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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

REPUBLIC OF KENYA

Radiation Protection Board (RPB)

Nairobi, Kenya

22 to 26 October 2007

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE

IRRS

Under the terms of Article III of its statute, the International Atomic Energy Agency (IAEA) has the mandate to establish or adopt, in consultation and, where appropriate, in collaboration with competent organizations, standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards to its own operations as well as to assisted operations and, at the request of the parties, to operations under bilateral or multilateral arrangements or, at the request of a State, to any of that State's activities concerning peaceful nuclear and radiation activities. This includes the publication of a set of Safety Standards, whose effective implementation is essential for ensuring a high level of safety. As part of its providing for the application of safety standards, the IAEA provides Safety Review and Appraisal Services, at the request of Member States, which are directly based on its Safety Standards.

In the regulatory framework and activities of the regulatory bodies, the IAEA has been offering, for many years, several peer review and appraisal services. These include: (a) the International Regulatory Review Team (IRRT) programme that provides advice and assistance to Member States to strengthen and enhance the effectiveness of their legal and governmental infrastructure for nuclear safety; (b) the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) that assesses the effectiveness of the national regulatory infrastructure for radiation safety including the safety and security of radioactive sources; (c) the Transport Safety Appraisal Service (TranSAS) that appraises the implementation of the IAEA's Transport Regulations; and (d) the Emergency Preparedness Review (EPREV) that is conducted to review both preparedness in the case of nuclear accidents and radiological emergencies and the appropriate legislation.

The IAEA recognized that these services and appraisals had many areas in common, particularly concerning the requirements on a State to establish a comprehensive regulatory framework within its legal and governmental infrastructure and on a State's regulatory activities. Consequently, the IAEA's Department of Nuclear Safety and Security has developed an integrated approach to the conduct of missions on legal and governmental infrastructure to improve their efficiency, effectiveness and consistency and to provide greater flexibility in defining the scope of the review, taking into account the regulatory technical and policy issues.

The new IAEA peer review and appraisal service is called the Integrated Regulatory Review Service (IRRS). The IRRS is intended to strengthen and enhance the effectiveness of the State's regulatory infrastructure in nuclear, radiation, radioactive waste and transport safety, whilst recognizing the ultimate responsibility of each State to ensure the safety of nuclear facilities, the protection against ionizing radiation, the safety and security of radioactive sources, the safe management of radioactive waste, and the safe transport of radioactive material. The IRRS is carried out by comparisons against IAEA regulatory safety standards with consideration of regulatory technical and policy issues.

The new regulatory service is structured in modules that cover general requirements for the establishment an effective regulatory framework, regulatory activities and management systems for the regulation and control in nuclear safety, radiation safety, waste safety, transport safety, emergency preparedness and response and security. The aim is to make the IAEA services more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs

and priorities of the Member State. The IRRS is neither an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national regulatory body, considering the regulatory technical and policy issues, and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

a balance between technical and policy discussions among senior regulators;
sharing of regulatory experiences;
harmonization of the regulatory approaches among Member States; and
mutual learning opportunities among regulators.

Regulatory technical and policy discussions that are conducted during IRRS missions take into account the newly identified issues coming from the self-assessment made by the host organization, visits to installations to observe inspections and interviews with the counterparts.

Other legally non-binding instruments can also be included upon request of the Member States, such as the Code of Conduct (CoC) on the Safety and Security of Radioactive Sources, which was adopted by the IAEA Board of Governors in 2004 and for which more than 85 Member States have written to the Director General of the IAEA committing themselves to implementing its guidance, and the Code of Conduct on the Safety of Research Reactors, which was adopted by the IAEA Board of Governors in 2005.

The IRRS concept was developed at the IAEA Department of Nuclear Safety and Security and then discussed at the 3rd review meeting of the Contracting Parties of the Convention on Nuclear Safety in 2005. The meeting acknowledged the importance of the IAEA regulatory peer reviews now recognized as a good opportunity to exchange professional experience and to share lessons learned and good practices. The self-assessment performed prior to the IAEA peer review mission is an opportunity for Member States to assess their regulatory practices against the IAEA safety standards. These IAEA peer review benefits were further discussed at the International Conference on 'Effective Nuclear Regulatory Systems' in Moscow in 2006, at which note was taken of the value of IRRS support for the development of the global nuclear safety regime, by providing for the sharing of good regulatory practices and policies for the development and harmonization of safety standards, and by supporting the application of the continuous improvement process. All findings coming from the Convention on Nuclear Safety review meetings and from the Moscow conference are inputs for the IRRS to consider when reviewing the regulatory technical and policy issues.

In addition, the results of the IRRS missions will also be used as effective feedback for the improvement of existing safety standards and guidance and the development of new ones, and to establish a knowledge base in the context of an integrated safety approach. Through the IRRS, the IAEA assists its Member States in strengthening an effective and sustainable national regulatory infrastructure thus contributing towards achieving a strong and effective global nuclear safety and security regime.

The Global Nuclear Safety Regime has emerged over the last ten years, with international legal instruments such as safety Conventions and Codes of Conduct and significant work towards a suite of harmonized and internationally accepted IAEA safety standards. The IAEA will continue to support the promotion of the safety Conventions and Codes of Conduct, as well as the application of the IAEA safety standards in order to prevent serious accidents and continuously improve global levels of safety.

With regard to the IRRS, the Director General of the IAEA, Dr Mohamed El Baradei, has stated that; 'The General Conference Resolution of September 2006 related to measures to strengthen international cooperation in nuclear, radiation and transport safety and waste management: "recognizes the importance of an effective regulatory body as an essential element of national nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat's new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS".

At his opening speech of the fiftieth regular session of the General Conference in 2006, the Director General stated that; "The Agency's safety review services use the IAEA Safety Standards as a reference point, and play an important part in evaluating their effectiveness. This year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS). This new service combines a number of previous services, on topics ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security. The IRRS approach considers international regulatory issues and trends, and provides a balance between technical and policy discussions among senior regulators, to harmonize regulatory approaches and create mutual learning opportunities among regulators".

In his introductory statement to the IAEA Board of Governors on 5th March 2007, the Director General said; "The newly established Integrated Regulatory Review Service (IRRS) is intended to help Member States enhance their legislative and regulatory infrastructures, and to harmonize regulatory approaches in all areas of safety. It will also be one of the most effective feedback tools on the application of Agency standards. The first full scope IRRS was conducted last year in France".

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

THE GOVERNMENT OF THE REPUBLIC OF KENYA

RADIATION PROTECTION BOARD (RPB)

Nairobi, Kenya

22 to 26 October 2007

REPORT

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

Mission date: 22 to 26 October 2007

Regulatory body: RPB (Radiation Protection Board)

Location: Nairobi, Kenya

Regulated facilities and activities: medical, industrial and research applications

Organized by: IAEA

IAEA Review Team:

BAILEY, Ed	(USA ,Team Leader)
FENNELL, Stephen	(Ireland , Reviewer)
ZAKARAUSKIENE, Irma	(Lithuania , Reviewer)
HEINBERG, Cynthia	(IAEA/NSRW, Team Coordinator)

IAEA-2007 07
Issue date: December 2008

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

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EXECUTIVE SUMMARY

At the request of the Chief Radiation Protection Officer of the Radiation Protection Board (RPB), an international team of four experts in radiation safety visited the Radiation Protection Board (RPB) from 22 to 26 October 2007 to conduct an Integrated Regulatory Review Service (IRRS) mission to review the Kenya's regulatory framework and its effectiveness. RPB is the regulatory body responsible for radiation protection and safety in relation to activities involving radiation sources and radiation facilities in Kenya.

The purpose of this IRRS mission was to conduct a review of Kenya's regulatory framework and the regulatory activities in all regulated areas including sources, facilities and activities, to review its regulatory effectiveness and to exchange information and experience in the areas considered by the IRRS. It is expected that the IRRS mission will facilitate regulatory improvements in Kenya and throughout the world from the knowledge gained and experiences shared by RPB and the IRRS reviewers through the evaluation of the effectiveness of the regulatory framework.

The scope of the mission included sources, facilities and activities regulated by RPB: medical activities, industrial and research activities, and safety of radioactive sources.

The significance of the IRRS mission for RPB is increased by the revision of the legislative and regulatory framework currently conducted by the management of RPB. The objectives of this revision are:

- to improve the national radiation safety regulatory infrastructure,
- to ensure, to the largest extent possible, its compliance with international standards,
- to implement the regulatory activities assigned to RPB.

The IRRS Review Team consisted of senior regulatory experts from three Member States and one staff member from the IAEA. The IRRS team carried out the review of RPB in all relevant areas: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; activities of the regulatory body, including the authorization process, review and assessment, inspection and enforcement and the development of regulations and guides, safety of radioactive sources, the management system and information management.

From a series of intensive interviews and discussions with key personnel at RPB, review of documentation provided during the course of the mission and two site visits, the team presented its findings based on the IAEA safety standards. Additionally, the IRRS team, together with RPB, discussed some policy issues relating to the regulation of radiation safety. The results of the discussions will serve as a useful basis for the evolution of future IRRS missions and will assist with continuous improvement in the regulation of radiation safety.

