IAEA-NS-IRRS-2014/08
ORIGINAL: English

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

THE REPUBLIC OF ZIMBABWE

Harare, Zimbabwe

9 to 18 November 2014

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

IAEA Integrated Regulatory Review Service IRRS

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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)
REPORT TO
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Mission date:	*9 to 18 November 2014*
Regulatory body:	*Radiation Protection Authority of Zimbabwe*
Location:	*Harare, Zimbabwe*
Regulated facilities and activities:	*Radiation Sources in industrial and medical facilities, emergency preparedness and response, medical exposure, occupational exposure*
Organized by:	*International Atomic Energy Agency (IAEA)*

IRRS REVIEW TEAM

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

TABLE OF CONTENTS

EXECUTIVE SUMMARY

At the request of the Government of the Republic of Zimbabwe (Zimbabwe), an international team of senior safety experts met representatives of the Radiation Protection Authority of Zimbabwe (RPAZ) from 9 to 18 November 2014 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place mainly at the headquarters of RPAZ in Harare. The purpose of the peer review was to review the national regulatory framework for radiation safety of Zimbabwe.

The review compared the Zimbabwe regulatory framework for radiation safety against the IAEA Safety Standards as the international benchmark for safety. The mission was also used as an opportunity to exchange information and experience between the IRRS review team and the RPAZ counterparts in the areas covered by the IRRS.

The IRRS review team consisted of six senior regulatory experts from six IAEA Member States, two IAEA staff members and one IAEA administrative assistant. The IRRS review team carried out the review in the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection, enforcement, scope and content of regulations and guides; emergency preparedness and response; control of medical exposures; occupational radiation protection; transport of radioactive material; and radioactive waste management.

The IRRS mission also included policy discussions on the topics of the Use of Whole Body Scanners in the Diamond Industry and Involvement of Interested Parties in the Regulatory Decisions.

RPAZ provided the IRRS review team with advanced reference material and documentation including the results of self-assessment in all areas within the scope of the mission which also included an action plan. The mission included observations of regulatory activities and interviews and discussions with RPAZ staff, the Department of Civil Protection and Board members of RPAZ. These activities included observations of inspections at Parirenyatwa Hospital in Harare and Delta Beverages in Harare industrial facility. The IRRS review team members observed the working practices during inspections carried out by RPAZ, including discussions with the licensee personnel and management.

Throughout the mission, the IRRS review team was extended full cooperation in regulatory, technical, and policy issues by all parties; in particular, the staff of RPAZ provided the fullest practicable assistance and demonstrated extensive openness and transparency.

The IRRS review team identified a number of good practices and made recommendations and suggestions where improvements will enhance the effectiveness of the regulatory framework and functions in line with the IAEA Safety Standards. The IRRS review team recognized that the IRRS findings broadly correlated with the action plan prepared by RPAZ as a result of the self-assessment.

The IRRS review team made the following general observations:

- Very good and important work was performed during the last few years and overall, RPAZ is moving in the right direction in strengthening the regulatory processes and improving the management of radiation safety in the Republic of Zimbabwe;
- RPAZ is an effectively independent regulatory body;
- A legal and regulatory framework exists but important issues such as the prime responsibility for safety, avoiding conflict of interest, management of disused and orphan sources and radioactive waste, among others, are not adequately covered
- Zimbabwe should improve its participation in the international legal instruments related to nuclear and radiation safety;
- Considerable work has been done by RPAZ to establish a management system; however harmonisation of the management system documents and effective implementation needs to be improved.

The IRRS review team believes that RPAZ faces some challenges over the next several years, which include:

- Updating the legislative and regulatory framework and developing new regulations and guides;
- Further development and implementation of its Integrated Management System; and
- Securing sufficient resources, human and financial, to strengthen its infrastructure and implement its strategic plans

The IRRS review team identified good practices and made recommendations and suggestions where improvements are necessary to strengthen and enhance the regulatory functions in line with the IAEA Safety Standards.

Among the strengths and good practices identified by the IRRS review team are the followings:

- The change to the organisational structure to report directly to the Office of the President and Cabinet gives more effective independence to RPAZ.
- RPAZ includes, in its organisational structure, a Corporate Communications Officer, reporting to the CEO, whose primary responsibility is communications with all interested parties.
- RPAZ is a signatory to the Memorandum of Cooperative Arrangements where 15 nations share information amongst each other through establishment of the voluntary Southern African Development Community Nuclear Regulators Network.

The IRRS review team identified issues warranting attention and taking them into consideration would enhance the overall performance of the regulatory system:

- Revision of the legal and regulatory framework so that the provisions of the international safety standards are more completely addressed.
- Establishment of a national policy and strategy for safety and a policy to include financial provisions for decommissioning of facilities, the safe management and disposal of radioactive waste.
- Provisions for building and maintaining the available national arrangements for education and training to address the competence needs of all relevant parties involved in radiation safety, based on competence analysis
- An awareness of internal safety culture by ensuring it is in the training programme for all regulatory staff
- Implementation of a graded approach in all activities;
- Development, in cooperation with the emergency response coordinating authority, an incident command and control system as well as intervention and action levels;
- Development of guides for all regulated practices.

The IRRS review team findings are summarized in Appendix 5.

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

I. INTRODUCTION

At the request of the Government of Zimbabwe, an international team of senior safety experts met representatives of the Radiation Protection Authority of Zimbabwe (RPAZ) 9 to 18 November 2014 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of the peer review was to review the Zimbabwe regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of Zimbabwe in September 2013. A preparatory mission was conducted 9 to 10 June 2014 at the Radiation Protection Authority Headquarters in Harare to discuss the purpose, objectives, scope and detailed preparations of the review in connection with the facilities regulated by Radiation Protection Authority of Zimbabwe and selected safety aspects.

The IRRS review team consisted of 6 senior regulatory experts from 6 IAEA Member States, 2 IAEA staff members and 1 IAEA administrative assistant. The IRRS review 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, patient protection, transport of radioactive material; and radioactive waste management.

In addition, policy issues were discussed, including: Use of Whole Body Scanners in the Diamond Industry and Involvement of Interested Parties in the Regulatory Decisions.

RPAZ conducted a self-assessment in preparation for the mission and prepared a preliminary action plan. The results of RPAZ' self-assessment and supporting documentation were provided to the team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics by reviewing the advance reference material, conducting interviews with management and staff of RPAZ and performed direct observation of RPAZ working practices during inspections. Meetings with the Department of Civil Protection, the Board members of RPAZ were also organised.

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

II. OBJECTIVE AND SCOPE

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

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

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

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of Zimbabwe, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 9 to 10 June 2014. The preparatory meeting was carried out by the appointed Team Leader Ms Patricia Holahan and the IRRS IAEA Team representatives Mr Ahmad Al Khatibeh and Mr Ibrahim Shadad.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of RPAZ represented by Mr Reward Severa, Chief Executive Officer and other senior management and staff. The discussions resulted in agreement that the regulatory functions covering the following facilities and activities were to be reviewed by the IRRS mission:

- Radiation sources facilities;
- Patient protection;
- Transport
- Radioactive waste management
- Occupational radiation protection;
- Emergency preparedness and respons
- Management system of the regulatory body;
- Selected policy issues.

The Executive Director of RPAZ made presentations on the national context, the current status of RPAZ 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 Zimbabwe in November 2014.

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

The RPAZ Liaison Officer for the preparatory meeting and the IRRS mission was Mr Justice Chipuru.

RPAZ provided IAEA (and the review team) with the advance reference material for the review at the end of August 2014, including the self-assessment results. In preparation for the mission, the IAEA review team members conducted a review of the advance reference material and provided their initial review comments to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCE FOR THE REVIEW

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

C) CONDUCT OF THE REVIEW

An opening IRRS review team meeting was conducted on Sunday, 9 November, 2014 in Harare by the IRRS Team Leader and the IRRS IAEA Team Coordinator to discuss the general overview, the focus areas and specific issues of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers. They also presented the agenda for the mission.

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

The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 10 November 2014, with the participation of RPAZ senior management and staff. Opening remarks were made by Deputy Chief Secretary, Mr J. H. Mupamhanga, Ms Patricia Holahan, IRRS Team Leader and Mr Ahmad Al Khatibeh, IRRS Team Coordinator. Mr Reward Severa, Chief Executive Officer of RPAZ gave an overview of the Zimbabwe context, RPAZ activities and the action plan prepared as a result of the self-assessment.

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

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

The IRRS exit meeting was held on Tuesday, 18 November 2014. The opening remarks at the exit meeting were presented by Mr Ahmad Al Khatibeh on behalf of the IAEA, Deputy Director General, Department of Nuclear Safety and Security and were followed by the presentation of the results of the mission by the IRRS Team Leader Ms Patricia Holahan. Closing remarks were made by Deputy Chief Secretary, Mr J. H. Mupamhanga.

An IAEA press release was issued at the end of the exit meeting.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The Zimbabwe national safety policies to ensure the protection of people and environment against the hazards of ionizing radiation are mainly addressed in the Radiation Protection Act [Chapter 15:15] (the Act). The fundamental safety principles expressed in this law are to establish measures to protect the public and workers from dangers resulting from the use or abuse of equipment, devices or materials capable of producing ionising radiation.

The Act incorporates provisions in the area of protection against harmful effects of ionising radiation, such as penalties on activities without authorisation; and other enforcement actions. However, the IRRS review team found that not all fundamental safety principles established in the IAEA Safety Fundamentals SF-1 are addressed in the present Zimbabwe framework for safety. Furthermore, the national policy and strategy is not documented as a statement formulating the government's intent.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Fundamental safety principles such as responsibility for safety, priority for safety, leadership and management for safety, and the protection of present and future generations are not covered by the existing safety legislation. A documented strategy and policy do not exist.
(1)	**BASIS: GSR Part 1 Req. 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 para 2.3 states that** *"National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing national policy."*
(3)	**BASIS: GSR Part 1 para 2.3 (a) states that** *"…In the national policy and strategy, account shall be taken of…The fundamental safety objective and the fundamental safety principles established in the Fundamental Safety Principles."*
R1	**Recommendation: The government should establish a national policy and strategy for safety to ensure that the Safety Fundamentals are explicitly adopted in a high level document.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The Act established the regulatory body and defined its main functions and responsibilities, provided the basis for inspection of facilities and activities and for the enforcement of regulations.

According to this Act, the following types of facilities and activities should be authorised by the regulatory body and meet the requirements prescribed by regulations made under this Act:

- possessing, using, operating, manufacturing, processing, storage, disposal, transport or use of nuclear materials, radioactive sources, radioactive waste;
- production, installation, use and maintenance of the equipment containing radioactive sources;
- commissioning of equipment generating ionising radiation;
- mining, milling and processing of radioactive material;
- administration of radioactive substances to humans; and

- import and export of radioactive waste and radioactive sources.

The present legislation does not cover all requirements of the international standards in the IAEA GSR Part 1. Examples of this are clear assignment of the prime responsibility for safety, clear provisions to empower the regulatory body to liaise with advisory bodies, provisions for the involvement of interested parties and for their input to decision making, the use of a graded approach and clear regulatory role of the regulatory body for Emergency Preparedness and Response (EPR).

The IRRS review team was informed that a new draft Act on the general framework of radiation safety and safeguards is under development. For the government to establish an effective safety framework it is recommended that all missing requirements of the international standards should be covered by the new Act.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Several elements for an effective governmental and legal framework for safety are missing from the existing law.
(1)	**BASIS: GSR Part 1 para. 2.5 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:* *(5) Provision for the involvement of interested parties and for their input to decision making;* *(6) Provision for assigning legal responsibility for safety to the persons or organizations responsible for the facilities and activities, and for ensuring the continuity of responsibility where activities are carried out by several persons or organizations successively;* *(11) Provision for appeals against decisions of the regulatory body;* *(12) Provision for preparedness for, and response to, a nuclear or radiological emergency;* *(17) The criteria for release from regulatory control."*
(2)	**BASIS: GS-R-2 para. 3.2 states that** *"The arrangements for emergency response actions both within and outside facilities, if applicable, or elsewhere under the control of the operator, are dealt with through the regulatory process…"*

R2	**Recommendation: The government should ensure that the proposed new law addresses the following issues in accordance with GSR Part 1:**
	• **Assigning prime responsibility for safety to the authorised party;**
	• **Ensure that donations, bequests, grants or loans do not create a conflict of interest;**
	• **Explicitly mention regulating the licensees' emergency preparedness and response obligations and capabilities among the functions of the Radiation Protection Authority of Zimbabwe;**
	• **Use of a graded approach in all regulatory activities;**
	• **Involvement of interested parties and for their input to decision making;**
	• **A provision for use of advisory bodies or support organizations in the conduct of the regulatory activities;**
	• **A provision for management of disused and orphan sources and radioactive waste;**
	• **The following items, already identified by the Radiation Protection Authority of Zimbabwe, should be included:**
	  ○ **Regulatory control for ionising radiation;**
	  ○ **System for the administration of safeguards, coordination of nuclear security, control of import/export of radioactive sources and equipment;**
	  ○ **Regulatory control for transport of radioactive materials.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Radiation Protection Authority of Zimbabwe (RPAZ) was established by the Act under the Minister of Health and Child Welfare. The Statutory Instrument [Assignment of Functions (Office of the President and Cabinet) (SI

162 of 2012)] issued by the President assigned RPAZ to the Office of the President and Cabinet which uplifted RPAZ to be effectively independent from the governmental departments or offices promoting radiation technology.

The Act assigns RPAZ to be the regulatory body for radiation safety in Zimbabwe. Article 4(l) of the Act provides for the functions and powers of RPAZ which includes:

- issue standards and norms governing exemption, notification, registration and licensing of radiation sources and radiation protection and safety;
- define in regulation standards and norms the exposures that are excluded from regulatory requirements on the basis that they are not capable of being subjected to regulatory control;
- issue authorisations for the possession and use of radiation sources;
- define in regulations and authorisations the detailed obligations to be placed on those who possess radiation sources;
- conduct inspections and obtain performance information concerning radiation sources;
- take such action as is necessary to enforce any prescribed requirements;
- protect the health and safety of workers and the members of the general public;
- accredit persons as suppliers of certain services or facilities.

The Act provides for the establishment of a Board for RPAZ under Section 5. The Board of RPAZ is comprised of 10 members appointed by the Office of the President and Cabinet. The Board has the responsibility to formulate the general policy of RPAZ and control its operations.

RPAZ is enabled to draft regulations that are approved by the Office of the President and Cabinet in consultation with the Board. The gazetted regulations include:

- Radiation Protection (Safety and Security of Radiation Sources) Regulations, SI-62 of 2011;
- Radiation Protection (Medical Practices) Regulations, SI-91 of 2014;
- Radiation Protection (Naturally Occurring Radioactive Material) Regulations, SI-99 of 2013.

RPAZ is administratively under the Office of the President and Cabinet. The Office of the President and Cabinet provides policy directions to the Radiation Protection Board and is responsible for presenting the RPAZ' annual budget to the Treasury for funding consideration. RPAZ' overall financial resources are obtained through direct state funding, licence and service fees and donations, grants, bequests or loans (see Recommendation 2).

About 60% of RPAZ' current budget is funded by license fees and service charges. However, this does not entirely cover RPAZ' direct regulatory activities.

RPAZ' offices are now situated in rented premises. In 2012 the government provided RPAZ with a piece of land to construct permanent offices and laboratories. Since then no funds were provided for construction. However, the IRRS review team was informed that this might be considered in the budget of 2015. The government should consider allocating more resources for RPAZ to build its infrastructure and implement its strategic plans to efficiently and effectively meet its statutory obligations in regulating radiation facilities and activities in the country.

1.4. COMPLIANCE WITH REGULATIONS AND RESPONSIBILITY FOR SAFETY

The existing radiation safety legal and regulatory framework in Zimbabwe does not assign the prime responsibility for safety to operators and authorised parties nor is it clearly expressed that the compliance with issued regulations, licence conditions, etc. will not relieve the authorised party of the prime responsibility for safety (see Recommendation 2).

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

RPAZ is the competent authority regarding radiation protection in Zimbabwe with its responsibilities defined in the Act establishing the authority. All the ministries and interested parties have the opportunity to provide comments on various legal proposals and before any legal documents are enacted. Section 4(2) of the Act empowers RPAZ to cooperate with authorities having regulatory or other responsibilities for radiation safety.

Currently, RPAZ has one signed Memorandum of Understanding (MoU) with Zimbabwe Revenue Authority (ZIMRA) which describes the role of each authority in controlling the export and import of radiation sources. RPAZ has two other draft MoUs with Ministry of Health and Child Care and the Environmental Management Agency (EMA). MoUs with Zimbabwe Republic Police and the Department of Civil Protection are under development. Furthermore, RPAZ has not yet formalised its coordination with the other national authorities having responsibility for safety, including the Ministry of Labour, Mining and Transport. The government has established a national committee for the safety and security of radiation sources which performs a certain level of coordination amongst relevant government agencies.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The government does not have formalised coordination with all government agencies with responsibilities for radiation safety.
(1)	**BASIS: GSR Part 1 para. 2.18 states that** *"The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as: (1) safety of workers and the public; (2) protection of the environment; (3) applications of radiation in medicine, industry and research; (4) emergency preparedness and response…"*
S1	**Suggestion: The government should consider strengthening coordination between the national authorities having responsibilities for radiation safety.**

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE UNREGULATED RADIATION RISKS

There are no provisions in the Act to assign responsibility to make the necessary arrangements to deal with unregulated radiation risk (e.g. orphan sources, contamination from old practices). In addition, a system for protective actions to reduce existing or unregulated radiation risks has not yet been established. The government has no policy and strategy for search or regaining control of orphan sources. The organisation responsible for making the necessary arrangements and a mechanism to manage such situations has not been established. RPAZ has some arrangements in place in case of discovery of orphan sources but it is neither comprehensive nor documented (see Recommendation 2).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: A system to carry out protective actions to reduce undue radiation risks associated with unregulated sources and contamination from past activities or events does not exist.
(1)	**BASIS: GSR Part 1 Requirement 9 states that** *"The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural or artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization."*
(2)	**BASIS: GSR Part 1 para. 2.6 states that** *"Where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within the governmental, legal and regulatory framework for safety."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R3	**Recommendation: The government should designate a responsible organisation and create a system to ensure that protective actions to reduce risks from unregulated sources and past contamination can be carried out.**

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

The Zimbabwe legislative framework on radiation safety makes provisions for some elements of the safe management of radioactive waste. However, the legislation or regulations do not define requirements concerning pre-disposal management, decommissioning of facilities or disposal of radioactive waste.

