework governing radiation sources in Malta is primarily established by CAP.585 and SL585.01. These texts provide the national framework for the protection of individuals and the environment from the harmful effects of ionizing radiation, while ensuring the safe and secure use of radiation sources.

CAP.585 establishes the legal basis for notification, authorization, inspection, and enforcement concerning practices involving radiation sources. More detailed technical and operational requirements are provided in SL 585.01 regulations, which are aligned with the IAEA safety standards.

SL 585.01 establishes a graded system of regulatory control for facilities and activities involving radiation sources. This includes, among others, requirements for notification of practices involving radiation sources, exemption from notification where activity concentrations or total activities fall below prescribed exemption levels, registration and licensing, licensing requirements, clearance from regulatory control, dose limits, radiation protection measures for workers, patients, and the public, and safety assessments.

The IRRS team noted that provisions ensuring protection and safety in the handling of deceased persons or human remains known to contain sealed or unsealed radioactive sources have not yet been formally established in Malta. The team therefore encouraged the RPC to develop such provisions, despite the currently limited use of therapeutic nuclear medicine procedures, the absence of implanted sealed-source brachytherapy procedures, and the limited range of other applications involving radioactive material in the country.

9.4. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

The regulations do not require a final decommissioning report to be presented to the RPC for review and approval. The IRRS team was informed that the RPC performs an inspection prior to terminating the authorisation for the facility to confirm that the undertaking has removed all the disused sources, and that a radiological survey has been carried out to verify that there are no areas with residual contamination. **This issue is addressed in Recommendation R5 in section 1.7.**

9.5. REGULATIONS AND GUIDES FOR TRANSPORT

Given the limited scope of transport activities in Malta, CAP.585 adopts the latest versions of SSR-6, ADR, IMO and ICAO requirements as the applicable regulations for the transport of radioactive material. Entities wishing to transport radioactive material are required to obtain authorization from the RPC. Applicants seeking to transport Class 7 material by road are required to submit their emergency procedures at the authorization stage, and specific conditions are imposed on licences to minimize the risks associated with transport operations.

The RPC has recognized the need to develop specific transport guidance for applicants, and work to this effect has already been initiated. **This issue is addressed in Recommendation R10 in section 5.1.**

9.6. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The main regulations and guidance documents governing occupational exposure to ionizing radiation in Malta are based on the national framework established under CAP.585 and SL 585.01.

Key regulatory requirements on occupational exposure include classification of exposed workers, designation of controlled and supervised areas, dose constraints and limits for workers, optimization of protection, personal dosimetry and workplace monitoring, health surveillance, training and information for workers, responsibilities of authorized parties, qualification and recognition of RPEs, protection of pregnant and breastfeeding workers and arrangements for outside workers.

Health surveillance of all exposed workers is mandatory and is based on the general principles governing occupational medicine. The regulations establish specific requirements for health surveillance of category

A workers, including the requirement for such surveillance to be conducted by medical practitioners or occupational health services approved by the RPC. No specific requirements have been established for category B workers other than the general provisions related to occupational health and safety at work.

The RPC has also issued guidance documents supporting the implementation of the regulatory requirements, including guidance on controlled and supervised areas and criteria for approval of RPEs and guidance for the designation of RPOs.

The IRRS team noted that further guidance documents on occupational radiation protection still need to be developed and encourages the RPC to address this, in particular with regard to the conditions governing access of persons under the age of 18 to controlled areas and the national methodology for the assessment of occupational doses to air crew.

9.7. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

The legal and regulatory framework governing medical exposure is established under CAP 585 and SL 585.01, setting out comprehensive requirements related to medical exposure. These include roles and responsibilities of health professionals involved in medical radiological procedures, such as practitioners and MPEs as well as the principles of generic and individual justification, the establishment of Diagnostic reference levels (DRLs), and the use of dose constraints of carers, comforters, and volunteers participating in medical biomedical research. In addition, it establishes requirements for radiation protection of pregnant and breast-feeding female patients, as well as measures for prevention and reporting unintended or accidental medical exposures.

Practitioners and persons involved in the practical aspects of medical exposures are required to undertake appropriate training and retraining in radiation protection, according to the requirements established under regulations. The IRRS team was informed that the RPC is in the process of developing radiation protection training Syllabi and for approving organizations to provide training in line with the requirements of regulations.

Acceptance and constancy testing must be performed in accordance with international standards. The calibration of equipment used for such testing is required to be traceable to an accredited standards dosimetry laboratory and shall be routinely recalibrated according to its instructions for use. In the absence of any specified dosimeter re-calibration period, the equipment calibration period must not exceed a period of two years. The IRRS team was informed that the RPC is developing guidance on requirements for acceptance and constancy testing of equipment used for medical exposure.

Regulations provide that patients who have undergone a nuclear medicine procedure are required to be given instructions on how to restrict radiation doses to other persons, however, no specific requirements are in place for the release of patients who have undergone therapeutic radiological procedures using unsealed sources.

DRLs were established in 2022 for medical exposures associated with some medical imaging procedures. The RPC published a guidance on the establishment and application of DRLs for medical exposures in 2025, which also includes some updated DRLs based on national survey results and where such information was not available, European DRLs were used as a reference. DRLs for image guided interventional procedures have not yet been established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Government has assigned the RPC the responsibility for establishing diagnostic reference levels. While diagnostic reference levels have been established for some radiodiagnostic procedures, they have not been established for image-guided interventional procedures. Additionally, no specific requirements are in place for the release of patients who have undergone therapeutic radiological procedures using unsealed sources, or for patients who still retain implanted sealed sources, which was identified in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 3 Requirement 34 states that** *"The government shall ensure that relevant parties are authorized to assume their roles and responsibilities, and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established*."
R15	**Recommendation: The RPC, in consultation with other relevant parties with assumed responsibilities, should ensure the establishment of:** - **Diagnostic reference levels for image guided interventional procedures; and** - **Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources.**

Note: The above issues were highlighted in a recommendation of the IRRS follow up mission conducted in March 2020 and have been partially implemented.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Malta's regulatory framework does not provide for consultation between the health authority and relevant professional bodies to carry out generic justification.	
(1)	**BASIS: GSR Part 3 para. 3.56 states that** *"Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments."*
R16	**Recommendation: The Government should ensure that the health authority, in consultation with appropriate professional bodies generic justification of radiological procedures is carried out.**

9.8. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The RPC has developed the national Radon Action Plan, which is under implementation. The actions foreseen in the first phase of implementation have been completed. Implementation of the second phase of the Radon Action Plan is underway; that include measures such as the development of further nation-wide studies on radon concentrations. The RPC plans to initiate discussions as required with other authorities

(e.g. Health and Building Construction Authority) to introduce an information campaign and to update building codes and develop guidelines to optimise radiation dose and consider the effects of exposure to radon.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC has developed a Radon Action Plan. While the first phase actions have been completed, the second phase is still under implementation. The issue was already included by Malta in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 3 Requirement 50 states that** *"The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors"*
(2)	**BASIS: GSR Part 3 Requirement 50, para. 5.19 states that** *"As part of its responsibilities, (…), the government shall ensure that:* *(a) Information is gathered on activity concentrations of radon in dwellings and other buildings with high occupancy factors for members of the public through appropriate means, such as representative radon surveys;* *(b) Relevant information on exposure due to radon and the associated health risks, including the increased risks relating to smoking, is provided to the public and other interested parties."*
S10	**Suggestion: The RPC should consider completing the implementation of the Radon Action Plan.**

9.9. SUMMARY

The RPC has issued regulations setting out basic criteria for regulatory compliance in line with the IAEA safety standards. The RPC has a process for the development of regulations and supporting guidance documents, ensuring consistency with national legislation and international standards. However, the RPC does not yet have a process for reviewing regulations and extend this to guidance development.

