IAEA-NS-IRRS-2017/09

ORIGINAL: English

60 Years
IAEA Atoms for Peace and Development

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

REPUBLIC OF BOTSWANA

Gaborone, Botswana

15 to 24 October 2017

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA | Integrated Regulatory Review Service IRRS

Integrated
Regulatory
Review Service

IAEA | IRRS

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

Integrated Regulatory Review Service

IAEA | IRRS

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

Mission dates:	*15 to 24 October 2017*
Regulatory body visited:	*Radiation Protection Inspectorate*
Location:	*Gaborone, Botswana*
Regulated facilities and activities in the mission scope:	*Radiation Sources in Industrial and Medical Facilities, Waste Management Facilities, Decommissioning, Transport, Emergency Preparedness and Response, Medical Exposure, Occupational Exposure, Public and Environmental Monitoring*
Organized by:	*IAEA*

IRRS REVIEW TEAM	
KENNY Tanya	Team Leader (Ireland)
GELEEL Mohamed	Reviewer (Egypt)
LETZELTER Claire	Reviewer (France)
ÖHLÉN Elisabeth	Reviewer (Sweden)
REISNER Dominic	Reviewer (Austria)
SEVERA Reward	Reviewer (Zimbabwe)
SNEVE Malgorzata K.	Reviewer (Norway)
SOUFI Itimad	Reviewer (Morocco)
STEWART James	Reviewer (United Kingdom)
AL KAHTIBEH Ahmad	IAEA Team Coordinator
TOMAS ZERQUERA Juan	IAEA Review Area facilitator
SWOBODA Zumi	IAEA Administrative support

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

CONTENTS

EXECUTIVE SUMMARY

At the request of the Republic of Botswana, an international team of senior nuclear and radiation safety experts met with representatives of the Radiation Protection Board (RPB) and Radiation Protection Inspectorate (RPI) of the Ministry of Tertiary Education, Research, Science and Technology from 15 to 24 October 2017 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the IRRS mission was to perform a peer review of Botswana's national regulatory framework for nuclear and radiation safety against IAEA safety standards as the international benchmark for safety. The IRRS team received full cooperation from all parties in an open and transparent manner throughout the mission. The mission took place at the RPI Headquarters in Gaborone.

The IRRS team concluded that Botswana has made significant progress since the first IRRS mission they hosted in 2008 and it has a regulatory framework for safety in place and a strong commitment to nuclear and radiation safety as demonstrated during the mission.

RPI, through self-assessment, has identified some challenges that it faces. These challenges have been recognized by the Government and measures are underway to address them. It is necessary that the Government continues to support and provide resources to complete these important activities in a timely manner to ensure that effective regulatory oversight over all facilities and activities is established. In particular, focus should be directed towards continued building of RPI's technical capabilities and updating regulations and procedures for all activities and emergency preparedness and response.

The country has a long history in the use and regulation of ionizing radiation in medical and industrial applications, as well as in research and science. Notwithstanding, there are still challenges to be resolved related to the consistent and effective regulation of the use of ionizing radiation sources.

The IRRS team identified 4 good practices and also made recommendations and suggestions to indicate where improvements are necessary or desirable to further enhance and more closely align the regulatory framework with IAEA safety standards. The IRRS team noted that many of these areas had been identified by RPI prior to the mission and addressed in its action plan.

The good practices identified by the IRRS team include:

- Safety culture is an integrated part of the management system and RPI has recently assessed the technical staff´s experience on the safety culture aspects including leadership for safety.
- Through participation in a wide range of international instruments and bilateral and multilateral arrangements, as well as International Peer Reviews Botswana strongly recognizes the importance of International cooperation in relation to safety in contributing to the development of a global safety regime.
- RPI has established goals and strategies that are consistent with overall safety policy and the Strategic Plan of the Ministry.
- RPI has a system for providing information on transport operations by the shippers which improves knowledge of facilities and activities that should be regulated and as a result enables effective management of resources.

The IRRS team made observations that warrant additional emphasis. Specifically:

- The Government should establish and implement national policies and strategies for safety and for waste management, which achieve the fundamental safety objective and includes decommissioning, remediation and disposal and expresses long-term commitment to safety.
- The Government should ensure the legal and regulatory framework enables the effective independence of RPB and it is not subjected to pressures associated with political circumstances.
- RPB should initiate a process for reviewing and updating the regulations and guides to achieve consistency with the latest version of IAEA safety standards.
- The Government should develop an emergency plan at the national level to address nuclear and radiological emergencies, in a coordinated and integrated manner with other relevant national plans.
- The Government should make provisions for building and maintaining competence of all parties having responsibilities to the safety of facilities and activities, including provisions for ensuring the appropriate availability of medical physicists.

The IRRS mission covered all civilian nuclear and radiation facilities and activities regulated in Botswana. The mission was also used to exchange information and experience between the IRRS team members and the Botswana counterparts in the areas covered by the IRRS.

The IRRS team consisted of 9 senior experts from 9 IAEA Member States, 3 IAEA staff members. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; transport; control of medical exposures; occupational radiation protection; control of radioactive discharges and materials for clearance; environmental monitoring for public radiation protection purposes and control of chronic exposures and remediation.

The mission included observations of regulatory activities and interviews and discussions with Hon. Mr Fidelis M. Molao, Assistant Minister of Tertiary Education, Research, Science and Technology, Chairperson of the Radiation Protection Board, Ambassador Mr Molosiwa Selepeng and RPI senior management and staff. Activities included visits to the Gaborone private hospital, oncology centre (brachytherapy clinic) and Temporary storage facility for confiscated sealed sources (operated by Regulatory body).

The IRRS team observed the regulated activities and performance of inspection activities, and held discussions with the licensee's staff and management.

In preparation for the IRRS mission Botswana conducted a self-assessment and prepared a preliminary action plan to address the challenges that were identified. The results of the self-assessment, action plan and supporting documentation were provided to the IRRS team as advance reference material for the mission.

The IRRS team findings are summarized in Appendix V.

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

I. INTRODUCTION

At the request of the Government of the Republic of Botswana, an international team of senior safety experts met representatives of the Radiation Protection Inspectorate (RPI) of the Ministry of Tertiary Education, Research, Science and Technology (the Ministry) from 15 to 24 October 2017 to conduct an Integrated Regulatory Review Service (IRRS) Mission. The purpose of this peer review was to review Botswana's regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of the Republic of Botswana August 2015. A preparatory mission was conducted from 28 to 29 March 2017 at RPI Headquarters in Gaborone to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in The Republic of Botswana and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS team consisted of 9 senior regulatory experts from 9 IAEA Member States and 3 IAEA staff members. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, control of medical exposure, public and environmental exposure control, transport of radioactive material, waste management and decommissioning.

RPI did not have any policy issues that hindered their work as regulators.

In preparation for the mission RPI conducted a self-assessment and prepared a preliminary action plan. The results of RPI self-assessment and supporting documentation were provided to the IRRS team as advance reference material for the mission. During the mission the IRRS team performed a systematic review of all topics within the agreed scope through review of the advance reference material, conduct of interviews with management and staff from RPI and direct observation of working practices during conduct of a regulatory inspection. Meetings with the Assistant Minister Honourable Fidelis M. Molao and Acting Permanent Secretary Dr Kekgonne Baipoledi of the Ministry of Tertiary Education, Research, Science and Technology and the Chairperson of the Radiation Protection Board (RPB), His Excellency Ambassador Mr Molosiwa Selepeng were also organized.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review The Republic of Botswana's radiation and nuclear safety regulatory framework and activities against the relevant IAEA safety standards to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS review included all facilities and activities regulated in Botswana.

It is expected this IRRS mission will facilitate regulatory improvements in Botswana and other Member States, utilizing the knowledge gained and experiences shared between RPI and the IRRS reviewers and the evaluation of the effectiveness of Botswana's legal and regulatory framework for radiation safety, including its good practices.

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

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other states with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among states;

j) promoting the application of IAEA Safety Requirements; and

k) providing feedback on the use and application IAEA safety standards.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Botswana, a preparatory meeting for the IRRS was conducted from 28 to 29 March 2017. The preparatory meeting was carried out by the appointed Team Leader Ms Tanya Kenny, and the IRRS IAEA Team Coordinator, Mr Ahmad Al Khatibeh.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of RPI represented by Mr Thapelo Otukile, Director and National Liaison Officer (NLO), other senior management and staff. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides;

- Waste management facilities;
- Decommissioning;
- Radiation sources facilities and activities;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and Environmental exposure control;
- Selected policy issues.

RPI made presentations on the national context, the current status of RPI and the self-assessment results to date.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the tentative work plan for the implementation of the IRRS in Botswana in October 2017. The proposed composition of the IRRS team was discussed and tentatively confirmed. Logistics including meeting and work places, counterparts and Liaison Officer identification, proposed site visits, lodging and transportation arrangements were also addressed.

The RPI Liaison Officer for the IRRS mission was confirmed as Mr Richard Shamukuni.

RPI provided IAEA with the advance reference material (ARM) for the review in preparation for the mission, the IRRS team members reviewed the advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday, 15 October 2017 in Gaborone, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS programme. The

understanding of the methodology for review was reinforced. The agenda for the mission was presented to the Team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

The host Liaison Officer was present at the Initial Team Meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The Entrance Meeting was held on Monday, 16 October, 2017, with the participation of the Acting Permanent Secretary of the Ministry Dr Kekgonne Baipoledi and the Chairperson of the Radiation Protection Board – Ambassador Mr Molosiwa Selepeng; representative from National Disaster Management Office - Mr Nkosiyabo F. Moyo, and RPI senior management and staff. Opening remarks were made by Acting Permanent Secretary, and Ahmad Al Khatibeh IRRS Team Coordinator. Ms Tanya Kenny, IRRS Team Leader gave a presentation on the expections of the IRRS Mission. Mr Richard Shamukuni gave an overview of RPI activities and results of the self-assessment and the action plan.

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

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

The Exit Meeting was held on Tuesday, 24 October 2017. The opening remarks at the exit meeting were presented by Mr Oupa Masesane, Deputy Permanent Secretary, Ministry of Tertiary Eduction, Research, Scient and Technology and were followed by the presentation of the results of the mission by the IRRS Team Leader Ms Tanya Kenny. Closing remarks were made by Mr Peter Johnston, Director, Division of Radiation, Transport and Waste Safety, IAEA.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Government has established a legal and regulatory framework for safety, however, the Government has not yet established a national policy and strategy for safety that describes the fundamental safety objective, the international commitment to safety, the framework for safety, the commitment for adequate human and financial resources and the promotion of leadership and management for safety, including safety culture. RPI has identified this within its Action Plan and informed the IRRS team that it plans to propose to the government to develop a national strategy starting in January 2018.

RECOMMENDATIONS, SUGGESTIONS, AND GOOD PRACTICES	
Observation: There is no national policy and strategy for safety.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 1 states that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 1, para. 2.3 states that** *"the national policy and Strategy for Safety shall express a long term commitment of safety. The national policy shall be promulgated as a statement of the government's intent."*
R1	**Recommendation: The Government should establish and implement a national policy and strategy which achieves the fundamental safety objective.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The legal system in Botswana is set up of a three-tier system of government consisting of legislative, executive and judiciary. The constitutional law empowers parliament to pass laws, the executive power rests with the President and the Cabinet.

The High Court represents the highest judicial level in the country. It has the final decision regarding appeals and has the power to review a law to ensure its constitutionality.

The fundament for the framework for nuclear and radiation safety in Botswana is the *"Radiation Protection Act"* (the Act) passed by the National Assembly in July 2006. The Act provides for the safe use of atomic energy and nuclear technology and for matters incidental thereto. It also lays down the basic principles for radiation protection and applies '*to any person or body of persons whose undertaking involves or includes generally the use of atomic energy or nuclear technology and, in particular, the production, processing, handling, use, holding, possessing, storage, transport and disposal of natural and artificial radioactive materials and radiation devices in respect of any other activity, which involves a risk or harm arising from radiation'*.

The then responsible Minister for Communication, Science and Technology has issued regulations with regard to:

- Administrative Requirements;
- Radiation Protection Performance Requirements;
- Management Requirements;
- Verification of Protection and Safety;
- Occupational Exposure Protection;
- Classification of Areas;
- Medical Exposure Protection;
- Public Exposure Protection;
- Requirements for the safety of sources;
- Radioactive Waste Management Requirements.

The Act and the Regulations establish the regulatory body, specify the types of regulated facilities and activities, empower the regulatory body for development and promulgation of regulatory requirements, require authorization for the operation of facilities and for the conduct of activities, and provide for the inspection and enforcement.

The Act requires that any person who wants to *"acquire, own possess, transfer, distribute…"* needs to be licensed by the Board, but does not provide for a graded approach. The Regulations, however, provide for a graded approach to authorization with the ability to have registration and licensing mechanisms commensurate with risk, which is in conflict with the Act. RPI currently uses licensing as the only form of authorization.

In addition, the Act does not provide the Board with the possibility to delegate certain aspects of its power to RPI. As the Board meets four times a year, this potentially could lead to late delays in issuing authorizations for facilities and activities.

The Act refers exclusively to "natural persons" while the Regulations allow "legal persons" to hold a license to engage with or possess a radiation source. This again constitutes a discrepancy as the Regulations provide for a legal definition that is not in the Act.

The Act does not have provisions regarding the termination of licenses at the end of an activity, nor does it provide for rules regarding the safe decommissioning of facilities and remediation of sites, the safe management and disposal of radioactive waste arising from facilities and activities.

RECOMMENDATIONS, SUGGESTIONS, AND GOOD PRACTICES
Observation 1: The Act does not provide for a graded approach while the Regulations provide for a graded approach to authorization with the ability to have registration and licensing mechanisms commensurate with risk, which contradicts the Act.
Observation 2: The Act does not provide the Board with the power to delegate its power to authorize to RPI, which may delay issuing authorizations in a timely manner.
Observation 3: The Act stipulates that only natural persons may hold a licence while the Regulations allow for issuing licences to legal persons. This constitutes a contradiction between the Act and the Regulations.
Observation 4: The Act does not have provisions for the termination of licences at the end of an activity.

RECOMMENDATIONS, SUGGESTIONS, AND GOOD PRACTICES	
Observation 5: The Act does not contain provisions for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities and does not address remediation.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 2, para. 2.5 (3) states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *The type of authorizations that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;"*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 16 states that** *"The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities."*
(3)	**BASIS: Safety Fundamentals Principle 1, para. 3.4 states that** *"Authorization to operate a facility or conduct an activity may be granted to on operating organization or to an individual, known as the licensee."*
(4)	**BASIS: GSR Part 1 (Rev 1) Requirement 2, para. 2.5 (16) states that** *"The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *…* *The criteria for release from regulatory control."*
(5)	**BASIS: GSR Part 1 (Rev 1) Requirement 10 states that** *"The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities and the safe management of spent fuel."*
(6)	**BASIS: GSR Part 1 (Rev 1) Requirement 6 para. 2.15 states that** *"This prime responsibility for safety includes, as appropriate, responsibility for the management of radioactive waste and the management of spent fuel, and responsibility for the remediation of contaminated areas."*
R2	**Recommendation: While amending the Act, the Government should ensure that:** • **the types type of authorizations that are required for the operation of facilities and for the conduct of activities, in accordance with a graded approach, are clearly stated.** • **the regulatory body is enabled to perform its functions more effectively by allowing the Board to delegate certain powers to RPI.**

RECOMMENDATIONS, SUGGESTIONS, AND GOOD PRACTICES	
	• **all organizations or individuals, natural or legal, who may be authorized to operate a facility or conduct an activity are covered.** • **criteria for release from regulatory control are established.** • **provisions for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities are included, and responsibility for the remediation of contaminated areas.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Act has established the Radiation Protection Board (RPB, or the Board) and the Radiation Protection Inspectorate (RPI). RPB, amongst other tasks, is empowered to authorize the peaceful use of atomic energy and nuclear technology, in particular the production, processing, handling, import, export, possession, storage, use, transport and disposal of radioactive material and related substances.

The Board constitutes of seven members. The Act empowers the Minister of Tertiary Education, Research, Science and Technology (Minister) to appoint the Chairperson and the members of Board. The IRRS team was informed that whenever there is a vacancy in the Board, RPI, provides a qualification profile to the Public Enterprises, Evaluation and Privatization Agency (PEEPA) who is tasked to find qualified candidates for the opening. PEEPA identifies three to five suitable candidates through interviews and evaluations and submits the results to RPI who in turn make recommendations to the Minister. However, there is no legal requirement for this procedure nor are there are legal requirements in regards to the necessary qualifications Board members must possess.

The Act implies that the Board may not receive directives with regards to its regulatory decisions. However, the Minister may give directions of a general character, to which the Board can issue a written reply as to why the directives can or cannot be implemented.

The Minister may remove Board members from office. The Act provides several grounds on which the Minister may remove Board members if they:

- are absent without reasonable cause from three consecutive meetings;
- are physically or mentally incapable of performing their duties efficiently;
- contravene the provisions of this Act or otherwise misconducts themselves;
- have failed to comply with any disclosure of interest;
- are inefficient.

As stated above, the Minister may remove a Board member if he considers them “inefficient”. The Act provides no guidelines as to what behaviours are considered “inefficient”. The lack of legal descriptions of what constitutes inefficiency gives the Minister broad discretionary powers regarding the removal of Board members, which may negatively impact the independent safety related decisions of the Board.

The Board is the only body under the Act authorized to issue licences, RPI conducts inspections and prepares decisions, but is not empowered to issue licences nor can the Board delegate that power to RPI under the Act. As the Board normally meets only four times a year this may lead to long waiting periods for the processing of applications. The IRRS team was

informed that for the upcoming meeting of the Board in November 2017, there are already 54 applications to be reviewed. The Act permits the Board to meet as often as necessary, however, this has happened only once in the last three years where the Board met five times in 2014.

RPI is led by a Director and according to the Public Service Act the Permanent Secretary is the supervising officer of the Director and both sides enter into a performance contract. The Permanent Secretary may issue directives to the Director and has the power to suspend him/her. According to the Act, the Director reports to the Board on all matters related to the regulatory functions of RPI.

As the Director reports to the Board and to the Permanent Secretary and may get conflicting instructions, this structure may impede the effective independence of RPI as there is the possibility for members of government not directly in charge of regulatory activities to influence their outcome and does not comply with international standards.

The IRRS team was informed that in addition to his role as head of RPI, the Director has been appointed by the Permanent Secretary as National Liaison Officer for Technical Co-operation (NLO) between Botswana and IAEA. This makes the Director the national contact point who is involved in several projects from various ministries concerning the promotion and use of nuclear technology. The role of the NLO is to promote the peaceful use of nuclear applications. Caution needs to be observed that while performing his duties as NLO his role as Director of RPI is not compromised.

RECOMMENDATIONS, SUGGESTIONS, AND GOOD PRACTICES	
Observation: The Minister is empowered to appoint and remove Board members including the chairperson. The removal on grounds of inefficiency gives broad discretionary powers to the Minister, which may negatively impact the effective independence of RPB.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 4 states that** "*The government shall ensure that the regulatory body is effectively independent in its safety related decision making …*"
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 4, para. 2.8 states that** *"the regulatory body shall be able to make independent regulatory judgements and regulatory decisions…shall be free from any pressures associated with political circumstances or economic conditions, or pressures from government departments…shall be able to give independent advice."*
R3	**Recommendation: The Government should ensure the legal and regulatory framework enables the effective independence of RPB and it is not subjected to pressures associated with political circumstances.**

RECOMMENDATIONS, SUGGESTIONS, AND GOOD PRACTICES	
Observation: The Director of RPI reports to the Board and to the Permanent Secretary in the Ministry. This could potentially lead to receiving conflicting instructions.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 2 states that** "*The government shall*

RECOMMENDATIONS, SUGGESTIONS, AND GOOD PRACTICES	
	establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated".
R4	**Recommendation: The Government should ensure that the legal and regulatory framework for safety clearly allocates the responsibilities to all involved.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The Regulations clearly assign the prime responsibility to the licensee to establish and implement organizational measures that are needed for ensuring protection and safety for the practices and sources for which they are authorized and for compliance with all applicable requirements of the regulations.