The IRRS Review Team noted the significant effort made by RPB in the preparation of the mission. The IRRS Review Team made recommendations and suggestions that indicate where improvements are necessary or desirable to further enhance the legal and governmental infrastructure for radiation and safety and improve effectiveness of regulatory controls. These recommendations and suggestions are made to an organization that is seeking to improve its performance and some of them are related to areas in which RPB has already initiated a programme for change. In addition, the IRRS Review Team has identified an example of good practice that the RPB has undertaken. The IRRS Review Team believes that consideration of the following items should be given high

priority because the experts considered that they will contribute significantly to the enhancement of the overall performance of the regulatory system:

- On an urgent basis the RPB should adopt a plan and schedule to revise its regulations and guides to be compatible with currently accepted standards for radiation safety regulations and guides. This schedule should place priority on the development of regulations based on the risks associated with the practice. It is suggested in developing revised regulations and guides that Kenya seeks the cooperation and assistance from other international organizations (such as IAEA) and governmental bodies that have state of the art radiation control regulations and guides. The Minister of Health should give high priority and urgency to approving the proposed regulations.
- The Government of Kenya should review and revise the Radiation Protection Act to ensure that is consistent with international standards.
- The Government of Kenya should bring the new planned central radioactive waste management facility into operation.
- The RPB needs to develop formal written procedures for all of its regulatory activities including authorization and inspection.

The review team also identified an example of good practice that could be shared with regulatory bodies in other countries. The RPB has developed a Scheme of Service for Radiation Protection Officers, which clearly describes the recruitment, hiring, promotion and professional development of all Radiation Protection Officers in the RPB. In producing this document the RPB has demonstrated its commitment to continuous staff training and development thereby ensuring the highest professional standards of the staff of the RPB which would be to the benefit of all citizens of Kenya.

A summary of the recommendations, suggestions and identified good practices is provided in Appendix V.

There was a strong consensus among the IRRS Review Team that the RPB and IAEA Member States have been improving the regulation of radiation safety through IAEA regulatory review missions and services.

I. INTRODUCTION

At the request of the Chief Radiation Safety Officer of the Radiation Protection Board (RPB), an IAEA team consisting of three experts from Member States and one staff member from the IAEA visited the RPB from 22 to 26 October 2007 to conduct an Integrated Regulatory Review Service (IRRS)[1] .

The purpose of the mission was to conduct a review of the Kenya regulatory framework and the regulatory activities, to review the regulatory effectiveness of RPB and to exchange information and experience in the areas considered by IRRS. The areas reviewed were: legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment; inspection and enforcement; the development of regulations and guides; safety of radioactive sources; the management system and information management.

In addition, the regulatory technical and policy issues considered in this review provide a greater understanding of the regulatory issues that may have international implications and assist in addressing specific technical issues relevant to the regulation of radiation safety.

During the mission, RPB made available a collection of reference material for the team to review. This material consisted of legal and regulatory documents. During the mission the team performed a systematic review of all topics using this reference material, interviews with RPB and direct observation of their working practices.

IRRS activities took place mainly at the RPB headquarters, Nairobi. Two site visits took place at the Kenyatta National Hospital and the Ministry of Roads and Public Works (see Appendix III).

[1] This mission was initially organized with the Radiation Safety and Security Infrastructure Appraisal (RaSSIA) protocol, and later converted using the IRRS Guidelines, but without changing its scope.

II. OBJECTIVE AND SCOPE

The purpose of the mission was to conduct an IRRS mission to review the Kenyan legal and governmental infrastructure for radiation safety and the effectiveness of the Kenyan regulatory body (RPB) and to exchange information and experience between the RPB and the IRRS team with a view to contributing to harmonizing regulatory approaches and creating mutual learning opportunities among regulators.

The key objectives of this mission were to enhance radiation safety by:

- ✓ Providing Kenya (RPB and governmental authorities) with a review of its radiation safety regulatory technical and policy issues;
- ✓ Providing Kenya (RPB and governmental authorities) with an objective evaluation of their radiation safety regulatory activities with respect to international safety standards;
- ✓ Contributing to the harmonization of regulatory approaches among Member States;
- ✓ Promoting sharing of experience and exchange of lessons learnt;
- ✓ Providing key staff in Kenya (RPB and governmental authorities) with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- ✓ Providing Kenya (RPB and governmental authorities) with recommendations and suggestions for improvement;
- ✓ Providing other States with information regarding good practices identified in the course of the review;
- ✓ Providing reviewers from States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field; and
- ✓ Providing Kenya through completion of the IRRS questionnaire with an opportunity for self-assessment of its activities against international safety standards.

The scope requested by Kenya for this IRRS mission was:

- Radiation safety in medical, industrial and research activities;
- Safety of radioactive sources;
- Management system; and
- Information management.

III. BASIS FOR THE REVIEW

A) Preparatory work and IRRS Review Team

The preparatory work for the mission was carried out by the IAEA Team Coordinator Cynthia Heinberg, NSRW/IAEA. According to the IRRS guidelines, the IRRS Team Leader, Mr. Ed Bailey, belongs to an IAEA Member. In accordance with the request from the RPB, and taking into account the scope as indicated above, it was agreed that the IAEA review team would comprise three external experts and one staff member (see Appendix I).

The details and organizational aspects were defined with Mr. Joel Kamande, the RPB Chief Radiation Protection Officer (CRPO) and Mr. Arthur Koteng of the RPB.

A significant amount of work was carried out by the reviewers and by the IAEA staff in the evenings in order to prepare the draft report about the status of regulatory infrastructure in Kenya, to prepare for the interviews and direct observations at the sites, and to identify additional relevant material necessary to review during the mission.

A team briefing was conducted on 21 October 2007 to discuss the specifics of the mission, to clarify the basis for the review, background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers.

B) References for the Review

The main reference documents provided by the RPB for the review mission are listed in Appendix VI. The most relevant IAEA safety standards and other reference documents used for the review are listed in Appendix VII.

C) Conduct of the Review

During the mission, a systematic review was conducted for all the review areas with the objective of providing the RPB with recommendations and suggestions as well as of identifying good practices. The review was conducted through meetings, interviews and discussions with the RPB, visits to relevant organizations, assessment of the reference material, and direct observations regarding the national practices and activities, particularly in the context of inspections.

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

The entrance meeting was held on Monday, 22 October 2007 with the participation of RPB senior management. Opening remarks were made by the CRPO of the RPB, the IRRS Team Leader and the IAEA Team Coordinator.

The exit meeting was held on Friday, 26 October 2007 with the CRPO and senior regulatory staff of the RPB. The main conclusions were presented by the Team. The draft mission report was handed over to RPB at the end of the meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

Policy Issues

Independence of the regulatory body

Background:

Although increasing numbers of States have effective independent regulators, the issue of independence is still a challenge.

Key elements:

- Legislation establishes effectively independent regulatory body
- Access to independent resources and technical advice
- Funding independence
- Balance between the Operators and Regulators responsibilities

Discussion:

The IRRS review team introduced this topic by giving an example of how, in some countries, the independence of the regulatory authority may occasionally come under pressure from external influences such as persons/organizations involved in the promotion of nuclear applications.

The CRPO advised that in Kenya, the RPB would not be liable to come under such pressure as it is not responsible for the promotion of nuclear technology. In Kenya this function would come under the remit of both the National Council for Science and Technology (NCST), which is responsible for the promotion of technology, and the Society for the Promotion of Nuclear Technology (SPNA), which aims to promote nuclear applications. The RPB in its capacity as a regulatory body works closely with NCST, which is the national organization responsible for IAEA matters.

In any consideration of the independence of a regulatory body it is essential to evaluate whether this independence is effective. For instance, a regulatory authority, which is under the office of the president, was cited as an example where such independence is not effective in practice. In this case, the president of the country holds the office of the chairman of the regulatory body, but owing to the pressures of other work, is not able to devote sufficient time to the regulatory body. Overall, CRPO believes that the RPB is independent and that this independence can be demonstrated by, for example, the fact that the Board is able to initiate enforcement actions without having to obtain authorization from its parent department and by having its own budget line and associated Authority to Incur Expenditure (AIE). The RPB also allows for a certain degree of independence for its licensed facilities (licensees). This can be best demonstrated by considering the requirement that each licensee must appoint a suitably qualified person to perform the duties of a Radiation Safety Officer (RSO). Once appointed this person must fulfil certain responsibilities and plays a vital role in dictating whether safety is ensured or not within the facility.

Legislative and statutory framework

GS-R-1 § 2.2 (1)

The legislative and regulatory framework for the safety of facilities and activities is established through the Radiation Protection Act, Chapter 243 (1985) [hereafter Act].

The Act and regulatory framework are currently being revised for updating and addition of several aspects to bring the Kenyan law into compliance and compatibility with current international standards, principles, and terminology. Many of these aspects will be addressed in later portions of this report. This draft legislative is currently at the stakeholder review phase of the legislative adoption process.

The Scope and Section 8 of the Act clearly state that radiation from machine sources and radioactive materials are subject to the Act. The Act contains no exclusions, but Sections 3 and 18(j) provide certain exemptions.

Establishment of an effectively independent regulatory body

GS-R-1 § 2.2 (2)

The Act in Section 5 establishes a single regulatory body in the Radiation Protection Board (Board) which is not subordinate to any other governmental body. The Board has the power to establish committees. The Board has membership from a number of named Ministries and is chaired by the Ministry of Health.