The government has not established a national policy and strategy for the management of radioactive waste. In addition, there are currently no arrangements for decommissioning of facilities and activities and management of radioactive waste. Currently, radioactive waste and discovered orphan sources are stored in a small interim storage facility owned and controlled by RPAZ. Disused sources are stored at the premises of the licensees due to the limited capacity of the interim storage facility. A mechanism for financing these activities is yet to be established.

The Deputy Chief Secretary in the Office of the President and Cabinet in his opening speech of the IRRS mission indicated that the government has allocated land for RPAZ which includes land for a waste management facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The government has no national policy or strategy for radioactive waste management in place, and decommissioning of facilities and activities has not been addressed adequately in the framework for safety. Financial aspects are neither addressed for decommissioning nor for waste remediation.
(1)	**BASIS: GSR Part 5, Requirement 1 states that** *"The government shall provide for an appropriate national legal and regulatory framework…"*
(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…"*
(3)	**BASIS: GSR Part 1, Requirement 10 states that** *"Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel. 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 1 para. 2.28 states that** *"Decommissioning of facilities and the safe management and disposal of radioactive waste shall constitute essential elements of the governmental policy and the corresponding strategy over the lifetime of facilities and the duration of activities."*
(5)	**BASIS: GSR Part 1 para. 2.33 states that** *"Appropriate financial provision shall be made for:* *(a) Decommissioning of facilities;* *(b) Management of radioactive waste, including its storage and disposal;* *(c) Management of disused radioactive sources and radiation generators;* *(d) Management of spent fuel."*
R4	**Recommendation: The government should establish a national policy and strategy to include financial provisions for the decommissioning of facilities, the safe management and disposal of radioactive waste.**

1.8. COMPETENCE FOR SAFETY

The government has not yet established a national education and training programme for radiation safety. The universities in Zimbabwe do not include subjects on radiation safety in their academic syllabi. Zimbabwe has three schools for medical radiographers; the IRRS review team was informed that these schools provide some training and courses on radiation safety. In addition, the IRRS review team was informed that RPAZ conducts lectures to the students of these schools to increase their radiation safety awareness.

The IRRS review team was informed that some training events are performed by RPAZ for the Radiation Safety Officers (RSO) of the authorised facilities on its safety requirements. Licensees are not required to provide training and verification of competence of personnel in the field of work they perform. No research and development activities are in place in the field of radiation safety.

RPAZ has not performed an analysis of competence needs and the existing available national arrangements for education and training, which could be provided to the government for further action.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Availability of academic programmes, existing technical centres and various national arrangements for education and training are not sufficient to build and maintain the competence needed by all Zimbabwe parties having responsibilities in relation to safety.
(1)	**BASIS: GSR Part 1 Requirement 11, states that** *"The government shall make provisions 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, 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..."*
R5	**Recommendation: The government should provide for building and maintaining the available national arrangements for education and training to address the competence needs of all parties in relation to safety of facilities and activities, based on proper analysis.**

1.9. PROVISION OF TECHNICAL SERVICES

Section 4(1)(h) of the Act empowers RPAZ to accredit persons as suppliers of certain radiation safety services. In this regard the IRRS review team was informed that a total of nine accreditations were issued for services in the fields of supply, installation, maintenance and repair of medical and industrial equipment; training; and radiation safety consultancy.

RPAZ is providing dosimetry services and is the only provider for this service in the country. Currently there is no calibration facility in the country; the IRRS review team was informed that calibration services are being performed outside of Zimbabwe.

1.10. SUMMARY

The IRRS review team found that not all fundamental safety principles established in the IAEA Safety Fundamentals SF-1 are addressed in the present Zimbabwe framework for safety. Furthermore, the national policy and strategy are not documented as a statement formulating the government's intent. The Act established the regulatory body and defined its main functions and responsibilities. The SI 162 of 2012 by the President assigned RPAZ to the Office of the President and Cabinet which uplifted RPAZ to be effectively independent from the government departments or offices promoting radiation technology. However, several elements for an effective governmental and legal framework for safety are missing from the existing law. Currently, RPAZ has one signed MoU with ZIMRA which describes the role of each authority in controlling the export and import of radiation

sources and several others are under development. The government does not have formalised coordination with all government agencies with responsibilities that impinge upon radiation safety.

There are no provisions in the Act to assign responsibility for making the necessary arrangements to deal with unregulated radiation risk. The Zimbabwe legislative framework makes provision for some elements of the safe management of radioactive waste. The decommissioning of the facilities and activities and the management of the radioactive waste from the facilities have not been adequately addressed. The government has no national policy or strategy for radioactive waste management in place.

Availability of academic programmes, existence of technical centres and various national arrangements for education and training appear to be insufficient to build and maintain the competence needed by all relevant parties in Zimbabwe having responsibilities in radiation safety. RPAZ is providing dosimetry services and it is the only provider for this service in the country.

2. GLOBAL NUCLEAR SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Zimbabwe has ratified the African Nuclear-Weapons Free Zone Treaty (Treaty of Pelindaba), however, it has not ratified a number of international instruments related to nuclear safety and radiological protection:

- Convention on Early Notification of a Nuclear Accident;
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency;
- Convention on Nuclear Safety;
- Vienna Convention on Civil Liability for Nuclear Damage and the protocol amending it;
- Joint Convention on Safety of Spent Fuel Management and on Safety of Radioactive Waste Management.

Zimbabwe has made a political commitment to work towards implementing the provisions of the Code of Conduct on the Safety and Security of Radioactive Sources, but has yet to make a political commitment to the Supplementary Guidance on Import and Export of Radioactive Sources.

With regards to international cooperation, Zimbabwe has at least two bilateral agreements and cooperation programmes with South Africa and Zambia. The bilateral arrangement with the Department of Health in South Africa is with respect to all categories of sources, imported and exported. They also have a bilateral arrangement with Zambia as they work to set up a regulatory system.

Zimbabwe is taking full benefit from and contributing to the technical cooperation programme of the IAEA, particularly in the field of nuclear and radiation safety and has hosted multiple regional training events (e.g. Code of Conduct training for AFRA countries, regional training course on train –the - trainers for radiation protection, workshop on Nuclear Information Management System). Zimbabwe is a member of the IAEA working group on radioactive source security.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Zimbabwe has not ratified a number of international instruments related to nuclear safety and radiological protection or made a political commitment to the supplementary Guidance on Import and Export of Radioactive Sources.
(1)	**BASIS: GSR Part 1 Recommendation 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 to enhance safety globally."*
R6	**Recommendation: The government should ratify the international instruments related to nuclear safety and radiological protection and should demonstrate that respective international obligations are fulfilled by participation in its relevant international arrangements.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Zimbabwe takes part in a number of international activities intended to exchange regulatory experience. Lessons learned from the experience of other countries were used to prepare the country's safety regulations and instructions. RPAZ has appointed a national officer for the International Nuclear and Radiological Events Scale (INES) and participates in international exchanges of information on radiation events and incidents.

Improvements based on operating and regulatory experience are implemented on a case-by-case basis and are not subject to a systematic approach. When information comes in about an event either in another country or domestically, they share the information internally and then they informally communicate it to the RSOs at the facilities and activities. Since feedback from experience is a fundamental way of enhancing safety and improving

the regulatory control, the IRRS review team believes that RPAZ would benefit from more active involvement in the process of exchanging experience with authorised parties.

Zimbabwe has also signed a Memorandum of Cooperative Arrangements (MCA) for Regulators of Nuclear and Radiation Safety in the Southern African Development Community (SADC). The purpose of this MCA is to foster cooperation of nuclear regulatory bodies in the SADC region for the attainment of regional cooperation on matters related to radiation protection and nuclear safety and security; adherence to nuclear safety and security internationally binding and non-binding legal instruments; cooperation and exchange of information on good regulatory practices while respecting the principles of sovereignty, equality, mutual benefit, territorial integrity and non-intervention in respective domestic affairs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Zimbabwe has signed a Memorandum of Cooperative Arrangements (MCA) for Regulators of Nuclear and Radiation Safety in the Southern African Development Community (SADC).
(1)	**BASIS: GSR Part 1, Requirement 15, para 3.5 states that** *"To enhance the safety of facilities and activities globally, feedback shall be provided on measures that have been taken in response to information received via national and international knowledge and reporting networks."*
GP1	**Good Practice: Being a signatory to the MCA, where 15 nations share information amongst each other through establishment of the voluntary Southern African Development Community Nuclear Regulators Network.**
	Observation: RPAZ has not made arrangements to be actively involved in sharing operational and regulatory experience with authorised parties to enhance safety and improving the regulatory control.
(1)	**BASIS: GSR Part 1 Requirement 15, para. 3.4 states that** *"The regulatory body shall establish and maintain a means for receiving information …. and from authorized parties, as well as a means for making available to others lessons learned from operating experience and regulatory experience."*
S2	**Suggestion: RPAZ should consider establishing a formal process for identifying and sharing lessons learned from operating experience and regulatory experience.**

2.3. SUMMARY

Zimbabwe has signed the MCA for Regulators of Nuclear and Radiation Safety in the SADC which fosters cooperation of nuclear regulatory bodies (15) in the SADC region on matters related to radiation protection and nuclear safety and security. In addition, they have signed bilateral arrangements with Department of Health in South Africa as well as Zambia. They are also taking full benefit and contributing to the technical cooperation programme of the IAEA, particularly in the field of nuclear and radiation safety.

Zimbabwe has not ratified most of the international instruments related to nuclear and radiation safety nor have they made a political commitment to the Guidance on Import and Export of Radioactive Sources.

To benefit from more active involvement in the process of exchanging experience, RPAZ should not only receive and share information on operational experience but also provide such within the broader international community and to authorised parties.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

The organisational structure of RPAZ, whose authority is laid out in the Act is provided in Appendix IX. It previously reported to the Minister of Health and Child Welfare, but now reports to the Office of the President and Cabinet as per SI 162 of 2012. There is a 10 member Board of Directors responsible for formulating the general policy of the Authority and controlling its operations. The Chairman of the Board is appointed by the Office of the President and Cabinet in consultation with the President. RPAZ is headed by a Chief Executive Officer (CEO) appointed by the Board. The CEO supervises and manages the Authority's affairs and reports directly to the Board and the Office of the President and Cabinet. There are eight individual departments within the authority, as shown in Appendix IX.

The Board also has several committees on legal, technical, finance, human resources, and audit and risk management issues. Each committee is headed by a member of the Board, who advises the Board on matters of policy. The Chairman of the Board is not allowed to be a member of the Audit and Risk Management Committee or the Technical Committee, but is a member of the Finance Committee.

The budget of RPAZ is funded directly from the government, fees collected from authorised parties, donations, loans, bequests and grants. The budget is proposed to the Board on annual basis. After consideration by the Board the budget is sent to the Ministry of Finance which allocates the funds after getting parliamentary approval of the government's appropriation. The government has allocated seven hectares of land for the authority for offices for RPAZ as well as a waste remediation facility. However, the funds to develop that land are still to be identified. The responsibility for getting the funds lies with the Authority for infrastructure development and the funds are being requested in the budget.

The fee structure for authorised parties is based on socio-economic factors, not risk basis. For example, large-scale mines and industrial radiography users pay a higher fee than medical and gauge users. The current policy for authorisations is to renew them annually which requires resources to process. The medical practice regulations state that all licenses are renewed annually. RPAZ does not consider a risk-based approach when authorising different activities.

Currently RPAZ is conducting a baseline of annual inspections at all facilities but eventually they will go to a more risk-informed approach. For radiotherapy centres, they are conducting inspections more frequently than once a year. RPAZ has the flexibility to modify the inspection schedule because inspections are considered an operational issue.

The authority currently has two offices – one in Harare, which is primarily responsible for all licensing activities as well as inspections in the northern part of the State, and one in Bulawayo, which has responsibility for inspections in the southern part of the State. There is a system in place to ensure coordination of activities between the Bulawayo and Harare offices. The existence of only two offices may compromise emergency response times to other parts of the country and may limit its functions of inspection and enforcement. Given the risk of the activities that currently exist in the country, this is adequate. However, re-evaluation of activities outside these primary areas may be necessary if additional higher risk activities are introduced in the country. RPAZ should also work with other agencies (e.g. Department of Civil Protection) and make provisions in the ensuing MoUs to have the ability to respond out of those agencies' offices.

RPAZ currently has 34 staff on board between the 2 offices although they have an allowance on their staffing plan for up to 63 posts. This is based on needs for the future and additional positions will be filled as the needs arise and the budget allows.

There appears to be a conflict of interest regarding the delivery of technical services and the inspection procedure functions. The dosimetry section is within the inspection department and provides services to the authorised parties. The IRRS review team is of the view that a greater degree of functional separation between technical services and the regulatory function would be appropriate in order to minimise any potential conflicts of interest.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ is providing personal dosimetry services for the radiation workers of the authorised parties within the inspection department.
(1)	**BASIS: GSR Part 1 para. 4.7 states that** "*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.*"
S3	**Suggestion: RPAZ should consider providing for a further operational separation between technical services and the regulatory function to minimize the potential for conflicts of interests.**
	Observation: The current policy and medical regulation state that authorisations are renewed annually.
(1)	**BASIS: GSR Part 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."*
(2)	**BASIS: GSR Part 1 Requirement 24 para. 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
	See Recommendation 11 in module 4.1.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY ACTIVITIES

Section 3 of the Act gives the power to the Authority to function as a body corporate and permits it to exercise all the functions listed in paragraph 1 of the same section. The CEO interfaces with the Office of the President and Cabinet on operational issues and the Board interfaces with the Office of the President and Cabinet on policy issues. The regulatory authority has independence to make immediate safety decisions and inform the Board at a subsequent time.

To formalise cooperative arrangements, there is a signed MoU between RPAZ and ZIMRA. Under development are additional MoUs with Zimbabwe Republic Police (theft, enforcement, build awareness on radiation safety and security, border monitoring) and Department of Civil Protection (national agency to coordinate EP activities but making it clear that RPAZ has lead role in responding to nuclear incidents and also to build capacity for other response agencies). In final draft form there are MoUs with the Ministry of Health and Child Care (concerning issues of radiation protection for public hospitals and health facilities), and Environmental Management Agency (to define areas of cooperation and the roles of RPAZ and EMA in terms of protecting the environment). These are also discussed in further detail in Module 1.

Employees and Board members are required to sign a declaration of interest to prevent conflict of interest. That form specifically asks what activities they are involved in that may impact their work activities either as members of the Board or individually as employees of RPAZ. Where a conflict of interest arises, they are required to recuse themselves from working in those activities. In addition, Board members are put through Corporate Governance

Training and sign a performance contract with the Office of the President and Cabinet. The Board members are not involved in the day to day running of RPAZ but only provides policy direction. The committee system provides recommendations to the Board which is another means of prevention of conflict of interest.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ now reports to the Office of the President and Cabinet in accordance with SI 162 of 2012.
(1)	**BASIS: Requirement 17 states that** *"Effective independence in the performance of regulatory functions. The regulatory body shall perform its functions in a manner that does not compromise its effective independence."*
GP2	**Good Practice: The change to report directly to the Office of the President and Cabinet rather than the Ministry of Health and Child Welfare gives RPAZ effective independence.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

RPAZ currently has 34 staff members, however the organisational structure allows for filling up to 63 positions to achieve the goals set out in the five year strategic plan (2012-2016). The strategic plan includes environmental monitoring, non-ionising radiation, emergency preparedness and waste remediation, none of which are currently budgeted for. There are departments listed on the organisational structure for non-ionising and emergency preparedness but there is no separate department for waste remediation. Rather than compromise the integrity of the staffing by keeping that aspect under inspections, we suggest that the organisational structure be modified to specify waste remediation.

The budget is specified for capital expenditures, recurring expenditures (including staffing costs), and daily operational costs. The budget is presented annually to Parliament by the Minister of Finance.

Human resources policy identifies recruitment activities, specifically those positions to be filled. In the interim, RPAZ has the flexibility to move personnel around (e.g., rotating licence reviewers to the inspection department). The human resources policy allows the Authority to advertise for positions at employment agencies and in newspapers, and there is a link to its website. They can hire a person as an employee who is neither a citizen nor a resident of Zimbabwe but with sufficient justification (guided by the National Employment Regulations). There is an internship program for up to 12 months where they can seek students from universities in a technical field. These can then form a pool of potential employees. RPAZ staff also goes on fellowships to other countries and receives fellows from other countries (2-5 months). Additionally, four RPAZ staff members graduated from IAEA Post Graduate Educational Courses (PGEC) in Ghana. Ten staff members have also gained one month regional training course on Authorization and Inspection of radiation sources.

There is no formalised training program for regulatory staff (including licence reviewers and inspectors) where they teach them about radiation safety and security. They have collaborated with IAEA on provision of technical training programs. See also modules 4, 5, 6, and 7. There is also no formalised program for knowledge management. The first 4 weeks are considered as an induction period where new employees learn regulatory aspects and safety considerations. That training also emphasises how to function in a professional manner and within its authority in relation to safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ does not have a formalised training program for regulatory staff.
(1)	**BASIS: GSR Part 1 Recommendation 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."
(2)	**BASIS: GS-R-3 para. 4.3 states that** *"The Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained."*
(3)	**BASIS: GS-R-3 para 4.4 states that** *"Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives."*
R7	**Recommendation: RPAZ should develop a formal program and competence requirements for training of regulatory staff with essential knowledge and skills.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

RPAZ collaborated with the IAEA on the provision of technical training programmes and expert missions and made requests to the Technical Cooperation Department at IAEA for equipment. RPAZ does not obtain technical or other expert professional advice or services as necessary in support of its regulatory functions with the exception of IAEA. It needs to be clearly articulated in the amended Act that they can utilise advisory bodies or dedicated technical support organisations in the conduct of their activities (See Recommendation 2).

If the Act is amended to allow RPAZ to use advisory bodies or dedicated technical support organisations, arrangements need to be made to ensure that there is no conflict of interest for those organisations that provide the regulatory body with advice or service. However obtaining advice or assistance does not relieve RPAZ from its assigned responsibilities and maintaining a core competence to make informed decisions.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

RPAZ communicates routinely with authorised parties through issuance of authorisations and inspection reports. They also communicate through newsletters and regulatory notices which are put on the website and made available to the public and they meet routinely with the professional societies.