Within the regulations, areas for alignment with the provisions of IAEA safety standards include consideration of funding of radioactive waste management activities; DRLs for image guided interventional procedures; criteria and guidelines therapeutic radiological procedures using unsealed or sealed sources; for the review of the emergency procedures of transport companies.

In addition, the RPC would benefit from establishing or expanding additional guides to assist the authorized parties in implementing the regulations.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS

Responsibilities for emergency response are assigned by the Government to the RPC, the Civil Protection Department and the Superintendent of Public Health. Authorized parties are required to make arrangements for emergencies arising from their activities. Coordination among the responsible parties is currently maintained through established working relationships, and the RPC has recognised the need to formalise this through memoranda of understanding and updated emergency response documentation.

Even though the RPC made informal arrangements and cooperation with the operating organisations for the management and secure control of orphan sources in case of an emergency response event, there is no national strategy for the identification, recovery, management safe and secure control of orphan sources. **This issue is addressed in Recommendation R4 in section 1.6.**

10.2. REGULATIONS AND GUIDES ON ON-SITE EPR OF OPERATING ORGANIZATIONS

The legislative framework establishes provisions for emergency response at both the facility and national levels. Authorized parties are required to develop emergency response plans and to notify the regulatory body immediately in the event of an emergency, taking initial actions to mitigate the consequences. The RPC reviews emergency preparedness and response plans of authorized facilities prior to issuing an authorization.

Both the RPC and CPD have responsibilities with regard to communicating relevant information regarding radiological hazards to the public. The RPC has not yet established guidance to the operating organization for performing this function.

10.3. VERIFYING THE ADEQUACY OF ON-SITE EPR OF OPERATING ORGANIZATIONS

The procedure for verifying the adequacy of the on-site EPR plan for operating organizations in Malta is integrated into the regulatory authorization and inspection process.

The RPC reviews the emergency plans submitted by applicants to ensure compliance with the requirements of SL585.01. However, there is no specific internal procedure in place to assess the content of the emergency plans of the authorized facilities required to have such a plan.

Current inspection checklists address the availability of procedures and equipment but do not include specific criteria for the assessment of on-site emergency preparedness and response arrangements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The RPC has not established a specific internal procedure to assess the content of the on-site emergency plans of authorized facilities that require such a plan, including the integration with the off-site emergency arrangements. The issue was already included by Malta in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 7, para. 4.14. states that "***Before commencement of operation of the facility or commencement of the activity, the regulatory body shall ensure, for all facilities and activities under regulatory control that could necessitate emergency response actions, that the on-site emergency arrangements:(a) Are integrated with those of other response organizations, as appropriate; (b) Are integrated with contingency plans in the context of Ref. [9] and with security plans in the context of Ref. [10]; (c) Provide, to the extent practicable, assurance of an effective response to a nuclear or radiological emergency.***"**
R17	**Recommendation: The RPC should establish an internal procedure to verify that authorized facilities requiring on-site emergency plans have appropriate emergency arrangements in place before the commencement of operation.**

10.4. ROLES OF THE REGULATORY BODY IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

Under the national emergency plan, the Civil Protection Department (CPD), as the lead technical agency, coordinates the response, assessment, mitigation, and external notification with the RPC support. The RPC provides advice to CPD and other organizations involved in small or large scale events to manage the radiological emergency.

CAP.585 under the regulatory framework (Part III) assigns the functions and duties of the regulatory body for the on-site Emergency Preparedness and Response (EPR). Part IX – Emergency Response of CAP.585 mentions the necessity of the point of contact for international legal instruments, the IRRS team was informed that Malta has not yet ratified the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, which limits its formal integration into the global nuclear safety and emergency response regime. **This issue is addressed in Suggestion S2 in section 2.1.**

Health Care Services in collaboration with RPC provide medical response, treatment, monitoring, and public information, and should be involved in all emergencies. However, there is a lack of integration of health response in emergency preparedness and response. There are no operational procedures nor training with regards to medical response in connection with radiological emergencies.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The medical response for radiological emergencies is not integrated into the operational procedures and not further specified in the national emergency plan. The issue was already included by Malta in the initial action plan prepared for the mission.

(1)	**BASIS: GSR Part 7 Requirement 12 states that** „*Managing the medical response in a nuclear or radiological emergency The government shall ensure that arrangements are in place for the provision of appropriate medical screening and triage, medical treatment and longer term medical actions for those people who could be affected in a nuclear or radiological emergency."*
R18	**Recommendation: The Government should ensure that medical response to radiological emergencies are integrated into the operational procedures and the national emergency plan as advised by the RPC and the Ministry of Health.**

The RPC and the CPD have regular meetings and organize tabletop exercises as part of maintaining capabilities with regards to EPR. However, field-based drills and exercises for personnel with assumed responsibilities in emergency situations have not been established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Emergency preparedness and response exercises conducted by the RPC and CPD are mainly tabletop exercises. Field-based drills exercises involving response organizations have not been conducted. The issue was already included by Malta in the initial action plan prepared for the mission.	
(1)	**Basis: GSR Part 7 Requirement 25**: *Training, drills and exercises for emergency preparedness and response. The government shall ensure that personnel relevant for emergency response shall take part in regular training, drills and exercises to ensure that they are able to perform their assigned response functions effectively in a nuclear or radiological emergency.*
(1)	**BASIS: GSR Part 7 Requirement 25 para. 6.30 states** *that exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response and all organizational interfaces are tested at suitable intervals….*
(2)	**BASIS: GSR Part 7 Requirement 25 para. 6.31 states** *that personnel responsible for critical response functions shall participate in drills and exercises on a regular basis so as to ensure their ability to take their actions effectively.*
S11	**Suggestion: The RPC should consider expanding its emergency preparedness and response exercise programme to include field-based drills in order to ensure that real-time response capabilities and organizational interfaces are effectively tested and maintained.**

Note: The above issues were highlighted in a recommendation of the IRRS follow up mission conducted in March 2020 and have been partially implemented.

10.5. SUMMARY

Malta has established a regulatory framework for EPR under CAP.585. However, several areas require further development to fully align with IAEA GSR Part 7 requirements.

