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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

MISSION

TO

REPUBLIC OF KENYA

Nairobi – Kenya
11– 20 July 2016

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

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

IRRS TEAM AND COUNTERPARTS

Integrated Regulatory Review Service

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

Mission dates:	*11 to 20 July 2016*
Regulatory body visited:	*Radiation Protection Board*
Location:	*Nairobi, Kenya*
Regulated facilities and activities in the mission scope:	*Radiation Sources in Industrial and Medical Facilities,Transport, Emergency Preparedness and Response, Medical Exposure, Occupational Exposure, Public and Environmental Exposure*
Organized by:	*IAEA*

IRRS REVIEW TEAM

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IAEA-2016

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

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EXECUTIVE SUMMARY

At the request of the Government of the Republic of Kenya, an international team of senior radiation safety experts met with representatives of the Government and of the Radiation Protection Board (RPB) from 11 to 20 July 2016 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place at the RPB Headquarters in Nairobi. Meetings were organized with the Ministry of Health and with the National Commission for Sciences, Technology and Innovation (NACOSTI), of the Ministry of High Education. The purpose of the IRRS mission was to perform a peer review of Kenya's national regulatory framework for radiation safety.

The IRRS mission covered all civilian radiation source facilities and activities regulated in Kenya. The review compared the Kenyan regulatory framework for safety against IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS review team members and the Kenyan counterparts in the areas covered by the IRRS.

The IRRS team consisted of 9 senior regulatory experts from 8 IAEA Member States, 2 IAEA staff members, 1 IAEA administrative assistant. The IRRS 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 authorization, review and assessment, inspection and enforcement processes, development and content of regulations and guides; emergency preparedness and response; control of medical exposures, occupational radiation protection, control of radioactive discharges and materials for clearance, environmental monitoring, transport, and radioactive waste management.

The IRRS mission included one policy issue discussion on the role of technical services organizations (TSOs) in the regulatory process. The discussion revealed the need for RPB to clarify the roles and responsibilities of the TSOs and to strengthen the legal basis for their certification.

The mission included observations of regulatory activities and interviews and discussions with staff of RPB. Activities included visits to: Kenyatta National Hospital and the Kenya Bureau of Standards. The IRRS team members observed regulated activities and performance of inspection activities, including discussions with the licensee personnel and management.

In preparation for the IRRS mission, Kenya conducted a self-assessment and prepared a preliminary action plan to address weaknesses that were identified. The results of the self-assessment and supporting documentation were provided to the team as advance reference material for the mission. Throughout the mission, the IRRS review team was extended full cooperation in the regulatory, technical, and policy issues by all parties in a very open and transparent manner.

The IRRS team observed that the RPB counterparts were committed to provide the regulatory oversight of all activities with radiation sources. The invitation of the IRRS mission demonstrates the RPB's commitment to improve the national legal and regulatory framework for radiation safety.

The most significant challenges for the regulatory body are the lack of effective independence of RPB and the incompleteness of the regulatory framework for radiation safety.

The IRRS review team identified a good practice and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue enhancing the effectiveness of regulatory functions in line with IAEA safety standards. The IRRS team recognized that some of its findings confirmed the actions identified by RPB as a result of its self-assessment.

The good practice identified by the IRRS review team is the initiative taken by RPB to provide training on enforcement and prosecution for its inspectors.

The IRRS review team identified certain issues warranting attention or in need of improvement and believes that consideration of these would enhance the overall performance of the regulatory system:

- The Government should:
  - develop a policy and strategy for safety;
  - revise and complete the national legal framework to ensure consistency with IAEA safety standards;
  - ensure separation of RPB from entities having responsibilities or interests that could unduly influence its decision-making;
  - provide for building and maintaining the necessary competencies for all parties having responsibilities in relation to the safety of facilities and activities.

- RPB should:
  - ensure that it takes decisions in a manner which does not compromise its independence and put in place mechanisms to prevent conflicts of interest in all of its regulatory activities;
  - establish and implement an integrated management system consistent with the IAEA safety standards;
  - develop and implement policies and procedures to ensure that the regulatory control of facilities and activities is consistent and stable;
  - carry out a human resources needs analysis and develop and implement the resulting human resources plan and the associated staff training programme;
  - establish and publish regulations that systematically cover all types of practices using radiation sources, in particular transport of radioactive material and management of radioactive waste, emergency preparedness and response as well as the control of all categories of exposure (occupational, public and medical) in compliance with IAEA Safety Standards GSR Part 3;
  - ensure that all radiation sources, including disused sources and radioactive waste, are appropriately authorized;
  - develop and implement achievable authorization and inspection programmes in accordance with a graded approach;
  - ensure that safety measures and nuclear security measures are designed and implemented in an integrated manner.

The IRRS review team findings are summarized in Appendix V.

An IAEA press release was issued and a press conference was organized at the end of the IRRS Mission.

I. INTRODUCTION

At the request of the Government of the Republic of Kenya, an international team of senior safety experts met representatives of the Radiation Protection Board (RPB) from 11 to 20 July 2016 to conduct an Integrated Regulatory Review Service (IRRS) mission. The purpose of this peer review was to review the Kenyan regulatory framework for radiation safety. The review mission was formally requested by the Government of the Republic of Kenya in November 2014. A preparatory mission was conducted 2 to 3 February 2016 at RPB Headquarters in Nairobi to discuss the purpose, objectives and detailed preparations of the review in connection with regulated facilities and activities in Kenya and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS review team consisted of 9 senior regulatory experts from 8 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 safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; occupational radiation protection, control of medical exposure, public and environmental exposure control and transport of radioactive material.

In addition, a policy issue was discussed: the role of technical service organizations in the authorization process.

In preparation of the mission, RPB conducted a self-assessment and prepared a preliminary action plan. The results of RPB's self-assessment and supporting documentation were provided to the IRRS review team as advance reference material for the mission. During the mission the IRRS review team performed a systematic review of all topics within the agreed scope by reviewing the advance reference material, conducting interviews with management and staff from RPB and direct observation of working practices during conduct of a regulatory inspection. Meetings with representatives of the Ministry of High Education and the Ministry of Health were also organized.

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

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review Kenya's radiation safety regulatory framework and activities against the relevant IAEA safety standards to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The IRRS review scope included all facilities and activities regulated by RPB. 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 Kenya and other Member States from the knowledge gained and experiences shared between RPB and IRRS reviewers and through the evaluation of the effectiveness of the Kenya regulatory framework for nuclear safety and its good practices.

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

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

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

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

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

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

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

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

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

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

j) promoting the application of IAEA Safety Requirements; and

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

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of the Republic of Kenya, a preparatory meeting for the IRRS mission was conducted from 2 to 3 February 2016. The preparatory meeting was carried out by the appointed Team Leader Mr Javier Zarzuela, and the IAEA Team Coordinator Mr Hilaire Mansoux.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of RPB represented by Mr Arthur Koteng, Assistant Chief Radiation Protection Officier, some Board Members, other senior management and staff of RPB. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Waste Management Facilities;
- Radiation sources facilities and activities;
- Transport of radioactive materials;
- Control of medical exposure;
- Occupational radiation protection;
- Public and environmental exposure control;
- Selected policy issues

Mr Arthur Koteng made presentations on the national context, the current status of RPB 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 Kenya in July 2016.

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

RPB Liaison Officer for the IRRS mission was confirmed as Arthur Koteng.

RPB provided IAEA with the advance reference material (ARM) for the review at the end of May 2016. In preparation for the mission, the IAEA review team members reviewed the Kenya ARM and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

B) REFERENCES 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. The complete list of IAEA publications used as the references for this mission is provided in Appendix VIII.

C) CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday 10 July 2016 in Nairobi, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the bases for the review and the background, context and objectives of the IRRS mission programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS

Guidelines, the reviewers presented their initial impressions of the ARM and highlighted significant issues to be addressed during the mission.

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

The IRRS entrance meeting was held on Monday, 11 July 2016, with the participation of RPB's senior management and staff as well as several RPB Board members. Opening remarks were made by Mr Gatebe Gatika, Chairman of the Board, Mr Javier Zarzuela, IRRS Team Leader and Mr Hilaire Mansoux, IRRS Team Coordinator. Mr Arthur Koteng gave an overview of RPB activities.

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

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

The IRRS exit meeting was held on Wednesday, 20 July 2016. The opening remarks at the exit meeting were presented by Mr Gatebe Gatika, Chairman of the Board and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Javier Zarzuela. Closing remarks were made by Mr Peter Johnston, IAEA, Director, Division of Radiation, Transport and Waste Safety.

A joint IAEA and RPB press conference took place at the end of the mission.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1. NATIONAL POLICY AND STRATEGY FOR SAFETY

The policy guidelines for safety are provided in the legislation (Radiation Protection Act Cap. 243, rev. 2014, hereafter referred to as "the Act"). The Act provides for the regulation of practices and facilities using ionizing radiation to protect the public and radiation workers. However, the Act does not establish the fundamental safety objective to meet the requirements of IAEA Fundamental Safety Principles, and a documented policy and strategy does not exist. Essential elements including long-term commitment to safety and promotion of, leadership and management for safety, including safety culture, are not covered in the existing legislation.

Kenya does not have a stand-alone document that highlights the national policy and strategy for safety in the utilization of ionizing radiation for the protection of people and the environment against its harmful effects.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no documented national policy and strategy for safety in the utilization of ionizing radiation for the protection of people and the environment.	
(1)	**BASIS: GSR Part 1 Requirement 1 states that** *"The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals."*
R1	**Recommendation: The Government should establish a national policy and strategy for safety whose implementation should follow a graded approach.**

1.2. ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The legal basis for the national framework of safety is the Act. The government in implementing the Act, has established the Radiation Protection Board (RPB) as the regulatory body for radiation safety in Kenya under the Ministry of Health and has promulgated two regulations, Radiation Protection (Standards) Regulations, 1986 (LN54/1986) and Radiation Protection (Safety) Regulations, 2010 (LN160/2010). The Act and the two regulations constitute the legal and regulatory framework for safety. The absence of other regulations that are provided for in Section 18 of the Act makes the framework incomplete. Recommendation 28 in Section 9 addresses this issue.

The national framework for safety does not cover all aspects of GSR Part 1 Requirement 2, such as protection of the environment from radiation risk, allocation of responsibilities for safety, involvement of interested parties, provisions to appeal against any regulatory decision, criteria for release from regulatory control, preparedness and response to radiological emergencies, interface with nuclear security and the system for accounting and control for nuclear material. Provisions for the control of transport of radioactive materials are not included in the legal framework of safety.

The IRRS team noted that Kenya is drafting a new Nuclear and Radiation Safety Bill.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: A legal and regulatory framework exists that does not exhaustively cover all safety provisions of GSR Part 1.	
(1)	**BASIS: GSR Part 1 Requirement 2 states that** *"The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated."*
(2)	**BASIS: GSR Part 1 Requirement 2, 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*: *(1) The safety principles for protecting people — individually and collectively — society and the environment from radiation risks, both at present and in the future;* *(2) The types of facilities and activities that are included within the scope of the framework for safety;* *(3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach;* *(4) The rationale for the authorization of new facilities and activities, as well as the applicable decision making process;* *(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; in accordance with a graded approach;* *(7) The establishment of a regulatory body, as addressed in Requirements 3 and 4;* *(8) Provision for the review and assessment of facilities and activities, in accordance with a graded approach;* *(9) The authority and responsibility of the regulatory body for promulgating (or preparing for the enactment of) regulations and preparing guidance for their implementation;* *(10) Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach;* *(11) Provision for appeals against decisions of the regulatory body;* *(12) Provision for preparedness for, and response to, a nuclear or radiological emergency;* *(13) Provision for an interface with nuclear security;* *(14) Provision for an interface with the system of accounting for, and control of, nuclear*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	material; *(15) Provision for acquiring and maintaining the necessary competence nationally for ensuring safety;* *(16) Responsibilities and obligations in respect of financial provision for the management of radioactive waste and of spent fuel, and for decommissioning of facilities and termination of activities;* *(17) The criteria for release from regulatory control;* *(18) The specification of offences and the corresponding penalties;* *(19) Provision for controls on the import and export of nuclear material and radioactive."*
R2	**Recommendation: The Government should revise the legal and regulatory framework to include all the relevant safety provisions of GSR Part 1.**

1.3. ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The Act establishes RPB as the regulatory body, conferring powers to perform functions listed under Section 7 of the Act. RPB is administered by a Board of Directors appointed by the Minister of Health. The Board has four Committees. The Minister of Health appoints the Chief Radiation Protection Officer (CRPO), who also acts as the Secretary to the Board. The Public Service Commission employs RPB staff. The National Treasury through the Ministry of Health provides for RPB funding. According to the Act, RPB's Radiation Protection Officers (RPOs) have to be furnished with certificates of appointment signed by the Minister of Health to enable them to carry out their duties as inspectors. Section 18 of the Act makes provisions for the Minister of Health to make regulations in consultation with RPB.

The Government of Kenya has established RPB as the regulatory body for radiation safety under the Ministry of Health who, among others, handles human resource issues, provides for funding and can review RPB's budget. RPB is not effectively independent as it reports to the Minister of Health, who has conflicting responsibilities, since medical facilities are within the regulatory control of RPB. Additionally, some members of the Board and some members of the four Committees are at the same time authorized parties Recommendation 10 Section 3 addresses this issue.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Act establishes the regulatory body, RPB, under the Ministry of Health which is a user and promoter of radiation technologies.	
(1)	**BASIS: GSR Part 1 Requirement 4 states that** "The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making."
(2)	**BASIS: GSR Part 1 Requirement 17, para. 4.9 states that** *"To maintain its effective independence, the regulatory body shall ensure that, in its liaison with interested parties, it has a clear separation from organizations or bodies that have been assigned*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	responsibilities for facilities or activities or for their promotion."
R3	**Recommendation: The Government should ensure separation of RPB from entities having responsibilities or interests that could unduly influence its decision-making.**

1.4. RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The existing legal and regulatory framework for radiation safety in Kenya does not expressly assign the prime responsibility for safety to authorized parties and does not clearly express that the compliance with regulations, or licence and other conditions, will not relieve the authorized party of the prime responsibility for safety. Responsibility for safety does not cover all stages in the lifetime of a facility/activity, for example decommissioning and transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The prime responsibility for safety is not assigned to the authorized parties and the responsibility for safety does not cover all stages in the lifetime of the facility/activity, as decommissioning and transport are not included.	
(1)	**BASIS: GSR Part 1 Requirement 5 states that** *"The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance."*
(2)	**BASIS: GSR Part 1 Requirement 6 para 2.15 states that** *"The prime responsibility for safety shall extend to all stages in the lifetime of facilities and the duration of activities, until their release from regulatory control; i.e. to site evaluation, design, construction, commissioning, operation, shutdown and decommissioning.*"
R4	**Recommendation: The Government should revise the legislation and assign the prime responsibility for safety to the authorized parties and ensure that the responsibility covers all stages in the lifetime of the activity/facility.**

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

There are no legal provisions regarding the cooperation of RPB with other authorities having responsibilities for safety.

RPB collaborates with the National Environment Management Authority (NEMA), National Commission for Science, Technology and Innovation (NACOSTI), Institute of Nuclear Science & Technology of Nairobi University and National Disaster Management Unit. The cooperation of RPB with other organizations is not formalized (eg. MoU or signed agreements between the Boards). This is also the case for the modal regulatory authorities for the transport of class 7 dangerous goods (radioactive materials).

The only MoU in place relevant to safety is with the Institute of Primate Research that was negotiated in line with the setting up of radioactive waste management facility. Three MoUs in the area of nuclear

security have been established with the Kenya Ports Authority, Kenya Maritime Safety and the Kenya Revenue Authority.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are some arrangements in place for cooperation between the RPB and different authorities having responsibilities for safety, but these arrangements are not formalized.	
(1)	**BASIS: GSR Part 1 Requirement 7 states that** *"The government shall ensure that there is appropriate coordination of and liaison between the various authorities."*
R5	**Recommendation: The Government should make provision for effective coordination and liaison between RPB and other authorities having responsibilities for safety.**

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

There are no formal provisions to deal with existing or unregulated radiation risks. In practice RPB retrieves orphan sources and sources involved in illicit trafficking and stores these sources in a bunker within its premises.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The provisions in place do not 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.	
(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."*
R6	**Recommendation: The Government should establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources and contamination from past activities or events, and develop a legal safety framework for existing exposure situations.**

1.7. PROVISIONS FOR THE MANAGEMENT OF RADIOACTIVE WASTE

The legal framework does not provide for the safe management of radioactive waste. The Minister of Health is empowered to issue regulations on waste management. Radioactive waste management regulations are still in draft form. The IRRS team noted that the Radioactive Waste Management Policy and Strategy for the Republic of Kenya, dated September 2013, is still in draft form.