RPI may confiscate sources for safety reasons, in which case they store the sources in their temporary storage facility. A fine may be levied to the licensee for breaches of their authorization. The IRRS team was informed there are no charges indicated in the Act for storing sources after being confiscated

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

The Board is the only entity empowered by the Act to authorize nuclear safety and radiation protection aspects in Botswana, with the preparatory work on review and assessment being done by RPI. Regarding inspections and enforcement, the Act empowers RPI for these tasks.

In order to assist with the detection of unregulated sources RPI has signed a Memorandum of Understanding (MoU) with the Botswana Unified Revenue Service (BURS), which is responsible for border security and allows for mutual information and support. The IRRS team was informed that there is also close cooperation between RPI and other government departments, e.g. Police, and State security, with RPI requesting in writing support from departments where help is necessary.

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

The IRRS team was informed that the Government has established a system for protective actions through continuous checks both through inspectors and nineteen environmental monitoring stations situated at meteorological stations across the country to reduce undue radiation risks associated with unregulated sources. In case of elevated radiation levels, RPI would initiate an investigation. Furthermore, at seventeen ports of entry into the country, RPI has deployed twenty-two hand-held radiation detection equipment (Radeyes) to detect sources.

As described in Section 1.5, to further reduce the risk emanating from unregulated radiation sources, RPI cooperates formally with BURS, however the cooperation with other government institutions is not formalized yet.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: RPI cooperates with other branches of government to reduce the risk from

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
unregulated sources, but some of these arrangements are not formalized.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 9, para. 2.26 states that** *"the regulatory body] shall establish the regulatory requirements and criteria for protective actions in cooperation with the other authorities involved, and in consultation with interested parties, as appropriate."*
S1	**Suggestion: To further reduce the risk emanating from unregulated sources the Government should consider ensuring that all relevant authorities cooperate to achieve this.**

1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

Botswana does not have nuclear industry, research reactors or other facilities or activities generating significant amounts of radioactive waste. As required by the Act, licensees make arrangements to return sources when they no longer need them to suppliers and/or manufacturers. Botswana does not have a national centralized facility for storage of orphan, disused or damaged sealed sources in the cases where they are unable to return them to suppliers/manufactures. The IRRS team was informed that disused sources are temporarily stored at end-user facilities which may lack adequate security conditions and this has resulted in some sources being stolen.

Some disused sealed sources, together with some low level radioactive waste (arising from an accident with a stuck source in a mine) are stored in different places within facilities which are not licensed for this purpose. RPI has informed the Ministry of this situation and emphasised on the need for establishing national centralized storage facility. The Ministry has delegated the overall responsibility for the process of defining a site for and establishing the national storage facility to RPI. The budget has been allocated and the project is being implemented. These decisions will lead to a situation in which RPI as regulator will have to authorize and supervise itself as the operator of this facility.

A national policy and strategy for the management of radioactive waste, with provisions for decommissioning including disposal of radioactive waste and disused sealed sources, which expresses long term commitment to safety has not been established. Neither the Act nor the Regulations cover decommissioning of facilities, disposal of radioactive waste, and the issues associated with uranium mining and milling.

The IRRS team was informed that Botswana plans to initiate uranium mining in the country. RPI has reviewed the Environmental Impact Assessment (EIA) prepared for this purpose. The IRRS team noted that the EIA has addressed decommissioning and remediation of the expected NORM waste with the associated radioactive and chemical waste. However, neither the Act nor the Regulations have requirement for decommissioning fund to be established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no national policy and strategy for the management of radioactive waste, which includes provisions for decommissioning and remediation.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 1 states that** "*The government shall*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	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. *……* 2.3. *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. In the national policy and strategy, account shall be taken of the following:* *… (d) The need and provision for human and financial resources;"*
(2)	**BASIS: GSR Part 5 Requirement 2 states that** *"To ensure the effective management and control of radioactive waste, the government shall ensure that a national policy and a strategy for radioactive waste management are established."*
(3)	**BASIS: GSR Part 1 (Rev 1) Requirement 10 states that** *"The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel."*
(4)	**BASIS: GSR Part 3 Requirement 49: Para 5.11 states that** "*The government shall ensure that a strategy for radioactive waste management is put in place to deal with any waste arising from the remedial actions and that provision for such a strategy is made in the framework for protection and safety."*
R5	**Recommendation: The Government should establish a national policy and a strategy for radioactive waste management that includes decommissioning and disposal and expresses long term commitment to safety.**

1.8. COMPETENCE FOR SAFETY

The Government has made provisions in regard to building and maintaining the necessary level of competence for persons with responsibilities for safety in facilities and activities through the Regulations. The Regulations require the licensee to ensure that all personnel on whom protection and safety depend are appropriately trained and qualified with the requirement for periodical retraining. To build and maintain the competences in the radiation protection area, the IRRS team was informed that "Radiation Science and Health Physics programmes" are offered at the University of Botswana and the Botswana International University of Science and Technology.

The Regulations also require the qualification of the radiation safety experts to include a level of academic knowledge and of professional experience compatible with the levels of risks associated with the authorized practices or sources within a practice. Recognition of these experts is based on qualifications submitted to RPI of which there are currently five experts

recognized. However, there is no formal recognition process and criteria for these experts.

The Government makes a financial provision to the regulatory body (RPB and RPI) to ensure funding of strategy, including the development of competency. Furthermore, financial allocations are made to train staff from authorized parties.

The IRRS team was informed that there are certain skill sets and competences that have been identified of which there is a national shortage, for example medical physicists and senior radiation protection experts, which are key for the safe operation of licensed facilities and also a key competence for the regulator.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is a national shortage of specific competences such as medical physicists and senior radiation protection experts.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 11 states that** "*The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.*"
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 11 para 2.34 states that** "*As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available.*"
(3)	**BASIS: GSR Part 1 (Rev 1) Requirement 11 para 2.34 (b) states that** "*The government: Shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety.*"
R6	**Recommendation: The Government should make provisions for building and maintaining competence of all parties having responsibilities for the safety of facilities and activities.**

1.9. PROVISION OF TECHNICAL SERVICES

Botswana has made the necessary provisions for technical services relating to safety. The Government, through RPI, has made provisions for Dosimetry Services, Environmental Monitoring Services. In addition, an Instrumentation Laboratory undertakes calibration of instruments by outsourcing. According to RPI's Management System Manual technical service providers need to be certified through ISO.

1.10. SUMMARY

While Botswana has not established a national policy and strategy of safety RPI has recognized the need to provide one in its initial action plan.

A framework of safety has been established through the Act and the Regulations, a functioning regulatory body that Botswana may review according to the recommendations in this report.

Botswana has established RPB and RPI with clearly defined powers to carry out its regulatory

functions. However, there are clarifications necessary with regards to the effective independence of RPB and RPI.

Botswana has proactively engaged with Universities to encourage establishing courses in ‘Radiation Science and Health Physics’ to ensure the necessary competences are available within the country.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Botswana is a contracting party to a range of nuclear safety related international conventions and Agreements, including the:

- Convention on the Physical Protection of Nuclear Material (1991) and its amendment (2011);
- Convention on Early Notification of a Nuclear Accident (1991);
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1991);
- Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention (2001);
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (2001);
- Agreement between Botswana and the IAEA for the application of IAEA Safeguards and protocols additional to the Agreement.

As Botswana does not have any nuclear materials and there are no plans to have nuclear power plants or research reactors in the near future, it is currently not a contracting party to the Convention on Nuclear Safety (1997) however, there are plans to consider becoming party to the CNS at a future date. Botswana has subscribed to IAEA technical co-operation activities, some of which are complete and others, which are in progress.

The global nuclear safety regime for Botswana also includes international peer review. This is the second IRRS Mission to be undertaken in Botswana, the first being conducted in 2008. The value of the peer review is evident in the significant progress Botswana has made in establishing its legal and regulatory framework for nuclear and radiation safety.

Botswana also has a number of bilateral and multilateral agreements in place to enhance regional safety through harmonized approaches within the regions (Southern Africa) particularly around import and export of radiation sources. These include the Pelindaba Treaty and the IAEA Illicit Trafficking Database.

Botswana also participates in The African Regional Cooperative Agreement for Research, Development and Training Related to Nuclear Science and Technology (AFRA) agreement, which provides a framework for African Member States to intensify their collaboration through programmes and projects focused on the specific shared needs of its members. It is a formal inter-governmental agreement, which entered into force in 1990.

RPI also participates in the Southern African Regulators Network SADC-NRN where there is a memorandum of cooperative agreement in draft form. The promotion of participation in SADC nuclear regulators Network has been identified in the action plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: Botswana is a contracting party to a wide range of nuclear safety related international conventions and agreements and has a number of bilateral and multilateral

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
agreements in place and participates in international peer reviews that enhances safety through harmonized approaches.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 14 states that** *'The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally'*
GP1	**Good Practice: Through participation in a wide range of international instruments and bilateral and multilateral arrangements, as well as International Peer Reviews Botswana strongly recognizes the importance of International cooperation in relation to safety in contributing to the development of a global safety regime.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

RPI staff participate in IAEA organized training events which also provide good opportunities for experience exchange and lessons learned and as a means for establishing strong international relationships and performing common projects. The IRRS team was informed that RPI has learned and improved its regulatory framework through these training events.

Internally, RPI uses reports from staff returning from these training events to provide feedback of regulatory experience in other States to the regulatory body. RPI Staff recently participated in an IAEA workshop to establish a Regional African ALARA Network (AFAN) focussed on occupational radiation protection. The main objectives of AFAN is to share and exchange information and to contribute to the harmonisation of radiation protection policies.

Arrangements within RPI to disseminate information include working with certain sectors. For example, the IRRS team was informed that RPI has engaged with the Dental Association, which has improved compliance levels, and shared information with the Botswana Mining Workers Union focusing on occupational exposure.

RPI reviews events in order to establish lessons learned, but does not share the information widely. There is no formal procedure captured within the management system to analyse and screen international experiences and learnings from operational experience to improve regulatory process and practices.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI does not have a formal procedure to analyse and screen international experiences and learnings from operational experience to improve regulatory process and practices.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 15 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'.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S2	**Suggestion: RPI should consider establishing formal procedures to analyse and screen international and operational experience to improve its regulatory practices.**

2.3. SUMMARY

Botswana is a contracting party to a range of nuclear safety related international conventions and Agreements. RPI has a number of bilateral agreements in place that enhances safety through harmonized approaches. RPI staff participate in IAEA scientific visits to the international regulators inputting to strengthening their regulatory framework. RPI actively engage with various regulated sectors to disseminate information that enhances compliance with the regulations.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The Board and RPI were established in 2008 in order to implement the Act. The Board consists of a chairperson and six other members, who are experts in various fields from medicine to radiation protection. The responsibility for authorization lies with the Board. RPI consists of a director, a deputy director and currently 43 other staff members who are appointed according to the Public Service Act.

RPI is set up in four divisions; Licensing and Inspection (responsible for licensing, import, export, license permits); Environmental Monitoring and Radioactive Waste Management (responsible for Implementation of environmental protection strategies, safe disposal and management of radioactive waste); Standards and Instrumentation (responsible for commission of installations, procurement and maintenance of all radiation measuring equipment, radiation monitoring services internal and external); and Corporate Services (responsible for administrative support, IT support, procurement of services and supplies, collection of revenue on behalf of RPI). Appendix VIII show the organizational chart of RPI.

RPI has its budget as part of the budget of the Ministry. The IRRS team was informed that while the budget is part of the Ministry's, there is a strict dividing line between RPI's budget and those of other divisions in the Ministry. The Director of RPI manages the budget and any changes to the overall budget need his consent. The principal spending power lies with the Director, although the Permanent Secretary could issue directives that may influence how the budget is utilized. The IRRS team was informed that additional resources may be allocated if necessary.

For the most part, the available budget appears sufficient for RPI and the Board to fulfil the requirements as laid down in the Act. However, in regards to the domestic travel expenses the IRRS team was informed that the provided funds do not enable RPI to fund all inspection trips for their inspectors due to a governmental freeze on increasing domestic travel budgets across all government departments.

While RPI appears to have sufficient staff to fulfil its functions, the IRRS team found that the allocation of personnel resources is not optimized. It was noted that a "follow-up" inspection of Gaborone Private hospital was carried out 24 months later.

The Act does provide for a graded approach and recognizes licensing as the only form of authorization. Therefore, resources in RPI are not optimized as they are required to perform the same level of regulatory control on low and high risk facilities and activities. Due to this RPI is not implementing a graded approach in executing its regulatory programme which presents a considerable challenge on optimizing resources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI is not following a graded approach and optimizing its resources in the implementation of its regulatory programme.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 16 para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach".
R7	**Recommendation:** RPI should prioritize its tasks and optimise its resources through application of a graded approach in implementing its regulatory programme.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

The Board authorizes the handling and possession of radiation sources and use of radiation applications. RPI is mandated to carry out inspections and prepares regulatory decisions for the Board, and may close down non-compliant facilities. As stated in Section 1.3 the current setup of RPI and the Board may hinder the effective independence in making safety related decisions.

According to the Act, the Director of RPI reports to the Board in all radiation safety issues. However, as a Public Officer the Director also reports to the Permanent Secretary of the Ministry, which could potentially result in receiving conflicting instructions.

RPI operates a radioactive source storage facility that has not been licensed according to the Act, which conflicts with their responsibilities as regulators.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI is assuming the role of operator of a radioactive source storage facility, which conflicts with its responsibilities as regulator.	
(1)	**BASIS: GSR Part 1 (Rev 1) Req 4** "*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."*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 17 para 4.7 states that** *"The regulatory body shall perform its functions in a manner that does not compromise its effective independence* *4.7. The regulatory body shall prevent or duly resolve any conflicts of interests or, where this is not possible, shall seek a resolution of conflicts within the governmental and legal framework."*
R8	**Recommendation: RPI should maintain its effective independence and request the Government to assign the operation of the radioactive source storage facility to another entity.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

RPI has 45 staff members, including the Director, the Deputy Director, 26 of whom are inspectors. Five positions are currently vacant, 2 of them senior level inspectors. RPI does not have qualified legal personnel on staff, but may draw on the lawyer of the Ministry or the Attorney General Chambers. The latter is providing the legal expertise for drafting amendments to the Act and the Regulations.

The IRRS team was informed that in order to ensure the continuing development of competencies and qualifications, RPI has established training plans and competency mappings, which according to the Initial Action Plan will lead to a holistic HR plan.

Qualification for senior staff is acquired on site in RPI. The IRRS team was informed that high potential employees get the chance to improve their qualifications through in-house training or external programmes to acquire the necessary skills to become senior staff and this is captured in the training plan.

RPI faces a challenge in recruiting qualified staff at the senior level as the pool of suitable qualified candidates in Botswana is limited. The IRRS team was informed that there is a lack of availability of certain skills and competences, such as medical physicists. These skills are key to the safe operation of licensed facilities and also a key competence needed by the regulator.

During the site visits, the IRRS team noted that there were gaps in certain competences for the performance of inspections in the medical and waste management fields. Furthermore, the IRRS team noted that RPI does not have a structured and formalized training programme to develop and maintain the required competences and skills to implement its statutory mandate.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI does not have a complete set of competence and skills to enable it to fulfil its statutory obligations.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff."*
(2)	**BASIS: GSR Part 2 Requirement 9 states that** *"Senior management shall determine the competences and resources necessary to carry out the activities of the organization safely and shall provide them."*
(3)	**BASIS: GSR Part 2 Requirement 9 para 4.26 states that** "*All individuals in the organization shall be trained in the relevant requirements of the management system. Such training shall be conducted to ensure that individuals are knowledgeable of the relevance and the importance of their activities and of how their activities contribute to ensuring safety in the achievement of the organization's goals."*
R9	**Recommendation: RPI should ensure that it employs sufficient number of qualified staff and to develop and implement a training programme to build and maintain the required competence for its staff.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

RPI requests and receives support through the technical cooperation provided by the IAEA. Furthermore, RPI has a budget to hire outside experts if so required. For services that cannot be provided domestically, RPI employs external experts, mostly from South Africa. The IRRS team was informed that this is required for the assessment of shielding calculations for newly built facilities. The IRRS team was informed there are formalized government arrangements in acquisition and procurement of expert services through Public Procurement and Asset Disposal Board (PPADB).

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

RPI formally communicates with authorized parties through official letters, inspections and reports. RPI has established templates and checklists, especially for inspections by way of their management manual.

In addition, formal communications for government entities such as RPI are laid down in the Botswana Correspondence Manual (The Government Correspondence Manual, published by the Directorate of the Public Service Management Office of the President, revised edition 1993) applicable to all governmental entities in Botswana.

RPI communicates informally with authorized parties by phone and email at the discretion of the responsible inspectors.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

RPI has established procedures in regards to the following:

- Issuing Licenses
    - Work Instruction for Assessment of license applications;
    - Work Instruction for Preparation and Issuance of Licenses;
    - Work Instruction for Updating of RAIS;
    - Work Instruction for Payment of Licensing and Inspections services;
- Application for permits
    - Work Instruction for assessment of applications for import permits;
    - Work Instruction for assessment of applications for export permits;
    - Work Instruction for assessment of applications for transport permits;
- Conducting an Inspection
    - Work Instruction for Inspection planning;
    - Work Instruction for Conducting an Inspection;
    - Work Instruction for writing an Inspection Report.

To assist the applicants in fulfilling the requirements, RPI has developed the following checklists;

- for license applications;
- Import/Export Permit;
- for temporary Import/Export permit.

RPI also has a slightly different version of the above three checklists that its staff uses to assess applications for licences and permits. RPI has also forms which are filled by applicants requesting for licences and permits. RPI staff have to give a written justification to applicants for any adverse decision against a facility such as denial of a permit or licence application, or

closure of a facility. All records of the above documents are filled and kept by the Records Management Unit at RPI. The IRRS team noted that RPI does not have a requirement to review or revise its regulations.

3.7. SAFETY RELATED RECORDS

The Act requires the Director of RPI to maintain a national inventory of all sources and radiation generators and a register of all licensees and radiation workers. The RAIS system is used for the registration of sources. The IRRS team was informed that record keeping is in accordance with the RPI Control of Records procedure that refers to the Records Management Manual by the Botswana National Archives and Records Services. RPI has established an archive system that stores information on all inspected facilities and license holders.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The Act requires RPI to provide governmental bodies, national and international organizations and the public with information on incidents and abnormal occurrences, and their effect on the public. However, there are no provisions regarding the information to the public on regulatory decisions, nor does RPI provide information on regulatory judgements and decisions on a voluntary basis.

