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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

MALTA

Pietà, Malta

22 February to 3 March 2015

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

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IAEA Integrated Regulatory Review Service IRRS

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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
REPORT TO
MALTA

The Malta IRRS Team and their Counterparts

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

MALTA

Mission date:	*22 February 2015 to 3 March 2015*
Regulatory body:	*Radiation Protection Board*
Location:	*Occupational Health and Safety Authority Building, Pietà, Malta*
Regulated facilities and activities:	*Radiation sources in industrial and medical facilities, emergency preparedness and response, medical exposure, occupational radiation protection, public and environmental exposure control.*
Organized by:	*International Atomic Energy Agency (IAEA)*

IRRS REVIEW TEAM	
MAGNÚSSON Sigurður	Team Leader (Iceland)
BLY Ritva	Reviewer (Finland)
DELRUE Andrée	Reviewer (France)
TOMÁS ZERQUERA Juan	Reviewer (Cuba)
ZOMBORI, Peter	Reviewer (Hungary)
TIRMARCHE Margot	Observer (FRA)
EVANS Stephen	IRRS Team Coordinator (IAEA)
SWOBODA Zumi	IRRS Administrative Assistant (IAEA)

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 representatives of the Malta Radiation Protection Board (RPB) and its member organizations from 22 February to 03 March 2015 to conduct an Integrated Regulatory Review Service (IRRS) mission. During the mission there were also meetings with senior officials of government and representatives of other organizations having responsibilities for radiation protection and safety in Malta. The purpose of the peer review was to review the Maltese regulatory framework for nuclear and radiation safety and to exchange knowledge and experience on regulatory issues.

The review compared the Maltese regulatory framework for safety against IAEA safety standards as the international benchmark for safety and, given Malta's status as a member state of the European Union, its obligation to be in compliance with the equivalent EU Directives. The mission was also used to exchange information and experience between IRRS team members and Maltese counterparts in areas covered by the IRRS.

The IRRS team comprised five senior regulatory experts from five IAEA Member States, one observer, one IAEA technical officer and one IAEA administrative assistant. The IRRS team carried out the review in the following areas:

- Responsibilities and functions of the government;
- The global nuclear safety regime;
- Responsibilities and functions of the regulatory body;
- The management system of the regulatory body;
- The activities of the regulatory body including authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, public and environmental exposure control, waste management and decommissioning.

In addition, policy issues of current high priority for Malta were discussed specifically; effective independence of the regulatory body and managing regulatory issues within a small regulatory body.

The IRRS review addressed the national framework for safety, regulatory infrastructure and the regulatory control of all facilities and activities regulated by the RPB. The RPB, which comprises four government entities, has no staff, but benefits from experienced, technically competent regulatory officers employed by the Radiation Protection Section of the Occupational Health and Safety Authority (OHSA).

The mission included observations of regulatory activities and interviews and discussions with regulatory staff, representatives from various Ministries and representatives of other organizations in order to assess the effectiveness of the regulatory system and to validate the comprehensive, transparent and thoroughly considered self-assessment performed by Malta in the months preceding the mission.

Site visits were made to a hospital and a Non-Destructive Testing (NDT) Company. The IRRS team members observed regulatory working practices during inspections carried out by OHSA inspectors, including discussions with licensee personnel and management.

RPB provided the IRRS team with advance reference material and documentation including the results of the self-assessment in all areas within the scope of the mission. Throughout the mission, the IRRS team was extended full cooperation in regulatory, technical, and policy issues by all parties; in particular, the

staff of OHSA and other Malta organizations involved in the regulatory control of radiation safety, provided the fullest practicable assistance and demonstrated openness and transparency.

The IRRS team made recommendations and suggestions where improvements will enhance the effectiveness of the regulatory framework and functions in line with the IAEA Safety Standards and in support of Malta's endeavours to effectively transpose the various EU Directives for radiation protection and safety. The IRRS team recognized that the IRRS findings broadly correlated with the action plan prepared by RPB as a result of the self-assessment.

The main findings of the IRRS mission are:

- The government of Malta should develop a policy for nuclear and radiation safety to achieve the fundamental safety objective and apply the fundamental safety principles in accordance with national circumstances and with the radiation risks associated with facilities and activities in the country.
- There is a need for a dedicated nuclear and radiation safety Act to regulate those engaged in activities related to ionizing radiation and establish a legal framework for conducting such activities in a manner which protects individuals, workers and the environment.
- A regulatory body should be established in the Act, effectively independent in its decision-making and functionally separate from entities having responsibilities or interests that could unduly influence its decisions.
- The government should make provision for building and maintaining the competence of all parties having responsibilities in relation to safety of facilities and activities and ensure there will be sufficient regulatory staff having the necessary skills and experience to fully implement the regulatory programme for Malta now and into the future.
- The government should establish within the legal framework for radiation safety, processes for establishing or adopting, promoting and amending regulations and guides, including consultation, with account taken of internationally agreed standards and the feedback of relevant experience.
- A management system should be implemented by the regulatory body to ensure its regulatory responsibilities are discharged efficiently, effectively, consistently.
- A number of recommendations, of a technical nature with regard to medical exposure, patient protection, occupational radiation protection and other areas, should be expedited, primarily by the regulatory body, to ensure the radiation protection and safety of the public, patients, workers and the environment of Malta.

The Maltese action plan for improvements to the national framework and regulatory infrastructure for nuclear and radiation safety was discussed in the context of the IRRS mission recommendation and suggestions. The IRRS mission has, to a large extent, validated the Maltese self assessment which generated the current action plan. However, it is agreed that a number of refinements to the action plan will be necessary. Malta will update its action plan at the earliest opportunity in order to implement the recommendations of the IRRS mission.

The IRRS team findings are summarized in Appendices V.

An IAEA press release was issued at the end of the IRRS mission.

I. INTRODUCTION

At the request of the Government of Malta, an international team of senior safety experts met representatives of the Radiation Protection Board, the regulatory body of Malta from 22 February to 3 March 2015 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the peer review was to review the Maltese national regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Malta in May 2013. A preparatory mission was conducted 14 – 15 October 2014 at the Radiation Protection Board (RPB) Headquarters in Pietà to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the facilities regulated by RPB and selected safety aspects.

The IRRS team consisted of five senior regulatory experts from five IAEA Member States, one international observer, one IAEA technical officer and one IAEA administrative assistant. The IRRS team reviewed the following areas: Responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, patient protection, public and environmental exposure control.

The RPB conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of the RPB's self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and regulatory staff and performing direct observation of the RPB's working practices during inspections. Meetings at the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties, were also organized with the member entities of the RPB.

Throughout the mission the IRRS team received excellent support and cooperation from the RPB.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the Malta's radiation and nuclear safety regulatory framework and activities to review its effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities regulated by the RPB. The review compared existing arrangements against the IAEA safety standards.

It is expected that the IRRS mission will facilitate regulatory improvements in Malta and other Member States from the knowledge gained and experiences shared between the RPB and IRRS reviewers and through the evaluation of the effectiveness of the Maltese regulatory framework for nuclear safety and its good practices.

The key objectives of this mission were to enhance nuclear and radiation safety, emergency preparedness and response, thereby:

- providing Malta and the RPB, through completion of the IRRS questionnaire, with an opportunity for self-assessment of regulatory activities against IAEA safety standards;
- providing Malta and the RPB with a review of the regulatory programme and peer discussion on policy issues relating to nuclear and radiation safety, and emergency preparedness;
- providing Malta and the RPB with an objective evaluation of its nuclear safety and emergency preparedness and response regulatory activities with respect to IAEA safety standards;
- contributing to the harmonization of regulatory approaches among IAEA Member States;
- promoting the sharing of experience and exchange of lessons learned;
- providing reviewers from IAEA Member States and IAEA staff with opportunities to broaden their experience and knowledge of their own fields;
- providing regulatory staff with an opportunity to discuss their practices with reviewers who have experience with different practices in the same field;
- providing Malta and the RPB with recommendations and suggestions for improvement; and
- providing other States with information regarding good practices identified in the course of the review.

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 14 to 15 October 2014. The preparatory meeting was carried out by the appointed Team Leader Mr Sigurður Magnússon and the IAEA representative, Mr Ahmad Al Khatibeh, who met with Government officials and the senior management of the RPB represented by Mr. Paul Brejza, Executive Chairperson, and other members of the RPB. The preparatory mission addressed the Maltese regulatory programme, policy issues and mission logistics. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS mission:

- Radiation sources facilities;
- Patient protection;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Selected policy issues.

Mr. Paul Brejza made presentations on the national context, the current status of the Maltese regulatory framework and the self-assessment results to date.

The IAEA representative presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Malta in February 2015.

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

It was confirmed that the Liaison Officer for the preparatory meeting and the IRRS mission was Mr Paul Brejza.

The Radiation Protection Board provided IAEA (and the review team) with the advance reference material for the review, including the self-assessment results, in early December 2014. In preparation for the mission, the IAEA review team members conducted a review of the advance reference material and provided their initial review comments to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCE FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

An opening IRRS team meeting was conducted on Sunday, 22 February, 2015 in Pietà by the IRRS Team Leader and the IRRS IAEA Team Coordinator to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. The reviewers reported their first impressions of the advance reference material. The agenda for the mission was also presented and confirmed.

The Liaison Officer was present at the opening IRRS team meeting, in accordance with the IRRS Guidelines, and presented the logistical arrangements for the mission.

The IRRS entrance meeting was held on Monday, 23 February, 2015, with the participation of government officials from entities represented in the RPB, and members of the RPB. Opening remarks were made by Hon Dr Helena Dalli, Minister for Social Dialogue, Consumer Affairs and Civil Liberties (Responsible for OHSA/RPB), Mr Sigurður Magnússon, IRRS Team Leader, Mr Stephen Evans, IRRS Team Coordinator and Mr Paul Brejza, Malta IRRS Liaison Officer, who gave an overview of Malta's context and RPB activities and the action plan prepared as a result of the self-assessment.

During the mission, a review was conducted for all the agreed areas with the objective of providing the Government of Malta and the RPB with recommendations and suggestions for improvement as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to facilities and direct observations regarding the national facilities and activities.

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

The IRRS exit meeting was held on Tuesday 3 March, 2015. Opening remarks were made by Mr Joseph Camilleri, Permanent Secretary to the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties and were followed by the presentation of mission results by the IRRS Team Leader Mr Sigurður Magnússon. Closing remarks at the exit meeting were presented by Mr Stephen Evans on behalf of the IAEA Deputy Director General, Department of Nuclear Safety and Security.

An IAEA press release was issued at the end of the mission.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The government of Malta demonstrates its commitment to safety through its membership of the IAEA and implementation of the IAEA Safety Standards, by being party to most applicable international conventions including the Convention for Nuclear Safety and the Joint Convention and, as an EU Member State, through compliance with its obligations under the Euratom Treaty.

As a member state of the European Union it is to be expected that Malta's national policy and strategy for safety will be framed by the Euratom Treaty and relevant EU Directives. However, Malta has not yet developed a policy for nuclear and radiation safety and thus, has no defined strategy to achieve the fundamental safety objective and apply the fundamental safety principles in accordance with national circumstances and with the radiation risks associated with facilities and activities in the country.

Malta is committed to radiation safety and has made clear it is working towards the necessary legislative and structural reforms to bring the Maltese national framework for radiation safety into line with international requirements. To this end, the Honourable Dr Helena Dalli Minister for Social Dialogue, Consumer Affairs and Civil Liberties stated at the entrance meeting of this IRRS mission that; "*Malta is constantly looking to improve the health and safety of all its citizens and recognizes the need to reduce unnecessary radiation doses to the Maltese population. In view that the greatest use of radiation is in the medical field, Malta is particular aware of the need to ensure that medical doses of radiation are justified and optimized for the benefit of the patients."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GSR Part 1, Requirement 1 states that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."*
(2)	**BASIS:GSR Part 1, Requirement 1; para. 2.3 states that** "*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*."
R1	**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.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Maltese legal texts having relevance to nuclear safety and radiation protection are:

- Legal Notice (LN) 245 of 30 August 2002 on Radiological Emergency Regulations, Information to the Public etc.
- Legal Notice (LN) 44 of 28 January 2003 on Nuclear Safety and Radiation Protection Regulations. LN 44 makes provision for the protection of workers, the public and environment against the adverse effects of ionising radiation. It should be noted that this is also the legal document that establishes the Radiation Protection Board (RPB).
- Legal Notice (LN) 173 of 20 April 2004 amending LN 44 on Nuclear Safety and Radiation Protection Regulations.
- Legal Notice (LN) 242 of 30 April 2004 on Importation Control Regulations.
- Legal Notice (LN) 416 of 20 September 2004 on Dual–use Items (Export Control) Regulations.
- Legal Notice (LN) 13 of 13 January 2006 on Control and Security of High-Activity Radioactive and Orphan Sources.
- Legal Notice (LN) 48 of 13 February 2009 on Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations.
- Legal Notice (LN) 353 of 19 October 2012 on Medical Exposure (Ionizing Radiation) Regulations.
- Legal Notice (LN) 186 of 16 July 2013 on Management of Radioactive Waste Regulations.
- Legal Notice (LN) 187 of 16 July 2013 amending LN 44 on Nuclear Safety and Radiation Protection (Amendment) Regulations.
- Legal Notice (LN) 36 of 2003 on General provisions for Health and Safety at work places.

LN 44 of 2003 in article 2 stipulates:
The scope of the regulations above is to:

(i) allow beneficial and justified uses of ionizing radiation;

(ii) provide for adequate protection of people in current and future generations against the harmful effects of ionizing radiation and for the safety of radiation sources;

(iii) provide for the physical protection of nuclear material

(iv) provide a mechanism whereby these objectives are achieved through the establishment of a Radiation Protection Board to act as the competent national authority, by co-ordinating the activities of the regulatory authorities in the field of nuclear safety and radiation protection.

In addition, the following Acts include provisions relating to the functions and responsibilities of the various Authorities that comprise the Radiation Protection Board (RPB):

- Civil Protection Act (CAP 411) ACT XV of 1999
- Environment and Development Planning Act (CAP 504) ACT X of 2010, as amended by Legal Notices 57 of 2011, 229 of 2012, and 52 and 121 of 2013.
- National Interest (Enabling Powers) Act (CAP 365) ACT XX of 1993, as amended by Act V of 2000; and Legal Notice 425 of 2007.
- Occupational Health and Safety Authority Act (CAP 424) ACT XXVII of 2000, as amended by Act XXXII of 2007; Legal Notice 426 of 2007; and Act X of 2013.

- Public Health Act (CAP 465) ACT XIII of 2003, as amended by Act III of 2004 and Legal Notice 427 of 2007.