Regulatory body - assigned responsibilities, authority, and resources

GS-R-1 § 2.2 (3)

The responsibility for authorization, regulatory review and assessment, inspection and enforcement and for establishing safety principles, criteria, regulations and guides is vested in the Board by Section 7 of the Act as follows:

Authorization

The Board is empowered to grant or refuse to grant or to extend licences issued under the Act and to impose any necessary conditions on a licence so granted (Section 7(c)).

Regulatory Review and Assessment

The CRPO and all Radiation Protection Officers (RPO, Staff from RPB) are empowered to make such examinations and enquiries as may be necessary to ascertain whether the provisions of the Act are being complied with (Section 14.1(c)).

Inspection

The CRPO or RPO is empowered to inspect and examine any premises or any part thereof, booth, motor vehicle, vessel, aircraft or any other vehicle in or upon which he has reasonable cause to believe that an irradiating device, radioactive material or any other source of ionizing radiation is stored, used, transported or disposed of (Section 14.1(a)).

Enforcement

The Act provides for enforcement authority in Sections 16 and 17 and includes the provision that the CRPO or RPO is authorized to institute proceedings and may appear and prosecute in those proceedings.

Establishing regulations, safety principles, criteria and guides

The Minister may, in consultation with the Board, make regulations (Article 18).

GS-R-1 § 2.2 (4)

Funding comes directly from the Government and fees which are specifically budgeted through the Ministry of Health. The Government funds personnel salaries and benefits. Monies collected from fees are used for management and operations. These funding mechanisms ensure that adequate funding is provided to adequately staff the RPB so it may discharge its assigned responsibilities.

GS-R-1 § 2.2 (6)

Although not currently in place, funding is available and work is under way to establish a central waste management facility to be located on a ten acre site that the Board has recently been provided.

GS-R-1 § 2.2 (7)

Although there are no regulations or formal written memoranda of understanding with other governmental organizations to arrange for the safe transport of radioactive material, the Board presently works in coordination with Customs and the Kenyan Police to ensure the safe transport of these materials. The Board has begun the development of comprehensive transport regulations. In addition, the Board has been providing training courses to the staffs of Customs and Kenyan Police.

GS-R-1 § 2.2 (8)

An effective system of governmental emergency response is in place through the National Disaster Coordination Centre.

Operator responsibility

GS-R-1 § 2.3

The Act, Section 12(1) places the primary responsibility for the safe use, operation, waste management, and transport of sources of radiation on the holder of the licence.

Legislative requirements

GS-R-1 § 2.4

The Act provides for the effective control of radiation safety in the following areas:

- sets out objectives for protecting the public and radiation workers from radiation hazards;
- specifies facilities, activities and material that are included in the scope of the legislation and nothing is excluded;
- establishes authorization and notification and exemption, but does not have a graded approach;
- establishes a regulatory body but does not address all the provisions specified in GS-R-1;
- provides for adequate funding of the regulatory body;
- establishes a procedure for review of, and appeal against, regulatory decisions;
- defines what is an offence and the corresponding penalties.

However, it is not fully compliant with GS-R-1 since the following requirements are not properly addressed:

- process for removal of a facility or activity from regulatory control;
- implementation of any obligations under international treaties, conventions or agreements;
- involvement of the public and other bodies in the regulatory process.

Authority of the Regulatory Body

GS-R-1 § 2.6 (1)-(14)

Under the Act, the regulatory body has the authority to:

- establish regulations and issue guidance (Sections 7(b) and 18);
- require any operator to conduct a safety appraisal, although the legislation is broad rather than explicit with respect to safety appraisals (Section 14.1(c));
- require that any operator provide it with any necessary information (Section 14.1(c));
- issue, amend, suspend or revoke authorizations and to set conditions (Section 11);
- require an operator to perform a periodic systematic safety review, although the legislation is broad rather than explicit (Section 14.1(c));
- enter a site or facility at any time to carry out an inspection (Section 14.1(a));
- enforce regulatory requirements (Section 17);
- advise the Minister when such communication is considered to be necessary for effectively exercising the functions of the RPB (Section 7(a));
- obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate although the legislation is broad rather than explicit (Section 14.1(c)).

The Act does not give the RPB the authority to:

- develop safety principles and criteria;
- independently communicate its regulatory requirements, decisions and opinions and their basis to the public, although in practice the RPB communicates regulatory requirements; dissemination of information on decisions and opinions needs Ministerial approval;
- make available, to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate;
- liaise and coordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods, although in practice the RPB works with Kenya Police and Customs on issues involving illicit trafficking;
- liaise with regulatory bodies of other countries and with international organizations to promote cooperation and the exchange of regulatory information.

The draft Radiation Protection Act provides for a regulatory body with the authority to:

- develop regulations and guidance which are issued by the Minister (Section 48);
- require that any operator provide it with any necessary information (Sections 33.1(c),(g));
- issue, amend, suspend or revoke authorizations and to set conditions (Sections 5(c), 29.5);
- enter a site or facility at any time to carry out an inspection (Section 31.1(a));
- enforce regulatory requirements (Sections 33.1(d), 35, 37);
- advise the Minister on all matters relating to radiation safety (Section 5(a));
- make such examinations and enquiries as may be necessary to ascertain whether the provisions of the Act are being complied with (Section 33.1(g));
- provide guidelines and support such measures as may be necessary for the protection of the public in a radiological or nuclear emergency (Section 5(i)) and publish reports on radiological emergency occurrences in consultation with the relevant authority on emergency response (Section 46.3);

- enhance cooperation and coordination between the Government, and other stakeholders involved in the implementation of the provisions of the Act (Section 5(d));
- facilitate national and international programmes, research and training in radiation safety (Section 5(f)).

However, the draft Radiation Protection Act does not give the regulatory body the authority to:

- develop safety principles and criteria;
- require any operator to conduct a safety appraisal;
- require an operator to perform a periodic systematic safety review;
- independently communicate its regulatory requirements, decisions and opinions and their basis to the public.

CONCLUSIONS	
(1)	**BASIS:** GS-R-1 §2.2(1) states: *"A legislative and statutory framework shall be established to regulate the safety of facilities and activities."*
C1	**Conclusion:** The legislation was adopted in 1984 and revised in 1985. This law predates GS-R-1 and as a consequence it is not fully consistent with current international standards.
(1)	**BASIS:** GS-R-1 §2.2 (2) states: *"A regulatory body shall be established and maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities."*
C2	**Conclusion:** The present law establishes a single regulatory body for radiation safety.
(1)	**BASIS:** GS-R-1 §2.3 states: *"The prime responsibility for safety shall be assigned to the operator."*
C3	**Conclusion:** The present law assigns the prime responsibility for radiation safety to the operator, which is consistent with GS-R-1.
(1)	**BASIS:** GS-R-1 §2.2(6) states: *"Adequate infrastructural arrangements shall be made for decommissioning, close-out or closure, site rehabilitation, and the safe management of spent fuel and radioactive waste."*
(2)	**BASIS:** GS-R-1 §6.10 states: *"Government shall ensure that adequate arrangements are made for the safe storage and disposal of radioactive waste."*
C4	**Conclusion:** The current arrangements for handling radioactive waste are not sufficient to address long-term needs for managing radioactive waste and disused and orphan sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R1** §2.2
R1	**Recommendation:** The Government of Kenya should review and revise the Radiation Protection Act to ensure that is consistent with international standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R1** §2.2(6) states: *"Adequate infrastructural arrangements shall be made for decommissioning, close-out or closure, site rehabilitation, and the safe management of spent fuel and radioactive waste."*
(2)	**BASIS:** GS-R-1 §6.10 states: *"Government shall ensure that adequate arrangements are made for the safe storage and disposal of radioactive waste."*
R2	**Recommendation:** The Government of Kenya should bring the new planned central radioactive waste management facility into operation.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Regulatory body - fulfilling statutory obligations

GS-R-1 § 3.1

The Regulations define criteria for dose limits.

A draft national policy and strategy for radioactive waste has been prepared.

GS-R-1 § 3.2 (1)

The Act Sections 7(b) and 18 give the RPB the authority to develop regulations and guides, which may only be issued by the Minister. Regulations have been issued ("The Radiation Protection (Standards) Regulations, 1986" and "The Radiation Protection (Structural Requirements and Inspection of Buildings) Regulations, 1986") covering occupational radiation exposure, public radiation exposure, dose limits, medical exposure and emergency exposure situations. There are draft regulations on management of radioactive waste and transport of radioactive material.

GS-R-1 § 3.2 (2)

The RPB reviews and assesses applications for authorization and conducts inspections prior to issuing the licence. Users prepare codes of practice, which are reviewed by the RPB. Licences are valid for only one year so there is also annual inspection.

GS-R-1 § 3.2 (3) (i)-(x)

Authority for the Board to issue licences is established in the Act (3rd and 4th subsections of Section 11). The authority to apply conditions to authorizations is established in the Act (Section 7(c)). Individual licences are issued for each source, even if more than one source is found at a facility; facilities and workers are also licensed. Owners or users of a radiation facility are required by the Act (Section 10.4) to notify the RPB, within one month, of any change to the facility that renders the information provided in the notification inaccurate. "The Radiation Protection (Standards) Regulations, 1986" (Legal Notice No. 54) spell out in greater detail than the Act what the obligations of the operator are with respect to its facility, equipment, radiation sources and personnel. Dose limits are also established in Legal Notice No. 54. However, the Act (Section 3.3) also states that the standards of radiation protection to be observed shall be those contained in the Act or any guidelines established and published by the International Commission on Radiological Protection (ICRP), the IAEA or the World Health Organization. There are draft regulations on radioactive waste.