The construction of the Central Radioactive Waste Processing Facility (CRWPF) is currently underway.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The legal and regulatory framework for safety does not have provisions for: the safe decommissioning of facilities, the responsibility for maintaining institutional control, financial provisions for decommissioning of facilities and management of radioactive waste including disused radioactive sources. There is no policy and strategy on the management of radioactive waste and disused sources.	
(1)	**BASIS: GSR Part 1 Requirement 10 states that** *"The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities."*
(2)	**BASIS: GSR Part 1 Requirement 10, para. 2.28 states that** *"Decommissioning o f 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."*
(3)	**BASIS: GSR Part 1 Requirement 10, para. 2.31 states that** *"If institutional control after the closure of a disposal facility for radioactive waste is deemed to be necessary, the responsibility for maintaining institutional control shall be clearly assigned."*
(4)	**BASIS: GSR Part 1 Requirement 10, para. 2.33 states that** *"Appropriate financial provision shall be made for decommissioning of facilities; management of radioactive waste, including its storage and disposal; management of disused radioactive sources."*
R7	**Recommendation: The Government should develop and implement a national policy and strategy on the management of radioactive waste and disused radioactive sources, including regulatory provisions.**

1.8. COMPETENCE FOR SAFETY

Kenya does not have a national education and training policy that sets guidelines in the development and maintenance of competences for radiation safety. However, the University of Nairobi conducts a postgraduate course in Applied Radiation Protection that runs for 3 months, and it is under consideration to upgrade the course to a postgraduate diploma that will run for a period of about 6 months, a Master of Science Degree in Nuclear Science and Technology, a Master of Science in Radiation Protection, a Master of Science in Radiology. In addition, BSc and diplomas in Radiography, Medical Imaging science, Radiation Therapy, and Non-Destructive Testing are conducted in the country. On the other hand, there are no education or training programs on medical physics available in the country, so in practice practitioners in the field are trained abroad. For specific needs, Kenya relies on the training provided by IAEA.

The regulatory framework does not define the necessary competence levels for individuals involved in different practices and activities in the country. The Licensing and Technical Advisory Committee of the Radiation Protection Board considers on a case-by-case-basis the competences of radiation workers who hold qualifications obtained abroad and also stipulates the necessary competences to be acquired by specific users on a case-by-case basis.

In Kenya, all civil servants are submitted to a scheme of progress in their careers that requires them to successfully pass training courses. At RPB, this scheme implies that its staff have to pass prescribed training courses when they join RPB to be qualified as RPO in order to be entitled to perform their assigned duties as inspectors, etc. As they advance through their careers, all RPOs have to follow the training courses as mandated by RPB.

For specific needs, Kenya relies on the training provided by IAEA, US-DoE, EU CBRN CoE, among other developing partners.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The legal and regulatory framework for safety does not provide for the building and maintaining of competencies for all parties and does not have provisions for defining the levels of competencies for safety including regular verification of technical competencies.	
(1)	**BASIS: GSR Part 1 Requirement 11, para. 2.34 states that** "*As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available.*"
(2)	**BASIS: GSR Part 1 Requirement 11, para. 2.35 states that** *"The building of competence shall be required for all parties with responsibilities for the safety of facilities and activities, including authorized parties, the regulatory body and organizations providing services or expert advice on matters relating to safety."*
(3)	**BASIS: GSR Part 1 Requirement 11, para. 2.36 (a) states that** *"The Government shall stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities."*
(4)	**BASIS: GSR Part 1 Requirement 11, para. 2.36 (b) states that** *"The Government shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety."*
(5)	**BASIS: GSR Part 1 Requirement 11, para. 2.36 (c) states that** *"The Government shall make provision for adequate arrangements for increasing, maintaining and regularly verifying the technical competence of persons working for authorized parties."*
(6)	**BASIS: GSR Part 1 Requirement 11, para. 2.37 states that** *"In cases where the training programmes available in the State are insufficient, arrangements for training shall be made with other States or with international organizations."*
R8	**Recommendation: The Government should revise the legal and regulatory framework for radiation safety with regard to building and maintaining the necessary competencies for all parties having responsibilities in relation to the safety of facilities and activities.**

1.9. PROVISION OF TECHNICAL SERVICES

There are a number of organizations, called Technical Services Organizations (TSO), who provide services to licencees. Only RPB certified and registered TSOs may carry out radiation protection services. TSOs have been certified for individual external dosimetry (four) and for environmental monitoring, but none for internal dosimetry. Fifteen TSOs have also been certified for carrying out radiation safety assessments and for performing QA/QC test measurements. Calibration services are provided by the Kenya Bureau of Standards which operates an SSDL (see also Section 11).

While RPB registers and certifies TSOs, it has not been provided with the necessary legal basis to do so.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Technical services to provide individual external dosimetry for workers are available in Kenya. Some facilities and activities require internal dosimetry services to be arranged. There is no appropriate legal or regulatory basis for the oversight of TSOs.	
(1)	**BASIS: GRS Part 1 Requirement 13, states that** *"The government shall make provision, where necessary, for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment."*
S1	**Suggestion: The Government should consider establishing internal dosimetry services.**
(1)	**BASIS: Requirement 13, Para 241 states that** "*The Regulatory body shall authorize technical services that may have significance for safety, as appropriate."*
S2	**Suggestion: RPB should consider revising and strengthening the legal basis for the certification of TSOs.**

At the request of RPB, a policy issue discussion took place on the role of Technical Service Organizations (TSOs) in the authorization process. The session was attended by the whole IRRS team, the staff of the RPB secretariat, as well as the Chief Economist of the Ministry of Health, representing the Board.

RPB explained how it introduced in 2010 the use of TSOs to provide technical service and advice to licensees mainly but also to RPB on matters of radiation safety. There are currently 12 TSO in Kenya offering external dosimetry, radiation safety assessment of facilities, environmental and food stuff monitoring and calibration of equipment. The TSO have to be certified annually by RPB. There are no clear criteria for the certification process, but RPB inspects the TSO. TSO have to pay registration fee, annual certification fees and verification fee each time they submit a report to RPB.

The need of these TSOs arose from the increasing number of radiation facilities and the low number of technical staff within RPB and also from the fact that RPB wanted to stop its activities of service provisions in line with IAEA requirenments/standards (in individual dosimetry for example). A source of confusion between the role of the TSO and the role of the RPB is the inspections that both entities perform prior to the authorization of a facility. The IRRS team advised that the visit made by the TSO, which is not mandatory, should not be called an inspection but rather an audit or a technical visit. Only the visit of RPB, which is mandatory prior to authorization, should be called inspection. Another source of confusion is the fact that TSOs can also provide services to RPB.

IAEA clarified that the term TSO is generally reserved for Technical Support Organizations, that provide expertise and advice exclusively to the regulatory body, for instance for the review and assessment of complex or new types of applications. There are currently no such technical support organizations in Kenya.

IRRS team members shared their national experience on the existence of technical support organizations to the regulatory bodies and technical service providers to users. Some clarification questions were asked by the Kenyan counterparts.

The first outcome of the discussions is that these services providers are never called technical service organization, but rather radiation protection advisers (RPA), radiation protection experts (RPE), radiation protection specialist (RPS), or simply technical service providers.

In most countries, these technical service providers are accredited by thenational accreditation organization, and are approved (or licensed) by the regulatory body, who can inspect them and take enforcement actions.

Another common feature is that these technical service providers do not have to pay licensing fees to the regulatory body, they only need to pay for their accreditation to the relevant organization. They charge their services to the licensees according to the market prices.

In general, the role of these service providers should be clearly defined in the regulations, including the services they can offer to licensees.

Team members made it very clear that the prime responsibility for safety rests with the licensee, even if they use the services of technical service providers. The documents produced by the service providers (radiation safety assessment for instance, dosimetry reports) should be delivered to the regulatory body by the licensee, with whom the regulatory body has any official communication.

By the end of the meeting RPB agreed that the term used (TSO) and the conditions under which TSOs provide services need clarification/should be revised to give the correct picture.

1.10. SUMMARY

The Government of Kenya has established a legal and regulatory framework for safety which should be revised and completed in order to become consistent with international safety standards.

The Act establishes RPB as the regulatory body in the country and defines its main functions and responsibilities. The Government should make provisions for ensuring its effective independence.

National policies and strategies for safety and for the management of radioactive waste and disused radioactive sources have to be established and implemented.

2. THE GLOBAL SAFETY REGIME

2.1. INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

Kenya is party to the following international conventions and instruments;

- Treaty on the Non-Proliferation of Nuclear Weapons,
- Comprehensive Test Ban Treaty,
- Convention on Physical Protection of Nuclear Material,
- African Nuclear Weapon Free Zone,
- Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Waste within Africa,
- Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal,
- Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matters (London Dumping Convention),
- International Convention for the Suppression of Acts of Nuclear Terrorism and
- United Nations Security Council Resolution 1540.

However, the country is not party to the following conventions that are very essential to radiation safety;

- Convention on Nuclear Safety (the CNS),
- Convention on Early Notification of a Nuclear Accident,
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency,
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

Kenya has not expressed support to the Code of Conduct for Safety and Security of Radioactive Sources and its Supplementary Guidance on the Import and Export of Radioactive Sources. The IRRS team was informed that RPB has initiated the process for expression of political commitment to the CoC.

Kenya is represented in several IAEA Safety Standards Committees, (NUSSC, RASSC, TRANSSC and WASSC).

At the regional level the country is an active member of the Forum of Nuclear Regulatory Bodies in Africa (FNRBA).

RPB has signed an MoU with the Tanzania Atomic Energy Commission dealing with the trans-border movement of radioactive material.

RPB has negotiated an MoU with the Atomic Energy Council of Uganda for technical cooperation. The MoU awaits signature.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Government is state party to a number of international conventions and treaties. However, it is not party to the Convention on Nuclear Safety, the Convention on Early Notification of a Nuclear Accident, the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and has not expressed political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources and its Supplementary Guidance on the Import and Export of Radioactive Sources.	
(1)	**BASIS: GSR Part 1, Requirement 14, states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally."*
S3	**Suggestion: The Government should consider becoming party to the Convention on Nuclear Safety, the Convention on Early Notification of a Nuclear Accident, the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and expressing political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources and its Supplementary Guidance on the Import and Export of Radioactive Sources.**

2.2. SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

Kenya actively participates in a number of international activities aimed at fostering exchange of regulatory experience.

Kenya has hosted a number of missions including:

- Radioactive waste management infrastructure review mission in November 2006,
- IRRS mission in October 2007,
- EPREV Mission in March 2015,
- INIR mission in August 2015.

Kenya contributed personnel to the following international peer review missions:

- Peer review on compliance assurance in the safe transport of radioactive materials under RAF 9046 (year 2014 – 2015),
- IRRS Mission to Tanzania, October 2015.

There are no mechanisms or arrangements in place for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience or for the dissemination of the lessons learned and for their use by authorized parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: There are no mechanisms and arrangements for analysis to be carried out to identify lessons to be learned from both operating and regulatory experience, and for the dissemination of the

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
lessons learned.	
(1)	**BASIS: GSR Part 1, Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned .and for their use by authorized parties, the regulatory body and other relevant authorities."*
R9	**Recommendation: RPB should establish arrangements to receive, analyse, disseminate and implement the lessons learned from operating and regulatory experience.**

2.3. SUMMARY

Kenya is a party to some international conventions and instruments, but has not yet ratified some of the most important international instruments related to nuclear and radiation safety nor has it made a political commitment to the Code of Conduct and the its Supplementing Guidance on the Import and Export of Radioactive Sources.

At the national level, RPB should benefit more from the exchange of experience and establish arrangements to receive, analyse, disseminate and implement the lessons learned from operating and regulatory experience.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

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

According to the Act, RPB Board consists of:

(a) a Chairman appointed by the Minister

(b) the Director of Medical Services

(c) The following persons appointed by the Minister:

i. a public officer nominated by the Minister for the time being responsible for labour
ii. a public officer nominated by the Minister for the time being responsible for higher education
iii. a public officer nominated by the Minister for the time being responsible for industry
iv. a public officer nominated by the Minister for the time being responsible for agriculture
v. a public officer nominated by the National Council for Science and Technology
vi. not more than two persons having special knowledge in safe handling of radiation sources
vii. a public officer nominated by the Minister for the time being responsible for foreign affaires
viii. an officer from the Kenya Defence Forces
ix. an officer from the National Intelligence Service
x. an officer from the National Police Service and
xi. an officer from the Kenya Revenue Authority.

(d) the Chief Radiation Protection Officer (CRPO) who shall act as the secretary to the Board but shall not vote on any matter brought before the Board.

IRRS team members were informed that in addition to the above, a member of the Attorney General's office sits on the Board according to a Government's Cabinet decision.

The Board has four Committees:

- Audit, Legal and External Relations Committee (ALERC)
- Licensing and Technical Advisory Committee (LTAC)
- Nuclear Security and Safeguards Committee (NSSC)
- Research and Development Committee (RDC)

The organizational structure of RPB was provided to the IRRS team. The Secretariat is headed by a CRPO and comprises of 26 officers. RPB has offices in the capital city, Nairobi and operates six regional offices across the country. Each regional office has allocated officers, financial and logistical resources for discharging its duties.

From the discussion with the counterparts (see also Sections 5 to 9), the IRRS team came to the conclusion that the distribution and management of available resources within RPB do not assure the effective discharge of its regulatory responsibilities. In addition, IRRS team considers that RPB does not allocate resources commensurate with radiation risks associated with facilities and activities in accordance with a graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB is not structured in a way that enables it to discharge its responsibilities effectively and resources are not allocated in a graded approach.	
(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 16 para 4.5 states that** "*The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively….. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach."*
S4	**Suggestion: RPB should consider revising its structure and should consider allocating resources commensurate with the radiation risks associated with facilities and activities in accordance with a graded approach.**

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

RPB is appointed by and is accountable to the Minister of Health. The National Treasury through the Ministry of Health provides for RPB funding.

The functional separation from undue influence and from promotion or application of radiation technologies has to be further interrogated since:

a) RPB falls under a Ministry that uses radiation technology (Ministry of Health)

b) decisions within RPB are taken by the four Committees and are then ratified by the Board, some members of which are at the same time authorized parties. In particular, the LTAC , which is responsible for making decisions on license applications, has thirteen members eight of which are either users or promoters of radiation technology.

c) some RPB staff members occasionally perform duties for the Technical Service Organizations (TSOs).

The staff of RPB are employed by the Public Service Commission and are bound by the Civil Servants and Public Officers Ethics Act, the Public Service Commission Rules and Regulations and the Code of Conduct. However, there are no measures in place for the prevention or resolution of conflicts of interest.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: RPB is not independent in its decision-making and does not have functional separation from entities having responsibilities or interests that could unduly influence its decision-making. There are no mechanisms to prevent any conflicts of interests and staff of RPB occasionally serve as consultants to licensees providing TSO support.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 Requirement 17 states that** *"The regulatory body shall perform its functions in a manner that does not compromise its effective independence."*
(2)	**BASIS: GSR Part 1 Requirement 17, para 4.6 states that** *"Requirements 3 and 4 in Section 2 stipulate that the government establish and maintain a regulatory body that is effectively independent in its decision making and that has functional separation from entities having responsibilities or interests that could unduly influence its decision making. This imposes an obligation on the regulatory body to discharge its responsibilities in such a way as to preserve its effective independence."*
(3)	**BASIS: GSR Part 1 Requirement 17, 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.*"
(4)	**BASIS: GSR Part 1 Requirement 17, para 4.9 states that** *"To maintain its effective independence, the regulatory body shall ensure that, in its liaison with interested parties, it has a clear separation from organizations or bodies that have been assigned responsibilities for facilities or activities or for their promotion."*
R10	**Recommendation: RPB should ensure that it takes decisions in a manner which does not compromise its independence. It should put in place mechanisms to prevent conflicts of interest in all of its regulatory activities.**

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

The Public Service Commission's Scheme of Service for the Radiation Protection Officer Cadre of 2004 guides recruitment, promotion and advancement of staff.