The Maltese governmental, legal and regulatory framework for safety is set out in regulations (LN 44 of 2003 under the National Interest (Enabling Powers) Act) and not in an Act dedicated to nuclear and radiation safety.

The member organizations of the RPB as defined in LN 44 of 2003 are:

(1) The Occupational Health and Safety Authority set up in terms of the Occupational Health and Safety Authority Act, a member of the RPB with regards to the protection of workers from exposure to radiation sources at work;

(2) The Environment Protection Directorate or other competent authority as established by virtue of article 6 of the Environment Protection Act, a member of the RPB with regards to protection of the environment from radiation sources;

(3) The Superintendent of Public Health in terms of the Department of Health (Constitution) Ordinance, a member of the RPB with regards to protection of the general population from radiation sources;

(4) The Civil Protection Department established by the Civil Protection Act, a member of the RPB with regards to in relation to preparation for and response to civil emergencies.

Several organizations are assigned regulatory responsibilities through LN 44 of 2003. They are the constituent members of the RPB which is also established by the same Legal Notice and the RPB is functionally an advisory body to its member organizations. The constituent members can make regulatory decisions independently from the RPB with regard to the sectors for which they are otherwise the competent authorities (as has happened in the case of medical exposure regulations first issued in 2004 (LN 472 of 2004) and later replaced by the current medical exposure regulations (LN 353 of 2012)). LN 44, part 3, art. 9 assigns to the RPB a number of functions such as authorization and inspection, that are more properly addressed in an Act.

The national framework for safety is also incomplete as there is no Act which adequately deals with radiation and nuclear issues.

The current legal, governmental and regulatory framework for radiation safety appears little changed since the 2005 IAEA RaSSIA mission, which reported similar findings and made a number of recommendations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GSR Part 1, Requirement 2, *Establishment of a framework for safety,* para. 2.4 (9) states that** "*The government shall establish and maintain an appropriate governmental,legal and regulatory framework for safety within which responsibilities are clearly allocated."*
R2	**Recommendation: Government should establish a dedicated nuclear and radiation safety Act. The Act should regulate the conduct of legal or natural persons engaged in activities**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Radiation Protection Board (RPB) is stated by Maltese counterparts to be the regulatory body established by LN 44 of 2003. Thus, it is assigned legal authority through a regulation rather than an Act.

In view that LN 44 of 2003 is written under the National Interest Act, the RPB is accountable to the Prime Minister's Office, but in practice, the IRRS team understands that regulatory issues are dealt with by the Ministry responsible for the Occupational Health and Safety Authority or one of the other three member organizations of the RPB.

Part 3 of LN 44 of 2003 establishes the Radiation Protection Board, and stipulates statutory obligations (functions and responsibilities), composition and funding.

The manner in which the RPB has been established means it does not function as a regulatory body in accordance with internationally recognized definitions (notably GSR Part-1). The RPB is not an executive body because its decisions are enacted by its individual member organizations, each of which can also make regulatory decisions independently from the RPB. It functions as an advisory body to its constituent members (the Occupational Health and Safety Authority, the Environment Protection Directorate, the Civil Protection Department and the Superintendent of Public Health).

An example of this in practice is the manner in which the medical exposure regulations were promulgated. The initial regulation was drafted and published by the Ministry of Health but the IRRS team understands it had shortcomings because the consultation was not comprehensive, leading to the need for these regulations to be revised, the Superintendent of Public Health (SPH) sought the advice of the RPB when redrafting the regulations.

LN 44 says in Part 3, 12. (1) "*The Occupational Health and Safety Authority shall ensure sufficient funding to enable the Board to fulfill its obligations*". Hence the RPB does not have its own budget.

From Malta's Advance Reference Material (ARM) and confirmed by interviews with Maltese counterparts, it is evident that RPB does not have the necessary legal authority, competences or resources to fulfil its statutory obligations. RPB has no employees. The regulatory functions of the RPB are undertaken by two full-time staff of the Radiation Protection Section (RPS) of the Occupational Health and Safety Authority (OHSA), one of the constituent member organizations of the RPB. Tasks delegated to other RPB entities are performed by persons not solely engaged in activities associated with nuclear and radiation safety.

The RPB cannot act independently of its member entities and is not effectively independent in its safety related decision-making. For example, in matters of regulation and enforcement of medical exposures the Superintendent of Public Health (SPH) as a member entity of RPB, may overrule its decisions. Functional separation from entities having responsibilities or interests that could unduly influence its decision making has not been ensured. This appears to be the case most particularly where enforcement actions against governmental medical establishments are performed by the SPH.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GSR Part 1, Requirement 3: Establishment of a regulatory body, para. 2.6 states that** *"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."*
(2)	**BASIS: GSR Part 1, Requirement 4: Independence of the regulatory body, para. 2.6 states that** *"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."*
R3	**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.**

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

LN 44 of 2003 assigns prime responsibility for safety in the broadest sense, of the worker and the public to the 'radiation employer' but there is no specific reference to the environment. The term 'radiation employer' is applied in Maltese legislation to the person or organization responsible for the radiation facility or activity. According to Art. 6(1) of the OSHA Act, responsibility for safety cannot be delegated. LN 44 does not explicitly state that prime responsibility for safety covers all stages in the lifetime of a facility or an activity.

The RPB, through LN 44 of 2003, has the authority to require the radiation employer to comply with stipulated regulatory requirements regarding workers and the public, as well as to demonstrate such compliance and can in the case of non-compliance initiate legal proceedings through the appropriate member organization.

The government has stipulated, through Art. 6 of the Occupational Health and Safety Act, that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety of the public and workers. However protection of the environment is not explicitly mentioned in terms of prime responsibility for safety.

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

The key entities having responsibility for radiation safety are defined in LN 44 of 2003 as the:

- Occupational Health and Safety Authority for the protection of workers from exposure to radiation sources at work;

- Environment Protection Directorate (within Malta Environment and Planning Authority) for protection of the environment from radiation sources;
- Superintendent of Public Health (Healthcare Regulation within the Ministry of Health) for protection of the general population from radiation sources;
- Civil Protection Department established in relation to the preparation for and response to civil emergencies.

These entities are the constituent members of the RPB and have a joint duty according to LN 44 of 2003 to ensure that the overall functions of the RPB are carried out in close collaboration.

Regulation 10(8) of this Legal Notice states:

(8) It shall be the joint duty of the member agencies constituting the Board to ensure that the overall functions of the Board are carried out in close collaboration and as efficiently as possible, and the Occupational Health and Safety Authority shall take the lead in co-ordinating the administrative actions of the Board.

The High-Level Framework Operating Procedure, an internal procedure of RPB, approved by the members of the RPB in December 2013, facilitates the coordination and liaison of the authorities involved in the regulatory process.

The RPB has a Memorandum of Agreement (MoU) with the Customs Department and a detailed standard operating procedure for response to radiation portal alarms at ports. A MoU with the Transport Authority has also been drafted which envisages separate operating procedures for land, sea and air transport.

1.6. SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

The IRRS team was informed by Maltese counterparts that they consider orphan sources to be the main unregulated radiation risk in Malta. Provision for the system of source regulation is made in LN 44 of 2003 and issues connected with orphan sources are dealt with specifically through LN 13 of 2006.

Previously conducted radon surveys confirm that levels of radon are low and well below reference levels in international standards (see references).

Maltese counterparts consider that contamination from past activities or events is not significant given the historical uses of radiation sources in Malta.

The RPB gives advice and assistance to the Civil Protection Department (CPD) in accordance with RPB's radiological emergency operating procedure; for example, in the case of suspected orphan sources and contaminated finished goods imported or in transit at ports.

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

Provisions for decommissioning are given in LN 44 of 2003, which requires Radiation Employers to inform the RPB of any such activity.

Appropriate financial provisions are made for safe management of disused high activity sealed radioactive sources through LN 13 of 2006 which requires that Radiation Employers have adequate provision, by way of a financial security or any other equivalent means appropriate to the source in question, for the safe management of sources when they become disused sources, including the case where the holder becomes insolvent or goes out of business.

The RPB has not invoked this regulation to date, since most sources imported are for medical use, with a short half-life. The Management of Radioactive Waste Regulations LN 186 of 2013 (SL 365.45) and RPB-OP-S-Waste-2014-1 require that sealed sources imported for industrial purposes are covered by agreements between buyer and seller to return the source to the supplier after use.

LN 186 of 2013 addressing regulations for management of radioactive waste states that licence holders are responsible for their radioactive waste and responsible for all financing of the management of their waste.

LN 186 of 2013 makes provision for safe management of radioactive waste and this is regulated through the '*National Framework for Radioactive Waste Management'* established by RPB and incorporating the policy and strategy for waste as required by LN 186/2013. Provisions for final disposal of radioactive waste have not been made but are considered in the National Framework.

There is no spent nuclear fuel in Malta and therefore to date, no need for provisions for its safe management.

1.8. COMPETENCE FOR SAFETY

The IRRS team understands that the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced regulatory staff is not formally provided for in legislation or stipulated in the procedures of the RPB.

LN 44 of 2003 requires that the radiation employer provides workers with appropriate information, instruction and training, but there are no other requirements regarding the competences of others having responsibilities for the safety of facilities and activities, including organizations providing services or expert advice on matters relating to safety.

There are no structured arrangements for technical training and the maintenance of technical and professional competences, nor for research and development work.

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** *"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."*
R4	**Recommendation: 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.**

1.9. PROVISION OF TECHNICAL SERVICES

Regulation 13 of LN 44 states that RPB is *"entitled to engage persons to serve as individual expert advisers or to set up advisory committees…"* Nevertheless, due to the small size and population of Malta, there are no local Technical Support Organizations so that overseas TSOs are used by each member entity of RPB.

The cost of such services is provided from the general budgets of the member entities of RPB.

1.10. SUMMARY

The government of Malta demonstrates its commitment to safety through its membership of the IAEA and implementation of the IAEA Safety Standards, by being party to most applicable international conventions including the Convention for Nuclear Safety and the Joint Convention and as an EU Member State, through compliance with its obligations under the Euratom Treaty. Malta is committed to radiation safety and has made clear it is working towards the necessary legislative and structural reforms to bring the Maltese national framework for radiation safety into line with international requirements.

The Maltese governmental, legal and regulatory framework for safety is set out in regulations (LN 44 of 2003 under the National Interest (Enabling Powers) Act) and not in an Act dedicated to nuclear and radiation safety. LN 44, part 3, art. 9 assigns to the RPB a number of functions such as authorization and inspection, that are more properly addressed in an Act. The national framework for safety is also incomplete as there is no Act which adequately deals with radiation and nuclear issues.

The current legal, governmental and regulatory framework for radiation safety appears little changed since the 2005 IAEA RaSSIA mission which reported similar findings and made a number of recommendations.

The manner in which the RPB has been established means it does not function as a regulatory body in accordance with internationally recognized definitions (notably GSR Part-1).

The entities that are members of RPB can make regulatory decisions independently from the RPB. The RPB does not have a budget nor the necessary legal authority, competences or resources to fulfil its statutory obligations. The RPB cannot act independently of its member entities and is not effectively independent in its safety related decision making. The member entities have a joint duty according to LN 44 of 2003 to ensure that the overall functions of the RPB are carried out in close collaboration.

LN 44 of 2003 assigns prime responsibility for safety in the broadest sense, of the worker and the public to the 'radiation employer' but there is no specific reference to the environment. It also gives provisions for decommissioning and LN 186 of 2013 makes provision for safe management of radioactive waste.

General provisions have not been made for building and maintaining the competence of parties having responsibilities for safety.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Malta participates in the following international arrangements for enhancement of safety globally:

- Comprehensive Nuclear-Test Ban Treaty ratified on 23rd July 2001, (LN 156 of 2001) .
- Convention on the Physical Protection of Nuclear Material, came into force on 16 October 2003, (LN 44 of 2003).
- Amendment to the Convention on the Physical Protection of Nuclear Material, acceptance instrument deposited 16th September 2013, (LN 187 of 2007).
- Agreement between the European Atomic Energy Community, its non nuclear weapon Member States and the IAEA came into force on 1st July 2007, (LN 182 of 2007).
- Convention on Nuclear Safety came into force 13 February 2008, (LN 440 of 2007).
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management came into force on 15 December 2013 (LN 186 of 2013).
- Malta joined the IAEA Illicit Trafficking Data Base on 13th May 2009.

Malta has not ratified the Conventions on Early Notification and Assistance.

In March 2004 Malta declared its political commitment to the Guidance of the Code of Conduct on the Safety and Security of Radioactive Sources but has not yet formally committed to the associated Guidance on the Import and Export of Radioactive Sources.

Maltese regulatory staff are familiar with IAEA safety standards, which are actively used in the establishment of Maltese safety regulations, increasingly in the context of the applicable EU Directives. Due to the limited resources Malta has been unable to participate in the work of the IAEA Safety Standards Committees (namely, the Nuclear Safety Standards Committee (NUSSC), the Radiation Safety Standards Committee (RASSC), the Transport Safety Standards Committee (TRANSSC) and the Waste Safety Standards Committee (WASSC)) or to participate in IAEA safety review missions where IAEA safety standards are used as basis fo the review.

Malta has not established bilateral or multinational regulatory cooperation programmes and has limited opportunity to actively participate in international cooperation to enhance safety due to available resources.

Malta has a technical cooperation agreement with the IAEA, through which this IRRS mission was organized and implemented.

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 particpate 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** *"The government shall fulfil its*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally."
(2)	**BASIS: GSR Part 1 Requirement 15: Sharing of operating experience and regulatory experience para. 3.2 (9) states that** *"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."*
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: 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.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Due to limited resources, the RPB has not had the opportunity to identify and share lessons-learned from operating and regulatory experience. The RPB receives information from other states regarding operating and regulatory experience through membership of the EU and the IAEA but has no arrangement for dissemination or feedback on measures taken in response to information received. See recommendation R5 above.

2.3. SUMMARY

Malta has ratified most of the international instruments related to nuclear and radiation safety except for the Conventions on Early Notification and Assistance.

Malta has declared its political commitment to the Guidance of the Code of Conduct on the Safety and Security of Radioactive Sources but has not yet formally committed to the associated Guidance on the Import and Export of Radioactive Sources.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The Radiation Protection Board (RPB) was established by LN 44 of 2003. It is an inter-ministerial body with representatives from Occupational Health and Safety Authority (OHSA), the Environment Protection Directorate (EPD), the Civil Protection Department (CPD) and the Superintendent of Public Health (SPH). RPB has no staff; RPB regulatory functions and activities are undertaken by two officers of the Radiation Protection Section (RPS) of OHSA.