Specific issues and events may get identified through mail or e-mail to the RSOs (Point of Contact) for either a specific category of authorised user or more generically to all authorised users. For example, when the licencing conditions change, the RSO is informed. Also, the calls for training of RSOs are sent electronically. Training for RSOs also includes a summary of incidents and accidents. For example, one incident of a source that couldn't be accounted for was investigated and found at another location of the authorised party. However there is no formal mechanism to communicate to authorized parties on safety related issues.

RPAZ does not currently provide the justification and explanation of regulatory decisions to authorised parties, because these are existing authorised parties. The IRRS review team considers that developing an approach to provide justification and explanation to existing and new activities would enhance their compliance with international standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There is no formal mechanism to communicate to authorised parties on safety related issues, including justification and explanation of regulatory decisions to all authorised parties.
(1)	**BASIS: GSR Part 1 Requirement 21 states that** *"The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues,*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	conducting a professional and constructive liaison."
R8	**Recommendation: RPAZ should develop a formal mechanism to communicate with authorised parties on all safety related issues.**

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

RPAZ embraces a risk-informed decision making approach to regulatory functions. However, RPAZ does not have a formal process articulated through specific policies, principles, and associated criteria in their management system to ensure that the regulatory control is consistent throughout the Authority. The policies state that regulatory activities shall be conducted in a manner commensurate with radiation risks associated with the facility or activity in accordance with the graded approach based on the risk categories of facilities and activities. The practice is that those activities with the highest risk are given more attention in terms of the authorisation requirements, compliance inspections, and reporting requirements. The decision making (approval) authority is specified in some policies, for example, inspections. However, in terms of enforcement, there is nothing documented about when to take action in the event of immediacy of an unsafe practice. The common practice has been that a staff member initiates an action, which then goes to department manager and ultimately the CEO, always providing the basis. RPAZ does not have clear criteria for decision making and therefore allows for some subjectivity.

RPAZ notifies proposed changes, and their basis, to the regulations on their website as well as in the media. RPAZ holds meetings with interested parties and incorporates their views. The bases for the changes are sent to the Board for approval. The Board approves these proposed changes and sends them to the Office of the President and Cabinet. The Office of the President and Cabinet forwards it to the Attorney General's Office for legal drafting of the regulations. After completing drafting the regulations the Attorney General sends them back to the Office of the President and Cabinet for gazetting.

All department managers are required to ensure that all activities carried out in their areas are conducted in a safe manner. However, employees are encouraged, not required, to develop a questioning attitude on issues that compromise safety. It is not clear how the internal safety culture of the Authority is applied. This is further discussed under module 4.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ does not have a formal process articulated through specific policies, principles, and associated criteria to ensure that the regulatory control is consistent throughout the Authority that may result in the appearance of subjectivity.
(1)	**BASIS: GSR Part 1 Requirement 19 states that** *"The regulatory body shall ensure that regulatory control is stable and consistent."*
(2)	**BASIS: GS-R-3 para. 3.5 states that** *"Senior management shall ensure that it is clear when, how and by whom decisions are to be made within the management system."*
R9	**Recommendation: RPAZ should ensure that decision making is applied and documented to ensure that regulatory control is consistent throughout the Authority.**

3.7. SAFETY RELATED RECORDS

RPAZ currently makes use of both a paper based system and the Regulatory Authority Information System (RAIS), Version 3.2 for maintaining safety related records. However, the information that RAIS is not capable of capturing is currently being stored in paper form. RPAZ has started transferring both paper documents and those that are in RAIS to an Electronic Data Management System to maintain all records electronically. This will allow a search of all the records related to a specific authorised user to be identified quickly rather than the time consuming search

through paper files. They maintain records of the register of sealed radioactive sources and radiation generators, authorisations, inspections, enforcement actions, occupational doses, events and inventories of radioactive waste. In addition, authorised parties maintain records for training, calibration of sources and equipment, quality control, maintenance of equipment, occupational doses, and the register of sources. The inspectors verify the authorised parties' records when they do their routine inspections.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The organisational structure of RPAZ has a Corporate Communications Officer (CCO) reporting to the CEO. The CCO is responsible for communications with all interested parties. RPAZ has developed brochures for the public on the topics of radiation basics, pregnancy and medical radiation, transport of radioactive substances, corporate profile of RPAZ and applications of radiation. RPAZ is open to the public and they make them aware of what RPAZ does in terms of protecting public health and safety and the environment. They also conduct media campaigns through radio and television. In terms of corporate governance RPAZ holds annual general meetings which are advertised in the newspaper and on their website 21 days in advance to allow for public participation and makes available to the public an annual report.

In addition, the staff makes presentations to professional societies. Regulatory notices of proposed new regulation, call for renewal of licences and interested parties' meetings are published in the newspaper as well as on RPAZ' website. RPAZ also addresses judicial officers and prosecutors to raise awareness of radiation and its associated risks.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The organisational structure of RPAZ includes a Corporate Communications Officer, reporting directly to the CEO, whose primary responsibility is communications with all interested parties including the media.
(1)	**BASIS: GSR Part 1 Requirement 36 states that** *"The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body."*
GP3	**Good Practice: RPAZ has a Corporate Communications Officer whose primary responsibility is communicating with all interested parties.**

3.9. SUMMARY

The organisational structure of RPAZ is sound. However, funds for RPAZ to fully carry out its regulatory obligations remain an issue. The budget comes from the government as well as fees collected from authorised parties. The responsibility for getting funds for infrastructure development lies with the Authority and is being requested in the budget. The current policy for authorisations is to renew them annually which requires resources to process.

RPAZ is independent in making immediate safety decisions and informing the Board at a subsequent time. New employees and Board members are expected to sign a declaration of interest to avoid potential conflict.

There is no formalised training program for regulatory staff, however, RPAZ collaborates with the IAEA in getting the proper training for them.

The use of advisory bodies or dedicated technical support organizations in the conduct of their activities needs to be clearly articulated in the amended Act. There is no formal mechanism to communicate to authorised parties on safety related issues. In addition, the RPAZ does not provide the justification and explanation of regulatory decisions to authorised parties.

RPAZ does not have a formal process articulated through specific policies, principles, and associated criteria to ensure that the regulatory control is consistent throughout the Authority that may result in the appearance of subjectivity.

RPAZ currently maintains safety related records on RAIS 3.2 Web and a paper based records keeping system. It is also moving towards storing all safety related records in an electronic data management system. This will allow a search of all the records related to a specific authorized user to be identified quickly rather than the time consuming search through paper files.

RPAZ has a CCO, reporting to the CEO, whose primary responsibility is communicating with all interested parties to include the media.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

RPAZ has begun implementing a management system (RPAZ Integrated Regulatory Management System). The IRRS review team understands that management is fully supportive and committed to establish, implement, assess and continue to improve the management system (MS). The manual of MS (draft) describes the functions of the organisation which are stated in the Act, Section 4(1). In the Act under Section 4(2) it is also stated "For the better exercise of its functions, the Authority shall have power, subject to this Act, to do or cause to be done, either by itself or through its agents, all or any of the things specified in the First Schedule, either absolutely or conditionally and either solely or jointly with others". Section 4(2) is not explicitly included in the manual.

The MS is documented in a variety of documents. The MS manual contains the majority of required parts under GS-R-3 and consists of three levels:

- Level 1) The Integrated Regulatory Management System manual.
- Level 2) Key functions defined by the authority. Policies approved by the Board of Directors, the organisation's strategic plan, strategy supportive structure (organogram) and departmental or core functional policies including activities involving Authorization, Inspections, Enforcement, Human Resources, Finance, Procurement, Information Communication Technologies, Communication, and Records Management.
- Level 3) Procedures, job descriptions, flow charts, guides and standard operating procedures/work instructions for the various documented processes.

One of the principal aims of development of a five year strategic plan (2012-2016) is to improve regulatory outputs. It is further stated that the establishment of a management system is a key priority in terms of the organisation's strategic plan 2012-2016. The implementation is in progress and some policies and procedure documents are to be finalised. A number of policies have been developed across departments and functions of the regulatory body.

Strategies, policies and procedures describe the actions that are necessary to provide confidence that the requirements of managing the regulatory body are fulfilled. The IRRS review team has noticed that there is no clear consistency between functions and activities described in the MS. For example inspection is not identified as an activity but there is a policy and procedure for it. Emergency preparedness and response is identified as an activity but there is no policy or procedures (for further information on EPR see module 10).

The IRRS review team also noticed that the manual does not refer to other documents, for example, procedures. This makes a gap between the manual and the rest of the document and leads to an inconsistency making it difficult to fully understand the MS. The MS refers to a safety policy and a quality policy but they are not currently in place. The IRRS review team considers that RPAZ includes relevant material in the manual of the management system (electronic or paper based) that provides the staff with an overall understanding of the management system. Procedures are available through RAIS and organised by licensing department and the quality assurance manager is responsible for assuring that the approved MS documents are available in RAIS. RPAZ has recently established an Electronic Document Management System (EDMS). The work of saving documents in the EDMS has begun.

Vision, mission and values are stated in the strategic plan and, under Section 2.4 in the manual on safety culture, it is stated that safety is both paramount and fundamental. The priority and the responsibility to safety should be clear in the MS and given an overarching position in the MS in addition to the vision, mission and values.

Continuous improvement is expressed in various places in the manual but not explicitly addressed as an area there. The IRRS review team was informed that improvements are identified, discussed and documented in departmental meetings. Discussion on improvements is also a part of the senior management meetings.

Safety Culture

Safety culture is addressed in the MS and it is stated that all departmental managers are the custodians of the safety policy and required to ensure that all activities carried out in their areas are conducted in a safe manner. Employees are encouraged to develop a questioning attitude on issues that compromise safety. In the inspection procedure it is mandatory to have the appropriate personal protective equipment (PPE), dose monitors in working condition and personal monitoring badges. Management prioritises the safety of workers in the conduct of regulatory activities through provision of PPE and adequate authority to not enter any unsafe places. All personnel with a safety responsibility such as inspectors are involved in the development of all procedures and are expected to understand the safety concerns of different facilities and activities.

The IRRS review team concluded that internal safety culture issues are addressed in the concept of radiation protection. Safety culture should be explicitly addressed and communicated to staff in a more comprehensive and systematic way to ensure a common understanding and a learning and questioning attitude in all levels of RPAZ. The importance of continually developing, assessing and improving safety culture should also be more completely addressed as a part in the manual of the MS. Avoiding regulatory capture would necessitate the development, assessment and improvement of the safety culture, any implications on safety culture in relation to independence in the performance of regulatory functions/activities.

Graded approach

Graded approach is addressed in the manual under regulatory philosophy. Regulatory activities are based on the risks associated with a practice or activity which determine the level of attention that is required. High risk activities require more stringent conditions, frequent inspections, strict workplace monitoring and availability of qualified experts. For example, at present RPAZ inspections are performed at least annually to get a baseline but in the future, the plan is to conduct inspections more with a graded approach. It is not clear to the IRRS review team whether this approach has been utilised in all activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The management system is described in a variety of documents. There is a gap between the manual and other documents. The vision, mission and values are not stated in the manual and the priority to safety is not given an overarching position in the MS.
(1)	**BASIS: GSR Part 1 Requirement 19 states that** *"The regulatory body shall establish, implement and assess and improve a management system that is aligned with its safety goals and contributes to their achievement."*
(2)	**BASIS: GS-R-3 para 2.1 states that** *"A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:* • *Bringing together in a coherent manner all the requirements for managing the organization;* • *Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;* • *Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety."*
(3)	**BASIS: GS-R-3 para 2.2** ***states that*** *"Safety shall be paramount within the management system, overriding all other demands."*
S4	**Suggestion: RPAZ should consider continuing to establish the management system in a consistent, coherent manner.**
	Observation: Internal safety culture issues are currently addressed in the concept of radiation

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	protection. The concept of internal safety culture is not treated explicitly and addressed and communicated to staff in a more comprehensive manner.
(1)	**BASIS: GS-R-3 para. 2.5 states that** *"The management system be used to promote and support a strong safety culture by:* • *Ensuring a common understanding of the key aspects of safety culture within the organization;* • *Providing the means by which the organization supports individuals and team in carrying out their task safely and successfully, taking into account the interaction between individuals, technology and the organization;* • *Reinforcing a learning and questioning attitude at all levels of the organization;* • *Providing the means by which the organization continually seek to develop improve its safety culture."*
R10	**Recommendation: RPAZ' senior management should promote an awareness of internal safety culture by ensuring that it is in their training programme and is appropriately reflected within its management system.**
	Observation: The MS addresses a graded approach to the regulatory decision making but the approach is not fully implemented.
(1)	**BASIS: GSR 3 Requirement 2.6 states that** *"The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:* • *The significance and complexity of each product or activity;* • *The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity;* • *The possible consequences if a product fails or an activity is carried out incorrectly."*
(2)	**BASIS: GSR 3 Requirement 2.7 states that** "*Grading of the application of management system requirements shall be applied to the products and activities of each process."*
R11	**Recommendation: RPAZ should implement a graded approach in all activities and processes.**

4.2. MANAGEMENT RESPONSIBILITY

Management responsibilities are addressed in the MS and state that RPAZ management is fully committed to the development and implementation of the management system and continuous improvement, ensuring its effectiveness by:

- communicating to all employees the importance of meeting clients and stakeholders as well as statutory requirements;
- establishing a quality policy;
- establishing quality objectives;
- conducting management reviews on the effectiveness of the management system;
- ensuring the availability of resources to implement the management system.

Responsibilities for all managers and staff are also stated in the Act, policies and procedures. For fully understanding the different kind of responsibilities RPAZ may consider describing responsibilities in one document or have a reference in the manual where other responsibilities are described.

RPAZ informed the IRRS review team that its senior management has developed goals, strategies, plans and objectives consistent with the policies. The five-year strategic plan is the main blue print guiding the implementation of policies for the regulatory body. The plan contains goals, strategies and objectives. Plans are drawn annually to accomplish the goals set in the strategic plan document. One example is goal (7.2) in the Five-Year Strategic Plan "Improve internal Processes for effective service provision" through establishment of a quality management system.

The organisational structure includes a Quality Assurance (QA) department responsible for coordinating the development, implementation and assessment of the management system. The QA manager reports to the Chief Executive Officer on the performance of the system and for the need of improvement. The QA manager has two officers assisting in fulfilling the obligations of the management system.

There is no decision making procedure but for example in the inspection procedure there is a section describing approval of inspection reports and when deviations are identified they shall be included. The IRRS review team was informed that an inspector can do so after approval from the CEO. The enforcement policy does not state who is responsible for enforcement decisions and there are no procedures for such decisions (see Recommendation 9 in module 3.6).

4.3. RESOURCE MANAGEMENT

Resource requirement was identified by the strategic plan taking into account the scope and amount of work that has to be carried out. Financial resources are determined on the basis of the annual work plan. Resources for the development and improvement of the MS are provided through the annual budget process. Further discussion is provided in module 3.

RPAZ management has developed a plan to ensure competence development in order for staff to perform their work assignments. However, this is work-in-progress and will take a few more years to ensure that everyone has the desired levels of competence. For conducting inspections, the regulatory body employs technical staff with basic qualifications in science. Then they are trained through on-the-job training and training through IAEA courses, workshops, and fellowships. There is no formal training programme for the regulatory authority (see Recommendation 7 in module 3.3).

Working environment requirements are stated in the policy for safety, health and environment. The policy is currently in draft and one of the requirements is risk analysis of the working environment.

4.4. PROCESS IMPLEMENTATION

RPAZ management system is largely procedure oriented. The IRRS review team has seen examples of the authorisation and inspection processes but it is not referred to in the procedure. The MS includes a section generally describing process management but there is no procedure describing, for example, methods and responsibilities. In supporting a process oriented MS it is required to identify, develop and manage the processes in the most appropriate way. It is further required to determine which processes are to be documented, on the basis of applicable regulatory and statutory safety requirements, the nature of the organisation's functions, activities and overall strategy. In addition a common understanding is needed for what a process is, how many processes are in place, how they interrelate and who are the process owners. Some organisations have found it beneficial to structure their process as follows:

- Core processes, the output of which is critical to the success of the organisation or activity, e.g., licensing process, inspection process;
- Supporting processes, which provide the infrastructure necessary for the core processes e.g. training, finances, managing records and archiving; and
- Management processes, which ensure the operation of the entire management system.

The organisational structure is approved by the Board. The IRRS review team was informed that RPAZ can make changes within the organisational structure based on needs throughout the organisation. The MS has a general description of managing organisational change but there is no procedure that describes the process in more detail.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The MS is largely procedure based. There is an overall description in the MS of process management but there is no further procedure that describes the concept of process

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	orientation. RPAZ has no procedure for organizational change.
(1)	**BASIS: GS-R-3, para. 5.1 to para. 5.29 states that** *"The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements….. communicated, monitored, tracked and recorded to ensure that safety is not compromised."*
R12	**Recommendation: RPAZ should identify, analyse and implement relevant processes and procedures including process owners, education and training on the management system and communication to the staff.**

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Strategies, policies and procedures are subject to evaluation which assesses the level of fulfilment of the requirements. Evaluations are scheduled to be conducted every second year. Annually, reports are made to assess performance against established goals. All departments conduct annual appraisals including reviews of regulatory activities. Reviews are also done by the Quality Assurance Department whose role is to assess the level of fulfilment of the requirements of the MS done by the various departments or sections.

RPAZ is subject to independent assessments of all systems by the Auditor General's Office on behalf of the government. These are done annually and whenever the Auditor General's Office deems appropriate. The regulatory body is also open to peer reviews conducted within the IAEA framework. Work is in progress to engage the Standards Association of Zimbabwe to certify the system in due course.

Independent assessments are done and coordinated by the Internal Auditor according to procedure RPAZ/IRMS/PR/IA/01. The senior management has appointed staff in all departments for the task but since they currently do not have training, the Internal Auditor is responsible for conducting internal audits.

Non-conforming products are suitably identified by a label or marking, and segregated from others, wherever possible. These include licences with incorrect information, incorrect inspection, dose and enforcement reports as well as incorrect allocation of monitoring badges. Where non-conforming products have been despatched, customers are informed of non-conformances and details are recorded in incident reports, which are retained and reviewed by the management. Records of non-conformity are maintained and analysed as part of management review. Output material or service non-conformities are reviewed by authorised staff in order to determine any remedial action and outputs are subsequently inspected. Further details are also contained in the Control of Non-Conformance Procedure. Identifying potential non-conformances is part of the procedure but not fully implemented.