RPB has 26 technical staff distributed across the various departments and the six regional offices. In addition, four RPOs are employed on a one-year contract basis as well as five interns in order to augment the staff capacity. There are 22 vacancies in RPB.

From the information given to the IRRS team, the current staffing level does not allow the effective discharge or regulatory responsibilities (see Sections 5 and 7). RPB has not used an objective and scientific method to determine its staffing needs and optimize its resources.

Currently, there are 14 RPOs holding M.Sc., 11 holding B.Sc. and one holding diploma in radiography. The following competences are lacking and need to be enhanced: regulation of NORM, review and assessment, authorization and inspection of linear accelerators, cyclotrons and nuclear medicine facilities. RPB does not have a continuous training programme to ensure that the inspectors maintain their competences.

RPB has not developed a long-term human resource and succession planning and recruitment process nor a formalized training programme for its staff. The area of knowledge management is still in its infancy. Individuals who have attended training courses are encouraged to share their experience through seminars. There is no mechanism to capture knowledge when staff resign or retire.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB is currently unable to discharge its annual work programme in fulfilment of its regulatory functions and lacks a formal training programme for its staff.	
(1)	**BASIS: GSR Part 1 Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
(2)	**BASIS: GSR Part 1 Requirement 18, para 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(3)	**BASIS: GSR Part 1 Requirement 18, para 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
(4)	**BASIS: GSR Part 1 Requirement 18, para 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills."*
R11	**Recommendation: RPB should carry out a human resources needs analysis, making use of an objective and scientific methodology, and develop and implement a human resources plan and associated staff training programme to ensure the discharge of its regulatory functions in an effective and efficient manner.**

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

Advisory bodies to RPB include the Government Agencies represented on the Board and those provided under statutes (laws, MoUs). Other advisory organizations may be invited on an ad-hoc basis to give advice on specific issues.

There are no Technical Support Organizations currently providing technical advice or services to RPB.

There are several TSOs in Kenya that provide services to the users/licensees. Details on TSOs are given in Section 1.9.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

RPB communicates with authorized parties through letters, emails, RPB's website and notices placed in newspapers. The IRRS team noted that there has been no updates to the RPB website in the last two years.

RPB does not organize meetings systematically with authorized parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB does not adequately engage with authorized parties, nor does it clearly explain the basis for its regulatory decisions.	
(1)	**BASIS: GSR Part 1 Requirement 21 states that** *"The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison."*
(2)	**BASIS: GSR Part 1 Requirement 21, para 4.24 states that** *"The regulatory body shall foster mutual understanding and respect on the part of authorized parties through frank, open and yet formal relationships, providing constructive liaison on safety related issues."*
(3)	**BASIS: GSR Part 1 Requirement 21, para 4.25 states that** *"The decisions of the regulatory body shall be justified as appropriate, and the basis for the decisions shall be explained."*
S5	**Suggestion: RPB should consider fostering effective formal and informal mechanisms of communication with authorized parties.**

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

RPB uses application forms for the various applications to be authorized and inspection protocols for the different facilities and activities to be inspected (diagnostic X-ray facilities, nuclear medicine, radiotherapy, veterinary, dealers of irradiating devices and radioactive materials, research and educational institutions, fixed gauges, industrial radiography), though many of these are out of date. Documents outlining the regulatory process for setting up a radiation facility and for the registration and licensing of radiation workers are in place but not formally approved.

There are no policies, principles, criteria or safety objectives set by RPB for the implementation of its core functions assuring predictability and consistency of the regulatory decision making process and avoiding subjectivity on it.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB has not adopted any policies, principles, criteria or safety objectives which support its regulatory decision making processes, ensuring predictability and consistency, avoiding subjectivity.	
(1)	**BASIS: GSR Part 1 Requirement 22, para. 4.34 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system. The process shall ensure the stability and consistency of regulatory control and shall prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body shall be able to justify its decisions if they are challenged. In connection with its reviews and assessments and its inspections, the regulatory body shall inform applicants of the objectives, principles and associated criteria for safety on which*

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	its requirements, judgements and decisions are based."
R12	**Recommendation: RPB should develop and implement policies and procedures to ensure that the regulatory control of facilities and activities is consistent and stable.**

3.7. SAFETY RELATED RECORDS

RPB is mandated by the Act to access safety records from authorized parties. Such records include safety assessment reports, maintenance and calibration reports, personal dose records, and training records. The records can also be used by RPB in court proceedings for litigation as part of enforcement actions.

RPB holds the following safety related records mostly on hard copy: register of radioactive sources, irradiating devices and owners, register of radiation workers and the individual dose results (not cumulative dose), radiation safety assessment reports for radiation facilities and activities. However, there is no mechanism to ensure that these records are complete and up to date. The IRRS team noted some missing records during a review of licencees files.

There are no adequate security measures to ensure that sensitive information like the national inventory of sources is maintained. The IRRS team was informed about the system of record keeping at RPB, mainly based on hard copies. These are archived in dossiers per facility, minutes of RPB meetings, etc.

Additionally to the above, there is an Excel data base that records meaningful data of each facility and allows for obtaining basic statistics. The hard copies are stored at RPB premises, within filing cabinets in a room which is locked during non-office hours. There is no fire protection or any other measure to protect the information from hazards.

The IRRS team was informed that RPB was using the IAEA system RAIS version 3.3, but the server crashed in February 2016. RPB has acquired a new server, however they did not manage to restore the information. RPB is in the process of re-entering the information in RAIS.

There is no off-site back-up of records.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB does not adequately maintain the records necessary to demonstrate the safe operation of facilities and the safe conduct of activities.	
(1)	**BASIS: GSR Part 1 Requirement 35, para. 4.63 states that** *"The regulatory body shall make provision for establishing and maintaining the following main registers and inventories."*
(2)	***BASIS: GSR P*art 1 Requirement 35, para. 4.65 states that** *"Regulatory body shall use such records in support of its regulatory functions and to support the enforcement of regulatory requirements."*
S6	**Suggestion: RPB should consider developing and implementing a records management policy to ensure that it adequately maintains all the records necessary**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	to account for the safe operation of facilities and the safe conduct of activities.

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

RPB communicates with interested parties using various platforms which include, notices in the print media every May or June addressing issues of regulatory requirements related to the renewal of authorizations, as well as seminars, open days, exhibitions (trade fairs), special features in the print media, website postings, email and videos (recorded audio visuals).

An open day is held once a year at RPB premises where members of the public and interested parties have the opportunity to interact with RPB management and staff.

There is no information policy that underpins the communication and consultation with interested parties. No press releases have been issued so far by RPB. RPB does not produce any annual or other type of report intended to inform the public and other interested parties about its activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB does not have appropriate means for informing and consulting with interested parties and the public about radiation risks associated with facilities and activities and about its processes and decisions.	
(1)	**BASIS: GSR Part 1 Requirement 36, para. 4.67 states that** *"The regulatory body, in its public informational activities and consultation, shall set up appropriate means of informing interested parties, the public and the news media about the radiation risks associated with facilities and activities, the requirements for protection of people and the environment, and the processes of the regulatory body."*
R13	**Recommendation: RPB should adopt appropriate means for informing and consulting with interested parties and the public.**

3.9. SUMMARY

RPB responsibilities and functions are included in the Act, however RPB should revise its structure and manage its resources using a graded approach in order to discharge its regulatory functions in a more efficient and effective manner.

RPB should have functional separation from entities having competing responsibilities or interests. It should put in place mechanisms to prevent conflicts of interest in all of its regulatory activities.

Other areas of improvement are: development and implementation of policies and procedures to ensure that the regulatory control of facilities and activities is consistent and stable, maintaining the records necessary to account for the safe operation of facilities and the safe conduct of activities and the establishment of mechanisms to communicate with interested and authorized parties on safety related issues.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

4.1. IMPLEMENTATION AND DOCUMENTATION OF THE MANAGEMENT SYSTEM

RPB functions are stated in Section 7 of the Act.

RPB does not have a manual to describe its management system. The main reference document for RPB management system is the 2012-2016 Strategic Plan, which presents the guiding priorities for RPB. The plan defines RPB mission, vision, core values as well as its objectives. RPB plans to develop its next strategic plan in the course of this financial year.

RPB work is described in the draft Business Process Document of 2015, which outlines the composition of the Board, the overall organizational structure and departmental functions. The document describes processes related to the authorization of facilities, licensing of radiation workers as well as enforcement actions. Other regulatory and support processes are not described.

The roles and responsibilities of RPB, its Committees and Secretariat are not sufficiently elaborated.

Promotion of Safety Culture

The 2012-2016 Strategic Plan puts an emphasis on promotion of safety. However, there are no provisions in place to build safety culture in regulatory activities such as training programmes, systems to ensure that safety is always the paramount priority nor a learning and questioning environment or leadership for safety. An "Inspector's Manual" has been prepared and remains to be completed for all inspection types and to be implemented within everyday practice of RPB (see Section 7).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB does not have a management system that meets the requirements of the IAEA safety standards.	
(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 2.5 states that** *"The management system shall be used to promote and support a strong safety culture by [...]"*
(3)	**BASIS: GS-R-3 para 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."*
(4)	***BASIS: GS-R-3 para 2.8 states that*** *"The documentation of the management system shall include the following:* • *The policy statements of the organization;* • *A description of the management system;* • *A description of the structure of the organization;* • *A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work;* • *A description of the processes and supporting information that explain how work*

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	is to be prepared, reviewed, carried out, recorded, assessed and improved."
(5)	**BASIS: GS-R-3 para 3.1 states that** *"Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities."*
(6)	**BASIS: GS-R-3 para 3.7 states that** *"Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization."*
(7)	**BASIS: GS-R-3 para 4.1 states that** *"Senior management shall determine the amount of resources necessary and shall provide the resources to carry out the activities of the organization and to establish, implement, assess and continually improve the management system."*
(8)	**BASIS: GS-R-3 para 5.1 states that** *"The processes of the management system that are needed to achieve the goals, provide the means to meet all requirements and deliver the products of the organization shall be identified, and their development shall be planned, implemented, assessed and continually improved."*
(9)	**BASIS: GS-R-3 para 6.1 states that** *"The effectiveness of the management system shall be monitored and measured to confirm the ability of the processes to achieve the intended results and to identify opportunities for improvement."*
(10)	**BASIS: GS-R-3 para 6.2 states that** *"Senior management and management at all other levels in the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture."*
R14	**Recommendation: RPB should establish and implement an integrated management system consistent with the IAEA safety standards.**

4.2. MANAGEMENT RESPONSIBILITY

There is no formal commitment from senior management for the establishment, implementation, assessment and continuous improvement of the Management System.

The development, documentation, communication and evaluation of organizational policies have not been addressed.

4.3. RESOURCE MANAGEMENT

The 2012-2016 Strategic Plan identified the critical needs for human and financial resources in order for RPB to achieve its mandate. One strategic goal achieved has been the establishment of regional offices in order to deploy the organization across the country. Section 3 addresses the issue of RPB resources allocation.

4.4. PROCESS IMPLEMENTATION

In the absence of a Management System Manual, the development and documentation of processes is not defined. There have been attempts to document sub-processes under authorization, inspection and enforcement and a set of draft procedures and protocols have been written, however they have not been properly reviewed and formally approved.

The process description does not provide the scope of process such as owner responsibilities, records expected, inter-link with other sub-processes, as well as internal and external communication processes and the management of change in the organization.

RPB has contracted an external consultant to help the Board in the description of the business processes of RPB, to explain the organizational chart of RPB, to outline the function of each RPB organizational unit, as well as to outline the process of the various functions of RPB. Some work has been done within this contract, however this is not finished yet.

4.5. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

RPB has in place a system for the measurement and assessment of individual performance as well as the overall organizational performance. The Board signs a performance contract with the Minister of Health highlighting the broad performance targets for each year. The performance contract is reviewed quarterly and the results are shared with the Ministry. A consultant is engaged at the end of the year to evaluate the annual performance report and make recommendations and suggestions on areas of improvement. These are incorporated into the successive year's plan.

The IRRS team was informed that individual workers of RPB are subjected to performance evaluation, signing annual performance contracts evaluated by the respective heads of departments and the CRPO.

There is no evidence of internal monitoring of the performance of elements of the management system. RPB is however open to peer reviews and a number of review missions have been undertaken. Results of the mission are used to ensure continuous improvement of the organization.

4.6. SUMMARY

The main reference document for RPB management system is the 2012-2016 Strategic Plan, which defines RPB mission, vision, core values and objectives, its guiding priorities as well as RPB's critical needs for human and financial resources. RPB work is described in the draft Business Process Document of 2015, which outlines the composition of the Board, the overall organizational structure and departmental functions. The document describes processes related to the authorization of facilities, licensing of radiation workers as well as enforcement actions.

RPB does not have a manual to describe its management system.

Even if there are some elements of a management system, RPB should establish and implement an integrated management system consistent with the IAEA safety standards.

5. AUTHORIZATION

5.1. GENERIC ISSUES

Section 7 of the Act provides a statutory basis for RPB to grant, refuse or extend licences and to keep a register of owners of irradiating devices and radioactive sources. Within RPB, the Radiation Control Inspectorate has the delegated responsibility for the radiological licensing function. In accordance with Section 8 of the Act, all persons manufacturing, producing, possessing, using, selling, disposing, leasing, loaning, dealing with, importing or exporting any irradiating device or radioactive material must do so in accordance with a licence issued under the Act.

In the event that RPB decides not to grant or renew a licence, or cancels or suspends a licence, the applicant is entitled to appeal RPB's decision to the Minister for Health in accordance with Section 15 of the Act. However RPB has not documented any procedures that detail how it amends, renews, suspends, revokes a licence. A recommendation on this is made in Section 3.6.

While Section 18 (i) of the Act provides for the Minister for Health to make regulations for exempting irradiating devices and/or radioactive materials from licensing requirements, in practice these regulations have not been made and accordingly there are no exemptions from licensing in Kenya. Therefore each individual irradiating device and radioactive source must be licensed by RPB. However, the IRRS team was informed that the Board took a decision not to require ionization chamber smoke detectors used in domestic dwellings to be licensed, though there is no legal basis for the Board to make such an exemption. In addition Section 9 (2) of the Act requires all persons who administer ionizing radiation to another person to be licensed by RPB. For all other radiation workers, including biomedical engineers, installation engineers and service engineers, RPB requires them all to be registered.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Although the Act makes provisions for regulations to be enacted to provide for exemption, in practice this concept is not being used.	
(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."*
S7	**Suggestion: RPB should consider adopting the concept of exemption in its graded approach to authorization.**

Section 7 of the Act allows RPB to impose any necessary conditions on a licence it grants. One of the standard conditions attached to each licence requires the licensee to comply with the Act, and by inference, any regulations made thereunder. However, RPB has not enacted the necessary regulations, which would set out the radiation protection requirements licensees need to comply with, as provided for under the provisions of Section 18 of the Act. A recommendation on this is made in Section 9.4.

All licences granted are valid for one year, regardless of the nature of the source or the activities that the workers are engaged in. There is no provision for alternative forms of authorization such as registration or notification only. This "one size fits all" approach to authorization is not consistent with

a graded approach. The one exception to this is the import and export licences which are issued for just one month. Upon the expiry of a licence, the licensee is required to apply for a renewal of the licence. RPB will renew the licence once it is satisfied with the information submitted, the fee has been paid and in some cases an inspection of the facility has been carried out.

RPB publicises the requirement for workers to be licensed through placing notices in newspapers and workers are also made aware of the need to be licensed during their educational training. RPB also places notices in newspapers advising licensees that their licences fall due for renewal at the end of June each year.

The Second Schedule to LN 160 provides the application forms that applicants should use when applying for a licence. Six application forms are available covering various activities relating to irradiating devices or radioactive material:

- Deal/import/export/transport
- Possess or Use
- Disposal
- Radiation Workers
- Service Providers
- Any other purpose

RPB has published a general guide on the regulatory process for setting up a radiation facility which details the process applicants should follow and the types of information that RPB requires when a licence application is being made. However, no further guidance has been published that details the additional information that would be required in the case of applications for more complex or high risk activities such as radiotherapy. Furthermore the general guide does not provide any information on the content of the information that must be submitted. For example, no guidance has been published on the role, responsibilities or qualifications for the Radiation Safety Officer (RSO) that the applicant must appoint. Therefore applicants are not aware of all the information that must be submitted when applying for a licence or of RPB's expectations. A recommendation on this is made in Section 9.4.