RPB does not have its own budget and relies on funds allocated by the RPB member entities through OHSA coordination (Regulations 10.8 & 12.1 of LN 44).

As pointed out by RPB in the IRRS Advance Reference Material (ARM), in practice each entity funds its own radiation protection activities and in some cases carries out regulatory activities without reference to, or coordination with RPB.

This issue is addressed in paragraph 1.3 and the relevant recommendation is included there as R3.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

RPB has limited authority to discharge its responsibilities and functions due to the fact that RPB regulations come under various parent Acts. As a consequence, each of the four agencies that comprise RPB can act independently on regulatory matters and their respective responsibilities are not clearly defined, leading to potential gaps and overlaps in regulatory oversight.

The RPB cannot communicate with government directly on matters affecting radiation safety as required by GSR Part 1, 4.66 (b) and as a consequence of its organizational structure it maybe influenced in its regulatory decisions by organizations having responsibility for the promotion of radiation facilities or activities. This is not in accordance with GSR Part 1, 4.9.

Thus, the independence of the RPB is potentially compromised because its various entities are capable of making regulatory decisions independently and some are involved in the promotion of radiation technologies (e.g. healthcare activities).

This issue is addressed in Module 1 and the relevant recommendation is included there as R3.

This situation has not changed significantly since the RaSSIA mission of 2005.

New regulations are drafted by RPB (or individual members organizations of RPB) and then submitted to Government for approval in accordance with a Maltese Government process established for all regulations generally (see Module 9).

In its ARM, RPB proposes to take advantage of the opportunity arising from transposition of the 2013/59/EURATOM Directive to create a specific Radiation Act.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

No regulatory staff are assigned to RPB. Regulatory activities are managed by two officers of the Radiation Protection Section of OHSA (one of the member organizations of RPB). Some regulatory

functions and activities can be performed by individual RPB member organizations acting without reference to RPB. This situation has not changed since the 2005 RaSSIA mission.

The regulatory programme is not complete because there are insufficient resources, in particular adequate numbers of staff with the necessary skills, competencies and experience. Furthermore, as a consequence the RPB cannot fulfil its statutory regulatory functions, such as issuing authorizations for each facility or activity. (This is further described in Modules 5 and 7).

There are no planned programmes of training for existing staff and staffing plans, including requirements for staff qualifications for recruitment, so that the avalaibility of necessary skills regarding high risk activities cannot be assured (e.g. for radiotherapy, where new technologies are currently being installed).

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 "***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."*
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 facitlites and activities in Malta, together with Malta's responsibilities for, and contribution to nuclear and radiation safety internationally.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

Regulation 13 of LN 44 states that RPB is *"entitled to engage persons to serve as individual expert advisers or to set up advisory committees…"* Nevertheless, due to the size of Malta, there are no local Technical Support Organizations, however each member entity of RPB has access to TSOs overseas if necessary. To date, the RPB has not actively entered into arrangements with advisory bodies and support organizations in other states but does on occasion seek the advice of the IAEA.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

RPB communicates with radiation employers via e-mail. Information is available on the Radiation Protection pages of the OHSA website. RPB shares comprehensive information with authorized parties through its website.

In case of issuing a new regulation, information is shared by RPB with authorized parties through a general governmental process which may not be sufficiently in accordance with IAEA requirements (Further details in Module 9). As recommendation 2.10 of RaSSIA 2005 stated that; "*RPB shall develop*

formal procedures for collecting and disseminating information to radiation users…". The IRRS Team considers that this recommendation is still not implemented.

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** *"The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues,conducting a professional and constructive liaison."*
R7	**Recommendation: The regulatory body should establish formal and informal mechanisms of communication with authorized parties on all safety related issues.**

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

In the absence of a formal management system (see Module 4) it is apparent that stability and consistency of regulatory control cannot be assured.

Moreover, during discussions on authorization and inspection processes, it became clear that a formal process and specified procedures to prevent subjectivity and ensure stability and consistency in the functioning of the regulatory body is not in place (Further details in Modules 5 and 7).

Formal procedures have not been established for many of the regulatory functions, including the development, issue and review of new regulatory requirements.

This is further addressed in Module 4 (Management System). See Recommendation R10 (Module 4)

3.7. SAFETY RELATED RECORDS

Pursuant to Regulations 9 3 g) & j) of LN 44 it shall be the function of RPB to; *"compile a national register of practices, work activities and sources"* and to *"gather the required data to enable an assessment of total exposure from all practices and work activities in Malta and including the distribution of the individual occupational and public exposure…and to enable the setting up of a National Register for Occupational Exposure to Ionising Radiation."*

RPB keeps:

- files on every radiation employer including authorization and inspection documents and related correspondence; these files also contain information about accidents or significant events;
- the national inventory of sources using RAIS and MS Excel (including an inventory of radiation generators);
- a centralized inventory of disused sealed sources.

RPB checks radiation employers' records through inspection.

RPB does not keep records of individual and workplace monitoring of occupational exposure. There is no centralized database for Maltese occupational doses.

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 "***The regulatory body shall make provision for establishing and maintaining the following main registers and inventories :… Records of occupational doses."*
(2)	**Basis GSR Part 3 requirement 25 para. 3.107 states that** *"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."*
R8	**Recommendation: The regulatory body should extend its national registers to include records of the occupational exposure history of each worker.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The RPB has not yet established a management system (See Module 4) and does not have a process or procedures for informing the public, public representatives, the media and others on regulatory issues.

There are also no documented procedures for the involvement of stakeholders (e.g. professional bodies, trade unions) in decisions regarding radiation protection and safety.

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** *"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."*
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.**

3.9. SUMMARY

The Radiation Protection Board (RPB) established by LN 44 of 2003 is an inter-ministerial body with representatives from Occupational Health and Safety Authority (OHSA), the Environment Protection Directorate (EPD), the Civil Protection Department (CPD) and the Superintendent of Public Health (SPH). RPB has no staff; RPB regulatory functions and activities are undertaken by two officers of the Radiation Protection Section (RPS) of OHSA. To ensure that nuclear and radiation safety functions are effectively fulfilled and the independence of the RPB guaranteed there should be a sufficient number of

regulatory staff including senior experts as well as new highly qualified recruits, that could benefit from exchange of experience with the initial staff members. Systematic training for current and new members should be established as well as a formal mechanism for communication with authorized parties, professionals, employers of radiation workers, trade unions and general public.

Malta would benefit from more international exchanges with other authorities and international organizations in order to strengthen knowledge and experience and to contribute to Malta's responsibilities for nuclear and radiation safety on an international level.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

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.

Each of the four entities that comprise the RPB have their own approach to management and there is no evidence of shared or integrated management processes designed to ensure, in accordance with GS-R-3 that safety is paramount within the RPB management system, overriding all other demands and interests, including those of the member entities.

Elements of a management system are in place, including written procedures for some activities of the RPB, but these procedures are not process orientated. There is no overall process of leadership and control sufficient to provide confidence that the statutory obligations placed on the regulatory body are being fulfilled. Internal safety culture issues should be addressed.

A graded approach to management of RPB functions and activities has not been developed to ensure the deployment of appropriate resources, on the basis of significance and complexity of each activity, the hazards and the magnitude of the potential impact (risks) associated with the safety, the health, environmental, security, quality and economic elements of each activity or the possible consequences if an activity is carried out incorrectly.

RPB documentation of its policies, structure, functional responsibilities, authorities and activities, interactions, work and performance is not organized and, other than procedures documents for some regulatory activities, there are limited documented processes that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GS-R-3 para. 2.1 states that** *"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:* *—Bringing together in a coherent manner all the requirements for managing the organization;* *—Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;* *—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."*
R10	**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.**

4.6. SUMMARY

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. There is no evidence of shared or integrated management processes across the organizations that comprise the RPB, designed to ensure that safety is paramount, overriding all other demands and interests, including those of the member entities.

Elements of a management system are in place, including written procedures for some activities of the RPB, but these procedures are not process orientated. There is no overall process of leadership and control sufficient to provide confidence that the statutory obligations placed on the regulatory body are being fulfilled. Internal safety culture issues should be addressed.

A graded approach to management of RPB functions and activities has not been developed to ensure the deployment of appropriate resources, on the basis of significance and complexity of each activity, the hazards and the magnitude of the potential impact (risks) associated with the safety, the health, environmental, security, quality and economic elements of each activity or the possible consequences if an activity is carried out incorrectly.

RPB documentation of its policies, structure, functional responsibilities, authorities and activities, interactions, work and performance is not organized and, other than procedures documents for some regulatory activities, there are limited documented processes that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.

The activities of the RPB should be process-oriented, with safety culture explicitly addressed and communicated. Once established, the effectiveness of a management system should be monitored and measured by self assessments and audits.

5. AUTHORIZATION

5.1. GENERIC ISSUES

LN 44 empowers RPB to issue authorizations and to grant exemptions concerning the possession and use of radiation sources, subject to any condition that may be required in the opinion of the RPB and to revoke at any time any such authorizations if the RPB considers the facility or activity is not in compliance with the required standards or levels of safety. An authorization can only be granted on the condition the radiation employer submits all relevant information which the RPB considers necessary.

LN 44 17(1) lists the facilities and activities that require authorization. LN 44 also prescribes that an authorization shall be issued with or without limit of time and may be revoked in writing at any time.

There is no documented appeal procedure, however the self-assessment included with the IRRS ARM describes a process whereby the radiation employer may ask RPB to reconsider its decision. However, there appears to be no formal written procedure or guidance regarding this option.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GSR Part 1 Reguirement 24 states that** *"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."* **BASIS: GSR Part 1 Requirement 24 para. 4.32 states that** *"The regulatory body shall establish a process that allows the authorized party to appeal against a regulatory decision relating to an authorization for a facility or an activity or a condition attached to an authorization."*
R11	**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.**

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

In accordance with LN 44 the radiation employer has a duty to obtain prior authorization from RPB for the disposal, recycling or reuse of radioactive substances or materials containing radioactive substances arising from any practice or work activity subject to the requirement of notification or authorization.

Waste management facilities have not been established in Malta and according to information provided, there are not significant quantities of radioactive waste in the country. This is because unsealed radioactive sources, capable of causing radioactive contamination, are used only in the nuclear medicine departments of three hospitals and in all cases they contain only short half-life radionuclides. However, in Malta there are several disused sealed radioactive sources stored in various sites and premises. The RPB keeps an inventory of these sources, and randomly checks on the presence of the sources where they are stored. The companies and/or organizations responsible for the safe management of these sources have not been granted an authorization for storing the sources, a situation which is not in compliance with Maltese regulatory requirements for facilities and activities involving the use and possession of radioactive sources and materials.

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES

Malta is an EU Member State and is in the process of transposing into its own legal system the relevant EU regulations in the field of radiation safety and implementation of radiation activities which address, among others, exemption levels, authorization requirements for activities with sources of ionizing radiation and conditions for their use.

A formal written notification must be submitted to the RPB at least thirty days beforehand. The radiation employer shall submit to the RPB all relevant information about the practice or work activity which may be considered necessary by the RPB and which shall include documents such as:

- plans for installations involving an exposure risk, expressed in a safety assessment and of the proposed siting, design and operation of such installations within the territory conserned, from the point of view of radiation protection;
- the protection measures to be adopted.

Prior to authorizations of facilities and activities relating to medical exposure, an inspection is carried out and information according to the standard check list must be provided (see Module 7).

An authorization is granted for a facility, but there is no list of equipment attached. In the case of new medical radiation equipment, a notification is required and in due course, the results of acceptance testing. A permission to use the equipment in the facility is given by e-mail.

The IRRS team took notice of the graded approach applied to authorizations in medical uses of radiation. Authorizations for radiation therapy and use of unsealed sources are valid for one year, medical imaging for two years, three years, or four years according to the equipment installed and the radiological activities undertaken. However, dental facilities are not yet authorized even though notifications have been received.

Not all industrial uses of radiation are yet authorized. The IRRS team emphasized in discussions that a higher priority should be given to authorization of high category sources.

The authorizations for medical exposure have been issued to facilities and activities, but the sources of radiation have been subject only to a process of notification. According to the graded approach, medical facilities should be authorized and controlled through inspection and enforcement of regulations. Unless a list of the sources is included in the licence, this international requirement is not met. According to European Council Directive 2013/59/2013 Article 27 authorization is required for activities such as "*operation of radiation generators or accelerators or radioactive sources for medical exposures..*". For unsealed sources there should be a stated maximum activity to limit the use of radiation to that verified through safety assessment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GSR Part 1 Requirement 24 states that** *"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."* **BASIS: GSR Part 1 Requirement 24 para. 4.29 states that** *"Different types of*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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." **BASIS: GSR Part 3 Requirement 6 states that** "*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."* **BASIS: GSR Part 3 Requirement 7 states that** "*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."*
R12	**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.**
S3	**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.**

5.4. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

So far no authorizations are issued for decommissioning activities. The regulatory provisions are that Radiation Employers must inform the RPB of any decommissioning activities by virtue of regulation 17(1,ii) and 19(1a) of LN 44.

5.5. SUMMARY

The RPB has sufficient authority to issue authorizations and to grant exemptions concerning the possession and use of radiation sources. There is no formal appeal procedure, however, it is understood the radiation employer may request that the RPB reconsiders its decision.

So far medical facilities and activities are authorized (excluding dental practices due to insufficient resources) as well as few industrial ones. Authorizations for medical facilities and activities are valid for different time periods according to a graded approach. Based on the risk categorization of sources in IAEA RS-G-1.9 the first priority should be given in future to authorizations of higher risk industrial facilities and activities.

Authorization certificates do not have adequate information on authorized medical facilities and activities. There should be a list of sources and in the case of unsealed sources, a maximum stated activity.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

No specific procedures for review and assessment are in place. However, for medical facilities and activities a standard inspection checklist is used for review and assessment, as applicable. For industrial facilities and activities a standard inspection checklist for occupational exposure is used.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

There is currently no formal process or procedures for review and assessment. (see Module 4).

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

On pre-authorizing inspections of medical facilities and activities, review and assessment is an integrated part of an inspection. However, due to limited inspector resources, the RPB has neither authorized dental facilities and activities nor non-medical facilities and activities at present time. Where necessary expertise is available from Public Health to assist the RPB with the technical aspects of a review and assessment (see 6.1.4).

Capacity building to understand better regulatory requirements (e.g. diagnostic reference levels) should be taken into account in the management system.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The checklists for review and assessment identify the regulations in which they have their basis.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

Review and assessment is carried out using a standard inspection check list that covers among other issues, review of the procedures and risk assessments produced by the radiation employer as required by the regulations.