Management System reviews are conducted once a year according to a methodology described in the procedure RPAZ/IRMS/PR/MR01.

4.6. SUMMARY

RPAZ has begun establishing and implementing a management system but the manual is in draft while the majority of policies are in place.

The management system is not process oriented and the existing procedures are not brought together in a coherent manner. Safety goals are not addressed in an overarching manner in the management system. Addressing internal safety culture more explicitly would ensure a common understanding and a learning and questioning attitude in all levels in RPAZ. The importance of continually developing, assessing, and improving safety culture should also be part of the management system. A graded approach is not applied in a broad manner. Assessments of the MS are done on regular bases. There is a strong commitment from senior management to improve the management system.

5. AUTHORIZATION

5.1. GENERIC ISSUES

RPAZ has a policy on authorisation which states that no activity involving radiation should be undertaken without authorisation. It is stated that the purpose of the *Authorization Policy* is to provide guidance to RPAZ in conducting its notification, authorisation and exemption activities in a consistent and systematic manner. The scope of the policy includes the following areas: System of notification; Authorisation of practices and activities involving radiation; Accreditation of service providers; and Information management for authorisation. The policy on notification as a requirement is intended to establish justification by RPAZ of the practice. The policy states that RPAZ shall use registration and licensing as means of authorisation on a risk-informed decision making basis. RPAZ also undertakes in the policy to authorise transport, transit and export and import of radiation sources. RPAZ undertakes to maintain an up to date register of sources and to keep a record of all notifications and authorizations. In the implementation section of the policy RPAZ develops requirements, procedures and guidance for notification, authorisation, review and assessment, and a database and filing system. Under the section for *responsibilities* the roles of the CEO and Licensing Manager are assigned for the implementation of the policy.

Submission of information by the applicant is a pre-requisite for authorisation. Review and assessment of applications is done to determine if applicants comply with regulatory requirements, including pre-authorisation inspections prior to authorisation. The review and assessments lead to approval or rejection of the authorisation and such decision is recorded.

Renewal of authorisation is done by 31 December while amendments of authorisation are made after the licensee informs RPAZ of safety related changes. Exemptions are issued based on the applicant meeting regulatory requirements.

In terms of legal provisions, Section 14 of the Act prohibits various acts unless it is done in accordance with prescribed requirements or is exempted. The administration of radiation exposure to another person without a licence is also not permitted. Provisions are made for the issuance of a licence only after the applicant has submitted an application in the prescribed format and satisfied the Board that the proper person and facilities are deployed to ensure safety. The licence is issued in the prescribed format, with conditions, specifying the time frame and the actions to be carried out under the licence.

It is stated in the regulations that authorisation is in the form of either registration or licensing, but currently RPAZ only issues licences for all facilities and activities. Registrations and licensing are defined in the regulations.

A list is provided of practices and activities that require making notification and the forms to be submitted. There is an authorisation process which guides RPAZ staff. A list of practices and activities that require authorisations is provided as well as a description of the corresponding documentation needed prior to authorisation. Each practice has an application form and guidance on how to complete the application form.

There is an *Authorization Procedure Manual*, which provides guidance on the following: policy requirements for submission of notification; documents to be submitted for authorization; creating records and filing; review and assessment of applications; issuing of authorizations; renewal of authorization; amending of authorization; exemptions; suspensions and revocation of license. The procedure manual also includes the following procedures: procedures for receiving applications; processing applications; assessing; determination of decisions; issuance and setting of license conditions; register of licenses; licensee interview; and pre-licensing inspections.

Furthermore, the operation of the dosimetry service needs to be formally accredited and the responsibilities for it be transferred to a unit of RPAZ that does not perform regulatory functions such as authorisation, inspection and enforcement (see module 3).

Similarly radioactive waste management needs to be authorised in accordance with the provision of the Act (see Recommendation 2).

Licence certificates are issued with the conditions attached as an annex. The licence certificate provides mainly for operation, use, possession and storage of the radiation sources. Persons involved in the use or operation of radiation sources are also licenced.

There are also accreditation requirements for the following: Radiation Safety Training; Installation, Maintenance and Repair of Radiation Generating Equipment; Suppliers of Radiation Generating Equipment and Radioactive Materials; and Radiation Protection Consultancy.

5.2. AUTHORISATION OF RADIATION SOURCES AND FACILITIES

Authorization by RPAZ through registration and licensing is a prerequisite for all practices and facilities. Licensing is clearly defined in the Act. Authorisation is defined in the Regulations (Safety and Security of Radiation Sources) SI 62 of 2011 and it is stated that it shall be done by either registration or licensing. The definitions of registration and licence are also consistent with that of GSR Part 3. Currently authorisation is done through licensing for all facilities and activities.

RPAZ uses a list specifying which practices are subject to authorisation, which may imply that all other practices not listed would either be exempted or authorisation by notifications is sufficient. The exemption criteria are not used in the context of Section 6 of the Regulations. Facilities and activities for which authorisation by notification only is sufficient are not specified, as stated under Section 5 of the Regulations (Safety and Security of Radiation Sources).

Sufficient requirements are in place to ensure that applicants provide a safety case to support an application for authorisation of an activity or facility. A notification is expected to be made for RPAZ to establish the justification of the practice. If justified, the applicant is required to complete and submit an application form for which guidance is provided on how to be completed. The application forms are also available on the web site of RPAZ. The guidance provides the applicant with information on how to demonstrate that the facility or activity will satisfy the safety objectives, principles and requirements. It specifically relates to administrative arrangement; competency of staff; occupational exposure control; equipment performance; facility design and layout, etc. The guidance does not comprehensively provide information on public exposure control or workplace monitoring programme. Including public exposure would improve the guidance.

Even though it is provided for in the Regulations (Medical), SI 91 of 2014, the authorisation system does not allow for multi-stage authorisation (i.e. design, construction, commissioning, operation and decommissioning). Multistage *approval* is granted in the form of a letter, but not as an authorisation.

Various individuals on whom safety depends are accredited and authorised. Requirements have been established to provide guidance to these individuals.

Sufficient controls, limits and conditions are imposed in the authorisation when granted to licensees as required under Section 4.31 of the regulations. Currently the conditions are provided as an annex to the licence.

Section 19 of the Act establishes sufficient mechanisms for an applicant to appeal against a regulatory decision relating to an authorisation. Guidance is provided to applicants on the information to be provided in a prescribed format and the specific documents to be attached in support of the application. Clear procedures have been established in support of the processes and requirements necessary prior to amendment, renewal, suspension or revocation of an authorisation. Pre-authorisation inspections are conducted to confirm the safety case. Results of inspections and reviews and assessment are fed into the regulatory process.

Recording of regulatory decisions and feedback to the applicants is documented, but it is not consistent and systematic. Separate files are kept for licencing and inspections. It is important to note that the inspection results should be fed into the regulatory decision process. Records have been observed of regulatory decisions and communication to the applicant. As a quality control measure the keeping of record should be traceable with dates, time, responsible persons, and decisions.

Approval of persons having responsibilities for radiation protection is provided in Section 4(1)(i) of the Act. RPAZ issues licenses for the majority of workers using radiation sources after demonstrating that they are competent in the scope of work for which they are responsible. Some types of workers fill out forms and RPAZ conducts an assessment for licensing. Approval as stated in the Act is not defined in the regulations and RPAZ issues licences instead of approvals.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ does not have specific guidance for the activities and facilities to be either authorised by notification or exempted.
(1)	**BASIS: GSR Part 3 Requirement 8, para 3.10 states that** *"The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards, including the requirements for notification, registration or licensing, using as the basis for this determination the criteria for exemption specified in Schedule I or any exemption levels specified by the regulatory body on the basis of these criteria."*
(2)	**BASIS: GSR Part 3 Requirement 7, para 3.7 states that** *"Any person or organization intending to carry out any of the actions specified in para. 3.5 shall submit a notification to the regulatory body of such an intention18. Notification alone is sufficient provided that the exposures expected to be associated with the practice or action are unlikely to exceed a small fraction, as specified by the regulatory body, of the relevant limits, and that the likelihood and magnitude of potential exposures and any other potential detrimental consequences are negligible."*
S5	**Suggestion:** RPAZ should consider developing guidance on the facilities and activities to be authorized by notification or exempted from its regulatory control.
	Observation: RPAZ does not implement a multi-stage authorisation system.
(1)	**BASIS: GSR Part 1 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. The regulatory body shall be able to modify authorizations for safety related purposes. For a facility, the stages in the lifetime usually include: site evaluation, design, construction, commissioning, operation, shutdown and decommissioning (or closure)…"*
R13	**Recommendation:** RPAZ should implement a multi-staged authorisation system for facilities and activities as appropriate.
	Observation: RPAZ does not use a graded approach in their authorisation system for facilities and activities.
(1)	**BASIS: GSR Part 1, para 4.33 states that** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment [8], which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
	See Recommendation 11 in module 4.1.

5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

Section 14 of the Act prohibits the disposal of radioactive material unless it is in accordance with prescribed requirements. Section 15 provides powers for RPAZ to issue authorisation to dispose of radioactive materials. According to Section 12 of the Radiation Protection (Medical Practices) Regulations (SI 91 of 2014) waste

management and disposal of radioactive sources is an activity which requires authorisation. Section 4(7) of the same regulation obligates the licensee to comply with radiation safety requirements during the stage of decommissioning (partial or total) and return or disposal of radioactive sources.

The IRRS review team was informed that RPAZ has custody of an interim waste storage facility where some conditioned radioactive sources are stored and that this facility is not licenced. This ultimately would be best accomplished by moving the interim waste management facility to a utility outside RPAZ to ensure no conflicts of interest. However, an interim solution might be moving it to an organisational unit within RPAZ which has no authorisation or inspection roles and then licensing it.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ has custody of an interim storage facility which is not licensed.
(1)	**BASIS: GSR Part 1 Requirement 23 states that** *"Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process."*
(2)	**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."*
R14	**Recommendation:** RPAZ should license the interim waste storage facility to a unit within its organisation that is not tasked with authorisation or inspection until such time that custody can be transferred to a proper utility outside RPAZ.

5.4 SUMMARY

RPAZ has established a procedure for authorisation but it needs to be done using the graded approach so that not all facilities and activities are authorised by licensing and a multi-stage authorisation is deployed. The operation of the dosimetry service needs to be formally accredited and the responsibilities for it be transferred to a unit of RPAZ that does not perform regulatory functions such as authorisation, inspection and enforcement. Furthermore, the interim storage facility under the custody of RPAZ needs to be licensed to a unit that does not have regulatory functions.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

An *Authorisation Procedure Manual* is in place and includes policy statements and procedures relating to review and assessment. The *Authorisation Policy* states that review and assessment of applications shall be done to determine whether facilities and activities comply with regulatory requirements.

RPAZ has developed *Review and Assessment Forms* which are specific for the different facilities and activities to be authorized. Prior to authorisation, the applicant is required to submit an application and the review and assessment follows thereafter, which include evaluation of the information / data; interviewing the applicant / RSO and a pre-licensing inspection.

The purpose of the review and assessment is to acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based, and the operating principles proposed by the operator.

The *Authorisation Procedure Manual* also states that an integrated approach shall be adopted in the review and assessment.

There are various procedures outlined in the *Authorisation Procedure Manual*, which includes: Receiving of Applications; Processing Applications; and Procedures for Assessment of Applications. There is a procedure for assessment and review of applications to ensure consistency and adherence to regulatory policy in the assessment of licence applications. The roles and responsibilities of the assessing officer, the processing officer and inspection team in relation to completeness of information and inspection reports prior to making recommendations on authorisation are also clarified.

The procedures provide guidance to the assessors in terms of the performance areas to review and assess. At the completion of a review and assessment the application is fed into the authorisation process. Check lists are used for the review and assessment of different facilities and activities. The following are considered during the review and assessment: personnel resources and competence; facilities, sources and equipment, transport; justification, optimisation, calibrations; occupational and public exposure; and working rules, records, emergency procedures and audits.

Guidance is provided to the reviewer on the procedure to be followed when interviewing a licensee or RSO. The procedures provide guidance in terms of telephonic and in-person interviews. A Standard Operating Procedure is used during the assessment phase of the Review and Assessment stage; the licensee interview and evaluation forms are used during the procedure. Checklists are provided and used for the interview of the RSO and for the review and assessment of different practices.

A procedure is described to guide pre-licensing inspections. Inspections are carried out in accordance with the inspection procedure. Assessing officer(s) and inspectors use a Standard Operating Procedure during the assessment phase of the Review and Assessment stage. The licensee interview and evaluation forms are used during the inspection procedure.

6.2. REVIEW AND ASSESSMENT OF RADIATION SOURCES, FACILITIES AND ACTIVITIES

RPAZ has procedures in place to review and assess the information submitted in support of the applications and also interviews the applicant and conducts a pre-authorisation inspection prior to authorisation. The purpose of the review and assessment as stated in the policy is to acquire an understanding of the design of the facility or equipment, the safety concepts on which the design is based, and the operating principles proposed by the operator.

RPAZ in the review and assessment process uses different forms. The IRRS review team noticed that the forms are almost identical and the graded approach concept is not used and was informed that pre-licensing-inspections for authorisation are being conducted for all types of facilities and activities.

A multi-stage approach during review and assessment (i.e. at design, construction, commission, operation, etc.) for medical activities is provided for in the regulations SI 91 of 2014, but not implemented. Furthermore, this multi-stage approach is not formalised nor implemented for other activities.

Results of the review and assessment are not systematically documented and there are cases where the regulatory decisions are not recorded and fed into the regulatory process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ does not apply a graded approach to review and assessment of facilities and activities.
(1)	**BASIS: GSR Part 1 Requirement 25 states that** *"Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.*"
	See Recommendation 11 in module 4.1.

6.3 REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

RPAZ has a procedure in place for the review and assessment of facilities and activities. This procedure includes the review of information, interview of applicants or RSO and a pre-authorisation inspection. There is no record of an application form for radioactive waste facilities; no review and assessment form for the radioactive waste management and disposal facilities, including the interim waste storage facility in the custody of RPAZ.

6.4 SUMMARY

Graded approach is not used in carrying out Review and Assessment. RPAZ needs to consolidate in one file the report of the Review and Assessment with those from inspections and authorisation.
RPAZ needs to conduct a review and assessment of the interim waste storage facility under its custody.

7. INSPECTION

7.1. GENERIC ISSUES

Section 18 of the Act empowers RPAZ to conduct inspection of facilities and premises to ascertain compliance with regulatory requirements. An *Inspection Policy* has been developed to *provide* guidance for conducting inspections in a manner that is consistent with the provisions of the Act, regulations and international best practice. The policy provides for the following: develop and maintain an annual schedule; the allowance for reactive and investigative inspections; resource mobilisation and the provision of the report to the facility; keeping the database up to date and the use of checklist. The roles and responsibilities for the implementation of the policy to various levels of the hierarchy of RPAZ are assigned.

An inventory of the *2013 Compliance Inspections* shows a list of practices with date of inspection, type of inspection, name of facility and type of facility. The types of inspections include pre-authorisation, scheduled, investigative, review, follow-up, verification, and *ad hoc*. A document *Breakdown of Inspected Facilities by Sectors* shows that 125 inspections were done in the medical, industrial, dental and veterinary sectors. Another document *2014 Compliance Inspection Status Report* provides a report of the inspection activities from January to August 2014. It shows that 60.8 % of the planned inspections were done in the same period.

It is further stated that the inspection programme was planned on the basis of the following performance parameters: resources available at the time to carry out inspection activities; license holder risk ranking; compliance history; incidents and accidents history; date of last inspection. The annual reports of RPAZ on inspection state that compliance is based on licensees meeting the regulations and license conditions.

The *2014 Compliance Inspection List* gives the names of the facility, types of facilities and inspections to be conducted. The types of inspections include pre-authorisations, routine, follow-up, enforcement, investigative and reactive.

There are also various inspection checklists for different practices: nuclear medicine; radiation therapy; linear accelerator; dental facilities; industrial facilities; and diagnostic radiology facilities. However, there is no checklist for waste facilities.

Templates are also provided for guidance in writing inspection reports of various practices as well as guidance for quality control test to verify the performance of medical equipment.

The interim waste management facility under the custody of the RPAZ is being inspected by the inspection Department of RPAZ.

7.2. INSPECTION OF RADIATION SOURCES FACILITIES

Records show that RPAZ conducts inspections to verify compliance with regulations and with the terms and conditions of authorization. RPAZ performs different types of inspections including planned (announced, unannounced) and ad hoc (investigative or reactive) inspections. RPAZ has no clear guidance for criteria of conducting the different types of inspections. It would thus suffice to develop guidance for types of inspections to be taken.

It is stated in the policy that the inspection programme is planned on the basis of the performance parameters and license holder risk ranking. The IRRS review team observed that the development of the inspection programme is not based on graded approach as intended.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Even though it is stated in the Inspection Policy document that the inspection

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	programme is based on risk ranking, there is no explicit evidence that this provision is implemented.
(1)	**BASIS: GSR Part 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."*
	See Recommendation 11 in module 4.1.

7.3. INSPECTION OF WASTE MANAGEMENT FACILITIES

The Act also empowers RPAZ to enter, inspect and examine waste management facilities. RPAZ has developed an inspection programme, but it does not include waste management facilities. The checklists do not include radioactive waste storage facilities either as indicated above.
The IRRS review team was informed that the interim storage facility under the custody of RPAZ is being inspected regularly.

7.4. SUMMARY

RPAZ has established procedures for conducting inspections, but appropriate use of the procedures needs to be put in place. Furthermore, inspection reports are filed separately from the records of the Authorization Department on the application for authorisation; and the review and assessment report. It is nevertheless commendable that inspections are conducted by teams of representatives from both the Inspections and Dosimetry Department and the Licensing Department.
The interim storage facility under the custody of RPAZ is being inspected.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESSES

The Act empowers RPAZ to take actions as necessary to enforce its provisions and defines what constitutes an offence. For example, it empowers RPAZ to seize any substance or equipment or any book, record or document contravening the Act.

There is an *Enforcement Policy* which states that enforcement actions shall properly reflect the safety or security significance of the violations and shall be carried out on a risk graded approach. The policy allows for a graded approach to be adopted, based on the following performance parameters: the safety and security risk posed by the violation; the complexity of the corrective action that is needed; whether it is a repeat violation; whether there has been wilful violation of the limits and conditions specified in the authorization or in regulations; and the licensee's compliance history.