The IRRS team was informed that RPI communicates extensively with the public, by participating in radio shows to provide information, where the public can phone in and ask questions. Also, RPI operates a Facebook page to pass on information to the public. In addition, RPI participates in Kgotla meetings, traditional meetings called by the Chiefs of villages where information is shared and discussed, such as the meetings held with regards to uranium mining and the Pilikwe Storage site.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: While RPI communicates with interested parties and the public on some issues it does not communicate with them on regulatory judgements and decisions.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 36, para 4.66 (a) states that** *"The regulatory body shall establish, ..., provision for effective mechanisms of communication, ……. This communication shall include constructive liaison such as:* *(a) Communication with interested parties and the public on regulatory judgements and decisions"……*
S3	**Suggestion: RPI should consider communicating with interested parties and the public on regulatory judgements and decisions.**

In addition, the IRRS team noted that there is insufficient consultation with interested parties in relations to proposed changes to regulatory requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: There is insufficient consultation of interested parties in relation to proposed changes to regulatory requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 22, para 4.27 states that** *"The regulatory body shall emphasize the continuous enhancement of safety as a general objective. However, it shall also recognize the risks associated with making modifications to well established practices. Prospective changes in regulatory requirements shall be subject to careful scrutiny, to evaluate the possible enhancements in safety that are to be achieved. The regulatory body shall also inform and consult interested parties in relation to the basis for such proposed changes in regulatory requirements*.
S4	**Suggestions: RPI should consider informing and consulting interested parties in relation to changes in regulatory requirements.**

3.9. SUMMARY

RPI appears to have sufficient staff and resources to fulfil its functions. RPI operates a source storage facility that has not been licensed according to the Act, which conflicts with its responsibilities as regulator and which could negatively impact the effective independence.

RPI faces a challenge in recruiting qualified staff at the senior level as the pool of suitable qualified candidates in Botswana is limited. Furthermore, RPI does not have a structured and formalized training programme to develop and maintain the required competences and skills to implement its statutory mandate.

RPI requests and receives support through the technical cooperation provided by the IAEA. Furthermore, RPI has a budget to hire outside experts if so required. There is active communication between RPI and authorized and interested parties and the public.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

RPI has since 2015 established a management system according to the international standard for "Quality management systems (ISO 9001:2015)" and the laboratory activities are accredited against the standard "General" requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005) by the Southern African Development Community Accreditation Service (SADCAS). In August 2017 the Director of RPI authorized a recently developed management system manual, in line with the requirements of GSR Part 2.

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

The Management System (MS) Manual includes a management system policy, RPI vision and mission, as well as core values of the organization (collegiality, excellence, innovation, efficiency, transparency) defining individual and institutional expectations. The Safety Policy of RPI is also included in the MS Manual thereby stipulating the leadership commitment for safety. The senior management has the responsibility to ensure that the policy, vision, mission and values are communicated, understood and implemented by staff members at all levels.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The Ministry has developed a five-year strategy, covering April 2017 to March 2022, in which the objectives are outlined including the specific overall objective applicable for RPI to *"Promote the safe and secure use of nuclear technology"*. The objective details associated initiatives to be implemented by specified dates, namely; *Develop nuclear waste management system; Implement Nuclear material import/export controls; and Implement radiation monitoring system.* These objectives are then transferred to the annual performance plan for the Ministry and further to an annual performance plan developed by RPI. This performance plan, which is consistent with the safety policy, is further elaborated and some additional objectives are added. The objectives have appointed owners at relevant levels. For each objective there are corresponding target values and measurements. This structure of objectives and measures gives a comprehensive overview ensuring clarity with a defined link to the safety goals.

Interested parties are identified by the senior management of RPI and there exists a strategy for communication with them. However, this strategy is not an integrated part of the management system. The communication strategy is, according to the MS Manual, divided into four stages; Preparation; Planning; Implementation and Monitoring and Evaluation. The expectations of the interested parties are established through different feedback mechanisms, such as complaints, evaluation and customer feedback. Customer feedback could be in the form of letters in a "suggestion box" in the reception of RPI, letters, e-mails or a customer complaint form could be used on request. Interactions with the public occurs occasionally in different exhibitions, or what is called "call-in programmes" where the Minister answers questions from the public. The public can also send specific questions to be answered by RPI.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The current structure of the Governmental Strategic Plan specifying objectives and measures which are then captured within the annual performance plan of RPI provides an integrated approach to achieving safety policy.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 2 Requirement 4 states that** *"The senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the organization's safety policy."*
(2)	**BASIS: GSR Part 2 Requirement 4 para 4.4 states that** *"Senior management shall ensure that measurable safety goals that are in line with these strategies, plans and objectives are established at various levels in the organization."*
GP2	**Good practice: RPI has established goals and strategies that are consistent with overall safety policy and the Strategic Plan of the Ministry. The integration of Ministry Strategic Plan with key measurable of RPI is noted as a good practice enhancing overall safety policy.**

4.3. THE MANAGEMENT SYSTEM

The organizational structure of RPI, the responsibilities and accountabilities at different levels of authority are specified in the MS Manual. The process owners are appointed but the IRRS team found that the responsibility of the process owners are only specified in the implementation plan for the improvement of the management system.

RPI has developed an overall process map consisting of six management processes, seven core processes; Authorization and Notification; Inspections; Review and Assessment of Facilities and Activities; Enforcement of Regulatory Requirements; Emergency Preparedness and Response; Monitoring; Preparation of Legislation and Guides as well as six supporting processes.

Management system documents are prepared, reviewed, revised and approved in a controlled manner following the procedure for Document Control. All the issued management system documents are listed in a Master List, grouped according to the type of document. The issued documents are stored and distributed in a controlled way; Policy documents and IMS manual, procedures and work instructions are stored in hard copies with the management system representative, lower level documents are stored in hard copies with the process owners respectively. The documents are stored electronically on the file server readily available to all staff. However, the IRRS team noticed that all the documentation of the Management System was not always known or used by the staff.

In the newly developed MS Manual the responsibilities of the staff is to read and understand the contents of the MS Manual and to comply at all times with the policies, procedures, work instructions and all the associated documentation that are part of the management system. In practice this is done by meeting with process owners and process users. The process owners will at these meetings describe and explain, and the staff can ask questions. The staff members would sign a declaration that they have understood the information.

Incoming and outgoing records related to safety are collected, filed and stored as hard copies (originals) at the Record Management Unit, following the Records Management Procedure Manual issued by the Botswana National Archives and Records Services. The records related to the safety of facilities and activities are registered manually and kept in the Records office. The IRRS team has noted that there could be a risk that information related to safety might be

accidentally lost or not easily retrievable. The records in hard copy are not archived in a controlled environment. Electronically kept documents and records (including the database for radioactive sources, RAIS) are stored on a central server, however back-ups of the information were only done once a month. Even though some work is ongoing, RPI at the moment does not have a comprehensive classification system for registration of records, which could pose a future problem when the amount of records is substantially higher.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The organizational structure of RPI, the responsibilities and accountabilities at different levels of authority are specified in the management system manual. The process owners are appointed but the responsibility of the process owners are not specified in the management system manual.	
(1)	**BASIS: GSR Part 2 Requirement 6, para. 4.11 states that** *"The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system."*
S5	**Suggestion: RPI should consider including and specifying the responsibilities, accountabilities and level of authority of the process owners in the management system manual.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is a potential risk that information related to safety could be accidentally lost or not easily retrievable due to lack of a comprehensive classification system, deficiencies in control of the environment of the archive and insufficient back-up frequency of electronically kept documents and records.	
(2)	**BASIS: GSR Part 2 Requirement 8, states that** *"The management system shall be documented. The documentation of the management system shall be controlled, usable, readable, clearly identified and readily available at the point of use."*
S6	**Suggestion: RPI should consider improving its system for record keeping so that it makes better provision for maintaining and retrieving adequate records relating to safety.**

4.4. MANAGEMENT OF RESOURCES

The IRRS team has reviewed management of resources in Section 3.1.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

Processes are described on an overall level in the MS Manual but are not clearly defined. The sequencing of the processes and interactions between processes are not yet described. Necessary supporting documentation such as procedures and work descriptions are not in place for all processes and therefore the degree of implementation of the management system in all levels of the organization is not sufficient. However, RPI has started a project in May 2017 for the implementation plan for improvement of the management system aiming at

further development of the MS Manual, processes, procedures, work instructions etc. The IRRS team was informed that this project will be completed in year 2020.

In the implementation plan there are no predefined criteria how to apply a graded approach when developing the processes. The MS Manual requires that a graded approach is to be applied in all regulatory processes; however, there are no criteria for how to apply the graded approach. This could eventually lead to inefficiency in the regulatory work of RPI.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Processes are not defined and the activities of the processes are not described and necessary supporting documentation such as procedures and work descriptions are not in place for all processes and the degree of implementation of the management system in all levels of the organization is not sufficient.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 19 para 4.14 states that** *"The regulatory body shall establish and implement a management system whose processes are open and transparent. The management system of the regulatory body shall be continuously assessed and improved.*
(2)	**BASIS: GSR Part 2, Requirement 7 states that** *"The management system shall be developed and applied using a graded approach."* *4.15. The criteria used to grade the development and application of the management system shall be documented in the management system……*
(3)	**BASIS: GSR Part 2, Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organization's goals without compromising safety.* *4.28…..Processes shall be documented and the necessary supporting documentation shall be maintained…."*
R10	**Recommendation: RPI should continue the work to implement, continuously assess and improve its management system, including developing, documenting and effectively managing its processes and activities and maintaining the necessary supporting documentation following a graded approach to achieve the organization´s goals without compromising safety.**

4.6. CULTURE FOR SAFETY

The issue of safety culture has recently been incorporated in the management system. RPI has recently developed a tool to assess the safety culture on a yearly basis. The tool that has recently been used for the first time consists of a questionnaire to the staff about their experience on the level of safety culture including questions on leadership.

At the daily meetings in the different Divisions, the staff are encouraged to have a questioning and learning attitude supported by the managers.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The issue of safety culture is incorporated in the management system. RPI has recently put in means for assessing the staff´s experience on the safety culture aspects including leadership for safety and also an assessment of safety culture is performed in the technical staff.	
(1)	**BASIS: GSR Part 2 Requirement 12 states that** *"Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture*."
(2)	**BASIS: GSR Part 2 Requirement 14 states that** *"Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization."*
GP3	**Good Practice: Safety culture is an integrated part of the management system and RPI has recently assessed the technical staff´s experience on the safety culture aspects including leadership for safety.**

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Each objective of the Annual Performance Plan is monitored and measured against preset baselines and targets to be followed up by a designated person, called the "Measure Owner". The annual objectives are reviewed on a quarterly basis by the Performance Improvement Committee chaired by the Director and consisting of senior management, Section Heads, and the Performance Improvement Coordinator. This Committee meets quarterly. Objectives are also analyzed during the Annual Management System Review. The IRRS team noted that reviews performed by RPI provide for continual improvement.

Internal audits are performed at planned intervals, at the moment once a year since 2016, covering the entire management system. The group of internal auditors with representatives from each Division conduct internal audits to find non-conformities in the application of the management system. The results of each internal audit is reported to the Management System Representative, including a list of found non-conformities. Corrective actions will then be taken by the responsible manager followed up by the Management System Representative within the stipulated timelines. Approximately 80 % of the corrective actions as a result of the internal audit in 2016 are closed. Records of the preventive and corrective actions are filed on paper and archived.

4.8. SUMMARY

RPI has a management system according to ISO 9001 and ISO 17025 and has recently authorized a Management System Manual in line with the requirements of GSR Part 2. The Manual includes an overall process map consisting of management, core (regulatory) and supporting processes. The organizational structure of RPI and most of the responsibilities and accountabilities at different levels of authority are specified in the management system manual, however the responsibility of process owners are not specified.

The issue of safety culture has recently been incorporated in the management system and a tool to assess the safety culture has been developed. The tool includes questions concerning

leadership for safety culture. The staff is encouraged to have a questioning and learning attitude supported by the managers.

Although described in an overall way, processes are not clearly defined and the activities of the processes are not described in detail. Necessary supporting documentation such as procedures and work descriptions are not entirely in place for all processes and the degree of implementation of the management system is not sufficient. There is no predefined criteria how to apply a graded approach when developing the processes, nor are there any criteria for how to apply the graded approach in regulatory activities, which could lead to inefficiency in the regulatory work of RPI.

The structure of objectives and measures in the annual performance plan of RPI gives a very comprehensive overview that is easily followed showing the linkage to the safety goals and show consistency to the safety policy. The objectives of the Annual Performance Plan is monitored, measured and reviewed against preset baselines and targets. Internal audits are performed at planned intervals and corrective actions are taken within stipulated timelines. The IRRS team noted that reviews performed by RPI provide for continual improvement.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The Board is the only authority responsible for granting licences allowing one to acquire, own, possess, transfer, distribute, sell, use, manufacture, transport, import or export any radioactive material or sources as provided for by the Act. The Board meets four times a year and considers applications for licencing of facilities and activities during these meetings. This results in some licences getting issued after an excess of 90 days from the time the applications are made. Import and export permits which are issued by RPI have much shorter turnaround times.

Authorization of facilities and activities is done through licencing, with a licence being valid for 2 years. The Regulations include provisions for exemption and for authorization through notification and registration. However, the Act only has provision for authorization through licensing which made the provisions in the regulations inoperable until such a time the Act is revised to include those provisions.

The Act empowers the Board to issue, amend, suspend or revoke licences. This is done through the Licencing and Inspections Division of RPI which is responsible for the assessment of the applications and the preparation of such licences. The Licencing and Inspections Division currently has a staff compliment of 10 (6 appointed inspectors and four officers who are undergoing on-the-job training). The four will be eligible to be appointed as inspectors after having acquired one year of experience.

Interested parties and the public have an opportunity to give their views on applications for authorization as the applications are gazetted by RPI prior to the applications being sent to RPB for adjudication with the views raised being part of the considerations made by the Board in the decision-making process. The adjudication summaries are signed by the Board and afterwards RPI informs the applicants of the decisions of the Board in writing. The bases of the decision for unapproved applications are captured. However, bases for approved applications are not captured.

At the time of the IRRS mission, the country's inventory included 312 facilities (suppliers, medical and industrial facilities and activities), 240 of which have valid licences. Licensees are reminded to renew their licences 3 months before the licence expiry.

RPI is yet to formalize its cooperation and collaboration with other authorities having safety-related responsibilities like the Health Inspectorate of the Ministry of Health and Wellness which authorizes services in medical facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Currently, a licence is the only type of authorization issued by the RPB.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 2, para. 2.5 states that** "*the government shall promulgate laws and statues to make provisions for an effective governmental legal and regulatory framework for safety. This framework for safety shall set out …….;* *……..* (3) *"The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach"……..*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R	**Recommendation: See Recommendation R2 in Section 1.2.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB does not formally record the basis for its decision on the authorization of a facility or an activity.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 24, para. 4.39 states that** *"The regulatory body shall record formally the basis for its decision on the authorization of a facility or an activity, or on its amendment, renewal, suspension or revocation, and shall inform the applicant, in a timely manner, of its decision, and provide the applicant with reasons and a justification for the decision."*
R11	**Recommendation: RPB should ensure that it formally records the basis for its decisions on the authorization of a facility or an activity.**

5.2. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The Regulations state that licensees are responsible for the safe management of the radioactive waste generated by the practices or sources for which they are authorized and need to take all necessary steps to this aim including keeping the generation, the activity and volume of radioactive waste to the minimum practicable by suitable design, operation and decommissioning of its facilities.

Currently, spent sealed sources are either sent back to suppliers or temporarily stored on-site at end user's temporary stores, under the supervision of RPI, until decayed or shipped back to supplier for further management. All sealed sources are registered by RPI using RAIS and access to this system is controlled. Provisional improvised storage occurs at the user's premises for liquid and solid wastes and these storage facilities are not licensed. The Government has plans to construct a national centralized facility for the storage and conditioning of all spent sources currently kept at the end-user's facilities to ensure the proper management and accountability of these sources and radioactive waste in the country. A decision has been made that RPI will be the operator of the facility. This implies that RPI, in its role as regulator, will authorize and supervise itself.

The Regulations establish provisions for the regulatory control of the processing, storage, and disposal of radioactive waste. However, requirements in the Regulations relevant to the control of discharges and disposal of waste are not being enforced as scenarios of potential release of radioactive materials to the environment have not been identified in the country and decisions on disposal have not been adopted. The Regulations require that any person who applies for a license has to prepare and present a safety assessment and an environmental safety assessment as part of the application.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI currently operates a temporary source storage facility and the Government has decided to assign RPI the responsibilities for the construction and operation of the projected national centralized facility for the storage and conditioning of waste and disused sources. This creates a situation in which RPI, in its role as regulator, will authorize and supervise itself.	
(1)	**BASIS: GSR-Part 1 Requirement 4 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.*"
(2)	**BASIS: GSR-Part 1 Requirement 4 para 2.11 states that** "*In the event that a department or agency of government is itself an authorized party operating an authorized facility or facilities, or conducting authorized activities, the regulatory body shall be separate from, and effectively independent of, the authorized party*."
R	**Recommendation: See recommendation R8 in section 3.2.**

5.3. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

During the authorization process, the compliance with the regulatory requirements are assessed by the Licensing & Inspections (L&I) division of RPI, working in collaboration with Standards & Instrumentation (S&I) division and with Environment monitoring (EM) divisions when the application covers unsealed sources. The assessment includes a pre-authorization inspection. A pre-authorization inspection is not usually conducted for renewal of licences unless the facility has a poor safety record and a history of non-compliances.

Those importing radioactive sources are required to have an agreement with the supplier/manufacturer for the return of the radioactive source to the manufacturer at the end of its use. However, due to the lack of a provision for financial assurance for the management of disused sources as an authorization requirement, some of the disused radioactive sources may not be sent back to the manufacturer due to lack of funds for pre-shipment and shipment costs. Additionally, there are situations where the supplier may cease to exist and the disused source end up having to be stored in the country.

L&I Division has established procedures and some guidelines for authorization of various facilities (diagnostic radiology, nuclear medicine and industrial radiography) and work instructions that have to be followed during the authorization process. The prospective licensee is given the application requirements that include the requirements checklist, application forms and the appropriate guideline for developing the Radiation Protection and Safety Programme. The Regulations require the submission of relevant information necessary to support the application, including a safety assessment in cases where this is prescribed by the inspectorate. A safety assessment is required for all activities and facilities without exception, but what will vary is the level of detail and complexity of the safety assessment in line with the level of risk of the facility or activity. There is no regulatory requirement for the applicant to have an independent verification of the safety assessment done before it is submitted to the regulatory body. RPI considers that most of the content of a safety assessment (safety, security and emergency elements) are described, if necessary, in the

Radiation Protection and Safety Programme, which are assessed by the RPI-L&I, according to a specified procedure.

There is no formal multi-stage licensing process for complex facilities such as nuclear medicine and radiotherapy although RPI conducts some activities at various stages like construction inspection and commissioning. The IRRS team observed that the Board issues authorization if necessary with attached conditions prior to any inspection having been conducted by RPI. RPI then conducts the inspection that is supposed to be a form of pre-authorization after the authorization has already been issued.

The lack of multi-stage authorization process could present a challenge that may arise from the licensee being given an authorization prior to a comprehensive review and assessment.

RPI-L&I verifies the qualifications of the radiation safety officer appointed by the applicant and a list of radiation operators is included in the application file. The condition of their qualification is included in the licence. The qualification of the licensee staff is verified during the review and assessment of the application for authorization with medical personnel required to have certification and registration with the Botswana Health Professions Council. RPI has specified essential professions that are needed in complex facilities such as nuclear medicine (Nuclear Medicine Physician, Medical Physicist and Nuclear Medicine Radiation Technologist) and radiotherapy (Radiation Oncologist, Medical Physicist, Radiation Technologist, Oncology Nurses).