Medical radiation equipment is subject to notification, but there is no formal authorization procedure for such equipment. However, some review and assessment is carried out without a formal procedure. For verification of acceptance test results of medical equipment RPB has access to medical physics expertise within the Public Health. In accordance with LN 353, acceptance tests are required to be carried out using international standards. There are no criteria to verify survey measurements or patient dosimetry.

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** *"The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by theregulatory 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."*
(2)	**BASIS: GSR Part 1 Requirement 26 states that** *"Review and assessment of a facility or*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."
(3)	**BASIS: GS-R-3 Para 5. 9 states that:** "*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."*
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.**

6.2. SUMMARY

No specific procedures for review and assessment are in place. A standard inspection check list is used for review and assessment of medical facilities and activities. Review and assessment for industrial facilities and activities is carried out using a standard inspection checklist for occupational exposure. There should be standard review and assessment procedures for all facilities and activities and procedures should be in accordance with a graded approach.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION APPROACHES, METHODS AND PLANS

Regulation 9 3 f) of LN 44 specifies that it is the function of RPB to coordinate and conduct inspections to assess radiation safety and compliance with regulatory and authorization requirements but LN 353 "*Medical Exposure Regulations*" does not clearly empower RPB to perform inspections with regard to medical exposure and patient protection (see Module 11a and R3 in Module 1). Nevertheless, in practice, medical inspections are carried out by Occupational Health and Safety officers from the Radiation Protection Section and the "Medical Inspection Checklist" covers both occupational exposure and medical exposure.

Article 16.1a) of the "Occupational Health and Safety Act" enables Occupational Health and Safety Officers (primarily the two current officers of the Radiation Protection Section of OHSA) to *"enter freely at any time without previous notice in any work place at any time of day or night."* Moreover, Regulation 9.3h) of LN 44 enables RPB to authorize persons to carry out inspections on its behalf. The IRRS team was informed that this possibility is not currently used by RPB.

The "*RPB-OP-S-Regulation of Medical Establishments*" procedure was drafted in 2014, especially for medical establishments. This procedure introduces the practice of "*Pre-authorization inspections*" for all new and existing sites in order to authorize all notified sites in terms of LN 44. Authorization inspections began in July 2013. The procedure also states that every change notified by a site will be inspected for amendment of an existing authorization if necessary, and inspections are also carried out for re-issuing an authorization.

Inspections in medical facilities include:

- Pre-authorization inspections in case of a new facility or activity or in the case of a change in an existing facility or activity. These inspections occur before issuing the authorization.
- Inspections prior to re-issuing of authorization in the preceding two months of the renewal date.
- Follow-up inspections performed one or two months after the primary inspection.
- Unannounced inspections (e.g. in response to a complaint), but the case of reactive inspections is not taken into account.

These inspections are performed (excluding dental services) as part of the authorization process and their frequency is linked with the duration of each authorization (from 1 to 4 years).

Applying the aforementioned procedure, inspections are performed following the "*RPB Medical Inspection*" checklist and a report is issued within one week of the inspection and forwarded to the radiation employer.

The IRRS team was informed that unannounced inspections occur but there are no formal procedures.

Inspections in the industrial field are carried out following the "*RPB Occupational Regulatory Compliance*" checklist. However, procedures for the inspection process need to be developed and linked to the authorization of industrial facilities and activities.

A planned and systematic inspection programme based on a graded approach remains to be developed and the consistency of control of each facility undertaking the same activity has not been assured through management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GSR Part 1 Requirement 29 para. 4.50 states that** *"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."*
R14	**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.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: In the absence of documented procedures, stability and consistency of the regulatory control can not be guaranteed.
(1)	**BASIS: GSR Part 1 Requirement 22 para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatorybody shall be able to justify its decisions if they are challenged. In connectionwith its reviews and assessments and its inspections, the regulatory body shallinform applicants of the objectives, principles and associated criteria for safety onwhich its requirements, judgements and decisions are based."*
R15	**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.**

7.1.2 SITE VISITS TO OBSERVE ACTIVITIES OF THE REGULATORY BODY

Inspection at a Hospital

A limited scope inspection of the nuclear medicine department at a hospital was performed by one inspector and observed by members of the IRRS team. The inspection was carried out professionally. The inspector explained in the entrance meeting the scope of the inspection. The head of the department, other physicians and a radiographer were interviewed using a standard inspection check list that RPB had developed for the medical area. At the exit meeting the inspector concluded the inspection findings and

described the procedure to continue the inspection and to carry out a follow up inspection to verify the hospital's compliance with all applicable requirements.

The nuclear medicine department has three authorizations, one for the use of unsealed sources, one for medical imaging and one for temporary storage and discharge of radioactive waste. The authorization for unsealed sources was issued in January 2014 for one year and has expired. Given their extremely limited resources (two officers), preparation for the IRRS mission has had a short-term negative impact on the RPB's regulatory programme.

The authorization for unsealed sources included a list of radionuclides used in the hospital, but there were no maximum activities for these nuclides. In the authorization for radiodiagnostic imaging there is no list of equipment. However, equipment has to be notified to RPB and results of acceptance tests have to be sent to RPB for verification. The IRRS team understands that the RPB uses a Public Health medical physics expert for verification as well as for verification of the hospital's shielding calculations.

After the inspection the IRRS team interviewed the hospital staff without the inspector present.

Visit to an industrial application site

Within the framework of the IRRS mission a site visit was organized to a Non-Destructive Testing (NDT) company. The purpose of the visit was to observe an inspection.

The company performs non-destructive testing of integrity of metallic components on a regular basis. The applied method is industrial radiography, using radioactive sources and X-ray equipment.

The inspection was performed by one inspector and the activity was observed by two members of the IRRS team. It went by a well-defined checklist, starting with administrative matters, reviewing documents, plans and procedures, thoroughly following a detailed checklist.

The questions covered occupational radiation protection and emergency preparedness and response.

The document reviewing and personnel interviews were followed by a site inspection. It covered the checking of the physical protection of the source, the presence of the source, and the X-ray equipment, the safety arrangements, the appropriateness of the technical components etc.

The inspector noticed deficiencies which were recorded and included in the inspection report. An email with the main findings was sent to the inspected facility later in the day.

7.5. SUMMARY

RPB is empowered to coordinate and conduct inspections to assess radiation safety and compliance with regulatory and authorization requirements. However, Medical Exposure Regulations do not clearly empower RPB to perform inspections with regard to medical exposure and patient protection. Nevertheless, in practice, medical inspections are carried out by Occupational Health and Safety officers from the Radiation Protection Section and the "Medical Inspection Checklist" covers both occupational exposure and medical exposure. Inspections in the industrial field are carried out following the Occupational Regulatory Compliance checklist.

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. A planned and systematic inspection programme based on a graded approach, should be developed and the consistency of control of each facility undertaking the same activity should be ensured.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

Enforcement policy

Article 9.3 f) of LN 44 empowers RPB to *"coordinate and conduct enforcement actions".* However Article 67 of LN 44 splits the responsibilities of enforcement actions between the four member entities of RPB.

In the absence of a single Act regulating radiation protection, neither offences nor penalties, nor fines and prosecutions are specifically defined and despite the 2005 RaSSIA mission recommendations to this effect, RPB has not yet established an enforcement policy. In the case of occupational exposure RPB follows the procedures of OHSA but in the case of medical exposure, RPB refers to the Superintendent of Public Health who may decide to take enforcement actions in his sector.

Non-compliance with regulations or authorizations

Article 17 1) of the "Occupational Health and Safety Act" empowers OHSA officers to give verbal instructions and confirm these orders in writing which must be followed by the radiation employer. Article 19 2) of LN 44 enables RPB to revoke an authorization at any time in writing. The IRRS team has seen an example of suspended activity where there was no formal licence.

However, since legislation does not define the nature and scope of non-compliance and consequent sanctions, RPB has been unable to implement an enforcement policy in accordance with a graded approach. There is no procedure documenting the actions of RPB when a non-compliance is discovered.

The RPB does not have clear authority to undertake enforcement actions especially in the area of medical exposure. Enforcement is one of the fundamental functions of any regulatory body.

This issue is further addressed in Module 1 - See R3.

8.3. SUMMARY

RPB is empowered to coordinate and conduct enforcement actions. However, responsibility to implement enforcement actions is assigned to all four member entities of RPB. In the absence of a single Act regulating radiation protection, neither offences nor penalties, nor fines and prosecutions are specifically defined. OHSA officers are empowered to give orders to be followed by the radiation employer. However, there is no procedure documenting the actions of RPB when a non-compliance is discovered. The RPB does not have authority to undertake enforcement actions in the field of medical exposure and radiation protection (health is the main user of radiation technologies in Malta).

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

In Malta the legal basis for developing regulations for nuclear and radiation safety is set out in LN 44 paragraphs 93c and 93s which assign to RPB the authority to; '*coordinate the preparation of regulations governing notification and authorization…and establishing radiation protection and safety requirements'* and; *'the establishment of technical standards, preparation of codes of practice and other guidance documents…*'. Thus, the organizations that comprise the RPB are responsible for the development of regulations and RPB coordinates their activities in this regard.

In practice, the Radiation Protection Section (RPS) of OHSA drafts new or amended regulations and forwards the drafts for comment to the entities that comprise the RPB. Once RPB approval has been achieved, the draft is posted on the OHSA (RPS) website for public consultation. During this consultation period the RPS endeavours to contact the relevant stakeholders to make them aware and encourage their feedback.

An 'Impact Assessment Framework for Subsidiary Legislation' form must be completed by the drafting organization (in this case usually RPS) following the consultation period. The Impact Assessment form requires a justification for the regulation, evidence of consultation and a social, environmental and financial impact assessment of the proposed secondary legislation, together with a description of how it will be implemented and enforced. The form is signed by the drafter, the director of the sponsoring organization and finally the Permanent Secretary of the Ministry to which the sponsoring organization reports.

The Minister presents a memorandum to Cabinet seeking their approval of the proposed regulation. Once approval is obtained the Minister signs the regulation, after which it is published in the government gazette.

There appears to be no robust evaluation of the regulation other than the Impact Assessment Form and persusal by Cabinet.

The period of consultation can be quite short and is not formalized to take into account public representative organizations, professional bodies and other relevant stakeholders. There is no active promotion of the regulations (other than their publication on the OHSA website).

The decision to develop a regulation or update it is on the basis of new or revised EU Directives. To date, technological advances, research and development work, relevant operational lessons learned and institutional knowledge have not been directly applied in managing regulations. The current body of regulations has been developed to be in conformance with EU Directives, but a graded approach commensurate with the radiation risks associated with facilities and activities in Malta appears not to have been applied to the content of the regulations.

There appear to be no requirements for the review or revision of regulations and no process for the drafting, promotion and issue of regulatory guides.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GSR Part 1 Requirement 34, states that** "*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."* **BASIS: GSR Part 1 Requirement 34, Para 4.61. states that** "*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."* **BASIS: GSR Part 1 Requirement 34, Para 4.62 states that** "*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 forassessing 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."*
R16	**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.**

9.2. SPECIFIC REGULATIONS AND GUIDES FOR FACILITIES AND ACTIVITIES

The following practice-specific regulations have been issued:

- Control and Security of High-Activity Radioactive and Orphan Sources Regulations LN 13 of 2006
- Dual-Use Items (Export Control) Regulations LN 416 of 2004
- Freedom of Access to Information on the environment regulations LN 116 of 2005
  General Provisions for Health and Safety Regulations LN 36 of 2003
- Importation Control Regulations LN 242 of 2004
- Management of Radioactive Waste Regulations LN 186 of 2013
- Medical Devices Regulations LN 210 of 2008
- Medical Exposure (Ionising Radiation) Regulations LN 353 of 2012
- Merchant Shipping (Safety Convention) Rules LN 22 of 2003
- Minimum Requirements for the use of Personal Protective Equipment at Work LN 121 of 2003
- Motor Vehicles (Carriage of Dangerous Goods by Road) Regulations LN 211 of 2003

- Nuclear Safety and Radiation Protection (Amendment) Regulations LN 187 of 2013
- Nuclear Safety and Radiation Protection Regulations LN 44 of 2003
- Protection of Maternity at Work Places Regulations LN 92 of 2002
- Protection of Young Persons at Work Places Regulations LN 91 of 2000
- Radiological Emergency (Information to the Public Regulations) LN 245 of 2002
- Waste Management (Supervision and Control of Shipments of Radioactive Waste and Spent Fuel) Regulations LN 48 of 2009
- Personal Protective Equipment Regulations LN 371 of 2002
- Importation Control Regulations LN 242 of 2004
- Air Navigation (Dangerous Goods) Regulations LN 233 of 2006

9.3. SUMMARY

In Malta the legal basis for developing regulations for nuclear and radiation safety is set out in LN 44 which assign to RPB the authority to; '*coordinate the preparation of regulations governing notification and authorization…and establishing radiation protection and safety requirements'* and; *'the establishment of technical standards, preparation of codes of practice and other guidance documents…*'. Thus, the organizations that comprise the RPB are responsible for the development of regulations and RPB coordinates their activities in this regard.

There is a general governmental process for the approval, issue and promotion of regulations, including those drafted by RPB or its member organizations. The Minister presents a memorandum to Cabinet seeking their approval of a proposed regulation. Once approval is obtained the Minister signs the regulation, after which it is published in the government gazette.

There appears to be no robust evaluation of the draft regulation other than the Impact Assessment Form and persusal by Cabinet.

The period of consultation can be quite short and is not formalized. There is no active promotion of the regulations.

A graded approach commensurate with the radiation risks associated with facilities and activities in Malta appears not to have been applied to the content of the regulations.

There are no requirements for the review or revision of regulations and no process for the drafting, promotion and issue of regulatory guides.

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Basic responsibilities

The regulatory body which is responsible for all radiation safety issues is the RPB as set up by Regulation 9 of Legal Notice 44 of 2003 (LN 44). Legal Notice 13 of 2006 (LN 13) gives additional mandate to the RPB regarding control and security of high activity radioactive and orphan sources.

Specific mandate for emergency response activities is given to Civil Protection Department (CPD) by virtue of Regulation 56(1) of LN 44 and Regulation 14(1&2) of LN 13. CPD is one of the member entities of the RPB.

The national radiation emergency preparedness and response (EPR) system is outlined in RPB-OP-S-Emergency Framework-2010-1. The response activities of the RPB/CPD are described in this document.

Regulations 54, 55(1-2), 56(2), 57(1,2,3), 58(2) of LN44 state the roles of the Radiation Employee, with special emphasis on its obligation to establish emergency response arrangements and prepare emergency plans and procedures.

The regulatory body coordinates/provides advice to other organizations involved in EPR during the preparedness phase.

The coordination of emergency response is done through the application of RPB-OP-S-Emergency Framework-2010-1, in particular through the generic flow chart of 6.1 and 6.2.

