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**INTEGRATED
REGULATORY
REVIEW SERVICE (IRRS)
FOLLOW UP MISSION
TO
REPUBLIC OF MALTA**

Pietà, Malta

8 to 12 March 2020

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY



**Commission for the Protection
from Ionising and Non-Ionising
Radiation**



Integrated
Regulatory
Review Service
IRRS



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Mission dates: *08 to 12 March 2020*
Regulatory body visited: *Commission for the Protection from Ionising and Non-Ionising Radiation*
Location: *Pieta, Malta*
Regulated facilities and activities in the mission scope: *Radiation sources in industrial and medical facilities, emergency preparedness and response, medical exposure, occupational exposure and public exposure*
Organized by: *International Atomic Energy Agency*

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IAEA - March 2020

The number of recommendations, suggestions and good practices is in no way a measure of the status of the regulatory body. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of the Republic of Malta, an international team of senior safety experts met with representatives of the Commission for the Protection from Ionising and Non-Ionising Radiation (Commission) from 08 to 12 March 2020 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission. The purpose of the IRRS follow-up mission was to review Malta's progress against the recommendations and suggestions identified in the initial IRRS mission, which was carried out from 22 February to 03 March 2015. The follow-up mission took place at the Commission's Headquarters in Pieta Malta. The scope of the IRRS follow-up mission was the same as the scope of the initial mission in 2015, namely the regulatory framework for all radiation facilities and activities in Malta.

The IRRS team consisted of four senior regulatory experts from four IAEA Member States, and three IAEA staff members.

The IRRS team carried out a review of the progress made on each recommendation and suggestion that was documented in the 2015 IRRS mission report. These recommendations and suggestions cover the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection, enforcement and the development and content of regulations and guides; emergency preparedness and response; control of medical exposure; occupational radiation protection; control of radioactive discharges, materials for clearance and control of existing exposure situations and remediation; and environmental monitoring for public radiation protection.

To assess progress, the IRRS team conducted a series of interviews and discussions with Commission staff and reviewed the advance reference material provided by the Commission.

The IRRS team concluded that Malta, through the Commission, has been responsive to each recommendation and suggestion made in 2015, and continues to place appropriate focus on implementing a framework that provides for effective radiation safety for workers, patients, the public and the environment. 35 out of 42 recommendations and 4 out of 7 suggestions identified in 2015 have been closed.

The IRRS team noted that the Maltese Government and the Commission showed a strong commitment to radiation safety.

Since 2015, the Government has enacted a new nuclear safety and radiation protection law, established a new regulatory body and increased the Commission's budget for regulatory oversight.

Since 2015, the Commission has made good progress in establishing its management system.

Since 2015, the Commission has made a number of achievements in the following areas:

- Issue of new regulations in line with the international safety standards;
- Establishing a management system including processes implemented in accordance with a graded approach for the authorization of facilities and activities;
- Establishing processes for drafting, adopting, promoting and amending regulations and guides;
- Establishing a national emergency preparedness and response system.

The Commission is encouraged to continue its efforts to:

- Recruit new staff and develop its Human Resources Plan for staff training and knowledge management;
- Establish means of communication and consultation with interested parties;
- Complete and fully implement its management system;
- Establish procedures for review and assessment for all facilities and activities taking into consideration the graded approach;
- Develop and implement an inspection programme taking into consideration the graded approach.

The IRRS team also offered two new recommendations for the Commission's consideration:

- Establish, based on a graded approach, the regulatory requirements for emergency preparedness and response for licensees, covering all relevant general, functional and infrastructural elements;
- Ensure that diagnostic reference levels for medical exposures incurred in medical imaging, including image guided interventional procedures are established.

The specific findings of the follow-up mission are summarized in Appendices IV and V.

A press release was issued by the IAEA at the end of the IRRS follow-up mission.

I. INTRODUCTION

At the request of the Government of the Republic of Malta, an international team of senior safety experts met representatives from the Commission for the Protection from Ionising and Non-Ionising Radiation from 08 March to 12 March 2019 to conduct an Integrated Regulatory Review Service (IRRS) follow-up mission.

The purpose of the follow-up mission was to review the implementation of the recommendations and suggestions given to the Government of Malta during the IRRS Mission in February 2015. The follow-up mission was formally requested by the Government of Malta in September 2016. A preparatory meeting was conducted from 20 to 21 August 2019 at the Headquarters of the Secretariat for the Commission in Malta 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.

The IRRS team consisted of four senior regulatory experts from four IAEA Member States, and three IAEA staff members. The IRRS team carried out the review in the areas covered by the main mission in 2015.

The follow-up self-assessment report and supporting documentation were provided to the IRRS team as advance reference material (ARM) for the mission. During the mission, the IRRS team performed a systematic review of all topics by reviewing the advance reference material, additional information, and by conducting interviews with management and staff of the Commission.

All through the mission, the IRRS team received support and cooperation from the Commission.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS follow-up mission was to conduct a review of the implementation of the recommendations and suggestions given to the Government of Malta during the IRRS Mission in February 2015 and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities related to ionising radiation regulated by the Commission. The review was carried out by comparison of existing arrangements against the IAEA safety standards.

It is expected that the IRRS follow-up mission will facilitate regulatory improvements in Malta and other Member States from the knowledge gained and experiences shared between the Commission and IRRS reviewers and through the evaluation of the effectiveness of Malta's regulatory framework for radiation and nuclear safety.

III BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Malta, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 20 to 21 August 2019. The preparatory meeting was carried out by the appointed Team Leader Ms Ritva Bly, and IAEA Coordinator Mr Ibrahim Shadad and the representatives of the Commission.

The IRRS follow-up mission preparatory team had discussions regarding regulatory programmes with the senior management of the Commission represented by Paul Brejza, Executive Secretary. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS follow-up mission:

- Radiation sources facilities and activities;
- Control of medical exposure;
- Occupational radiation protection;
- Public exposure control.

Mr Paul Brejza made presentations on the national context, the current status of the Commission and the progress made since the initial mission of February 2015.

IAEA staff presented the process and methodology of conducting an IRRS follow-up mission. This was followed by a discussion on the tentative work plan for the implementation of the follow-up mission in Malta in March 2020.

The proposed IRRS team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the IRRS follow-up team was tentatively confirmed. Logistics including meeting and work space, counterparts and Liaison Officer, lodging and transport arrangements were also addressed.

The Liaison Officer for the preparatory meeting and the IRRS follow-up mission was Mr Paul Brejza.

The Commission provided the IAEA (and the review team) with the advance reference material for the review in January 2020 and additional materials. In preparation for the mission, the IRRS team members conducted a review of the advance reference material and provided their initial review comments to the IRRS Team Coordinator and Team Leader prior to the follow-up mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

An initial IRRS team meeting was conducted on Sunday 8 March 2020, in Pieta by the IRRS Team Leader and IAEA Team Coordinator to discuss the general overview, the focus areas and the specific issues of the mission; to clarify the basis for the review and the background and objectives of the IRRS; and to agree on the methodology for the review. The agenda for the mission was also presented.

The Liaison Officer, Mr Paul Brejza was present at the initial IRRS team meeting in accordance with the IRRS guidelines, and presented logistical arrangements planned for the mission.

The reviewers also reported their first impressions of the advance reference material. General approaches for mission conclusions drafting were agreed.

The IRRS entrance meeting was held on Monday, 9 March 2020 with the participation of senior management and staff of the Commission. Opening remarks were made by Dr Deo Debattista, Parliamentary Secretary, and the Team Leader, Ms Ritva Bly, gave a presentation on the expectations of the IRRS follow-up mission. Dr Lourdes Farrugia and Mr P Brejza gave an overview of the activities and response to the 2015 mission findings.

During the mission, a review was conducted for all the mission scope areas with the objective of reviewing the Government and the Commission's response to the recommendations and suggestions identified during the initial mission. The review was conducted through meetings, interviews and discussions regarding the national practices and activities.

The IRRS team performed its activities based on the mission programme given in Appendix III.

The IRRS exit meeting was held on Thursday 12 March 2020 where the IRRS Team Leader Ms Ritva Bly presented the results of the follow-up mission highlighting the main findings. This was followed by a statement by Dr Lourdes Farrugia, in response to the Team Leader's presentation. Closing remarks were made by Mr. Ibrahim Shadad on behalf of the Director of the Division of Radiation, Transport and Waste Safety, Department of Nuclear Safety and Security.

A press release was issued by the IAEA at the end of the IRRS follow-up mission.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: The government should establish a national policy and strategy for safety, taking into account current and future risks associated with radiation facilities and activities in Malta. Implementation of the policy should be subject to a graded approach.</p>
(1)	<p>BASIS: GSR Part 1 Requirement 1 states that <i>“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 Fundamentals.”</i></p>
(2)	<p>BASIS: GSR Part 1 Requirement 1 para. 2.3 states that <i>“National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government’s intent. The strategy shall set out the mechanisms for implementing the national policy.”</i></p>
R1	<p>Recommendation: The Government should establish a national policy and strategy for safety, taking into account current and future risks associated with radiation facilities and activities. Implementation of the policy should be subject to a graded approach according to the radiation risk associated with facilities and activities in Malta.</p>

Changes since the original IRRS mission

Recommendation 1: The Government’s policy and strategy for safety is established through the Nuclear Safety and Radiation Protection Act Chapter 585 of 2018 (Act) and regulations made under it. The Act is the prime legislation addressing many of the fundamental safety objectives and safety principles defined in IAEA SF-1, such as justification, limitations of risks to individuals and graded approach. The scope of the Act includes the provision for adequate protection of people in current and future generations against the harmful effects of ionizing radiation and for the safety of radiation sources.

However, the Act does not fully address the following components of a national policy and strategy for safety:

- prime responsibility for safety;
- binding international legal instruments, such as conventions and other relevant international instruments;
- research and development activities;
- mechanisms for taking into account social and economic developments.

The IRRS team was informed that some of the above components are not included in the Act and regulations as they are currently not a priority of the Government or there are no activities to the regard, such as research and development.

The IRRS team encourages the Government to seek assistance from the IAEA to improve and provide clarity to the Act and regulations made under it.

Status of Recommendation 1

Recommendation R1 is closed on the basis of progress made and confidence in effective completion in due time, as the Government enacted the Nuclear Safety and Radiation Protection Act and regulations made under it, since most of the elements of the policy and strategy for safety are established by them.

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: The national framework for safety and in particular, the Radiation Protection Board (RPB) has not been established by a Maltese Act. The use of various non-radiation-related Acts as the basis for radiation safety regulations has led to regulatory responsibilities not being clearly allocated.</p>
(1)	<p>BASIS: GSR Part 1 Requirement 2 <i>Establishment of a framework for safety, para. 2.4 (9) states that</i> “<i>The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.</i>”</p>
R2	<p>Recommendation: The Government should establish a dedicated nuclear and radiation safety Act. The Act should regulate the conduct of legal or natural persons engaged in activities related to fissionable materials, ionizing radiation and exposure to natural sources of radiation and provide a legal framework for conducting activities related to nuclear energy and ionizing radiation in a manner which protects individuals, property and the environment.</p>

Changes since the original IRRS mission

Recommendation 2: The Government has established a dedicated Nuclear Safety and Radiation Protection Act. The House of Representatives passed the Act at sitting on the 21st May 2018. The Act was published on the 25th May 2018.

The Act establishes the framework for safety. The applicability of the Act includes practices and work activities which involve a risk from ionising radiation from an artificial source or from a natural radiation source in cases where natural radionuclides are or have been processed in view of their radioactive, fissile or fertile properties.

Status of Recommendation 2

Recommendation R2 is closed, as the Government established the Nuclear Safety and Radiation Protection Act in 2018.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: The RPB has been established through regulation rather than an act and has not been assigned all functions and responsibilities necessary to fulfil its obligations as a regulatory body for radiation safety, particularly the capacity to promulgate and enforce regulations. Key elements that ensure the effective independence of RPB are not in place.</p>
(1)	<p>BASIS: GSR Part 1 Requirement 3: Establishment of a regulatory body, para. 2.6 states that <i>“The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.”</i></p>
(2)	<p>BASIS: GSR Part 1 Requirement 4: Independence of the regulatory body, para. 2.6 states that <i>“The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making.”</i></p>
R3	<p>Recommendation: The Government should ensure that the nuclear and radiation safety Act includes provisions to establish an effectively independent regulatory body functionally separated from entities having responsibilities or interests that could unduly influence its decision-making.</p>

Changes since the original IRRS mission

Recommendation 3: The Act assigns the responsibility and authority for regulatory control of nuclear and radiation related activities to the Commission for the Protection from Ionising and Non-ionising Radiation (Commission). The Act also establishes the Secretariat for the Commission (Secretariat), which shall act as its executive in the field of nuclear safety and radiation protection. The composition of the Commission and the functions of the Commission and the Secretariat are outlined in the Act.