When submitting an application for a licence, the applicant is required to perform a safety assessment and provide this report in support of the application. However, this requirement does not appear in the Act, regulations, guides or application forms issued by RPB, nor is any guidance available on the content of this assessment. In order to meet this requirement, applicants engage a TSO to undertake this safety assessment on their behalf.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Every licence application must be supported by a documented safety assessment when applying for a new, or the renewal of an existing, licence. However, this requirement does not appear in the Act, regulations, or any guidance issued by RPB.	
(1)	**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 [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."*
R15	**Recommendation: RPB should explicitly state the requirement that all licence**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	applications must be supported by a documented safety assessment.

5.2. AUTHORIZATION OF RADIATION SOURCE FACILITIES AND ACTIVITIES

Section 8 of the Act includes a requirement that all persons possessing any irradiating device or radioactive material must be licensed. RPB licensing programme covers the medical, dental, veterinary, industrial, distribution and educational sectors throughout Kenya. However, the current regulatory requirement, whereby every licence expires on the same day every year, places huge pressure on the resources of RPB who is unable to renew the licences promptly. This results in delays in issuing new licences which, by implication, means that irradiating devices and radioactive sources throughout Kenya become unlicensed.

The IRRS team carried out a review of three licensee files, selected at random from the fields of soil measurements, industrial radiography, and radiotherapy. All three files contained records of the application form submitted by the applicant, the licence fees in respect of the application and the safety assessment for the installation as submitted by the applicant. For two of the files reviewed, the applicants had sought approval to possess and use radioactive sources, namely Cs-137 and Am-241, for soil measurements, and Ir-192 for industrial radiography, and were issued licences authorizing the import of these sources into Kenya. However, the IRRS team noted that only one of the three licensees had been granted a licence to possess and use a radioactive source, namely the Ir-192 industrial radiography source, whereas neither of the other two licensees had been granted a licence for possession or use. The files did not indicate whether such an authorization had in fact been either granted or refused, and accordingly RPB was not aware of whether the device, containing the Cs-137 and Am-241 sources, is in the country or not.

Within Kenya, radioactive waste is generated as a direct consequence of the use of unsealed radioactive sources in hospital-based nuclear medicine departments and research facilities. Examples of such waste generated include material contaminated with carbon-14, technetium-99m, iodine-131 and tritium. Short lived solid radioactive waste is collected and stored on site for an appropriate time to allow for radioactive decay before it is disposed of in clinical waste streams. Liquid waste from nuclear medicine departments is collected and stored for decay before being discharged to the sewers. In the case of longer lived unsealed waste from research facilities, this is held on licensees' premises pending the opening of the CRWPF to where it will eventually be transferred. In the absence of radioactive waste management regulations, which are currently in draft form, the management and storage of radioactive waste is currently not licensed in Kenya.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Under the current regulatory requirements, whereby all licences must be renewed each year, irradiating devices and radioactive sources become unlicensed due to delays in processing the licence applications. In addition, the management and storage of radioactive waste generated at research facilities and hospital nuclear medicine departments is currently 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."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R16	**Recommendation: RPB should ensure all irradiating devices and radioactive sources throughout Kenya are appropriately authorized and that authorizations cover the management of radioactive waste generated at licensees' facilities.**

5.3. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

According to both Section 11(1) of the Act, and Section 4 (1) of LN 160, it is prohibited to dispose of any radioactive material and operate or own a radioactive waste management facility without authorization from RPB. Moreover, Section 11 (3) e of the Act allows RPB to include on a licence granted other conditions as the Board deems necessary for the safe disposal of all radioactive material resulting from the proposed operation, process or facility.

In accordance with Section 6 of LN 160 all new facilities must be designed to ensure that persons in adjoining facilities and persons within the vicinity are appropriately protected from radiation exposure. In addition, the plans must be submitted to RPB for approval. In the case of the new CRWPF, which has recently completed phase 1 of its construction, RPB was involved in the design and specification of the facility and as RPB owns the facility no licence was ever issued. Waste from the Ministry for Roads and Public Works' Material Testing and Research Department was transferred there, however the facility is still unlicensed.

Radioactive waste is processed by a dedicated facility at the Material Testing and Research Department operated by the Ministry for Roads and Public Works. This facility conditions and immobilises disused sealed sources, collected from industrial facilities and educational institutions, and orphan sources in a concrete matrix within 200 litre drums and stores these on site. However these activities are not licensed. RPB is of the opinion that no licence is required as the conditioned waste is its property.

RPB uses a disused radiotherapy bunker at its premises in Nairobi for the storage of radioactive sources and other items. These sources include both orphan and seized sources involved in illicit trafficking, and are held as evidence for possible future prosecutions. While RPB provided an inventory of these sources to the IRRS team, it was unable to identify which sources were still present in the bunker, and which had been moved to the CRWPF.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The radioactive waste management activities at both the Ministry of Roads and Public Works' conditioning facility and the CRWPF are **RPB**not licensed. Similarly, storage of disused radioactive sources held on RPB's premises in Nairobi is not licensed. RPB.	
(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."*
R17	**Recommendation: RPB should ensure that all radioactive waste management activities are properly licensed, based upon a review and assessment, in accordance with the provisions of the Act.**

5.4. AUTHORIZATION OF TRANSPORT

The Act does not identify RPB as the competent authority in respect of the IAEA Regulations for the Safe Transport of Radioactive Material.

Although there is an "Application For Registration And Licence To Deal/ Import/Export/Transport Irradiating Device Or Radioactive Material" (GKLRP1) RPB does not issue a licence for transport activities but rather they issue an "Authority to Move Radioactive Sources". This is not stipulated in the Act.

The transport authorizations issued carry a list of conditions which must be complied with by the consignor. These conditions include that "*the selected service provider (TSO) will carry out a verified inventory exercise, comprehensive radiation safety survey and physical security assessment and submit a detailed report to the Board, before renewal of annual operating licences are issued*."

Since the TSO is a consultant to the consignor, the inclusion of the condition in the consignor's authorization imposes a regulatory requirement on a third party. This leads to the question of who is held responsible should this condition not be complied with.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The authorization for transport, issued to the consignor imposes a condition upon the TSO. This raises the question as to who RPB will take action against in the event that this condition is not complied with.	
(1)	**BASIS: GSR Part 1 Requirement 24 Para 4.31 states that** "*In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party's subsequent activities."*
R18	**Recommendation: RPB should refrain from imposing responsibilities upon the TSO within the conditions of transport authorization issued to the consignor.**

5.5. SUMMARY

RPB has been provided with the necessary legislative basis for issuing licences as required under the provisions of the Act. However it has not adopted a graded approach to authorization and, in the absence of regulations for exemption criteria being adopted, all irradiating devices and radioactive material must be licensed for one year, regardless of their associated risks.

While RPB's licensing framework covers all sectors in Kenya where sources of ionizing radiation are used, it does not cover activities associated with the generation and management of radioactive waste or transport of radioactive material. In addition, the current regulatory process results in some irradiating devices and radioactive sources being unlicensed for several months each year due to delays in issuing renewed licences. RPB needs to review its current licensing arrangements to address this situation.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

Neither the Act nor regulations make any provision for a graded approach in review and assessment. The IRRS team was informed that in practice this provision is implicitly built into the process by the fact that the contents of the safety assessment are expected to be more rigorous and comprehensive for high risk practices than for lower risk practices. Recommendation 11 and Suggestion 4 in Section 3 raise the issue of graded approach.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

A licence application is reviewed by two or three competent RPOs in the Technical Assessment Division who then submit a report to the CRPO. A larger review team may be appointed for the review of more complex activities, such as those involving a linear accelerator or cyclotron. A pre-licensing inspection is then undertaken by RPB to verify details on the application form and information contained in the radiation safety assessment report. Subject to a satisfactory inspection, the CRPO will then submit a report of the licence application review to the LTAC which takes a decision as to whether the licence should be granted.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

RPB estimates that there are approximately 1200 irradiating devices and radioactive sources throughout Kenya. As licences are valid for only one year RPB has to carry out a review and assessment for each licence every year.

This practice to renew all licences and registrations on an annual basis, together with the associated requirement to carry out a pre-authorization inspection, places a significant burden on the annual workload of RPB. It is not clear to the IRRS team if this annual renewal programme adds any additional value to the radiation protection framework in Kenya and the resources currently involved in this activity could be better used for other activities. Suggestion 4 in Section 3.1 addresses the issue.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

Review and assessment is based primarily on both the information submitted by applicant and the outcome of a pre-licensing inspection conducted by RPB. The information submitted by the applicant must include details of the source, plans of the facility, details of the RSO and a safety assessment.

The IRRS team was informed that RPB uses IAEA standards as the basis of its review and assessment. However, RPB has not formally documented and made available a specific list of the IAEA standards it uses for review and assessment for either its own staff or for licence applicants. Therefore applicants are not aware of the criteria against which a licence application will be assessed. Recommendation 29 in Section 9 addresses this issue.

The safety assessment, conducted by the TSOs, is an essential component of every licence application and forms the basis for most of the review and assessments carried out. RPB has not issued any guidance on the format or content of a safety assessment in relation to any licensable activity. In the absence of documented guidance on safety assessments, RPB has held two meetings with TSOs during which it has set out its requirements and expectations on the content of these assessments. However

this information is not made available to licence applicants. Recommendation 29 in Section 9 addresses this issue.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

RPB does not have any documented procedures or checklists for the review and assessment of licence applications. However, the IRRS team was shown examples of draft checklists, specific to individual activities, which will be a useful training resource and should assist RPOs undertake review and assessment activities when finalised. The advance material provided to the IRRS team suggested that RPB undertakes the following action when reviewing and assessing a licence application:

- A review of the written material submitted by the applicant
- A pre-authorization inspection
- Interviews with personnel at the facility

However a review of a number of sample licensee files by the IRRS team was unable to find any documentary evidence that either a review and assessment had been carried out for the licence applications and associated safety assessments included in the files, or that pre-authorization inspections had been undertaken, despite the fact that copies of licenses issued had been filed.

6.2. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

The new CRWPF has recently completed phase 1 of its construction and some conditioned radioactive waste has already been transferred from the Ministry of Roads and Public Works' conditioning facility to it. While RPB was involved in the design specification for the facility, taking account of operating experience at a similar facility in Belgium, no formal review and assessment was ever carried out for it.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Based upon the files reviewed by the team, there is no documentary evidence to demonstrate that RPB carries out reviews and assessment on licence applications received. In addition, no formal review and assessment was carried out and documented for the new CRWPF.	
(1)	**BASIS: GSR Part 1 Requirement 26, para. 4.48 states that** *"The regulatory body shall record the results and decisions arising from reviews and assessment."*
R19	**Recommendation: RPB should record the results and decisions arising from reviews and assessment of applications.**

6.3. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

The review and assessment for radiation sources facilities and activities is described in the sections above.

6.4. REVIEW AND ASSESSMENT FOR TRANSPORT

There is no evidence that, prior to granting a transport authorization, RPB conducts a review of documentation submitted in support of the application, including submitted safety assessments. In one instance observed by the IRRS team, the transport authorization was issued before the holder had submitted the transport plan (which included the safety assessment for the transport). In this instance

the transport plan had in fact been submitted only upon completion of the requested and approved transport action. Recommendation 19 in Section 6.2 addresses this issue.

6.5. SUMMARY

RPB's Technical Assessment Division is responsible for carrying out review and assessment of applications as part of the authorization process to determine whether facilities and activities comply with regulatory requirements. The IRRS team identified a number of areas where improvements could be made to the process, in particular in relation to how the results of the licence reviews and decisions taken are documented and maintained.

The requirement for all licences to be renewed each year places a significant burden on the resources of RPB. It is not clear as to whether the short licence durations used add significant value to the radiation safety framework and consideration should be given to extending these durations to allow RPB to reallocate its resources to other regulatory activities.

7. INSPECTION

7.1. GENERIC ISSUES

The Act provides RPB with the statutory authority to carry out inspections of radiation facilities and activities including radioactive waste management facilities, transport of radioactive materials and import/export activities. The primary purpose of the inspections is to ensure that any authorized facility or activity complies with the safety requirements stipulated in the legislation, with the conditions specified in the granted licence and to verify information provided by the licensee.

7.1.1. INSPECTION PROGRAMME

According to the ARM and discussions held with the counterparts, RPB is supposed to perform inspections before granting or renewing licences, effectively imposing a requirement for an annual inspection of each licensed facility or activity, even though the legal basis (LN 160 Section 7-2) only requires for a pre-authorization inspection before the radiation facility is first put in use.

RPB prepares an "Annual Inspections Planner", including announced and unannounced inspections, for all licensed radiation facilities/activities. The target frequencies range from every 6 months to every 24 months, according to the level of risk associated with the different activities. The setting of target inspection frequencies is consistent with a graded approach. The requirement to carry out a pre-authorization inspection prior to renewing the annual licences conflicts with this graded approach.

RPB does not have adequate resources to carry out the number of inspections at the currently defined inspection frequencies. RPB has reported 295 inspections during the last year. According to the target frequencies, more than 450 should have been conducted. In conclusion, these target frequencies are unrealistic.

RPB also conducts reactive inspections, mainly upon receiving complaints about non-compliance or unlicensed activities.

Upon the request of the Ministry of Health, RPB can participate, with other regulatory bodies (the Medical Practitioners Dentists Board, the Pharmacy and Poisons Board), in joint inspections of medical services.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB has adopted target inspection frequencies in accordance with a graded approach. In practice, RPB cannot implement an annual inspection programme based on these inspection frequencies.	
(1)	**BASIS: GSR Part 1 Requirement 29, para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach."*
R20	**Recommendation: RPB should develop and implement an achievable annual**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	inspection programme in accordance with a graded approach.

7.1.2. INSPECTION PROCESS AND PRACTICE

RPB has developed an "inspectors' manual" in which the inspectors can find the procedures to carry out an inspection. The procedures cover the preparatory phase and the field inspection phase. RPB has developed forms which may be used by the inspector:

- A facility evaluation form, to be completed in preparing for the inspection;
- An inspection protocol form, to be used during the inspection;
- A summary inspection form, filled at the end of the inspection and left with the licensee;
- An inspection report to be written after the inspection.

According to the records made available to the IRRS team, these documents are not systematically used and the procedures are not systematically followed by the inspectors.

The "inspectors' manual" does not address the post-inspection process, as there is no documented procedure dealing with the follow-up process and the close out of the inspection findings.

According to the counterparts, the inspections findings could be used as inputs for the licence making decision process or for the enforcement process.

The documents within the manual are not formally approved nor properly updated. As a consequence, during the inspection, some inspectors are still following outdated inspection protocol forms.

The inspection starts by a presentation of RPB and the purpose of the inspection, then inspectors proceed to document review, staff interviews and visits to the location where sources of ionizing radiations are held. The inspection ends with an exit meeting, where the inspectors report their findings to the responsible staff of the facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB has developed an "inspector's manual" that sets out procedures for planning and undertaking inspections. However, the manual has not been formally approved nor does it address post-inspection activities. In addition the procedures are not adhered to and complete records of RPB inspection activities are not maintained.	
(1)	**BASIS: GSR Part 1 Requirement 29, para. 4.51 states that** *"The regulatory body shall record the results of inspections and shall take appropriate action (including enforcement actions as necessary). Results of inspections shall be used as feedback information for the regulatory process and shall be provided to the authorized party.*"
(2)	**BASIS: GSR Part 1 Requirement 22, para. 4.26 states that** *"The regulatory process shall be a formal process that is based on specified policies, principles and associated criteria, and that follows specified procedures as established in the management system."*
R21	**Recommendation: RPB should revise its "inspector's manual" to include all pre-inspection, inspection and post-inspection activities.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R22	**Recommendation: RPB should formally approve the "inspector's manual" and ensure that all inspectors follow the procedures contained therein.**

7.1.3. INSPECTORS

RPB currently has 26 staff members, 18 of whom routinely carry out inspections, based in six regional offices. At least two inspectors are posted in each regional office, for a period of three to five years.

Newly recruited inspectors must hold relevant qualifications as described in the Republic of Kenya Scheme of Service for radiation protection officers. After recruitment, inspectors receive a specific three-months training in relevant fields, provided by the Institute of Nuclear Sciences and Technologies. A radiation protection certificate is granted to the inspector at the end of this initial training. The inspector then undergoes an internal induction period, mentored by senior inspectors for one year. RPB has not documented its RPO training programme and how inspectors are initially deemed competent and periodically evaluated. Recommendation 11 in Section 3.3 addresses this issue.