Neither the Act nor the Legal Notice No. 54 specifies:

- the requirements for incident reporting;
- the reports that the operator is required to make to the RPB;
- the records that the operator is required to retain; or
- the emergency preparedness arrangements.

GS-R-1 § 3.2 (4)-(6)

The RPB carries out annual inspections and ensures that corrective actions are taken if unsafe or potentially unsafe conditions are detected. The RPB takes necessary enforcement actions, including acting as prosecutor, in the event of violations of safety requirements.

Regulatory body – discharging its main responsibilities

GS-R-1 § 3.3 (1)

The RPB has established a process for dealing with applications, although there are no formal procedures. The Act does not address the removal of a facility or activity from regulatory control.

GS-R-1 § 3.3 (2)

Neither the Act nor the RPB specifies the process for changing the conditions of authorization.

GS-R-1 § 3.3 (4)

The Act Section 14.1(c) gives authority to the Chief Radiation Protection Officer or any radiation protection officer to make such examinations and enquiries as may be necessary to ascertain whether the provisions of the Act are being complied with.

GS-R-1 § 3.3 (6)

The Act (Section 7(a)) empowers the Board to advise the Minister on matters relating to radiation protection and radioactive waste disposal. It is not empowered to independently communicate its regulatory requirements, decisions and opinions and their basis to the public. This requires Ministerial approval and is done in practice.

It is also not empowered to make available, to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate.

The RPB communicates with and provides information to other competent governmental bodies and the IAEA.

GS-R-1 § 3.3 (9)

The Act (Section 3.3) specifies that the standards of radiation protection to be observed shall be those contained in the Act or any guidelines established and published by the International Commission on Radiological Protection (ICRP), the IAEA or the World Health Organization.

GS-R-1 § 3.3 (10)

The RPB reported that the Act (Section 14.1(c)) empowers the CRPO or any radiation protection officer to require an operator to perform a periodic systematic safety review when appropriate, although the Act is not explicit in this regard.

GS-R-1 § 3.3 (11)

The Act has a provision for the regulatory body to advise the Minister on matters related to the safety of facilities and activities (Section 7(a)).

GS-R-1 § 3.3 (12)

Applicants for authorization must include in the application information about the RSO, users, drawings, monitoring of workers and general measures for radiation protection. The applicant also submits a code of practice that includes information about the radiation protection programme. The application is reviewed and assessed by the regulatory body. Before a licence is issued, an inspection is carried out. Act Section 14(1) gives the CRPO or any RPO the authority to enter a site or facility at any time to carry out an inspection.

Regulatory body – cooperation with other relevant authorities

GS-R-1 § 3.4

The RPB cooperates with other relevant national authorities in relation to the implementation of the regulatory programme, although there are no Memoranda of Understanding in place:

- National Environmental Management Agency with respect to environmental protection;
- Department of Public Health (MoH) with respect to public and occupational health and radionuclides in water and food;
- Kenya Revenue Authority (Customs) and Kenya Police with respect to the import and export of radioactive sources;
- National Disaster Operations Centre with respect to emergency planning and preparedness;
- Ministry of Public Works (manpower and training) with respect to radioactive waste management, including determination of national policy;
- Kenya Police with respect to transport of dangerous goods.

Regulatory body – additional functions

GS-R-1 § 3.5

The RPB has additional functions:

- Dosimetry services managed in the Personal Monitoring Laboratory
- Monitoring of foodstuffs managed in the Multichannel Analyzer Laboratory
- Patient management in radiotherapy and nuclear medicine

CONCLUSIONS	
(1)	**BASIS:** GS-R-1 §3.2(3) states: *"In fulfilling its statutory obligations, the regulatory body…shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified)… the requirements for incident reporting…and the emergency preparedness arrangements."*
C5	**Conclusion:** Neither the Act nor the Legal Notice No. 54 require the regulatory body to be responsible for requiring licensees, through licence conditions, to prepare emergency preparedness plans or to report incidents.
(1)	**BASIS:** GS-G-1.5 §3.38 states: *"The regulatory body should establish internal procedures to be followed in the review and assessment of an application for authorization, to provide assurance that all topics significant to safety will be covered and that operators for similar facilities or activities will be treated equally."*
C6	**Conclusion:** The Board does not have any formal procedures for the review and assessment of licence applications.
(1)	**BASIS:** GS-R-1 §3.3(3) states: *"…the regulatory body… shall provide guidance to the operator on developing and presenting safety assessments or any other required safety*

CONCLUSIONS	
	related information".
C7	**Conclusion:** The Board has not developed any guidance for operators on the development of safety assessments or any other safety related information.
(1)	**BASIS:** GS-R-1 §2.6(13) states: "*The regulatory body shall have the authority to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods".*
(2)	**BASIS:** GS-G-1.5 §5.10 states: *"…the regulatory body should identify areas where co-ordination and co-operation with other local, national and international organizations are needed to fulfil its mandate. When such needs are identified, the regulatory body, together with the other organizations involved at the local and national levels, should establish specific arrangements for co-ordination and co-operation."*
C8	**Conclusion:** The RPB would benefit from strengthening its relationships with other national organizations through establishing more formal arrangements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R-1 §3.2(3) states: *"In fulfilling its statutory obligations, the regulatory body…shall provide for issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, that are clear and unambiguous and which shall specify (unless elsewhere specified)… the requirements for incident reporting…and the emergency preparedness arrangements."*
R3	**Recommendation:** The legislation should be revised to oblige the regulatory body to include in licence conditions the requirement for licensees to prepare emergency preparedness plans and to report incidents.
(1)	**BASIS:** GS-G-1.5 §3.38 states: *"The regulatory body should establish internal procedures to be followed in the review and assessment of an application for authorization, to provide assurance that all topics significant to safety will be covered and that operators for similar facilities or activities will be treated equally."*
S1	**Suggestion:** The RPB should develop formal procedures for the review and assessment of licence applications.
(1)	**BASIS:** GS-R-1 §3.3(3) states: *"…the regulatory body… shall provide guidance to the operator on developing and presenting safety assessments or any other required safety related information".*
R4	**Recommendation:** The RPB should develop guidance for operators on the development of safety assessments and other safety related information.
(1)	**BASIS:** GS-R-1 §2.6(13) states: "*The regulatory body shall have the authority to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS:** GS-G-1.5 §5.10 states: *"…the regulatory body should identify areas where co-ordination and co-operation with other local, national and international organizations are needed to fulfil its mandate. When such needs are identified, the regulatory body, together with the other organizations involved at the local and national levels, should establish specific arrangements for co-ordination and co-operation."*
S2	**Suggestion:** The RPB should formalize its relationships with other relevant national organizations by developing Memoranda of Understanding.

3. ORGANIZATION OF THE REGULATORY BODY

Policy Issues

Enhancing regulatory effectiveness and competence

Background:

Challenges in maintaining and enhancing regulatory effectiveness and competence remain in many Member States.
Key elements:

- Harmonization with International practices
- Commitment to resource planning
- Commitment to knowledge management
- Assessment of workforce competencies
- Commitment to staff training and development
- Commitment to continuous improvement and safety management systems
- Promote sharing experience and lessons learned
- Use of regulatory performance indicators

Discussion:
The CRPO is confident that the RPB is significantly improving each year. This can be demonstrated by considering that there was a time when facilities would be inspected once every three years and subsequently issued a licence. Through the successful introduction of more effective work procedures and with the appointment of extra staff, each facility is now subject to an annual inspection.

Another area that has helped improve regulatory effectiveness and competence is training. Newly appointed staff of RPB undertake extensive on-the-job training with experienced inspectors and are not permitted to undertake inspection alone. The duties and responsibilities for all Radiation Protection Officers of the RPB are set out in the *Scheme of Service for Radiation Protection Officers* issued by the Office of the President. Newly appointed Radiation Protection Officers are deemed to be trainees and on probation for two years. Those that successfully meet the appraisal criteria are retained; those that fail are let go.

In practice, all inspections are undertaken by an inspection team comprised of two inspectors and a registry (non-technical) staff member – one inspector does not actively participate in the inspection and thus can serve as a potential prosecutor if required, the second undertakes the actual inspection procedures and the third is responsible for checking details of the licensed items and updating the register where required.

Two teams of three persons may be out undertaking inspections at any one time. They would typically carry out a programme of inspections over a two-week period. The duration of an inspection will depend on the size and nature of the activities carried out by the facilities – inspection protocols are available for all inspectors in the inspectors' manual. Inspectors are required to fill out an appraisal form for each facility prior to undertaking the inspection. Upon completing the inspection they complete a separate appraisal form which is then compared to the pre-inspection form to identify any non-compliance. The completed form are provided to the designated person in charge of the relevant province in which the inspections were undertaken, who

is then responsible for deciding the appropriate action, i.e. whether the facility should continue to be licensed or an enforcement action initiated.

The review team suggested that inspectors' performances could be assessed on a periodic basis though for example a process of inspection witnessing by a more senior inspector. This could, for example, assess an individual inspector's questioning style or performance and could lead to further refinements in the inspection protocol.