Key improvements include the integration of the medical response arrangements into national emergency planning and operational procedures, supported by appropriate training. Also, the RPC should improve its internal procedure for verifying the emergency response plan of authorized parties that require such a plan. Finally, the emergency exercise programme should be expanded beyond tabletop exercises to include practical field drills that test response capabilities and coordination among all relevant organizations.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

CAP.585 contains provisions relevant to safety, nuclear security and safeguards. These include requirements relating to safeguards, nuclear security, and the establishment of a State system of accounting for and control of nuclear material. CAP.585 designates the RPC as the central authority responsible for the physical protection of nuclear material and for coordinating recovery and response in the event of theft or unlawful taking of nuclear or other radioactive material. SL585.01 similarly contains provisions addressing both safety and security in separate contexts, including requirements for security plans for high activity sealed sources and the definition of security culture.

While these provisions establish requirements for safety and for security in their respective domains, they do not articulate how the two sets of requirements interact, how conflicts between safety and security considerations are to be resolved, or how the interface between the two domains is to be managed across the regulatory framework as a whole. The IRRS team was informed that the RPC has identified this as an area requiring attention and has committed to initiating a review of regulatory infrastructure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: While the legal framework establishes requirements for both radiation safety and nuclear security, it does not address their interface. The issue was already included by Malta in the initial action plan prepared for the mission.	
(1)	**BASIS: GSR Part 1 (Rev. 1) Requirement 12, para. 2.40 states that** *"The government shall ensure that, within the governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material."* *Para. 2.40: "Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security."*
R19	**Recommendation: The Government should ensure that interfaces of safety with arrangements for nuclear security are adequately addressed in Malta's legal and regulatory framework and associated regulatory infrastructures.**

11.2. REGULATORY OVERSIGHT ACTIVITIES

Under CAP.585, the RPC has been assigned the responsibility for oversight and enforcement of arrangements for safety, nuclear security and the system of accounting for, and control of nuclear material.

The RPC has developed in its management system a procedure that provides the basis for reporting under Malta's trilateral Safeguards Agreement (INFCIRC/193) with the IAEA and the European Atomic Energy Community, covering nuclear material accountancy and the associated record-keeping obligations.

The RPC provides specialist advice to the Customs Department on the safety and security aspects of radioactive material detected at the Freeport. This advice is documented in a procedure that establishes the working arrangements between the RPC and the Customs Department for responding to such detections.

The RPC staff address both safety and security aspects during reviews, assessments and inspections of authorized parties. This is reflected in specific inspection checklists that include questions on security alongside those on safety. The security of radioactive material in storage is addressed in other review and assessment processes, which include requirements covering access control, security planning, accounting and security event reporting.

The RPC also provides specialist safety and security advice to the CPD, which acts as the lead technical agency in national radiological emergencies. Procedures to that effect also address the security of any radioactive material involved in an emergency, including arrangements for ensuring appropriate security measures for its storage.

While these oversight activities demonstrate that the RPC has given practical consideration to both safety and security in its work, they have not been developed within an overarching regulatory framework that systematically addresses the interface between the two domains. The RPC plans to review this regulatory infrastructure. **This issue is addressed in Recommendation R19 in section 11.1.**

11.3. INTERFACE AMONG AUTHORITIES

CAP.585 establishes the RPC as the single regulatory body with responsibility for regulation and oversight of both safety and security of nuclear and other radioactive materials. This consolidated mandate avoids institutional fragmentation that can arise when safety and security responsibilities are distributed across separate bodies and provides a foundation for managing their interface at the regulatory level.

The RPC has signed MoUs with the CPD and the Customs Department and has developed some associated operating procedures. These arrangements provide a degree of formal structure to the coordination between the RPC and these bodies on matters involving both safety and security aspects, including the national response to radiological emergencies and the detection of radioactive material at ports.

The RPC participates in the IAEA Incident and Trafficking Database (ITDB) as the national contact point. The RPC reviews incident notifications received through the ITDB and distributes relevant information to stakeholders in Malta. In addition, the RPC posts relevant information on the database. This participation is a positive element in Malta's overall approach to managing the interface between safety and security, consistent with the spirit of IAEA requirements on maintaining awareness of radioactive material out of regulatory control.

At the national level, the CPD, as mandated under the Civil Protection Department Act (CAP.411), has overarching responsibility for the preparation and response to national emergencies, including radiological emergencies. Under this framework, the RPC can be called upon by the CPD to provide specialist safety and security advice as required. This existing legal basis provides a degree of national coordination for radiological emergency response that encompasses both safety and security considerations.

11.4. SUMMARY

Malta's legal framework establishes requirements for both safety and nuclear security. However, it does not address their interface. The RPC acknowledges this as a gap that requires attention. Some coordination arrangements between the RPC and other relevant authorities have been established through MoUs and operating procedures. In particular, CAP. 411 provides an overarching framework for the preparation and response to emergencies, including radiological emergencies initiated either by accidents or nuclear security

events. Nevertheless, a more systematic approach to managing the safety-security interface within the regulatory framework remains necessary.

To improve the interfaces between safety and security, the RPC will initiate a review of the legal and regulatory framework to ensure that interface between safety and security is effectively managed in all areas and situations, including during the response to nuclear or radiological emergencies.

12. POLICY DISCUSSIONS AND MEETING WITH PERMANENT SECRETARY

12.1. Challenges in maintaining and enhancing regulatory effectiveness and competence in states with small populations.

The policy issue discussion took place in the RPC Headquarters, Mosta, Malta, on 29 May 2026.

Representatives from the Board and the Secretariat of the RPC participated in the discussions with the IAEA IRRS team.

The policy issue discussion focused on knowledge and capability management, including succession planning, aiming to ensure the stability and sustainability of the regulatory body in small countries. The discussions highlighted the importance of establishing a comprehensive and national regulatory framework that remains stable beyond personnel changes. Emphasis was placed on maintaining effective independence of the regulatory body, increasing its visibility and strengthening competence through strong leadership, building trust, outreach activities, mentoring and human resource development as well as effective communication with interested parties. The IRRS team shared the experience of Mauritius, Portugal, Greece and Argentina on these specific issues.

The main challenges were around the risk of loss of technical and institutional knowledge, particularly as two experienced staff of the RPC will shortly retire. The existence of single points of expertise was identified as a critical vulnerability and proposed solutions were for the RPC to consider: a two persons competence, cross training, digitalisation and IMS improvement. Recognition for staff retention and attraction being influenced by both financial and non-financial factors, including flexible working arrangements, wellbeing and culture, job stability, leveraging international support and assistance and professional development opportunities.

APPENDIX I – RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

MODULE	R: Recommendation S: Suggestion G: Good Practice	Recommendations, Suggestions or Good Practices
1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	**R1**	The Government should establish and implement a national policy and strategy for safety consistent with the IAEA safety standards, the implementation of which should be subject to a graded approach commensurate with the radiation risks associated with facilities and activities in Malta.
	R2	The Government should strengthen arrangements for staffing and competence development of RPC, based on a comprehensive human resources plan, to ensure that it maintains sufficient in-house expertise and effective independence in carrying out its regulatory functions.
	R3	The Government should ensure that the RPC is not assigned with responsibilities that will compromise its effective independence, in particular with regard to the funding, management and operation of the CSF.
	S1	The RPC should consider establishing a process for the periodic review and assessment of formal cooperation arrangements and operational coordination mechanisms with relevant national authorities to ensure their continued effectiveness.
	R4	The Government should establish and implement arrangements for the identification, recovery, safe management and secure control of orphan sources.