The Act, under Section 14 (1) provides any person appointed as an RPO access to authorized facilities and activities but it does not clearly provide RPO the authority to enter any premises at any time.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The Act does not provide RPO the authority to enter any premises at any time.	
(1)	**BASIS: GSR Part 1 Requirement 29, para. 4.52 states *that*** *"Regulatory inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach."*
R23	**Recommendation: RPB should ensure that inspectors have the legal authority to access any facility at any time.**

7.2. INSPECTION OF WASTE MANAGEMENT FACILITIES

To date, disused sealed sources collected from educational institutions and industrial organizations and are conditioned, immobilized and stored by the Material Testing and Research Department operated by the Ministry of Roads and Public Works. Inspections of waste management activities at this site are carried out during routine inspection of this licensee. Some of the conditioned waste have been recently moved to the CRWPF which is not inspected yet.

7.3. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

RPB conducts inspections of authorized facilities and activities to ensure they comply with its safety requirements. The IRRS team witnessed two inspections.

Inspection of an industrial facility (X-ray dosimetry calibration)

IRRS team members observed an inspection of an industrial facility at Kenya Bureau of Standards (KEBS) in Nairobi.

At the start of the inspection, the lead inspector gave an overview of the role of RPB and the purpose of the inspection. The RPOs performed the inspection using the summary inspection report form. The inspection consisted of a review of documents and records and interviews with licensee staff, dealing with relevant areas such as workers dose monitoring, inventory of sources, equipment maintenance, licence validity, licensee's code of practice, RSO's duties, quality assurance control and security access. The locations where sources of ionizing radiation are held were visited, giving the opportunity to check the safety devices and warnings. The findings were clearly explained to the RSO, as well as the corrective actions expected by RPB at the end of the walk around. An exit meeting was carried out to brief the head of the facility on the findings and gaps identified. The non-compliances were reported as well as the time period given for implementation of corrective measures by the facility. The licensee was requested to sign the original copy of the summary inspection report which was then left with him. Finally, the RPOs explained the inspection follow up process.

Inspection of a nuclear medicine department

IRRS team members observed an inspection of the Nuclear Medicine Department at Kenyatta National Hospital in Nairobi.

At the start of the inspection, the lead inspector gave an overview of the role of RPB and the purpose of the inspection. The lead inspector did not use any form to guide the inspection. The inspection was conducted mainly by interviews along the visit of the department, reviewing documents and records when evidences were needed. In addition to the topics covered during the inspection of KEBS, the RPO reviewed the use of shielding devices, personal protective equipment, the staff's knowledge of good practices to avoid contamination issues and the management of waste. At the end of the inspection, the RPO informed the staff that the recommendations would be sent by letter and a follow up inspection would be carried out to assess the implementation of the required corrective actions.

Both inspections were performed by RPOs in a very professional manner. However, the comparison of the two inspections shows an inconsistency between inspections performed on the different facilities and between the different inspectors. The implementation of the procedures and the training of the inspector should improve the consistency of the regulatory control.

The IRRS team met with representatives of both licensees after the inspections. The IRRS team was advised that licensees recognized the authority of RPB, that the inspectors were considered to be competent and knowledgeable of the activities carried out by the licensees.

Both licensees pointed out that there was good engagement with RPB when the initial licence applications were being processed but that there had been little interaction since. Neither licensee had been inspected in many years.

In addition the licensees made reference to the lack of independence of RPB and the ineffective dissemination of information relating to the role of TSO, standards and criteria that licensees are expected to adhere to and the enactment of the new regulations.

7.4. INSPECTION OF TRANSPORT

RPB currently does not carry out any inspections of transport operations. The standard inspection checklist used for nuclear medicine department inspections does not contain any questions related to the transport of the technetium generators, which might flag the inspector to check documents related to transport. There is a draft checklist which does contain questions related to the transport but this checklist is currently not in use. This checklist asks explicitly whether the transport complies with the IAEA Regulations for the Safe Transport of Radioactive Material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB does not carry out routine inspections of transport related activities.	
(1)	**BASIS: GSR Part 1 Requirement 27 states that** *"The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory Requirements."*
R24	**Recommendation: RPB should extend the scope of its annual inspection programme to cover transport related activities.**

7.5. SUMMARY

RPB conducts planned and reactive, announced and unannounced, pre-authorization and routine inspections, in order to ensure that the authorized facilities and activities comply with the regulatory requirements. Although the established frequencies of inspection for each type of activity are consistent with a graded approach, they seem not to be actually achievable regarding the current available RPB's human resources. RPB currently has 18 qualified and trained inspectors in position, performing inspections in a professional manner and addressing relevant issues in accordance with the activity. The inspection procedure should be fully documented, regarding all types of activities, including radioactive waste management, and fully implemented by the inspectors, in order to improve the consistency of the regulatory control.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

RPB has been provided with the legal basis to carry out enforcement actions in accordance with a graded approach under the provisions of the Act.

RPB does not have a documented enforcement policy, though the IRRS team was provided with a draft version in advance of the mission. In the absence of an approved enforcement policy, there are no clear criteria as to when an enforcement action should be taken, the nature of that action or where the responsibility lies for taking the decision to commence the action.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB has not developed a documented policy on its enforcement activities.	
(1)	**BASIS: GSR Part 1 Requirement 30, states that** *"The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization."*
R25	**Recommendation: RPB should establish and implement an enforcement policy.**

Section 15 of the Act provides a legal basis for an applicant or licensee to make an appeal to the Minister for Health against the cancellation, suspension, or refusal to grant or renew a licence. However the Act does not provide for an appeal to be made against other RPB enforcement actions, such as those that may be made by an RPO in the exercise of the power provided under Section 14 (1) d of the Act. Recommendation 2 in Section 1.2 addresses this issue.

In 2000 the Board of RPB took a decision to arrange for paralegal training to be provided to all RPOs. This initiative is included in RPB's Scheme of Service for RPOs and provides for RPOs to spend one month at the Criminal Investigation Department of the National Police Service where they study for a Certificate in Investigation and Prosecution. RPOs who successfully obtain their Certificate are officially recognized as public prosecutors. An additional benefit of this training initiative is to broaden the RPOs awareness of enforcement activities to include topics such as forensics, the gathering of evidence, appearing as an expert witness in court and undertaking prosecutions. Since 2000, thirteen RPOs have been gazetted as public prosecutors and can initiate and carry out legal prosecutions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In 2000 RPB took a decision to arrange for training of RPOs on enforcement and prosecution. Thirteen inspectors have since been gazetted as public prosecutors.	
(1)	**BASIS: GSR Part 1 Requirement 31, para 4.55 states** *"Regulatory enforcement may also entail prosecution, especially in cases where the authorized does not cooperate satisfactorily in the remediation or resolution of the non-compliance"*
GP1	**Good Practice: The initiative taken by RPB to provide training on enforcement and**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	prosecution for its inspectors is recognized as a good practice

8.2. ENFORCEMENT IMPLEMENTATIONS

The IRRS team was informed that to date, RPB has successfully used its enforcement powers and has undertaken 82 enforcement actions comprising of one prosecution case, the imposition of 25 closure notices, 21 arrests and issued 35 warning letters.

The IRRS team was informed that RPB expects a licensee to provide written correspondence informing on the corrective action carried out to address the non-compliances. However, RPB does not acknowledge the licensee's correspondence nor does it confirm that it is satisfied with the actions taken.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB does not currently confirm that the licensee has effectively implemented any necessary corrective actions in response to its findings.	
(1)	**BASIS: GSR Part 1 Requirement 31, para 4.60 states that states *that*** *"Finally, the regulatory body shall confirm that the authorized party has effectively implemented any necessary corrective actions".*
R26	**Recommendation: RPB should make provisions to confirm that the authorized party has implemented any necessary corrective actions**.

Since there is no legal basis for RPB to regulate transport, no enforcement would be possible should transgressions be identified.

8.3. SUMMARY

The Act provides RPB with a legal basis to carry out enforcement actions in accordance with a graded approach and RPB has used its powers to take action in situations where non-compliances with its regulatory requirements were identified. However, as RPB does not have a documented enforcement policy, there are no clear criteria as to when an enforcement action should be taken, the nature of that action or where the responsibility lies for taking the decision to commence the action.

In 2000 RPB introduced an initiative in its Scheme of Service for RPOs whereby training on enforcement and prosecution is provided to RPOs in order to provide them with detailed understanding of legal matter associated with enforcement actions, allowing them to be formally recognized as public prosecutors.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

Section 18 of the Act provides for the Minister, in consultation with RPB, to make regulations to provide for a more robust regulatory protection framework in Kenya.

Two regulations are currently enacted:

- Radiation Protection (Standards) Regulations, LN 54/1986 dealing with dose limits to the workers, public and the medical exposure.
- Radiation Protection (Safety) Regulations, LN 160/2010 dealing with the safety of workers and sources.

To date, two guides have been published by RPB:

- Regulatory process for the registration and licensing of radiation workers,
- Regulatory process for setting up a radiation facility.

When looking to develop or review a regulation or a guide, RPB forms an ad hoc committee, engages stakeholders and submits its recommendations to the Board. No documented procedures have been developed which govern how these new regulations or guides are developed or existing ones reviewed.

A consultation process with interested parties is required under statutory instrument No 23 of 2013, whenever new regulations are developed. This instrument states that before making a regulation, the relevant authority shall make appropriate consultations with persons who are likely to be affected by the proposed regulation. The consultation shall involve notification, either directly or by advertisement of interested parties and invite submissions by a specified date or might invite participation in public hearings. There is no evidence that interested parties have ever been consulted during a regulation-making process.

The process to consult the stakeholders during the development of guidance documents is not formalized. In practice, RPB has consulted twice with interested parties to present and discuss the drafts:

- A meeting was set up in May 2015 to consult TSO/RSO on the framework of the EIS guide
- A letter was sent to the TSO to present the project of guide on Safety Assessment contents, following the introduction of new regulations in 2010.

The IRRS team was advised by licensees, during the witnessed inspections, that this process should be improved, as they were not included in these consultations and they were unaware of the implications arising from the enactment of the 2010 regulation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: No documented procedures have been developed which describe how new regulations or guides are developed or existing ones reviewed. No formal process exists for stakeholder consultation during the development of guides.	
(1)	**BASIS: GSR Part 1 Requirement 34, para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides, with account taken of internationally agreed standards and the feedback of relevant experience. Moreover, technological advances, research and development work, relevant operational lessons learned and institutional knowledge can be valuable and shall be used as appropriate in revising the regulations and guides."
R27	**Recommendation: RPB should establish and document a process for drafting and revising regulations and guides, which should include provisions for consultation with interested parties in the development of guides.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are currently no regulations in Kenya addressing the transport of radioactive material, the management of radioactive waste nor other topics listed in Section 18 of the Act.	
(1)	**BASIS: GSR Part 1, Requirement 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."*
(2)	**BASIS: GSR Part 5 Requirement 3, para. 3.7 states that** *"General requirements for the protection of human health and the environment are usually stated in national policy and set out in legislation. The regulatory body has to establish regulatory requirements specific to the predisposal management of radioactive waste, on the basis of national policy and legislation and with due regard to the objectives and principles set out in Section 2."*
R28	**Recommendation: RPB should establish and adopt regulations that systematically cover all types of practices, in particular the transport of radioactive material and the management of radioactive waste.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB has not produced sufficient guides to help applicants and licencees in understanding regulatory requirements.	
(1)	**BASIS: GSR Part 1 Requirement 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."*
R29	**Recommendation: RPB should publish guides that assist applicants and licensees to understand and comply with its regulatory requirements.**

9.2. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

According to both Section 11(1) of the Act, and Section 4 (1) of LN 160, it is prohibited to dispose of any radioactive material and operate or own a radioactive waste management facility without authorization from RPB. Whereas Section 18 of the Act provides for the Minister, in consultation with RPB, to make regulations, in particular for prescribing "methods of disposing of radioactive waste products from any source", no regulation has been promulgated relating to the radioactive waste management activities, although draft regulations have been in existence for many years.

To date, RPB has not published any guide that assists applicants and licensees to understand and comply with its regulatory requirements.

9.3. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

RPB has published a guide on the regulatory process for setting up a radiation facility which describes the general process applicants should follow when applying for an authorization. However no further guidance has been published that details the content of the information that must be submitted to support the licence application.

The second guide published by RPB addresses the radiation worker registration and licensing, setting out the list of documents which have to be submitted in support of the application.

RPB has not developed guides to assist applicants and licencees in understanding their regulatory obligations in relation to issues such as:

- The nature and content of documents which must support the application for a licence,
- The content of the safety assessment specific to various activities,
- The specific ICRP, IAEA or WHO guidelines it uses when assessing licence applications as provided for in Section 3 (3) of the Act,
- The roles, responsibilities and training requirement for the RSO,
- The role of the TSO is assisting applicants and licensee meet RPB's regulatory requirements,
- Medical exposure control.

9.4. REGULATIONS AND GUIDES FOR TRANSPORT

Although Section 18 of the Act confers upon the Minister, in consultation with the Board, the powers to make regulations to provide for a more robust regulatory protection framework in Kenya, to date no regulations have been made in relation to activities associated with the transport of radioactive material.

It was noted that there are no guides to assist holders in understanding their obligations with respect to the transport of radioactive material.

9.5. SUMMARY

While the Act provides for the Minister to make regulations to further strengthen the radiation protection framework in Kenya, to date only two regulations have been made. In particular, no regulations relating to the radioactive waste management activities and to the transport of radioactive material have been enacted.

RPB has published relatively few general guides to date. There is a need for RPB to publish guidance documents that systematically cover all types of regulated facilities and activities. RPB should establish a process to ensure that interested parties are consulted during the development of these guides.

10. EMERGENCY PREPAREDNESS AND RESPONSE – REGULATORY ASPECTS

10.1. GENERAL EPR REGULATORY REQUIREMENTS

Emergency management system

The Act established RPB within the Ministry of Health as the regulator, overseeing safety of radioactive material.

RPB has been designated by the Government of Kenya as the National Competent Authority (NCA) for emergency preparedness and response.

The emergency management system in Kenya is defined by the National Emergency Response Plan (NERP), adopted in June 2014.

Basic responsibilities in emergency preparedness and response

The Board is mandated by the Act to oversee the safety of radioactive materials and practices. However, emergency preparedness and response is not mentioned in the Act, although there is provision for the Board to enact regulations for emergency. During the licensing process, depending on the level of radiation risk, the Board may require the applicant to demonstrate capability for emergency response, but this is not a legal requirement. Currently there are no regulations on Emergency Preparedness and Response (EPR). Neither is any guidance given to the applicant on how to prepare these emergency plans and procedures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: As EPR is not mentioned in the Act, there is no mandate or legal provision for RPB to request the applicants and licensees to establish sufficient capabilities for EPR (plans, procedures, equipment staff training etc.).	
(1)	**BASIS: GSR Part 1, Requirement 8 states that** *"The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency."*
(2)	**BASIS: GSR Part 7, para 4.11 states that** *"The government shall ensure that arrangements for preparedness and response to a nuclear or radiological emergency for facilities and activities under the responsibility of the operating organization are dealt with through the regulatory process."*
R30	**Recommendation: The Government should amend its relevant legislative framework to include provision for RPB to develop and enforce its regulations related to emergency preparedness and response.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: There are neither regulations on emergency preparedness and response nor guidance

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
on how to prepare emergency plans and procedures.	
(1)	**BASIS: GSR Part 7, paragraph 4.12 states** *"The regulatory body is required to establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."*
(2)	**BASIS: GSR Part 7, paragraph 4.13 states** *"The regulatory body shall require that arrangements for preparedness and response for a nuclear or radiological emergency be in place for the on-site area for any regulated facility or activity that could necessitate emergency response actions. Appropriate emergency arrangements shall be established by the time the source is brought to the site, and complete emergency arrangements shall be in place before the commencement of operation of the facility or commencement of the activity. The regulatory body shall verify compliance with the required arrangements."*
R31	**Recommendation: RPB should develop regulations and guides on Emergency Preparedness and Response in compliance with GSR Part 7.**

Hazard assessment

Currently there are no regulatory requirements or guidance on hazard assessment as basis for EPR plans. However, RPB has trained a team of regulatory staff on these assessments so as to make the regulatory body an intelligent customer when requiring and guiding licensees on hazard assessment as the basis for their EPR Plans.