The RPB also undertake in-house training in courtroom skills through the use of moot courts.

Leadership and management of safety

Background:

Leadership in nuclear and radiation safety matters has to be demonstrated at the highest levels in an organization. The importance of human and organizational aspects of safety and safety culture is widely accepted. An effective management system is considered essential to support leadership in order to maintain and continuously enhance a good safety culture. Assessment tools for safety culture are being developed. Advanced decision-making techniques are increasingly needed to apply resources where they will do the most good.

Key elements:

- Safety policy defined
- Safety management system
- Integration of the elements of the safety management system (safety culture, environment, quality, financial, etc.)
- Internal assessment of safety culture
- Open dialogue between regulatory body and senior industry executives
- Internal decision making appeal process
- Value and ethics programmes
- Self assessment
- Regulatory experience included in appointing senior executives

Discussion:

All staff in the RPB report directly to a senior officer. The RPB provides an opportunity for all staff to discuss issues at its monthly staff meetings. In addition, when required meetings of the senior staff are convened by the Chief Radiation Protection Officer.

In response to a query from the review team as to what mechanisms exist to appeal decisions of the RPB the team was advised that the law allows users of sources of ionizing radiation to lodge an appeal against a decision of the RPB within one month of the decision. This appeal is made to the Board of the RPB and in the event that the appellant is not satisfied with the Board's decision they may then take their appeal to the Minister.

In relation to the appointment of senior positions within the RPB, explicit requirements are available in the *Scheme of Service for Radiation Protection Officers*. This clearly sets out the qualifications and experience necessary to enable any inspector to be eligible for promotion to a more senior position. In order to ensure that individuals with the appropriate expertise are appointed to the Board of the RPB the revised draft of the new Act will require that persons so appointed must hold scientific qualifications.

The mission statement of the RPB is "To accelerate, regulate and expand the contribution of nuclear and irradiation technology to the Kenyan economy through the promotion of nuclear and radiation safety culture."

Human resources and knowledge management

Background:

There is a movement towards revitalization of the human resource in some Member States. The need for knowledge management a creation of new knowledge, preservation of the existing resource, and knowledge sharing - is recognized. The new move towards network building for global knowledge sharing and management is showing promising results. Efforts in this direction need to continue to ensure availability of resources. Also, facilities critical to the conduct of important safety research need to be preserved.

Key elements:

- Plans to attract and retain staff
- Existing strategies to identify, capture, and transfer knowledge internally and externally
- National or Regional training centres
- Identified specialized skills and identified strategies to maintain and build competence
- Appropriate emphasis on regulatory research and technical support organizations

Discussion:

The review team noted that the age profile of the inspection staff was relatively young and enquired as to what implications, if any, would this have for the RPB.

The team was advised that the current CRPO is the oldest person in the RPB and has possibly only four more years until retirement. The area of human resources is taken seriously in the RPB. In the past, problems were encountered with newly recruited staff leaving the RPB relatively soon after completing their training. To address this problem the RPB encourages staff to stay by providing a very clear career structure as outlined in the *Scheme of Service for Radiation Protection Officers*. As well as providing clear guidance for staff on the eligibility requirements necessary for promotion it has been useful for interviewers when developing interview questions. The RPB has been extremely successful to date in recruiting new staff from within Kenya – there has been no need to look further afield for new staff.

The review team enquired as to whether the RPB had any sort of policy in relation to whether staff sent on training course were required to impart any knowledge or skills gained to other staff members. In response, the CRPO advised that only those staff that had been trained for "Train up Trainers (TUT)" would be expected to pass on new knowledge to their colleagues –to date three staff members had completed this training. The only situations where knowledge was routinely passed on to other colleagues were when staff had attended talks/seminars.

The CRPO also informed the review team that the RPB had recently developed its first Strategic Plan and that this document was currently at stakeholders review stage. This plan sets out the objectives of the RPB for the five year period 2007-2011. Responsibility for reviewing progress on the plan would be assigned to the Admin and Finance committee; however the CRPO was pleased to note that even at this early stage in the life of the plan several of the objectives were currently being addressed. The RPB also noted that there is also a document (at stakeholders stage) – Strategic Plan. This is the first such document ever written. While many such documents could just

sit on a shelf, the RPB reported that they already accomplishing some of the things that have been written.

Annual work plans are prepared for each section within the RPB based upon the objectives in the Strategic Plan. Sections can be based upon activities, e.g. food and environment section, or on geographical areas, e.g. Nairobi, North East, Rift Valley, etc. Each section is responsible for reporting to the Admin and Finance committee the completed results for the relevant plan, e.g. number of facilities, number of licences issued, prosecutions undertaken, etc.

Organizational structure, size and activities

GS-R-1 § 4.1

The Board is organized as shown in Figure 1. At the present time the Board has a Chief Radiation Protection Officer and 23 trained physicists located in the Headquarters offices and two regional offices to perform the technical and regulatory functions of the Board. All 23 of the physicists are trained as inspectors and perform inspections in addition to other duties and functions that may be assigned to them. The RPB reports that they have support staff and legal support to effectively discharge the RPB's responsibilities and functions.

The RPB reports that it has adequate staff and organizational structure to effectively discharge its present responsibilities.

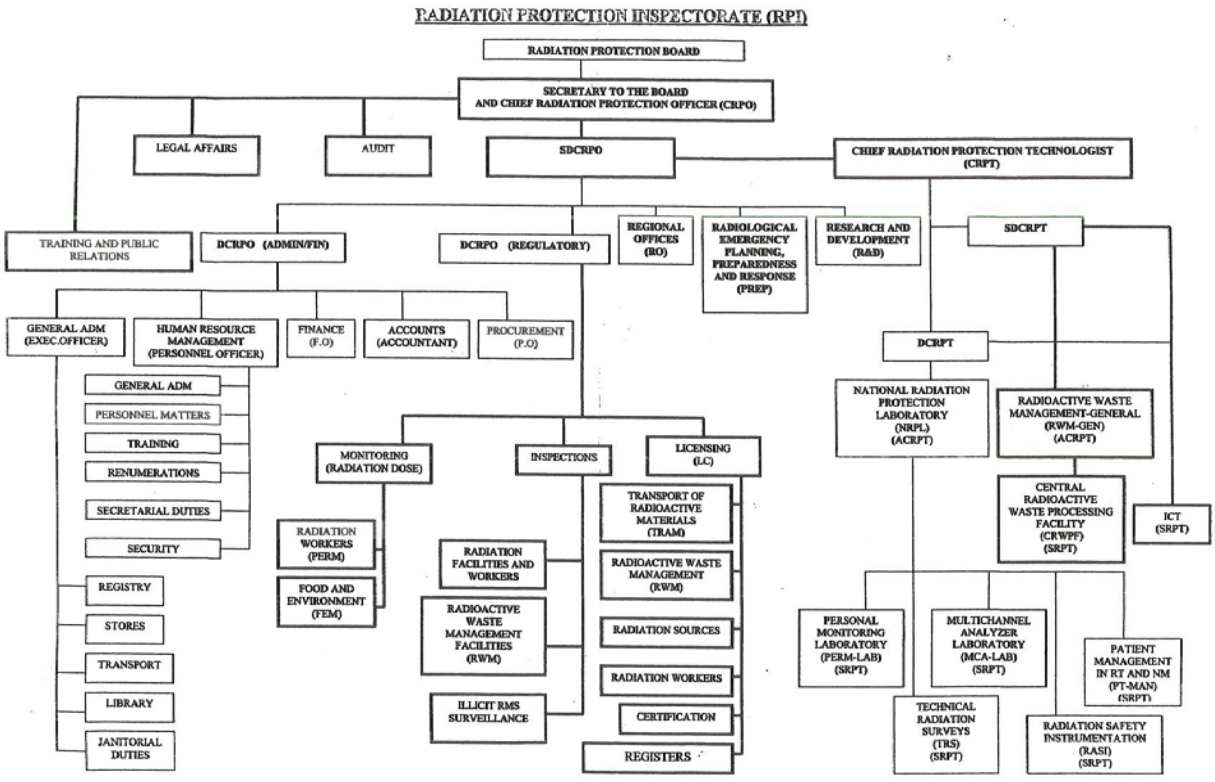

Figure 1

GS-R-1 § 4.2

Since the RPB is the only radiation regulatory agency in Kenya the requirements with respect to a regulatory body consisting of more than one authority are not applicable to Kenya.

Use of consultants and contractors

GS-R-1 § 4.3

The RPB does not seek advice or assistance from consultants, therefore this requirement is not applicable to Kenya.

Relief from responsibility for decisions and recommendations

GS-R-1 § 4.4

Because the RPB does not use the services of consultants this requirement is not applicable.

Systematic approach to quality management

GS-R-1 §4.5

The RPB has established procedures to regularly review the effectiveness of the overall safety programme, authorization process, inspection priorities, the planned inspection process, equipment needs and staff training needs.

The RPB has not established and implemented appropriate arrangements for a systematic approach to quality management that extend throughout the range of responsibilities and functions undertaken by the regulatory body. For example, the RPB has not established procedures to regularly review the effectiveness of its radiation protection programme with reference to changes in the national personal monitoring dose profile.

The RPB is subject to periodic internal audits by its authorization process and its inspection and enforcement processes. The RPB has been subjected to external audits by the IAEA among others.