MODULE	R: Recommendation S: Suggestion G: Good Practice	Recommendations, Suggestions or Good Practices
	R5	The Government should review the legal and regulatory framework to ensure that it provides for the safe decommissioning of all relevant facilities.
	R6	The Government should establish, as part of its national policy and strategy for safety, a policy and strategy for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.
2. THE GLOBAL SAFETY REGIME	**S2**	The Government should consider acceding or ratifying the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	**R7**	The RPC should strengthen its human resources planning through a comprehensive competence analysis to ensure that it has sufficient staff with the necessary knowledge, skills and abilities to perform all assigned regulatory functions, including in anticipation of future needs.
	S3	The RPC should consider improving its information management system for its safety related records to enhance accessibility, traceability and ease of retrieval of regulatory information.
	R8	The RPC should establish arrangements including a communication strategy for informing and consulting interested parties and the public on radiation risks associated with facilities and activities, as well as on its regulatory processes and decisions.

MODULE	R: Recommendation S: Suggestion G: Good Practice	Recommendations, Suggestions or Good Practices
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**S4**	The RPC should consider further developing its management system to cover all its regulatory functions.
	R9	The RPC should establish and implement arrangements for the periodic review, assessment and continuous improvement of its management system, including evaluation of its effectiveness.
5. AUTHORIZATION	**S5**	The RPC should consider establishing processes for using registration as a form of authorization, taking into account a graded approach.
	R10	The RPC should issue guidance for applicants on the process of authorization and the format and content of the documents to be submitted in support of the different types of authorizations and, where applicable, authorization stages, including for the renewal and modifications of the authorizations.
	S6	The RPC should consider establishing a procedure for the amendment, renewal, suspension or revocation of authorizations for facilities or activities.
	S7	The RPC should consider establishing specific requirements and criteria for the authorization of technical service providers that may have significance for safety, including providers of personal dosimetry and calibration services.

MODULE	R: Recommendation S: Suggestion G: Good Practice	Recommendations, Suggestions or Good Practices
	R11	The RPC should publish or make available on request, as appropriate, the results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure, as well as other relevant information.
	R12	The RPC should establish provisions to ensure that authorized parties are required to publish or make available on request, as appropriate, the results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure.
6. REVIEW AND ASSESSMENT	R13	The RPC should establish criteria and develop checklists for conducting the review and assessment of all types of facilities and activities in accordance with a graded approach.
7. INSPECTION	S8	The RPC should consider expanding its inspection programme for the transport of radioactive material to include inspections carried out during physical transport activities.
8. ENFORCEMENT	S9	The RPC should consider further developing its enforcement processes and procedures.
	R14	The Government should establish and implement procedures and guidance for the practical operation of the appeals process for regulatory and enforcement decisions.

MODULE	R: Recommendation S: Suggestion G: Good Practice	Recommendations, Suggestions or Good Practices
9. REGULATIONS AND GUIDES	**R15**	The RPC, in consultation with other relevant parties with assumed responsibilities, should ensure the establishment of: - Diagnostic reference levels for image guided interventional procedures; and - Criteria and guidelines for the release of patients who have undergone therapeutic radiological procedures using unsealed sources.
	R16	The Government should ensure that the health authority, in consultation with appropriate professional bodies generic justification of radiological procedures is carried out.
	S10	The RPC should consider completing the implementation of the Radon Action Plan.
10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS	**R17**	The RPC should establish an internal procedure to verify that authorized facilities requiring on-site emergency plans have appropriate emergency arrangements in place before the commencement of operation.
	R18	The Government should ensure that medical response to radiological emergencies are integrated into the operational procedures and the national emergency plan as advised by the RPC and the Ministry of Health.

MODULE	R: Recommendation S: Suggestion G: Good Practice	Recommendations, Suggestions or Good Practices
	S11	The RPC should consider expanding its emergency preparedness and response exercise programme to include field-based drills in order to ensure that real-time response capabilities and organizational interfaces are effectively tested and maintained.
11. INTERFACE WITH NUCLEAR SECURITY	**R19**	The Government should ensure that interfaces of safety with arrangements for nuclear security are adequately addressed in Malta's legal and regulatory framework and associated regulatory infrastructures.

APPENDIX II – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
Ms Eleftheria Carinou	The Greek Atomic Energy Commission (EEAE)	Eleftheria.carinou@eeae.gr
Mr Faradally A. Ollite	Radiation Safety and Nuclear Security Authority (RSNSA)	faradally@gmail.com
Mr Phiphat Phruksarojanakun	Office of atoms for peace (OAP)	Phiphatnor@gmail.com
Mr Pedro Rosário	Portuguese Environmental Agency (APA)	Pedro.rosario@apambiente.pt
Mr Walter Truppa	Autoridad regulatoria nuclear (ARN)	Wtruppa@arn.gob.ar
Ms Houda Idihia	Moroccan agency for nuclear and radiological safety and security (AMSSNUR)	H.idihia@amssnur.org.ma
IAEA STAFF		
Mr Manuel Recio	Division of Radiation, Transport and Waste Safety (NSRW) Department of Nuclear Safety and Security International Atomic Energy Agency	M.Recio@iaea.org
Ms Baan Fischer	Division of Radiation, Transport and Waste Safety (NSRW) Department of Nuclear Safety and Security International Atomic Energy Agency	B.fischer@iaea.org
LIAISON OFFICER		
Mr Paul Brejza	Commission for the Protection From Ionising and Non-Ionising Radiation	paul.brejza@gov.mt
Mr Joseph Cremona	Commission for the Protection From Ionising and Non-Ionising Radiation	joseph.cremona@gov.mt

GROUP PHOTO



APPENDIX III – LIST OF IRRS REVIEWERS AND COUNTERPARTS

	IRRS EXPERTS	LEAD COUNTERPART	SUPPORT STAFF
1.	**LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES**		
	Mr Faradally A. Ollite	Ms Loudes Farrugia Mr Paul Brejza	Mr Nasiru Bello
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Mr Phiphat Phruksarojanakun	Mr Paul Brejza	
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		
	Mr Faradally Ollite	Mr Paul Brejza	
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Mr Faradally Ollite	Mr Paul Brejza	
5.	**AUTHORIZATION**		
	Mr Pedro Rosário Ms Houda Idihia Mr Walter Truppa	Mr Joseph Cremona	Ms Ruslana Tripailo Mr Luke Farrugia Ms Monique Mizzi
6.	**REVIEW AND ASSESSMENT**		
	Mr Pedro Rosário Ms Houda Idihia Mr Walter Truppa	Mr Joseph Cremona	Ms Ruslana Tripailo Mr Luke Farrugia Ms Monique Mizzi
7.	**INSPECTION**		
	Mr Pedro Rosário Ms Houda Idihia Mr Walter Truppa	Mr Joseph Cremona	Ms Ruslana Tripailo Mr Luke Farrugia Ms Monique Mizzi
8.	**ENFORCEMENT**		
	Mr Faradally Ollite	Mr Paul Brejza	
9.	**REGULATIONS AND GUIDES**		
	Mr Pedro Rosário Ms Houda Idihia Mr Walter Truppa	Mr Paul Brejza Mr Joseph Cremona	Ms Ruslana Tripailo Mr Luke Farrugia Ms Monique Mizzi
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**		