The policy provides for revocation of authorisation for serious or gross non-compliance, either temporary or permanently and it provides for prosecution, stating the cases when prosecution may be considered.

8.2. ENFORCEMENT IMPLEMENTATION

RPAZ has the legal authority to establish and implement an enforcement policy. The *Policy on Enforcement* has been established, but it is not implemented in a graded approach. Further expansion to some of the generic statements made in the policy may be required. The parameters have been identified which shall be used to define the graded approach for enforcement of compliance. Further clarity can be provided to what constitutes a serious or gross non-compliance, thus underscoring the need for written procedures and guidelines.

There is evidence of a case where RPAZ has invoked the provisions of the Act by prohibiting the use of a radiation source.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ has no written procedures and guidelines for enforcement
(1)	**BASIS: GS-G- 1.5 para. 3.85 states that** *"The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures. The procedures should specify the policy of the regulatory body with regard to the use of regulatory actions and enforcement measures, and the associated delegated authority given to inspectors and to other staff of the regulatory body."*
S6	**Suggestion: RPAZ should consider developing written procedures and guidelines for enforcement and provide training for its use in collaboration with relevant government agencies.**

8.3. SUMMARY

The Act, clearly describes and defines what constitutes a violation or an offence, and provides ample powers for enforcement. The enforcement actions may, however, require the support and cooperation of other government agencies with responsibilities for law enforcement. Hence, there is a need for RPAZ to formalise its cooperation with these government agencies.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The Act mandates RPAZ to issue standards and norms governing exemption, notification, registration and licensing of radiation sources and radiation protection and safety. Furthermore, it empowers the Office of the President and Cabinet, after consultation with the Board, to make regulations on all matters prescribed by the Act.

The scope of activities and practices for which regulations are specified to be made include the following matters: the precautions to be taken to prevent injury being caused by ionizing radiation to the health of persons employed in places where irradiating devices, radioactive materials or other radiation sources manufactured, stored, or disposed of or of persons likely to be exposed to harmful radiation; the methods of disposing of radioactive waste products; the precautions to be taken to prevent injury being caused by the transportation of irradiating devices, radioactive materials or other radiation sources to the health of persons engaged therein and other persons; the manner in which and the conditions subject to which irradiating devices or radioactive materials or other radiation sources may be stored or used; the making of returns by owners and persons in possession of irradiating devices, radioactive materials or other radiation sources giving such details as may be required; the security of radiation sources so as to prevent theft and acts of terrorism; and the fees payable in respect of any licence and services offered by the Authority.

There is a policy and procedures for the Development and Review of Regulations and Guides. RPAZ undertakes to establish a process and consult broadly in the development and review of regulations and guides; take into account international standards and experience. A procedure is described to guide the process of development of regulations and guides.

The current regulations include the following: Radiation Protection (Safety and Security of Radiation Sources) SI 62 of 2011; and the Radiation Protection (Medical Practices) Regulations, SI 92 of 2014; Radiation Protection (Naturally Occurring Radioactive Material) Regulations, SI 99 of 2013.

There are existing draft guidance documents including guidance for completing application forms and a transport guide which are awaiting approval.

RPAZ does not have guidance for the different types of practices (e.g. radiotherapy, diagnostic radiology, industrial radiography, waste management facilities) that are being regulated.

Interested parties are involved in the development of Regulations. RPAZ has a programme in place for the promotion of the regulations and guides among interested parties and in particular notifying interested parties and the public through workshops, radio and the internet.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ does not have guidance for all types of activities being regulated.
(1)	**BASIS: GSR Part 1 req. 32 states that** *"The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
R15	**Recommendation:** RPAZ should develop guides for all regulated activities.

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

The Act charges RPAZ with the responsibility of advising government on matters relating to the safety of radiation sources and the management of radioactive waste materials or irradiating devices. It also empowers the Office of

the President and Cabinet in consultation with the Board to make regulations prescribing the methods of disposing of radioactive waste products and precautions to be taken for protection of people against disposed radioactive material. The Act empowers RPAZ to issue standards and norms governing exemption, notification, registration and licensing of radiation sources and radiation protection and safety.

Some regulations have been established under the Regulations (Safety and Security), SI 62 of 2011, which has provisions for radioactive waste management. Developing detailed regulations and guides specific to the management and disposal of radioactive waste would improve the regulatory framework for safety.

9.3. SUMMARY

Development of regulations and guidance are adequately provided for in the Act. Procedures for developing and reviewing regulations have been issued. In addition, the medical regulations and the safety and security of radiation sources regulations have been issued. Guides and manuals need to be issued including those on radioactive waste management.

10. EMERGENCY PREPAREDNESS AND RESPONSE

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Basic responsibilities

A legislation has been adopted to allocate clearly the responsibilities for radiation emergency preparedness and response (EPR). The Act and the Radiation Protection Regulations (Safety and Security of Sources) named RPAZ as the regulatory body mandated to ensure that on-site (operator's) emergency arrangements provide a reasonable assurance of an effective response.

RPAZ is responsible for drafting all regulations, processing authorisations, inspecting facilities and monitoring emergency exercises. It acts as the Lead Technical Agency (LTA) during response, advising the government on actions to be taken.

In the Act, RPAZ' role in regulating licensees regarding their EPR arrangements is vaguely mentioned ("to protect the health and safety of workers and the members of the general public"). Thus the regulatory role of RPAZ for EPR is rather implicit. At the same time RPAZ is mandated "to ensure that adequate national arrangements for response to radiological accidents are established", which is more related to its role within the national system for EPR.

SI 62 of 2011 states that "Registrants and licensees shall…ensure that an emergency plan …is prepared and kept operational".

The prime responsibility of the licensee for safety, in general, and specifically for on-site EPR, is not spelled out in any legal document. This would be needed for RPAZ to have legal reference when regulating the licensees on this issue. This is a general problem and it is discussed elsewhere (see Recommendation 2). Nevertheless, it is mandatory for every facility to develop and implement a radiation emergency programme suitable for their operations. These programmes are reviewed annually by the operator and approved by the regulatory body.

Assessment of threats

No radiation threat assessment has been done so far. This should be part of a regulation that requires the applicant of a licence to establish its own EPR arrangements (emergency plan, procedures, equipment, facilities, staff training, drills and exercises, etc.) in accordance with the outcome of the threat assessment.

For the registered radiation sources a threat categorisation is in place which is in line with the threat categories shown in Table I of GS-R-2. Aside from the four radiation sources that would fall in threat category III, all the other radiation sources in the national inventory are in threat category IV.

Domestication of the IAEA GS-R-2 categorisation system is partially implemented. However, it is limited to the registered sources and does not take other possible hazard scenarios into consideration.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There are no regulatory requirements and no guidance for the licensees to develop threat assessment as the basis of their EPR planning.
(1)	**BASIS: GS-R-2 para. 3.15 states that** *"The nature and extent of emergency arrangements [for preparedness and response] shall be commensurate with the potential magnitude and nature of the [threat]… associated with the facility or activity."*
R16	**Recommendation: RPAZ should develop regulatory and guidance documents for the licensees to perform threat assessment on which their EPR arrangements will be based.**
	Observation: The assessment of radiation emergency hazard on the national level is limited to assigning the threat categories defined in GS-R-2 to the radiation sources registered in RAIS, but it does not cover many other scenarios that would warrant emergency response.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-2 para. 3.15 states that** *"…The full range of postulated events shall be considered in the threat assessment. In the threat assessment, emergencies involving a combination of a nuclear or radiological emergency and a conventional emergency such as an earthquake shall be considered. Any threat associated with nuclear facilities in other States shall also be considered…"*
S7	**Suggestion: RPAZ should consider extending its threat assessment beyond the threat categorization of sources registered in RAIS, to cover all possible radiation emergency scenarios.**

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Establishing emergency management and operations

At the national level, the national disaster management organisation (Department of Civil Protection, DCP) is empowered to coordinate the emergency response and to execute any instructions based on the advice they receive from RPAZ' technical assessment.

Response organisations and other interested parties will be coordinated by DCP (responsibilities will be allocated after the finalisation of the national plan). Arrangements have not yet been made for the implementation of a command and control system for the response to a nuclear or radiological emergency. This is planned to be established after the national plan is adopted.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Arrangements have not been made for the implementation of a command and control system for the response to a nuclear or radiological emergency.
(1)	**BASIS: GS-R-2 para. 4.10 states that** *"Arrangements shall be made for the implementation of a command and control system for the response to a nuclear or radiological emergency. This shall include arrangements for co-ordinating activities, for developing strategies and for resolving disputes between the response organizations15 concerning functions, responsibilities, authorities, the allocation of resources and priorities. In addition, arrangements shall be made for obtaining and assessing the information necessary in order to allocate resources for all response organizations."*
R17	**Recommendation: RPAZ should develop, in cooperation with the emergency response coordinating authority, an incident command and control system.**

Identifying, notifying and activating

In Zimbabwe, all facilities and activities are required to develop radiation protection programmes that cover all aspects of emergency preparedness and response, including identification of potential exposure situations.

Activities falling in threat category IV are required to have qualified experts who can make an assessment of the emergency in consultation with the regulatory body. Such facilities are required to check the safety and security of their sources on a regular basis.

Classification of emergency action levels is still in draft form for the radiological emergency preparedness and response programme for the country. This classification includes the level of risk associated with the radiation sources used. It is still to be elaborated in accordance with the classification requirements of GS-R-2.

The legal requirements mandate operators and users to report to the authorities any emergency situation within a 24 hour period from occurrence. The IRRS review team was informed that all RSOs and some qualified experts are competent to classify emergencies as well as to notify RPAZ.

A contact (notification) point has been established which is responsible for receiving emergency notifications 24 hrs/day and 7 days/week. However, it is a person with a mobile phone, who may or may not be available. A permanent National Warning Point is yet to be established.

The emergency response actions initiated promptly upon the receipt of a notification about an actual or potential transnational emergency that could affect Zimbabwe and its nationals are as follows:

- Assessment of the national radiological implications of the emergency
- Initiating the national response system based on the assessment results.

Annual refresher training for facility RSOs and management of facilities like scrap metal dealers is conducted by RPAZ to raise awareness among them. Some local officials have been trained on radiation protection and safety. There are plans to carry out regular awareness campaigns for threat category IV facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: A contact (notification) point has been established which is responsible for receiving emergency notifications 24 hrs/day and 7 days/week. However, it is a person with a mobile phone who may or may not be available. This is not sufficient to function as a National Warning Point.
(1)	**BASIS: GS-R-2 para. 4.16 states that** *"Notification points shall be established that are responsible for receiving emergency notifications of an actual or potential nuclear or radiological emergency. The notification points shall be continuously available to receive any notification or request for assistance and to respond promptly or to initiate an off-site response."*
R18	**Recommendation: The government should establish a permanent contact point for notification of a radiation emergency, both for domestic emergency notification and also to function as a National Warning Point.**

Taking mitigatory actions

SI 62 of 2011 states that "Registrants and licensees shall…be responsible for …protective actions". The IRRS review team was informed that arrangements have been made to provide expertise and services in radiation protection promptly to local officials and first responders responding to actual or potential emergencies and that RSOs, customs and security officials have been trained on radiation protection and safety.

RPAZ indicated that some officials and first responders have been trained to use radiation detection devices to assist in threat assessments. The increasing number of inspections carried out by the regulator is another useful tool to ensure threats are continually assessed and that the country is in the process of acquiring portal monitors.

RPAZ provides guidance to first responders in case of transport related emergencies and suspected illicit trafficking involving radioactive material.

Operators are supposed to contact the national emergency coordinator if there is a noted elevation in the dose rate or contamination levels and cordon off the area.

There are arrangements to initiate a prompt search and issue a warning to the public in the event of a *dangerous source* being lost or illicitly removed. A national committee for safety and security of radiation sources has been established to deal with such cases. However, there are no procedures available for such search activity.

Protection of external emergency responders is not considered by either the licensee or by the regulator.

Taking urgent protective action

SI 62 of 2011 defines the responsibility of the licensee and that of RPAZ in taking urgent protective action.

Optimised national intervention levels for taking urgent protective actions in accordance with international standards have not been adopted.

The IRRS review team was informed that all facilities in threat category III have emergency response plans, comprehensive radiation protection programmes and competent response teams in place. Furthermore, it was informed that most operators of medical, mining and manufacturing facilities and activities where safety is a priority have plans for evacuation and taking protective actions in the event of an emergency.

Facilities have designated RSOs whose role is to communicate in the event of an emergency with exposed staff, management, RPAZ and other response organisations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There are no generic and operational intervention and action levels available in Zimbabwe.
(1)	**BASIS: GS-R-2 para. 4.45 states that** *"Optimized [national] intervention levels [for taking urgent protective actions] shall be [established that are in accordance with international standards…"*
(2)	**BASIS: GS-R-2 para. 4.71 states that** *"…arrangements shall be made for promptly assessing the results of environmental monitoring and monitoring for contamination on people in order to decide on or to adapt urgent protective actions to protect workers and the public, including the application of operational intervention levels (OILs) with arrangements to revise the OILs as appropriate to take into account the conditions prevailing during the emergency."*
R19	**Recommendation: RPAZ should develop generic and operational intervention and action levels, in accordance with the international standards.**

Providing information and issuing instructions

Arrangements have not been made to promptly provide a warning and instruction to permanent, transient and special population groups or those responsible for them and to special facilities in the Precautionary Action Zone and the Urgent Protective Action Planning Zone upon declaration of an emergency class, because there are no category I or II facilities in Zimbabwe.

Protecting emergency workers

Although the term "emergency worker" is not defined in Zimbabwe, arrangements have been made for taking all practicable measures to provide protection for workers involved in emergency response operations, for the range of anticipated hazardous conditions. There are practicable measures in place such as electronic dosimeters, HAZMAT suits, respirators and other protective equipment for these workers.

The IRRS review team was informed that most first responders are trained on basic radiation protection and safety, and awareness campaigns are done for most first responders and the members of public.

There are mandatory regulatory requirements for facilities to assign RSOs to coordinate events in emergency situations and for all radiation workers to be under personal monitoring.

All workers involved in emergency operations are monitored through passive personal monitoring devices such as TLDs and OSLDs.

Currently there are no regulations for emergency workers regarding dose guidance values.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Although arrangements have been made for taking measures to provide protection for workers involved in emergency response operations, the term "emergency worker" is not defined in Zimbabwe. Consequently, the requirements on protection for these emergency workers are not defined.
(1)	**BASIS: GS-R-2 para. 4.57 states that** *"Arrangements shall be made to designate as emergency*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	workers those who may undertake an intervention…"
(2)	**BASIS: GS-R-2 para. 4.60 states that** *"National guidance that is in accordance with international standards shall be adopted for managing, controlling and recording the doses received by emergency workers. This guidance shall include default operational levels of dose for emergency workers for different types of response activities, which are set in quantities that can be directly monitored during the performance of these activities (such as the integrated dose from external penetrating radiation). In setting the default operational levels of dose for emergency workers the contribution to doses via all exposure pathways shall be taken into account."*
R20	**Recommendation: RPAZ should initiate the process, in cooperation with other government agencies, needed for officially defining the term "emergency workers" and developing the regulatory provisions for their protection.**

Assessing the initial phase

The IRRS review team was informed that arrangements have been in place to assess promptly abnormal conditions at the facility or practice, including potential or actual radioactive releases, as well as characterisation of abnormal exposures and the extent and significance of contamination.

Furthermore it was informed that facilities have radiation protection programmes that comprehensively cover EPR and workplace and personnel monitoring and that RSOs in such facilities are also trained in implementing procedures. However, there was no evidence of performing workplace monitoring on these facilities which was confirmed during the site visits.

The capabilities and competence for assessing the initial phase is not always available for the licensees. In such cases the assessment is done by RPAZ.

The IRRS review team was informed that medical physicists and RSOs from selected institutions and inspectors from RPAZ form the specialists' team and that each team will have alpha, beta and gamma spectrometers as well as general radiation survey and contamination monitors.

Managing the medical response

In Zimbabwe medical personnel are made aware of symptoms of radiation exposure as part of their curriculum. However it is felt that there is still a need for RPAZ to conduct awareness programmes to broaden this awareness. The IRRS review team was informed that all radiation exposure symptoms are reported to RPAZ as soon as they are identified and they coordinate with the DCP while investigating the source and circumstances of exposure. An emergency medical response team is included as part of the DCP disaster management plan. This team conducts early diagnosis and treatment of radiation injuries.

The radiation emergency plans and procedures are in draft form and are yet to be finalised. A National Cancer Registry exists, which keeps record/track of people in those groups that are at risk of sustaining detectable increases in the occurrence of all forms of cancer, including cancers as a result of radiation exposure.

Other activities in emergency preparedness

National intervention levels and action levels for agricultural countermeasures, countermeasures against ingestion and longer term protective actions have not yet been established in Zimbabwe. It is planned that these will be developed after the national emergency response plan is adopted and approved.

No arrangements are in place for taking effective agricultural countermeasures, including restriction of the consumption, distribution and sale of locally produced foods and agricultural produce following a release of radioactive material. In addition, no arrangements for taking effective longer term countermeasures are in place.

The non-radiological consequences of the response have been considered in order to ensure that the response actions do more good than harm. The Incident Commander within the DCP coordinates all the information that is communicated by the media. RPAZ' Inspection Department in cooperation with the CCO is responsible for carrying

out awareness campaigns and also demystifying rumours and misinformation to the public after verifying the non-existence of malice or serious hazards in public areas.

Arrangements have not been made for the transition from emergency phase operations to routine long term recovery operations. The allocation of responsibilities has not yet been finalised. The national plan to contain the arrangements is still being drafted.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: There are no national intervention levels and action levels for agricultural countermeasures, countermeasures against ingestion and longer term protective actions established in Zimbabwe.
(1)	**BASIS: GS-R-2 para. 4.88 states that** *"Optimized [national] intervention levels and action levels for agricultural countermeasures, countermeasures against ingestion and longer term protective actions shall be established that are in accordance with international standards, modified to take account of local and national conditions…"*
R21	**Recommendation: The government should adopt, based on proposals and regulatory requirements developed by RPAZ, the optimized intervention levels and action levels for agricultural countermeasures, countermeasures against ingestion and longer term protective actions.**
	Observation: RPAZ has regulatory responsibility in the recovery operations (e.g. transition threshold, workers protection, response criteria etc.) but the relevant regulations have not yet been developed.
(1)	**BASIS: GS-R-2 para. 4.100 states that** *"Decisions to cancel restrictions and other arrangements imposed in response to a nuclear or radiological emergency shall be made by a formal process that is in accordance with international guidance. "The regulatory body shall provide any necessary input to the intervention process. Such input may be advice to the government or regulatory control of intervention activities…"*
R22	**Recommendation: RPAZ should develop the necessary requirements regulating the recovery operation and facilitating the smooth transition to normal social and economic conditions.**

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Authority, organization, coordination of emergency response

In emergency situations all communications are done through the national coordinating authority (DCP) which works together with RPAZ (acting as the LTA) to advise response organisations on assessment and protective actions.