Assessment of threats

The term threat assessment is not used in the relevant regulations but Radiation Employers are required to perform a radiological risk assessment in terms of regulation 27 of LN 44 and to consider the risks associated with accidents under this regulation. There is no specific guidance for radiological risk assessment, except that the licensee who performs the assessment may decide to consult a radiological expert (which is often a qualified expert in terms of LN 44).

Threat categorization is contained within RPB-OP-S-Emergency Threat Assessment. According to this document categories III, IV and V (as defined by GS-R-2: 3.6 Table 1) are to be planned for although this may change in the future.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GS-R-2 para. 3.16 states that** *"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)."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S4	**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.**

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Establishing emergency management and operations

Radiation Employers are required to have an emergency plan. Requirements for Radiation Employer's Emergency Plan are given in Regulation 26(3a), 54 & 55, 56(2), 57 of LN 44.

However, there is no verification in place, the occupational inspection checklist does not cover this area in detail.

Identifying, notifying and activating

The requirement for licensee to classify emergencies is not addressed in the relevant Maltese regulations, the RPB argues that Malta does not have any threat category I or II sites.

RPB-OP-S-Emergency Framework-2010-1 defines 2 classes:

- On-site emergency, such emergencies are contained within the perimeter of the facility-/ site;
- Off-site emergency, such emergencies are not confined within a perimeter.

This classification, although not fully consistent with GS-R-2, may be sufficient for the country with such limited radiological hazard profile.

It may happen that Malta needs to interpret emergency classification of other countries (e.g. informed through the IAEA notification system) which would require the definition and use of the emergency classes proposed by the relevant Agency standards.

Regarding regulatory requirements for notification of an emergency by licensees the Radiation Employers are required, by virtue of regulation 57(1) of LN 44, that "…The radiation employer shall immediately notify the Board and the Civil Protection Department, by the quickest practicable means, of any radiological emergency and shall take all appropriate action to reduce the consequences."

Scrap metal issues are covered by LN 13.

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** *"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…"*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S5	**Suggestion: The regulatory body should consider modifying its emergency classification system to be consistent with the classification given in GS-R-2.**

Taking mitigatory actions

Radiation Employers are required, by virtue of regulation 57(1-3) of LN 44, to provide emergency services at the licensed facilities. These services can include external emergency services as part of the licensee's plan to take mitigatory actions. According to Regulation 57(1) of LN 44 "…The radiation employer shall immediately notify the Board and the Civil Protection Department, by the quickest practicable means, of any radiological emergency and shall take all appropriate action to reduce the consequences."

There is no procedure in place to verify that this is effectively implemented, inspection checklists do not go into this issue in detail.

Taking urgent protective action

The regulatory body has a role in establishing regulations or levels for the protection of public in an emergency. Emergency occupational levels are given in Regulation 58(1) of LN 44, the other levels are not given in regulations but rather in RPB-OP-S-Emergency Framework-2010-1. Schedule 7 of LN 44 is giving guidance for the workers undertaking intervention, based on the relevant IAEA standards.

Values in RPB-OP-S-Emergency Framework-2010-1 are taken from IAEA TECDOC-953 Appendix 1.

Regarding the role of the regulatory body in the definition of emergency planning zones and consistency of the zones with IAEA guidance one has to consider that Malta does not have any category I or II facilities and therefore the issue of emergency planning zones is not applicable for the country. (GS-R-2; Page 33; 4.48 implies that this is only a requirement for category I or II facilities.)

Providing information and issuing instructions

Considering the role, responsibility and cooperation of the regulatory body in regulating the licensee's activity in instructing public and keeping the public informed the relevant IAEA standard (GS-R-2) Paras 4.54 and 4.55 state that this is only a requirement for threat category I or II facilities. Malta does not have this threat category facilities.

The role of informing public is assigned to the Civil Protection Department, which is a member entity of the RPB. Under LN 245 of 2002 it is for the Director of Civil Protection Department to issue information prior to and during a radiological emergency.

There are no regulatory requirements for radiation employers to provide information to the public although Regulation 55 (3g) of LN 44 states that "… The Radiation Employer shall identify the public information arrangements in the event of an emergency."

Protecting emergency workers

The issue of emergency worker protection is covered by Regulation 58(1) of LN 44 which states that "…The Board shall establish exposure levels, taking into account the technical obligations and health risks, for situations where workers or intervention personnel involved in different kinds of intervention are liable to be subjected to emergency exposure resulting in doses in excess of the occupational dose limits for exposed workers. These levels are given in Schedule 7 and shall serve as operational guides."

Schedule 7 is broadly in line with GS-R-2, Annex 1, although there are some differences in the doses emergency workers can receive, namely that for non-life threatening and non-catastrophic situations the dose limits are half of those given by GS-R-2. In addition, 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.

The threat categories are not stated in the regulations however the threat categories used in the RPB threat assessment (RPB-OP-S-Emergency Threat Assessment, not linked to SARIS) are in line with GS-G-2.1 Table 4 and Section 4.

There is no regulation to require the response organizations and the licensees to assess and record the doses to emergency workers.

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 site56, 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.**

Assessing the initial phase

Although this requirement is not specified in the regulations the RPB operating procedure in RPB-OP-S-Emergency Framework-2010-1 has a simple classification system (given in section 4 and 5).

Managing the medical response (in emergency situations)

RPB does not have a direct role in regulating medical response management by the licensees. Radiation Protection Section of OHSA is working with the main government hospital to develop their response capabilities to radiation incidents.

There is no standard operating procedure, nor a training programme in place, for medical response in emergency situations.

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** *"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-up60, 61 of persons subjected to radiation exposure or contamination…"*
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.**

Other activities in emergency preparedness

Regarding the role, responsibility and cooperation of the regulatory body in defining criteria for agricultural countermeasures and countermeasures against ingestion and longer-term protective actions the RB has limited role to play. Basic countermeasures are mentioned in RPB-OP-S-Emergency Framework-2010-1 but levels have not been defined. The levels in the planning document are based on the recommendations of the international standards (e.g. GS-R-2) but they are guidance levels and they have not been incorporated into the country's legal system.

As for the role, responsibility and cooperation of the regulatory body in mitigating the non-radiological consequences of the emergency and response, (also related to rather reassuring and not needlessly alarming the public) is not covered by regulation although Regulation 55(2g) of LN 44 states that "… The radiation employer shall … – …identify the public information arrangements in the event of an emergency".

The regulatory body does not seem to have any role in regulating recovery operations, although such a role is assumed in the IAEA standards document GS-R-2, (paragraph 4.98). Basic responsibilities are mentioned in RPB-OP-S-Emergency Framework-2010-1, but it does not contain regulatory function of regulating the recovery work.

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 status (not legally

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	binding).
(1)	**BASIS: GS-R-2 para. 4.88 states that** *"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."*
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.**

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** *"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."*
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.**

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Authority, organization and coordination

No Radiation Employers in Malta have separate emergency response organizations, therefore there are no specific requirements for Radiation Employers to have specific staffing with regard to emergency response but they are required by Regulation 55(2e) of LN 44 to "provide for training personnel involved in implementing emergency plans and for rehearsals at suitable intervals in conjunction with designated authorities."

The issue of coordination of licensee's and off-site emergency services is not covered by a regulation but rather by RPB-OP-S-Emergency Framework-2010-1.

Plans and procedures

Regulatory requirements on plans and procedures for licensees are covered by Regulation 55(2) of LN 44.

The RPB requires that plans are done but does not approve or take responsibility for them. No procedure is in place on how the regulatory body ensures that the emergency plans are adequate, other than the normal inspection process.

The regulatory body's control over the testing of the licensees' emergency plans (i.e. the evaluation of the exercises) is weak and indirect.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GS-R-2 para. 3.8 states that** *"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."*
(2)	**BASIS: GS-R-2 para. 5.33 states that** *"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 experience gained …"*
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.**

Logistical support and facilities

Bearing in mind that Malta's maximum threat category is III, it is considered that the requirements stipulated in Regulation 55 LN 44 is appropriate for Malta. The requirements of Regulation 55 are sufficiently in line with GS-R-2; 5.25. GS-R-2 5.26–5.27 are not applicable to Malta as there are no category I or II sources.

Verification of effectiveness and adequacy of logistical support and facilities is done through regulatory inspections.

Training, drills and exercises

The licensee is required under LN 44 to organize proper training and drills, exercises for the employees. The Radiation Employer is required under Regulation 55(2b) of LN 44 to test their emergency plan.

There is no system in place for the evaluation of licensee's training programme, and exercises other than the general RPB inspections. The RPB inspection checklist does not ask specific questions about emergency plans or rehearsals of emergency plan.

Quality assurance programme

Whereas the RPB has set up emergency response procedures through RPB-OP-S-Emergency Framework-2010-1 there is no quality assurance programme in place for the EPR processes.

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** *"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)…"*
(2)	**BASIS: GS-R-2 para. 5.39 states that** *"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."*
R20	**Recommendation: The regulatory body should develop regulatory requirements for EPR quality assurance programme to be established and maintained by the licensees.**

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

Regulation 56 of LN 44 states that "… *every radiation employer shall ensure that appropriate on-site intervention plans, taking account of the general principles of radiation protection for intervention referred to in regulation 53 (2) and of the appropriate intervention levels established by the Board, are drawn up, in order to deal with various types of radiological emergency and that such plans are tested to an appropriate extent at regular intervals*". Furthermore, "… (4) *The Board shall be kept informed of: (a) The current situation and its expected evolution; (b) The measures taken to terminate the accident and to protect workers and members of the public; and (c) The exposures that have been incurred and that are expected to be incurred".*

Responsibilities of the RPB as a whole and the constituent entities of the RPB are laid down in 3.1-3.5 of RPB-OP-S-Emergency Framework-2010-1 which states that *"…RPB should:*

- *seek to ensure that all government agencies have their own plans in place and that their plans are in line with this framework document;*
- *support the development of guidelines to the various government entities that could be party to such an emergency; and*

- *it shall also, in consultation with the CPD, notify international response organizations or other interested International Agencies. ...*"

RPB-OP-S-Emergency Framework-2010-1 serves as the basic plan for the regulatory body related to its role in EPR.

Coordination with other organizations are defined in section 3.6 of RPB-OP-S-Emergency Framework-2010-1, which states that "…other Governmental agencies (not entities of RPB) may be involved through the procedures of CPD, RPB, Health, OHSA and MEPA. In particular:

- Malta Police will provide assistance for securing any perimeter as envisaged necessary by CPD.
- Armed Forces of Malta will provide logistical support at the request of CPD.
- Department of Information (DOI) (in case of a large response) is responsible for issuing any public or media information as envisaged necessary by the LTA.
- The Office of the Prime Minister (OPM) shall be kept informed by LTA of all developments during the emergency. The OPM will be responsible for co-ordinating with other relevant bodies, including ministries, to allow for the easy and quick access for any required needs as envisaged by the LTA, including but not limited to import/export of equipment, access to Maltese Territory of any foreign expertise, divulging any information to the LTA deemed relevant to the emergency that could safeguard the safety of emergency workers."

Whereas there is the Emergency Framework document there is no internal quality assurance programme in place for CPD. There is no procedure for calibration of radiation monitors within CPD.

No programme for staff training, drill and exercise is in place. Given the small size and long-time experience of the current staff this is not an issue. However, if the staff increases or changes the problem of training and exercising will arise.

Regarding facilities, support and logistics for the EPR programme the Modus Operandi is specified in RPB-OP-S-Emergency Framework-2010-1. CPD is well equipped although equipment needs re-calibration.

Malta does not have complete radionuclide analytical laboratory capacity or passive personal dosimeter analysis.

10.5. SUMMARY

The basic components of regulating radiological emergency preparedness and response in Malta are established. Regulations 53-59 of Legal Notice 44 give the legal framework for the regulatory body, the licensees and the off-site emergency response organizations regarding their obligations, roles and responsibilities in case of a radiation emergency.

Some of the regulatory tools are missing (e.g. regulating the agricultural countermeasures, the recovery work and quality control of EPR processes) or weak (e.g. verifying the appropriateness of the emergency plans, evaluating the licensees' exercise and drills etc.). The missing regulatory tools are to be established, whereas those identified as insufficient or weak areas require strengthening or amendment.

11. ADDITIONAL AREAS

It should be noted that Module 11 is mostly concerned with technical aspects of the regulatory control of radiation protection and safety associated with specific facilities and activities . The recommendations and suggestions for this Module are mostly directed to the regulatory body and the majority are technical in nature.

11.1. CONTROL OF MEDICAL EXPOSURES

Responsibilities of the government

Medical exposures are not stipulated in an Act. The regulation on medical exposure 353 of 2012 has transposed the MED directive 97/43/Euratom and covers most of the requirements of GSR Part 3 for medical exposure. This was also the conclusion of the Maltese self assessment.

According to the self-assessment there is no Act having regard to medical exposures that would ensure relevant parties are authorized to assume their roles and responsibilities and that diagnostic reference levels (DRLs), dose constraints, and criteria and guidelines for the release of patients are established. However, roles and responsibilities, DRLs and release of patients after radionuclide therapy are included in the regulation for medical exposure to some extent.

In the regulation 353 of 2012 medical facilities are required to establish diagnostic reference levels (DRLs) and to compare patient doses to them. However, the concept of DRLs recommended by ICRP and adopted by EU in MED directive 97/43/Euratom and used in the GSR Part 3 is such that medical facilities compare their average patient doses to the national DRLs established by the regulatory body. There is a need to develop national DRLs and the responsibility to establish them should be stipulated to the regulatory body.

Regulations and guidance for the release of patients from hospitals after radionuclide therapy are inadequate. This was also noted in the Maltese self-assessment. The radiological medical practitioner should ensure that no patient is discharged from a medical radiological facility until it has been established by either a medical physicist or the facility's radiation protection officer that the activity of radionuclides in the patient is such that doses that might be received by members of the public and family members would be in compliance with the requirements set by the relevant authorities and written instructions provided (GSR Part 3, Requirement 40, para 3.177).

The IRRS team was informed that the profession of medical physicist is not yet recognized in Malta. However, medical physicists should carry out many responsibilities for patient safety (see R4). The government of Malta is encouraged to find a solution for the recognitions process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GSR Part 3 Requirement 34 states that** "*The government shall ensure that relevant parties are authorized to assume their roles and responsibilities and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	established." **BASIS: GSR Part 3 Requirement 40 states that** "*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.*"
R21	**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.**

Responsibilities of the regulatory body

The Maltese self assessment acknowledged that the power of the RPB in issues relating to medical exposures is limited because the medical exposure regulations fall under the Public Health Act and as such the Superintendent of Public Health is the final arbiter.