The Act requires that a new application be submitted in the case of any change to the conditions endorsed by the current licence.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no conditions on authorization to ensure the licensees make provisions for the financial assurance for the management of disused sources.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 10, para. 2.33 states that** *"Appropriate financial provision shall be made for (c) Management of disused radioactive sources and radiation generators."*
R	**Recommendation: See Recommendation R5 in Section 1.7.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB does not use a formal multi-stage licencing process when authorizing complex facilities.	
(1)	**BASIS: GSR Part 1(Rev 1) Requirement 24, para. 4.29 states that** *"Different types of authorization shall be obtained for the different stages in the lifetime of a facility or the duration of an activity."*
(2)	**BASIS: GS-G-1.5 para. 3.34 states that** *"For complex facilities such as industrial irradiators and facilities for industrial radiography, nuclear medicine and radiotherapy, the regulatory body may require a multistage*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	process of authorization."
R12	**Recommendation: RPB should ensure that it implements a formalized multi-stage licensing process for complex facilities.**

5.4. AUTHORIZATION OF TRANSPORT

Authorization of transport for geological samples and mining activities is within the regulations but is not carried out in practice as a result of the need for a more effective interface with the Department of Mines and their approval process.

In authorizing transport activities, RPI uses the Act and the Regulations. Other regulations exist (see section 9.4) governing the transport of radioactive material, but RPI does not use them. The Act indicates that the licensee is a natural person. This is an issue that is important for transport, particularly for international shipments. This issue is reported to be one of the areas where clarification is being sought in the revision of the Act.

RPI issues permits, in accordance with the Act, to the person transporting radioactive material and not to the consignor, which places the responsibility on the driver. This is not in compliance with SSR-6.

The primary "authorization" is either an import or a transport permit issued for each single shipment. The permit is issued by an inspector on behalf of the Director of RPI. While the Act empowers the Minister to issue regulations on permits, the Act requires a person to hold a "licence" to transport radioactive material.

The package and licencing requirements of SSR-6 are not included in the Act or the Regulations, and RPI does not issue these types of licencing.

5.5. SUMMARY

The Board is the only authority responsible for granting licences allowing one to acquire, own, possess, transfer, distribute, sell, use, manufacture, transport, import or export any radioactive material, radioactive substance or radiation source. There is no graded approach in authorization as authorization is exclusively done through licencing except in the case of permits for import/export of radioactive materials. The Board does not formally record the basis for its decision on the authorization of a facility or an activity. The Board does not use a multi-stage licencing process when authorizing complex facilities.

There are no conditions on authorization to ensure the licensees make provisions for the financial assurance for the management of disused sources. Disused sealed radioactive sources and radioactive waste are currently stored in improvised storage at end-user's facilities without the necessary licencing. RPI has been designated to manage the disused sealed radioactive sources and radioactive waste management facility that Government plans to construct.

The authorization of transport places the responsibility on the driver of a truck rather than the consignor.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

The licence application forms are reviewed by at least two technical staff[1] of RPI. The technical staff receiving the application records his/her name and the date of receipt of the application. As part of authorization, the applicant is required to prepare a Radiation Protection and Safety Programme (RPSP), which includes elements of safety assessment. A "pre-authorization inspection" is conducted by at least two inspectors. The adjudication summary is prepared by the L&I inspector and endorsed by the Head of Division.

There are no specific provisions to ensure that the applicant's safety assessment is carried out by suitably qualified and experienced persons and that it is independently verified.

The same check list is used to record the review and assessment for all activities but a "non-applicable" response is available to adapt the depth and scope of the review and assessment with the radiation risks associated with the facility or activity. In every case, the review and assessment process involves two technical staff, regardless of the level of radiation risk associated with the facility/activity.

All the findings are compiled in an assessment report and a written feedback is given to the applicant. Where deficiencies are identified, the applicant is required to correct them.

RPI conducts "pre-authorization inspections" systematically for a new facility or activity. During the construction, the inspectors can carry out a site visit to check the compliance of the building with the approved design. The findings are communicated to the applicant in writing within two weeks from the date of the site visit. Then, after the installation of the equipment, a "pre-authorization inspection" is carried out to verify that the regulatory requirements are met. However, these "pre-authorization inspections" do not represent a formal multistage licencing.

During the inspection, the inspectors review the documents justifying the compliance of the installation to the approved designs and the QC test records and measure radiation levels and do QC checks. Inspectors compile non-compliance in the "exit sheet" and prescribe the required corrective actions. The "exit sheet" is signed by the inspectors and the licensee/applicant. The inspectors can implement enforcement measures if necessary. The inspection report is sent to the licensee/applicant within 4 weeks. If necessary, the inspectors can recommend a follow-up inspection to check the progress in addressing the corrective actions or request, within a given time period, the facility to submit a progress report regarding the status of implementing corrective actions.

Any modification of the licence conditions is subject to a new application, it is also subjected to a review and assessment by RPI. Periodic review and assessment is carried out during the routine inspection of the licensed facilities or activities.

[1] RPI refer to their technical staff as Radiation Protection officers (RPO). To avoid confusion with the definition of RPO in the safety standards the term" technical staff " is used.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI review and assessment process is not commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 25 para 4.40 states that** *"The depth and scope of the review and assessment of the facility or activity by the regulatory body shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach".*
R	**Recommendation: See the Recommendation R7 in Section 3.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no specific provisions in the Act and in the Regulations to ensure that the safety assessment made by the applicant is carried out by suitably qualified and experienced persons and independently verified.	
(1)	**BASIS: GSR Part 4 Requirement 3, para. 4.2 states that** *"The safety assessment has to be carried out by a team of suitably qualified and experienced people who are knowledgeable about all aspects of safety assessment and analysis that are applicable to the particular facility or activity concerned."*
(2)	**BASIS: GSR Part 4 Requirement 21, para. 4.66 states that** *"The operating organization is to carry out an independent verification to increase the level of confidence in the safety assessment before it is used by the operating organization or submitted to the regulatory body."*
R13	**Recommendation: The Government, while amending the Act should ensure there are provisions to require that safety assessment is carried out by suitably qualified and experienced persons and is independently verified.**

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

RPB has formal arrangements for obtaining technical or other expert professional advice or services in support of its regulatory functions and may obtain technical or expert professional advice through the IAEA technical cooperation programme. RPI staff is trained through training activities organised by the IAEA and on-the-job training.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

The Act provides that RPB should "*review and assess submissions on safety from the operators both prior to authorization and periodically during operation*". The review and assessment is carried out to determine whether the facility or activity complies with the relevant objectives, principles and associated criteria for safety. The Regulations make a provision for RPI to prescribe cases in which safety assessments are required, which is inconsistent with IAEA safety standards.

The Act requires that a safety and environment assessment needs to be made and submitted to RPB as part of the application for authorization, where the potential for exposure is greater than any level specified by RPB. In addition, the Regulations require provision of a determination of the characteristics and activity of any radioactive material to be discharged to the environment with an assessment of the resulting doses to the critical group.

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The Regulations include provisions for the review and assessment of predisposal waste management facilities. However, provisions for review and assessment of safety in waste management facilities and activities are not in full compliance with the latest IAEA safety standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Provisions for review and assessment of safety in predisposal waste management facilities and activities are not in full compliance with IAEA safety standards.	
(1)	**BASIS: GSR Part 5 Requirement 3 states that** *"The regulatory body shall establish the requirements for the development of radioactive waste management facilities and activities and shall set out procedures for meeting the requirements for the various stages of the licensing process. The regulatory body shall review and assess the safety case and the environmental impact assessment for radioactive waste management facilities and activities, as prepared by the operator both prior to authorization and periodically during operation."*
R	**Recommendation: See Recommendation R18 in Section 9.1.**

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

RPI reviews and assesses licence applications for facilities intending to possess and use radioactive sources according to a defined "work instruction for assessment of licence applications". The review and assessment does not take into account risks that are not related to radiation that may arise in the operation of facilities or the conduct of activities, this is evident when reviewing and assessing application for the mining industry.

The RPSP for radiation generators is to be reviewed by at least two technical staff. The S&I Division assesses the plans of the premises where radiations generators and sealed sources are used. The EM Division and the S&I Division jointly assess plans for facilities using unsealed sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The decision making process to grant an authorization does not take into account the non-radiological risks, particularly in the mining industry.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 26, para. 4.47 states that** *"Risks that are not related to radiation may arise in the operation of facilities or the conduct of activities, and these risks shall also be taken into account in the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	decision making process of the regulatory body."
R14	**Recommendation: RPB should take into account, in its decision-making process, risks that are not related to radiation but might arise in the operation of facilities or conduct of activities.**

6.4. REVIEW AND ASSESSMENT FOR TRANSPORT

The most significant issue for Botswana with regards to transport safety is the need for RPI to be able to review and assess packages which do not require competent authority certification in the country of origin. This is not included in the Regulations.

The permit system in place in Botswana does not collect adequate information from the applicant in order to complete the details of the permit, nor is there a process for checking the information in a robust and systematic manner. The review and assessment instructions are currently not sufficient to ensure adequate consideration of safety issues, in particular there is insufficient checking of the "special form" aspects of a source during inspections, which may result in errors in permits.

There is insufficient technical competence in key areas within RPI such as verifying structural integrity of packagings of various types. In addition, there is a lack of clarity over where this TSO support can be obtained in Botswana.

One particular area where assessment may be required on an urgent basis is that of special arrangement, which can be an important method for recovery from an accident. This concept requires an approval similar to the permits currently being issued, but also requires specific areas of technical competence in the regulatory body. RPI is not cognisant of special arrangements, but following clarification RPI identified it could add value to their regulatory capability.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI does not gather sufficient information to review and assess packagings that do not require competent authority approval in the country of origin and does not have adequate procedures and instructions for this review and assessment. In particular, there is insufficient recognition of the importance of the integrity of Special Form Material.	
(1)	**BASIS: SSR-6 Requirement 307 states that** *"The competent authority shall assure compliance with these Regulations."*
(2)	**BASIS: SSR-6 Requirement 801 states that** *"For package designs where it is not required that a competent authority issue a certificate of approval, the consignor shall, on request, make available for inspection by the relevant competent authority, documentary evidence of the compliance of the package design with all the applicable requirements."*
R15	**Recommendation: RPI should review its procedures and instructions to ensure sufficient information is gathered, reviewed and assessed in order to verify the continued safety of transport packages that do not require competent authority approval in the country of origin and any special form material.**

6.5. SUMMARY

RPI conducts review and assessment of applications that includes the conducting of pre-authorization inspections. There are no provisions in the Act and in the Regulations to ensure that the safety assessment made by the applicant is carried out by suitably qualified and experienced persons and independently verified. RPI's review and assessment procedure is not commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach and the decision making process to grant an authorization does not take into account the risks that are not related to radiation but may arise in the operation of facilities or the conduct of activities. RPB does not have adequate arrangements for obtaining technical or other expert professional advice or services in support of its regulatory functions.

Provisions for review and assessment of safety in waste management facilities and activities are not in compliance with IAEA safety standards.

RPI does not gather sufficient information to review and assess packages that do not require competent authority approval and does not have adequate procedures and instructions for this review and assessment. The importance of the integrity of Special Form Material is not sufficiently recognized.

7. INSPECTION

7.1. GENERIC ISSUES

7.1.1. INSPECTION PROGRAMME

The Act empowers RPI to carry out inspections of facilities and activities to verify that authorized parties are in compliance with safety requirements and the conditions specified in the authorization.

RPI does not have formal arrangements to liaise with relevant organizations for joint inspections where necessary. Two joint inspections have been done: one with an international expert for a radiotherapy facility and the other with a mine inspector.

The Regulations require that the "*licensee shall bear the responsibility for establishing and implementing the technical and organisational measures that are needed for ensuring protection and safety for the practices and sources for which they are authorised and for compliance with all applicable requirements of these Regulations".* In particular, the Regulations specify that the monitoring and measurements of the parameters necessary for verification of compliance with the requirements of these Regulations and the licence conditions need to be conducted by licensees.

RPI conducts several types of inspections:

- pre-authorization;
- routine;
- follow-up.

Most of the inspections carried out by RPI are announced. Reactive or unannounced inspections may be conducted at any time in case of incident reported or a received customer complaint, but in practice they are rarely carried out. Furthermore, unannounced inspections are not included in the inspection programme.

An annual inspection plan is developed according to a defined procedure, detailing the planned frequency of inspections, depending on the level of risk associated with the facility or activity as indicated below:

- every year for high risk sources (e.g.: NDT, radiotherapy…);
- every 2 or 3 years for medium risk sources (e.g.: nuclear medicine, gauges…);
- every 4 years for low risk sources (e.g.: dental, baggage scanners…)

For the period ranging from May 2017 to April 2018, 48 inspections have been planned. The IRRS team was informed that in practice the annual programme is not always fully implemented and the planned frequencies are not achieved due to a governmental freeze on domestic travel budget provisions

The programme is organized taking into account long-distance sites where many inspections are grouped to avoid the repetition of long distance travels. However, the IRRS team observed that inspections of one site were performed 8 times in a period of less than one year. This site is licensed for 10 diagnostic radiology and 6 dental X-ray devices; 6 of the 8 inspections were conducted on only one device.

Every year, an average of 12 unplanned inspections (pre-authorization or follow up) are conducted.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI does not liaise with relevant organizations for joint inspections where necessary.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 29, para. 4.53 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including (…) Liaison with the relevant organization for joint inspections, where necessary.*
S7	**Suggestion: RPI should consider liaising with relevant organizations for joint inspections where necessary.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI does not carry out unannounced inspections and it does not include them in its inspection programme.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 28 states that** *"Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced."*
(2)	**BASIS: GSR Part 1 (Rev 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."*
R16	**Recommendation: RPI should carry out unannounced inspections and include them in its inspection programme.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The annual inspection plan is not always fully implemented while some sites are repeatedly inspected unnecessarily.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 29 Para 4.50 states that** "*the regulatory body shall develop and implement a programme of inspections…"*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 29 states that** *"Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R	**Recommendation: See Recommendation R7 in Section 3.1.**

7.1.2. INSPECTION PROCESS AND PRACTICE

A comprehensive set of documents and guidelines related to inspection are available. In particular, the different steps of the inspection process until the reporting phase are described in the inspection procedure. The documents cover all the technical aspects of the inspection.

A set of checklists, forms and report templates are also available to ensure the consistency of the control and the proper recording of the findings, including the results of the measurements.

Different inspection methods are employed: document review, interviews with the licensee staff, direct observation of operations, survey and QC checks.

An exit meeting is held at the end of the inspection where major observations and findings are conveyed to the licensee, the need for a follow-up inspection is indicated if necessary. The noncompliance and corrective actions are compiled in the "exit sheet", which is signed by the inspectors and the licensee. The inspectors can implement enforcement measures if necessary. All the verifications done, the results of quality controls and the conclusions of the inspection are recorded in the appropriate "safety assessment" template. A printed version is kept in the facility file. A complete inspection report detailing the findings, the associated requirements or recommendations is sent within 4 weeks after the inspection to the licensee. The licensee is required to implement the corrective actions within 21 days, as indicated in the inspection report. In some cases, the RPI requires a progress report on the implementation of the corrective actions to be transmitted to it. The IRRS team noted that RPI does not follow up to confirm that the authorized party has effectively implemented as necessary corrective actions within the specified time frame.

RPI has 198 various radiation monitoring equipment that is used during inspections. 128 of the devices have valid calibrations whilst 70 do not. Botswana does not have calibration services and it uses test sources for checking the survey meters. RPI has to send the devices abroad for calibration, a process that may take up to a year and they request the users to also calibrate their equipment.

7.1.3. INSPECTORS

The Act states that a radiation inspector "*may, at any time enter, inspect and examine or search any premises, vehicle, vessel, aircraft or any carriage where he or she has reasonable grounds to believe that radioactive material or any source of ionizing radiation is stored, used, transported or disposed of, in such premises, or vehicle, vessel, aircraft or carriage".*

Inspections are carried out by a team of two inspectors (at least one is gazetted[2]) and these are always rotated to ensure continuity and reduce any chances of the regulatory body's responsibility being compromised. As part of the training a third new recruited inspector can join the team.

[2] The term gazetted means that the inspector is duly appointed and authorized by the Minister to act as a radiation inspector

When necessary, the inspection team can be composed of one inspector from the L&I division and one inspector from the S&I or EM division.

Possessing a university degree is necessary for a person to be recruited as an inspector. On-the-job training is given by senior inspectors for all types of regulated activities. An annual training plan is elaborated, mainly taking advantage of the training events offered by IAEA. The IRRS team was informed that Government funded long-term training is more difficult to set up.

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

In Botswana, spent sources have the same legal status as sources in active use as they are all subject to the same regulatory requirements and are to be kept safe and secure. Additionally, once sources are taken out of active use the licensee is required by the Act to notify RPI. RPI is empowered to confiscate a radioactive source that is no longer in use and is not properly secured. The IRRS team was informed that RPI conducts periodic inspections to source storage facilities at the user sites as well as their temporary source storage facility.

Site Visit

The IRRS Team visited a temporary source storage facility owned by RPI and made several observations. The facility basically consists of a transport container adapted for this purpose. According to the documentation kept on the site, only one package containing a Cs and Am-Be source, in one device, was stored in the facility. The facility is equipped with an alarm and secured around and inside. Inside the facility there is a space adapted to store several source containers. The IRRS team observed that in the facility there was one more empty container intended for higher activity sources. RPI inspectors were wearing their TL dosimeters. It was not possible to check the dose rates inside and around the facility, as the inspectors did not carry any measuring equipment to check the dose rates. Inside the facility there was no information about the sources, just shelves and doors leading to smaller boxes secured by padlocks, but all of the padlocks had the key inserted.

The only source in the facility was in the cabin, but not secured. RPI has inspection procedures established, they were not adequately followed in this case as RPI did not perceive it to be a formal inspection.

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

The IRRS team observed an inspection performed at the Gaborone private hospital on a brachytherapy facility. The inspection was conducted in a professional manner by two inspectors. The inspection started by a short introduction of the agenda of the day and of the scope of the inspection, which was mainly the verification of the implementation of the corrective actions required from the previous inspection done in 2015. The verification began by an interview with the medical physicist. Then a review of the relevant documents and records was performed. The inspectors checked the functionality of the warning light at the bunker access and of the radiation monitor of the treatment room. They also checked the availability of the emergency equipment. At the end of the inspection, an exit sheet was completed. The inspectors reported their major findings to the licensee during an exit meeting and the exit sheet was signed by both parties. The inspectors informed the licensee that all the requirements and recommendations would be stated in an inspection report, sent by letter, and a follow up inspection would be carried out to assess the implementation of the required corrective actions.

The IRRS team met with the licensee after the inspection and was informed that the relationship with RPI is cooperative. The licensee also highlighted the good engagement of the RPI when new projects are undertaken.

The licensee pointed out the following:

- a wider experience of similar practices for the inspectors could improve the effectiveness of the inspection;
- the personal dosimetry service provided by RPI is not done with the proper periodicity but RPI still consider this as a non-compliance;
- The administrative process of obtaining import/export permits is seen as inefficient, particularly where sources need to be replaced frequently;
- The communication with the RPI could be improved through for example the use of emails and the website.

It is important to note that those were the views of the licensee and do not necessarily represent the IRRS team's views. They are included here for RPI's consideration.

After the site visit the IRRS team made the following observations:

- The previous inspection was carried out in 2015. During that inspection, corrective actions were prescribed and RPI took no action to confirm their implementation until this 2017 follow up inspection.
- During the discussion of a nonconformity identified in 2015 related to the CT simulator, the hospital indicated it decommissioned the simulator. Then CT scanning is now being done in another hospital, which can be an issue regarding the optimization of the brachytherapy and even more radiotherapy treatments.
- The validity of the calibration certificate of the licensee's survey meters were not checked by the inspectors, while the IRRS team noted the calibration is no longer valid on one survey meter.
- Not all of the non-compliances identified were captured in the exit sheet and conveyed to the licensee during the exit meeting.
- As this facility is the most significant from the point of view of safety in the country, it is the perception of the IRRS team that RPI could contribute in a more significant way to the improvement of the safety culture in this facility through closer consultation.