Activities of different response organisations are coordinated. DCP coordinates responses to all national emergencies in the country. It therefore harmonises its coordination of response overseeing the actions of all response organizations. RPAZ, as the regulatory body, ensures that the co-ordinated arrangements are implemented adequately by the operators.

The draft National Radiological Emergency Plan (NREP) provides information about the documents where the information about the key positions (responsible persons for the performance of the response functions) are contained and described.

Plans and procedures

It is mandatory for every facility to develop and implement a radiation emergency programme suitable for their operations. These programmes are reviewed annually by the operator and approved by RPAZ. There is no guidance given to the applicants/licensees on how to prepare the emergency plans.

The Act mandates RPAZ "to ensure that adequate national arrangements for response to radiological accidents are established", which is directly related to its role within the national system for EPR. On this basis RPAZ is tasked to draft the NREP. The draft NREP provides for setting up response teams at facility, district, provincial and national levels to which transfer of authority will be made depending on the complexity of the situation. It categorizes facilities according to the threats they pose and outlines specific response for each type and level of emergency.

Just a few response organisations have prepared a general plan for coordinating and performing their assigned functions during a nuclear or radiological emergency. They have plans that are general and designed to respond to emergencies without specially addressing the radiological aspects.

Most of operating and response organisations have developed the necessary procedures, analytical tools and computer programs in order to be able to perform the functions during emergency conditions. But these procedures have not yet been tested in all cases.

Emergency plans are attached to the licence applications and they are evaluated during the authorisation process. However, there are no clear acceptance criteria for the evaluation. Emergency arrangements are checked during inspections (this was confirmed during the site visits).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ has an important role in developing the national radiation emergency response plan. This plan is in draft form, its finalization would be a major step in strengthening the national emergency response capabilities.
(1)	**BASIS: GS-R-2 para. 5.13 states that** *"Plans or other arrangements shall be made for co-ordinating the national response to the range of potential nuclear and radiological emergencies. These arrangements for a co-ordinated national response shall specify the organization responsible for the development and maintenance of the arrangements; shall describe the responsibilities of the operators and other response organizations; and shall describe the co-ordination effected between these arrangements and the arrangements for response to a conventional emergency. The arrangements should include provisions that can be used to formulate in detail a response to situations such as: a serious exposure or contamination resulting from contact with a source by a member of the public; the notification of a potential transboundary release of radioactive material; the discovery of a shipment containing a dangerous source that is not under control; the notification of the potential re-entry of a satellite; public concern or rumours about a threat; and other unanticipated situations warranting a response."*
S8	**Suggestion: RPAZ should consider finalizing the draft national radiation emergency plan and forward it to the relevant national authorities for review and approval.**
	Observation: The regulations requiring the applicants of licenses to establish emergency preparedness capabilities exist, the emergency planning is clearly requested but there is no guidance given to the applicants/licensees on how to prepare the plan. In addition, there are no clear acceptance criteria for the emergency plans.
(1)	**BASIS: GS-R-2 para. 3.9 states that** *"In fulfilling its statutory obligations, the regulatory body… shall establish, promote or adopt regulations and guides upon which its regulatory actions are based…"*
R23	**Recommendation: RPAZ should develop guidance for the applicants/licensees on the preparation of emergency plans for facilities and activities. This should also serve as acceptance criteria for the evaluation of the emergency plans during the authorization process.**

Logistical support and facilities

The IRRS review team was informed that arrangements have been made for providing adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (such as procedures, checklists,

telephone numbers and manuals) for performing functions required for emergency preparedness and response. Arrangements have been made at facility level but some of the equipment and supplies are inadequate.

Equipment such as multi-channel analysers has been procured but emergency staff has not been trained to use them. There is still a further need to procure equipment such as isotope identifiers for the secondary response team. Procedures and checklists for emergency situations are still to be developed. Emergency numbers have been provided to all known facilities and also to the DCP.

The adequacy and effectiveness of the available logistical support and facilities are best tested and verified by exercises and through regular use. However, a national exercise that would test all the equipment and facilities and their coordinated use has not yet been organized, it is foreseen to happen after the national plan is approved.

Training, drills and exercises

SI 62 of 2011 requires that "licensees shall ensure that all personnel on whom protection and safety depend are appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgement and according to the defined procedures and are periodically retrained or re-qualified as may be appropriate."

The IRRS review team was informed that arrangements have been made for providing training which ensures that the emergency response personnel have the requisite knowledge, skills and abilities to perform their assigned response functions. They were also informed that a detailed training programme is in place to develop the response team's expertise. Some first responders have already been trained such as customs officers, state security officers, etc. The training programme is derived from the IAEA guidelines for first responders.

It is a statutory requirement for threat category III facilities to develop emergency plans suitable for their operations. The IRRS review team was informed that employees of such facilities have been trained on the roles they play on their specific emergency response mechanisms and that some of these facilities regularly conduct drills and exercises to tests their plans. However, the facilities visited during the site visits have never conducted drills and exercises.

Arrangements have not been made for providing exercise programmes to ensure that all specified functions required to be performed for emergency response and all organisational interfaces are tested at suitable intervals. The issues of first responder training and exercise were discussed with the director of the DCP, who indicated that such programmes will be developed and implemented when the NREP is adopted. Training requirements for the officials off site, responsible for making decisions on protective actions, do exist. RPAZ indicated that all decision makers will be trained in order to comprehend technical advice from radiation experts and to communicate efficiently. Training requirements have provisions for communication to the public as well as decision makers to implement various interventions at different levels.

Quality assurance programme

RPAZ informed the IRRS review team that arrangements are in place for ensuring a high degree of availability and reliability of all the supplies, equipment, communication systems and facilities necessary to perform the emergency response functions. These arrangements refer also to maintenance, reviewing and updating of emergency plans, procedures and other arrangements and incorporating lessons learned from research, operating experience (i.e. response to emergencies) and emergency drills and exercises.

Facilities with sources in threat categories III and IV are supposed to submit a Radiation Protection Program which encompasses the quality assurance programme for all supplies and equipment.

The facilities are requested to submit their emergency safety plans and in those plans facilities are supposed to conduct mock drills and exercises in preparation for emergencies. RPAZ evaluates all emergency plans of all facilities.

No calibration facility is available for dose rate monitor calibration (there is no SSDL in Zimbabwe). If such calibration is needed it is usually done abroad.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

RPAZ is responsible (beyond drafting all regulations, processing authorisations, inspecting facilities and monitoring emergency exercises) to act under the coordination of DCP as the LTA during response, advising the government on actions to be taken. Nevertheless, RPAZ has not developed its own emergency response plan yet.

EPR is not consistently included in the management system of RPAZ as mentioned in Module 4.

There is no domestic training for RPAZ' emergency response staff. They can benefit from the IAEA training activities (regional and national courses).

The facilities and logistical support available for the RPAZ EPR staff is rather limited (portable radiation meters, dosimeters, PPE etc.). They are short of transport means, which is essential to quickly respond to an emergency, especially in areas far from the capital city.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Although RPAZ is considered to be part of the national radiation emergency response system, the Lead Technical Agency and the advisor of the government, it does not have an organizational emergency response plan.
(1)	**BASIS: GS-R-2 para. 5.14 states that** *"Each response organization "shall prepare a general plan or plans for coordinating and [performing their assigned functions as specified in Section 4]. This includes situations involving such sources of exposure as sources illegally brought into the country, falling satellites equipped with sources or radioactive materials released in accidents beyond national borders." … "Emergency plans shall be prepared which specify how the responsibilities for the management of interventions will be discharged on the site, off the site and across national [borders], as appropriate, in separate but interconnecting plans."*
R24	**Recommendation: RPAZ should develop its own radiation emergency response plan.**

10.5. SUMMARY

The main conclusions regarding regulating emergency preparedness and response in Zimbabwe are as follows:

- RPAZ is the sole regulator in Zimbabwe regarding emergency preparedness and response.
- The primary responsibility of the licensees in establishing emergency response capabilities and performing emergency response in their facilities is not spelled out explicitly in the legal and regulatory documents. This needs development of legal and regulatory framework that clearly defines the licensee's responsibility.
- There are no regulatory requirements for several functions of EPR (e.g. threat assessment, establishment of emergency management and operations, identification and classification of situations warranting emergency response, intervention and action levels, protection of emergency workers, recovery operations etc.). Developing these regulations, together with the relevant guidance documents will help the licensees (and applicants of future practices) to establish proper on-site EPR arrangements.
- RPAZ' own emergency plan is yet to be developed.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

The legal basis for medical exposure control in Zimbabwe is given in the Act and the implementing Radiation Protection (Safety and Security of Radiation Sources) Regulations of 2011, which is based on the IAEA BSS 115. Additionally, the Radiation Protection (Medical Practices) Regulations of 2014 detail a number of additional obligations specifically applicable to the medical practices.

There are two authorities involved in the regulatory framework of radiation protection and safety related to medical exposures: the Ministry of Health and Child Care and RPAZ.

The practice specific regulations in the medical field have been drafted by RPAZ and are in well-advanced stage. These practice specific regulations are supposed to resolve a large number of the discrepancies that currently exist between the current regulations and the requirements of GSR Part 3.

Justification of medical exposure

Although the requirement to justify medical exposures is clearly stipulated in the regulations, this seems to be limited to the justification of the medical procedure in general terms. There are no requirements for the justification of medical exposure for an individual patient. The IRRS review team was informed that no national referral guidelines are published with respect to radiological medical procedures.

In the Radiation Protection Regulations attention is given to the justification of medical exposures to individuals undergoing health screening. However, the protection of volunteers in biomedical research is not addressed in these regulations. The actual decisions on both health screening and biomedical research programmes are taken by the national Ethics Committees that were founded for these purposes. However, the IRRS review team was informed that RPAZ is not represented in these committees.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: RPAZ is not represented in the national Ethics Committees on screening programmes and on biomedical research housed in the Medical Research Council.
(1)	**BASIS: GSR part 3 Para. 3.151 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 similar functions by the relevant authority) …"*
(2)	**BASIS: GSR part 3 Para. 3.160 states that** *"The medical exposure of volunteers as part of a programme of biomedical research is deemed to be not justified unless:* *(b) It is subject to approval by an ethics committee (or other institutional body that has been assigned similar functions by the relevant authority), subject to any dose constraints that may be specified (as required in paras 3.148(a)(ii) and 3.173), and subject to applicable national regulations and local regulations."*
S9	**Suggestion: The government should consider having representatives from RPAZ on the Ethics Committee on screening programmes and on the Ethics Committee on biomedical research.**

Optimisation of medical exposure

Therapeutic medical exposures are excluded from the general principle of optimisation of exposures from any particular source in a practice in Zimbabwe. Furthermore, diagnostic reference levels (DRL) have not yet been published by the regulatory authority, although the regulations explicitly foresee this. This is also valid for the values of the dose constraints for the exposures of comforters and carers. Dose constraints for volunteers participating in programmes of biomedical research are not addressed in the regulations.

The regulations do not require licensees to ensure that the particular aspects of medical exposures are considered in the optimisation process in case of paediatric patients, individuals subject to health screening programmes,

volunteers within programmes of biomedical research, procedures resulting in a relatively high doses to the patient, radiological procedures in which the abdomen or pelvis of a pregnant woman could receive a significant dose or a breast-fed infant as a result of a female patient undergoing a radiological procedure with radiopharmaceuticals.

There is no independent verification required by the regulations for the calibration of radiotherapy units, the calibration of dosimeters used for patient dosimetry or for the calibration of sources to be traceable to a standards dosimetry laboratory.

Licensees are not required to ensure that local assessments are made at given intervals for the radiological procedures for which diagnostic reference levels should have been established. In addition, reviews are not conducted to determine whether the optimisation of protection and safety for patients is adequate, whether corrective action is required if the typical doses or activities exceed or are substantially below the relevant diagnostic reference level.

There are no mandatory requirements for licensees to take into account the principles established by the World Health Organization (WHO) when applying the requirements of GSR Part 3 with respect to management systems. The responsibilities of the medical physicist in terms of QA and QC are insufficiently described in the regulations.

Regular and independent audits of the programmes of QA for medical exposures are not addressed by the regulations in Zimbabwe.

Release of patients

There are currently no formal criteria established for the release of patients who underwent therapeutic procedures using unsealed radioactive sources or for patients retaining implanted sealed sources although this is required by the regulations.

Pregnant and breast feeding women

The current regulations do not provide requirements for licensees to ensure appropriate radiation protection in cases where a woman is or might be pregnant or is breast-feeding. These requirements are however checked during inspections by RPAZ staff, which was confirmed during the site visits.

Review and records

There are mandatory requirements for licensees to ensure that radiological reviews are performed periodically at medical radiation facilities. There are however no requirements regarding keeping records pertaining to delegation of responsibilities, nor for maintaining records of local assessments and reviews regarding DRL or records of exposure of volunteers taking part in biomedical research programmes.

Unintended medical exposures

Although the regulations require the licensees to promptly investigate any unintended exposure and to implement any relevant corrective action, there are no provisions requiring licensees to take all practical measures to minimise the likelihood of unintended or accidental medical exposures.

Site visit to a medical installation

Some members of the IRRS review team accompanied RPAZ inspectors during an inspection of the radiotherapy and radiology departments of the Parirenyatwa Hospital at Harare.

The inspections started with an entrance meeting, led by the RPAZ manager for inspection and dosimetry. The Director of Operations of the hospital was briefed on the scope and the objectives of the inspections.

The inspection at the radiotherapy department was led by an RPAZ inspector who was accompanied by the Chief Radiation Protection Officer of the hospital. Practice specific checklists for brachytherapy and radiotherapy were used as guidance for the inspections. The inspector conducted his work in a professional manner and kept redirecting the inspection to the objectives using the checklists. This is commendable as at times focus was lost as hospital staff began to provide explanations on the operations of the facility. The checklist was adhered to throughout the inspection. The preparation prior to the inspection may provide further focus and identify key issues to address during the inspection.

The inspection at the diagnostic radiology facility was also conducted by an RPAZ inspector in the presence of a radiographer. A checklist specifically designed for diagnostic radiology was used as guidance. The inspection in this case was a follow-up and it was clear that there had been preparations prior to the inspection. The inspection was focused on issues identified in previous inspections. Realisation of corrective actions required after the previous inspection were verified as well as other parameters subject to change over time, including performance of the equipment. At the end of the inspection, the inspector shared the outcome of the inspection with the hospital personnel and made sure that the implications were understood.

During the exit meeting, the head of the RPAZ inspection team provided a briefing to the hospital staff on the findings of the inspections. It is commendable that the RPAZ team provided these outcomes and further elaborated on RPAZ expectations. The hospital staff was requested to timely and swiftly address the issues of non-compliance.

The inspections covered a wide range of issues, but interrogation of occupational exposure records was an obvious omission.

In both cases, the hospital staff appreciated the role of RPAZ as an authority to enhance and promote safety. Training among the operators is an important aspect which was highlighted as a tool to promote safety culture.

There is much added value when the inspectors have in-depth technical knowledge and experience of the operations of the facility under inspection. For this reason, training of the inspectors at the facilities would be very useful.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The current status of the regulations on radiation protection in Zimbabwe is not fully compliant with the requirements of GSR part3.
(1)	**BASIS: GSR Part 3 Para. 3.156 states that** *"The justification of medical exposure for an individual patient shall be carried out through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or paediatric, of:* *(a) The appropriateness of the request;* *(b) The urgency of the procedure;* *I The characteristics of the medical exposure;* *(d) The characteristics of the individual patient;* *I Relevant information from the patient's previous radiological procedures."*
(2)	**BASIS: GSR Part 3 Para. 3.157 states that** *"Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure."*
(3)	**BASIS: GSR Part 3 Para. 3.160 states that** *"The medical exposure of volunteers as part of a programme of biomedical research is deemed to be not justified unless:* *(a) It is in accordance with the provisions of the Helsinki Declaration [20] and takes into account the guidelines published by the Council for International Organizations of Medical Sciences [21], together with the recommendations of the ICRP [22];* *(b) It is subject to approval by an ethics committee (or other institutional body that has been assigned similar functions by the relevant authority), subject to any dose constraints that may be specified (as required in paras 3.148(a)(ii) and 3.173), and subject to applicable national regulations and local regulations."*
(4)	**BASIS: GSR Part 3 Para. 3.163 states that** *"For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, shall ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances."*
(5)	**BASIS: GSR Part 3 Para. 3.146 states that** *"The government, in accordance with paras 2.13–2.28, shall ensure with regard to medical exposures that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the relevant parties identified in*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	paras 2.40 and 2.41 are authorized to assume their roles and responsibilities, and shall ensure that they are notified of their duties in relation to protection and safety for individuals undergoing medical exposures."
(6)	**BASIS: GSR Part 3 Para. 3.147 states that** *"The government shall ensure, as part of the responsibilities specified in para. 2.15, that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, a set of diagnostic reference levels is established for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality, to enable the requirements of para. 3.168 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."*
(7)	**BASIS: GSR Part 3 Para. 3.148 states that** *"The government shall ensure that, as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the following are established:* *(a) Dose constraints, to enable the requirements of paras 3.172 and 3.173 respectively to be fulfilled for:* *(i) Exposures of carers and comforters;* *(ii) Exposures due to diagnostic investigations of volunteers participating in a programme of biomedical research;* *(b) Criteria and guidelines for the release of patients who have undergone therapeutic procedures using unsealed sources or patients who still retain implanted sealed sources."*
(8)	**BASIS: GSR Part 3 Para. 3.165 states that** *"Registrants and licensees shall ensure that the particular aspects of medical exposures are considered in the optimization process for:* *(a) Paediatric patients subject to medical exposure;* *(b) Individuals subject to medical exposure as part of a health screening programme;* *I Volunteers subject to medical exposure as part of a programme of biomedical research;* *(d) Relatively high doses43 to the patient;* *I Exposure of the embryo or foetus, in particular for radiological procedures in which the abdomen or pelvis of the pregnant woman is exposed to the useful radiation beam or could otherwise receive a significant dose;* *(f) Exposure of a breast-fed infant as a result of a female patient undergoing a radiological procedure with radiopharmaceuticals."*
(9)	**BASIS: GSR Part 3 Para. 3.166 states that** *"The medical physicist shall ensure that:* *I Calibrations of radiotherapy units are subject to independent verification prior to clinical use;* *(d) Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory."*
(10)	**BASIS: GSR Part 3 Para. 3.168 states that** *"Registrants and licensees shall ensure that:* *(a) Local assessments, on the basis of the measurements required in para. 3.167, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established (para. 3.147);* *(b) A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure:* *(i) typical doses or activities exceed the relevant diagnostic reference level; or* *(ii) typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient."*
(11)	**BASIS: GSR Part 3 Para. 3.169 states that** *"Registrants and licensees, in applying the requirements of these Standards in respect of management systems, shall establish a comprehensive programme of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiation technologists and, for complex*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	nuclear medicine facilities, radiopharmacists and radiochemists, and in conjunction with other health professionals as appropriate. Principles established by the World Health Organization, the Pan American Health Organization and relevant professional bodies shall be taken into account."
(12)	**BASIS: GSR Part 3 Para. 3.170 states that** "*Registrants and licensees shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility:* *(a) Measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist:…"*
(13)	**BASIS: GSR Part 3 Para. 3.171 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."*
(14)	**BASIS: GSR Part 3 Req. 39 states that** *"Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a woman is or might be pregnant or is breast-feeding."*
(15)	**BASIS: GSR Part 3 Req. 36 states that** *"Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks."*
(16)	**BASIS: GSR Part 3 Para. 3.182 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 principal parties…"*
(17)	**BASIS: GSR Part 3 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 records of calibration, dosimetry and quality assurance:…* *(c) Records of local assessments and reviews made with regard to diagnostic reference levels …"*
(18)	**BASIS: GSR Part 3 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 for medical exposure:…* *(e) Exposure records for volunteers subject to medical exposure as part of a programme of biomedical research;…"*
(19)	**BASIS: GSR Part 3 Para. 3.178 states that** *"Registrants and licensees … shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error.*
R25	**Recommendation: RPAZ should revise the current legal and regulatory framework to bring it in line with the requirements of GSR Part 3.**

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and regulatory framework

An adequate and functioning legislative and regulatory framework to provide for occupational radiation protection has been established in Zimbabwe. It is almost entirely based on the Radiation Protection Regulations under the Act.