	IRRS EXPERTS	LEAD COUNTERPART	SUPPORT STAFF
	Mr Walter Truppa	Mr Luke Farrugia	
11.	**INTERFACE WITH NUCLEAR SECURITY**		
	Mr Phiphat Phruksarojanakun	Mr Nasiru Bello	

APPENDIX IV – MISSION SCHEDULE

IRRS MISSION TO MALTA

Mosta, Malta | 25 May to 3 June 2026

Monday 25 May

Entrance meeting | 09:00 – 10:40, DoubleTree by Hilton Hotel

---

1. *Welcome address* — *Prof. Lourdes Farrugia*
   – *Mr Carlos Tabone*
2. *Opening comments* — *Ms Elefteria Carinou (TL)*
3. *Introduction of IRRS Team Members and Counterparts* — *All*
4. *National context and self-assessment* — *Mr. Paul Brejza*
   - Overview of the national context, including the regulatory framework in Malta
5. *Agenda of the mission* — *Mr Manuel Recio (TC)*
6. *Logistics* — *Mr Paul Brejza (LO)*
   – *Mr Joseph Cremona (DLO)*
7. *Closing remarks* — *Prof. Lourdes Farrugia*
   – *Ms Elefteria Carinou (TL)*
8. *Group photo*

Mission activities | 11:00 - 24:00

11:00 – 11:45	Meeting with the members of the Board of the Commission for the Protection from Ionising and Non-Ionising Radiation (Commission) to discuss roles and functions of the Board.	TL, C and module 1 reviewer attend the meeting at Sybile meeting room at **DoubleTree by Hilton Hotel**
11:00 – 11:45	Interviews	Reviewers meet counterparts at Zeus meeting room at **DoubleTree by Hilton Hotel**
11:45	Departure from the hotel	**DoubleTree by Hilton Malta**
12:15 – 14:00	Standing lunch at the Commission premises	
14:00 – 16:45	Interviews	Reviewers meet counterparts
16:00 – 16:45	Preparation of site visits to: - ***Site Visit Oncology at Mater Dei Hospital***	Designated reviewer meets Commission's inspectors to discuss the work programme of the visit.
16:45	Departure to the hotel	**DoubleTree by Hilton Malta**
17:15 – 18:15	Daily Team Meeting	Quick brief from reviewers (5 max) and first exchange of views
18:15 – 20:00	Break for dinner	(Individual arrangements)
20:00 – 24:00	Writing the report	Meeting room at the **DoubleTree by Hilton Malta** (if needed)

Tuesday 26 May

08:45 – 09:15	Pick up and travel from hotel	**DoubleTree by Hilton Malta**
09:15 – 13:00	Site visits: - ***Site Visit Oncology at Mater Dei Hospital***	(Exact time to be determined)
09:15 – 09:30	Short meeting between team Leads and LOs	(if necessary)

09:30 – 12:00	Interviews	(Individual arrangements)
10:30 – 12:00	Meeting with the Permanent Secretary, Office of the Prime Minister – Equality, Reforms and Social Dialogue - ***Mr Carlos Tabone***	(Note: TL, C and module 1 reviewer travel to Valetta. The meeting is scheduled between 11:00 and 12:00)
12:00 – 13:00	Standing lunch at the Commission premises	(Note: Reviewer participating in site visits and the meeting in Valetta may have late lunch until 14:00)
13:00 – 16:45	Interviews	
16:00 – 16:45	Preparation of site visits: - ***Site Visit Central Storage Facility***	Designated reviewer meets Commission's inspectors to discuss the work programme of the visit.
16:45	Departure to the hotel	**DoubleTree by Hilton Malta**
17:15 – 18:15	Daily Team Meeting	Quick brief from reviewers (5-minute max) and exchange of views
18:15 – 20:00	Break for dinner	(Individual arrangements)
20:00 – 24:00	Writing the report	Meeting room at the **DoubleTree by Hilton Malta** (if needed)

Wednesday 27 May

08:45 – 09:15	Pick up and travel from hotel	**DoubleTree by Hilton Malta**
09:15 – 13:00	Site visits: - ***Site Visit Central Storage Facility***	(Exact time to be determined)
09:15 – 09:30	Short meeting between team Leads and LOs	(as necessary)
09:30 – 12:00	Interviews	(Individual arrangements)
12:00 – 13:00	Standing lunch at the Commission premises	(Note: Reviewers participating in site visits may have late lunch until 14:00)

13:00 – 16:00	Interviews	
16:00 – 16:45	**Written preliminary findings delivered**	
16:45	Departure to the hotel	**DoubleTree by Hilton Malta**
17:15 – 18:15	Daily Team Meeting	Quick brief from reviewers (5-minute max) and exchange of views
18:15 – 20:00	Break for dinner	(Individual arrangements)
20:30 – 24:00	Daily Team Meeting	Meeting room at the **DoubleTree by Hilton Malta**

Thursday 28 May

08:45 – 09:15	Departure from hotel	**DoubleTree by Hilton Malta**
09:15 – 09:30	Short meeting between team Leads and LOs	(as necessary)
09:30 – 12:00	- *Final interviews (as needed)* - *TL & TC review introduction*	
12:00 – 13:00	Standing lunch at the Commission premises	
13:00 – 16:45	- *Follow-up interviews (if necessary)* - *TM write report*	
16:45	Departure to the hotel	**DoubleTree by Hilton Malta**
17:15 – 18:15	Daily Team Meeting	Quick brief from reviewers (5-minute max) and exchange of views
18:15 – 20:00	Break for dinner	(Individual arrangements)
20:30 – 24:00	Daily Team Meeting	Meeting room at the **DoubleTree by Hilton Malta**

Friday 29 May

08:45 – 09:15	Departure from hotel	**DoubleTree by Hilton Malta**

09:15 – 09:30	Short meeting between team Leads and LOs	(as necessary)
09:30 – 11:00	- *Discussion of Observations (Rec., Sug. and GP) with counterparts*	
11:00 – 12:00	Draft text to TL for initial review	
12:00 – 13:00	Standing lunch at the Commission premises	
13:00 – 14:00	Policy discussion: "Challenges in maintaining and enhancing regulatory effectiveness and competence in states with small populations."	
14:00 – 17:45	Cross-reading by TM	
15:30	Departure to the hotel	**DoubleTree by Hilton Malta**
17:15 – 18:15	Daily Team Meeting	Quick brief from reviewers (5-minute max) and exchange of views
18:15 – 20:00	Break for dinner	(Individual arrangements)
20:30 – 24:00	Daily Team Meeting	Meeting room at the **DoubleTree by Hilton Malta**