7.4. INSPECTION OF TRANSPORT

The system of requiring permits for each transport has proved to be an effective means of identifying not only transport activities but also facilities where radioactive material is used. While the administrative burden on the licensees could be reduced this system improves resource allocation in inspection.

The Act provides Inspectors to enter premises or conveyances for the purpose of inspection, however this is limited to locations and conveyances where the radioactive material is or is suspected to be. For transport this may leave a gap, in that inspections for transport often need to take place where there is no radioactive material present (for example documentation may be held at headquarters of an airline).

While the transport permit and the Regulations should be the basis against which an inspection is to be carried out, in practice there is no initial verification of the accuracy of the

transport permit contents, nor is an inspection carried out against it. The relevant parts of SSR-6 that would provide an inspection reference are not included in the Regulations.

The most significant transport in Botswana relates to sealed sources and the integrity of the sources is often the containment system. It is important that verification of the continued integrity of sources is carried out. This includes inspection of the applicable special form certificate. This currently does not take place.

The Botswana Police Services routinely carry out roadside vehicle checks at checkpoints, and RPI is informed of any radioactive materials in transport. RPI does not actively work with police in the performance of checks, however they provide training police officers in radiation safety and identification of radioactive sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In order to ensure effective compliance assurance it is important to have an adequate knowledge of the activities within the state, for a developing regulator this can be a challenge. The transport and import permit system provides a good method for addressing this challenge.	
(1)	**BASIS: GSR Part 1(Rev 1) Requirement 16 states that** *"The regulatory body shall … manage its resources …*
GP4	**Good Practice: RPI has a system for providing information on transport operations by the shippers which improves knowledge of facilities and activities that should be regulated and as a result enables effective management of resources.**

7.5. SUMMARY

RPI conducts pre-authorisation, routine and follow-up inspections of facilities and activities to verify that the authorized party is in compliance with safety requirements and the conditions specified in the authorization. RPI's annual inspection plan does not include unannounced inspections and the annual inspection plan is never fully implemented while some sites are repeatedly inspected unnecessarily. RPI does not confirm that the authorized party has effectively implemented necessary corrective actions within the specified timeframe. RPI does not have formal arrangements to liaise with relevant organizations for joint inspections where necessary.

The transport and import permit system being used by RPI provides a good method to have an adequate picture of the activities within the state to ensure effective compliance assurance.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

According to the Act, the Board may suspend or revoke a licence where it is satisfied that the licensee has contravened this Act or a term or a condition of a licence.

The Regulations have provisions for the Board to revoke, suspend or modify an authorization to use a radiation source, or prohibit the possession of a radiation source, levy fines, or make recommendations for prosecution upon finding an undue threat to health and safety or non-compliance with the Regulations.

An enforcement policy has been established and implemented for responding to non-compliance with Regulations. A graded approach is applied and the enforcement actions are commensurate with safety significance and range from a simple written warning to a licensee up to a formal prosecution.

The enforcement actions provided by the policy include:

- regular interaction to facilitate rectify/avoid minor non-compliances (discussions/meetings/letters);
- written notice or warning letters;
- increased regulatory scrutiny (more frequent inspections);
- an order by an inspector or designated officer (Prohibiting the use of radioactive source/generators);
- Suspension of licence;
- Revocation of licence;
- Investigation and prosecution.

When a non-compliance with the Regulations occurs, inspectors evaluate the degree of risk posed by that non-compliance to determine whether immediate action is required. If the non-compliance is of such safety significance that adequate protection is no longer provided, inspectors may direct immediate action, up to and including a shutdown and/or suspension of licenced activities.

A meeting may be conducted with a licensee before making an enforcement decision to obtain information that will assist in determining the appropriate enforcement action. This may include reaching a common understanding of facts, root causes and missed opportunities associated with the apparent violations; understanding of corrective action taken or planned, and an understanding of the significance of issues and the need for lasting comprehensive corrective action.

An enforcement procedure is not yet in place which may impact stability and consistency of enforcement.

The licensee is required to remedy the non-compliance, to perform a thorough investigation in accordance with an agreed time-scale, and to take all necessary measures to prevent recurrence. Licensees are required to send documentation proving that they have taken the necessary actions and in certain circumstances, RPI conducts follow up inspections.

8.2. ENFORCEMENT IMPLEMENTATIONS

Enforcement actions have been taken on 33 facilities out of the 72 that are without valid licences for the current year.

The IRRS team noted that there is no systematic way of confirming that the authorized party has effectively implemented any necessary corrective actions with some corrective actions remaining open for long periods. In particular, after an inspection RPI does not always follow up to confirm that the authorized party has effectively implemented necessary corrective actions within the specified time frame.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: After an inspection RPI does not always follow up to confirm that the authorized party has effectively implemented necessary corrective actions within the specified time frame.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 31, para. 4.60 states that** *"……. the regulatory body shall confirm that the authorized party has effectively implemented any necessary corrective actions."*
R17	**Recommendation: RPI should ensure that authorized parties implement necessary corrective actions within the specified time frame.**

8.3. SUMMARY

RPB is empowered to take enforcement action in cases of non-compliance. The enforcement actions follow a graded approach. Inspectors have authority to take on-the-spot enforcement action. RPI has no systematic way of confirming that the authorized party has effectively implemented any necessary corrective actions.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

RPB has established regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgments, decisions and actions are based. RPB has initiated the review and revision of the Regulations to align them with latest IAEA safety standards.

In the name of RPB, RPI has established the following guidelines:

- *Guideline for radiation protection in well logging, portable gauging, detection & analytical devices (2018);*
- *Guidelines for X-Ray rooms design and recommendations (draft);*
- *Guideline for import and export of radioactive sources and X-ray generators (2008);*
- *Inspection guideline procedure for medical diagnostic X-ray facilities in Botswana (draft);*
- *Guide for developing a radiation protection and safety programme - Industrial Radiography (2016);*
- *Guide for developing a radiation protection and safety programme for well logging, portable gauging, detection and analytical devices (2011);*
- *Guideline for Nuclear Medicine (no date);*
- *Radiation safety guides for the management of spent & disused sealed sources (2009);*
- *Guide for the safe use of ionising radiation in senior secondary schools (2013);*
- *Radiation safety guides for the design of the on-site temporary storage facility for spent or disused radiation sources (2009, draft);*
- *Emergency response guidelines for a dispersion of alpha emitters (2016);*
- *Emergency response guidelines for a dispersion of laboratory accident (2016);*
- *Emergency response guidelines for a dispersion of source or contamination (2016);*
- *Emergency response guidelines for a dispersion of unshielded source (2016);*
- *Guideline for responding to a lost or stolen radioactive source (2016);*
- *Guideline for responding to a transportation accident/incident involving radioactive materials (2016).*

RPI has prioritized the development of guides for radiation protection programme for industrial radiography, brachytherapy, tele-therapy, and construction of nuclear medicine facilities.

The Regulations are published in the government gazette.

RPI has not established processes for establishing or adopting, promoting and amending regulations and guides that involve consultation with interested parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Regulations are not up to date with the latest IAEA safety standards.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration taken of relevant international safety standards and technical standards and of relevant experience gained."*
R18	**Recommendation: The Government should ensure that all regulations**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	related to radiation safety are updated to be consistent with the latest IAEA safety standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI has no process for reviewing or updating the regulations and guides. Furthermore RPI does not consult with interested parties while developing or updating regulations.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 34, para 4.61 states that** *"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."*
R19	**Recommendation: RPI should develop and implement a process for reviewing and updating the regulations and guides and ensure that interested parties are involved.**

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The Act establishes a general framework on which specific regulations concerning radiation protection are based. The Regulations cover the aspects related to the regulatory control in the management of radioactive waste. However, the regulations do not cover financial provisions for management of radioactive waste, but they require licensees to keep waste generation to the minimum practicable.

The Regulations are not aligned with the Fundamental Safety Principles SF-1 to ensure that future generations are adequately protected.

The Regulations establish that waste is to be stored under conditions that ensure the protection of human health and the environment avoiding risks associated with degradation of waste integrity. There is no provision for the other elements such as storage in conditions that allow for inspection, monitoring, retrieval and preservation, subsequent management taking due account of the expected period of storage.

Provisions for decommissioning are not included in the current regulatory framework.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The regulations do not address the following: • Protection of future generation; • development of plans for design and operation, and the development of the safety case for operational safety; • waste packages and unpackaged accepted for processing, storage and/or disposal;

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
• provision for development, operation and closure of disposal facilities.	
(1)	**BASIS: GSR-Part 5 Requirement 11 para. 4.23 states that** *"When it is proposed to store radioactive waste for a long period of time, consideration has to be given to the protection of present and future generations in accordance with the fundamental safety principles (Principle 7of IAEA SF-1)"*
(2)	**BASIS: GSR Part 5 Requirement 13 states that** *"The operator shall prepare a safety case and a supporting safety assessment. In the case of a step by step development, or in the event of modification of the facility or activity, the safety case and its supporting safety assessment shall be reviewed and updated as necessary."*
(3)	**BASIS: GSR Part 5 Requirement 12 states that** *"Waste packages and unpackaged waste that are accepted for processing, storage and/or disposal shall conform to criteria that are consistent with the safety case."*
(4)	**BASIS: SSR- 5 Requirement 1 states that** *"The government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need for disposal facilities of different types; specification of the steps in development and licensing of facilities of different types; and clear allocation of responsibilities, securing of financial and other resources, and provision of independent regulatory functions relating to a planned disposal facility."*
R	**Recommendation: See recommendation 18 in Section 9.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Provisions for decommissioning are not included in the current legal and regulatory framework.	
(1)	**BASIS: GSR-Part 6 Requirement 5 states that** "*The regulatory body shall regulate all aspects of decommissioning throughout all stages of the facility's lifetime, from initial planning for decommissioning during the siting and design of the facility, to the completion of decommissioning actions and the termination of authorization for decommissioning. The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides. The regulatory body shall also take actions to ensure that the regulatory requirements are met."*
R	**Recommendation: See Recommendation 5 in section 1.7.**

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

This part is covered under Section 9.1.

9.4. REGULATIONS AND GUIDES FOR TRANSPORT

The Regulations only partially implement the transport requirements from SSR-6. Particular areas from SSR-6 that are missing are:

- Packaging standards
- Test requirements
- Approval requirements

The Regulations for transport operations sometimes summarise the full text of SSR-6.

There are no package approvals requirements in regulations that recognize approvals by other states and prevent unlicensed packages being used.

A Permit issued by RPI contains information that is not necessary for radiation safety, but could be seen as a "Permit" for transporters to operate contrary to other conventional transport legislation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI include instructions in the transport permits that may conflict with other national legislation.	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 7, states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties."*
S8	**Suggestion: RPI should consider ensuring that transport permits do not include instructions that may be in conflict with requirements in other national legislation.**

9.5. SUMMARY

Radiation Protection Regulations of 2008 and a number of guides are in place. The Regulations are not up to date with the latest IAEA safety standards and do not have provisions for decommissioning. RPI has no process for reviewing or updating the regulations and guides and does not consult with interested parties while developing or updating regulations.

The country has a number of different overlapping regulations in the area of transport of radioactive material that duplicate requirements and establish conflicting oversight and enforcement principles.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

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

The Act and the Regulations set out the basis for regulating EPR of licensees. The Act includes requirements for the licensee to develop and maintain emergency preparedness arrangements and an onsite response plan, which needs to be approved by RPI. The Act also specifies the responsibilities of the licensee including developing emergency preparedness arrangements, submitting an incident response plan when applying for a licence and reporting to RPI any case of overexposure, loss, theft or diversion of radioactive material within 12 hours.

The IRRS team was informed that RPI provides a one-week training to entities conducting similar activities, with half a day dedicated to emergency response considerations, including off site responsibilities.

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

Although the Act did not explicitly identify EPR as an area where regulations need to be developed, part XIII of the Regulations provides for *"Requirements for Emergency Intervention"* and address:

- The responsibilities of licensees to keep an emergency plan prepared and operational,
- The content of this emergency plan,
- The implementation of intervention, by taking protective actions and by informing RPI of any accident situation,
- Intervention doses, provides for the dose to the worker during the intervention,
- The requirement for the licensee to make periodic review and to update the emergency plan.

The Regulations provide a basis for regulating EPR. However, there are examples of aspects not explicitly addressed in the regulations or not fully consistent with IAEA GSR Part 7. For example presently there is no requirement for the licensee to develop and conduct exercises and no requirement for RPI to evaluate some of the exercises conducted by the licensee.

The Regulations establish dose limit for workers undertaking an intervention similar to dose limits for occupational exposure. They also specify that this dose may be exceeded by those who are volunteers, but without setting any dose limits. This is not fully consistent with the IAEA guidance values for restricting exposure of emergency workers, as specified in GSR Part 7.

The following points are further examples of aspects not explicitly addressed in the Regulations:

- emergency classification used by the licensee and the class emergency declaration;
- documenting, protecting and preserving data and information important to analyse the emergency and the response;
- analysing the emergency and response to avoid other emergencies and to improve the arrangements;
- sufficient number of qualified personnel;
- exercise program;
- quality management program;
- revise emergency arrangements prior to any changes in the facility or activity that affect the existing hazard assessment and when new information become available that provides insights into the adequacy of existing arrangements.

The Regulations require *"the licensee to take protective actions to protect workers and the public set forth in the licence application and emergency plans, or required by RPI to protect, mitigate or remediate a hazardous situation involving the licensee's sources"*. The IRRS team was informed that RPI will do so if the licensee does not have the capacity to take protective actions and to mitigate the consequences on site. This may lead RPI taking responsibility for onsite protective actions, which might compromise its role as regulator.

RPI recognizes the need to revise the regulations against IAEA requirements, including EPR requirements. The IRRS team was informed that RPI drafted revised regulations that improve consistency with IAEA requirements.

In addition to the Regulations, RPI developed six Emergency Response Guidelines in 2016 to provide guidance for responding to the dispersion of alpha emitters, a laboratory accident, a lost or stolen radioactive source, a dispersion of source or contamination, a transportation accident/incident involving radioactive materials, a dispersion of unshielded source. The IRRS team noted that for most guidelines, the text is almost identical. Only the flowchart at the end of the guideline is specific to the purpose and scope of the guideline.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The provisions relevant to EPR in the Regulations are not in full compliance with the requirements in GSR Part 7.	
(1)	**BASIS: GSR Part 7 para. states that** *"The RB is required to establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based [7]. These regulations and guides shall include principles, requirements and associated criteria for EPR for the operating organization (see also paras 1.12 and 4.5)."*
R	**Recommendation: See Recommendation R18 in Section 9.1.**

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

The regulatory body (RPB and RPI) has the responsibility to regulate onsite emergency arrangements of licensees based on the Act and the Regulations, and is expected to:

- review and assess the EPR related documentation submitted by the licensee;
- approve on-site emergency plan, submitted in support of license applications;
- inspect on site EPR to check compliance with the regulations and the license conditions;
- assess some exercises.

Except of assessing exercises, the Act and the Regulations give the authority to the RPB and RPI to review, assess, approve the emergency plan, authorize, inspect and enforce regulatory requirements.

The IRRS team was informed that 4 staff members of the Division of Environment Monitoring in RPI are in charge of reviewing EPR arrangements of licensees (review and assessment, inspections, regulations and guidelines). They are trained through their participation in IAEA training events.

The IRRS team was also informed that there are presently various nuclear gauges and industrial radiography sources used in the industrial sector and two brachytherapy sources used in a private hospital. Nuclear medicine using I131 is foreseen in the near future. The IRRS team noted that there

are no specific guidance on procedures for RPI to follow a graded approach in regulating EPR and no training programme to develop and maintain the necessary competence and skills in view of review, assessment and inspection based on assessed hazards.

RPI has established various checklists and forms to support its verification activities of review, assessment and inspection. The following documents are available:

- a check list of documents that need to be in the license application which includes the emergency preparedness plan.
- forms on safety assessment of soil moisture/density gauges and of radiotherapy and brachytherapy installations and those also include provisions on emergency preparedness.
- check list for inspection and facility inspection exit sheet for performing inspections but with no specific provisions on EPR.
- accident registration forms with the purpose to report accidents, either in an unforeseen location or in a facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI has not established a specific and formalized guidance regarding the application of a graded approach in regulating EPR (Review and assessment, inspection).	
(1)	**BASIS: GSR Part 1(Rev1), Req. 26 states that** *"Review and assessment of a facility or activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with graded approach."*
(2)	**BASIS: GSR Part 7 (Rev1), Req. 29 states that** *"Review Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach."*
R	**Recommendation: See Recommendation 7 in Section 3.1.**
Observation: RPI has no training program to develop and maintain the necessary competence and skills in view of review and assessment and inspection based on assessed hazards.	
(1)	**BASIS: GSR Part 1(Rev1), Req. 18 para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills. The training programme shall cover principles, concepts and technological aspects, as well as the procedures followed by the regulatory body for assessing applications for authorization, for inspecting facilities and activities, and for enforcing regulatory requirements."*
(2)	**BASIS: GSR Part 7, Req. 2 para. 4.8 states that** *"The government shall ensure that ROs, OOs, and the RB have the necessary human, financial and other resources, in view of their expected roles and responsibilities and the assessed hazards, to prepare for and to deal with both radiological and non-radiological consequences of a N/RE, whether the emergency occurs within or beyond national borders."*
R	**See Recommendation R9 in Section 3.3.**

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

RPI is part of the national EPR framework as described in the *"Country Emergency Preparedness and Response Plan to Nuclear and Radiological Emergencies"*(The Plan). This Plan provides information on RPI's role and responsibilities in Nuclear and Radiological Emergencies, its resources and the response tasks for the main response organizations (National Disaster Management Office, Botswana Police Service, Fire Services, Medical/health authority, Botswana Defence Force, Customs and Consumer Affairs, Ministry of Agriculture and Food Security, Ministry of Health and Wellness (Food Control Unit)). Based on this document, RPI has the responsibility to ensure the general direction and implementation of the radiological response, the complete operability during the radiological emergency response, to deploy necessary resources on the scene, to decide on the activation and deactivation, and to communicate with the public. The Plan has been prepared, approved and authorized by RPI.

RPI procedures for responding to radiological emergencies are still to be developed.

At the national level, the National Disaster Management Office (NDMO) leads and coordinates all the emergency responses in the country. The National Committee on Disaster Preparedness (NCDP) is gathering representatives of the main response organizations. The main roles of the NDMO are to activate district disaster management committees to determine the status of non-radiological response requirements.

The Plan seems to be a combination of the National Emergency Plan and the RPI Plan to respond to nuclear and radiological emergencies. This is not consistent with IAEA standards, as there is no basis, at the governmental level, for the national response and, in particular, for RPI responsibilities and the Plan.

Regarding the interface between RPI and NDMO in terms of directing the intervention at the national level, making decisions, and communicating with the public, the IRRS team was informed that on the scene the Botswana Police Service will likely be the incident commander supported by RPI and that at the national level, NDMO will be coordinating among responding organizations, including RPI. The IRRS team was also informed that while the director of RPI has the responsibility of communicating with the public, the communication will remain supervised by the NDMO, if activated.

There are no formalized arrangements for coordination between RPI and NDMO, or another off-site response organisation including the Botswana Police Service, Fire Services or paramedics that will intervene on the scene.

Past incidents involved mainly three stolen nuclear gauges, a lost Cs 137 source that was crushed and led to radioactive contamination and clean-up of the site. There are inspection reports, but no systematic incident investigation reports after each incident drawing and identifying lessons learned.