There is a number of areas in which Zimbabwe is yet to adopt the new Basic Safety Standards, GSR Part 3. Several of these deviations from the international requirements were identified by RPAZ during the self-assessment.

A programme for managing, controlling and recording the doses received by emergency workers during an emergency has not yet been put in place and the regulation does not provide guidance values for the exposure of workers during emergency situations (see details in module 10).

Dose limits in line with the international requirements are specified, except for the lens of the eye, where an annual dose limit of 150 mSv for adults and 50 mSv for apprentices and students between 16 and 18 years old is being used. Additionally, with respect to the equivalent dose limit applicable to the skin, the regulations do not specify that this is applicable to the most exposed part of the skin. There are no requirements on the exposure of persons under the age of 16 years, although employment of these persons involving contact with hazardous substances is prohibited by the Labour Relations Regulations (1997, Section 3(1)(2)).

The current regulations require the monitoring and recording of occupational exposures only for workers in controlled areas.

The regulations do not address requirements for the protection of workers in existing exposure situations. This is a direct result of the fact that the concepts of planned and existing exposure situations have not yet been implemented in the legal and regulatory framework of Zimbabwe. As a consequence, no requirements for the protection of workers against exposure to radon or exposure of aircrew due to cosmic radiation is established, nor planned.

General responsibilities of registrants, licensees and employers

The regulations define and assign the responsibilities for the protection of workers, occupational exposure and for compliance with the requirements of these regulations to the licensees. They require that occupational exposure is controlled so that the dose limits are not exceeded, except for workers exposed to radiation from sources not required or not directly related to their work. In this case the regulations do not specify explicitly that the activity should be regulated in accordance with the requirements for public exposure. There are no regulatory provisions for workers exposed to a source that is not under the control of their employer.

The regulations require that occupational protection and safety is optimised and that exposures are kept as low as reasonably achievable. The concept of a dose constraints, actions levels and investigation levels are not provided for in the regulations.

The requirement to give priority to safety by design and technical measures within the hierarchy of protective measures for controlling occupational exposure is not addressed in the regulations, nor the fact that licensees should minimise the need to rely on administrative controls and personal protective equipment.

The health surveillance of workers is required according to the dispositions of the Act, although no further details on this requirement are given in the regulations. The IRRS review team was informed that there is actually no health surveillance being implemented in Zimbabwe.

The regulations do not require licensees to record all reports from workers identifying circumstances that could affect compliance with the regulations, nor to take appropriate actions.

General Responsibilities of workers

The current regulations in Zimbabwe do not attribute any responsibilities to the workers for protection and safety. This discrepancy was clearly identified by RPAZ during the self-assessment. The regulatory authority is currently working on establishing regulations that will include the responsibilities of workers. Also, consultation between employers and workers or their representatives in the area of protection and safety is currently not foreseen.

Requirements for radiation protection programmes

Licensees are required to designate the relevant areas of their workplaces as controlled or supervised areas. However, the regulations do not oblige them to undertake area-specific measures for controlling exposures, for preventing the spread of contamination or for preventing or limiting the likelihood and magnitude of exposures in anticipated operational events and accident conditions. It seems that the same protective measures apply to controlled and supervised areas.

Licensees are required to provide workers with suitable and adequate personal protective equipment and are responsible for making arrangements for assessing the occupational exposure for workers with approved dosimetry

service providers. In addition, they are required to establish and maintain a programme for workplace monitoring. However, there is no obligation in the regulations that this programme would be under the supervision of a qualified expert or a RSO. The precise content of this programme for workplace monitoring has not yet been issued by RPAZ although required by the regulations.

The regulations mention explicitly that the conditions of service of workers has to be independent of whether they are or could be subject to occupational exposure and that no compensatory arrangements or preferential considerations can exist.

Monitoring programmes and technical services

Only RPAZ is currently providing individual dosimetry services, while workplace monitoring is not provided for within Zimbabwe. RPAZ currently does not operate its dosimetry service under a quality management system, but is looking into implementing ISO 17025. The service offered by RPAZ in the field of individual monitoring is currently covering the needs of the country.

Other services that are provided for within Zimbabwe are radiation protection training; radiation protection consultancy; and supply, installation, maintenance and repair of medical and industrial equipment. The providers of these services require an accreditation from RPAZ.

Site visit to an industrial installation

Some members of the IRRS review team accompanied the RPAZ inspectors during an inspection of the brewery *Delta Beverages* at Southerton, Harare. The purposes of this visit were related to the following issues:

- Inspection of the occupational exposure conditions of the workers at the bottling lines of the brewery;
- Progress in implementation of the corrective actions imposed after previous inspections.

Before leaving for the inspection, a pre-inspection status report on the licensee was circulated amongst the inspectors. Although containing very useful information, this document would be even more useful if it contained more detailed technical information.

The inspection started off with an entry meeting, stating clearly to the licensee the role and functions of the people present and the scope of the inspection. Following this, an instruction on the industrial safety rules applicable in the plant was given by the licensee. The inspection was performed in a professional and knowledgeable manner by the RPAZ inspectors. In particular, it was noted that the inspectors performed several independent measurements of the radiation levels around the sources in operation and around the disused sources in storage. They also checked contamination levels of the source holders of the two disused sources. No verification of the contamination levels of the source containers of the sources in use was performed. The serial numbers of sources and source containers were recorded.

During the exit meeting, the head of the RPAZ inspection team provided a briefing to the licensee on the findings of the inspection and elaborated on RPAZ expectations, specifically with respect to dosimetry of the workers and returning the disused sources.

The management of the licensee appreciates the effectiveness of RPAZ in giving additional incentives for further enhancing radiation safety in the plant.

There is clearly an added value coming from the inspections performed by RPAZ, which could be enhanced by training the inspectors further e.g. in the field of radiological measurement techniques.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: The current status of the regulations on radiation protection in Zimbabwe is not fully compliant with the requirements of GSR part3.
(1)	**BASIS: GSR Part 3 Para. 4.12 states that** *"The government shall establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers,*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	which shall be implemented by response organizations and employers."
(2)	**BASIS: GSR Part 3 Schedule III-1 states that** *"For occupational exposure of workers over the age of 18 years, the dose limits are:* *(b) An equivalent dose to the lens of the eye of 20 mSv per year averaged over 5 consecutive years (100 mSv in 5 years) and of 50 mSv in any single year."*
(3)	**BASIS: GSR Part 3 Schedule III-2 states that** *"For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies, the dose limits are: … (b) An equivalent dose to the lens of the eye of 20 mSv in a year;"*
(4)	**BASIS: GSR Part 3 Schedule III-1.c states that** *"The equivalent dose limits for the skin apply to the average dose over 1 cm² of the most highly irradiated area of the skin."*
(5)	**BASIS: GSR Part 3 Requirement 20 states that** *"The regulatory body shall establish and enforce requirements for the monitoring and recording of occupational exposures in planned exposure situations."*
(6)	**BASIS: GSR Part 3 Para. 2.29 states that** *"The regulatory body shall establish requirements for the application of the principles of radiation protection specified in paras 2.8–2.12 for all exposure situations and shall establish or adopt regulations and guides for protection and safety."*
(7)	**BASIS: GSR Part 3 Para. 3.78 states that** *"Employers, registrants and licensees shall ensure that workers exposed to radiation from sources within a practice that are not required by or directly related to their work have the same level of protection against such exposure as members of the public."*
(8)	**BASIS: GSR Part 3 Para. 3.85 states that** *"If workers are engaged in work that involves or that could involve a source that is not under the control of their employer, the registrant or licensee responsible for the source and the employer shall cooperate to the extent necessary for compliance by both parties with the requirements of these Standards."*
(9)	**BASIS: GSR Part 3 Requirement 25 states that** *"Employers, registrants and licensees shall be responsible for making arrangements for assessment and recording of the occupational exposure and for workers' health surveillance."*
(10)	**BASIS: GSR Part 3 Requirement 22 states that** *"Workers shall fulfil their obligations and carry out their duties for protection and safety."*
(11)	**BASIS: GSR Part 3 Requirement 24 states that** *"Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure."*
(12)	**BASIS: GSR Part 3 Para. 3.93 states that** *"Employers, registrants Employers, registrants and licensees shall minimize the need to rely on administrative controls and personal protective equipment for protection and safety by providing well engineered controls and satisfactory working conditions, in accordance with the following hierarchy of preventive measures:* *(1) Engineered controls;* *(2) Administrative controls;* *(3) Personal protective equipment."*
	Refer to Recommendation 25 of module 11.1.

11.3. SUMMARY

The legislative and regulatory framework of Zimbabwe in the field of radiation protection is in place and relatively well-developed. There are however a number of discrepancies with respect to the requirements of GSR Part 3 both

for occupational and medical exposure. A large number of these discrepancies in the medical field would be resolved following finalisation of the practice specific regulations, which are currently in preparation.

11.4. TRANSPORT OF RADIOACTIVE MATERIAL

11.4.1. GENERAL ISSUES

The Act prohibits the transport of radioactive material unless it is done in accordance with prescribed requirements. Requirements for authorisation are provided under the Act, including the responsibility of the licensee to ensure optimisation during transport. Inspections and enforcement provisions relating to transport of radioactive material is also provided under the Act. The Act empowers the Office of the President and Cabinet to make regulations relating to the transport of radioactive material. But RPAZ does not issue authorisations for the transport of radioactive material and sources within the country except when such material or sources are in transit through Zimbabwe. Inspections are not carried out for conveyors of radioactive material within the country and in transit.

The IAEA Safe Transport Regulations TS-R-1 have been adopted by reference as provided in SI 62 of 2011 and shall remain up to date as reviewed by the IAEA from time to time.

There is a Transport Guide in place which includes the following provisions of the IAEA Transport Regulations: submission of an application for transport prior to authorization; obligation of applicants to comply with the IAEA Transport Regulations; responsibilities of the carriers and consignee; documentation in support of an application and what should be the content of the documents; monitoring of all workers involved in transport of RM; workers training and advice on the content of the training; keeping of records related to transport of radioactive material; requirements to be met before any shipment is undertaken (i.e. transport of other goods; segregation; transport and storage in transit; stowage during transport and transit); guidance on when RPAZ may consider transport under special arrangements; guidance on determination of transport index; guidance on Marking, labelling and placarding.

There are also minimum requirements for authorisation to transport radioactive material within or outside Zimbabwe and to transit through Zimbabwe. The document provides for the administrative requirements to be met for authorisation to transport radioactive material; guidance and information on inspections to be conducted; the RSO to be appointed; personal monitoring programme; the radiation protection programme to be in place; and the requirements for transport.

In the context of the legislative provisions, the regulatory activities (notification, authorisation, review and assessment; inspection and enforcement) equally apply to the transport of radioactive material and hence all comments made in this respect in modules 5-9 are relevant to this section.

The IRRS review team was informed that there are no transport companies in the country and transport of all radioactive material and sources are being done by the licensees.

RPAZ does not have coordination with the Ministry of Transport and other government agencies that may be involved in the safety of transport of radioactive material and sources (see Suggestion 1 in Module 1.5.).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	Observation: Effective regulatory control of transport of radioactive material and sources is not in place yet.
(1)	**BASIS: GS-G-1.5 para. 5.6 states that "***The role of the regulatory body in relation to transport will normally include requirements relating to the approval of package designs, the approval of transport and, as determined by national legislation, the tracking of sources. National infrastructures for transport safety, in general, can be very complex. The regulatory body's role for the safe transport of radioactive material may need to be shared with other governmental agencies having competences*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	and responsibilities for the safe transport of other dangerous goods."
S10	**Suggestion:** RPAZ should consider strengthening its regulatory activities to control the transport of radioactive material and sources within the country and in transit.

11.4.2. SUMMARY

Authorisations are not issued for the transport of radioactive material within the country except when such material is in transit. Inspections are not carried out for conveyors of radioactive material within the country and in transit.

There is a guidance document that refers to regulations which are based on the IAEA Regulations for the Safe Transport of Radioactive Material. In view of the limited number of itinerant practices in the country, it may be effective to update the guidance document so that it can be used to license transport of radioactive sources.

12. POLICY ISSUES

12.1. USE OF WHOLE BODY SCANNERS IN THE DIAMOND INDUSTRY

Background

The diamond industry in Zimbabwe uses whole body scanners as part of its security screening protocol. Miners are scanned each time they exit the mining area to ensure there is no unauthorized movement of diamonds out of the mine. This is done as part of the country's fulfilment of the requirements including the Kimberly Process Certification Scheme that requires appropriate accounting and control of the diamonds. Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (GSR Part 3), Requirement 10 on justification of practices states that, *"Human imaging using radiation for theft detection purposes shall be deemed to be not justified"* (paragraph 3.19).

There are about eight diamond mines in Zimbabwe, some of which use whole body scanning for security screening. However, the Kimberly Process Certification Scheme does not specify systems that should be used for security screening, but simply requires that there be a system in place to prevent pilferage.

Discussion Points

- If there are alternative systems other than whole body scanning for preventing pilferage, then it should be used. If not then whole body scanning for security screening should be justified and captured in a policy.
- As a means of reducing exposure doses to the mine workers, random scanning could be used instead of scanning every worker.
- To avoid possible future litigation, RPAZ should carry out research and collect scientific based evidence, showing a trend that may lead to some malignancy. This may be used as support as RPAZ carries out its mandate to protect workers.
- An example from Namibia is that:-

a) The Government of Namibia has justified the screening of workers through legislation;
b) As a means of optimisation of protection, a dose limit of 1 milliserviet per year was imposed for the mine workers;

- Zimbabwe should consider study tours to other countries that have achieved Kimberly process certification and learn the types of security systems used for screening workers.

12.2. INVOLVEMENT OF INTERESTED PARTIES IN REGULATORY DECISIONS

Background

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3 Requirement 3 on Responsibilities of the regulatory body states that, "*The regulatory body shall establish a regulatory system for protection and safety that includes provision of information to, and consultation with, parties affected by its decisions and, as appropriate, the public and other interested parties"* (paragraph 2.30f).

This requirement directs the regulator to involve the parties affected by its decisions including the public and interested parties and to provide them with sufficient information.

Discussion Points

- It is evident that RPAZ is far ahead on this policy issue as a lot has already been done regarding the issue of involving interested parties in regulatory decisions.

- There is need for a policy and structure on how to carry out consultation and communication with stakeholders. There should be proper and careful selection of the communication method, the language to be used and all these issues should come out in the policy which is to be reviewed from time to time.
- It is important to be able to define the audience and to make the public understand what RPAZ does as a regulator.
- There must be a feedback mechanism, and a means of informing the public that their views have been evaluated.
- A best practice from Pakistan is that they start teaching children at school on issues of radiation, that way it removes the misconceptions attached to radiation issues.
- When a licence is given, RPAZ may need to speak to the locals who stay close to the facility that has been licensed.
- It is important to document regulatory decisions and to make long term investments in communication. Further the regulator should be able to communicate not only the positive side of radiation technologies, but also inform stakeholders when things go wrong.
- RPAZ should be careful not to appear as if it is promoting use of radiation technologies.