Saturday 30 May

08:45 – 09:15	Departure from hotel	**DoubleTree by Hilton Malta**
08:45 – 12:00	Reading (TL, TC…)	**DoubleTree by Hilton Malta** Reviewers remain available for consultation as needed.
12:00 – 13:00	Lunch	(Individual arrangements)
13:00 – 18:15	Finalisation of Draft Report	**DoubleTree by Hilton Malta** Reviewers remain available for consultation as needed.
18:15 – 20:00	Dinner	(Individual arrangements)

20:00 – 22:00	Submission of the Draft to the Host	TC and TL meet to finish the report and submit it to the host

Sunday 31 May

	Free for reviewers	(Social event: pick up at 08:45 at DoubleTree by Hilton, return to hotel by 13:00)
	Lunch and dinner	(Individual arrangements)
	Host reads the report	

Monday 1 June

09:15 – 11:00	Written comments provided by the Host	(Team will meet as soon as written comments are received)
10:30 – 11:00	Departure from hotel	**DoubleTree by Hilton Malta**
11:00 – 12:00	Team meeting to discuss host comments	Final editing of the report to consider host comments
12:00 – 13:00	Standing lunch at the Commission premises	
13:00 – 16:45	Team meeting to discuss host comments (cont.)	Final editing of the report to consider host comments
16:45	Departure to the hotel	**DoubleTree by Hilton Malta**
17:15 – 18:16	TC, TL prepare Executive Summary	
18:15 – 20:00	Break for dinner	(Individual arrangements)
20:30 – 24:00	TC, TL prepare Exit Presentation and Press Release	

Tuesday 2 June

08:45 – 09:15	Departure from hotel	**DoubleTree by Hilton Malta**

09:15 – 12:00	Plenary (Team + Host) to discuss host comments and finalize the report	
12:00 – 13:00	Standing lunch at the Commission premises	
13:00 – 16:00	Final discussion of the Report by the Team	
16:00 – 16:45	Team discusses the Mission and provides IAEA with feedback	
16:45	Departure to the hotel	**DoubleTree by Hilton Malta**
17:15 – 18:15	Finalisation of the press release and of the preliminary report	
19:00 – 21:00	Farewell Dinner	(Arrangements to be determined by host)

Wednesday 3 June

09:00 – 10:00	Submission of the Preliminary Report	
10:00 – 11:30	**Exit Meeting**	**DoubleTree by Hilton Malta**
11:30	Meeting adjourned	

APPENDIX V – SITE VISITS

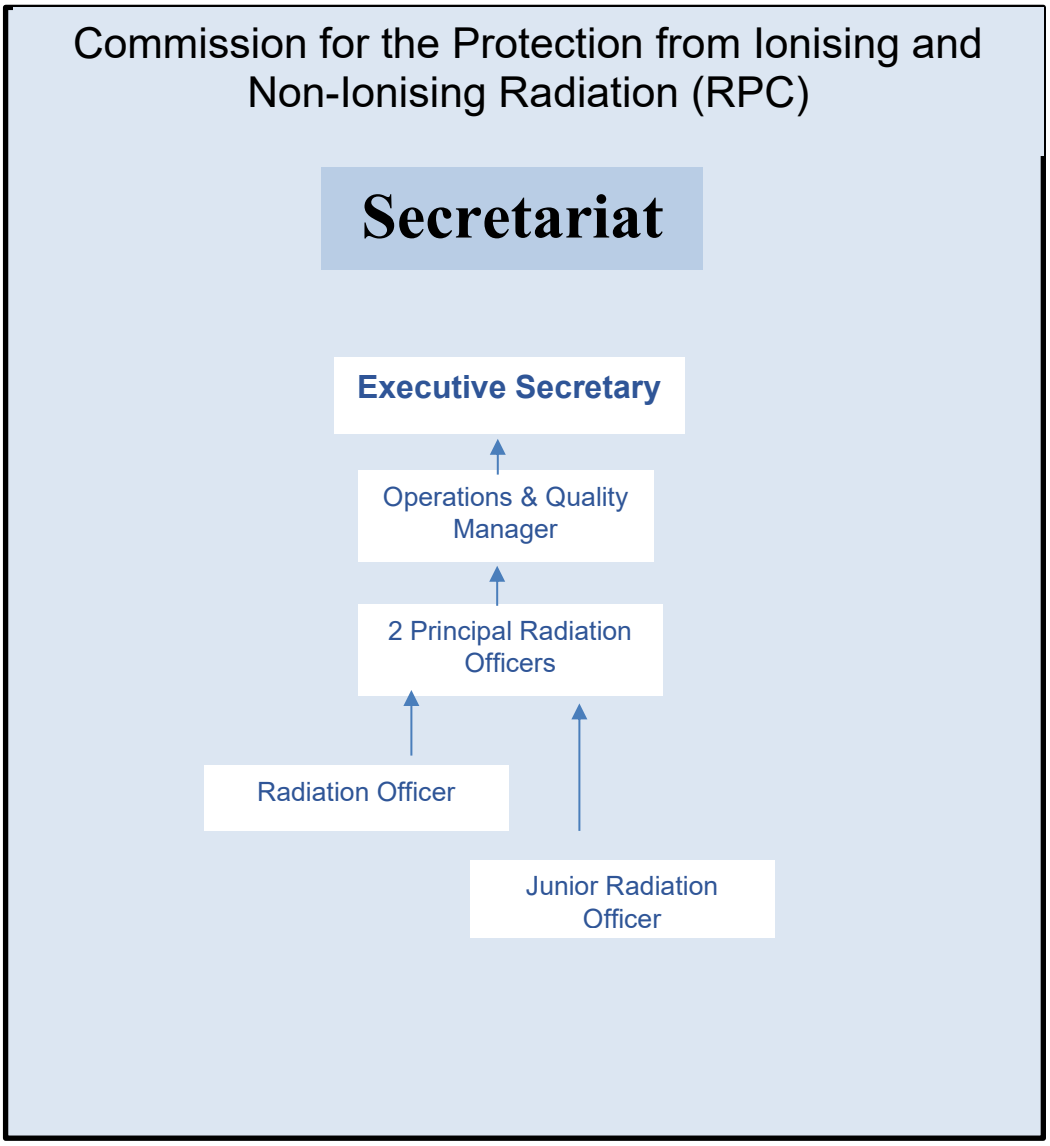
Tuesday 26th May 2026 Morning

Houda Idihia	Joseph Cremona Ruslana Tripailo	Site Visit Oncology at Mater Dei Hospital