The Plan provides for periodic emergency drills/exercises to be held and for lessons learned to be recorded. Within RPI, the Environment Monitoring Division is coordinating the response to radiological emergencies. There are 13 trained staff members who could be mobilized during an emergency and still need to be familiarized with the Plan to understand their roles. The IRRS team was informed that they are participating in IAEA training events addressing EPR and that Botswana, in December 2015, conducted a national exercise simulating a transport accident with contamination and injured persons, with the support of IAEA. The IRRS team was also informed that at the national

level, RPI provides half a day training in the Botswana Police College to all new recruits and one-week training to frontline officers.

The IRRS team noted that there are no formalized training or exercise programmes to ensure that all personnel involved in the response has the necessary skills and that the response is effective.

The Plan requires actions to ensure that equipment is operational and available through inventory checks, routine inspections, maintenance and calibration programmes.

The Plan and a radiation safety guideline on intervention levels and action levels in emergency exposure situations provide for generic intervention levels for urgent protective actions for sheltering, evacuation and iodine prophylaxis but no justification for such protective actions is provided.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no basis established at the governmental level for the national response and in particular for RPI responsibilities and plan for responding to nuclear and radiological emergencies at the national level.	
(1)	**BASIS: GSR Part 7 Requirement 23 para. 6.17 states that** *"Each response organization shall prepare an emergency plan or plans for coordinating and performing their assigned functions as specified in Section 5 and in accordance with the hazard assessment and the protection strategy. An emergency plan shall be developed at the national level that integrates all relevant plans for emergency response in a coordinated manner and consistently with an all-hazards approach. Emergency plans shall specify how responsibilities for managing operations in an emergency response are to be discharged on the site, off the site and across national borders, as appropriate. The emergency plans shall be coordinated with other plans and procedures that may be implemented in a N/RE, to ensure that the simultaneous implementation of the plans would not reduce their effectiveness or cause conflicts."*
R20	**Recommendation: The Government should develop an emergency plan at the national level to address nuclear and radiological emergencies, in a coordinated and integrated manner with other relevant national plans.**
S9	**Suggestion: Once the national emergency plan has been developed, RPI should consider reviewing and updating its emergency plan to be consistent with the national emergency plan.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPI has not developed procedures and analytical tools to perform its response functions.	
(1)	**BASIS: GSR Part 7 Requirement 23 para. 6.20 states that** *"The operating organization and response organizations shall develop the necessary procedures and analytical tools to be able to perform the functions specified in Section 5 for the goals of emergency response to be achieved and for the emergency response to be effective."*
R	**Recommendation: See recommendation R10 in Section 4.5.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Coordination arrangements with NDMO and other response organizations (as needed) are not formalized.	
(2)	**BASIS: GSR Part 7 Requirement 22 para. 6.12 states that** *"6.12. Arrangements shall be developed, as appropriate, for the coordination of EPR and of protocols for operational interfaces between OOs and authorities at the local, regional and national levels, including those organizations and authorities responsible for the response to conventional emergencies and to nuclear security. The arrangements shall be clearly documented and the documentation shall be made available to all relevant parties. Arrangements shall be put in place to ensure effective working relationships among these organizations, both at the preparedness stage and in an emergency".*
S10	**Suggestion: RPI should consider establishing formal coordination arrangements with NDMO and as appropriate with other response organizations.**

10.5. SUMMARY

The Act and the Regulations set out the basis for regulating on site emergency arrangements (EPR) of licensees and give this authority to RPB and RPI. On that aspect, the main findings are:

- While revising the regulations, RPI should ensure a better consistency with IAEA EPR requirements (GSR Part 7).
- With the increasing number and hazards of regulated activities and facilities, RPI should develop and implement a graded approach in regulating EPR. This will contribute to optimize its resources and enhance its effectiveness.
- RPI should develop a training program to develop and maintain the necessary competence and skills in view of review and assessment and inspection based on assessed hazards.

RPI is part of the national emergency preparedness and response framework and as response organization is given the responsibility to ensure the general direction and implementation of the radiological response. However, the national response framework, including RPI responsibilities, lack the governmental basis. To this end, the Government of Botswana should develop a national emergency plan that addresses nuclear and radiological emergencies, in a coordinated and integrated manner with other relevant national plans. Once this plan is developed, RPI should review and update accordingly its own emergency plan. On that basis, RPI should establish formal coordination arrangements with the National Disaster Management Office (NDMO), that leads and coordinates all the emergency responses in the country, and as appropriate, with other national response organizations. RPI should also develop the procedures and analytical tools needed to perform its response functions.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

Applications with the use of radiation sources for medical purposes in Botswana include 184 medical facilities. There is 1 medical radiotherapy facility (including 1 LINAC, and 1 brachytherapy), 1 nuclear medicine facility (with 1 gamma camera but not operational); 81 X ray diagnostic radiology services (including conventional, computed tomography, mammography, fluoroscopy), and 103 X ray dental diagnostic radiology facilities.

Responsibilities of the government

The Act, together with the Regulations, establish provisions for requiring the relevant parties dealing with medical exposures to have an authorization for assuming their roles and responsibilities. Requirements relevant for medical exposures in the Regulations are mainly based on previous Basic Safety Standard of the IAEA (SS-115, 1996), so the used terminology is not in full agreement with the one in GSR Part 3.

Responsibilities of the regulatory body

Regulation[3] 14(4) in the Regulations requires legal persons responsible for a source intended for medical use to demonstrate the adequate qualification in radiation protection of medical practitioners during the licensing process. However, the IRRS team was informed that in practice RPI automatically recognizes the certification of competence as medical practitioners issued by the Botswana Health Professional Council to practitioners intended to prescribe radiological procedures without establishing any additional requirements related to their competence in radiation safety matters. At the same time, regulation 39(1)(a) requires the licensees to ensure that medical, paramedical and other health professionals have appropriate training and to be adequately experienced to discharge assigned tasks in the conduct of the diagnostic or therapeutic procedures that medical practitioners prescribe. In this regard, the IRRS team was informed that there is a lack of adequately qualified personnel for ensuring an adequate patient protection. There is only one medical physicist working in a private hospital, and the rest of hospitals do not have the services of any medical physicist.

Responsibilities of registrants and licensees

The Regulations require the authorized parties to ensure that no patient is administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner and that medical practitioners are assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription, of and during the delivery, of medical exposure. While responsibilities of the authorized parties related to protection of carers and comforters are established in the Regulations, responsibilities for the protection of individuals being exposed as part of a programme of biomedical research have not been clearly established. Requirements establishing the responsibility of authorized parties for ensuring the supervision or advice of a medical physicist during the performance of calibration, dosimetry and quality assurance, and acceptance and commissioning of equipment are in place, but in practice cannot be enforced because of the lack of medical physicists and appropriate equipment in the country.

[3] The Regulations use the term "regulation" instead of "article".

Justification of medical exposure

The Regulations establish provisions for individual justification of medical exposure, but they do not include provisions for the generic justification of radiological procedures with medical purposes. The current provisions for justification of exposures in the frame of a health screening programme for asymptomatic populations are not clearly established, as they do not establish the need of being performed previously by the health authority in conjunction with appropriate professional bodies. In this regard, the IRRS team was informed that a programme for screening population for detection of tuberculosis is about to commence and justification of the exposures associated with this programme has not been established. There are no provisions in the Regulations for justification of exposure of asymptomatic individuals with the purpose of the early detection of a disease when this exposure is not a part of an approved health screening programme.

Optimization of medical exposure

Design considerations in optimizing medical exposures are addressed in the Regulations. No reference is made to the need for considering IEC and ISO international standards in design considerations for optimization. The IRRS team was informed that although this is not considered explicitly in the Regulations, the conformity with these recommendations is taken into account in practice when assessing the feasibility of authorizing the use of the medical equipment. Regarding the operational considerations in optimization, exposures of individuals in health screening programmes and of volunteers in a medical research programme are not addressed in the Regulations. Dosimetry of patients, as well as recording of patient doses are not addressed in the Regulations as well. The Regulations adopted the guidance levels proposed in previous version of the basic safety standards, but the IRRS team was informed that these guidance levels are not used in practice for optimization purposes. Regulation 39 establishes requirements for the use of guidance levels in medical exposure. According to this regulation, medical practitioners are to use guidance levels in conducting both diagnostic and therapeutic procedures. This statement contradicts the relevant provisions in the previous and current IAEA Basic afety Standards (SS-115 and GSR Part 3), which established guidance levels and reference levels in medical exposures only for diagnostic procedures, and just as a tool for optimization of the protection and not for establishing criteria for individual cases of application of related procedures. The Regulations exclude radiotherapy for the application of optimization, statement which is not consistent with the concept of optimization of medical exposures. The implementation of quality audits is not required by the Regulations. Dose constraints have been established for carers and comforters, but provisions requiring the establishment of dose constraints on a case by case basis for exposures associated with programmes of biomedical research have not.

Pregnant and breast feeding women

The Regulations do not include provisions for ensuring adequate signs or communication means for requesting female patients who are to undergo a radiological procedure to notify on the possibility of being pregnant or the fact that she is breast feeding in the case of procedures that involve the administration of a radiopharmaceutical. In addition, the Regulations do not require the implementation of procedures for ascertaining the pregnancy status of a female patient of reproductive capacity before any radiological procedure and for establishing that a female patient is not currently breast-feeding before the administration of a radiopharmaceutical. However, the IRRS team was informed that in practice signs and instructions for female patients in this regard is required by RPI and verified during inspections.

Release of patients after radionuclide therapy

Provisions in the Regulations for the release of patients after radionuclide therapy refer to the Schedule IV. In this schedule only a single value of 1100 MBq appears as guidance level for

discharge of patients from hospitals. Dosimetric criteria for protection of the members of the public and family members that could be applicable to any situation of patient's release have not been established.

Unintended and accidental medical exposures

The Regulations require authorized parties to ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures and that registrants and licensees promptly investigate unintended or accidental medical exposures and, if appropriate, implement corrective actions.

Reviews and records

Requirements for periodic safety reviews are required by the Regulations as part of the provisions for the establishment of quality assurance programs by licensees. Authorized parties are not required by the Regulations to maintain personnel related records, calibration, dosimetry and quality assurance records and records for medical exposure of patients and volunteers, as well as reports of investigations of unintended and accidental medical exposures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is a lack of radiological medical practitioners, medical physicists, medical radiation technologists, paramedics and other health professionals adequately qualified in radiation protection and safety for ensuring an adequate patient protection, which limits the possibilities of RPI of enforcing provisions in Regulations relevant for protection and safety in medical exposures.	
(1)	**BASIS: GSR Part 3 Requirement 2, para. 2.21 states that** *"The government shall ensure that requirements are established for:* *(a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;* *(b) The formal recognition of qualified experts;* *……".*
(2)	**BASIS: GSR Part 3 Requirement 2, para. 2.22 states that** *"The government shall ensure that arrangements are in place for the provision of the education and training services required for building and maintaining the competence of persons and organizations that have responsibilities relating to protection and safety".*
(3)	**BASIS: GSR Part 3 Requirement 35, para. 3.150 states that** *"The regulatory body shall ensure that the authorization for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, medical physicists, medical radiation technologists and any other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these Standards only if they:* *……..* *(b) Meet the respective requirements for education, training and competence in radiation protection……"*
R21	**Recommendation: The Government, with the support of RPI, should initiate actions for the establishment at the national level of a programme for education and training in radiation protection of personnel with responsibilities for radiation protection and safety in medical facilities.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Responsibilities of authorized parties for the protection of individuals being exposed to medical exposure as part of a program of biomedical research have not been clearly established in national regulations.	
(1)	**BASIS: GSR Part 3 Requirement 36, para. 3.152 states that** *"Registrants and licensees shall ensure that no individual incurs a medical exposure as part of a programme of biomedical research unless the exposure has been approved by an ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority) ..... and a radiological medical practitioner has assumed responsibility ..... Registrants and licensees shall ensure that the requirements .....are fulfilled for the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research."*
R	**Recommendation: See recommendation R18 in Section 9.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Regulations require authorized parties to ensure the supervision or advice of a medical physicist during the performance of procedures for calibration, dosimetry and quality assurance, as well as during acceptance and commissioning of equipment. However, in practice this cannot be enforced because of the lack in the country of medical physicists and appropriate equipment.	
(1)	**BASIS: GSR Part 3 Requirement 2, para. 2.21 states that** *"The government shall ensure that requirements are established for:* *(a) Education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety;* *(b) The formal recognition of qualified experts;* *……".*
(2)	**BASIS: GSR Part 3 Requirement 3, para. 2.32 states that** *"The regulatory body shall ensure the application of the requirements for education, training, qualification and competence in protection and safety of all persons engaged in activities relevant to protection and safety."*
(3)	**BASIS: GSR Part 3 Requirement 36, para. 3.152 states that** *"3.154. Registrants and licensees shall ensure that:* *…….* *(d) For therapeutic radiological procedures, the requirements …… for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, ……., are fulfilled by or under the supervision of a medical physicist;* *(e) For diagnostic radiological procedures and image guided interventional procedures, the requirements ……. for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	equipment, ……., 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; *…….. .”*
(4)	**BASIS: GSR Part 3 Requirement 14, para. 3.38 states that** *“Registrants and licensees and employers shall ensure that:* *(a) Monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements…..;* *(b) Suitable equipment is provided…….;* *……..”.*
R	**Recommendation: See recommendation 7 in Section 1.8.**
R22	**Recommendation: RPI should require authorized parties to ensure the availability of the equipment needed for performing calibration, dosimetry and quality assurance in all medical facilities that carry out radiological procedures.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Regarding justification of medical exposures, national regulations do not include adequate provisions, in compliance with relevant provisions in GSR Part 3, for: • the generic justification of radiological procedures with medical purposes; • justification of exposures in the frame of a health screening program for asymptomatic populations; • justification of exposure of asymptomatic individuals with the purpose of the early detection of a disease when this exposure is not a part of an approved health screening program.	
(1)	**BASIS: GSR Part 3 Requirement 37, para. 3.156 states that** *“Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technological developments.”*
(2)	**BASIS: GSR Part 3 Requirement 37, para. 3.159 states that** *“Justification for radiological procedures to be performed as part of a health screening programme for asymptomatic populations shall be carried out by the health authority in conjunction with appropriate professional bodies.”*
(3)	**BASIS: GSR Part 3 Requirement 37, para. 3.160 states that** *“Any radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not as part of an approved health screening programme, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines of relevant professional bodies or the health authority. As part of this process, the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure”.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R	**Recommendation: See recommendation 18 in Section 9.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In relation to optimization in medical exposures, national regulations are not in full compliance with relevant provisions in GSR Part 3, in particular: • in design considerations, reference is not made to the need of considering IEC and ISO international standards; • in operational considerations, the optimization of exposures of volunteers in a medical research program and of individuals in health screening programs is not addressed; • dosimetry of patients, as well as recording of patient doses is not addressed in Regulations; • regulations adopted, to some extent with some inconsistencies, the guidance levels proposed in previous version of the basic safety standard and they are not enforced by RPI; • regulations exclude radiotherapy for the application of optimization, statement which is not consistent with the concept of optimization of medical exposures; • the implementation of quality audits is not required; • provisions requiring the establishment of dose constraints on a case by case basis for exposures associated with programs of biomedical research have not been established.	
(1)	**BASIS: GSR Part 3 Requirement 38, para 3.162 states that** *"..... registrants and licensees, in cooperation with suppliers, shall ensure that medical radiological equipment and software that could influence the delivery of medical exposure are used only if they conform to the applicable standards of the International Electrotechnical Commission and the International Organization for Standardization or to national standards adopted by the regulatory body".*
(2)	**BASIS: GSR Part 3 Requirement 38, para 3.166 states that** *"Registrants and licensees shall ensure that the particular aspects of medical exposures are considered in the optimization process for:* *……..* *(b) Individuals subject to medical exposure as part of an approved health screening programme;* *(c) Volunteers subject to medical exposure as part of a programme of biomedical research;* *…… ."*
(3)	**BASIS: GSR Part 3 Requirement 38, para 3.168 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 radiological procedures, typical doses to patients for common procedures;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	(b) For image guided interventional procedures, typical doses to patients; *(c) For therapeutic radiological procedures, absorbed doses to the planning target volume for each patient treated with external beam therapy and/or brachytherapy and absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner;* *(d) For therapeutic radiological procedures with unsealed sources, typical absorbed doses to patients".*
(4)	**BASIS: GSR Part 3 Requirement 34, para 3.148 states that** *"The government shall ensure, as part of the responsibilities specified ……., that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.169 to be fulfilled. Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances."*
(5)	**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".*
(6)	**BASIS: GSR Part 3 Requirement 38, para 3.172 states that** *"Registrants and licensees shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks".*
(7)	**BASIS: GSR Part 3 Requirement 38, para 3.174 states that** *"Registrants and licensees shall ensure that dose constraints specified or approved by the ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority) on a case by case basis as part of a proposal for biomedical research …. are used in the optimization of protection and safety for persons subject to exposure as part of a programme of biomedical research".*
R	**Recommendation: See recommendation 18 in Section 9.1**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: In regard to protection of pregnant, breast-feeding female patients and their infants, the Regulations do not include provisions for: • ensuring adequate signs or communication means for requesting female patients who are to undergo a radiological procedure to notify on the possibility of being pregnant or the fact that she is breast feeding in the case of procedures that involve the administration of a radiopharmaceutical; • the implementation of procedures for ascertaining the pregnancy status of a female patient of reproductive capacity before any radiological procedure and for establishing that a female

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
patient is not currently breast-feeding before the administration of a radiopharmaceutical.	
(1)	**BASIS: GSR Part 3 Requirement 39, para 3.175 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 might be pregnant;* *(b) She is breast-feeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical".*
(2)	**BASIS: GSR Part 3 Requirement 39, para 3.176 states that** *"Registrants and licensees shall ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus, so that this information can be considered in the justification for the radiological procedure …… and in the optimization of protection and safety".*
R	**Recommendation: See recommendation 18 in Section 9.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Criteria for the release of patients after radionuclide therapy are not in full compliance with relevant provisions in GSR Part 3.	
(1)	**BASIS: GSR Part 3 Requirement 40, para. 3.178 states that** *"The radiological medical practitioner shall ensure that no patient who has undergone a therapeutic radiological procedure with a sealed source or an unsealed source is discharged from a medical radiation facility until it has been established by either a medical physicist or the facility's radiation protection officer that:* *(a) The activity of radionuclides in the patient is such that doses that could be received by members of the public and family members would be in compliance with the requirements set by the relevant authorities; and* *(b) The patient or the legal guardian of the patient is provided with:* *(i) Written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination;* *(ii) Information on the radiation risks".*
R	**Recommendation: See recommendation 18 in Section 9.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Authorized parties are not required by the Regulations to maintain personnel related records, calibration, dosimetry and quality assurance records and records for medical exposure of patients and volunteers, as well as reports of investigations of unintended and accidental medical exposures.	
(1)	**BASIS: GSR Part 3 Requirement 42, para. 3.183 states that** *"Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following personnel records:* *(a) Records of any delegation of responsibilities by a principal party…..;* *(b) Records of training of personnel in radiation protection".*
(2)	**BASIS: GSR Part 3 Requirement 42, para. 3.184 states that** *"Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records of calibration, dosimetry and quality assurance:* *(a) Records of the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients;* *(b) Records of dosimetry of patients, …… ;* *(c) Records of local assessments and reviews made with regard to diagnostic reference levels, …..... ;* *(d) Records associated with the quality assurance programme, ...)".*
(3)	**BASIS: GSR Part 3 Requirement 42, para. 3.185 states that** *"Registrants and licensees shall maintain for a period as specified by the regulatory body and shall make available, as required, the following records for medical exposure:* *(a) For diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures;* *(b) For image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired;* *(c) For nuclear medicine, the types of radiopharmaceutical administered and their activity;* *(d) For external beam radiation therapy or brachytherapy, a description of the planning target volume, the absorbed dose to the centre of the planning target volume, and the maximum and minimum absorbed doses delivered to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume, and the absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner; and in addition, for external beam radiation therapy, the dose fractionation and the overall treatment time;* *(e) Exposure records for volunteers subject to medical exposure as part of a programme of biomedical research;* *(f) Reports on investigations of unintended and accidental medical exposures."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R	**Recommendation: See recommendation 18 in section 9.1.**

11.2. OCCUPATIONAL RADIATION PROTECTION

The programme of application of radiation sources in Botswana includes 615 sealed sources and 424 radiation generators used in medical, industrial applications (industrial radiography, well logging, mining, level gauges) and research. This programme involves approximately 1761 occupationally exposed workers.