Article 10 (5) of the Act states that it is the Minister who appoints the members of the Commission and that no members shall be responsible for the use of any form of ionising radiation. According to the Act *“Minister responsible for matters related to and incidental to this Act and such Minister shall not have under his responsibility any form of ionising or non-ionising radiation facility or source.”*

Since January 2020, the ministry responsible for the Radiation Protection Commission has changed from the Ministry of European Affairs and Equality to the Ministry of Tourism and Consumer Protection (Ministry). This change took place following the submission of the ARM.

Status of Recommendation 3

Recommendation R3 is closed, as the Act assigns the responsibility and authority for Nuclear and Radiation related activities to the Commission and provides that no members shall be responsible for the use of any form of ionising radiation.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

There were no findings in this area in the original IRRS mission.

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

There were no findings in this area in the original IRRS mission.

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

There were no findings in this area in the original IRRS mission.

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

There were no findings in this area in the original IRRS mission.

1.8. COMPETENCE FOR SAFETY

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: LN 44 of 2003 requires that the radiation employer provides workers with appropriate information, instruction and training, but maintenance and verification of the competences of regulatory staff is not formally provided for in legislation or stipulated in the procedures of the RPB and there are no similar requirements regarding the competences of others responsible for the safety of facilities and activities, including TSOs or expert advisers on matters relating to safety.
(1)	BASIS: GSR Part 1 Requirement 11: Competence for safety para. 2.33 states that <i>“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.”</i>
R4	Recommendation: The Government should, in the legal framework for safety, stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities, make provision for adequate arrangements for the regulatory body to build and maintain expertise in the disciplines necessary for discharge of the regulatory body’s responsibilities and provide for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties.

Changes since the original IRRS mission

Recommendation 4: Subsidiary legislation 585.01 Basic Safety Standards for Ionising Radiation Regulations of 2018 (BSS) stipulate the requirements for persons with responsibilities in relation to the safety. More specifically, the persons that have responsibilities for safety and their competence criteria are as follows:

- Radiation Protection Experts – regulation 106 of BSS;
- Medical Physics Experts - regulation 109 of BSS;
- Radiation Protection Officers - regulation 110 (4) of the BSS;
- Persons involved in medical exposures - regulation 18 (2) and the 17th Schedule to the BSS.

Article 12 and 13 of the Act stipulate that the executive functions of the Commission are to be performed by the Secretariat. Currently two senior staff are performing the work of the Secretariat.

Availability of sufficient financial resources for the Secretariat is a prerequisite for both employing and training of new staff. The IRRS team was informed that the Government is making provision for arrangements for the Secretariat to build expertise as illustrated by an increased budget allocated to the Commission.

The IRRS team was informed that the Ministry issues a rolling three-year human resource plans for Governmental departments, including the Secretariat. A human resource (staffing) plan for the period 2019 to 2022 has been developed for the Secretariat and approved by Ministry responsible for the Commission. According to this plan, recruitment and appointment of new staff is to be done throughout this three-year period.

The IRRS team was informed that for 2020, the Government has increased the budget allocated to the Secretariat for the staffing of three radiation protections staff. The staffing process is currently underway and it is envisaged that three staff will be hired by the summer of 2020.

The IRRS team was informed that it may be challenging for the Secretariat to obtain suitably qualified staff for working in the field of radiation safety.

In order to emphasise the need for building expertise within the Secretariat a proposed amendment to the BSS states: *“The Commission shall allocate necessary resources in order that staff of its Secretariat to obtain, maintain and further develop expertise and skills required in discharging the Commission’s responsibilities”*. A training plan has been developed by the Secretariat *“OP-20 Recruiting and basic training of new staff”*.

Adequate arrangements for the regulatory body to build and maintain expertise is further discussed in recommendation R6.

The responsibility resides with undertakings for ensuring that persons are provided with the necessary technical competence. Sections 14 and 15 of the BSS stipulate training expectations. In accordance with these regulations, the Commission approves the syllabi for radiation protection training and issues certificates of training performed.

Training by radiation employers is further discussed in recommendations R33.

Status of Recommendation 4

Recommendation R4 is closed on the basis of progress made and confidence in effective completion in due time as the BSS stipulate requirement for persons with responsibilities for safety as well as requirements for verification by the Commission for technical competence. However, adequate arrangements for the Commission to build and maintain expertise is outstanding and training by radiation employers is not ensured.

1.9. PROVISION OF TECHNICAL SERVICES

There were no findings in this area in the original IRRS mission.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Malta has not ratified the Conventions on Early Notification and Assistance and has not formally committed to the Guidance on the Import and Export of Radioactive Sources. Maltese experts have limited opportunities to participate in international cooperation activities for safety.
(1)	BASIS: GSR Part 1 Requirement 14: International obligations and arrangements for international cooperation para. 3.1 (9) states that <i>“The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally.”</i>
(2)	BASIS: GSR Part 1 Requirement 15: Sharing of operating experience and regulatory experience para. 3.2 (9) states that <i>“The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities.”</i>
R5	Recommendation: The Government should provide resources that enable active participation in international cooperation activities for safety such as sharing of regulatory experience and participation in IAEA safety review missions.
S1	Suggestion: The Government should consider ratification of the conventions on Early Notification and Assistance and making a political commitment to the Guidance on Import and Export of Radioactive Sources.

Changes since the original IRRS mission

Recommendation 5: Sufficient human resources are needed to participate in international cooperation activities.

The IRRS team was informed that increased participation in international cooperation activities is envisaged once additional staff for the Secretariat is engaged.

Status of Recommendation 5

Recommendation R5 remains open as no progress has been made in the participation of international cooperation activities for safety.

Changes since the original IRRS mission

Suggestion 1: Article 10(2)(e)(f) of the Act stipulates that a function of the Commission is to give effect to international decisions and implement the regulatory requirements of Conventions.

The Commission discussed Notification and Assistance Conventions during the meeting held on 30th October 2019 with the Ministry of Foreign Affairs. The Ministry of Foreign Affairs responded expressing concerns on several items including the article on privileges, immunities and facilities.

The Ministry of Foreign Affairs concluded stating that it had reservations on the ratification of the conventions on Early Notification and Assistance.

The previous regulatory body (RPB) sent a letter to the IAEA, dated 20th April 2015, making a political commitment to the Guidance on Import and Export of Radioactive Sources.

Status of Suggestion 1

Suggestion S1 remains open as discussions to ratify the conventions on the Early Notification and Assistance are ongoing.

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

There were no findings in this area in the original IRRS mission.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

There were no findings in this area in the original IRRS mission.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

There were no findings in this area in the original IRRS mission.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: In relation to the scope of the regulatory programme, in terms of facilities, activities and the regulatory functions of the RPB, there appears to be insufficient numbers of expert personnel to fulfil its mission as a regulatory body.
(1)	BASIS: GSR Part 1 Requirement 18 Staffing and competence of the regulatory body, states that “ <i>the regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.</i> ”
R6	Recommendation: The Government should ensure the regulatory body employs a sufficient number of staff in accordance with the extent, scope and complexity of the regulatory programme for radiation safety.
S2	Suggestion: The Government should consider in the short term, prioritizing measures to ensure knowledge and experience is shared between senior members and new recruits and in the long-term to maintain staff having the competences and experience necessary for effective current and future regulatory oversight of all facilities and activities in Malta, together with Malta’s responsibilities for, and contribution to nuclear and radiation safety internationally.

Changes since the original IRRS mission

Recommendation 6: Currently the Secretariat is comprised of two persons. The numbers of staff of the Secretariat has not changed since the IRRS 2015.

With existing staff, the Commission is unable to completely fulfil its statutory obligations for regulatory control in the field of radiation and nuclear safety.

The IRRS team was informed that the Ministry is aware of the need for extra staff in order for the Commission to be able to perform its legally assigned functions.

The number of planned positions for the Secretariat are:

- 3 radiation protection staff in 2019 (planned hiring already passed);

- 2 radiation protection staff, 2 junior radiation protection staff, 1 clerk in 2020;
- 2 radiation protection staff in 2021;
- 1 junior radiation protection staff in 2022.

The Secretariat performed a task-based analysis based on historical activities to determine the human resources and expertise needed to build the staff of the Secretariat.

The IRRS team was informed that the hiring process is under way for the 3 radiation protection staff and it is envisaged that these will be filled in 2020.

For the years following 2020, the Secretariat intends to continue with new employments, however no financial arrangements are in place for this. The Secretariat is financed from funds allocated to it by the Government that are held by the Ministry responsible for the Commission. The budget is allocated annually to Secretariat. For 2021 and 2022, a request to Government will be needed to increase the budget for staffing.

Status of Recommendation 6

Recommendation R6 remains open as, although some progress towards employing more staff has been made, to date no staff has yet been employed by the Secretariat.

Changes since the original IRRS mission

Suggestion 2: There has been no new recruitment to the Secretariat.

A training procedure, *OP-21 Staff Development and Maintaining of Skill*, has been developed for new staff to be recruited.

Increased training activities are envisaged for current staff once additional staff for the Secretariat will be in place.

The IRRS team noted that the current two staff in the Secretariat are approaching retirement. Due to the considerable loss of knowledge in the organization that will take place following the retirement of experienced personnel, it will be essential that the Commission have adequate time to train new personnel.

Status of Suggestion 2

Suggestion S2 remains open although some progress towards employing more staff has been made, to date no staff has yet been employed by the Secretariat.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

There were no findings in this area in the original IRRS mission.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The regulatory body has not developed formal procedures for collecting and disseminating information to radiation employers.
(1)	BASIS: GSR Part 1 requirement 21 states that “ <i>The regulatory body shall establish formal and informal mechanisms of communication with authorized</i>

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>parties on all safety related issues, conducting a professional and constructive liaison.”</i>
R7	Recommendation: The regulatory body should establish formal and informal mechanisms of communication with authorized parties on all safety related issues.

Changes since the original IRRS mission

Recommendation 7: The IRRS team was informed that under general governmental procedures all new legislation goes out for consultation, and an Impact Assessment Framework submission is made.

The development of documentation that warrants input from stakeholders is addressed in procedure *OP-30 Communication with authorised third parties*. In addition, *OP-01 Notification and Authorization* provides notification and authorization procedures with undertakings.

Status of Recommendation 7

Recommendation R7 is closed as the Commission has developed procedures for communications with authorized parties.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

There were no findings in this area in the original IRRS mission.

3.7. SAFETY RELATED RECORDS

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The records maintained by the RPB are incomplete regarding monitoring of occupational exposure.
(1)	Basis GSR Part 1 requirement 35 para 4.63 states that <i>“The regulatory body shall make provision for establishing and maintaining the following main registers and inventories :... Records of occupational doses.”</i>
(2)	Basis GSR Part 3 requirement 25 para. 3.107 states that <i>“If employers, registrants and licensees cease to conduct activities in which workers are subject to occupational exposure, they shall make arrangements for the retention of workers’ records of occupational exposure by the regulatory body or a State registry, or by a relevant employer, registrant or licensee, as appropriate.”</i>
R8	Recommendation: The regulatory body should extend its national registers to include records of the occupational exposure history of each worker.

Changes since the original IRRS mission

Recommendation 8: The IRRS team was informed that the National Dose Registry was set up in 2015 and includes occupational radiation doses since 2014. A system has been implemented for

collecting and recording individual occupational radiation dose. Prior to 2014, the licence holders maintain occupation radiation doses records.

The Commission’s procedure *OP-29 National Dose Register* explains how the national dose records are collected and recorded.

Status of Recommendation 8

Recommendation R8 is closed as the National Dose Register has been expanded to include records of the occupational exposure history of each worker.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: A documented process for informing the public and interested parties on regulatory related matters is not in place.
(1)	BASIS: GSR Part 1 Requirement 36 states that <i>“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.”</i>
R9	Recommendation: The regulatory body should promote the establishment of appropriate means of informing and consulting interested parties and the public about possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.

Changes since the original IRRS mission

Recommendation 9: The Act and regulations include some specific requirements for the Commission or Secretariat to inform the public and interested parties about possible radiation risks, for example to populations in connection with potential exposure situations, and emergency situation in articles 126 (4), and 93 and 94 of the BSS.

OP-30 Communication with authorised third parties’ outlines development of documentation that warrants input from stakeholders. The IRRS team was informed that within the management system several procedures make reference to posting information on the Commission website. However, the Commission website has not yet been developed. Currently information could only be posted on the Ministry website.

The IRRS team considers that there has not been sufficient progress in activities by the Secretariat to inform and consult interested parties and the public about radiation risks, and about these processes and decisions of the Commission. The IRRS team was informed that the lack of sufficient resources impacts that ability of the Secretariat to promote the processes and decisions of the Commission.