Protection strategy for an emergency

There is no protection strategy developed in the country for a radiological emergency. Protection strategy is a concept that has recently been introduced in the safety standards of the IAEA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no protection strategy developed in the country to address radiological emergencies.	
(1)	**BASIS: GSR Part 7, Requirement 5 states that** *"The government shall ensure that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency."*
R32	**Recommendation: The Government should ensure that an appropriate protection strategy is developed so that protective actions and other response actions are taken during a radiological emergency.**

10.2. FUNCTIONAL REGULATORY REQUIREMENTS

Identifying, notifying a nuclear or radiological emergency and activating an emergency response

RPB has sensitized licensees that they are responsible for emergency preparedness and initial response in their facilities. In addition, they are also responsible for notifying RPB in case of an emergency. RPB maintains a roster of duty officers for receiving these notifications; however, this is not in place 24/7.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB operates an on-call duty officer system to receive radiological emergency notifications; however, the system is not operational 24/7.	
(1)	**BASIS: GSR Part 7 para. 5.11 states that** *"The notification point(s) shall be maintained continuously available to receive any notification or request for support and to respond promptly or to initiate a pre-planned and coordinated off-site response."*
S8	**Suggestion: RPB should consider putting in place a system that allows it to respond to emergency notifications on a 24/7 basis.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no radiological emergency classification system to ensure that facilities and activities can categorize an emergency and initiate timely and appropriate response actions.	
(1)	**BASIS: GSR Part 7, para. 5.14 states that** *"The operating organization of a facility or activity in category I, II, III or IV shall make arrangements for promptly classifying, on the basis of the hazard assessment, a nuclear or radiological emergency warranting protective actions and other response actions to protect workers, emergency workers, members of the public and, as relevant, patients and helpers in an emergency, in accordance with the protection strategy."*
R33	**Recommendation: RPB should establish a system for classifying radiological emergencies.**

Taking mitigatory actions

In general, there are no regulations regarding the provision of off-site emergency services (like fire fighters, ambulance, law enforcement etc.) at the licensed facilities, therefore the operators have no proper planning and procedures for the use of these off-site emergency services. Recommendation 31 above addresses this issue.

Taking urgent protective action and other response actions

RPB may propose levels for public protection consistent with the IAEA safety standards in case of an emergency.

Providing instructions, warnings and relevant information to the public

While RPB is not the main responsible organization for providing instructions, warnings and relevant information to the public, it is assumed that RPB would be consulted in such matters in case of radiological incidents or emergencies.

Protecting emergency workers and helpers in an emergency

No provisions are in place regarding arrangements to implement emergency workers and helpers radiation protection while performing their functions. There are no regulatory provisions for managing, controlling and recording doses of first responders or other responders at the scene during a radiological emergency either.

Recommendation 35 and Suggestion 9 in Section 11.2 address these issues.

Managing the medical response in a nuclear or radiological emergency

The IRRS team was informed that regulating the medical emergency response capabilities is the responsibility of RPB, however, no specific arrangements or regulatory guidance is in place.

Other activities in emergency preparedness

There are a number of functional requirements in GSR Part 7 that are not properly addressed by RPB. The IRRS team considered that addressing these requirements during the upcoming revision of the regulatory system is important, and will, once completed, provide for full compliance with the current IAEA safety standards.

Regarding Requirement 17 of GSR Part 7 on 'requesting international assistance for preparedness and response' Kenya is not a signatory to the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency. However, RPB is the National Competent Authority–Domestic (NCA-D).

10.3. REGULATORY REQUIREMENTS FOR INFRASTRUCTURE

Authorities for emergency preparedness and response

Though emergency preparedness and response is not addressed in the Act, there is provision for RPB to enact regulations for emergency. Depending on the level of radiation risk, RPB may require the applicant to demonstrate capability for emergency response.

Organization and staffing for emergency preparedness and response

The Act provides that a licensee shall appoint an RSO within the facility. RPB verifies this requirement during the licensing process. The IRRS team was informed that the RSO is also responsible for EPR matters within the facility.

Logistical support and facilities for emergency response

There are national and county level response centres all over the country which are operated under the NDOC. These response centres do not have sufficient or adequate equipment for response to radiological emergencies. They mainly rely on the limited equipment available at RPB located in Nairobi and in six regional offices.

Training, drills and exercises for emergency preparedness and response

National Mass Casualty Drill and Exercise conducted on 18-22 April 2016 in Ukunda, Kwale Mombasa. The exercise, which was based on bio-chemical attack, created further knowledge among responders, test preparedness, response actions and recovery from mass casualty event among the National agencies and County authorities.

RPB organizes table top and field exercises, but not on a regular basis.

Quality management programme for emergency preparedness and response

RPB does not have regulations regarding quality assurance in EPR.

10.4. ROLE OF REGULATORY BODY DURING RESPONSE

RPB coordinates an 18-member national Committee whose Terms of Reference includes Emergency Preparedness and Response where RPB plays the role of coordinator. RPB is also a member of the National CBRN Initiative.

RPB supervises how licensees respond during an emergency at their installation, and coordinates such activities with response teams from relevant ministries/agencies, within the framework of the NERP and the future NREP.

10.5. SUMMARY

The legal mandate regarding emergency preparedness and response given to RPB is rather weak and the corresponding regulations are missing. The Government should amend its relevant legislative framework to provide sufficient mandate and legal authority for RPB to develop and enforce its regulations related to EPR. RPB should issue regulations and guidance for the operating organizations to ensure they develop appropriate arrangements for preparedness and response to a radiological emergency.

11. ADDITIONAL AREAS

11.1. CONTROL OF MEDICAL EXPOSURES

The legal basis for medical exposure control in Kenya is given by the Act and its implementing provisions issued as LN 54.

The Regulatory Body in Kenya for the control of radiation safety for medical exposures is the Radiation Protection Board (RPB).

In the current legislation there are limited provisions for the control of medical exposure. No regulations related to medical exposures are foreseen within the Act, except one for authorizing medical and dental practitioners to prescribe medical practices using radiation sources.

A definition of medical exposure is given in LN 54 and there is a clear statement that dose limits do not apply in medical exposure.

There are no guidelines for the control of medical exposure. In the Act, there is the statement that the documents issued by IAEA, ICRP and WHO could be accepted as such. Recommendation 29 in Section 9 addresses this issue.

Responsibilities of the Regulatory Body

There are no clear requirements regarding the responsibility of the government or the regulatory body specific to medical exposure. Practically, RPB entrusts the control of the medical exposure to the practitioners.

Responsibilities of registrants and licensees

The practitioners should be registered in their respective medical societies and then licensed by RPB.

The personnel of medical facilities should adhere to the basic principles of radiation protection.

There are no requirements for the medical staff education, training and competence in radiation protection. An RSO shall be appointed in the medical facilities. The IRRS team was informed that the specialties recognized by RPB for this role are radiologist, medical physicist or radiographer.

Justification of medical exposure

In the Act, there is a statement for the justification: "every medical practice should be prescribed by a licenced practitioner". There are no provisions for issuing referral criteria and the implementation of the justification principle is not controlled.

Optimization of medical exposure

In the Act, there is a reference to the optimization principle as a duty of the license holder. There are no requirements on the dosimetry of patients. Diagnostic reference levels (DRL) as well as dose constraints for carers or comforters or volunteers participating in programmes for biomedical research are not foreseen by the regulations. The regulations do not foresee the cooperation of a medical physicist when optimizing the exposure to the patient or calibration of the sources of ionizing radiation. There are a few medical physicists in Kenya; they are educated abroad because of the lack of educational programme in Kenya.

Release of patients

There are no regulatory provisions for release of patients after radionuclide therapy.

Pregnant and breast feeding women

There are no regulatory provisions for pregnant or breast feeding female patients.

Review and records

There are no regulatory provisions for review and records.

Unintended medical exposures

There are no regulatory provisions in the current regulations for unintended and accidental medical exposures.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The current regulations on protection and safety for medical exposure do not adequately address the requirements of GSR Part 3 including the implementation of diagnostic reference levels and dose constraints for carers and comforters or volunteers participating in programmes of biomedical research, the medical staff education, training and competence in radiation protection, the provisions for pregnant or breast feeding female patients, the dosimetry of patients, the release of patients after radionuclide therapy, the unintended and accidental medical exposures, the review and records. The principle of justification is not implemented.	
(1)	***BASIS: GSR Part 3 Requirement 34 states that*** *"The government shall ensure that relevant parties are authorized to assume their roles and responsibilities, and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established."*
(2)	**BASIS: GSR Part 3 Requirement 35 states that** *"The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they fulfil the requirements for education, training and competence in the relevant specialty. "*
(3)	**BASIS: GSR Part 3 Requirement 37 states that** *"Relevant parties shall ensure that medical exposures are justified."*
(4)	**BASIS: GSR Part 3 Requirement 38 states that** *"Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure."*
(5)	**BASIS: GSR Part 3 Para. 2.15 states that** *"The government shall ensure, as part of the esponsibilities 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. 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."*
(6)	**BASIS: GSR Part 3 Requirement 39 states that** *"Pregnant or breast-feeding female patients Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(7)	**BASIS: GSR Part 3 Requirement 40 states that** *"Registrants and licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy."*
(8)	**BASIS: GSR Part 3 Requirement 41 states that** *"Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures."* *Registrants and licensees shall promptly investigate unintended or accidental medical exposures and, if appropriate, shall implement corrective actions."*
(9)	**BASIS: GSR Part 3 Requirement 42 states that** *"Reviews and records Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained."*
R34	**Recommendation: RPB should revise the regulations on radiation safety for medical exposure to ensure compliance with IAEA Safety Standards GSR Part 3.**

11.2. OCCUPATIONAL RADIATION PROTECTION

Legal and regulatory framework

The legal and regulatory framework in the occupational radiation protection area consists of the Act, LN 54 and LN 160.

The Act provides requirements on the duties of licensees and owners of a facility concerning occupational exposure. It also provides for the appointment and duties of the RSO. Moreover, it calls for regulations on:

- *"the precautions to be taken to prevent injury being caused by ionizing radiation to the health of persons employed in places where irradiating devices or radioactive materials are manufactured, produced, treated, stored, or used, or of other persons likely to be exposed to harmful radiation and on the precautions to be taken to prevent injury being caused by ionizing radiation to the health of persons employed in places where irradiating devices or radioactive materials are manufactured, produced, treated, stored, or used, or of other persons likely to be exposed to harmful radiation*
- *the maximum working hours of persons employed in the manufacture, production, treatment, storage or use of irradiating devices or radioactive materials, regulating the employment of those persons, the maximum holidays to be taken by such persons and the medical examination of those persons."*

However, these regulations have not been published yet. Recommendation 28 in Section 9 addresses this issue.

LN 54 provides, regarding occupational exposure:

- dose equivalent limits for radiation workers, for students in educational institutions and for teaching staff and technicians in the education institutions;

- annual limit of intake of radionuclides for radiation workers ;
- dose limits for the pregnant women and the fœtus.

All these limits are not in line with the current international standards, regarding both the concept and the numerical values.

LN 54 requires workers involved in emergency operations to be informed by the owner of the involved radiation facility about the nature of the risks and must consent to such exposures before undertaking the special operations. There are no requirements to control, manage and record the doses of emergency workers.

LN 160 applies to the safety of radiation sources and workers and provides requirements on the use of radiation sources, the classification of areas, the radiation facilities and the warning signs.

There are no requirements for the protection of workers in the NORM industry. There are no requirements for the protection of workers against exposure to radon at workplaces or exposure of aircrew due to cosmic radiation.

There are a number of areas in which RPB is yet to adopt GSR Part 3. Several of these deviations from the international standards were identified by RPB in the ARM, especially concerning LN 54 which has to be reviewed, updated and completed.

A recommendation to RPB to review, update and complete the current regulations is given at the end of the Section.

General responsibilities of registrants, licensees and employers

The regulations define and assign the responsibilities for the protection of workers to the employers. Every employer shall ensure that protection and safety is optimized and that the dose limits for occupational exposure are not exceeded.

The regulations require also that the licensee uses dose constraints in the optimization of radiation protection and ensures that radiation doses for exposed workers, apprentice, students and members of the public do not exceed the prescribed limits.

The regulations require the owner of a facility to appoint an RSO who shall ensure that workers are monitored, provided with protective equipment and given proper instructions on radiation safety measures, and receive a medical check-up. The RSO shall ensure that exposure records are kept. No records of the medical check-up are kept.

General Responsibilities of workers

Radiation workers shall be licensed : An application form for registration and/or licensing of radiation workers (GK LRP4) as well as a guide for the Regulatory Process for the registration and licensing of radiation workers have been published by RPB.

The current regulations do not attribute responsibilities to the workers for protection and safety. Consultation between employer and workers or their representatives in the area of protection and safety is not clearly covered by the regulations.

A recommendation to RPB to complete the current regulations is given at the end of the Section.

Requirements for radiation protection programmes

Requirements on :

- implementing relevant areas of workplaces as controlled or supervised areas,

- providing workers with suitable and adequate personal protective equipment,
- making arrangements for assessing the occupational exposure of workers,
- making arrangements for health surveillance of the exposed workers,
- maintaining a programme for workplace monitoring,
- occupational exposure of women of reproductive capacity.

are provided by LN 54 but have to be revised to be in line with the current international standards.

The regulations require the owner of a facility to appoint an RSO. There are no criteria on a minimum qualification for appointing the RSO. The RSO shall ensure that:

- "all persons using or working in the facility are supplied with at least one monitoring device and any other protective accessories necessary to carry out radiation procedures with the lowest reasonably achievable risk;
- all radiation workers employed within the facility are given proper instructions on radiation safety measures and receive a check-up after every six months;
- proper care is taken of radioactive wastes if they appear in the course of the use of radiation sources as described in the code of practice for protection of persons exposed to ionizing radiation and that the wastes are only disposed of in accordance with the licence granted for that purpose;
- exposure records are kept as prescribed in the code of practice for users of ionizing radiation."

The regulations do not mention explicitly that the conditions of service of workers have to be independent of whether they are or could be subject to occupational exposure and that no compensatory arrangements or preferential considerations can exist.

A recommendation to RPB to review, update and complete the current regulations is given at the end of the Section.

Monitoring programmes and technical services

Individual external dosimetry

Since 2010, four private companies in Kenya provide individual external dosimetry services to licensees. These companies are registered and certified once a year by RPB. Licensees receive a report of individual dosimetry results of the monitored radiation workers which shall be kept and shown to the inspectors on request.

Individual internal dosimetry

No internal dosimetry is performed in Kenya, while activities such as nuclear medicine can cause internal contamination of the workers. There is no agreement with a laboratory outside the country. Suggestion to the Government of Kenya to establish internal exposure monitoring services is given in Section 1.9.

There is no biological dosimetry laboratory in Kenya, nor is there an agreement with a laboratory outside the country.

National Dose Register

Dosimetry services send the dose reports on individual external dosimetry to RPB which keeps them for 30 years. These dose reports are currently paper based. There is no computer based national dose registry. The advantages of an electronic registry include facilitating:

- keeping track of occupational doses;
- inspection optimization;
- dose optimization, and
- evaluating and reporting on the national radiation protection status.

Once a computer based dose registy is established, historical dose data should be input into it. The IRRS team was informed that RPB is currently developing such a national dose registry.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: RPB receives the dose reports for monitored workers as paper records and maintains a paper based national dose registry.	
(1)	**BASIS: GSR Part 3 para. 3.73 (e) states that** *"The regulatory body shall be responsible, as appropriate, for provision for maintaining exposure records and results of the assessment of doses from occupational exposure."*
S9	**Suggestion: RPB should consider establishing a computerized national registry of occupational dose records.**

Calibration services

There are no requirements in the regulations on the calibration and the maintenance of the radiation monitoring devices. A Secondary Standards Dosimetry Laboratory (SSDL) is operated by the Kenya Bureau of Standards (KEBS). The SSDL calibrates dose rate meters for gamma radiation and produces dosimeter calibration curves for the dosimetry service providers.