Legal and regulatory framework

The Regulations establish the responsibilities of employers, registrants and licensees for ensuring protection and safety in occupational exposure in planned exposure situations. Provisions for optimization are included in the Regulations as well. RPI requires applicants for an authorization to include the arrangements to be implemented for optimization of occupational exposures in the documentation. Dose limits for workers established in the Regulation are not in full compliance with dose limits recommended in GSR Part 3. In particular, values differ in the case of the dose limit for the lens of the eye, and extremities or skin for workers over the age of 18 years; and in the dose limit for the lens of the eye for exposure of apprentices in the age between 16 and 18 years. The Regulations establish provisions for requiring responsible parties to include design criteria and design features related to exposure of workers in the supporting documents There are also provisions requiring authorized parties to implement a programme for monitoring and recording occupational exposures, which are enforced by the RPI.

General responsibilities of registrants, licensees and employers

The Regulations include requirements establishing the responsibilities of registrants, licensees and employers for ensuring protection of workers against occupational exposure and for ensuring that protection and safety is optimized and that the dose limits for occupational exposure are not exceeded. There are no provisions requiring authorized parties to record decisions with regard to measures for protection and safety and to make them available to relevant parties. The Regulations require employers and authorized parties to implement arrangements for optimization, including the establishment of dose constraints, and this is enforced by RPI. The Regulations do not include requirements for recording any report received from a worker that could affect compliance with established safety requirements, stating that requirements in the Regulations do not relieve the employers from ensuring compliance with other applicable national and local laws and regulations governing hazards in the workplace and for ensuring that employers and authorized parties facilitate the compliance by workers with the relevant regulations for occupational exposure. Provisions requiring the authorized parties to provide workers with adequate information, instruction and training for protection and safety are in place, as well provisions for ensuring an adequate protection and safety for female workers and for persons under 18 years of age undergoing training. As part of the conditions of service the Regulations establish that employers, registrants and licensees do not offer benefits as substitutes for measures for protection and safety.

General responsibilities of workers

The Regulations do not establish provisions for ensuring that workers fulfil their obligations and carry out their duties for protection and safety.

Requirements for radiation protection programmes

According to the Regulations, authorized parties are required to establish and implement a radiation protection programme, which includes the designation of controlled and supervised areas, the establishment of local rules and procedures and the provision of personal protective equipment, the provisions for workplace monitoring and assessment of occupational exposure and workers' health surveillance.

Monitoring programmes and technical services

Personal dosimetry services are provided in Botswana by the National Dosimetry Laboratory (NDL) under RPI. The IRRS team was informed that this service covers 100 % of occupationally exposed workers in the country. Currently there are no requirements for the authorization or approval of individual monitoring and calibration services. RPI is the only provider of individual monitoring services in the country. Arrangements for authorization or approval of NDL as service provider for individual monitoring have not been initiated. For calibration services, RPI requires the use of service providers abroad which are recognized by RPI as part of the implementation of provisions of ISO17025.

Protection of workers in existing exposure situations

Regulatory requirements for the protection of workers in existing exposure situations have not been established in Botswana. There are no provisions for the protection of workers undertaking remedial actions, for the protection against the exposure to radon in workplaces and for protection of aircrews against the exposure to cosmic radiation.

Protection of workers in emergency exposure situations

On this topic, refer to Chapter 10 in this report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Dose limits for workers established in the Regulation are not in full compliance with dose limits recommended in GSR Part 3.	
(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 exposure".*
R	**Recommendation: See recommendation 18 in section 9.1**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: Regarding the responsibilities of authorized parties, the Regulations do not include: • requirements for recording any report received from a worker that could affect compliance with established safety requirements; • provision to ensure that requirements in the regulations do not relieve the employers from ensuring compliance with other applicable national and local laws and regulations governing hazards in the workplace; and

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
• provisions for ensuring that employers and authorized parties facilitate the compliance by workers of the relevant for occupational exposure regulations.	
(1)	**BASIS: 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 ……., and shall take appropriate action".*
(2)	**BASIS: GSR Part 3 Requirement 21, para. 3.81 states that** *"Nothing in …. Standards shall be construed as relieving employers from complying with applicable national and local laws and regulations governing hazards in the workplace".*
(3)	**BASIS: GSR Part 3 Requirement 21, para. 3.82 states that** *"Employers, registrants and licensees shall facilitate compliance by workers with the requirements of …. Standards".*
R	**Recommendation: See recommendation 18 in section 9.1**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Radiation Protection Regulations do not establish provisions for ensuring that workers fulfil their obligations and carry out their duties for protection and safety.	
(1)	**BASIS: GSR Part 3 Requirement 22 states that** *"Workers shall fulfil their obligations and carry out their duties for protection and safety".*
R	**Recommendation: See recommendation 18 in section 9.1**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Requirements for the authorization or approval of individual monitoring and calibration services are not in place. Therefore NDL has not been formally authorized or approved by RPI for providing services of individual monitoring.	
(1)	**BASIS: GSR Part 3 Requirement 20, para. 3.73 states that** *" The regulatory body shall be responsible, as appropriate, for:* *……* *(c) Authorization or approval of service providers for individual monitoring and calibration services;* *……".*
R	**Recommendation: See recommendation 18 in section 9.1**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Regulatory requirements for the protection of workers in existing exposure situations have not been established.	
(1)	**BASIS: GSR Part 3 Requirement 52 states that** *"The regulatory body shall establish and enforce requirements for the protection of workers in existing exposure situations".*
R	**Recommendation: See recommendation 18 in Section 9.1.**

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

Control of radioactive discharges and clearance

The Regulations include provisions for the control of discharges of radioactive materials to the environment. Criteria for authorizing radioactive discharges to the environment are based on values established for exemption, which can limit the options for the proper management of liquid or gaseous waste. In general requirements for the control of discharges are not in full compliance with current relevant IAEA standards. Nevertheless, presently requirements relevant for the control of discharges in the Regulations are not being enforced, as currently scenarios of potential release of these materials to the environment have not been identified. This situation is motivated by the assumption that there are no facilities and activities in the country dealing with unsealed sources. However, during the discussions carried out the IRRS team was informed that production of electricity in the country is based on the use of coal as fuel. This fact represents a potential for the release of radionuclides of natural origin due to the possible liberation of fly ashes into the atmosphere through power stations venting systems.

Regarding clearance, the Regulations establish as clearance levels the values of activity and activity concentrations given in First Schedule. However, additional criteria for clearance as in GSR Part 3 that could be applicable when deciding on authorizing a conditional clearance of certain materials have not been established.

RPI is in the position to develop national criteria for discharge limits and releases of radioactive substances to the environment. Nevertheless, the criteria are not established in the current regulations.

Environmental monitoring for public radiation protection purposes

The Act requires applicants for an authorization to submit an Environmental Impact Assessment (EIA) with an application for a license. This is also one of the requirements stated on the checklist used by RPI for reviewing license applications. Where the RPI deems necessary, the applicant is required to do an EIA. The EIA includes consultation with members of the public and informing them about the possible risks associated with proposed facilities. RPI receives the EIA for comments and approval, then following provide them respectively.

Currently RPI is the only organisation in the country competent to conduct environmental monitoring. Some measurements have been performed regularly during the last 5 years using TLD to measure radiation levels in 18 stations across the country. RPI has a laboratory equipped with gamma and alpha detectors and a device for measuring radon in air. Regarding the quality assurance programme, there are only some elements of it and calibration was not performed. Only one measurement was done at the potential site for a new uranium mine. There is no environmental monitoring programme for

radiation protection purposes or a national monitoring system for controlling the levels of radioactivity in foodstuffs and selected commodities. In implementing the provisions established in the Regulations related to environmental monitoring, the only laboratory in the country is the laboratory of RPI, which has very limited possibilities for measurements of radioactivity in environmental samples and foodstuffs, as well as of radon and radiation levels in the field, mines and other places.

Additionally, the IRRS team observed that, within the regulatory framework, there are gaps in the establishment of provisions for ensuring an adequate environmental monitoring programme at uranium and other types of mining sites, in the implementation of a national monitoring system for controlling the levels of radioactivity in foodstuffs and selected commodities and in the establishment of a framework for the control of radioactivity in materials for recycling (scrap yards, melting facilities, etc.).

Control of public exposure

The Regulations establish requirements for the control of public exposures. These requirements establish the responsibilities of licensees for ensuring an adequate protection of the members of the public against exposure due to sources under their responsibility, provisions for the control of visitors entering any controlled area, provisions for protection in case of the existence of sources of external irradiation and contaminated spaces, requirements for ensuring the establishment of adequate monitoring programmes and requirements related to the control of consumer products. These requirements are not in full compliance with current IAEA safety standards, as some requirements of these standards are missing in national regulations, in particular provisions establishing the responsibility of authorized parties in applying the principle of optimization of protection and safety in the design, planning, operation and decommissioning of a source (or for closure and the post-closure period for waste disposal facilities).

Control of existing exposure situations and remediation

The Regulations do not include provisions specific for the control of public exposure in existing exposure situations. Comprehensive studies for determining the levels of radon indoors and to assess the associated risks, in order to establish and implement, if needed, actions for controlling public exposure have not been carried out. Responsibilities for remediation of areas with residual radioactive material have not been established neither. Reference levels for the control of levels of radioactivity in foodstuffs, water and other commodities, as for example building materials, have not been established.

RPI has made some efforts to identify existing exposure situations in the country, e.g. in old gold mines. Some interest has been expressed for assessing radon concentrations in coal mines, but so far they have not been characterized because of the lack of equipment suitable to work in environmental conditions inside these mines. Due to limited availability of radon monitoring equipment, very few measurements have been made for verifying levels of radon concentrations in air inside public buildings, dwellings and mines. RPI recognizes that efforts to identify existing chronic exposure scenarios in the country lacked of a clear national roadmap or action plan, as some parts of the country were not covered. Hence, there is a need to develop a well thought out action plan to identity more legacy sites that could be assessed for possibility of contributing to public exposure.

Regarding remediation, the IRRS team was informed that an accident involving a Cs-137 source which remained stuck in a mine and was damaged during the extraction for its recovery resulted in contamination of surrounding area. RPI requested and controlled the clean-up process, but the radioactive waste generated during clean-up process was stored in barrels in facilities not adequate for this purpose. The barrels were stolen, and their content was spread over the site, generating more waste and after that an additional clean-up was carried out. The generated waste is still stored at the facilities of the mining company.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Criteria for controlling radioactive discharges are not established in current regulations.	
(1)	**BASIS: GSR Part 3 Requirement 30, states that** *"The regulatory body shall establish or approve operational limits and conditions relating to public exposure, including authorized limits for discharges".*
R	**Recommendation: See recommendation 18 in Section 9.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Environmental monitoring programmes with purpose of public radiation protection have not been implemented. A national monitoring system for controlling the levels of radioactivity in foodstuffs and selected commodities is not in place. The Regulations do not include provisions for the control of radioactivity in materials for recycling (scrap yards, smelting facilities, etc.).	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 32, para. 3.135 states that** *"The regulatory body shall be responsible, as appropriate, for:* *…* *(c) Making provision for an independent monitoring programme;* *….*
(2)	**BASIS: GSR Part 3 Requirement 51 states that** *"The regulatory body or other relevant authority shall establish reference levels for exposure due to radionuclides in commodities".*
R	**Recommendation: See recommendation 18 in Section 9.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation*:* The current general provisions in place for the control of public exposure are not in compliance with relevant requirements in GSR Part 3.	
(1)	**BASIS: GSR Part 3 Requirement 29 states that** *"The government or the regulatory body shall establish the responsibilities of relevant parties that are specific to public exposure, shall establish and enforce requirements for optimization, and shall establish, and the regulatory body shall enforce compliance with, dose limits for public exposure."*
R	**Recommendation: See recommendation 18 in Section 9.1.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The current provisions specific for the control of public exposure in existing exposure situations and for remediation are not in compliance with relevant requirements in GSR Part 3.	
(1)	**BASIS: GSR Part 3 Requirement 47 states that** *"The government shall ensure that*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection".
(2)	**BASIS: GSR Part 3 Requirement 47 states that** *"The government shall ensure that provision is made for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; and for putting in place an appropriate strategy for radioactive waste management".*
R	**Recommendation: See recommendation 18 in Section 9.1.**

11.4. SUMMARY

Regulatory framework in Botswana includes provisions for radiation protection and safety in medical, occupational and public exposures. This framework includes provisions for safety in the transport of radioactive material as well. These provisions are mainly contained in the Regulations, which in general are consistent with the previous version of IAEA Basic Safety Standards (BSS, SS-115). Due to this, several requirements incorporated in the latest version of IAEA BSS are missing in Regulations.

In the case of medical exposures, non-compliances were identified in the provisions for the protection of persons exposed not as patients (volunteers in biomedical research programmes, cares and comforters), in provisions for justification and optimization, as well as in the provisions for the protection of the pregnant and breast feeding women, the release of patients after radionuclide therapy and the recording of relevant for radiation protection of the patients information. Additionally, some gaps were identified related to the lack of appropriate competence in radiation protection and safety of persons with responsibilities for safety in medical facilities, and the lack of medical physicist for ensuring the fulfilment of provision in regulations for the protection against medical exposure.

In relation to occupational exposures non-compliance with some dose limit values was observed, some of the responsibilities of authorized parties and responsibilities of workers established in IAEA safety standards are not addressed in current regulations. There are no provisions for the approval of technical services in support of radiation protection programmes and provision for the occupational protection in existing exposure situations are not in place.

National regulations include provisions for the control of discharges of radioactive materials to the environment. However, corresponding requirements are not being enforced, as scenarios of potential release of radioactive material to the environment have not been identified yet. Criteria for clearance as in established in IAEA safety standards have not been established. Regulations establish requirements for the control of public exposures and provisions for environmental monitoring programme, but they are not in full compliance with IAEA safety standards. RPI is the only organisation competent to conduct environmental monitoring and measurements, but they have very limited possibilities. Regulations do not include provisions for the control of public exposure in existing exposure situations. The framework for the control of radioactivity in materials for recycling has not been developed. Exhaustive studies on radon concentrations in air inside public buildings, dwellings and mines have not been carried out. Reference levels for the control of levels of radioactivity in foodstuffs, water and other commodities have not been established. There is a need to

identify existing exposure situations in the country and to increase safety of facilities where radioactive waste and disused sources are currently stored.

APPENDIX I LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS			
1.	KENNY Tanya	Environmental Protection Agency Ireland	T.Kenny@epa.ie
2	LETZELTER Claire	ASN – Division de Paris Frane	claire.letzelter@asn.fr
3.	MOHAMED Galeel	Egyptian Atomic Energy Authority	mageleel2000@gmail.com
4.	ÖHLÉN Elisabeth	Swedish Radiation Safety Authority	Elisabeth.Ohlen@ssm.se
5.	REISNER Dominic	Austrian Federal Ministry of Science, Research and Economy (BMWFW)	Dominik.Reisner@bmwfw.gv.at
6.	SEVERA Reward	Radiation Protection Authority of Zimbabwe	rsevera@rpaz.co.zw
7.	SNEVE Malgorzata	Dep. of Nuclear Safety and Environmental Radioactivity Norway	Malgorzata.K.Sneve@nrpa.no
8.	SOUFI Itimad	Ministry of Energy, Mines and Sustainable Development, Morocco	i.soufi@mem.gov.ma
9.	STEWART James	Senior Expert	jim@torrens.demon.co.uk
IAEA STAFF MEMBERS			
1.	AL KHATIBEH Ahmad	Division of Radiation, Transport and Waste Safety	A.Al-Khatibeh@iaea.org
2.	TOMAS ZERQUERA Juan	Division of Radiation, Transport and Waste Safety	J.Tomas-Zerquera@iaea.org
3.	SWOBODA Zumi	Division of Radiation, Transport and Waste Safety	Z.Swoboda@iaea.org
LIAISON OFFICER			
1.	SHAMUKUNI Richard	Liaison Officer Radiation Protection Inspectorate	rshamukuni@gov.bw

APPENDIX II LIST OF COUNTERPARTS

IRRS EXPERTS	COUNTERPART
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	
Tanya Kenny Dominik Reisner	Tshegofatso Zwikula
GLOBAL SAFETY REGIME	
Tanya Kenny Dominik Reisner	Thapelo Abel Otukile
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	
Tanya Kenny Dominik Reisner	Tshegofatso Zwikula
MANAGEMENT SYSTEM	
Elisabeth Öhlén	Disho Gokatweng
AUTHORIZATION	
Claire Letzelter Reward Severa Mohamed Geleel Malgorzata Sneve James Stewart	Golebaone Esther Mokopasetso Richard Shamukuni Tumelo Baraedi
REVIEW AND ASSESSMENT	
Claire Letzelter Reward Severa Mohamed Geleel Malgorzata Sneve James Stewart	Golebaone Esther Mokopasetso Richard Shamukuni Tumelo Baraedi
INSPECTION	
Claire Letzelter Reward Severa Mohamed Geleel	Golebaone Esther Mokopasetso Richard Shamukuni

IRRS EXPERTS	COUNTERPART
Malgorzata Sneve James Stewart	Tumelo Baraedi
ENFORCEMENT	
Claire Letzelter Reward Severa Mohamed Geleel Malgorzata Sneve James Stewart	Golebaone Esther Mokopasetso Richard Shamukuni Tumelo Baraedi
REGULATIONS AND GUIDES	
Claire Letzelter Reward Severa Mohamed Geleel Malgorzata Sneve James Stewart	Golebaone Esther Mokopasetso Richard Shamukuni Tumelo Baraedi
EMERGENCY PREPAREDESS AND RESPONSE	
Itimad Soufi	Kenneth Gabanamotse
ADDITIONAL AREAS - Medical Exposure	
Juan Tomas Zerquera	Boaz Modise Tladi
ADDITIONAL AREAS - Occupational Exposure	
Juan Tomas Zerquera	Keolopa Gabobofane
ADDITIONAL AREAS - Control of radioactive discharges and materials for clearance, Environmental monitoring associated with authorized practices for public radiation protection purposes **Control of chronic exposures**	
Malgorzata Sneve	Thapelo Nthokana

APPENDIX III MISSION PROGRAMME

BOTSWANA IRRS MISSION PROGRAMME Gaborone, Botswana, 15 – 24, October 2017			
Sunday, 15/10			
Time	**Activity**		**Venue**
13:30 - 17:30	**Initial IRRS Review Team Meeting**		
	• Opening remarks (IRRS Team Leader: Ms Tanya Kenny) • Introduction (IAEA) • Self-introduction of all attendees (All IRRS team, LO) • IRRS Process (IAEA) • Report writing (IAEA) • Schedule (TL, IAEA, LO) • First impression from experts arising from the Advanced Reference Material (ARM) (All IRRS team) • Administrative arrangements (LO, IAEA) • Detailed Mission Programme (LO, IAEA)		**Venue:** TBD **Participants:** the IRRS team + LO
Monday 16/10			
08:00	**Pick up from the hotel**		
IRRS Entrance Meeting			
09:00 – 12.00	09:00 09:15 09:30 09:45	Arrival of IRRS team at (location of meeting) – Registration Welcoming Address (Senior Government) The IRRS programme (IRRS Coordinator) Expectations for the Mission and introduction of the IRRS team (IRRS Team Leader) Introduction of the **DRPI** counterparts Group photo of the meeting participants	**Venue:** RPI **Participants:** Senior Government representative, Senior management **DRPI** (+ LO) and staff, Officials from relevant organizations, the IRRS team.