Status of Recommendation 9

Recommendation R9 remains open as there has not been sufficient progress by the Commission to inform and consult interested parties about radiation risks and the processes and decisions of the Commission.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: The RPB has not yet established a management system to ensure responsibilities assigned to the regulatory body are properly discharged, efficient, effective and assuredly consistent by means of the planning, control and supervision of its safety related activities.</p>
(1)	<p>BASIS: GS-R-3 para. 2.1 states that <i>“A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:</i></p> <p><i>—Bringing together in a coherent manner all the requirements for managing the organization;</i></p> <p><i>—Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;</i></p> <p><i>—Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.”</i></p>
R10	<p>Recommendation: The regulatory body should adopt or develop a management system compatible with international requirements and appropriate to its size and the scope and extent of its regulatory functions and activities.</p>

Changes since the original IRRS mission

Recommendation 10: The management system is based on the one of the Icelandic Radiation Safety Authority using Microsoft Excel. The IRRS team acknowledged the efforts taken to adapt an existing system to the Commission’s purposes. The Management system is divided into 11 elements as follows:

- Workings of the Commission;
- Management of the Secretariat;
- Finance;
- Document Management;
- Staff;
- Computer System;
- Education;
- Authorisation and Inspections;
- Dose & Environmental Monitoring;
- Emergency Preparedness;

- Others.

Each element has its own procedures. Procedures may have supporting documentation, including instructions, checklists, documents, standard forms, and standard letters or email texts. Many of the existing supporting documentation are hyperlinked to facilitate use.

The management system is in use by the staff of the Secretariat. However, more work needs to be carried out to provide adequate confidence that all requirements for managing the organization are satisfied.

Pending work on the management system includes mostly procedures and supporting other documents as follows:

- Administrative arrangements that will depend on such issues as:
 - Premises for the Commission;
 - Final staff complement of the Secretariat;
 - Fees and fines.
- Procedures and supporting guidelines for reviewing and assessment of licence applications (see R13 and R15).
- Authorization procedures and supporting guidelines for dental practices (see R12).
- Procedures and supporting guidelines for authorization of radiotherapy facilities and activities from installation to decommissioning.
- Records of the training and re-training of the Commission.

The IRRS team considers that the control of documents, beginning from the initial development, is insufficient and not in line with the requirements in GS-R-3 or GSR Part 2 Requirement 8.

The IRRS team was informed that currently the development of the management system can only be finalized once the administrative structure is fully in place and there is enough resources and time available. Furthermore, the effectiveness of a management system needs to be monitored and measured by self-assessment and audits for which additional resources need to be allocated.

Status of Recommendation 10

Recommendation R10 is closed on the basis of progress made and confidence in effective completion in due time, as significant progress has been made in establishing a management system, however it needs to be completed with additional processes, procedures, supporting guidelines and records.

5. AUTHORIZATION

5.1. GENERIC ISSUES

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: There is no documented appeal procedure, however the self-assessment describes a process whereby the radiation employer may ask RPB to reconsider its decision.</p>
(1)	<p>BASIS: GSR Part 1 Requirement 24 states that <i>“The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.”</i></p> <p>BASIS: GSR Part 1 Requirement 24 para. 4.32 states that <i>“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.”</i></p>
R11	<p>Recommendation: The regulatory body should 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.</p>

Changes since the original IRRS mission

Recommendation 11: The legal basis for appeals against a regulatory decision is provided in Article 14 of the Act. The Minister will establish the Appeal Tribunal to hear and decide on appeals from any decision taken by the Secretariat. The detailed procedure to be used for an appeal to be made is further described in operating procedures OP-01 *Notification and Authorisation* and OP-02 *Inspection*.

Status of Recommendation 11

Recommendation R11 is closed as the legal provisions and operating procedures that allows an authorized party to appeal against a regulatory decision are in place.

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

There were no findings in this area in the original IRRS mission.

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: RPB issues authorizations for medical facilities and activities. The sources of radiation are subject only to notification. For unsealed sources there is no stated maximum activity to limit the use of radiation to that verified through safety assessment. Only medical facilities are subject to a graded approach for regulatory control.</p>

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

<p>(1)</p>	<p>BASIS: GSR Part 1 Requirement 24 states that <i>“The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.”</i></p> <p>BASIS: GSR Part 1 Requirement 24 para. 4.29 states that <i>“Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure). This includes, as appropriate, the management of radioactive waste and the management of spent fuel, and the remediation of contaminated areas. For radioactive sources and radiation generators, the regulatory process shall continue over their entire lifetime.”</i></p> <p>BASIS: GSR Part 3 Requirement 6 states that <i>“The application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures.”</i></p> <p>BASIS: GSR Part 3 Requirement 7 states that <i>“Any person or organization intending to operate a facility or to conduct an activity shall submit to the regulatory body a notification and, as appropriate, an application for authorization.”</i></p>
<p>R12</p>	<p>Recommendation: The regulatory body should establish a process in accordance with a graded approach, for all facilities and activities subject to authorization according to GSR Part 1 and GSR Part 3. The requirements for authorization should include the detailed specification of all radiation sources / devices associated with the facility or activity.</p>
<p>S3</p>	<p>Suggestion: The regulatory body should require that a detailed list of sources be included with the submission for authorization and as an attachment to the authorization (licence). In the case of unsealed sources there should be a maximum stated activity.</p>

Changes since the original IRRS mission

Recommendation 12: The BSS contain provisions for the application of a graded approach to regulatory control. Article 32 states that: “Regulatory control through the notification, registration/licensing and the inspection process shall use a graded approach.”

The application of a graded approach is supported by the procedure *OP-01 Notification and Authorization*, which outlines the notification and authorization process for the operation of any X-ray equipment and the use of sealed and unsealed sources. This procedure further refers to the document *QS-REF-06 Practice Characterisation*, which provides a detailed list of practices grouped on the basis of the type of sources used (sealed sources, unsealed sources, X-ray equipment and other practices involved with ionising radiation) and classified in relation to several elements of regulatory control, such as need for notification, registration, licensing, duration of an authorization, inspection frequency and if a radiation protection expert is required for a specific practice.

In the case of new medical radiation equipment or radioactive source, a notification is required in due time and a new authorization certificate is issued. In the case of dental practice, authorization is not yet required. Based on the results of acceptance testing, the equipment is registered and a permission to use the equipment in the facility is only given by e-mail.

The graded approach to regulatory control is also reflected in the application of a requirement related to qualification and experiences for persons involved in medical exposures, provided in Seventeenth Schedule of the BSS. This Schedule provides the categorisation of medical exposures based on the different risk levels (high, medium and low); e.g. radiotherapy, brachytherapy, nuclear medicine (diagnostic and therapeutic) interventional radiology, fluoroscopic techniques, CT and mammography are categorized as high level, while general diagnostic radiography and dental radiography as a medium level and low output diagnostic radiography (e.g. bone density) as low risk level. It is highlighted in the BSS that this categorisation is being done only in relation to qualification and experience for persons performing the work.

Progress has been made in addressing the findings through new regulations and management system processes. Currently, authorization by licensing has been issued for high risk practises, including medical (excluding dental), industrial NDT, and transport applications. However full implementation has not yet been achieved due to limited human resources and the fact that this graded approach model has been introduced recently.

The IRRS team noted that more effort is needed to implement the authorisation process in accordance with the graded approach.

Status of Recommendation 12

Recommendation R12: is closed on the basis of progress made and confidence in effective completion in due time, as significant progress has been made in establishing the authorisation process in accordance with a graded approach; however, the authorization process is not fully implemented, particular in the case of lower risk facilities and activities.

Changes since the original IRRS mission

Suggestion 3: An indicative list of information required from the applicants for an authorisation is provided in the Eighth Schedule of the BSS. Pursuant to Regulation 37, the Commission issues an authorization certificate (template QS-REF-17), which, as an integral part, includes a detailed list of sources.

Status of Suggestion 3:

Suggestion S3 is closed, as a list of sources is required with the submission for authorization and the site inventory is now an integral part of the authorization certificate.

5.4. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

There were no findings in this area in the original IRRS mission.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

There were no findings in this area in the original IRRS mission.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

There were no findings in this area in the original IRRS mission.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

There were no findings in this area in the original IRRS mission.

6.1.3. BASIS FOR REVIEW AND ASSESSMENT

There were no findings in this area in the original IRRS mission.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There are only two standard inspection forms used for review and assessment: one for medical exposure and one for occupational exposure.
(1)	BASIS: GSR Part 1 Requirement 25 states that <i>“The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization.”</i>
(2)	BASIS: GSR Part 1 Requirement 26 states that <i>“Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.”</i>
(3)	BASIS: GS-R-3 Para 5. 9 states that <i>“The work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions...[...] that are periodically reviewed to ensure their adequacy and effectiveness.”</i>
R13	Recommendation: The regulatory body should develop procedures for review and assessment for all facilities and activities. Review and assessment should be performed in accordance with a graded approach.

Changes since the original IRRS mission

Recommendation 13: Review and assessment procedures are addressed in procedure *OP-01 Notification and Authorization*, but these are general procedures that do not reflect the specificity of the practice and the associated risk. The IRRS team considers that the implementation of review and assessment needs to be improved, in particular for high risk activities, in accordance with the graded approach.

Status of Recommendation 13

Recommendation R13 remains open, as only general review and assessment procedures have been developed which do not reflect the specificity of the practice and the associated risk. In addition, the implementation of review and assessment needs to be improved, in accordance with the graded approach.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION APPROACHES, METHODS AND PLANS

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: The RPB has not established a planned and systematic inspection programme or a management system to ensure consistency and stability in the regulatory process.</p>
(1)	<p>BASIS: GSR Part 1 Requirement 29 para. 4.50 states that <i>“The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach.”</i></p>
R14	<p>Recommendation: The regulatory body should develop and implement a programme of inspections that confirms compliance with regulatory requirements and specifies the types of regulatory inspection, the frequency of inspections and utilizes a graded approach.</p>

Changes since the original IRRS mission

Recommendation 14: The procedure *OP-02 Inspections* outlines the inspection process for the operation of any facility using X-ray, sealed and unsealed sources and the inspection protocol *QS-REF-04* and the inspection check list are available. The IRRS team considers these documents together with the *QS-REF-06 “Practice Characterisation”* provide a basis for the development of an annual inspection programme.

The Commission has developed the annual inspection programme that currently consists of 37 facilities to be inspected. The programme is updated automatically, and the next inspection is determined based on the predefined inspection frequency and the date of license validity. The license that has expired will be marked with a red box, whilst yellow box represents a licence expiring within one month. Inspections are recorded separately on a monthly report.

The IRRS team was informed that the inspection programme has not been fully implemented due to insufficient regulatory staff and inspections to new installations and hospitals are prioritized.

Status of Recommendation 14

Recommendation R14 remains open, as no significant progress has been made regarding the implementation of inspection programmes using the graded approach.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: In the absence of documented procedures, stability and consistency of the regulatory control can not be guaranteed.</p>

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<p>BASIS: GSR Part 1 Requirement 22 para. 4.26 states that <i>“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 the 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.”</i></p>
R15	<p>Recommendation: The regulatory body should implement a process that follows specified procedures to ensure the stability and the consistency of regulatory control and to prevent subjectivity in decision.</p>

Changes since the original IRRS mission

Recommendation 15: Operational procedures *OP-01 Notification and Authorisation* and *OP-02 Inspection* and supporting documentation to conduct some regulatory activities are in place. To ensure the stability and the consistency of regulatory control, there is a need to develop additional processes and procedures to fully support regulatory activities. For example, there is a lack of specific review and assessment procedures.

The IRRS team was informed that plans for further development and update the management system to reflect the development of the regulatory system in line with existing national requirements and to provide training to the newly recruited staff.

Status of Recommendation 15

Recommendation R15 is closed on the basis of progress made and confidence in effective completion in due time, as significant steps to ensure the stability and the consistency of regulatory control have been made, however, there is a need to develop additional processes and procedures to fully support regulatory activities.