Staffing and training of the regulatory body

GS-R-1 §4.6

The RPB employs sufficient number of staff to handle the current workload for licensing, inspection, and enforcement. There are 24 technical staff in the Radiation Protection Inspectorate, which is the secretariat. All are health physicists. All 24 act as inspectors and they also are involved in review and assessment of applications for authorization.

RPB personnel are subject to trustworthiness checks.

There is a Scheme of Service for Radiation Protection Officers, October 2003, issued by the Permanent Secretary/Director of Personnel Management, Office of the President. One of the problems encountered in the past by the Kenya Radiation Protection Board was the retention of recently recruited staff after having invested not inconsiderable time and resources in their training. In order to address this problem a Scheme of Service for Radiation Protection Officers was developed. This scheme provides for a well-defined career structure to attract, motivate and retain suitably qualified and competent Radiation Protection Officers. In addition, the Scheme sets out clearly defined job descriptions, duties and responsibilities at all levels within the RPB together

with standards for recruitment, training and promotion. Finally the Scheme provides a career plan for all staff and should ensure succession management for the RPB.

The Scheme is administered by the Permanent Secretary, Ministry of Health, in conjunction with the Public Service Commission and in consultation with the Permanent Secretary/Director of Personnel Management.

It includes a clear commitment that its provisions will be strictly observed to ensure fair and equitable treatment of all staff and that appropriate training opportunities and facilities will be provided to assist serving officers obtain the necessary additional qualifications and experience for both efficient performance of their duties and advancement within the Scheme. The "Radiation Protection Functions" of the Radiation Protection Board are also included in this document.

For each grade within the RPB the expected duties and responsibilities are clearly defined together with the requirements for appointment to that grade. These job and appointment specifications are provided for all grades ranging from a recruitment post up to and including the post of Chief Radiation Protection Officer. A list of recognized educational qualifications for the purpose of the scheme is included.

GS-R-1 §4.7

The RPB has implemented a well-defined training programme for its staff, which is included in Scheme of Service. Training is provided by various means including:

- mandatory induction training programme at University of Nairobi – the duration is 3 months for full-time training and 6 months for part-time required;
- post-graduate course in S. Africa – this is currently being provided to 3 staff;
- IAEA training;
- training in illicit trafficking provided by Argonne National Laboratory in the United States of America;
- IAEA fellowships – recently 2 staff received these;
- MSc in nuclear science, radiation protection, physics – 4 staff, recently or currently.

GS-R-1 §4.8

The RPB does not use the services of consultants to undertake any of its functions.

GS-R-1 §4.9

Inspectors review licence applications, prepare recommendation and draft licences, which are reviewed by the Licensing and Technical Advisory Committee before being sent to the Board for issuance. The Committee is appointed by the Board.

International cooperation

GS-R-1 §4.11

Kenya, with the assistance of the regulatory body, does not have formal arrangements for the exchange of safety related information with neighbouring or other interested States, although Tanzania has been used for a one-week training course and for calibration of RPB's radiation measuring instruments and South Africa has been used for post-graduate courses.

The National Council for Science and Technology coordinates Kenya's actions in respect of international cooperation on radiation safety.

Kenya has arrangements for the exchange of safety related information with the IAEA.

Kenya has established the Eastern Africa Association of Radiation Protection.

CONCLUSIONS	
(1)	**BASIS:** GS-R-1 §4.6-4.7
C9	**Conclusion:** The Scheme of Service is a clear example of how the RPB takes its human resource responsibilities seriously and could be used as a model for all other regulatory bodies.
(1)	**BASIS:** GS-R-1 §4.5 states: *"The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken."*
C10	**Conclusion:** The RPB has not established and implemented appropriate arrangements for a systematic approach to quality management which extends throughout the range of responsibilities and functions undertaken.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS**: GS-R-1 §4.5 states: *"The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken."*
R5	**Recommendation:** The RPB should establish and implement appropriate arrangements for a systematic approach to quality management which extends throughout the range of responsibilities and functions undertaken.
(1)	**BASIS**: GS-R-1 § 4.5
S3	**Suggestion:** The RPB should establish procedures to evaluate the effectiveness of its radiation protection programme with reference to changes in the national personal monitoring dose profile. A baseline dose profile should be done as soon as possible based on personal radiation dose monitoring available from the dosimetry records held by the Board. The baseline information and subsequent updates should be reported for inclusion in the IAEA personal monitoring dose profile.
(1)	**BASIS:** GS-R-1 §4.6-4.7
G1	**Good Practice:** The RPB should be highly commended for the development of the Scheme of Service for Radiation Protection Officers. It is an exemplary initiative undertaken by the RPB. The Scheme of Service clearly describes the recruitment, hiring, promotion and professional development of all Radiation Protection Officers in the RPB. It demonstrates the RPB's commitment to continuous staff training and development, thereby ensuring the highest professional standards of the staff of the RPB which would be to the benefit of all citizens of Kenya. The document is made available to all staff within the RPB. The review team encourages the RPB to share this Scheme of Service with regulatory bodies in other countries.

4. ACTIVITIES OF THE REGULATORY BODY

Policy Issues

Regulatory approach: risk-informed and deterministic

Background:

In some Member States, there is a trend towards a risk-informed approach to regulation, rather than a wholly compliance-based approach (deterministic and prescriptive).

Key elements:

- Guidance exist for risk informed regulatory decision making
- Process for determining the safety significance of regulatory actions
- Defined outcomes based on promoting safety
- Prioritize regulatory activities based on safety significance
- Expectations for balancing risk-informed and deterministic decision-making

Discussion:

The review team asked the Chief Radiation Protection Officer whether he favoured prescriptive or performance based regulations for a regulatory programme.

In response the CRPO stated that the authorization process requires all users/facilities to ensure that responsible persons are appropriately trained and that they develop their own code of practice. The RPB prompts a culture whereby any individual is encouraged to report an incident to it; however, the responsibility for officially reporting such incidents clearly rests with the appointed RSO. When undertaking inspections of facilities, the inspectors will require that the appointed RSO to demonstrate to the inspectors all relevant records including, for example, personal dose records, maintenance/servicing reports, etc. He gave the example of a large hospital which has sent their RSO to South Africa for additional training. The RPB places huge importance on the role of the RSO in ensuring radiation safety on a local level and encourages the larger facilities to recruit a trained graduate to act as the RSO.

Notification

GS-R-1 §5.2, BSS §2.10, GS-G-1.5 §3.25

The RPB considers notification to be a part of the authorization process, so notification is accomplished through application for authorization. The Act (Section 10.2) requires that an owner or user of an irradiating device or radioactive material shall notify the Board in writing of his intention to acquire, store, install or use the device. The notification is carried out through the application on the prescribed forms for a Compliance Certificate. The RPB has established the national register of the sources of ionizing radiation, but the regulatory body expects to add some more sources to the register, as they now have access to the northeast area of the country, which up to now was closed. The register was developed using MS Access (data input into Excel and exported to Access) and contains data on the following:

- Facility
- Facility owner
- Details of device or radioactive material
- Fees
- RPB licences

- Radiation workers
- Inspection findings and follow-up

Meanwhile, there are 181 radioactive sources (5 are Cat I at 4 facilities – 3 teletherapy and 2 irradiators for tsetse fly and livestock research; 9 are Cat II – 2 are disused, 1 is waste, 1 is at a shutdown facility). The Board is not using the Regulatory Authority Information System (RAIS) for its national register. The notification programme is used to maintain the source register.

Authorization

GS-R-1 §5.3

According the Act (Section 11), applicants for authorization are required to submit the prescribed application form to the Board for an appropriate licence or for a renewal of the licence. Applications for authorization are reviewed and assessed by the RPB, but there are no written procedures. The application forms for different practices are submitted. The extent of the control applied takes into account the potential magnitude and nature of the hazard presented. The application requires information about the RSO (radiation safety officer), users, drawings, monitoring of workers, and general measures for radiation protection. The applicant also submits a code of practice that includes information about the radiation protection programme. Some information is provided with the application, some based on request following review of the application. In the end, all of the necessary information is provided. All authorizations take the form of licences.

GS-R-1 §5.4

The regulatory body has issued guidance on the format of applications for authorization, but not on the content. There is currently no further guidance than the information provided on the application for authorization form. For complex facilities (e.g. radiotherapy unit), the authorization process involves several stages (e.g. siting, design, construction and operation, with appropriate review and assessment as well as feedback). For new applications, Compliance Certificates are issued for satisfactory radiation premises. Authorizations are provided for each discrete stage. Several kinds of licences may be issued to one facility:

- To possess radioactive material or irradiating device;
- To possess or use radioactive material;
- For disposal of radioactive materials;
- Radiation premises licence;
- For modification of radiation premises, material and devices;
- To sell, lease, loan, or deal with radiation devices or radioactive materials;
- To import/export radiation devices or radioactive materials;
- To administer ionizing radiation to persons;
- To install, service or maintain radiation devices or radioactive materials.

A licence is issued for each X-ray machine or device. Every radiation worker also is licensed by the regulatory body. Each of the above-mentioned licences should be reviewed and renewed annually.

Performance tests and radiation safety surveys are performed by the regulatory body.