All medical exposures are authorized, excluding dental practices (see Module 5) and inspected (see Module 7). However, it is not clear if OHS inspectors are empowered to inspect medical exposures. The Superintendent of Public Health is empowered to enforce in this sector. (see Module 8)

The IRRS team was informed that on pre-authorization inspections it is effectively verified that medical exposures are performed by personnel specialized in the appropriate area, meet the respective requirements for education and training and competence for radiation protection, and are listed by the licensee.

Responsibilities of registrants and licensees

Justification of medical exposure for self-referred patients and asymptomatic individuals are not specifically regulated. There was a conclusion in the self assessment that this should be regulated. Moreover, at a site visit to the hospital the physicians expressed need to regulate more the exposure of asymptomatic individuals.

As mentioned in the self assessment there is no requirement that patients or their legal representatives should be informed of the benefits and radiation risks to the patient prior to the exposure. Patients could make uninformed decisions on the benefits and risks of their medical exposure. Moreover, there is a contradiction between the GSR Part 3 Requirement 36 para 3.150 (d) and regulation 353 of 2012 para 20. (c) that states: "written instructions and information are provided to: ...where the patient is an adult who lacks capacity to consent, the practitioner shall decide in the best interest of the patient". In that case there is no need to give any information, not even to the legal representative of the patient.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**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*." **BASIS: GSR Part 3 Requirement 36, para 3.150 states that** *"Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic,undergoes a medical exposure unless:* *(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;* *(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;* *(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);* *(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."*
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.**

Biomedical research

The difficulty to observe if there is any biomedical research in the country using ionization radiation was discussed. Advice was given by the IRRS team how to raise discussions in the hospitals. The regulations cover justification of biomedical research.

Medical Physicist

It was noted in the self assessment that there is a need for the greater involvement of a medical physicist in interventional and some therapeutic procedures.

There was no requirement that radiation employers should ensure that sufficient medical personnel and paramedical personnel are available. It is not possible for the regulatory body to supervise without any requirement. However, it was discussed that it is hard to find good examples from any countries how to regulate the issue.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	paramedical personnel are available.
(1)	**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.*" **BASIS: GSR Part 3 Requirement 36, para 3.152 states that** "Registrants and licensees shall ensure that: *(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;* *(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;* *(c) Sufficient medical personnel and paramedical personnel are available as specified by the health authority;* *(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;* *(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;* *(f) Any delegation of responsibilities by a principal party is documented.*"
R24	**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.**
R25	**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.**

Justification of medical exposure

The IRRS team discussed with the RPB the levels of justification according to ICRP recommendations and also gave advice on practical methods to inspect justification.

Justification for medical exposure of asymptomatic patients is not clearly regulated (see R22). The IRRS team informed on current activities in Europe, especially among HERCA, to share experience on regulating the issue.

Optimization of medical exposure

Design considerations

The IRRS team was informed that all medical equipment is required to have an acceptance test and the test results are sent to be verified by the regulatory body before the equipment is put into use. The IRRS team considers that there is a notable practice that expertise of a medical physicist in the Public Health is used for the verification, when competence within the RPB is not sufficient.

Operational considerations

The IRRS team was informed that cooperation between practitioner, medical physicist and technologist could be better. There is nothing in the regulations or guidelines that requires the practitioner to consult medical physicists or other specialists in the optimization process.

Calibration

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 the regulations.

Dosimetry of patients

It is regulated that a medical physics expert should be involved as appropriate for consultation on optimization, including patient dosimetry. However, the GSR Part 3 requires patient dosimetry to be carried out under supervision of a medical physicist. The regulation should be revised to be in line with the GSR Part 3.

Quality assurance for medical exposures

It was pointed out in the self assessment that there is no definition of a quality assurance (QA) programme or radiation protection programme in the regulations and most radiation employers are not familiar of how quality systems work. However, QA is required to be performed and a medical physicist should be involved in that. It was advised by the IRRS team that QA should be taken to discussions with professional societies in Malta to get a common understanding of a quality system.

Dose constraints

Dose constraints are given for optimization purposes for careers and comforters. Employers are required to give dose constraint in biomedical research.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**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 ."* **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:* *(a) Appropriate medical radiological equipment and software and also, for nuclear medicine, appropriate radiopharmaceuticals;* *(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.* **BASIS: GSR Part 3 Para 3.166 states that** *"in accordance with para. 3.153(d) and (e), the medical physicist shall ensure that:* *(a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;* *(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;* *(c) Calibrations of radiotherapy units are subject to independent verification prior to clinical use;* *(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory.* **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:* *(a) For diagnostic medical exposures, typical doses to patients for common radiological*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	procedures; *(b) For image guided interventional procedures, typical doses to patients;*
R26	**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.**

Pregnant women and breast feeding women

There is a lot of regulation on protection of pregnant women and breast feeding women. It was emphasized by the IRRS team that breast feeding women are not a subject of protection, but a child is. 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).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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).
(1)	**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."* **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:* *(a) She is or she might be pregnant;* *(b) She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical.*
R27	**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.**

Release of patients

The criteria and guidance for releasing patients after radionuclide therapy or permanent implantation of sealed sources has not been established.

Unintended and accidental medical exposures

There is not any requirement in the regulation that radiological medical practitioner should inform patients or their legal representatives of the unintended or accidental medical exposure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**BASIS: GSR Part 3 Requirement 41 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."* **BASIS: GSR Part 3 Requirement 41, para. 3.180 (c) states** "*Registrants and licensees shall, with regard to any unintended or accidental medical exposures investigated as required in para. 3.179: Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorized representative of the unintended or accidental medical exposure."*
R28	**Recommendation: The regulatory body should add a requirement in regulations such that patients or their legal reprenetatives are required to be informed of unintended exposures.**

Reviews and records

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.

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***"Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained."* **BASIS: GSR Part 3 Requirement 41, para. 3.181 states that** *"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*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	performed in the medical radiation facility. of the unintended or accidental medical exposure."
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.**

11.2. OCCUPATIONAL RADIATION PROTECTION

Most of the requirements concerning occupational exposure are given in "Nuclear Safety and Radiation Protection Regulations" LN 44 of the 19th May 2003, amended. This regulation places a general duty on radiation employers to ensure radiation protection of their employees and in some cases, of other workers who may be affected by their work in a radiological area. Thus, this notice deals with many requirements of GSR Part 3, such as:

- Compliance with the 3 principles of justification, optimization and limitation,
- Operational radiation protection of exposed workers (risk assessment),
- Classification of exposed workers (including apprentices and students),
- Measures for restriction exposure (monitoring equipment, personal protective equipment, designation of controlled and supervised areas, information and training),
- Workplace and individual monitoring,
- Medical surveillance of exposed workers,
- Dose limits for different classes of persons,
- Radiation passbook and health record.

Several other regulations relating to general health and safety measures at workplaces are also used in the regulatory framework for preventing exposure to ionizing radiation, especially:

- General Provisions for Health and Safety Regulations LN 36 of 2003,
- Personal Protective Equipment Regulations LN 371 of 2002,
- Minimum Requirements for the Use of Personal Protective Equipment at Work LN
- 121 of 2003,
- Protection of Maternity at Work Places Regulations LN 92 of 2002,
- Protection of Young Persons at Work Places Regulations LN 91 of 2000.

The main output of the analysis of the Maltese assessment, is that even though many regulations comply on the whole with GSR Part 3, many of them have to be specified, detailed and enhanced to become feasible and implemented so that the safety of workers can be improved.

Dose limits

The limits set down in Schedule 3 of LN 44 for the lens of the eye are derived from BSS115, i.e.:

- 150 mSv in one year for workers,
- 50 mSv in one year for apprentices or students aged between 16 and 18.

In GSR Part 3, those limits are set to:

- 20 mSv per year averaged over 5 consecutive years (100 mSv in 5 years) and 50 mSv in any single year, for workers over the age of 18 years,

- 20 mSv in a year for apprentices from 16 to 18 years of age who are being trained for employment involving radiation and for students of age 16 to 18 who use sources in the course of their studies.

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** *"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."*
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.**

Young workers

LN 91 allows under conditions young person to perform work for a limited period of time with physical, chemical or biological agents (including ionizing radiation). LN 91 states that *"young person means a person under 18 years of age, and includes a child and an adolescent."*

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** *"Employers, registrants and licensees shall ensure that no person under the age of 16 years is or could be subject to occupational exposure."*
R31	**Recommendation: The regulatory body should add a requirement in regulations such that people under the age of 16 could not be expsosed to occupational exposure.**

Assessment and recording of aircrew doses

Regulation 48 (1) of LN 44 requires "*employers to assess the doses of aircrew and to keep records of doses for aircrew liable to be subject to exposure to more than 1 mSv/an."*
Air Malta compliance document with LN 44 states that *an assessment is conducted every year and records of assessment of the crew with the highest flying hours for each calendar year are kept.* This statement has to be checked by the regulatory body through an inspection to ensure compliance with regulation.

Dose received by emergency workers

LN 44 is in compliance with the international standards regarding the maximum doses which could be received by an emergency worker. But there is no compliance between LN 44 and the emergency

procedure RPB-OP-S-Emergency Framework -2010-1, which defines no level for workers involved in life saving operations.

Exposure to radon

Protection against exposure to 222Ra is not yet addressed in Maltese regulation. However studies were carried out in 2011. Their conclusions state *that the indoor radon gas concentration for the Maltese Islands are below* 100 Bq/m^3 . This value is well below the reference levels issued in GSR Part 3 (300 Bq/m^3 for public exposure and 1000 Bq/m^3 for occupational exposure).

Policies and procedures for radiological protection and the recording of non-compliances

Articles 31 1 & 2) of LN 44 require employers to assess and implement arrangements for radiological protection but do not clearly require documentation of these arrangements in Radiation Protection Programmes.

Article 42 3) of LN 44 gives duty to workers to *"report any deficiency in measures taken at the workplace aimed at minimising exposure to ionising radiation"* and Article 26 1 c) of LN 44 to employers to *"identify any failures and shortcomings in the protection and safety measures and resources, and take steps to correct them and prevent their recurrence."*

But there is no requirement to record the worker's reporting of deficiencies or the employer's consequent actions.

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: 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."*
(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.**

Health Surveillance Programmes

Articles 43 1) & 2 a) of LN 44 state that medical surveillance shall apply to Category A workers (as defined in European BSS and corresponding to radiation workers defined in paragraph 3.100 of GSR Part 3) and shall be carried out by medical practitioners or occupational health services approved by RPB (Article 11 1) of LN 44).

Although there is a requirement that employers provide for the medical surveillance of Category A workers, no occupational health services dedicated to radiation protection are available in Malta. However, for the time being there are no workers in Malta in Category A.

Information and training of workers

As is made clear in the Malta self-assessment, provisions regarding safety information, instructions and training of workers are given in Article 29 of LN 44 and Article 14 of LN 36 but there is no requirement for periodic or continuous professional development.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Employers are not required to provide periodic and on-going training for workers.
(1)	**BASIS: 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."*
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.**

Workers performing operations in a radiological area not under control of their employer

LN 44 defines an outside worker as *"a category A person (including trainees, apprentices or students over 18yeras) who carries out services in a controlled area of any employer (other than the controlled area of his own employer), whether employed temporarily, permanently, or as a self-employed person."*

Regulations 34 6) & 7) of LN 44 address some provisions for the radiological protection of these outside workers but by the above definition, these provisions only apply for Category A workers (only defined in Europeen BSS and corresponding to radiation workers defined in paragraph 3.100 of GSR Part 3) performing an operation in a controlled area. The issues are not taken into account for category B workers (only defined in Europeen BSS and corresponding to radiation workers defined in paragraph 3.101 of GSR Part 3) or tasks undertaken in a supervised area.

Moreover the allocation and documentation of the responsibilities between the employer and the registrant or licensee responsible for the source is not especially and clearly requested, including the sharing of the dosimetric information.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Necessary cooperation between employers to ensure the occupational radation 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: 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."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
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 between the parties, with appropriate allocation of responsibilities clearly documented.**

Responsibilities of workers

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.

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: 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."*
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**.

Personal Protective Equipment (PPE)

Provisions for PPE are given in LN 44, and more especially in LN 371 "Personal Protective Equipment Regulation" (§3.9 Additional requirements specific to particular risks: Radiation protection) and in LN 121 "Minimum Requirements for the Use of PPE at Work Regulations".

Individual and workplace monitoring of occupational exposure

Worplace monitoring is required by Regulation 37 of LN 44 but the frequency and type of workplace monitoring are to be more preciously defined. The appropriate monitoring in case of intakes of radionuclides is not yet addressed in the current regulation. However, there are two diagnostic nuclear medicine facilities, both using PET equipement, and one therapeutic nuclear medicine facility in Malta.

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** *"Employers, registrants and*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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."
(2)	**BASIS: GSR Part 3 Requirement 25 para. 3.102 states that** *"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."*
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.**

Investigation levels

Article 22 3) of LN 44 requires that in case of a worker exposure to an effective dose greater than 20 mSv/y, the employer must carry out investigations and notify the Board of that situation but there is no requirement for each employer to define in his local rules a particular investigation level.

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** *"Employers, registrants and licensees, in consultation with workers, or through their representatives where appropriate shall include in the local rules and procedures any relevant investigation level or authorized level, and the procedures to be followed in the event that any such level is exceeded."*
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.**

Radiation Protection Officer

Regulation 36 4a) of LN 44 states that a radiation employer should appoint one or more suitable radiation protection supervisors (RPS). However no criteria have been established by RPB to define qualifications for these supervisors, but it is understood that the role is not equivalent to that of a Radiation Protection Officer in the meaning of GSR Part 3 i.e. " *Persons technically competent in radiation protection matters relevant for a given type of practice who are designated by the registrant, licensee or employer to oversee the application of relevant requirements."*

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** *"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."*
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.**

Content of dose records

Article 37 2) of LN 44 requires that workplace monitoring shall be recorded. Regulation 38 1) of LN 44 states that there shall be an individual monitoring for each Category A worker (only defined in Europeen BSS and corresponding to radiation workers defined in paragraph 3.100 of GSR Part 3) and that the records shall be kept. Nevertheless, the current regulation does not specify the content of these exposure records.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The contents of records both for individual and for workplace monitoring are not defined in current regulations.
(1)	**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;* *(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;* *(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;* *(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."*
R39	**Recommendation: The regulatory body should add requirements in regulations about 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

Control of discharges and material for clearance

In Malta the only facilities releasing radioactive material to the environment are three nuclear medicine departments, which deals with radioactive unsealed sources containing short and very short lived radionuclides (I-131, Tc-99m, F-18, etc.). Regulations relevant to the control of radioactive discharges and material for clearance are included in Legal Notice No. 44 of 2003 "Nuclear Safety and Radiation Protection Regulations". Under this regulatory document RPB issues authorizations for discharges.