Training services and staff training and re-training

There is no requirement for training and re-training of radiation workers or RSOs in the current regulations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The current regulations on occupational radiation protection do not adequately address all the requirements of GSR Part 3 including the dose limits, the responsibilities of the workers, the conditions of service, the training of the radiation workers, the exposure of emergency workers, the exposure of aircrew, the criteria for appointing and training the RSO.	
(1)	**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."*
(2)	**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."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSR Part 3 Requirement 22 states that** *"Workers shall fulfil their obligations and carry out their duties for protection and safety."*
(4)	**BASIS: GSR Part 3 Para. 5.30 states that** *"The regulatory body or other relevant authority shall determine whether assessment of the exposure of aircrew due to cosmic radiation is warranted."*
(5)	**BASIS: GSR Part 3 Requirement 45 states that** *"The government shall establish a programme for managing, controlling and recording the doses received in an emergency by emergency workers."*
(6)	**BASIS: GSR Part 3 para. 2.22 states that** *"The government shall ensure that arrangements are in place for the provision of the education and training services required for building and maintaining the competence of persons and organizations that have responsibilities relating to protection and safety."*
R35	**Recommendation: RPB should revise the occupational radiation protection regulations to ensure compliance with IAEA Safety Standards GSR Part 3.**

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

The Act and LN54 and LN160 have very few requirements on control of radioactive discharges, materials for clearance, existing exposure situations and environmental monitoring.

11.3.1. MATERIAL FOR CLEARANCE

Some authorized parties, such as nuclear medicine departments, research laboratories, and university/ educational institutions, environmental laboratories etc, might have situations where certain radioactive material and objects might not require further regulatory control because they fall under the general criteria for Clearance. However, the Act does not provide for such situations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no process for the clearance from regulatory control of licenced material and items.	
(1)	**BASIS: GSR Part 1 Requirement 2 Para 2.5 (17) states that** *"The government shall promulgate laws and status to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following: (17) The criteria for release from regulatory control. "*
(2)	**BASIS: GSR PART 3 Requirement 8 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*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	criteria for exemption specified in Schedule I or any exemption levels specified by the regulatory body on the basis of these criteria."
R36	**Recommendation: RPB should establish clearance levels on the basis of the criteria specified in schedule-I of GSR Part 3 and ensure their implementation.**

11.3.2. DOSE LIMITS FOR THE PUBLIC

LN 54 specifies the dose limits for the public as follows "Dose equivalent limits for individual members of the public shall in all cases be one tenth of those for radiation workers set under Regulation 4. The Regulation 4 prescribes the equivalent dose limits to worker as 50mSv in one year.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The dose limit for the public is not consistent with GSR Part 3.	
(1)	**BASIS: GSR Part 3 Requirement 12 states that** *"The government or the regulatory body shall establish dose limits for public exposure, and registrants and licensees shall apply these limits."*
R37	**Recommendation: RPB should revise the public dose limits to comply with the GSR Part 3.**

11.3.3. RESPONSIBILITIES OF GOVERNMENT AND REGULATORY BODY FOR PUBLIC EXPOSURE

The Act provides an overall regulatory framework for the protection of the public from the dangers arising from the use of devices or material capable of producing ionizing radiation and for connected purposes. However,

a) RPB has not established any authorized limits for radioactive discharges (presently required for the nuclear medicine centres or research laboratories). Because of this, long lived wastes are currently being stored at the sites of research laboratories.

b) There are no criteria for assessing public exposure when safety assessments are carried out.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Though an overall regulatory framework for protection of the public exists as provided by the Act, a) No authorized limits for discharges are specified by RPB b) No operational limits and conditions relating to public exposure are specified. c) There is no reference to optimization or establishment of dose/ risk constraints for public protection.	
(1)	**BASIS: GSR Part 3 Requirement 29 *states that*** *"The government or the regulatory body shall establish the responsibilities of relevant parties that are specific to public*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	exposure, shall establish and enforce requirements for optimization, and shall establish, and the regulatory body shall enforce compliance with, dose limits for public exposure."
R38	**Recommendation: RPB should establish dose/risk constraints to be used by licensees to ensure the optimization of protection and safety for members of the public.**
R39	**Recommendation: RPB should establish operational limits and conditions relating to public exposure and authorized limits for discharges of wastes.**

11.3.4. MONITORING AND REPORTING

The Act does not provide for environmental monitoring or source monitoring

A guidance document on the aspects covering Environmental Impact Assessment is available. This document does not indicate the Radiological Impact Assessment or environmental monitoring programmes, but rather the format of submission of Environmental Impact Assessment report.

There are however attempts to carry out environmental monitoring as RPB has procured certain IAEA standards for environmental sampling. RPB has also procured instrumentation for measurement of low levels of radioactivity, though the IRRS team was informed that they are not currently functional.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is presently no appropriate environmental monitoring and source monitoring programme in place in Kenya.	
(1)	**BASIS: GSR Part 3 Requirement 32 states that** "*The regulatory body and relevant parties shall ensure that programmes for source monitoring and environmental monitoring are in place and that the results from the monitoring are recorded and are made available.*"
R40	**Recommendation: RPB should ensure that appropriate programmes for environmental monitoring and source monitoring are in place and that results from the monitoring are recorded and are made available.**

11.3.5. CONSUMER PRODUCTS

The only reference to consumer products appears in the third schedule of LN 160. This reference appears to address what is generally called commodities. Therefore there are no provisions for regulations of consumer products.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no provision for regulation of consumer products.	
(1)	**BASIS: GSR Part 3 Requirement 33 Para 3.139 states that** *"Upon receipt of a request for authorization to provide consumer products to the public, the regulatory body:* *(a) Shall require the provider of the consumer product to provide documents to demonstrate compliance with the requirements in paras 3.138–3.144;* *(b) Shall verify the assessments and the selection of parameters presented in the request for authorization;* *(c) Shall determine whether the end use of the consumer product can be exempted;* *(d) Shall authorize the provision to the public of the consumer product, where appropriate, subject to specific conditions of authorization."*
R41	**Recommendation: RPB should provide for the regulation of consumer products.**

11.3.6. EXISTING EXPOSURE SITUATIONS

As per the ARM, there are no facilities involved in extraction or processing of radioactive material in the country. However, the ARM states that there are facilities involved with mining of rare earth metals and mineral sand, which have elevated levels of natural radioactivity above the background level. No studies of these mining activities have been or are planned to be conducted**.**

A study on the natural radiation levels in Olkaria Geo-thermal area was carried out in 1999.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Comprehensive studies have not been carried out to identify existing exposure situations in the country.	
(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 3 Requirement 47 states that** "*The government shall ensure that existing exposure situations that have been identified are evaluated to determine which occupational exposures and public exposures are of concern from the point of view of radiation protection*."
(3)	**BASIS: GSR Part 3 Requirement 47, Para 5.2. states that** *"The government shall ensure that, when an existing exposure situation is identified, responsibilities for protection and safety are assigned and appropriate reference levels are established."*
(4)	**BASIS: GSR Part 3 Requirement 47 , Para 5.3. states that** *"The government shall include in the legal and regulatory framework for protection and safety (see Section 2) provision for the management of existing exposure situations. The government, in the legal and regulatory framework, as appropriate."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R42	**Recommendation: The government should ensure that existing exposure situations are identified and regulated.**

11.3.7. RADON

In 1999, the effective dose for indoor radon activity in dwellings has been estimated as 0.09mSv/year due to radon gas only and 1.87 mSv/yr due to short lived radon decay products.

The IRRS team was informed that more insight on Radon levels is expected in the future, as a research project on the subject, is underway.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There is no information available on indoor levels of radon to allow policy decisions to be made.	
(1)	**BASIS: GSR Part 3 Requirement 50 states that** "*The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors.*"
R43	**Recommendation: The Government should provide information on levels of radon indoors and the associated health risks and, if appropriate, should establish and implement an action plan for controlling public exposure due to radon indoors.**

11.3.8. COMMODITIES

There are no provisions for the regulation of commodities. Schedule three of LN 160 allows for TSOs to conduct radio analysis of commodities. The IRRS team was informed that when TSOs conducts such analysis, they deliver a certificate of non-contamination without specifying the reference levels used.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no provisions for the regulation of commodities and no established reference levels. The certificates issued by the TSOs to the client on the radionuclide analysis, do not include the reference levels used.	
(1)	**BASIS: GSR Part 3 Requirement 51 states that** "*The regulatory body or other relevant authority shall establish reference levels for exposure due to radionuclides in commodities.*"
R44	**Recommendation: RPB should establish reference levels for exposure due to radionuclides in commodities.**
S10	**Suggestion: RPB should consider instructing the TSOs to include reference levels established by RPB in the certificate of analysis provided to the clients.**

11.4. SUMMARY

The legislative and regulatory framework of Kenya in the field of radiation safety for the patient, the workers and the public is in place. However there are a number of discrepancies with respect to the requirements of GSR Part 3 for medical, occupational, and public exposure control. The legislative and regulatory framework requires further work to develop, review and approve the required regulations, instructions and guidance. The framework should be brought in line with the IAEA GSR Part 3 requirements.

12. INTERFACE WITH NUCLEAR SECURITY

12.1. LEGAL BASIS

There are no legal provisions for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material. However, the Act has been amended to include representatives of the Kenya Defence Forces, the Kenya Police Services, the National Intelligence Services and the Kenya Revenue Authority on to the Radiation Protection Board, to improve the coordination of RPB with the competent authorities.

The Government should amend the legislation to ensure that adequate arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material including oversight and enforcement and integration of emergency response arrangements for safety related and nuclear security related incidents. Recommendation 2 in Section 1.2 addresses this issue.

12.2. REGULATORY OVERSIGHT ACTIVITIES

There are no regulatory oversight activities related to the interface of safety with nuclear security in all the core regulatory activities of review and assessment, authorization, inspection and enforcement. The various forms used by RPB for authorization and the inspection checklists do not include nuclear security considerations or requirements. However the IRRS team noted that RPOs discussed the security matters during the two inspections witnessed. RPBs Committees NSSC and LTAC have responsibilities that span the area of regulatory oversight.

Physical security upgrades for facilities with category 1 and 2 radioactive sources were done through cooperation with the Department of Energy of the United States Government. Sustainability of the physical security systems is the responsibility of the facility owners.

RPB is awaiting the promulgation of the Nuclear and Radiation Safety Bill to implement the regulatory oversight on nuclear security fully in line with the GSR Part 1 requirements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: There are no regulatory oversight activities related to the interface of safety with nuclear security in all the core regulatory activities of review and assessment, authorization, inspection and enforcement.	
(1)	**BASIS: GSR Part 1 Requirement 12 para. 2.39 states that** *"Specific responsibilities within the governmental and legal framework shall include:* *(a) Assessment of the configuration of facilities and activities for the optimization of safety, with factors relating to nuclear security and to the system of accounting for, and control of, nuclear material being taken into account;* *(b) Oversight and enforcement to maintain arrangements for safety, nuclear security and the system of accounting for, and control of, nuclear material;* *(c) Liaison with law enforcement agencies, as appropriate;* *(d) Integration of emergency response arrangements for safety related and nuclear security related incidents."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 1 Requirement 12 para. 2.40 states that** "*Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that nuclear security measures do not compromise safety and safety measures do not compromise nuclear security.*"
R45	**Recommendation: RPB should ensure safety measures and nuclear security measures are designed and implemented in an integrated manner.**

12.3. INTERFACE AMONG AUTHORITIES

RPB has a Nuclear Security and Safeguards Committee that is responsible for coordinating nuclear security initiatives and collaboration with partners and international organizations.

The Kenya Nuclear Security Coordination Center (KNSCC) was established in 2012 under RPB. The main aim of the center is to assess nuclear security threats in the country, as well as coordinate and sustain a nuclear security regime.

The KNSCC comprises of eighteen stakeholders that are:

1) Kenya Revenue Authority (KRA)
2) Kenya Nuclear Electricity Board (KNEB)
3) National Commission for Science, Technology and Innovations (NACOSTI)
4) University of Nairobi
5) Kenya Medical Research Institute (KEMRI)
6) Anti-Terrorism Police Unit (ATPU)
7) Kenya Industrial Research and Development Authority (KIRDI)
8) Kenyatta National Hospital (KNH)
9) Institute of Nuclear Science and Technology
10) Criminal Investigation Directorate
11) Kenya Airport Authority
12) National Intelligence Service
13) Kenya Defence Forces
14) National Disaster Operation Centre
15) National Environment Management Authority
16) Regional Disaster Management Center of Excellence (RDM-CoE)
17) Ministry of Interior and Coordination of National Government
18) Radiation Protection Board

Stakeholders meet regularly under the chairmanship of the Ministry of Interior and Coordination of National Government. KNSCC has the following responsibilities:

- Coordinate activities related to nuclear security in the country.
- Encourage and coordinate networking of nuclear security experts and stakeholders;
- Identifying, coordinating and strengthening national risk mitigation capacities and post-accident recovery strategies associated with radioactive materials;

- Liaise with development partners in nuclear security matters such as IAEA, USA-NRC, USA-DOE, EU-CBRN Risk Mitigation Centres of Excellence Initiative, among others and drawing up MoUs where applicable;
- Maintain a register of radioactive sources and materials under IAEA category I, II & III and
- Any other function as directed by the Radiation Protection Board.

The KNSCC is the liaison organ on matters of Radiological & Nuclear within the initiative of European Union , Chemical Biological Radiological and Nuclear (CBRN) Centre of Excellence (CoE). The CoE was established in Nairobi, and covers the Eastern and Central African (ECA) Region. It forms one of the four subcommittees of the CoE in Kenya. Others are: Chemical Safety & Security; Biological Safety & Security; and Strategic Trade Control subcommittees. Through the EU initiative, Kenya has finalized a National Response Plan for responding to unauthorized events involving CBRN materials. Also, there has been capacity building and raising awareness for identifying and responding to threats from CBRN materials. A National CBRN Action Plan for Kenya based on need assessment is currently being developed.

12.4. SUMMARY

The Government has put in place mechanisms for coordination and cooperation of authorities having responsibilities for nuclear safety and security through the incorporation of security agencies into RPB and the formation the National Nuclear Security Committee.

APPENDIX 1 LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS			
1.	Javier ZARZUELA	Consejo de Seguridad Nuclear - Nuclear Safety Council (CSN) SPAIN	jzj@csn.es
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3.	Paul HINRICHSEN	National Nuclear Regulator (NNR) SOUTH AFRICA	phinrich@nnr.co.za
4.	Claire LETZELTER	Autorité de Sûreté Nucléaire FRANCE	claire.letzelter@asn.fr
5.	Marie-line PERRIN	Senior Expert FRANCE	marie-line.perrin@wanadoo.fr
6.	Reward SEVERA	Radiation Protection Authority of ZIMBABWE	rsevera@rpaz.co.zw
7.	Shantha THENUWARA	Sri Lanka Atomic Energy Regulatory Council (SLAERC) SRI LANKA	ssthenuwara@aerc.gov.lk
8.	Anuradha VANGALA	Atomic Energy Regulatory Board (AERB) INDIA	vanuradha@aerb.gov.in
9.	Peter ZOMBORI	Senior Expert HUNGARY	petezombori@gmail.com
IAEA STAFF MEMBERS			
1.	Hilaire MANSOUX	Division of Radiation Transport and Waste Safety	H.Mansoux@iaea.org
2.	Vasiliki KAMENOPOULOU	Division of Radiation Transport and Waste Safety	V.Kamenopoulou@iaea.org
3.	Zumi SWOBODA	Division of Radiation Transport and Waste Safety	Z.Swoboda@iaea.org
LIAISON OFFICERS			
1.	Arthur KOTENG	Radiation Protection Board Ministry of Health	aokoteng@gmail.com

APPENDIX II MISSION PROGRAMME

IRRS MISSION PROGRAMME		
Sunday 10 July		
IRRS Initial IRRS Review Team Meeting		
13:30 - 17:30	Opening remarks by the IRRS Team Leader (Javier Zarzuela) Introduction by IAEA Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (TL, IAEA) First impression from team members arising from the Advanced Reference Material (ARM) (all team members): Presentations Administrative arrangements (RPB, IRRS Liaison Officer, IAEA): Detailed Mission Programme	Venue: RPB Board Room Participants: the IRRS Team + the Liaison Officer (LO)
Monday 11 July 2016		
IRRS Entrance Meeting		
09:00 – 12.00	09:00 Arrival, registration, 09:30 Mr Gatebe Gatika, Chairman of the Board – Welcoming Address 09:45 IRRS Team Leader – Expectations for the Mission and introduction of the IRRS Team Introduction of the Main Counterparts from RPB 10:30Coffee 11:00 RPB presentation – Regulatory Overview, SARIS results (strength, challenges, action plan)	Venue Afya House Annexe Conference Room Participants: High Level Government Official, RPB Management and staff, Official from relevant organizations, the IRRS Team + the LO
12:00 – 13:00	Lunch	
13:00 – 17:00	Interviews and Discussions with Counterparts (parallel discussions)	Venue: RPB offices Participants: IRRS Team and Counterparts
17:00 - 18:00	Daily IRRS team meeting	Venue: RPB Board room Participants: the IRRS Team + the LO