7.1.2. SITE VISITS TO OBSERVE ACTIVITIES OF THE REGULATORY BODY

There were no findings in this area in the original IRRS mission.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCEDURES

There were no findings in this area in the original IRRS mission.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: The legal basis for developing regulations for nuclear and radiation safety is not clearly established in law. LN 44 only assigns the coordination of this activity to the RPB. Furthermore, the general process used for the development of regulations does not fully address public involvement in accordance with IAEA requirements. There is no review or revision of regulations and no process for drafting, promotion and issue of regulatory guides.</p>
(1)	<p>BASIS: GSR Part 1 Requirement 34 states that <i>“The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.”</i></p> <p>BASIS: GSR Part 1 Requirement 34 Para 4.61. states that <i>“The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience. Moreover, technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides.”</i></p> <p>BASIS: GSR Part 1 Requirement 34 Para 4.62 states that <i>“The regulations and guides shall provide the framework for the regulatory requirements and conditions to be incorporated into individual authorizations or applications for authorization. They shall also establish the criteria to be used for assessing compliance. The regulations and guides shall be kept consistent and comprehensive and shall provide adequate coverage commensurate with the radiation risks associated with the facilities and activities, in accordance with a graded approach.”</i></p>
R16	<p>Recommendation: The Government should establish within the legal framework for radiation safety, processes for establishing or adopting, promoting and amending regulations and guides, including consultation, with account taken of internationally agreed standards and the feedback of relevant experience.</p>

Changes since the original IRRS mission

Recommendation 16: Article 10 of the Act defines the functions of the Commission which includes the development of regulations. The Commission is responsible for co-ordinating the preparation of regulations governing any issues made in connection with the Act. In addition, Article 62 of the Act states that *“ the Minister may make regulations generally so as to give effect to the provisions of this Act, and for the better carrying out of any of the provisions of this Act including regulations implementing all international legal instruments relating to ionising and non-ionizing radiation, nuclear safety and security.”*

The Commission developed the procedure on communication with interested parties (*OP-30 Communication with authorized third parties*) to support the processes for establishing or adopting, promoting and amending regulations and guides.

Status of Recommendation 16

Recommendation R16 is closed, as the procedure for establishing, promoting and amending regulations and guides are in place.

9.2. SPECIFIC REGULATIONS AND GUIDES FOR FACILITIES AND ACTIVITIES

There were no findings in this area in the original IRRS mission.

10. EMERGENCY PREPAREDNESS AND RESPONSE

In line with the IRRS Guidelines, this follow-up mission review was done based on IAEA safety standards GS-R-2 “Preparedness and response for a nuclear or radiological emergency”, which was valid at the time of the IRRS 2015.

In November 2015, GS-R-2 was superseded by GSR Part 7. The IRRS team acknowledges that the improvements in relation to preparedness and response for a nuclear or radiological emergency have been done in line with the IAEA GSR Part 7.

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: Threat assessment presented in RPB-OP-S-Emergency Threat Assessment is not fully up to date, due to the change in the national inventory and lessons learned.</p>
(1)	<p>BASIS: GS-R-2 para. 3.16 states that <i>“Operators, the national co-ordinating authority (see para. 3.4) and other appropriate organizations shall periodically conduct a review in order to ensure that all practices or situations that could necessitate an emergency intervention are identified, and shall ensure that an assessment of the threat is conducted for such practices or situations. This review shall be undertaken periodically to take into account any changes to the threats within the State and beyond its borders, and the experience and lessons from research, operating experience and emergency exercises (see paras 5.33, 5.37 and 5.39).”</i></p>
S4	<p>Suggestion: The regulatory body, together with its national counterparts within the national Emergency Framework, should consider regular reviewing and updating the hazard assessment in its RPB-OP-S-Emergency Threat Assessment document and revise the National Radiological emergency plan accordingly.</p>

Changes since the original IRRS mission

Suggestion 4: The Commission and the Civil Protection Department (CPD) have formalized their collaboration through a Memorandum of Understanding, which has been signed by the two parties in December 2019. In parallel, the Commission and the CPD revised their national hazard assessment as described in *Doc-38 Radiological Hazard Assessment (Doc-38)* which was approved by the Secretariat in 2019. Doc-38 replaces the previous document entitled *RPB-OP-Emergency Threat Assessment-2010-1*. Emergency Preparedness Categories (EPCs) have been adopted in Doc-38 (Annex 1) and used for revising the hazard assessment, as per Table 1 in IAEA GSR Part 7. A provision is included in the Summary of Doc-38 that the hazard assessment “shall be reviewed once every two years or as soon as a new hazard is identified.” Doc-38 is a support document for the National Radiation Emergency Plan.

In relation to the revision of the National Radiation Emergency Plan (NREP) provisions are made in Article 31 of the Act for the Commission to take responsibility for developing and maintaining the NREP in collaboration with the CPD and other partner organizations and ministries. In line with the assigned responsibilities, the Commission developed *Doc-39 Radiological Emergency Response Framework (Doc-39)*, which replaces the *RPB-OP-S-Emergency Framework-2010-1*. Doc-39, which is the revised National Radiation Emergency Plan, describes the emergency

preparedness and response (EPR) framework of Malta in line with the revised hazard assessment, which has to be reviewed “once every two years or as soon as a new hazard is identified”.

Doc-38 and *Doc-39* support the implementation of Article 31 of the Act and provide a basis for the national emergency management system. Moreover, they are consistent with the IAEA safety standards on EPR.

Due to administrative changes at governmental level, the approval of *Doc-39* has been delayed and it is not yet done. The IRRS team was informed that *Doc-39* is in its final stage of approval at ministerial level, waiting for two more formal agreements from the Ministry of Health and Ministry for Home Affairs, Law Enforcement and National Security.

Status of Suggestion 4

Suggestion S4: is closed on the basis of progress made and confidence in effective completion in due time, as the Commission, together with its national counterparts within the national emergency framework, revised and updated the hazard assessment, replaced the RPB-OP-S-Emergency Threat Assessment document with *Doc-38 Radiological Hazard Assessment* and revised the national EPR planning in line with the hazard assessment under *Doc-39 Radiological Emergency Response Framework*, which is currently in its final stage of approval at ministerial level.

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The emergency classification system in Malta is not fully consistent with the one given in the relevant IAEA standard document (GS-R-2).
(1)	BASIS: GS-R-2 para. 4.19 states that “ <i>The operator of a facility or practice in threat category I, II, III or IV shall make arrangements for the prompt identification of an actual or potential nuclear or radiological emergency and determination of the appropriate level of response. This shall include a system for classifying all potential nuclear and radiological emergencies that warrant an emergency intervention to protect workers and the public, in accordance with international standards, which covers emergencies of the following types at facilities (1–4) and other emergencies...</i> ”
S5	Suggestion: The regulatory body should consider modifying its emergency classification system to be consistent with the classification given in GS-R-2.

Changes since the original IRRS mission

Suggestion 5: A revised emergency classification system in line with IAEA GSR Part 7 is included in both *Doc-38* (Annex 1) and *Doc-39* (chapter 5.2). *Doc-38* has been approved by the Commission in December 2019 and, as stated above, *Doc-39* is currently in the final stage of ministerial approval.

Status of Suggestion 5

Suggestion S5 is closed on the basis of progress made and confidence in effective completion in due time, as a revised emergency classification system in line with the international safety standards on EPR has been adopted by the Commission in its *Doc-38 Radiological Hazard*

Assessment and it is soon to be adopted also at ministerial level following the approval of *Doc-39 Radiological Emergency Response Framework*.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There are inconsistencies between Schedule 7, setting a 500 mSv limit for life saving actions, and the RPB-OP-S-Emergency Framework-2010-1 document, which states that such limit does not exist.
(1)	BASIS: GS-R-2 para. 4.62 states that “Arrangements shall be made for taking all practicable measures to provide protection for emergency workers for the range of anticipated hazardous conditions (see para. 4.61) in which they may have to perform response functions on or off the site ^{56, 57} . This shall include: arrangements to assess continually and to record the doses received by emergency workers; procedures to ensure that doses received and contamination are controlled in accordance with established guidance and international standards; and arrangements for the provision of appropriate specialized protective equipment, procedures and training for emergency response in the anticipated hazardous conditions.”
(2)	BASIS: GS-R-2 Annex I para. I-1 states that “When undertaking intervention..., all reasonable efforts shall be made to keep doses to workers below twice the maximum single year dose limit, except for life saving actions, in which every effort shall be made to keep doses below ten times the maximum single year dose limit in order to avoid deterministic effects on health. In addition, workers undertaking actions in which their doses may approach or exceed ten times the maximum single year dose limit shall do so only when the benefits to others clearly outweigh their own risk.”
S6	Suggestion: The regulatory body should consider revising the national radiation emergency preparedness and response planning document (RPB-OP-S-Emergency Framework-2010-1) to make it consistent with the national regulations and the international standards.

Changes since the original IRRS mission

Suggestion 6: The Commission has revised the RPB-OP-S-Emergency Framework-2010-1 and replaced it with *Doc-39*, which is currently in its final stage of approval at ministerial level. *Doc-39* includes in Table 3 (chapter 8) a guidance level for emergency workers of 500 mSv for life saving actions, which is in alignment with both the national provision set in the Article 63(2) of BSS and IAEA GSR Part 7.

Although the observation which generated Suggestion 6 is now met, not all provisions for radiation doses to emergency workers are equivalent in the two documents. For example, for emergency actions other than life saving, the Article 63(2) of BSS stipulates that “reference levels for emergency occupational exposure shall be an effective dose of 50 mSv”, while Table 3 of *Doc-39* includes a value of 20 mSv for emergency actions other than life saving and a *Note* on lowering these values below the 20 mSv “in an emergency exposure situation where appropriate protection can be provided without causing a disproportionate detriment from the corresponding countermeasures or an excessive cost”.

Guidance levels for emergency workers need to be consistent among the two documents (*BSS and Doc-39*) and in line with the IAEA GSR Part 7, paras. 5.54, 5.55 and 5.56.

Status of Suggestion 6

Suggestion S6 remains open, due to existing inconsistency in the BSS and *Doc-39* in relation to the guidance values for emergency workers.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There is no standard operating procedure, nor training programme in place for medical response in radiological emergency situations.
(1)	BASIS: GS-R-2 para. 4.80 states that <i>“Arrangements shall be made at the national level to treat people who have been exposed or contaminated. These shall include: guidelines for treatment; the designation of medical practitioners trained in the early diagnosis and treatment of radiation injuries; and the selection of approved institutions to be used for the extended medical treatment or follow-up of 60, 61 of persons subjected to radiation exposure or contamination...”</i>
S7	Suggestion: The regulatory body should consider working towards the development of the standard operating procedures for medical response, in radiological emergency situations as well as establishing the relevant training programme for medical professionals.

Changes since the original IRRS mission

Suggestion 7: The IRRS team considers that important steps have been made by the Commission towards the development of standard operating procedures for medical response in radiological emergency situations. As part of the recent activities at governmental level for establishing national Chemical, Biological, Radiological, Nuclear, and Explosive (CBRNE) response capabilities, the Secretariat is assisting the emergency medical staff with both training and development of relevant emergency procedures for the medical response in case of radiological emergency. A set of procedures for the medical response in case of radiological emergencies has been developed by the Secretariat (RPB-OP-S-MDH A&E Radiation Procedures) and presented to the relevant staff of the Mater Dei Hospital Accident and Emergency Department in January 2020. Training activities for the medical professionals are planned for the third quarter of 2020, once the medical response procedures will be adopted by those with responsibilities as per the National Radiation Emergency Plan (*Doc-39*).

While important progress has been achieved so far, the IRRS team encourages the Commission to continue supporting partner organizations to enhance their arrangements for responding to radiological emergencies.

Status of Suggestion 7

Suggestion S7 is closed on the basis of progress made and confidence in effective completion in due time, as the standard operating procedures have been elaborated by the Secretariat for the medical response in case of a radiological emergency and training activities for the medical professionals are planned to be conducted in the third quarter of 2020.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The framework document (RPB-OP-S-Emergency Framework-2010-1) contains agricultural action levels. However, this is not in the proper legal

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	status (not legally binding).
(1)	BASIS: GS-R-2 para. 4.88 states that <i>“Optimized [national] intervention levels and action levels [for agricultural countermeasures, countermeasures against ingestion and longer term protective actions shall be established that are in accordance with international standards], modified to take account of local and national conditions, such as: (a) the individual and collective [doses] to be averted by the intervention; and (b) the radiological and non-radiological health risks and the financial and social costs and benefits associated with the intervention.”</i>
R17	Recommendation: The regulatory body should develop, in cooperation with the authorities responsible for the food, health and agriculture, legally binding optimized national intervention levels, in accordance with the international standards.

Changes since the original IRRS mission

Recommendation 17: The Secretariat has revised the RPB-OP-S-Emergency Framework-2010-1 and replaced it with *Doc-39*, which is currently in its final stage of approval at ministerial level. *Doc-39* includes in chapter 11.3 (Tables 6, 7 and 9) the maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency as regulated by COUNCIL REGULATION (Euratom) 2016/52 of 15 January 2016. The levels are in line with the IAEA safety standards.

Status of Recommendation 17

Recommendation R17 is closed on the basis of progress made and confidence in effective completion in due time, as *Doc-39 Radiological Emergency Response Framework* which includes the optimized national intervention levels for food following a nuclear or radiological emergency has been developed and is currently in its final stage of approval at ministerial level.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	Observation: The regulatory body does not have any role in regulating recovery operations.
(1)	BASIS: GS-R-2 para. 4.100 states that <i>“Decisions to cancel restrictions and other arrangements imposed in response to a nuclear or radiological emergency shall be made by a formal process that is in accordance with international guidance. “The regulatory body shall provide any necessary input to the intervention process. Such input may be advice to the government or regulatory control of intervention activities. Principles and criteria for intervention actions shall be established and the regulatory body shall provide any necessary advice in this regard.” ... This process shall include public consultation. The process shall also provide for exceptions from compliance with national regulations and international standards, where justified.”</i>
R18	Recommendation: The Government should through legislation assign responsibilities and functions to the regulatory body for its role in recovery work and the transition to normal activities.