GS-R-1 §5.5

The Board is empowered by the Act (section 7.c) to grant or refuse an authorization. When granting an authorization, the RPB may, if appropriate, impose conditions or limitations on the operator's

subsequent activities in the licence. The RPB records the basis for the decisions taken in respect of the authorization application. The basis is in the file. If brought before the Board, the RPB has the evidence in the file. The Licensing and Technical Advisory Committee actually makes the decision and makes the recommendation to the Board. Usually the Board issues licences, which meets normally 3-4 times per year. But for import of short-lived sources (nuclear medicine), the Chief or one of two delegated senior inspectors has been given the authority to sign the import licence. The Chief can also sign a Certificate of Compliance to allow the applicant to begin operations before the Board meets.

GS-R-1 §5.6

The Act (section 11.(4)(a), (b)) provides for amendment at any time on written notice to the holder of the licence by the Board as well as suspension or revocation of the licence if the holder fails to comply with the conditions contained in the licence or laid down in the Act or in any regulations made thereunder. No formal written procedures are currently established. The length of validity of the licence – one year – is stated in the Act. The duration of the authorization is not based on the risk of the sources. The RPB while visiting the facility also takes into account the compliance history.

Review and assessment

GS-R-1 §5.7 - 5.11

The review and assessment is commensurate with the potential magnitude and nature of the hazard associated with the particular facility or activity. The regulatory body's established process does not require applications to be reviewed and assessed within a specified time frame. The Board has not defined its principles and associated criteria on which its judgements and decisions are based. For example, the application form asks about the radiation protection measures in general – the applicant would not know what the criteria are.

The regulatory body's processes are not adequate to ensure that the available information demonstrates the safety of the facility or activity. The information contained in the operator's submissions is not always sufficient to enable confirmation of compliance with regulatory requirements. An examination of the records of licensees demonstrated that radiation protection officers do not always adhere to standard processes. No written procedures are established for reviewing and renewing licences.

The RPB should be informed about any proposed modifications to safety related aspects of a facility or activity, according the Act (Section 10.(4)).

The Act (Section 8.(1)) does not allow transferring of radioactive sources from one person to another.

Following the requirements of the Act (Sections 8.(1), 10.(4)), a prompt or immediate notification should be given to the RPB of the transfer of ownership of a source.

A process of authorization for the import, export and transshipment of radioactive sources consistent with the Code of Conduct's "Guidance on the Import and Export of Radioactive Sources" is under establishment. The RPB issues a licence of import/export in case of transshipment of radioactive sources. According to this programme the intended importer or exporter is authorized to take possession of the source(s). The RPB has established a programme which is being worked to be consistent with Code of Conduct and Guidance on the Import and Export of Radioactive

Sources. It is being done for imports. RPB gives an export licence. Kenya has not yet written to the Director General of the IAEA expressing its support for the Code of Conduct and Guidance on the Import and Export of Radioactive Sources. They have not had the situation of transhipment.

Inspection

GS-R-1 §5.14

The RPB has established a planned and systematic inspection programme. However, the programme is not based upon any graded or risk based criteria and all licensed facilities are included on the programme each year.

The RPB has developed a general written procedure for field inspections which outlines the preparatory stage of the inspection as well as the basic information relating to rapid, scheduled and urgent inspection.

Inspections are undertaken by an inspection team comprised of two inspectors and a registry (non-technical) staff member. One inspector does not actively participate in the inspection, and thus can act as the prosecutor if required, the second inspector undertakes the actual inspection procedures and the third team member is responsible for checking details of the licensed items and updating the register where required. The registry staff member can also act as a witness in any prosecution that may be taken as a result of the inspection. The RPB does not use the services of external consultants to assist it with its inspection programme.

Inspection teams undertake a series of inspections, which may be announced or unannounced, over a two week period. The duration of an inspection will depend on the size and nature of the activities carried out by the facilities however, 15 inspections are typically completed over the two week period.

A review of the files for a few facilities (both industrial and medical) was conducted by an IRRS reviewer together with the chief inspector (or person in charge for the relevant province). It was found that the time limit for validity of licences was extended in most cases. Licences are usually valid for one year. One facility has several licences, because licences are issued not for the practice, but for the source, the premise and each worker.

The inspectors use written protocol forms for each inspection. Protocols have been developed for each type of licensee. The protocol is used as a technical checklist and allows the inspector to record the result of any measurements carried out. After each inspection the inspectors complete a report form which summarizes the inspection findings and a copy is provided to the licensee at the exit meeting. When the inspectors return to the office a report detailing the findings of the inspection is prepared for the Board within one week.

The review team accompanied RPB inspectors at the facilities listed below:

Facility Inspected	Type of Practice
Kenyatta National Hospital	Nuclear medicine Diagnostic radiology Radiotherapy
Ministry of Roads and Public Works	Industrial radiography

Nuclear gauges

A typical inspection of a medical facility would include an assessment of every room in which licensed items are located as well as QA test on each X-ray unit. The inspectors demonstrated for the review team how they would undertake an inspection using one of the general multipurpose rooms as an example:

- Entrance meeting with hospital administrator/CEO and Radiation Safety Officer (RSO);
- A review of the room layout, including confirmation of the composition and thickness of walls and windows, operator's console lead glass, etc. against the specification on file;
- Radiation survey of the room;
- Review of in-house basic quality control checks, where undertaken by hospital staff;
- Review of service engineer's reports;
- Review of personnel dosimetry records;
- Commissioning tests for new units to compare performance against manufacturer' specifications;
- Film processor tests;
- Exit meeting with hospital administrator/CEO and RSO.

In addition, the inspectors also carry out extensive QA for each unit including checks on parameters such as kV and mAs output, timer accuracy, half value layer, beam alignment, tube head leakage, etc. The results of these tests are compared against the baseline values established when the units were first commissioned.

While the inspectors undertook a comprehensive series of equipment performance tests the review team noted that there was relatively little emphasis on general radiation protection for members of the public (e.g. the provision of signs on public access doors, pregnancy warning notices, etc.) or on assessing the radiation safety culture within the hospital.

The review team accompanied an RPB inspector on an inspection of destructive testing laboratory of the Ministry of Roads and Public Works. This facility uses a number of nuclear moisture density gauges and undertakes non-destructive testing of samples using both X-ray and radioactive sources in either a dedicated radiography exposure room or at off-site locations.

The review team observed the inspector performing dose rate measurements at the surface, and at a distance of 1 m, from a few source storage containers. The inspector did not discuss radiation protection issues with the staff in the area where the sources were located. In the absence of national regulations for safe practice the radiation workers of the facility have adopted some international recommendations however detailed radiation safety procedures have not been drafted. The inspection protocol observed did not appear to include elements that the review team would normally have expected to observe such as:

- a comparison of the source inventory against the licensing register
- a review of radiation protection arrangements
- correct labelling of source containers
- availability of warning notices
- designation of supervised and controlled areas
- access to the sources.

GS-R-1 §5.15

The Team was informed that the NRB undertakes both announced and unannounced inspections.

GS-R-1 §5.16

"Urgent inspections" are specified in the procedure in response to abnormal events.

GS-R-1 §5.17

The summary inspection report is written immediately. The report to the Board on the findings at the facility is prepared within a week after return to the office. Summary report is given on the spot at the end of the inspection.

Inspection findings are not fed back into the regulatory process as an aid to future development.

Enforcement

GS-R-1 §5.18 - 5.23

The Act (Section 11.4(b)) states that a licence may be suspended or revoked by the Board if the licence holder fails to comply with conditions in the licence or any provisions in the Act or regulations. Section 17 gives the CRPO or RPO the authority to enforce regulatory requirements. Section 16 specifies the offences and corresponding penalties. According to Section 16.3 and 16.4, both the owner and RSO may be held responsible for offences under the Act or any regulations.

There is an informal enforcement policy (i.e. not written). This policy provides for a range of sanctions commensurate with the seriousness of the non-compliance.

RPB officers have been trained and designated as prosecutors, which is recorded in the Gazette. They actually appear in court and serve as prosecutors (i.e. they do not need to have a lawyer prosecute on their behalf). They also have established informal arrangements with police to arrest.

In all cases of non-compliance, is the operator required to rectify the non-compliance, perform a thorough investigation in an agreed time-scale (usually within 30 days), and take all necessary measures to prevent recurrence. If there is a non-compliance, the RPB follows up with an inspection to verify that the corrective measures have been taken. However, there are no written procedures. The RPB stated that for situations that are deemed to pose an imminent radiological hazard to workers, the public or the environment, it requires the operator to cease activities and to take prompt actions necessary to restore an adequate level of safety. The Team was informed that in the event of continual, persistent or extremely serious non-compliance, or a significant release of radioactive material to the environment due to serious malfunctioning at or damage to a facility, the RPB requires the operator to cease activities, suspends or revokes the licence, and directs the operator to eliminate the unsafe conditions. The RPB confirms all enforcement decisions in writing to the operator, which is signed by the CRPO.

The RPB has not documented in procedures the extent to which inspectors can take on-the-spot enforcement actions; however, the inspector uses professional judgement as allowed by the Act (Section 14.1(d)).

The RPB informed the Team that so far in 2007, five prosecutions have either been completed or are in process.

Regulations and Guides

GS-R-1 §5.25- §5.28

Regulations are developed by the Board and approved by the Minister of Health in accordance with the Act (Section 18).