IRRS MISSION PROGRAMME		
Tuesday 12 July 2016		
Daily Discussions / Interviews		
09:00 – 17:00	Interviews and discussions with counterparts (parallel discussions)	Venue: RPB offices Participants: IRRS Team and Counterparts
12:00 – 13:00	Lunch	
14:30 – 16:30	Visit Ministries(TL, TC, Reviewer Modules 1,2 and 3)	NACOSTI / NLO / MOFA & IT
17:00 – 18:00	Daily IRRS team meeting	Venue: RPB Board room Participants: the IRRS Team + the LO
Wednesday 13 July 2016		
Daily Discussions / Interviews		
08:00 –18:00	Site visits(medical: KENYATTA NATIONAL HOSPITAL, industrial: – KENYA BUREAU OF STANDARDS)	IRRS Experts and RPB Inspectors
09:00 – 12:00	Follow-up interviews and discussions with counterparts for all modules	Venue: RPB offices Participants: IRRS Team and Counterparts
12:00 – 13:00	Lunch	
13:00 – 17:00	Report preparation , first draft of preliminary findings (Recommendations, Suggestions, Good Practice)	Venue: RPB Board room Participants: The IRRS Team
17:00 – 18:00	Daily IRRS team meeting	Venue: RPB Board room Participants: the IRRS Team + the LO
Thursday 14 July 2016		
Daily Discussions / Interviews		
09:00 – 12:00	Follow-up Interviews and discussions with counterparts	Venue: RPB offices Participants: IRRS Team and Counterparts
13:00 – 17:00	Report preparation , final draft of findings (Recommendations, Suggestions, Good Practices)	The IRRS Team
17:00 – 18:00	Daily IRRS team meeting: recommendation, suggestions and good practices	Venue: RPB Board room Participants: the IRRS Team + the LO

IRRS MISSION PROGRAMME		
Friday 15 July 2016		
09:00 – 17:00	Team members write draft report.	Venue: RPB Board Room Participants: The IRRS Team
14:00 – 15:00	Policy issue discussion.	Afya House Annexe Conference Room Participants : the IRRS Team, Counterparts, DG NACOSTI / PS HEALTH / NLO
15:00 – 18:00	Report preparation, finalize text and discuss it with Counterpart per module	Venue: RPB Board Room Participants: The IRRS Team
Saturday, 16 July 2016		
Daily Discussions/ Interviews (if needed)		
09:00 – 18:00	Cross reading and finalizing the report text	Venue: RPB Board Room Participants: The IRRS Team
18:00	Draft report submitted to RPB for comments	The IRRS Team
Sunday 17 July 2016		
Daily Discussions		
09:00 – 18:00	IRRS Team rest day and social event	Nairobi National Park / Bomas Of Kenya
Monday 18 July 2016		
Daily Discussions		
09:00 – 12:00	RPB review the draft	
18:00	RPB summits comments to IRRS Team	
Tuesday 19 July 2016		
09:00 - 10	IRRS team review RPB comments	Venue: RPB Board Room Participants: The IRRS

IRRS MISSION PROGRAMME		
		Team
10:00 – 17:00	Report finalization by the team and handover the report to RPB.	Venue:Hotel Participants: The IRRS Team
19:00 – 21:00		Farewell Dinner (IRRS & RPB)
Wednesday 20 July 2016		
09:00 – 11:00	IRRS Exit meeting Main findings of the IRRS mission (Team Leader) Remarks by RPB in response to the Mission findings IAEA Official (Director NSRW) Closing	Venue: Afya House Conference Room Participants: Government Officials, RPB Management and staff, the IRRS Team + the LO
	Press conference and Publication of the IAEA press release	

(1) NACOSTI – National Committee for Science, Technology & Innovation (Ministry of Education)

- Also serves as the AFRA coordinator

(2) MOFA & IT – Ministry of Foreign Affairs & International Trade

(3) NLO – IAEA National Liaison Office

APPENDIX III SITE VISITS

1. KENYATTA NATIONAL HOSPITAL
2. KENYA BUREAU OF STANDARDS

APPENDIX IV LIST OF COUNTERPARTS

IRRS EXPERTS	COUNTERPART
RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	
Javier Zarzuela Reward Severa Shantha Thenuwara Vasiliki Kamenopoulou	Joseph Maina James Keter Edward Mayaka Isaac Waweru
GLOBAL SAFETY REGIME	
Javier Zarzuela Reward Severa Shantha Thenuwara Vasiliki Kamenopoulou	Joseph Maina James Keter Edward Mayaka Isaac Waweru
RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	
Javier Zarzuela Reward Severa Shantha Thenuwara Vasiliki Kamenopoulou	Joseph Maina James Keter Edward Mayaka Isaac Waweru
MANAGEMENT SYSTEM	
Javier Zarzuela Reward Severa Shantha Thenuwara Vasiliki Kamenopoulou	Joseph Maina James Keter Edward Mayaka Isaac Waweru
AUTHORIZATION	
Claire Letzelter Stephen Fennell Paul Hirichsen	Eric Ngotho John Opar Peter Kagiri
REVIEW AND ASSESSMENT	
Claire Letzelter Stephen Fennell Paul Hirichsen	Eric Ngotho John Opar Peter Kagiri

IRRS EXPERTS	COUNTERPART
INSPECTION	
Claire Letzelter Stephen Fennell Paul Hirichsen	Eric Ngotho John Opar Peter Kagiri
ENFORCEMENT	
Claire Letzelter Stephen Fennell Paul Hirichsen	Joseph Maina Eric Ngotho John Opar
REGULATIONS AND GUIDES	
Claire Letzelter Stephen Fennell Paul Hirichsen	Joseph Maina Eric Ngotho John Opar
EMERGENCY PREPAREDESS AND RESPONSE	
Peter Zombori	Beth Kaboro
ADDITIONAL AREAS - Medical Exposure	
Marie-Line Perrin Vasiliki Kamenopoulou	Alice Karigi
ADDITIONAL AREAS - Occupational Exposure	
Marie-Line Perrin	Alice Karigi
ADDITIONAL AREAS **Environmental monitoring associated with authorized practices for public radiation protection purposes, Control of chronic exposure remediation**	
Anuradha Vangala	Edward Mayaka Beth Kaboro
MODULE 12 INTERFACE WITH NUCLEAR SECURITY	

IRRS EXPERTS	COUNTERPART
Reward Severa	Alice Karigi

APPENDIX VRECOMMENDATIONS, 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 whose implementation should follow a graded approach.
		R2	The Government should revise the legal and regulatory framework to include all the relevant safety provisions of GSR Part 1.
		R3	The Government should ensure separation of RPB from entities having responsibilities or interests that could unduly influence its decision-making.
		R4	The Government should revise the legislation and assign the prime responsibility for safety to the authorized parties and ensure that the responsibility covers all stages in the lifetime of the activity/facility.
		R5	The Government should make provision for effective coordination and liaison between RPB and other authorities having responsibilities for safety.
		R6	The Government should establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources and contamination from past activities or events, and develop a legal safety framework for existing exposure situations.
		R7	The Government should develop and implement a national policy and strategy on the management of radioactive waste and disused

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			radioactive sources, including regulatory provisions.
		R8	The Government should revise the legal and regulatory framework for radiation safety with regard to building and maintaining the necessary competencies for all parties having responsibilities in relation to the safety of facilities and activities.
		S1	The Government should consider establishing internal dosimetry services.
		S2	RPB should consider revising and strengthening the legal basis for the certification of TSOs.
2.	**GLOBAL SAFETY REGIME**	S3	The Government should consider becoming party to the Convention on Nuclear Safety, the Convention on Early Notification of a Nuclear Accident, the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management and expressing political commitment to the Code of Conduct on the Safety and Security of Radioactive Sources and its Supplementary Guidance on the Import and Export of Radioactive Sources.
		R9	RPB should establish arrangements to receive, analyse, disseminate and implement the lessons learned from operating and regulatory experience.
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	S4	RPB should consider revising its structure and should consider allocating resources commensurate with the radiation risks associated with facilities and activities in accordance with a graded approach.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R10	RPB should ensure that it takes decisions in a manner which does not compromise its independence. It should put in place mechanisms to prevent conflicts of interest in all of its regulatory activities.
		R11	RPB should carry out a human resources needs analysis, making use of an objective and scientific methodology, and develop and implement a human resources plan and associated staff training programme to ensure the discharge of its regulatory functions in an effective and efficient manner.
		S5	RPB should consider fostering effective formal and informal mechanisms of communication with authorized parties.
		R12	RPB should develop and implement policies and procedures to ensure that the regulatory control of facilities and activities is consistent and stable.
		S6	RPB should consider developing and implementing a records management policy to ensure that it adequately maintains all the records necessary to account for the safe operation of facilities and the safe conduct of activities.
		R13	RPB should adopt appropriate means for informing and consulting with interested parties and the public.
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**	R14	RPB should establish and implement an integrated management system consistent with the IAEA safety standards.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
5.	**AUTHORIZATION**	S7	RPB should consider adopting the concept of exemption in its graded approach to authorization.
		R15	RPB should explicitly state the requirement that all licence applications must be supported by a documented safety assessment.
		R16	RPB should ensure all irradiating devices and radioactive sources throughout Kenya are appropriately authorized and that authorizations cover the management of radioactive waste generated at licensees' facilities.
		R17	RPB should ensure that all radioactive waste management activities are properly licensed, based upon a review and assessment, in accordance with the provisions of the Act.
		R18	RPB should refrain from imposing responsibilities upon the TSO within the conditions of transport authorization issued to the consignor.
6.	**REVIEW AND ASSESSMENT**	R19	RPB should record the results and decisions arising from reviews and assessment of applications.
7.	**INSPECTION**	R20	RPB should develop and implement an achievable annual inspection programme in accordance with a graded approach.
		R21	RPB should revise its "inspector's manual" to include all pre-inspection, inspection and post-inspection activities.
		R22	RPB should formally approve the "inspector's manual" and ensure that all inspectors follow the procedures contained therein.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R23	RPB should ensure that inspectors have the legal authority to access any facility at any time.
		R24	RPB should extend the scope of its annual inspection programme to cover transport related activities.
8.	**ENFORCEMENT**	R25	RPB should establish and implement an enforcement policy.
		GP1	The initiative taken by RPB to provide training on enforcement and prosecution for its inspectors is recognized as a good practice
		R26	RPB should make provisions to confirm that the authorized party has implemented any necessary corrective actions.
9.	**REGULATION AND GUIDES**	R27	RPB should establish and document a process for drafting and revising regulations and guides, which should include provisions for consultation with interested parties in the development of guides.
		R28	RPB should establish and adopt regulations that systematically cover all types of practices, in particular the transport of radioactive material and the management of radioactive waste.
		R29	RPB should publish guides that assist applicants and licensees to understand and comply with its regulatory requirements.
10.	**EMERGENCY PREPAREDNESS AND RESPONSE**	R30	The Government should amend its relevant legislative framework to include provision for RPB to develop and enforce its regulations related to emergency preparedness and response.

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
		R31	RPB should develop regulations and guides on Emergency Preparedness and Response in compliance with GSR Part 7.
		R32	The Government should ensure that an appropriate protection strategy is developed so that protective actions and other response actions are taken during a radiological emergency.
		S8	RPB should consider putting in place a system that allows it to respond to emergency notifications on a 24/7 basis.
		R33	RPB should establish a system for classifying radiological emergencies.
11.1	**CONTROL OF MEDICAL EXPOSURES**	R34	RPB should revise the regulations on radiation safety for medical exposure to ensure compliance with IAEA Safety Standards GSR Part 3.
11.2	**OCCUPTIONAL RADIATION PROTECTION**	S9	RPB should consider establishing a computerized national registry of occupational dose records.
		R35	RPB should revise the occupational radiation protection regulations to ensure compliance with IAEA Safety Standards GSR Part 3.
11.3	**CONTROL OF RADIOACTIVE DISCHARGES, MATERIAL FOR CLEARANCE, AND EXISTING EXPOSURES SITUATIONS; ENVIRONMENTAL MONITORING FOR PUBLIC RADIATION PROTECTION**	R36	RPB should establish clearance levels on the basis of the criteria specified in schedule-I of GSR Part 3 and ensure their implementation.
		R37	RPB should revise the public dose limits to comply with the GSR Part 3.
		R38	RPB should establish dose/risk constraints to be used by licensees to

Area		R: Recommendations S: Suggestions G: Good Practices	Recommendations, Suggestions or Good Practices
			ensure the optimization of protection and safety for members of the public.
		R39	RPB should establish operational limits and conditions relating to public exposure and authorized limits for discharges of wastes.
		R40	RPB should ensure that appropriate programmes for environmental monitoring and source monitoring are in place and that results from the monitoring are recorded and are made available.
		R41	RPB should provide for the regulation of consumer products.
		R42	The government should ensure that existing exposure situations are identified and regulated.
		R43	The Government should provide information on levels of radon indoors and the associated health risks and, if appropriate, should establish and implement an action plan for controlling public exposure due to radon indoors.
		R44	RPB should establish reference levels for exposure due to radionuclides in commodities.
		S10	RPB should consider instructing the TSOs to include reference levels established by RPB in the certificate of analysis provided to the clients.
12.	**INTERFACE WITH NUCLEAR SECURITY**	R45	RPB should ensure safety measures and nuclear security measures are designed and implemented in an integrated manner.

APPENDIX VI REFERENCE MATERIAL USED FOR THE REVIEW

1.	Guidance Document On Enviromental Impact Assessment Jan 2016 Version.pdf
2.	Inspection Protocol for a diagnostic x-ray facility.pdf
3.	Inspection Protocol for a nuclear medicine facility.pdf
4.	Inspection Protocol for a radiotherapy facility.pdf
5.	Inspection Protocol for a veterinary x-ray facility.pdf
6.	Inspection Protocol for dealers of irradiating devices radioactive materials.pdf
7.	Inspection Protocol for education and research facility.pdf
8.	Inspection Protocol for fixed nuclear gauge facility.pdf
9.	Inspection Protocol for industrial radiography facility.pdf
10.	IRRS ARM Module 10 with Conclusions.docx
11.	IRRS ARM Summary Template for Kenya FEB 2016.docx
12.	IRRS SELF ANALYSIS TEAM 2016.docx
13.	Kenya Radiation Protection Board Self-Assessment - Action Plan.pdf
14.	Kenya Radiation Protection Board Self-Assessment.pdf
15.	Kenya's status on various treaties and convetions.pdf
16.	Nuclear and Radiation Safety Bill 2014 Draft1.pdf
17.	Radiation Protection Act Cap 243, Revised in 2014.pdf
18.	Radiation Protection Board Strategic Plan 2012-2016.pdf
19.	Radioactive Waste Management Policy In The Republic Kenya Sept 2013.Pdf
20.	Regulatory Process for Setting up a Radiation Facility.pdf

21.	Regulatory Process for the Registration and Licensing of a Radiation Workers.pdf
22.	RPB 2015-2016 Performance Contract Rev 06.08.15.docx
23.	RPB ADVERT-2015_2016.pdf RPB Business Process Document - 2015.pdf
24.	Scheme of Service for Radiation Protection Officers April, 2004.pdf
25.	Staff Performance Appraisal Form - B.pdf
26.	Staff Performance Appraisal Form.pdf
27.	Statutory Instruments Act No.23 of 2013.pdf
28.	Subsidiary Legislations_
29.	Legal Notices 54 and 160.pdf
30.	DRAFT II RADIOACTIVE WASTE MANAGEMENT REGULATIONS 2013.pdf
31.	Draft Regulations for the Safe Transport of Radioactive Materials Version 0 Jan 2016.pdf
32.	Gazetted Prosecutors.pdf
33.	Form GKLRP 1.pdf application for registration and licence to deal/ import / form export/transport irradiating device or radioactive material*
34.	Form GKLRP 2.pdf application for registration and/or licence to possess or use
35.	Irradiating device/radioactive material
36.	Form GKLRP 3.pdf application for disposal of an irradiating device/
37.	Radioactive material/waste
38.	Form GKLRP 4.pdf application for registration and/or licensing of radiation workers
39.	Form GKLRP 5.pdf application for registration and/or certification of service provider
40.	Form GKLRP 6.pdf application for registration/licensing/certification for any other purpose*

APPENDIX VII IAEA REFERENCE MATERIAL USED FOR THE REVIEW

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

19. 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)

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

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

22. 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)

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

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

APPENDIX VIII ORGANIZATIONAL CHART