Changes since the original IRRS mission

Recommendation 18: Article 42 of the Act includes provisions for the roles and responsibilities of the Commission in recommending remedial actions. Furthermore, regulations 96, 124 and 126 of the BSS provide additional requirements for the Commission in relation to recovery/remedial actions.

Provisions are also included in the following documents which are currently under approval process: *Doc-39* which addresses the topic in chapter 10; and the proposed amendments of Regulation 91 of the BSS.

Status of Recommendation 18

Recommendation R18 is closed, as the revised legislation assigns responsibilities and functions to the Commission for its role in recovery work and the transition to normal activities.

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: The regulatory body’s control over assessing the appropriateness of the licensees’ emergency plans is weak and indirect. The regulatory body does not have strict criteria for the acceptance of the licensees’ emergency plans, neither does it verify by regular evaluation of the emergency drills and exercises.</p>
(1)	<p>BASIS: GS-R-2 para. 3.8 states that <i>“The regulatory body shall require that arrangements for preparedness and response be in place for the on-site area for any practice or source that could necessitate an emergency intervention. For a facility in threat category I, II or III “Appropriate emergency [preparedness and response] arrangements shall be established from the time that nuclear fuel [or significant amounts of radioactive or fissile material] is brought to the site, and complete emergency preparedness as described here shall be ensured before the commencement of operation.” ... The regulatory body shall ensure that such emergency arrangements are integrated with those of other response organizations as appropriate before the commencement of operation. The regulatory body shall ensure that such emergency arrangements provide a reasonable assurance of an effective response, in compliance with these requirements, in the case of a nuclear or radiological emergency. The regulatory body shall require that the emergency arrangements “shall be tested in an exercise before the commencement of operation [of a new practice]. There shall thereafter at suitable intervals be exercises of the emergency [arrangements], some of which shall be witnessed by the regulatory body.”</i></p>
(2)	<p>BASIS: GS-R-2 para. 5.33 states that <i>“Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III and the national level programmes for threat category IV or V are tested at suitable intervals. These programmes shall include the participation in some exercises of as many as possible of the organizations concerned. The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. The programme shall be subject to review and updating in the light of</i></p>

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>experience gained ...”</i>
R19	Recommendation: The regulatory body should strengthen its regulatory control of the licensees’ emergency planning for category I, II, III facilities and should verify the appropriateness and effectivity of these plans.

Changes since the original IRRS mission

Recommendation 19: Malta has currently no facilities in EPC I, II or III, as per Table 1 in IAEA GSR Part 7. Therefore, the recommendation from the IRRS 2015 is no longer applicable. Malta has activities in EPC IV, which need to be subjected to the regulatory control.

The IRRS team was provided with elements of the regulatory control in relation to EPR arrangements of licensees with activities in EPC IV (e.g. check lists and procedures for inspections). The IRRS team was informed that the regulatory control of licensees’ emergency planning is done in Malta through the review, assessment and inspection processes. However, no clear evidence was provided in relation to strengthening the regulatory control over the EPR arrangements of the licensees.

The IRRS team encourages the Commission to continue strengthening its regulatory control over the licensees’ emergency planning for all facilities and activities identified in the national hazard assessment, based on a graded approach. This is in line and supports also the Recommendation 14 of this Report.

Status of Recommendation 19

Recommendation R19 is closed, as it is no longer relevant for the actual conditions in Malta: according to the revised hazard assessment Malta has currently no facilities in EPC I, II or III.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	Observation: The regulatory body does not have regulations regarding quality assurance in EPR.
(1)	BASIS: GS-R-2 para. 5.37 states that <i>“The operator of a facility, practice or source in threat category I, II, III or IV and the off-site response organizations shall establish a quality assurance programme, in accordance with international standards, to ensure a high degree of availability and reliability of all the supplies, equipment, communication systems and facilities necessary to perform the functions specified in Section 4 in an emergency (see para. 5.25).”</i>
(2)	BASIS: GS-R-2 para. 5.39 states that <i>“The operator of a facility, practice or source in threat category I, II, III or IV and the off-site response organizations shall make arrangements to review and evaluate responses in emergencies and in drills and exercises, to record the areas in which improvements are necessary and to ensure that the necessary improvements are made.”</i>
R20	Recommendation: The regulatory body should develop regulatory requirements for EPR quality assurance programme to be established and maintained by the licensees.

Changes since the original IRRS mission

Recommendation 20: The Eighth Schedule of *Regulation 38* of BSS stipulates that licensee should have a quality assurance programme and it should be presented as part of a license application. Regulation 105 (2) of BSS provides the role of the radiation protection expert who shall be responsible for advising the undertaking on the quality assurance program.

Status of Recommendation 20

Recommendation R20: is closed, due to that regulatory requirements on quality assurance programmes of the licensees are included in the BSS.

New findings from the follow-up mission

At the time of the IRRS 2015, most of the regulatory requirements on EPR were included in the Legal Notice (LN) 44 of 2003. This has been repealed and some regulatory requirements on EPR are now included in the BSS, such as, the notification of an incident/accident, initial assessment of an emergency situation, taking mitigatory actions, assisting the response organizations with protective actions and public information.

Generic information on establishing emergency response plans and their content is provided in the Tenth Schedule of the BSS. It is not clear though to whom the requirements are addressed.

As per the Eighth Schedule, the licensee is required to provide emergency procedures as part of the radiation protection programme. As this is valid for practices with radioactive sources in category 4 or 5, for facilities and activities with radioactive sources in category 1, 2 or 3 an emergency plan needs to be established by the licensee and specific requirements of GSR Part 7 need to be applied. For example, specific regulatory requirements for facilities and activities using radioactive sources in category 1, 2 or 3 needs to include: the performance and periodical review of a hazard assessment; the development of a protection strategy with relevant protective actions; specific mitigatory actions for regaining control over the source; the development of an emergency plan and its periodical review; the establishment of an emergency response organization at the level of the licensee, with clear roles and responsibilities for its members; special training and exercise programmes for the duties within the emergency response organization.

As a result, the existing regulatory requirements in BSS need to be supplemented by additional specific regulatory requirements on EPR, to provide for alignment with GS-R-2, para. 3.9 and GSR Part 7, para. 4.12.

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Observation: LN 44/2003 with regulatory requirements for EPR arrangements of the licensees has been repealed in 2018. Currently, some regulatory requirements on EPR are included in BSS. They are addressed generically and cover only partially the IAEA safety requirements on EPR for licensees.

(1)	BASIS: GSR Part 1 Requirement 32 states that <i>“The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.”</i>
(2)	BASIS: GS-R-2 para. 3.9 states that <i>“In fulfilling its statutory obligations, the regulatory body... shall establish, promote or adopt regulations and guides upon which its regulatory actions are based; ... shall provide for issuing, amending, suspending or</i>

FU Mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<i>revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified): ... the requirements for incident reporting; ... and emergency preparedness arrangements."</i>
RF1	Recommendation: The regulatory body should establish, based on a graded approach, the regulatory requirements for emergency preparedness and response for licensees, covering all relevant general, functional and infrastructural elements in line with IAEA safety standards on preparedness and response for a nuclear or radiological emergency.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

There were no findings in this area in the original IRRS mission.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: There is no act to ensure that relevant parties are authorized to assume their roles and responsibilities in medical use of radiation. The proper use of Diagnostic reference levels is not ensured. Adequate criteria and guidelines for the release of patients after radionuclide therapy or with implanted sources have not been ensured.</p>
(1)	<p>BASIS: GSR Part 3 Requirement 34 states that <i>“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.”</i></p> <p>BASIS: GSR Part 3 Requirement 40 states that <i>“Registrants and licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.”</i></p>
R21	<p>Recommendation: The Government should 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 who have undergone therapeutic procedures using unsealed sources or patients who still retain implanted sealed sources.</p>

Changes since the original IRRS mission

Recommendation 21: Entitlement and approval, by the undertaking, of individuals to act in the different aspects of medical exposures and to assume their roles and responsibilities are set out in Regulations 67 and 68 of the BSS. Moreover, the undertaking is required by Regulation 66 (3) to establish and regularly review the diagnostic reference levels (DRLs). Dose constraints and guidance for carers and comforters are required for in regulation 66(6) and provision of information and appropriate instructions for the risks and the minimisation of doses received by persons in contact with the released patient are required for in regulation 66(7).

The IRRS team was informed that the Secretariat will monitor compliance and implementation through the review and assessment and the inspection procedures.

Status of Recommendation 21

Recommendation R21 is closed as the regulations have been revised to address most of the different components in this recommendation (see Recommendation RF2).

New observation from the follow-up mission

In the proposed amendment to Regulation 66 (3) of the BSS, the responsibility to establish and regularly review the DRLs is assigned to the Commission. A set of diagnostic reference levels for medical exposures is not established yet. Moreover, the BSS and the proposed amendment to it, state that the DRLs shall be established and regularly reviewed having regard to the current

European diagnostic reference levels, where available. There is no evidence that DRLs established in another European Member State are appropriate for the local circumstances.

FOLLOW UP MISSION RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
<p>Observation: Diagnostic reference levels for medical imaging, including image guided interventional procedures have not been established. There is no evidence that DRLs established in another European Member State are appropriate for the local circumstances.</p>	
(1)	<p>BASIS: GSR Part 3 Requirement 34 para. 3.148 states that <i>“The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.”</i></p>
RF2	<p>Recommendation: The Government should ensure that diagnostic reference levels for medical exposures incurred in medical imaging, including image guided interventional procedures are established and based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.</p>

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: Referrals for asymptomatic exposure and self-referred patients are not explicitly covered by the regulations. There is neither a requirement that patients or their legal representatives should be informed of expected benefits or risks. Instead, the medical practitioner is entitled to make a decision on behalf of a patient in case that the patient cannot do so himself.</p>
(1)	<p>BASIS: GSR Part 3 Requirement 36 states that <i>“Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks.”</i></p> <p>BASIS: GSR Part 3 Requirement 36 para 3.150 states that <i>“Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:</i></p> <p><i>(a) the radiological procedure has been requested by a referring medical practitioner and information on the clinical context has been provided, or it is part of an approved health screening programme;</i></p>

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p><i>(b) The medical exposure has been justified through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or it is part of an approved health screening programme;</i></p> <p><i>(c) A radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in para. 3.153(a);</i></p> <p><i>(d) The patient or the patient’s legal authorized representative has been informed, as appropriate, of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.”</i></p>
R22	Recommendation: The regulatory body should regulate asymptomatic exposures.
R23	Recommendation: The regulatory body should ensure through regulations that patients or their legal representatives are informed of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.

Changes since the original IRRS mission

Recommendation 22: The BSS include provisions for asymptomatic exposure that falls within the definition of “medical exposure” (Regulation 65(2i)).

Status of Recommendation 22

Recommendation R22 is closed as provisions for asymptomatic exposure are included in the BSS.

Changes since the original IRRS mission

Recommendation 23: The undertakings are required by the BSS to provide information to patients or their representatives, relating to the benefits and risks associated with the radiation dose from the medical exposure (Regulation 66(7) and 68(e)).

Status of Recommendation 23

Recommendation R23 is closed as provision of information to patients or their representatives, relating to the benefits and risks associated with their medical exposure is ensured through the BSS.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p>Observation: There is no requirement that a medical physicist should be involved in interventional radiology or therapeutic procedures, except in radiotherapy. There is no requirement that radiation employers should ensure that sufficient medical personnel and paramedical personnel are available.</p>
(1)	<p>BASIS: GSR Part 3 Requirement 36 states that “Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks.”</p>

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p>BASIS: GSR Part 3 Requirement 36, para 3.152 states that “Registrants and licensees shall ensure that:</p> <p><i>(a) The radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for ensuring overall protection and safety for patients during the planning and delivery of the medical exposure, including the justification of the procedure as required in paras 3.154–3.160 and the optimization of protection and safety, in cooperation with the medical physicist and the medical radiation technologist as required in paras 3.161–3.176;</i></p> <p><i>(b) Radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals with specific duties in relation to protection and safety for patients in a given radiological procedure have the appropriate specialization;</i></p> <p><i>(c) Sufficient medical personnel and paramedical personnel are available as specified by the health authority;</i></p> <p><i>(d) For therapeutic uses of radiation, the requirements of these Standards for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in paras 3.166, 3.167(c), 3.169 and 3.170, are fulfilled by or under the supervision of a medical physicist;</i></p> <p><i>(e) For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Standards for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in paras 3.166, 3.167(a), 3.167(b), 3.168, 3.169 and 3.170, are fulfilled by or under the oversight of or with the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks;</i></p> <p><i>(f) Any delegation of responsibilities by a principal party is documented.”</i></p>
R24	<p>Recommendation: The regulatory body should amend regulations to include a requirement that an appropriately specialized medical physicist be involved in interventional radiology or therapeutic procedures.</p>
R25	<p>Recommendation: The regulatory body should amend the regulations to include a requirement that radiation employers should ensure that sufficient medical personnel and paramedical personnel are available.</p>

Changes since the original IRRS mission

Recommendation 24: The definition of the “medical physics expert” is set out in Regulation 4 of the BSS and by virtue of Regulation 102, medical physics experts are to be approved by the Commission. Regulation 68(b) and 12th Schedule, Table 1 include requirements for their involvement in medical activities, including interventional radiology and therapeutic procedures. The IRRS team was informed that a number of medical physics experts have already been approved by the Commission.