The procedure that serves as a basis for issuing discharge authorizations is described in document RPB-OP-S-Control of Radioactive Discharges-2014-1. According to this procedure the RPB performs an assessment of the impact from discharges from Nuclear Medicine establishment and recommends discharge conditions. This approach is not in compliance with IAEA Standards. The RPB takes into account the generic dose constraint for the effective dose, applicable to a single practice or work activity and to the mean dose among individuals of the critical group of the public of 0.25 mSv per year.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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.
(1)	**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:* *(a) Shall determine the characteristics and activity of the material to be discharged, and the possible points and methods of discharge;* *(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;* *(c) Shall assess the doses to the representative person due to the planned discharges;* *(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;* *(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."*
R40	**Recommendation: The regulatory body should implement a procedure for approval of discharge limits in compliance with relevant requirements in GSR Part 3.**

According to requirements in LN No. 44 relevant for the control of radioactive discharges, the licensee authorized to discharge radioactive material is required to notify the RPB when changes take place in the discharge conditions established in the authorization. However, the regulations are not clear in

establishing that after this notification a regulatory decision related with the discharge authorization should be made.

Regarding the criteria for clearance of radioactive materials from regulatory control, although the definition of clearance included in the regulations is in compliance with the one in GSR Part 3, and clearance values have been established by RPB, criteria for adopting these values have not been described. At the same time the regulations do not differentiate clearly between the concepts of exemption and clearance, which can produce confusion at the time of making regulatory decisions on the management of radioactive waste. During discussions with the RPB counterparts it was evidenced that the concept of clearance as itself was not completely clear, as well as the difference with the concept of exemption. At the same time, 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. In particular, the 1 mSv per year criteria for clearance of materials candidate to be used as construction materials or capable of causing contamination of drinking water, and containing natural radionuclides, is not in place.

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** *"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."*
(2)	**BASIS: GSR Part 3 para. I.12 states that "***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 …"*
R41	**Recommendation: The regulatory body should establish in Maltese regulations criteria for clearance.**

Environmental monitoring fo public radiation protection

Under Legal Notice No. 44 of 2003 "Nuclear Safety and Radiation Protection Regulations", licensees are required to perform monitoring to assess doses by members of the public. During regulatory inspections, inspectors can ask to see radiation employer's documentation, including that relating to monitoring.

Annual reports on amounts of radioactive material discharged from the licensed facilities is required from the licensees by the RPB as part of the conditions established in the authorization. However, this requirement is not explicitly addressed in the regulations. Neither the need of reporting promptly to the

regulatory body any levels exceeding the operational limits and conditions relating to public exposure is required in existing regulations. Regulations do not establish the responsibility of RPB for making provision for maintaining records of discharges, results of monitoring programmes and results of assessments of public exposure.

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** *"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."*
(2)	**BASIS: GSR Part 3 para. 3.137 states that***"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."*
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.**

11.4. SUMMARY

Medical exposure

The regulatory control of Medical exposures and Patient protection are not stipulated in an Act. The regulation on medical exposure covers most of the requirements of GSR Part 3 for medical exposure. More emphasis has to be given to ensure that relevant parties are authorized to assume their roles and responsibilities. Moreover, more adequate regulation is needed on use of diagnostic reference levels and dose constraints. Criteria and guidelines are needed for the release of patients who have undergone therapeutic procedures using unsealed sources or patients with implanted sealed sources. In addition, regulations should be amended or improved on following areas: patients should get information of expected benefits and radiation risks and unintended exposures, exposure of asymptomatic individuals should be justified, medical physicists should be involved in interventional and therapeutic procedures, there should be sufficient medical and paramedical stuff available, dosimetry and calibrations should be in place, signs in appropriate languages should be placed in appropriate places to request female to notify the possible pregnancy or in case of nuclear medicine procedure breast feeding. The regulatory body should

revise regulations such that the concept of periodical radiological reviews / clinical audits would be included.

Occupational exposure

Most of requirements concerning occupational exposure are given in "Nuclear Safety and Radiation Protection Regulations" LN 44 of the 19th May 2003, amended. This regulation places a general duty on radiation employers to ensure radiation protection of their employees and in some cases, of other workers who may be affected by their work in a radiological area. Thus, this notice deals with many requirements of GSR Part 3. Several other national regulations relating to general health and safety measures at workplaces are also used in the regulatory framework for preventing exposure to ionizing radiation.

Nevertheless, even though many national regulations comply on the whole with GSR Part 3, some of them have to be specified, detailed and enhanced to become feasible and implemented.

In this way, the regulation should address new provisions or complete and precise existing ones concerning, the dose limits for the lens of the eyes, the clear interdiction for young workers to be exposed to radiation, the definition by employers of investigation levels in case of unexpected exposure, the designation by the employers of Radiation Protection Officers as defined in GSR Part 3, the definition of the content of radiation protection programmes and the content of dose records, the implementation of a national register records of the occupational exposure history for each worker, the way the monitoring of occupational exposure shall be performed, the radiation protection of workers performing operations in a radiological area not under control of their employer, the periodic information and training of radiation workers, and the responsibilities of workers regarding their protection against radiation.

Control of discharges and material for clearance. Environmental monitoring for public radiation protection purposes.

RPB issues authorizations for discharges to facilities releasing radioactive materials to the environment. A generic dose constraint of 0.25 mSv per year for the public has been established. This constraint is applied in the control of discharges. Regulations establish clearance levels values for the release of radioactive materials from regulatory control.

Existing RPB procedure for establishing authorized discharge limits impose 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.

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. 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.

12. POLICY ISSUES

IRRS Policy discussions.

At Malta's request, two policy issues were addressed in discussion with the international experts of the IRRS team. Malta provided detailed material with respect to these topics well in advance of the mission to ensure the most effective exchange of knowledge and experience with regard to these policy matters of current importance to Malta.

The two issues discussed were:

1. Justification for the effective independence of the regulatory body for Malta
2. Managing regulatory issues within a small regulatory body

1. Justification for the effective independence of the regulatory body for Malta

At the time the RPB was established, the Maltese Government did not have the benefit of knowledge of all radiation and nuclear issues to be addressed immediately and into the future. This IRRS mission has confirmed the Maltese self-assessment findings that current regulatory structures do not enable the RPB to act independently in its regulatory decision-making.

The concept of independence in decision-making is well established in European Directives relating to nuclear safety and in the IAEA safety standards, but if changes to the Maltese national framework for safety are to be implemented to best effect, it is essential this concept (which is founded in the IAEA Safety Fundamentals (SF-1)) be fully understood.

The IAEA Safety Fundamentals are exclusively concerned with the protection of people and the environment from harmful effects of ionizing radiation, without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks.

IAEA Safety Fundamentals, Principle 2, states: *'An effective legal and governmental framework for safety, **including an independent regulatory body,** must be established and sustained'.*

Principle 2 goes on to state that government is responsible for the establishment, through a legal Act, of an independent regulatory body having adequate legal authority, technical and managerial competence, and human and financial resources to fulfil its responsibilities and be effectively independent of the licensee, or any other body, so that it is free from any undue pressure from interested parties. Vitally, Principle 2 also makes clear that where the licensee is a branch of government, it must be effectively independent of the branches of government with responsibilities for regulatory functions.

This important principle is reflected in various IAEA Safety Standards publications, most notably GSR Part-1, Requirement 4 and also the equivalent EU Directives (notably Directives 2013/59/EURATOM Art. 76(1); 2014/87/EURATOM Art. 6) and 2011/70/EURATOM Art. 6).

The policy discussion considered these issues in the Maltese context, with emphasis on the necessity to ensure reforms to the national framework for safety will ensure control of radiation safety free of undue influence from those that promote the use of radiation technologies and with the prime objective of limiting radiation dose to the Maltese population, workers and environment to that which is justified and optimized. Examples of the importance of effective independence in regulatory decision-making were offered by the expert reviewers and it was concluded that this fundamental principle should be paramount in any Maltese Act dedicated to nuclear and radiation safety.

2. Managing regulatory issues within a small regulatory body

The IRRS team validates the view expressed in the Malta self-assessment that the fragmented structure of Maltese regulations for radiation safety together with the current structure of the RPB are not conducive to the development of a management system which would be effective in achieving the objectives set out in IAEA GSR Part-1 and GS-R-3.

GSR Part-1, Requirement 19 states that; '*the regulatory body shall establish, implement, and assess and improve* ***a management system*** *that is aligned with its safety goals and contributes to their achievement*'.

The management system of a regulatory body has three purposes:

1. To ensure responsibilities assigned to the regulatory body are properly discharged.
2. To maintain and improve the performance of the regulatory body by means of the planning, control and supervision of its safety related activities.
3. To foster and support a safety culture in the regulatory body.

The policy discussion recognized the difficulty in establishing an RPB management system that would achieve the objectives above, given the RPB's organizational structure and the diverse nature, interests and priorities of its constituent member organizations. The issue is closely aligned with establishing a regulatory body with effective independence in its decision-making (also the topic of a policy discussion during this mission).

It was agreed that a management system must provide confidence that the statutory obligations placed on the regulatory body are being fulfilled, and furthermore, that regulatory requirements are considered in conjunction with more general management to prevent safety being compromised. In other words, all management activities of the regulatory body put safety first.

The expert reviewers indicated that management system models exist which may easily be adopted by Malta, but in circumstances where the necessary organizational reform of the regulatory body, including the legal provision for its effective independence are already in place. Until this is achieved however, a great deal can be done to establish management processes and procedures to improve the efficiency and effectiveness of the RPB as currently structured, particular policies, procedures and document management. In this regard, the assistance of the IAEA can be requested.

The small size of the regulatory body for Malta does create some unique challenges. However, it was agreed that regulatory issues can be managed in an effective manner providing essential legal and organization reforms are implemented, including the following:

- A legal framework within which the regulatory body has clear responsibilities for the discharge of the full range of regulatory functions.
- A re-organization of the regulatory body structure, with dedicated staff having the necessary skills, competences and experience to perform the required functions in line with IAEA requirements and EU Directives.
- Assignment of the regulatory body as the competent authority for Malta's commitments and obligations internationally in terms of nuclear and radiation safety.
- The necessary agreements such as MoUs, with other organizations, nationally and internationally, having commitments and obligations relating to nuclear and radiation safety, including conventions and treaties.
- An appropriate route of accountability to government, taking into account the issues of effective independence.

- Financial resources assigned to and managed by the regulatory body; andA formal management system.

APPENDIX 1 LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS			
1.	**MAGNÚSSON** Sigurður	Icelandic Radiation Safety Authority	smm@gr.is
2	**BLY** Ritva	Radiation Practices Regulation; Radiation and Nuclear Safety Authority (STUK)	Ritva.Bly@stuk.fi
3.	**DELRUE** Andrée	Autorité de Sûreté Nucléaire - division de LILLE	Andree.DELRUE@asn.fr
4.	**TOMÁS ZERQUERA** Juan	Centro de Protección e Higiene de las Radiaciones (CPHR)	cphrjtomas@ceniai.inf.cu
5.	**ZOMBORI** Peter	Senior Expert, Hungary	Petezombori@gmail.com
6.	**TIRMARCHE** Margot	Autorité de Sûreté Nucléaire (ASN)	Margot.TIRMARCHE@asn.fr
IAEA STAFF MEMBERS			
1.	**Evans** Stephen	Division of Radiation, Transport and Waste Safety	S.Evans@iaea.org
2.	**SWOBODA** Zumi	Division of Radiation, Transport and waste Safety	Z.Swoboda@iaea.org
LIAISON OFFICER			
1.	**BREJZA** Paul	Liaison Officer	paul.brejza@gov.mt

APPENDIX II MISSION PROGRAMME

Daily Programme: IRRS Mission, Malta, 22 February – 03 March 2015									
Malta IRRS	Morning					Afternoon / evening			
	9:00-10:00	10:00-11:00	11:00-12:00	12:00-13:00	13:00-14:00	14:00-15:00	15:00-17:00	17:00-18:00	
Sat 21 Feb	*Arrival of Team Members*								
Sun 22 Feb	*Arrival of Team Members*			**Casual lunch**		**Venue:** OHSA, 17 Edgar Ferro Street, Pieta **Initial Team Meeting** (full IRRS Team + OHSA IRRS Liaison Officer)			
Mon 23 Feb	**Venue:** Ministry, Valletta **IRRS Entrance Meeting** (Full IRRS Team, host officials of government, RB and other organizations)			**Venue:** Ministry **Lunch** (IRRS Team and Counterparts)		**Venue:** OHSA, Pieta, Meeting rooms grd floor **Modules 1, 2**: Introduction - continue at Ministry - 24 Feb. IAEA (Full IRRS Team) OHSA (PB+JC) **Module 3:** IAEA (Full IRRS Team) OHSA (PB+JC) **Venue:** OHSA, Pieta, Meeting rooms grd floor **Module 10:** (*after Modules 1, 2, 3 Discussions):* IAEA (PZ) OHSA (PB) + other orgs (CPD)		**Venue:** OHSA Pieta Board Rm Daily IRRS Team meeting *(including Malta Liaison Officer)*	
Tue 24 Feb	**Venue:** OHSA, Pieta Ground floor meeting rooms **Module 10** (EPR)**:** IAEA (PZ) OHSA (PB) + other orgs **Module 11** (Patient Protection): IAEA (RB + AD) OHSA (PB) + others **Venue:** OHSA Pieta Ground floor meeting rooms			**Lunch as convenient**		**Venue:** Ministry, Valletta **Visit to Ministry** : **Modules 1, 2, 3:** IAEA (TL + TC + MT) **Venue:** OHSA, Pieta, Meeting rooms grd floor		**Venue:** OHSA, Pieta, Board Rm Daily IRRS Team meeting *(including Malta Liaison Officer)*	