APPENDIX I LIST OF PARTICIPANTS

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LIAISON OFFICER			
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APPENDIX II MISSION PROGRAMME

IRRS MISSION PROGRAMME	
Sunday, 9 November 2014	
Initial IRRS Review Team Meeting	
13:30 – 17:30	Opening remarks by the IRRS Team Leader (Ms Patricia Holahan) Introduction by IAEA Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (TL, IAEA) First impression from experts arising from the Advanced Reference Material (ARM) (All Experts) Administrative arrangements (RPAZ IRRS Liaison Officer, IAEA): Detailed Mission Programme
Monday, 10 November 2014	
IRRS Entrance Meeting	
09:00 – 09:30 09:30 – 09:45 09:45 – 10:00 10:00 – 10:30	Arrival, registration Welcome Remarks by the Deputy Chief Secretary, Mr J. H. Mupamhanga The IRRS Programme Outline - IRRS Coordinator, Mr Ahmad Al Khatibeh Expectations for the IRRS Mission and introduction of the team - IRRS Team Leader, Ms Patricia Holahan
10:30 – 11:15 11:15 – 11:30	Regulatory Overview, SARIS results: RPAZ Chief Executive Officer, Mr R. M. Severa Discussion
12:00 – 13:30	Lunch
13:30 – 17:00	Interviews and Discussions with Counterparts (parallel discussions)
17:00 - 18:00	Daily IRRS review team meeting
Tuesday, 11 November 2014	
Daily Discussions / Interviews	
09:00 – 17:00	Interviews and discussions with counterparts (parallel discussions)
09:00 – 12:00	Interviews and discussions with counterparts (parallel discussions)
12:00 – 13:30	Lunch
TBD	Interview with the Chairperson of the Board (TL, TC, Reviewer Modules 1,2 and 3)
17:00 – 18:00	Daily IRRS review team meeting
Wednesday, 12 November 2014	
Daily Discussions / Interviews	
09:00 – 17:00	Follow-up interviews and discussions with counterparts for all modules
08:30 – 13:30	Visit to medical facility
12:00 – 13:30	Lunch
13:30 – 17:00	Report preparation
17:30 – 18:30	Daily IRRS review team meeting
Thursday, 13 November 2014	
Daily Discussions / Interviews	
08:30 – 13:30	Visit to Industrial facility
09:00 – 17:00	Follow-up interviews and discussions with counterparts (parallel discussions)
13:30 – 15:30	Policy issue discussion
15:30 – 17:00	Report Preparation
17:00 – 18:00	Daily IRRS review team meeting: recommendation, suggestions and good practices

IRRS MISSION PROGRAMME	
Friday, 14 November 2014	
09:00 – 17:00	Report preparation: the IRRS review team
17:00 – 19:00	Cross reading
Saturday, 15 November 2014	
Daily Discussions/ Interviews (if needed)	
09:00 – 10:30	Finalizing draft to be sent to RPAZ by mid-day.
Sunday, 16 November 2014	
Daily Discussions	
09:00 –	RPAZ review the draft
Monday, 17 November 2014	
Daily Discussions	
08:00 – 11:00	RPAZ submit comments
11:00 – 15:00	Report finalization by the team and handover the report to RPAZ
Tuesday, 18 November 2014	
09:00 – 11:00	Opening remarks by IRRS Coordinator, Mr Ahmad Al Khatibeh
	Main findings of the IRRS mission by IRRS Team Leader, Ms Patricia Holahan
	Closing remarks and response to mission findings by Deputy Chief Secretary, Mr J. H. Mupamhanga

APPENDIX III SITE VISITS

Facilities visited:

1. Parirenyatwa Hospital in Harare (medical)
2. Delta Beverages in Harare (industrial)

APPENDIX IV LIST OF COUNTERPARTS

IRRS EXPERTS	COUNTERPART
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT, GLOBAL SAFETY REGIME	
Patricia Holahan Ibrahim Shadad	Vongai Mavurayi Justice Chipuru Brenda Ndinde
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	
Patricia Holahan Ibrahim Shadad	Justice Chipuru Amos Muzongomerwa
MANAGEMENT SYSTEM	
Anna Franzén	Justice Chipuru
AUTHORIZATION	
Shamsideen Elegba Axel Tibinyane	Sindiso Ncube Natsai Mutanga
REVIEW AND ASSESSMENT	
Shamsideen Elegba Axel Tibinyane	Sindiso Ncube Amos Muzongomerwa
INSPECTION	
Shamsideen Elegba Axel Tibinyane	Innocent Mayida Yeukai Mupfurutsa
ENFORCEMENT	
Shamsideen Elegba Axel Tibinyane	Innocent Mayida Primerose Ruhukwa

IRRS EXPERTS	COUNTERPART
REGULATIONS AND GUIDES	
Shamsideen Elegba Axel Tibinyane	Amos Muzongomerwa Brenda Ndinde
EMERGENCY PREPAREDESS AND RESPONSE	
Peter Zombori	Itai Chishanga Nyengerai Manjeru
ADDITIONAL AREAS - MEDICAL EXPOSURE	
Michel Sonck	Yeukai Mupfurutsa Innocent Mayida
ADDITIONAL AREAS - OCCUPATIONAL EXPOSURE	
Michel Sonck	Ngonidzashe Katsidzira Petronella Sithole Primerose Ruhukwa Amos Muzongomerwa

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 a national policy and strategy for safety to ensure that the Safety Fundamentals are explicitly adopted in a high level document.
		R2	The government should ensure that the proposed new law addresses the following issues in accordance with GSR Part 1: • Assigning prime responsibility for safety to the authorised party; • Ensure that donations, bequests, grants or loans do not create a conflict of interest; • Explicitly mention regulating the licensees' emergency preparedness and response obligations and capabilities among the functions of the Radiation Protection Authority of Zimbabwe; • Use of a graded approach in all regulatory activities; • Involvement of interested parties and for their input to decision making; • A provision for use of advisory bodies or support organizations in the conduct of the regulatory activities; • A provision for management of disused and orphan sources and radioactive waste; • The following items, already identified by the Radiation Protection Authority of Zimbabwe, should be included: o Regulatory control for ionising radiation; o System for the administration of safeguards, coordination of nuclear security, control of import/export of radioactive sources and equipment; o Regulatory control for transport of radioactive materials.
		S1	The government should consider strengthening coordination between the national authorities having responsibilities for radiation safety.
		R3	The government should designate a responsible organisation and create

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			a system to ensure that protective actions to reduce risks from unregulated sources and past contamination can be carried out.
		R4	The government should establish a national policy and strategy to include financial provisions for the decommissioning of facilities, the safe management and disposal of radioactive waste.
		R5	The government should provide for building and maintaining the available national arrangements for education and training to address the competence needs of all parties in relation to safety of facilities and activities, based on proper analysis.
2.	**GLOBAL NUCLEAR SAFETY REGIME**	R6	The government should ratify the international instruments related to nuclear safety and radiological protection and should demonstrate that respective international obligations are fulfilled by participation in its relevant international arrangements.
		GP1	Being a signatory to the MCA, where 15 nations share information amongst each other through establishment of the voluntary Southern African Development Community Nuclear Regulators Network.
		S2	RPAZ should consider establishing a formal process for identifying and sharing lessons learned from operating experience and regulatory experience.
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	S3	RPAZ should consider providing for a further operational separation between technical services and the regulatory function to minimize the potential for conflicts of interests.
		GP2	The change to report directly to the Office of the President and Cabinet rather than the Ministry of Health and Child Welfare gives RPAZ effective independence.
		R7	RPAZ should develop a formal program and competence requirements for training of regulatory staff with essential knowledge and skills.
		R8	RPAZ should develop a formal mechanism to communicate with authorised parties on all safety related issues.
		R9	RPAZ should ensure that decision making is applied and documented to ensure that regulatory control is consistent throughout the Authority.
		GP3	RPAZ has a Corporate Communications Officer whose primary responsibility is communicating with all interested parties.
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	S4	RPAZ should consider continuing to establish the management system in a consistent, coherent manner.

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R10	RPAZ' senior management should promote an awareness of internal safety culture by ensuring that it is in their training programme and is appropriately reflected within its management system.
		R11	RPAZ should implement a graded approach in all activities and processes.
		R12	RPAZ should identify, analyse and implement relevant processes and procedures including process owners, education and training on the management system and communication to the staff.
5.	**AUTHORIZATION**	S5	RPAZ should consider developing guidance on the facilities and activities to be authorized by notification or exempted from its regulatory control.
		R13	RPAZ should implement a multi-staged authorisation system for facilities and activities as appropriate.
		R14	RPAZ should license the interim waste storage facility to a unit within its organisation that is not tasked with authorisation or inspection until such time that custody can be transferred to a proper utility outside RPAZ.
6.	**REVIEW AND ASSESSMENT**		
7.	**INSPECTION**		
8.	**ENFORCEMENT**	S6	RPAZ should consider developing written procedures and guidelines for enforcement and provide training for its use in collaboration with relevant government agencies.
9.	**REGULATION AND GUIDES**	R15	RPAZ should develop guides for all regulated activities.
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R16	RPAZ should develop regulatory and guidance documents for the licensees to perform threat assessment on which their EPR arrangements will be based.
		S7	RPAZ should consider extending its threat assessment beyond the threat categorization of sources registered in RAIS, to cover all possible radiation emergency scenarios.
		R17	RPAZ should develop, in cooperation with the emergency response coordinating authority, an incident command and control system.

AREA		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R18	The government should establish a permanent contact point for notification of a radiation emergency, both for domestic emergency notification and also to function as a National Warning Point.
		R19	RPAZ should develop generic and operational intervention and action levels, in accordance with the international standards.
		R20	RPAZ should initiate the process, in cooperation with other government agencies, needed for officially defining the term "emergency workers" and developing the regulatory provisions for their protection.
		R21	The government should adopt, based on proposals and regulatory requirements developed by RPAZ, the optimized intervention levels and action levels for agricultural countermeasures, countermeasures against ingestion and longer term protective actions.
		R22	RPAZ should develop the necessary requirements regulating the recovery operation and facilitating the smooth transition to normal social and economic conditions.
		S8	RPAZ should consider finalizing the draft national radiation emergency plan and forward it to the relevant national authorities for review and approval.
		R23	RPAZ should develop guidance for the applicants/licensees on the preparation of facility emergency plans. This should also serve as acceptance criteria for the evaluation of the emergency plans during the authorization process.
		R24	RPAZ should develop its own radiation emergency response plan.
11.	**ADDITIONAL AREAS**	S9	The government should consider having representatives from RPAZ on the Ethics Committee on screening programmes and on the Ethics Committee on biomedical research.
		R25	RPAZ should revise the current legal and regulatory framework to bring it in line with the requirements of GSR Part 3.
		S10	RPAZ should consider strengthening its regulatory activities to control the transport of radioactive material and sources within the country and in transit.
12.	**POLICY ISSUES**		

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

Advance Reference Material provided by Zimbabwe:

1. Accreditation Requirements
2. Application form codes
3. Application Form Guide – Gauging and Detection and Other
4. Application Form Guide – X-Ray Equipment and Facilities
5. Application form guides
6. Application forms
7. Application receiving note
8. Application receiving and issuing note
9. Authorization Procedures Manual
10. Authorization process
11. Authorization Policy
12. Department-Performance Agreement_Licencing_2015
13. Licence certificate guide
14. Licence to operate template
15. Licence to use ionizing radiation apparatus template
16. Licencing conditions
17. MOU between RPAZ and ZIMRA
18. Notification overview
19. Requirements for authorization
20. Review and Assessment forms
21. Transport Guide
22. 2013 Compliance Inspections Conducted
23. 2013 Inspected Facilities breakdown by Sector
24. 2013 Occupational Exposure Report
25. 2014 Compliance Inspection Status Report
26. 2014 Compliance Inspections List
27. Certificate of Appointment for Radiation Protection Officer
28. Dental Checklist
29. Dental Quality Control Tests
30. Enforcement Policy
31. Inspection Checklist for Linear Accelerators
32. Inspection Follow-up Report Template
33. Inspection Schedule 2014
34. Inspection Status Report Template
35. Inspection Checklist for Diagnostic X-Rays
36. Inspection Checklist for Industrial Practices
37. Inspection Checklist for Nuclear medicine
38. Inspection Checklist for Radiotherapy
39. Inspections Policy
40. Quality Control Test Dental
41. Quality Control tests for Diagnostic facilities

42. Sample Industrial Inspection Report
43. Sample Medical Inspection Report
44. 2013 Audited Financial Statements
45. Debt Recovery Draft Policy and Procedures
46. Depreciation Policy
47. Draft RPAZ-EMA MOU
48. Draft RPAZ-MOHCC MOU
49. Five-Year Strategic Plan (2012-2019)
50. Informal Understanding - National Social Security Authority
51. Nuclear non-proliferation_status of treaties and conventions
52. Radiation Protection Board Committees
53. Radiation Protection Board Directors Profiles
54. RPAZ Agency Integrated Performance Agreement
55. RPAZ Clients Charter
56. RPAZ Code of Ethics
57. RPAZ Internal Audit Charter
58. RPAZ Organization Chart 2012 – 2016
59. RPAZ – ZIMRA MOU
60. Appointment of Radiation Protection Officer Certificate
61. Human Resources Status
62. Job Description for Internal Auditor
63. Job Description for Licencing Manager
64. Job Description for Quality Assurance Manager
65. Job Description for Radiation Scientist – Dosimetry
66. Job Description for Corporate Communications Officer
67. Job Description for Finance Manager
68. Job Description for Inspections and Dosimetry Manager
69. Job Description for Radiation Scientist – Inspections
70. Job Description for Radiation Scientist – Licencing
71. RPAZ Supportive Structure
72. Civil Protection Act
73. Constitution of Zimbabwe
74. Customs and Excise Act
75. Environmental Management Act
76. Factories and Works Act
77. Labour Act
78. Political Support for Import and Export Guidance
79. Presentation of Memorandum of Principles for Revision of Act
80. Procurement Act
81. Public Finance Management Act
82. Public Health Act
83. Radiation Protection (Safety and Security of Sources) (Amendment), 2012 (No.2) – SI 134 of 2012
84. Radiation Protection (Medical Practices) Regulations SI 91 of 2014
85. Radiation Protection (Naturally Occurring Radioactive Materials) Regulations SI 99 of 2013
86. Radiation Protection (Safety and Security of Sources) Regulations (SI 62 of 2011)
87. Radiation Protection Act (Chapter 15_15)

88. Radiation Protection (Safety and Security of Sources) (Amendment) Regulations , 2011 -SI 106 of 2011
89. Request for Support from IAEA Legal Affairs
90. Request Ratification of Early Notification
91. Revenue Authority Act
92. Revision of the Radiation Protection Act
93. RPAZ Development and Review of Regulations and Guides Policy
94. RPAZ Integrated Regulatory Management System Manual_updated
95. 2014 RPAZ Analysis and Action Plan
96. 2014 RPAZ SARIS Complete
97. SARIS Report _ Summary

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1. INTERNATIONAL ATOMIC ENERGY AGENCY - No. SF-1 - Fundamental Safety Principles
2. INTERNATIONAL ATOMIC ENERGY AGENCY - Governmental, Legal and Regulatory Framework for Safety General Safety Requirement Part 1 (Vienna2010)
3. INTERNATIONAL ATOMIC ENERGY AGENCY - Preparedness and Response for a Nuclear and Radiological Emergency Safety Requirement Series No. GS-R-2 IAEA Vienna (2002)
4. INTERNATIONAL ATOMIC ENERGY AGENCY The Management System for Facilities and Activities. Safety Requirement Series No. GS-R-3 IAEA, Vienna (2006)
5. INTERNATIONAL ATOMIC ENERGY AGENCY – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3, 2014 edition
6. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety assessment for facilities and activities, General Safety Requirements Part 4, No. GSR Part 4, IAEA, Vienna (2009)
7. INTERNATIONAL ATOMIC ENERGY AGENCY – Predisposal Management of Radioactive Waste General Safety Requirement Part 5, No. GSR Part 5, IAEA, Vienna (2009)
8. INTERNATIONAL ATOMIC ENERGY AGENCY – Decommissioning of Facilities Using Radioactive Material Safety, Safety Requirement Series No. WS-R-5, IAEA, Vienna (2006)
9. INTERNATIONAL ATOMIC ENERGY AGENCY - Organization and Staffing of the Regulatory Body for Nuclear Facilities, Safety Guide Series No. GS-G-1.1, IAEA, Vienna (2002)
10. INTERNATIONAL ATOMIC ENERGY AGENCY - Review and Assessment of Nuclear Facilities by the Regulatory Body, Safety Guide Series No. GS-G-1.2, IAEA, Vienna (2002)
11. INTERNATIONAL ATOMIC ENERGY AGENCY - Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Safety Guide Series No. GS-G-1.3, IAEA, Vienna (2002)
12. INTERNATIONAL ATOMIC ENERGY AGENCY - Documentation for Use in Regulatory Nuclear Facilities, Safety Guide Series No. GS-G-1.4, IAEA, Vienna (2002)
13. INTERNATIONAL ATOMIC ENERGY AGENCY- - Arrangements for Preparedness for a Nuclear or Radiological Emergency, Safety Guide Series No. GS-G-2.1, IAEA, Vienna (2007)
14. INTERNATIONAL ATOMIC ENERGY AGENCY – Criteria for use in Preparedness and Response for a Nuclear or Radiological Emergency, General Safety Guide Series No. GSG-2, IAEA, Vienna (2011)
15. INTERNATIONAL ATOMIC ENERGY AGENCY– Assessment of Occupational Exposure Due to Intake of Radionuclides Safety Guide Series No. RS-G-1.2, IAEA, Vienna (1999)
16. INTERNATIONAL ATOMIC ENERGY AGENCY - Assessment of Occupational Exposure Due to External Sources of Radiation Safety Guide Series No. RS-G-1.3, IAEA, Vienna (1999)
17. INTERNATIONAL ATOMIC ENERGY AGENCY - Building Competence in Radiation Protection and the Safe Use of Radiation Sources, Safety Guide Series No. RS-G-1.4, IAEA, Vienna (2001)
18. INTERNATIONAL ATOMIC ENERGY AGENCY – Classification of Radioactive Waste, General Safety Guide No. GSG-1, IAEA, Vienna (2009)
19. INTERNATIONAL ATOMIC ENERGY AGENCY – Regulatory Control of Radioactive Discharge to the Environment, Safety Guide Series No. WS-G-2.3, IAEA, Vienna (2000)
20. INTERNATIONAL ATOMIC ENERGY AGENCY – Safety Assessment for the Decommissioning of Facilities Using Radioactive Material, Safety Guide Series No. WS-G.5.2, IAEA, Vienna (2009)
21. INTERNATIONAL ATOMIC ENERGY AGENCY - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).
22. INTERNATIONAL ATOMIC ENERGY AGENCY - Generic Assessment Procedures for Determining Protective Actions during a Reactor Accident, IAEA-TECDOC-955, IAEA, Vienna (1997)

APPENDIX VIII ORGANIZATIONAL CHART

RPAZ Strategy Supportive Structure: 2012-2016