Status of Recommendation 24

Recommendation R24 is closed as the BSS requires the undertakings to involve appropriately specialised medical physicists in interventional radiology and therapeutic procedures.

Changes since the original IRRS mission

Recommendation 25: The IRRS team was informed that a license issued by the Department for Health Regulation is a prerequisite for the issuance of a license by the Commission. The IRRS team was informed that the Department for Health Regulation, prior to issuing a license, ascertain that sufficient medical personnel and paramedical personnel are available, pursuant to article 98 (2) of the Medical and Kindred Professions Ordinance.

Status of Recommendation 25

Recommendation R25 is closed as the availability of sufficient medical personnel and paramedical personnel is required by the Medical and Kindred Professions Ordinance.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p>Observation: The requirements for dosimetry and calibration of equipment are not specifically defined in the regulations including the traceability to standards dosimetry laboratory. Neither the responsibilities of medical physicists are in line with the requirements in the GSR Part 3.</p>
(1)	<p>BASIS: GSR Part 3 Requirement 38 states that “Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure .”</p> <p>BASIS: GSR Part 3 Para 3.162 states that “Radiological medical practitioner, in cooperation with the medical radiation technologist and the medical physicist, and if appropriate with the radiopharmacist or radiochemist, shall ensure that the following are used:</p> <p>(a) Appropriate medical radiological equipment and software and also, for nuclear medicine, appropriate radiopharmaceuticals;</p> <p>(b) Appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the procedure, with account taken of relevant norms of acceptable image quality established by relevant professional bodies and relevant diagnostic reference levels established in accordance with paras 3.147 and 3.168. 3.163. For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, shall ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances.</p> <p>BASIS: GSR Part 3 Para 3.166 states that “in accordance with para. 3.153(d) and (e), the medical physicist shall ensure that:</p> <p>(a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;</p>

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p><i>(b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body;</i></p> <p><i>(c) Calibrations of radiotherapy units are subject to independent verification prior to clinical use;</i></p> <p><i>(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory.</i></p> <p>BASIS: GSR Part 3 Para 3.167 states that “Registrants and licensees shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following:</p> <p><i>(a) For diagnostic medical exposures, typical doses to patients for common radiological procedures;</i></p> <p><i>(b) For image guided interventional procedures, typical doses to patients;</i></p>
<p>R26</p>	<p>Recommendation: The regulatory body should revise the regulations on dosimetry and calibration of equipment as well as the role and responsibilities of medical physicists in accordance with international best practice.</p>

Changes since the original IRRS mission

Recommendation 26: The BSS include requirements related to the calibration of equipment used for acceptance or constancy testing (Regulation 76) and for radiological surveillance of the workplace (Regulation 48(4)). The role and responsibilities of medical physics experts are provided in Regulation 107 of the BSS. The definition of the “medical physics expert” is included in the BSS. Medical Physics as a profession falls under Health Care Professions Act, Article 28.

In the proposed amendments to Regulations 76 and 48(4) of the BSS, the traceability to standards dosimetry laboratory is addressed.

Status of Recommendation 26

Recommendation R26 is closed on the basis of progress made and confidence in effective completion in due time as progress is made with regard to the requirements for dosimetry and calibration of equipment as well as the role and responsibilities of medical physicists and the proposed amendment to BSS provides for the traceability to standards dosimetry laboratory.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p>Observation: There is a lot of regulation on protection of pregnant women and breast feeding women. There is no requirement for signs to request female patients who are to undergo a radiological procedure to notify if they might be pregnant or breast feeding (at nuclear medicine departments).</p>
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Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1)	<p>BASIS: GSR Part 3 Requirement 39 states that “Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a woman is or might be pregnant or is breast-feeding.”</p> <p>BASIS: GSR Part 3 Para 3.174 states that “registrants and licensees shall ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate, to request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that:</p> <p>(a) She is or she might be pregnant;</p> <p>(b) She is breast feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical.</p>
R27	<p>Recommendation: The regulatory body should add a requirement into regulations for registrants and licensees to ensure that signs in appropriate languages are placed in appropriate places to request female patients who are to undergo a radiological procedure to notify the possible pregnancy or in case of nuclear medicine procedure breast feeding.</p>

Changes since the original IRRS mission

Recommendation 27: The BSS require the undertakings to take measures to increase the awareness of pregnant and breast-feeding individuals, through measures such as public notices in appropriate places (Regulation 82(4)).

Status of Recommendation 27

Recommendation R27 is closed as regulations have been revised to include the requirement that signs are placed in appropriate places to request female patients who are to undergo a radiological procedure to notify the possible pregnancy or, in case of nuclear medicine procedure, breast feeding.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p>Observation: There was not any requirement in the regulation that radiological medical practitioner should inform patients or their legal representatives of the unintended or accidental medical exposure.</p>
(1)	<p>BASIS: GSR Part 3 Requirement 36 states that “Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks.”</p> <p>BASIS: GSR Part 3 Requirement 36 para. 3.181 (e) states “Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.180: Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the</p>

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>patient’s legal authorized representative of the unintended or accidental medical exposure.”</i>
R28	Recommendation: The regulatory body should add a requirement in regulations such that patients or their legal representatives are required to be informed of unintended exposures.

Changes since the original IRRS mission

Recommendation 28: The BSS requires the undertakings to ensure that arrangements are made to inform, inter alia, the patients or their representatives about clinically significant unintended or accidental exposures and the results of the analysis (Regulation 83(d)).

Status of Recommendation 28

Recommendation R28 is closed as the BSS provide for the provision of information to patients or their representatives about unintended exposures.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	Observation: It was concluded in the self assessment that there is no requirement that reviews should include an investigation and critical reviews of the current practical application of radiation protection principles of justification and optimization. Neither period for retention of records of patient dosimetry are specified. No requirement for independent audits is required and as a consequence no third party verifications are carried out.
(1)	BASIS: GSR Part 3 Requirement 42 states that <i>“Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained.”</i> BASIS: GSR Part 3 Requirement 42 para. 3.182 states that <i>“Registrants and licensees shall ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiation technologists and the medical physicists. The radiological review shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility. of the unintended or accidental medical exposure.”</i>
R29	Recommendation: The regulatory body should revise regulations such that the concept of periodical radiological reviews / clinical audits would be included. The review should be performed by the radiological medical practitioners in cooperation with the medical radiation technologists and the medical physicists.

Changes since the original IRRS mission

Recommendation 29: The definition of “clinical audit” as a systematic examination or review of medical radiological procedures is encompassed in the BSS. The undertaking is required by Regulation 70(d) to include in the radiation protection programme (RPP), clinical audits that are carried out in accordance to the national procedures established by the Commission. Moreover, Regulation 100(2e) provides for periodic reviews of the RPPs by the undertakings. Malta is encouraged to finalise the national procedures foreseen in Regulation 70(d) of the BSS.

Status of Recommendation 29

Recommendation R29 is closed as the BSS require the undertakings to perform systematic examination or review of medical radiological procedures.

11.2. OCCUPATIONAL RADIATION PROTECTION

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The limits set down in LN 44 for the lens of eye are not in compliance with the international standards.
(1)	BASIS: GSR Part 3 Requirement 19 para. 3.71 states that <i>“The government or the regulatory body shall establish and the regulatory body shall enforce compliance with the dose limits specified in Schedule III for occupational exposures and public exposures in planned exposure situations.”</i>
R30	Recommendation: The Government or the regulatory body should establish compliance with the relevant dose limits specified in Schedule III for occupational exposure of GSR Part 3.

Changes since the original IRRS mission

Recommendation 30: The BSS includes the revised dose limit for the lens of eye that complies with the relevant dose limit specified in Schedule III for occupational exposure of GSR Part 3 (Regulation 9(3a)).

Status of Recommendation 30

Recommendation R30 is closed as the dose limit for the lens of eye have been revised in the BSS and conform to GSR Part 3.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There is no clear interdiction in regulations that a person under the age of 16 could not be subject to occupational exposure.
(1)	BASIS: GSR Part 3 Requirement 28 para. 3.115 states that <i>“Employers, registrants and licensees shall ensure that no person under the age of 16 years is or could be subject to occupational exposure.”</i>
R31	Recommendation: The regulatory body should add a requirement in regulations such that people under the age of 16 could not be exposed to

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

occupational exposure.

Changes since the original IRRS mission

Recommendation 31: The BSS do not allow persons under 16 years to exceed any public dose limit, by stating that persons under 18 years of age may not be assigned to any work which would result in them as being classed as an exposed workers subject to regulation 11(2) (Regulation 8). The definition of the “exposed worker” is included in the BSS.

The proposed amendment to Regulation 8 of the BSS provides more clarity by explicitly prohibiting any person under 16 years of age to be subject to any form of occupational exposure.

Status of Recommendation 31

Recommendation R31 is closed on the basis of progress made and confidence in effective completion in due time as the proposed amendment to the BSS adds more clarity, by explicitly prohibiting any person under 16 years of age to be subject to any form of occupational exposure.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	Observation: Regulations do not adequately define how and the extent to which radiation employers should document their arrangements for radiological protection and also the recording of non-compliances.
(1)	BASIS: <i>GSR Part 3 Requirement 21 para. 3.76 d) states that “Policies, procedures and organizational arrangements for protection and safety are established for implementing the relevant requirements of these Standards, with priority given to design measures and technical measures for controlling occupational exposure.”</i>
(2)	GSR Part 3 Requirement 21 para. 3.80 states that “Employers, registrants and licensees shall record any report received from a worker that identifies circumstances that could affect compliance with the requirements of these Standards and shall take appropriate action.”
R32	Recommendation: The Government should ensure that regulations clearly set out requirements for the documentation of arrangements for radiological protection and also the recording of non-compliances.

Changes since the original IRRS mission

Recommendation 32: The BSS require undertakings to establish a radiation protection programme (RPP) which shall be documented (Regulation 100 (2d)). Arrangements for radiological protection are included in the RPP (Regulations 100, 70 for medical exposure, 114(3) for radioactive sources).

The proposed amendment to Regulation 100(4) of the BSS requires undertakings to record any report received from a worker that identifies any radiological safety concerns or and shall take appropriate action.

Status of Recommendation 32

Recommendation R32 is closed on the basis of progress made and confidence in effective completion in due time as the proposed amendment to the BSS requires undertakings to record any report received from a worker that identifies any radiological safety concerns.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Employers are not required to provide periodic and on-going training for workers.
(1)	BASIS: <i>GSR Part 3 Requirement 21 para. 3.76 h) states that “Suitable and adequate human resources and appropriate training in protection and safety are provided, as well as periodic retraining as required to ensure the necessary level of competence.”</i>
R33	Recommendation: The Government should ensure that radiation employers provide training in protection and safety, as well as periodic retraining as required to ensure the necessary level of competence.

Changes since the original IRRS mission

Recommendation 33: The BSS require undertakings and employers of the outside worker to ensure that individuals whose tasks require specific competences in radiation protection shall have received appropriate radiation protection training before commencing work and that this training is repeated (Regulation 14(1)) and to provide appropriate radiation protection training and information programmes for exposed workers (Regulation 15(4)). Undertakings are also required to inform exposed workers about the radiation health risks involved in their work and the general radiation protection procedures and precautions to be taken (Regulation 15(1)). Regulation 14(2) of the BSS explicitly states that the Commission shall approve syllabi, for radiation protection training. This training syllabi have not been set up yet by the Commission.

Status of Recommendation 33

Recommendation R33 remains open as the pending radiation protection training syllabi does not ensure the provision of training in protection and safety by the radiation employers.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Necessary cooperation between employers to ensure the occupational radiation protection of workers performing activities in radiological areas not under control of their own employer is not fully addressed in requirements and allocation of responsibilities between the parties is not required to be documented.
(1)	BASIS: <i>GSR Part 3 Requirement 23 states that “Employers and registrants and licensees shall cooperate to the extent necessary for compliance by all responsible parties with the requirements for protection and safety.”</i>
R34	Recommendation: The regulatory body should ensure that radiation protection of workers performing activities in radiological areas not under control of their own employer is assured through the necessary cooperation

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

between the parties, with appropriate allocation of responsibilities clearly documented.