Wednesday 27th May 2026 Morning

Pedro Rosário	Joseph Cremona Luke Farrugia	Site Visit Central Storage Facility

APPENDIX VI – ORGANIZATIONAL CHART OF RPC



APPENDIX VII – MALTA'S REFERENCE MATERIAL USED FOR THE REVIEW

IMS Documents

- CHK-003 Inspection Checklist for Dentists
- CHK-006 Inspection Checklist for Medical X-ray
- CHK-007 Inspection Checklist for Nuclear Medicine
- CHK-008 Inspection Checklist for Radiotherapy
- CHK-009 Inspection Checklist for Nuclear Medicine and X-ray
- DOC-005 Justifiable Uses of Radiation
- DOC-006 Practice Characterisation
- DOC-015 Discharge Licence part 1
- DOC-016 Discharge Licence part 2
- DOC-017 Licence Template
- DOC-017a Agent Licence Template
- DOC-018 Licence Numbering
- DOC-035 Waste Characterisation
- DOC-038 Radiological Hazard Assessment
- DOC-046 Regulatory Management Storage of radioactive material
- DOC-047 Disused Source Storage Licence Template part 1
- DOC-051 Policy and Strategy for Safety
- DOC-058 Radioactive Waste Management Programme
- DOC-065 Code of Ethics
- DOC-069 Radon Action Plan
- DOC-072 Guidance on Use of Emails
- DOC-073 Staff Grading Structure under Directive 7
- DOC-074 Job Descriptions
- DOC-076 IMS Document Register
- DOC-077 Questions and Answers on Radon
- DOC-078 RPC Human Resource Plan
- DOC-079 Penalties for Regulatory Breaches
- FRM-002 Notification on the Use of Radiation Sources
- FRM-003 Warning letter and Inspection Report for X-ray Medical Facilities
- FRM-003a Warning letter and Inspection Report for Non- Medical Facilities
- FRM-003b Warning letter and Inspection Report for Nuclear Medicine Facilities
- FRM-009 Importing Agent Notification Form
- FRM-011 Shipment of Unsealed Sources
- FRM-020a Authorisation to Import Several Shipments of Radioactive Sources
- FRM-020b Authorisation to Import Single Radioactive Source
- FRM-026 Review and Assessment of Management System Checklist
- FRM-030 Annual Occupational Dose Records Return for RPC
- FRM-030a Annual Aircrew Dose Records Return for RPC
- FRM-031 Application to Discharge Radioactivity to the Environment
- FRM-046 Checklist for Reception of New RPC Staff
- FRM-079 RPC Rolling Annual Work Plan
- FRM-081 Conflict of Interest Confirmation under Directive 16

- FRM-083 Enforcement Order
- FRM-084a Acquisition or Transfer of Sealed Radioactive Sources
- FRM-084b Acquisition, Transfer, Decommissioning of Radiation Generators
- GDL-001 Criteria for the Recognition of Radiation Protection Experts
- GDL-002 Criteria for the Recognition of Medical Physics Experts
- GDL-003 Guidance on Applying for RPE & MPE Recognition
- GDL-004 Guidance on Diagnostic Reference Levels
- GDL-005 Guidance on Radiation Controlled and Supervised Areas
- MSM-001 Management System Manual
- OP-001 Notification and Authorisation
- OP-002 Inspection
- OP-003 Inventory
- OP-005 Accessing or creating undertaking files
- OP-006 Management System Upkeep
- OP-009 Work Plan
- OP-010 Review and Assessment of Management System
- OP-023 RPE application processing
- OP-024 Application for Import of Radioactive Sources
- OP-025 International Transport Certificate Validation
- OP-026 Import and Export through Agents
- OP-027 Transport Carrier Authorisation
- OP-029 National dose register
- OP-031 Control of Radioactive Discharges from Nuclear Medicine Departments
- OP-032 MPE application processing
- OP-038 Interaction between Board and Secretariat
- OP-040 Commission Response to Radiological Incidents
- OP-050 Notification and Authorisation for Storage Facility Operators
- OP-053 Occupational Health Service Providers
- OP-058 Specific Enforcement Guide for SL585.01
- OP-067 Radiological Emergency Response Framework
- OP-070 Documents and Records Management Policy and Procedure
- OP-072 Human Resource Handbook
- OP-075 General Enforcement
- OP-076 Management of Disused Sources
- OP-077 National Radioactivity Monitoring Programme
- OP-078 Staffing Plan and Recruitment
- OP-079 Staff Performance Assessment
- OP-080 Staff Training and Development
- OP-081 SOP MEGAPORTS v1.1 April 2025 approved (Customs Portal SOP)
- OP-082 Transport of Radioactive Materials
- OP-085 Development of Regulations and Associated Documents
- RPC-CPD MoU

Legislation

- CAP411 Civil Protection Act

- CAP452 Employment and Industrial Relations Act
- CAP465 Public Health Act
- CAP512 Small Business Act
- CAP 585 Nuclear Safety and Radiation Protection Act
- CAP586 Data Protection Act
- CAP595 Public Administration Act
- CAP646 Health and Safety at Work Act
- SL585.01 Basic Safety Standards for Ionising Radiation Regulations SL585.02
- SL585.02 Nuclear Safety Regulations
- SL585.03 Management of Radioactive Waste Regulations
- SL585.04 Commission for the Protection from Ionising and Non-Ionising Regulations
- SL452.126 Transparent and Predictable Working Conditions Regulations
- SL646.11 General Provisions for Health and Safety at Workplaces Regulations
- SL646.13 Minimum Requirements for the Use of Personal Protective Equipment at Work Regulations

- EU Regulation 2016/52 of 15 January 2016 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, and repealing Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90
- EU Regulation 2020/1158 of 5 August 2020 on the conditions governing imports of food and feed originating in third countries following the accident at the Chernobyl nuclear power station

APPENDIX VIII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Fundamental Safety Principles, No SF-1, IAEA, Vienna (2006)
2. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Governmental, Legal and Regulatory Framework for Safety, General Safety Requirements Part 1, No GSR Part 1 (Rev. 1), IAEA, Vienna (2016)
3. **INTERNATIONAL ATOMIC ENERGY AGENCY –** Leadership and Management for Safety, General Safety Requirements Part 2, No GSR Part 2, IAEA, Vienna (2016)
4. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, No GSR Part 3, IAEA, Vienna (2014).
5. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety assessment for facilities and activities, General Safety Requirements Part 4, No GSR Part 4 (Rev. 1), IAEA, Vienna (2016)
6. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Predisposal Management of Radioactive Waste, General Safety Requirements Part 5, No GSR Part 5, IAEA, Vienna (2009)
7. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Decommissioning of Facilities, General Safety Requirements No GSR Part 6, IAEA, Vienna (2014)
8. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Preparedness and Response for Nuclear or Radiological Emergency, General Safety Requirements No GSR Part 7, IAEA, Vienna (2015)
9. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Site Evaluation for Nuclear Installations, Specific Safety Requirements No SSR-1, IAEA, Vienna (2003)
10. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Power Plants: Design, Specific Safety Requirements No SSR-2/1 (Rev. 1), IAEA, Vienna (2016)
11. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Power Plants: Commissioning and Operation, Specific Safety Requirements No SSR-2/2 (Rev. 1), IAEA, Vienna (2016)
12. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Research Reactors, Specific Safety Requirements No SSR-3, IAEA, Vienna (2016)
13. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Safety of Nuclear Fuel Cycle Facilities, Specific Safety Requirements No SSR-4, IAEA, Vienna (2017)
14. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Disposal of Radioactive Waste, Specific Safety Requirements No SSR-5, IAEA, Vienna (2011)
15. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Specific Safety Requirements No SSR-6 (Rev. 2), 2025 Edition, IAEA, Vienna (2025)
16. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Classification of Radioactive Waste, General Safety Guide No GSG-1, IAEA, Vienna (2009)
17. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide No GSG-2, IAEA, Vienna 2011)
18. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Communication and Consultation with Interested Parties by the Regulatory Body, General Safety Guide No GSG-6, IAEA, Vienna (2017)
19. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Occupational Radiation Protection, Safety Guide No GSG-7, IAEA, Vienna (2018)

20. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Control of Radioactive Discharges to the Environment, Safety Guide No GSG-9, IAEA, Vienna (2018)
21. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization, Management and Staffing of the Regulatory Body for Safety, General Safety Guide No GSG-12, IAEA, Vienna (2018)
22. INTERNATIONAL ATOMIC ENERGY AGENCY - Functions and Processes of the Regulatory Body for Safety, General Safety Guide No GSG-13, IAEA, Vienna (2018)
23. INTERNATIONAL ATOMIC ENERGY AGENCY Leadership, Management and Culture for Safety in Radioactive Waste Management, Safety Guide No GSG-16, IAEA, Vienna (2022)
24. INTERNATIONAL ATOMIC ENERGY AGENCY - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide No GS-G-2.1, IAEA, Vienna (2007)
25. INTERNATIONAL ATOMIC ENERGY AGENCY - Modifications to Nuclear Power Plants, Safety Guide No SSG-71, IAEA, Vienna (2022)
26. INTERNATIONAL ATOMIC ENERGY AGENCY - Recruitment, Qualification and Training of Personnel for Nuclear Power Plants, Safety Guide No NS-G-2.8, IAEA, Vienna (2002)
27. INTERNATIONAL ATOMIC ENERGY AGENCY - Environmental and Source Monitoring for Purposes of Radiation Protection, Safety Guide No RS-G-1.8, IAEA, Vienna (2005)
28. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Radiation Generators and Sealed Radioactive Sources, Safety Guide No RS-G-1.10, IAEA, Vienna (2008)
29. INTERNATIONAL ATOMIC ENERGY AGENCY - Borehole Disposal Facilities for Radioactive Waste, Safety Guide No SSG-1, IAEA, Vienna (2009)
30. INTERNATIONAL ATOMIC ENERGY AGENCY - Deterministic Safety Analysis for Nuclear Power Plants, Specific Safety Guides No SSG-2, IAEA, Vienna (2010)
31. INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide No SSG-3, IAEA, Vienna (2010)
32. INTERNATIONAL ATOMIC ENERGY AGENCY - Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants, Specific Safety Guide No SSG-4, IAEA, Vienna (2010)
33. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Conversion Facilities and Uranium Enrichment Facilities, Specific Safety Guide No SSG-5, IAEA, Vienna (2010)
34. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium Fuel Fabrication Facilities Specific Safety Guide No SSG-6, IAEA, Vienna (2010)
35. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety of Uranium and Plutonium Mixed Oxide Fuel Fabrication Facilities, Specific Safety Guide No SSG-7, IAEA, Vienna (2010)
36. INTERNATIONAL ATOMIC ENERGY AGENCY - Licensing Process for Nuclear Installations, Specific Safety Guide No SSG-12, IAEA, Vienna (2010)
37. INTERNATIONAL ATOMIC ENERGY AGENCY - Geological Disposal Facilities for Radioactive Waste Specific Safety Guide No SSG-14, IAEA, Vienna (2011)
38. INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Spent Nuclear Fuel, Safety Guide No SSG-15 (Rev. 1), IAEA, Vienna (2020)
39. INTERNATIONAL ATOMIC ENERGY AGENCY - Periodic Safety Review for Nuclear Power Plants, Safety Guide No SSG-25, IAEA, Vienna (2013)
40. INTERNATIONAL ATOMIC ENERGY AGENCY - Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material Specific Safety Guide (2018 Edition) No SSG-26 (Rev.1), IAEA, Vienna (2022)

41. INTERNATIONAL ATOMIC ENERGY AGENCY - Commissioning for Nuclear Power Plants, Safety Guide No SSG-28, IAEA, Vienna (2014)
42. INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste from Nuclear Power Plants and Research Reactors, Safety Guide No SSG-40, IAEA, Vienna (2016)
43. INTERNATIONAL ATOMIC ENERGY AGENCY - Predisposal Management of Radioactive Waste from Nuclear Fuel Cycle Facilities, Safety Guide No SSG-41, IAEA, Vienna (2016)
44. INTERNATIONAL ATOMIC ENERGY AGENCY - Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education, Safety Guide No SSG-45, IAEA, Vienna (2019)
45. INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection and Safety in Medical Uses of Ionizing Radiation, Safety Guide No SSG-46, IAEA, Vienna (2018)
46. INTERNATIONAL ATOMIC ENERGY AGENCY - Decommissioning of Nuclear Power Plants, Research Reactors and Other Nuclear Fuel Cycle Facilities, Safety Guide No SSG-47, IAEA, Vienna (2018)
47. INTERNATIONAL ATOMIC ENERGY AGENCY – Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants, Safety Guide No SSG-48, IAEA, Vienna (2018)
48. INTERNATIONAL ATOMIC ENERGY AGENCY –Decommissioning of Medical, Industrial and Research Facilities, Safety Guide No SSG-49, IAEA, Vienna (2019)
49. INTERNATIONAL ATOMIC ENERGY AGENCY – Operating Experience Feedback for Nuclear Installations, Safety Guide No SSG-50, IAEA, Vienna (2018)
50. INTERNATIONAL ATOMIC ENERGY AGENCY - Accident Management Programmes for Nuclear Power Plants, Safety Guide No SSG-54, IAEA, Vienna (2019)
51. INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for a Nuclear or Radiological Emergency Involving the Transport of Radioactive Material, Safety Guide No SSG-65, IAEA, Vienna (2022)
52. INTERNATIONAL ATOMIC ENERGY AGENCY - Radiation Protection Programmes for the Transport of Radioactive Material, Safety Guide No TS-G-1.3, IAEA, Vienna, (2007)
53. INTERNATIONAL ATOMIC ENERGY AGENCY - The Management System for the Safe Transport of Radioactive Material Safety Guide No TS-G-1.4, IAEA, Vienna (2008)
54. INTERNATIONAL ATOMIC ENERGY AGENCY - Compliance Assurance for the Safe Transport of Radioactive Material, Safety Guide No TS-G-1.5, IAEA, Vienna (2009)
55. INTERNATIONAL ATOMIC ENERGY AGENCY - Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition), Specific Safety Guide No SSG-33 (Rev.1) IAEA, Vienna (2021)
56. INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide No WS-G-6.1, IAEA, Vienna (2006)
57. INTERNATIONAL ATOMIC ENERGY AGENCY - Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide NoWS-G-5.2, IAEA, Vienna (2009)
58. INTERNATIONAL ATOMIC ENERGY AGENCY - Storage of Radioactive Waste, Safety Guide No WS-G-6.1, IAEA, Vienna (2006)