10:15	**Coffee break**		
	10:45 - 11:45	**DRPI** presentation – Regulatory Overview – SARIS results (strengths, challenges, action plan) Discussion – Questions	
12:00 – 13:00	**Lunch**		
Daily Discussions / Interviews			
13:00 – 17:00	Interviews and Discussions with Counterparts (parallel discussions)		**IRRS Reviewers and DRPI Counterparts**
17:00 – 18:00	Daily IRRS Review Team meeting		**Venue:** conference room **Participants:** the IRRS team + LO.
18:00	**Transport to the hotel**		
18:30 -	Writing draft report		**IRRS team (each reviewer individually in his/her specific area e.g. hotel room).**
Tuesday 17/10			
08:30	**Pick up from the hotel**		
09:00 – 17:00	Interviews and discussions with counterparts (parallel discussions)		**IRRS Reviewers and DRPI Counterparts**
12:00 – 13:00	**Lunch**		
17:00 – 18:00	Daily IRRS Review Team meeting		**Venue**: Conference room **Participants:** the IRRS team + LO.
18:00	**Transport to the hotel**		
18:30 -	Writing draft report		**IRRS team**

Wednesday 18/10		
08:00	**Pick up from the hotel**	
Daily Discussions / Interviews / Site visits		
09:00– 17:00	Interviews and discussions with counterparts for all modules Report preparation	**IRRS Reviewers and DRPI Counterparts**
08:00 -13:00	Site Visits: Medical Facility: Industrial Facility:	**IRRS experts + DRPI inspectors**
10:00	Meeting with the Chairman of the Board	**DRPI Participants: IRRS TL+TC+ Expert M1 to 3**
12:00 – 13:00	**Lunch**	
14:30	Meeting with the Minister	**Participants: IRRS TL+TC+ Expert M1 to 3**
16:45 – 17:00	Quick briefing on all site visits	**IRRS team**
17:00 – 18:00	Daily IRRS Review Team meeting	**Venue:** conference room **Participants:** IRRS team + LO.
18:00	**Transport to the hotel**	
18:30 –	Writing draft report, Observations (Os), Recommendations (Rs), Suggestions (Ss) and Good Practices (GPs)	**IRRS team (each reviewer individually in his/her specific area e.g. hotel room)**
Thursday 19/10		
08:30	**Pick up from the hotel**	
Daily Discussions / Interviews		
09:00– 16:00	Follow-up interviews and discussions with counterparts if needed.	**IRRS Reviewers and DRPI Counterparts**
09:00 – 16:30	Team members finalize Os, Rs, Ss and GPs Team members finalise their part draft report text	**IRRS team**

	individually	
12:00 – 13:00	**Lunch**	
17:00 – 22:00	Daily IRRS Review Team Meeting: Team finalises Rs, Ss and GPs	**Venue:** DRPI meeting room **Participants:** the IRRS team + LO.
TBD	**Transport to the hotel**	
22:00 -	Writing draft report: Reviewers complete report text individually.	**IRRS team (each reviewer individually in his/her specific area e.g. hotel room).**
Friday 20/10		
08:30	**Pick up from the hotel**	
08:00 – 22:00	Team members finalises draft report.	**Venue:** DRPI meeting room IRRS team
12:00 – 13:00	**Lunch**	
Saturday 21/10		
Report drafting and finalization		
08:00 -10:00	TL + IAEA review the draft report	TL + TC Venue: Hotel
10:00	The draft report is submitted to LO for **DRPI** comments	**TC**
Sunday 22/10		
IRRS team Free Day – Cultural Programme		
All day	IRRS team rest day + Excursion (IRRS team)	
Monday 23/10		
08:30	**Pick up from the hotel**	

Report commenting and discussions		**Venue: DRPI**
09:00 –	**DRPI** submits comments on the draft report	LO
09:00 – 11:00	IRRS team reviews **DRPI** comments	IRRS team
Report reviewing and finalization		
11:00 – 12:30	IRRS team finalizes the draft report together with **DRPI**	The IRRS team + LO + **DRPI**
12:30 – 14:00	**Lunch (as convenient)**	
Tuesday, 24/10		
08:15	**Pick up from the hotel**	
IRRS mission exit meeting		
09:00 – 11:00	• Remarks (Senior Government Official) • Main findings of the IRRS mission (Team Leader) • Remarks by **DRPI** in response to the mission findings • Closing remarks by IAEA Official (Director NSRW) • IAEA press release	**Venue:** TBD **Participants:** Government officials, senior management and staff, officials from relevant organisations, the IRRS team + LO

APPENDIX IV SITE VISITS

- Medical site visited is Gaborone private hospital, oncology centre (brachy therapy clinic)
- Temporary storage facility for confiscated sealed sources (operated by Regulatory body)

APPENDIX V RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**	R1	The Government should establish and implement a national policy and strategy which achieves the fundamental safety objective.
		R2	While amending the Act, the Government should ensure that: • the types type of authorizations that are required for the operation of facilities and for the conduct of activities, in accordance with a graded approach, are clearly stated. • the regulatory body is enabled to perform its functions more effectively by allowing the Board to delegate certain powers to RPI. • all organizations or individuals, natural or legal, who may be authorized to operate a facility or conduct an activity are covered. • criteria for release from regulatory control are established. provisions for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities are included, and responsibility for the remediation of contaminated areas.
		R3	The Government should ensure the legal and regulatory framework enables the effective independence of RPB and it is not subjected to pressures associated with political circumstances
		R4	The Government should ensure that the legal and regulatory framework for safety clearly allocates the responsibilities to all involved.
		S1	To further reduce the risk emanating from unregulated sources the

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			Government should consider ensuring that all relevant authorities cooperate to achieve this.
		R5	The Government should establish a national policy and a strategy for radioactive waste management that includes decommissioning and disposal and expresses long term commitment to safety.
		R6	The Government should make provisions for building and maintaining competence of all parties having responsibilities to the safety of facilities and activities.
2.	**GLOBAL SAFETY REGIME**	GP1	Through participation in a wide range of international instruments and bilateral and multilateral arrangements, as well as International Peer Reviews Botswana strongly recognizes the importance of International cooperation in relation to safety in contributing to the development of a global safety regime.
		S2	RPI should consider establishing formal procedures to analyse and screen international and operational experience to improve its regulatory practices.
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	R7	RPI should prioritize its tasks and optimise its resources through application of a graded approach in implementing its regulatory programme.
		R8	RPI should maintain its effective independence and request the Government to assign the operation of the radioactive source storage facility to another entity.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R9	RPI should ensure that it employs sufficient number of qualified staff and to develop and implement a training programme to build and maintain the required competence for its staff.
		S3	RPI should consider communicating with interested parties and the public on regulatory judgements and decisions.
		S4	RPI should consider informing and consulting interested parties in relation to changes in regulatory requirements.
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	GP2	RPI has established goals and strategies that are consistent with overall safety policy and the Strategic Plan of the Ministry. The integration of Ministry Strategic Plan with key measurable of RPI is noted as a good practice enhancing overall safety policy.
		S5	RPI should consider including and specifying the responsibilities, accountabilities and level of authority of the process owners in the management system manual.
		GP3	Safety culture is an integrated part of the management system and RPI has recently assessed the technical staff´s experience on the safety culture aspects including leadership for safety.
		S6	RPI should consider improving its system for record keeping so that it makes better provision for maintaining and retrieving adequate records relating to safety.
		R10	RPI should continue the work to implement, continuously assess and improve its management system, including developing, documenting and effectively managing its processes and activities and maintaining the necessary supporting documentation following a graded approach

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			to achieve the organization´s goals without compromising safety.
5.	AUTHORIZATION	R	See Recommendation R2 in Section 1.2
		R11	RPB should ensure that it formally records the basis for its decisions on the authorization of a facility or an activity.
		R12	RPB should ensure that it implements a formalized multi-stage licensing process for complex facilities.
		R	See recommendation R8 in section 3.2
		R	See recommendation R8 in section 3.2
6.	REVIEW AND ASSESSMENT	R	See the Recommendation R7 in Section 3.1.
		R13	The Government, while amending the Act should ensure there are provisions to require that safety assessment is carried out by suitably qualified and experienced persons and is independently verified.
		R	See Recommendation R18 in Section 9.1
		R14	RPB should take into account, in its decision-making process, risks that are not related to radiation but might arise in the operation of facilities or conduct of activities.
		R15	RPI should review its procedures and instructions to ensure sufficient information is gathered, reviewed and assessed in order to verify the continued safety of transport packages that do not require competent

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			authority approval in the country of origin and any special form material.
7.	**INSPECTION**	S7	RPI should consider liaising with relevant organizations for joint inspections where necessary.
		R16	RPI should carry out unannounced inspections and include them in its inspection programme.
		R	See Recommendation R7 in Section 3.1.
		GP4	RPI has a system for providing information on transport operations by the shippers which improves knowledge of facilities and activities that should be regulated and as a result enables effective management of resources.
8.	**ENFORCEMENT**	R17	RPI should ensure that authorized parties implement necessary corrective actions within the specified time frame.
9.	**REGULATION AND GUIDES**	R18	The Government should ensure that all regulations related to nuclear and radiation safety are updated to be consistent with the latest IAEA safety standards.
		R19	RPB should develop and implement a process for reviewing and updating the regulations and guides and ensure that interested parties are involved.
		R	See recommendation 18 in Section 9.1.
		R	See Recommendation 5 in section 1.7.
		S8	RPI should consider ensuring that transport permits do not include

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			instructions that may be in conflict with requirements in other national legislation.
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R	See Recommendation R18 in Section 9.1.
		R	See Recommendation 7 in Section 3.1
		R	See Recommendation R9 in Section 3.3
		R20	The Government should develop an emergency plan at the national level to address nuclear and radiological emergencies, in a coordinated and integrated manner with other relevant national plans.
		S9	Once the national emergency plan has been developed, RPI should consider reviewing and updating its emergency plan to be consistent with the national emergency plan.
		R	See recommendation R10 in Section 4.5
		S10	RPI should consider establishing formal coordination arrangements with NDMO and as appropriate with other response organizations.
11.1	**CONTROL OF MEDICAL EXPOSURES**	R21	The Government, with the support of RPI, should initiate actions for the establishment at the national level of a programme for education and training in radiation protection of personnel with responsibilities for radiation protection and safety in medical facilities.
		R	See recommendation R18 in Section 9.1.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R	See recommendation 7 in Section 1.8.
		R22	RPI should require authorized parties to ensure the availability of the equipment needed for performing calibration, dosimetry and quality assurance in all medical facilities that carry out radiological procedures.
		R	See recommendation 18 in Section 9.1.
		R	See recommendation 18 in Section 9.1
11.2	**OCCUPTIONAL RADIATION PROTECTION**	R	See recommendation 18 in section 9.1
		R	See recommendation 18 in section 9.1
11.3	**CONTROL OF RADIOACTIVE DISCHARGES AND MATERIAL FOR CLEARANCE, ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES** **CONTROL OF CHRONIC EXPOSURES**	R	See recommendation 18 in Section 9.1.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

ADVANCE REFERENCE MATERIAL
DOCUMENTS
COUNTRY EMERGENCY PREPAREDNESS AND RESPONSE PLAN TO NUCLEAR AND RADIOLOGICAL EMERGENCIES.pdf
ENFORCEMENT POLICY.pdf
FORM_Storage Facility Radiation Area Survey (issue No 2.pdf
FORM_Storage Facility Radiological Movement (issue No 2.pdf
Guide for the Safe Use of Ionizing Radiation in Secondary Schools.pdf
Guideline for Design of X-Ray Rooms.pdf
Guideline for Developing a Radiation Protection and Safety Programme for Portable Gauges.pdf
Guideline for Import and Export of Sources and X-ray Generators.pdf
Guideline for Inspections of medical diagnostic X-ray and dental facilities.pdf
Guideline for Radiation Protection in Well Logging and Analytical Devices.pdf
Guideline for Radiation Protection Programme for Industrial Radiography.pdf
Guidelines for Design and Equipment Specifications for Nuclear Medicine Facilities.pdf
GUIDELINES FOR RESPONDING TO A Dispersion of alpha emitters.pdf
GUIDELINES FOR RESPONDING TO A Dispersion of Laboratory accident.pdf
GUIDELINES FOR RESPONDING TO A LOST OR STOLEN RADIOACTIVE SOURCE.pdf
GUIDELINES FOR RESPONDING TO A RADIOACTIVE SOURCE OR CONTAMINATION.pdf
GUIDELINES FOR RESPONDING TO A TRANSPORTATION EMERGENCY.pdf
GUIDELINES FOR RESPONDING TO A Unshielded Source.pdf
Guidelines for the Management OF SPENT and DISUSED SEALED SOURCES.pdf
MANUAL_INTEGRATED MANAGEMENT SYSTEM (Issue No 4 0).pdf
National Disaster Risk Reduction Strategy.pdf
National Policy On Disaster Management.pdf
PROCEDURE_01_CONDUCTING A PRE-AUTHORIZATION INSPECTION (Issue 1.0).pdf
PROCEDURE_01_DOCUMENT CONTROL (Issue 2 0).pdf
PROCEDURE_01_ENVIRONMENT MONITORING (Issue 1.0).pdf
PROCEDURE_01_ISSUING OF LICENSES (Issue 3.0).pdf
PROCEDURE_01_RESOURCE MANAGEMENT (Issue 1.0).pdf

ADVANCE REFERENCE MATERIAL

PROCEDURE_02_APPLICATION FOR PERMITS (Issue 2.0).pdf

PROCEDURE_02_CONTROL OF RECORDS (Issue 1.0).pdf

PROCEDURE_02_PURCHASING OF MONITORING AND MEASURING EQUIPMENT (Issue 1.0).pdf

PROCEDURE_02_RADIOACTIVE WASTE MANAGEMENT (Issue 1.0).pdf

PROCEDURE_03_CONDUCTING AN INSPECTION (Issue 2.0).pdf

PROCEDURE_03_CONTROL OF MONITORING AND MEASURING EQUIPMENT (Issue 1.0).pdf

PROCEDURE_04_COMMUNICATION (Issue 1.0).pdf

PROCEDURE_05_MANAGEMENT REVIEW (Issue 1.0).pdf

PROCEDURE_07_INTERNAL AUDITS (Issue 1.0).pdf

PROCEDURE_08_CONTROL OF NONCONFORMING PRODUCT OR SERVICE (Issue 1.0).pdf

PROCEDURE_09_CORRECTIVE AND PREVENTIVE ACTIONS (Issue 1.0).pdf

RADIATION PROTECTION Act.pdf

RADIATION PROTECTION REGULATIONS.pdf

Radiological Emergency Process Map.pdf

Radiological Emergency Register.pdf

RADIOLOGICAL INCIDENT and EMERGENCY FORMS.pdf

SEALED SOURCES STORAGE GUIDELINES.pdf

SECURITY OPERATIONAL PROCEDURES FOR THE STEEL CARGO STORAGE FACILITY.pdf

WI_01_01_ASSESSMENT OF LICENSE APPLICATIONS (Issue 2.0).pdf

WI_01_01_CONDUCTING A PRE-AUTHORIZATION INSPECTION (Issue 1 0).pdf

WI_01_01_RADON MONITORING (Issue 1 0).pdf

WI_01_02_AMBIENT BACKGROUND RADIATION MONITORING (Issue 1 0).pdf

WI_01_02_PREPARATION AND ISSUANCE OF LICENSE APPLICATIONS (Issue 2.0).pdf

WI_01_03_Updating of RAIS (Issue 1.0).pdf

WI_01_04_ PAYMENT FOR THE LI SERVICE S (Issue 2.0).pdf

WI_02_01_ASSESSMENT OF APPLICATIONS FOR IMPORT PERMITS (Issue 2.0).pdf

WI_02_01_CONDUCTING AN INSPECTION (Issue 1 0).pdf

WI_02_01_RECEIVING, HANDLING AND STORAGE OF RADIOACTIVE SOURCES (Issue 1.0).pdf

WI_02_02_ASSESSMENT OF EXPORT PERMIT APPLICATIONS (Issue 2.0).pdf

WI_02_03_ASSESSMENT OF TRANSPORT PERMIT APPLICATIONS (Issue 2.0).pdf

WI_03_01_INSPECTION PLANNING (Issue 2.0).pdf

WI_03_01_LU TEST AND HV ADJUSTMENT (Issue 1.0).pdf

ADVANCE REFERENCE MATERIAL

WI_03_02_CONDUCTING AN INSPECTION (Issue 2.0).pdf

WI_03_02_FHT1377 HV adjustment (Issue 1 0).pdf

WI_03_03_ FH 40 GL 10 Check Measurements.pdf

WI_03_03_REPORTING (Issue 2.0).pdf

SARIS

01 Responsibilities and Functions of the Government.pdf

02 The Global Safety Regime.pdf

03 Responsibilities and Functions of the Regulatory Body.pdf

04 Management System for the Regulatory Body.pdf

05 Authorization.pdf

06 Review and Assessment.pdf

07 Inspection.pdf

08 Enforcement.pdf

09 Regulations and Guides.pdf

10 Basic Primary responsibilities of the regulatory body RB in emergency.pdf

Interface with Nuclear Security.pdf

Regulation of decommissioning of facilities.pdf

Regulation of Radiation Sources.pdf

Regulation of Transport of Radioactive Material.pdf

Safety of Medical Exposure.pdf

Safety of Occupational Radiation Protection.pdf

Safety Requirements for Disposal of Radioactive Waste.pdf

Safety Requirements for Existing Chronic Exposure and remediation.pdf

Safety Requirements for Predisposal Management of Radioactive Waste.pdf

Safety Requirements for the Control of Public Exposure.pdf

SARIS Action Plan_2017.pdf

SARIS Summary Report_2017.pdf

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1(Rev 1) (Vienna2016)
3. INTERNATIONAL ATOMIC ENERGY AGENCY- Leadership and Management for Safety Requirement GSR Part 2 IAEA, Vienna (2016)
4. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, (2014)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4 (Rev 1), IAEA, Vienna (2016)
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities General Safety Requirement Part 6, No. GSR Part 6, IAEA, Vienna (2014)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Preparedness and Response for a Nuclear or Radiological Emergency General Safety Requirement Part 7, No. GSR Part 7, IAEA, Vienna (2015)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulations for the Safe Transport of Radioactive Material Specific Safety Requirements 6, No. SSR 6, IAEA, Vienna (2012)8.
10. 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)
11. 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)
12. 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)
13. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
14. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
15. 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)
16. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
17. 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)
18. 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)

19. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)

20. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)

21. 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)

22. INTERNATIONAL ATOMIC ENERGY AGENCY – Establishing the Safety Infrastructure for a Nuclear Power Programme Specific Safety Guide No SSG-16, IAEA, Vienna (2011)

23. INTERNATIONAL ATOMIC ENERGY AGENCY - Disposal of Radioactive Waste Specific Safety Requirements 5, No. SSR 5, IAEA, Vienna (2011)

APPENDIX VIII ORGANIZATION CHART