Changes since the original IRRS mission

Recommendation 34: In the BSS, workers performing activities in radiological areas not under control of their own employer (either controlled or supervised) fall within the definition of “outside worker”.

Cooperation between the parties and appropriate allocation of responsibilities related to the radiation protection of workers performing activities in radiological areas not under control of their own employer, are provided for in the BSS (Regulation 54 9th Schedule section (3), Regulations 61 and 40(4)).

Status of Recommendation 34

Recommendation R34 is closed as radiation protection of workers performing activities in radiological areas not under control of their own employer and appropriate allocation of responsibilities are assured through the provisions of outside workers given in the BSS.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	Observation: In the current regulations, there are no provisions regarding the proper use of monitoring equipment by workers and the sharing of information between workers and employers is neither addressed in LN 44 nor in LN 36.
(1)	BASIS: <i>GSR Part 3 Requirement 22 para. 3.83 b) and 3.83 d) state that “Workers: shall use properly the monitoring equipment and personal protective equipment provided and shall provide to the employer, registrant or licensee such information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others.”</i>
R35	Recommendation: The regulatory body should issue requirements applicable to workers, on the proper use of monitoring equipment and that workers should make available to the employer information on their past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others.

Changes since the original IRRS mission

Recommendation 35: Under the obligations of undertakings on radiation protection in the Act, undertakings are required to ensure that workers have received adequate radiation protection training including the use of radiation protection equipment (Article 25(2)).

Regulation 48 of the BSS sets specific requirements for monitoring, in terms of measurement of external dose rates, surface contamination and air activity concentration, and workplace radiological surveillance.

The proposed amendment to BSS requires workers to make information available to undertakings and employers on their other past and present work that is relevant for ensuring effective and comprehensive protection and safety for themselves and others.

Status of Recommendation 35

Recommendation R35 is closed on the basis of progress made and confidence in effective completion in due time as requirements applicable to workers, on making information available to undertakings and employers on their other past and present work, are included in the proposed amendment to the BSS.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Requirements regarding the frequency and type of workplace monitoring are not addressed as well as these about monitoring in case of intakes of radionuclides.
(1)	BASIS: GSR Part 3 Requirement 24 para. 3.97 states that <i>“Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure.”</i>
(2)	BASIS: GSR Part 3 Requirement 25 para. 3.102 states that <i>“Employers shall ensure that workers who could be subject to exposure due to contamination are identified, including workers who use respiratory protective equipment. Employers shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the measures for protection and safety and to assess intakes of radionuclides and the committed effective doses.”</i>
R36	Recommendation: The regulatory body should address through regulations the frequency and type of workplace monitoring as well as requirements for specific monitoring in case of intake of radionuclides.

Changes since the original IRRS mission

Recommendation 36: Regulation 48 of the BSS stipulates specific requirements for monitoring, in terms of measurement of external dose rates, surface contamination and air activity concentration, and workplace radiological surveillance.

Regulation 104 of the BSS requires dosimetry services to determine internal or external doses to exposed workers subject to individual monitoring, in cooperation with the undertaking or the employer and where relevant with the occupational health service.

Status of Recommendation 36

Recommendation R36 is closed as the BSS provide for workplace monitoring as well as for specific monitoring in case of intake of radionuclides.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Regulations do not require that radiation employers define investigation levels in cases of unexpected exposure.
(1)	BASIS: GSR Part 3 Requirement 24 para. 3.94 b) states that <i>“Employers, registrants and licensees, in consultation with workers, or through their representatives where appropriate shall include in the local rules and procedures</i>

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<i>any relevant investigation level or authorized level, and the procedures to be followed in the event that any such level is exceeded.”</i>
R37	Recommendation: The regulatory body should require that radiation employers establish the relevant investigation level and the procedures to be followed in the event that any such level is exceeded.

Changes since the original IRRS mission

Recommendation 37: The undertaking is required by the BSS to promptly notify the Secretariat of the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in authorising requirements with regard to, inter alia, occupational exposure, including the results of the investigation and the corrective measures to avoid such events (Regulation 121(b)).

Status of Recommendation 37

Recommendation R37 is closed as the establishment of operational limits for occupational exposure and the investigation of events resulting in the exposure of an individual beyond them are required by the BSS.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	Observation: Maltese legislation (including regulations) does not make provision for or set criteria for the role of Radiation Protection Officer (RPO) as defined in GSR Part-3. The role of ‘Radiation Protection Supervisor’ (RPS) is established in Malta, but the criteria and scope of this role is not in accordance with that of an RPO.
(1)	BASIS: GSR Part 3 Requirement 24 para. 3.94 e) states that <i>“Employers, registrants and licensees, in consultation with workers, or through their representatives where appropriate: Shall designate, as appropriate, a radiation protection officer in accordance with criteria established by the regulatory body.”</i>
R38	Recommendation: The regulatory body should require that radiation employers as appropriate designate a Radiation Protection Officer in accordance with criteria determined by the regulatory body for their designation, roles and responsibilities.

Changes since the original IRRS mission

Recommendation 38: The BSS include the definition of the “radiation protection officer” (Regulation 4) and require the undertakings and employers to designate radiation protection officers (Regulation 110). Moreover, the undertaking is required to specify the specific roles of the radiation protection officer (Regulation 111). The IRRS team noted that the Commission has not finalized the establishment of criteria for the designation of radiation protection officers.

Status of Recommendation 38

Recommendation R38 remains open as the establishment of criteria for the designation of radiation protection officers has not been finalized.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

	<p>Observation: The contents of records both for individual and for workplace monitoring are not defined in current regulations.</p>
<p>(1)</p>	<p>BASIS: GSR Part 3 Requirement 25 para. 3.105 states that “Records of occupational exposure shall include:(a) Information on the general nature of the work in which the worker was subject to occupational exposure;</p> <p>(b) Information on dose assessments, exposures and intakes at or above the relevant recording levels specified by the regulatory body and the data upon which the dose assessments were based;</p> <p>(c) When a worker is or has been exposed while in the employ of more than one employer, information on the dates of employment with each employer and on the doses, exposures and intakes in each such employment;</p> <p>(d) Records of any assessments made of doses, exposures and intakes due to actions taken in an emergency or due to accidents or other incidents, which shall be distinguished from assessments of doses, exposures and intakes due to normal conditions of work and which shall include references to reports of any relevant investigations.”</p>
<p>R39</p>	<p>Recommendation: The regulatory body should add requirements in regulations about the contents of records both for individual and workplace monitoring.</p>

Changes since the original IRRS mission

Recommendation 39: The BSS provide for individual monitoring record keeping (Regulation 52) and their contents (9th Schedule) and for workplace monitoring record keeping and their contents (Regulation 48).

Status of Recommendation 39

Recommendation R39 is closed as the BSS provide for the contents of records both for individual and workplace monitoring.

11.3. CONTROL OF DISCHARGES, MATERIALS FOR CLEARANCE, AND CHRONIC EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	<p>Observation: The existing procedure for establishing authorized discharge limits requires the RPB to carry out the radiological impact assessment on the basis of the primary information provided by the applicant for a discharge authorization. This approach is not in compliance with relevant requirements in GSR Part 3.</p>
(1)	<p>BASIS: GSR Part 3 para. 3.132 states that “Registrants and licensees, in cooperation with suppliers, in applying for an authorization for discharges, as appropriate:</p> <p>(a) Shall determine the characteristics and activity of the material to be discharged, and the possible points and methods of discharge;</p> <p>(b) Shall determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides could give rise to exposure of members of the public;</p> <p>(c) Shall assess the doses to the representative person due to the planned discharges;</p> <p>(d) Shall consider the radiological environmental impacts in an integrated manner with features of the system of protection and safety, as required by the regulatory body;</p> <p>(e) Shall submit to the regulatory body the findings of (a)–(d) above as an input to the establishment by the regulatory body, ..., of authorized limits on discharges and conditions for their implementation.”</p>
R40	<p>Recommendation: The regulatory body should implement a procedure for approval of discharge limits in compliance with relevant requirements in GSR Part 3.</p>

Changes since the original IRRS mission

Recommendation 40: According to Articles 28 and 29 of the Act, the Commission is empowered to establish requirements for discharges to the environment, exemption levels and clearance levels. These articles provide that approval prior to discharges need to be granted by the Commission. The Articles also provide for the Commission to issue discharge license for any discharge activity that will be done by a facility. The license specifies the activity limits and conditions for the discharges by any facility.

Regulation 87 of the BSS sets detailed requirements to any facility that may discharge radioactive effluents. These requirements include estimation of doses to the individuals and assessment and approval of plans for the discharges. In addition, the regulation requires the Commission to establish authorized limits and conditions for discharges that take into account optimisation and good practices.

The Commission established the form *FRM-31 on Application for Authorisation Discharge to the Environment*. The application form specifies the information needed to be submitted by the applicant for granting the license for discharges.

The IRRS team was informed that the staff of the Commission will review the application using the procedure *OP-31 "Control of Radioactive Discharges"*. This procedure provides steps and a check list that the inspector of the Commission will follow to decide on granting a license for discharges.

INS-09 will be used by the Commission to calculate the discharge levels and to check the dose to the individuals.

The IRRS team was informed that the procedures for licensing discharge activities were recently developed and are yet to be implemented.

The IRRS team was informed that currently only two hospitals in Malta have discharge activities and both are licensed by Commission to conduct these activities.

Status of Recommendation 40:

Recommendation R40 is closed as the Commission established procedures for approval of discharge limits by facilities.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Criteria established in Maltese regulations for release of material from regulatory control through clearance are not in fully compliance with criteria of GSR Part 3.
(1)	BASIS: GSR Part 3 para. I.10 states that <i>“The general criteria for clearance are that: (a) Radiation risks arising from the cleared material are sufficiently low as not to warrant regulatory control, and there is no appreciable likelihood of occurrence for scenarios that could lead to a failure to meet the general criterion for clearance; or (b) Continued regulatory control of the material would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or reduction of health risks.”</i>
(2)	BASIS: GSR Part 3 para. I.12 states that <i>“Radioactive material within a notified practice or an authorized practice may be cleared without further consideration provided that: (a) The activity concentration of an individual radionuclide of artificial origin in solid form does not exceed the relevant level given; or (b) The activity concentrations of radionuclides of natural origin do not exceed the relevant level given ...; or (c) For radionuclides of natural origin in residues that might be recycled into construction material, or the disposal of which is liable to cause the contamination of drinking water supplies, the activity concentration in the residues does not exceed specific values derived so as to meet a dose criterion of the order of 1 mSv in a year ...”</i>
R41	Recommendation: The regulatory body should establish in Maltese regulations criteria for clearance.

Changes since the original IRRS mission

Recommendation 41: Definition of Clearance level is provided in regulation 4 of the BSS. Regulation 39 of the BSS empowers the Commission to authorize all activities that include disposal, recycling or reuse of radioactive materials by authorized practice. This regulation stipulates the conditions of releasing these activities from regulatory control if the activity concentration is below the values stated in Schedule Six and Tables A part 1, for artificial nuclides, and Part 2 for naturally occurring radionuclides. The values in these tables are in alignment with IAEA safety standards.

Status of Recommendation 41

Recommendation R41 is closed as the BSS approved in July 2018 includes criteria for clearance.

Original mission RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Requirements on reporting or making available to the regulatory body and the public the results of environmental monitoring programs are not established in Maltese regulations.
(1)	BASIS: GSR Part 3 para. 3.136 states that <i>“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.”</i>
(2)	BASIS: GSR Part 3 para. 3.137 states that <i>“Registrants and licensees shall, as appropriate: (c) Report or make available to the regulatory body the results of the monitoring programme at approved intervals, including, as applicable, the levels and composition of discharges, dose rates at the site boundary and in premises open to members of the public, results of environmental monitoring and retrospective assessments of doses to the representative person. (d) Report promptly to the regulatory body any levels exceeding the operational limits and conditions relating to public exposure, including authorized limits on discharges, in accordance with reporting criteria established by the regulatory body. (e) Report promptly to the regulatory body any significant increase in dose rate or concentrations of radionuclides in the environment that could be attributed to the authorized practice, in accordance with reporting criteria established by the regulatory body. (h) Publish or make available on request, as appropriate, results from source monitoring and environmental monitoring programmes and assessments of doses from public exposure.”</i>
R42	Recommendation: The regulatory body should require that radiation employers make the results of environmental monitoring programmes and assessments of doses from public exposure available at specified intervals and should publish all such results.