Daily Programme: IRRS Mission, Malta, 22 February – 03 March 2015

Malta IRRS	Morning					Afternoon / evening			
	9:00-10:00	10:00-11:00	11:00-12:00	12:00-13:00	13:00-14:00	14:00-15:00	15:00-17:00	17:00-18:00	
	Modules 5, 6, 7, 8, 9: IAEA (Full IRRS Team) OHSA (JC and PB as required)				**Module 11** (Patient protection)**:** IAEA (RB + AD) OHSA (PB + JC + Health)				
Wed 25 Feb	**Venue: Hospital PET facility** **Site visit to Medical Facility:** IAEA (RB + JTZ + MT) OHSA (PB) **Venue: Industrial NDT Company** **Site visit to Industrial Facility:** IAEA (AD + TL + PZ) OHSA (JC)			**Lunch as convenient**	**Venue:** OHSA, Pieta, Meeting rooms grd floor **Module 11** (Occupational RP)**:** IAEA (AD + RB + MT) OHSA (JC) **Venue:** OHSA, Pieta, Meeting rooms grd floor **Module 11** (Control of discharges, Enviro' monitoring)**:** IAEA (JTZ + AD + MT) OHSA (PB + MEPA)			**Venue:** OHSA, Pieta, Board Rm Daily IRRS Team meeting *(including Malta Liaison Officer)*	
Thu 26 Feb	**Venue:** OHSA Pieta Ground floor meeting rooms **Module 4** (Mgt System)**:** IAEA (TL + TC + MT) OHSA (PB +JC)			**Lunch as convenient**	**Venue:** OHSA, Pieta **Follow-up discussions with counterparts as needed** (Full IRRS Team)			**Venue:** OHSA, Pieta, Board Rm Daily IRRS Team meeting *Recommendations, suggestions and good practice*	
Fri 27 Feb	**Venue:** OHSA Pieta Board Room **Preliminary draft IRRS Report preparation** (Full IRRS Team)			**Lunch as convenient**	**Venue:** OHSA, Pieta, Board Rm **Preliminary draft IRRS Report preparation**				

Daily Programme: IRRS Mission, Malta, 22 February – 03 March 2015

Malta IRRS	Morning					Afternoon / evening			
	9:00-10:00	10:00-11:00	11:00-12:00	12:00-13:00	13:00-14:00	14:00-15:00	15:00-17:00	17:00-18:00	
Sat 28 Feb	**Venue:** OHSA Pieta Board Room **Cross-reading** and **finalizing preliminary draft** (Full IRRS Team) (Review copy to OHSA by 14:00)					Working lunch and finalizing details of the report			
Sun 01 Mar	**OHSA review** of preliminary draft IRRS report								
	IRRS Team - Social Programme 9:00-17:00 including lunch hosted by OHSA at Seabank Hotel, Mellieha								
Mon 02 Mar	**Venue:** OHSA Pieta Board Room **OHSA / IRRS Team:** **Discussion** on OHSA draft IRRS comments			**Venue:** OHSA Pieta Board Room **IRRS Team report finalization**		**Working lunch**	**Venue**: OHSA, Pieta, Board Rm IRRS Team **report finalization** + **handover** to OHSA		
Tue 03 Mar	**Venue:** OHSA Pieta Board Room **IRRS Exit meeting:** (Full IRRS Team, host officials of government, RB and other organizations)			**Close of Mission**					

APPENDIX III SITE VISITS

1. Medical - Hospital PET

2. Industrial - NDT Company

APPENDIX IV LIST OF COUNTERPARTS

IRRS EXPERTS	COUNTERPART
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	
Sigurður M Magnússon Margot Tirmarche Steve Evans	Paul Brejza Joe Cremona
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	
Sigurður M Magnússon Margot Tirmarche Steve Evans	Paul Brejza Joe Cremona
GLOBAL NUCLEAR SAFETY REGIME	
Sigurður M Magnússon	Paul Brejza Joe Cremona
MANAGEMENT SYSTEM	
Sigurður M Magnússon Ms Margot Tirmarche Steve Evans	Paul Brejza Joe Cremona
AUTHORIZATION	
Ritva Bly Andrée Delrue Juan Tomás Zerquera	Paul Brejza Joe Cremona
REVIEW AND ASSESSMENT	
Ritva Bly Andrée Delrue Juan Tomás Zerquera	Paul Brejza Joe Cremona
INSPECTION	
Ritva Bly Andrée Delrue Juan Tomás Zerquera	Paul Brejza Joe Cremona
ENFORCEMENT	
Ritva Bly Andrée Delrue Juan Tomás Zerquera	Paul Brejza Joe Cremona

IRRS EXPERTS	COUNTERPART
REGULATIONS AND GUIDES	
Ritva Bly Andrée Delrue Juan Tomás Zerquera	Paul Brejza Joe Cremona
EMERGENCY PREPAREDESS AND RESPONSE	
Peter Zombori	Paul Brejza Albert Tabone Joe Grima
ADDITIONAL AREAS - Medical Exposure	
Ritva Bly Andrée Delrue Juan Tomás Zerquera	Paul Brejza Clive Tonna Dr Richard Zammit (SPH) Tilluck Bhikha Christine Baluci Mark Zammit
ADDITIONAL AREAS - Occupational Exposure	
Ritva Bly Andrée Delrue	Joe Cremona
ADDITIONAL AREAS – Environmental Monitoring associated with authorized Practices	
Juan Tomás Zerquera	Paul Brejza Kevin Mercieca
ADDITIONAL AREAS – Control of discharges	
Juan Tomás Zerquera	Paul Brejza Kevin Mercieca Matthew Yeomans

APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	**RESPONSIBILITIES AsND FUNCTIONS OF THE GOVERNMENT**	R1	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.
		R2	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.
		R3	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.
		R4	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.

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
2.	**GLOBAL NUCLEAR SAFETY REGIME**	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.
		S1	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.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	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.
		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 facitlites and activities in Malta, together with Malta's responsibilities for, and contribution to nuclear and radiation safety internationally.
		R7	The regulatory body should establish formal and informal mechanisms of communication with authorized parties on all safety related issues.
		R8	The regulatory body should extend its national registers to include records of the occupational exposure history of each worker.
		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.

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	R10	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.
5.	**AUTHORIZATION**	R11	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.
		R12	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.
		S3	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.
6.	**REVIEW AND ASSESSMENT**	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.	**INSPECTION**	R14	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.
		R15	The regulatory body should implement a process that follows specified procedures to ensure the stability and the consistency of

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			regulatory control and to prevent subjectivity in decision.
8.	**ENFORCEMENT**		
9.	**REGULATION AND GUIDES**	R16	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.
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	S4	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.
		S5	The regulatory body should consider modifying its emergency classification system to be consistent with the classification given in GS-R-2.
		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.
		S7	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.

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R17	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.
		R18	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.
		R19	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.
		R20	The regulatory body should develop regulatory requirements for EPR quality assurance programme to be established and maintained by the licensees.
11a.	**CONTROL OF MEDICAL EXPOSURES**	R21	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.
		R22	The regulatory body should regulate asymptomatic exposures.
		R23	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 of the radiation risks.
		R24	The regulatory body should amend regulations to include a requirement that an appropriately specialized medical physicist be

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			involved in interventional radiology or therapeutic procedures.
		R25	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.
		R26	The regulatory body should revise the regulations on dosimetry and calibration of equipment as well as responsibilities of medical physicists in accordance with international best practice.
		R27	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.
		R28	The regulatory body should add a requirement in regulations such that patients or their legal reprenetatives are required to be informed of unintended exposures.
		R29	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.
11b.	**OCCUPATIONAL RADIATION PROTECTION**	R30	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.
		R31	The regulatory body should add a requirement in regulations such that people under the age of 16 could not be expsosed to occupational exposure.

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R32	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.
		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.
		R34	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 between the parties, with appropriate allocation of responsibilities clearly documented.
		R35	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.
		R36	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.
		R37	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.
		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.

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R39	The regulatory body should add requirements in regulations about the contents of records both for individual and workplace monitoring.
11c	**CONTROL OF DISCHARGES, MATERIALS FOR CLEARANCE, AND CHRONIC EXPOSURES; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION**	R40	The regulatory body should implement a procedure for approval of discharge limits in compliance with relevant requirements in GSR Part 3.
		R41	The regulatory body should establish in Maltese regulations criteria for clearance.
		R42	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.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

1.	IAEA - Position statement radionuclide therapy Feb 2010.pdf
2.	Malta Freeport Dangerous Goods Policy.pdf
3.	MOU-RPB-Customs signed on 6 July 2011.pdf
4.	Radon study for Malta published 1997 in Xjenza.pdf
5.	Radon study for Malta published 2013 in Malta Medical Journal.pdf
6.	RaSSIA Final Report of 2005.pdf
7.	Regulation - Comprehensive Nuclear Test Ban Treaty LN 156 of 2001 (SL 365.11).pdf
8.	Regulation - Control and Security of High-Activity Radioactive and Orphan Sources LN 13 of 2006 (SL 365.21).pdf
9.	Regulation - Control and Security of High-Activity Radioactive and Orphan Sources Regulations LN 13 of 2006 (SL 365.21).pdf
10.	Regulation - Convention on Nuclear Safety Regulations LN 440 of 2007 (SL 365.26).pdf
11.	Regulation - Dual-Use Items (Export Control) Regulations LN 416 of 2004 (SL 365.12).pdf
12.	Regulation - Freedom of Access to Information on the environment regulations LN 116 of 2005 (SL 504.65).pdf
13.	Regulation - General Provisions for Health and Safety Regulations LN 36 of 2003 (SL 424.18).pdf
14.	Regulation - Importation Control Regulations LN 242 of 2004 (SL 117.14).pdf
15.	Regulation - Management of Radioactive Waste Regulations LN 186 of 2013 (SL 365.45).pdf
16.	Regulation - Medical Devices Regulations LN 210 of 2008 (SL 427.44).pdf
17.	Regulation - Medical Exposure (Ionising Radiation) Regulations LN 353 of 2012 (SL 465.01).pdf
18.	Regulation - Merchant Shipping (Safety Convention) Rules LN 22of 2003 (SL234.30).pdf
19.	Regulation - Minimum Requirements for the use of Personal Protective Equipment at Work LN 121 of 2003 (SL424.21).pdf
20.	Regulation - Motor Vehicles (Carriage of Dangerous Goods by Road) Regulations LN 211 of 2003 (SL 65.22).pdf
21.	Regulation - Nuclear Safety and Radiation Protection (Amendment) Regulations LN 187 of 2013 (SL 365. 15).pdf
22.	Regulation - Nuclear Safety and Radiation Protection Regulations LN 44 of 2003 (SL 365.15).pdf
23.	Regulation - Protection of Maternity at Work Places Regulations LN 92 of 2002 (SL 424.11).pdf
24.	Regulation - Protection of Young Persons at Work Places Regulations LN 91 of 2000 (SL 424.10).pdf
25.	Regulation - Radiological Emergency (Information to the Public Regulations) LN 245 of 2002 (SL 411.02).pdf
26.	Regulation - Waste Management (Supervision and Control of Shipments of Rad Waste and SF) LN 48 of 2009 (SL 504.38).pdf
27.	Regulation- Air Navigation (Dangerous Goods) Regulations LN 233 of 2006 (SL 499.44).pdf
28.	Regulation Importation Control Regulations LN 242 of 2004 SL 117 14.pdf
29.	Regulation -Personal Protective Equipment Regulations LN 371 of 2002 (SL 427.38).pdf
30.	Regulation -Treaty on the Non-Proliferation of Nuclear Weapons (Euratom Safeguard and AP) LN 182 of 2007 (SL 365.20).pdf
31.	RPB 01 General Notification Form.pdf
32.	RPB 03 Dental Notification Form.pdf

33.	RPB 04 Vet Notification Form.pdf
34.	RPB 05 Notification of site work.pdf
35.	RPB 11 Unsealed source import.pdf
36.	RPB 1493-93 Form.pdf
37.	RPB Diagrammatic Structure of the Radiation Protection Board.pdf
38.	RPB Medical Checklist.pdf
39.	RPB Occupational Checklist.pdf
40.	RPB-OP-HL-2013-1 RPB High Level Operating Procedure.pdf
41.	RPB-OP-S-Control of Radioactive Discharges-2014-1.pdf
42.	RPB-OP-S-ECURIE response.pdf
43.	RPB Diagrammatic Structure of the Radiation Protection Board.pdf
44.	RPB-OP-S-Emergency Framework.pdf
45.	RPB-OP-S-Environmental Monitoring.pdf
46.	RPB-OP-S-ITDB Distribution of INFs.pdf
47.	RPB-OP-S-Regulation of Medical Establishments-2014-1.pdf
48.	RPB-OP-S-Safeguards Reporting.pdf
49.	RPB-OP-S-Transport-2014-1.pdf
50.	RPB-OP-S-Waste-2014-1 approved 3 Oct 14.pdf
51.	Sample authorization accumulate and discharge waste.pdf
52.	Act - Authority to Transport Act (CAP 499).pdf
53.	Act - Civil Protection Act (CAP 411).pdf
54.	Act - Environment and Development Planning Act (CAP 50

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

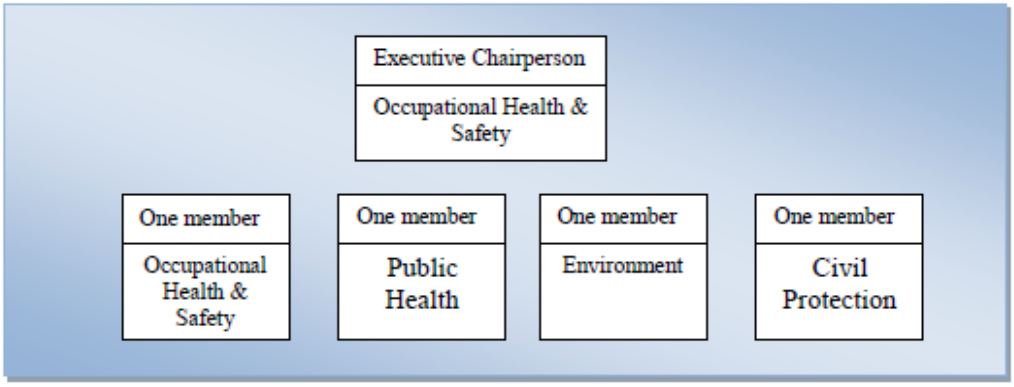
1. INTERNATIONAL ATOMIC ENERGY AGENCY - No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1 (Vienna2010)
3. INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for a Nuclear and Radiological Emergency Safety Requirement Series No. GS-R-2 IAEA Vienna (2002)
4. INTERNATIONAL ATOMIC ENERGY AGENCY The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3 IAEA, Vienna (2006)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, 2014 edition
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities Using Radioactive Material Safety, Safety Requirement Series No. WS-R-5, IAEA, Vienna (2006)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
13. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
14. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)
15. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
16. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
17. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)
18. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
19. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)
20. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)
21. INTERNATIONAL ATOMIC ENERGY AGENCY - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

APPENDIX VIII ORGANIZATIONAL CHART

Diagrammatic Structure of the Radiation Protection Board

The Radiation Protection Board (RPB) was set up as the national competent body for radiation protection and nuclear issues by the Nuclear Safety and Radiation Protection Regulations (Legal Notice 44 of 2003)

The internal structure of the RPB is show in the below diagram



Position of the Radiation Protection Board within the Maltese Administration