Changes since the original IRRS mission

Recommendation 42: Regulation 86(3)d of the BSS states that: “The Secretariat shall in particular require records relating to measurements of external exposure and contamination,

estimates of intakes of radionuclides, and the results of the assessment of the doses received by the representative person to be kept and be made available on request to all stakeholders”.

This regulation requires the licensees to make available to the relevant stakeholders the results of the environmental monitoring programmes and assessments of doses from public exposure .

Status of Recommendation 42

Recommendation R42 is closed as the regulations provide for the licensees to make available to the relevant stakeholders the results of the environmental monitoring programmes and assessments of doses from public exposure.

APPENDIX I LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS			
1.	BLY Ritva	Radiation and Nuclear Safety Authority (STUK) FINLAND,	Ritva.Bly@stuk.fi
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LIAISON OFFICERS			
1.	BREJZA Paul	Liaison Officer	paul.brejza@gov.mt

APPENDIX II LIST OF COUNTERPARTS

IRRS EXPERTS	COUNTERPART
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	
Nancy GREENCORN	Paul BREJZA Joseph CREMONA
GLOBAL SAFETY REGIME	
Nancy GREENCORN	Paul BREJZA Joseph CREMONA
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	
Nancy GREENCORN	Paul BREJZA Joseph CREMONA
MANAGEMENT SYSTEM	
Ritva BLY	Joseph CREMONA
AUTHORIZATION	
Jovica BOSNJAK	Paul BREJZA Joseph CREMONA
REVIEW AND ASSESSMENT	
Jovica BOSNJAK	Paul BREJZA Joseph CREMONA
INSPECTION	
Jovica BOSNJAK	Paul BREJZA Joseph CREMONA
ENFORCEMENT	
Jovica BOSNJAK	Paul BREJZA Joseph CREMONA
REGULATIONS AND GUIDES	
Jovica BOSNJAK	Paul BREJZA Joseph CREMONA

IRRS EXPERTS	COUNTERPART
EMERGENCY PREPAREDNESS AND RESPONSE	
Adriana BACIU	Paul BREJZA Joseph CREMONA
ADDITIONAL AREAS - Medical Exposure	
Stavroula VOGIATZI	Paul BREJZA Joseph CREMONA
ADDITIONAL AREAS - Occupational Exposure	
Stavroula VOGIATZI	Paul BREJZA Joseph CREMONA
ADDITIONAL AREAS - Control of radioactive discharges and materials for clearance, Environmental monitoring associated with authorized practices for public radiation protection purposes Control of chronic exposures	
Ibrahim SHADAD	Paul BREJZA Joseph CREMONA

APPENDIX III MISSION PROGRAMME

IRRS FOLLOW-UP MISSION TO MALTA

8 TO 12 MARCH 2020

IRRS FOLLOW-UP MISSION PROGRAMME		
Sunday 8 March 2020		
IRRS Initial Team Meeting		
14:00 - 17:00	Opening remarks by the IRRS Team Leader <ul style="list-style-type: none"> Introduction by IAEA Self-introduction of all attendees RRS Process and report writing (IAEA) Schedule (TL, IAEA) First impression from team members arising from the Advanced Reference Material (ARM) (all team members): Presentations Administrative arrangements (RPB Liaison Officer, IAEA): Detailed Mission Programme 	Location: Hotel Business Centre Board Room Level 7 Participants: IRRS team, Liaison Officer
17:15 - 19:00	Groups prepare for interviews; Module Leaders prepare TL presentation for the Entrance Meeting (if necessary)	Participants: the IRRS team
Monday 9 March 2020		
IRRS Entrance Meeting		
09:00 – 11:30	09:00 Arrival, registration, 09:30 Welcoming Address by Dr Deo Debattista, Parliamentary Secretary 9:45 Self-introduction of IRRS team Members and Chair, Deputy Chair and Executive Secretary of Commission 10:00 Opening remarks by IRRS Team Leader. Expectations for the Mission 10:30 presentation – Overview of the Malta regulatory approach since 2015 by Dr Lourdes Farrugia/Mr P Brejza 10:50 Photo session 10:50: Coffee 10:50 Interviews and Discussions with senior Ministerial staff	Location: Valletta, MUZA Camerone Hall Participants: High Level Government Official, Commission Management, Liaison Officer and staff, Official from relevant organizations, the IRRS team
12:00 – 13:00	Lunch	
13:00 – 17:00	Interviews and Discussions with Counterparts (parallel discussions)	Location: Commission Participants: the IRRS team
17:00 - 18:00	Daily IRRS team meeting	Location: Commission Participants: the IRRS team + the LO

IRRS FOLLOW-UP MISSION PROGRAMME		
Tuesday 10 March 2020		
Daily Discussions / Interviews		
09:00 – 12:00	Interviews and discussions with counterparts	Location: Hotel Business Centre Participants: the IRRS team
12:00 – 13:00	Lunch	
13:00 – 17:00	Interviews and discussions with counterparts	Location: Hotel Business Centre Participants: the IRRS team
17:00 – 18:00	Daily IRRS team meeting/ Discussion of the preliminary findings (conclusions)	Location: Hotel Business Centre Participants: the IRRS team + the LO
20:00 – 24:00	Report conclusions drafting	IRRS team
Wednesday 11 March 2020		
Daily Discussions / Interviews		
09:00 – 12:00	Follow-up Interviews as needed Written preliminary (conclusions) delivery to the Team Leader copied to IAEA Coordinator	Location: Hotel Business Centre Participants: the IRRS team
12:00 – 13:00	Lunch	
13:00 – 22:00	Team finalizes report and submit to Commission	Location: Hotel Business Centre IRRS team
Thursday 12 March 2020		
Daily Discussions / Interviews		
09:00 – 12:00	Discussion on Executive Summary. TL finalizes presentation TC drafts Press release	Location: Hotel Business Centre Participants: the IRRS team
12:00	Commission submit comments	Location: Hotel Business Centre Participants: the IRRS team
12:00 – 13:00	Lunch	
12:00 – 13:00	Team reviews report	Location: Hotel Business Centre Participants: the IRRS team
13:30 – 14:00	Final discussion of draft report with Commission	Location: Hotel Business Centre Participants: the IRRS team and the Commission
14:00 – 15:00	Main findings of the IRRS mission (Team Leader)	
	Remarks by Commission in response to the Mission findings.	
	IAEA Official Closing remarks delivered by IAEA Official	

**APPENDIX IV RECOMMENDATIONS (R) AND SUGGESTIONS (S) FROM THE 2015
IRRS MISSION THAT REMAIN OPEN**

Section	Module	R/S	Recommendations/Suggestions
2.1	2	R5	The Government should provide resources that enable active participation in international cooperation activities for safety such as sharing of regulatory experience and participation in IAEA safety review missions.
2.1	2	S1	The Government should consider ratification of the conventions on Early Notification and Assistance and making a political commitment to the Guidance on Import and Export of Radioactive Sources.
3.3	3	R6	The Government should ensure the regulatory body employs a sufficient number of staff in accordance with the extent, scope and complexity of the regulatory programme for radiation safety.
3.3	3	S2	The Government should consider in the short term, prioritizing measures to ensure knowledge and experience is shared between senior members and new recruits and in the long-term to maintain staff having the competences and experience necessary for effective current and future regulatory oversight of all facilities and activities in Malta, together with Malta's responsibilities for, and contribution to nuclear and radiation safety internationally.
3.8	3	R9	The regulatory body should promote the establishment of appropriate means of informing and consulting interested parties and the public about possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.
6.1.4	6	R13	The regulatory body should develop procedures for review and assessment for all facilities and activities. Review and assessment should be performed in accordance with a graded approach.
7.1.1	7	R14	The regulatory body should develop and implement a programme of inspections that confirms compliance with regulatory

Section	Module	R/S	Recommendations/Suggestions
			requirements and specifies the types of regulatory inspection, the frequency of inspections and utilizes a graded approach.
10.2	10	S6	The regulatory body should consider revising the national radiation emergency preparedness and response planning document (RPB-OP-S-Emergency Framework-2010-1) to make it consistent with the national regulations and the international standards.
11.2	11	R33	The Government should ensure that radiation employers provide training in protection and safety, as well as periodic retraining as required to ensure the necessary level of competence.
11.2	11	R38	The regulatory body should require that radiation employers as appropriate designate a Radiation Protection Officer in accordance with criteria determined by the regulatory body for their designation, roles and responsibilities.

APPENDIX V RECOMMENDATIONS (RF) SUGGESTIONS (SF) AND GOOD PRACTICES (GPF) FROM THE 2020 IRRS FOLLOWUP MISSION

Section	Module	RF/SF/GPF	Recommendations, Suggestions or Good Practices
10.3	10	RF1	The regulatory body should establish, based on a graded approach, the regulatory requirements for emergency preparedness and response for licensees, covering all relevant general, functional and infrastructural elements in line with IAEA safety standards on preparedness and response for a nuclear or radiological emergency.
11.1	11	RF2	The Government should ensure that diagnostic reference levels for medical exposures incurred in medical imaging, including image guided interventional procedures are established and based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

ARM Malta List

1.	Advance Reference Material – IRRS Follow-up Mission 2020 Malta
2.	Management of Radioactive Waste Regulations 585.03.pdf
3.	Medical and Kindred Professions Ordinance.pdf
4.	MoU between RPC and CPD signed 4 Dec 2019.pdf
5.	Nuclear Safety and Radiation Protection Act 585.pdf
6.	Nuclear Safety Regulations 585.02.pdf
7.	Basic Safety Standards Regulations 585.01.pdf
8.	DOC 38 Radiological Hazard Assessment unrestricted 7 Jan -20.pdf
9.	DOC 39 Radiological emergency framework.pdf
10.	Draft amendments to BSS Regulations as of 8 Jan 20.pdf
11.	EU regulation 2016 15 on contamination of food.pdf
12.	Financial Estimates (Draft) 2020 .pdf
13.	Health Care Professions Act.pdf
14.	Impact Assessment Framework for Legislation.pdf
15.	Management Systems – Quality system
16.	Management Systems – Checklists
17.	Management System – Documents, Forms, Instructions, Letters
18.	Management Systems – Job descriptions
19.	Management Systems – Operating procedures

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006)
- [2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).
- [3] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
- [5] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016).
- [6] INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).
- [7] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSG-2, IAEA, Vienna (2011).
- [8] INTERNATIONAL ATOMIC ENERGY AGENCY, Communication and Consultation with Interested Parties by the Regulatory Body, IAEA Safety Standards Series No. GSG-6, IAEA, Vienna (2017)
- [9] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018)
- [10] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (2018).
- [11] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Arrangements for Preparedness for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GS-G-2.1, IAEA, Vienna (2007).
- [12] ATOMIC ENERGY AGENCY, INTERNATIONAL CIVIL AVIATION ORGANIZATION, Arrangements for the Termination of a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSG-11, IAEA, Vienna (2017).
- [13] INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, Occupational Radiation Protection, IAEA Safety Standards Series No. GSG-7, IAEA, Vienna (2018).
- [14] INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing the Infrastructure for Radiation Safety, IAEA Safety Standards Series No. SSG-44, IAEA, Vienna (2018)

- [15] INTERNATIONAL ATOMIC ENERGY AGENCY, WORLD HEALTH ORGANIZATION, PAN AMERICAN HEALTH ORGANIZATION AND INTERNATIONAL LABOUR OFFICE, Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Safety Standards Series No. SSG-46, IAEA, Vienna (2018)
- [16] INTERNATIONAL ATOMIC ENERGY AGENCY, Environmental and Source Monitoring for Purposes of Radiation Protection, IAEA Safety Standards Series RS-G-1.8, IAEA, Vienna (2005)
- [17] INTERNATIONAL ATOMIC ENERGY AGENCY, Categorization of Radioactive Sources, IAEA Safety Standards Series No. RS-G-1.9, IAEA, Vienna (2005)
- [18] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Control of Radioactive Discharges to the Environment, IAEA Safety Standards Series No. GSG-9, IAEA, Vienna (2018).
- [19] INTERNATIONAL ATOMIC ENERGY AGENCY, Code of Conduct on the Safety and Security of Radioactive Sources, IAEA/CODEOC/2004, IAEA, Vienna (2004).
- [20] INTERNATIONAL ATOMIC ENERGY AGENCY, Guidance on the Import and Export of Radioactive Sources, IAEA, Vienna (2012).
- [21] INTERNATIONAL ATOMIC ENERGY AGENCY, Guidance on the Management of Disused Radioactive Sources, IAEA, Vienna (2018)
- [22] INTERNATIONAL ATOMIC ENERGY AGENCY, SARIS Guidelines, IAEA Services Series No. 27, IAEA, Vienna (2014).

APPENDIX VIII ORGANIZATION CHART



Commission for the Protection from
Ionising and Non-Ionising Radiation

DOC-10
Version 0.0

Originator: Quality Manager

Organisation structure