Currently there are two regulations in place:

- "The Radiation Protection (Standards) Regulations, 1986" – Legal Notice No. 54
- "The Radiation Protection (Structural Requirements and Inspection of Buildings) Regulations, 1986" – Legal Notice No. 55

The regulations of the RPB have not been revised or amended since 1986.

At this time only very basic dose regulations have been adopted. There is a recognized need for radiation protection regulations and regulations licensing and safety criteria for specific practices (e.g. diagnostic and therapeutic x-ray usage, industrial radiography, waste management, diagnostic and therapeutic nuclear medicine, irradiators, etc.) which exist in Kenya at the present time.

Draft regulations have been prepared on waste management and transportation, but are not likely to be approved until after government elections in December 2007.

The Board has indicated a desire to receive assistance in the development of regulations from other radiation regulatory bodies and international organizations such as the IAEA.

The Board has expressed the intention to establish regulations with which all operators must comply and to provide a framework by which more detailed conditions and requirements may incorporated into individual authorizations.

The Board has not issued guides at this time.

The Board has expressed an opinion that guides serve an excellent purpose by providing guidance on how to comply with regulations and provide information, data, analyses, and documentation to comply with requirements to apply for and obtain a licence.

The Board has expressed the intent to develop guides to supplement regulations as these regulations are approved and implemented.

The Board has expressed intent to seek comments and other input from interested parties and take into account international recognized standards and recommendation (such as IAEA safety standards) in the development of regulations and guides.

CONCLUSIONS	
(1)	**BASIS:** GS-R-1 §5.3 states: *"Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures..."*
C11	**Conclusion:** The RPB has not established any formal written procedures for the review and assessment of authorization applications.
(1)	**BASIS:** GS-R-1 §5.4 states: *"The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for*

CONCLUSIONS	
	authorization."
(2)	**BASIS:** GS-R-1 §5.6 states: *"Any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure."*
(3)	**BASIS:** GS-R-1 §5.8 states: *"In connection with its review and assessment activities, the regulatory body shall define and make available to the operator the principles and associated criteria on which its judgements and decisions are based."*
C12	**Conclusion:** Specific guidance does not exist on what information must be submitted by the applicant, or what criteria must be met for the authorization reviewer, in the case of licence applications, amendments or renewals.
(1)	**BASIS:** GS-R-1 §5.3 states: *"… The extent of the control applied shall be commensurate with the potential magnitude and nature of the hazard presented."*
(2)	**BASIS:** GS-G-1.5 §3.47 states: *"The regulatory body should require the renewal of an authorization after a set time interval."*
C13	**Conclusion:** The RPB does not undertake a graded approach for licence renewals which takes account of the risks associated with the licensed sources of ionizing radiation or practices undertaken.
(1)	**BASIS:** GS-G-1.5 §3.61 states: *"To ensure that all operators are inspected to a common standard and that the level of safety is consistent, the regulatory body should establish procedures for its inspectors. The procedures should be such as to ensure a systematic and consistent approach to inspection, allowing sufficient flexibility for inspectors to take the initiative in identifying and addressing new concerns as they arise. Appropriate information and guidance should be provided to the inspectors concerned…"*
C14	**Conclusion:** The inspection procedures are very general and could be broadened to include additional information in relation to how the inspection is undertaken.
	BASIS: GS-R-1 §5.12 states: *"Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility…Enforcement actions shall be applied as necessary by the regulatory body in the event of deviations from, or non-compliance with, conditions and requirements."*
C15	**Conclusion:** The enforcement process is well established and implemented.
(1)	**BASIS:** GS-R-1 §5.25 states: *"The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated."*
C16	**Conclusion:** The regulations of the RPB have not been revised or amended since 1986 and predate the BSS and other international standards and guidance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R-1 §5.3 states: *"Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures..."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R6	**Recommendation:** The RPB should establish formal written procedures for the review and assessment of authorization applications.
(1)	**BASIS:** GS-R-1 §5.4 states: *"The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization."*
R7	**Recommendation:** Specific guidance should be developed which details the information that must be submitted by the applicant, and the criteria by which the reviewer assess the information, in the case of licence applications, amendments or renewals.
(1)	**BASIS:** GS-G-1.5 §3.61 states: *"To ensure that all operators are inspected to a common standard and that the level of safety is consistent, the regulatory body should establish procedures for its inspectors. The procedures should be such as to ensure a systematic and consistent approach to inspection, allowing sufficient flexibility for inspectors to take the initiative in identifying and addressing new concerns as they arise. Appropriate information and guidance should be provided to the inspectors concerned…"*
S4	**Suggestion:** The inspection procedures should be revised to include additional information in relation to how inspections are undertaken. The revised procedures should also include a section to ensure that the inspectors can assess whether adequate radiation protection measures are in place to ensure the protection of workers, patients and the public. The review should take account of international guidance.
(1)	**BASIS:** GS-R-1 **§**5.25 states: *"The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated."*
R8	**Recommendation:** On an urgent basis the RPB should adopt a plan and schedule to revise its regulations and guides to be compatible with currently accepted standards for radiation regulations and guides. This schedule should place priority on the development of regulations based on the risks associated with the practice. It is suggested in developing revised regulations and guides that Kenya seek the cooperation and assistance from other international organizations (such as IAEA) and governmental bodies which have state of the art radiation control regulations and guides. The Minister of Health should give high priority and urgency to approving the proposed regulations.
R9	**Recommendation:** Regulations and codes of practice should be developed by the RPB for each practice which sets out the procedures that all facilities must adhere to.
(1)	**BASIS:** GS-G-1.5 §3.47 states: *"The regulatory body should require the renewal of an authorization after a set time interval."*
S5	**Suggestion:** The RPB should evaluate the licence renewal intervals with regard to the risks associated with the source or activity. They should also evaluate the benefits of issuing a single licence for each facility which would incorporate all sources of ionizing radiation. In undertaking these evaluations the RPB should consider the approaches used in other countries.

5. SAFETY OF RADIOACTIVE SOURCES

The Board has not formally adopted written procedures to address sources that may have been found or lost from authorized control; however the Board does collect and store recovered orphan and disused sources. The staff is trained in the processes to be utilized and have successfully conducted actual recoveries.

The process exists for the Board to respond to situations where a licensee ceases operations and to take measures to ensure the safety of radioactive sources. This process is not established in a formal written procedure.

The Board has access to equipment and facilities for the handling, transport, storage of radioactive sources following recovery of orphan and disused sources. Storage is currently at the Ministry of Roads and Public Works facility in Nairobi. The Board will move the processing and storage to the Board's new ten acre site.

The Board does not have a program to encourage scrap metal dealers to have appropriate radiation monitoring programs to detect radioactive sources in scrap metal.

The Board has not adopted regulations to ensure the safe transport of radioactive sources or the safe storage of radioactive materials when they may be routinely stored on vehicles or at field sites.

6. INFORMATION MANAGEMENT

Policy Issues

Openness, transparency and stakeholders involvement (including public communications)

Background:

Openness and transparency in regulation is essential to encourage continuous improvement of performance and building public confidence. The international community promotes openness through several services. However, finding a proper balance between public availability of information and protection of confidential data remains a challenge.

Key elements:

- Strategies for engagement of stakeholders
- Stakeholder involvement in regulatory decision making
- The basis for regulatory decisions made available to stakeholders
- Use of electronic communication, including the internet, for communication to stakeholders
- Low threshold for informing stakeholders of nuclear and radiation safety related information

Discussion:

The review team raised the common problem faced by many regulatory authorities of the need to find the right balance between having open and transparent processes, possibly through the involvement of stakeholders and in particular the public, with the potentially conflicting requirements for many bodies of having to keep certain information confidential.

The CRPO reassured the review team that getting this balance right is an issue of which the RPB is fully aware. In particular, it strives to achieve appropriate stakeholder involvement in its activities particularly in terms of the composition of its four advisory committees (admin and finance, licensing and technical advisory, radioactive waste management, and legal matters). These committees include representatives from training institutions (universities and institutes), medical scientists and non-destructive testing facilities (NDT) amongst others. The Licensing and Technical Advisory committee is composed of 14 members and its members comprise a broad range of people with relevant experience. There are also a number of subcommittees to the four advisory committees that will look at specific issues such as the licensing of (medical) workers who administer ionizing radiation to patients. These advisory and subcommittees allow for stakeholder involvement in the on-going activities of the RPB.

Representatives of the RPB have also appeared on local TV programmes. Participation by RPB staff in these programmes has proved to be extremely useful for educating the public and allaying fears that they may have in relation to sources of ionizing radiation and their uses. The RPB also has hosted trade stands at public events such as the Nairobi International Trade Fair. During these events they are available to provide information to the public through face-to-face contact, brochures and information videos. The RPB works closely with the Kenya police and criminal investigators on issues related to illicit trafficking but are conscious of not wanting to alarm the public.

Each year the secretary's report, which outlines the developments and work undertaken by the RBP during the previous year, is presented to the Board. While the report provides an opportunity to

update senior figures in the government on the work of the RPB, it is not made available to the public.

When asked by the review team whether the RPB had the authority to withhold information, other than classified material, from the public the CRPO described the process whereby all staff are required to undertake training at the criminal investigation department of the Kenya police. Following the completion of this training all staff are then vetted and assigned a classification as to the type of information that they are allowed access to – restricted, secret, very secret, etc.

In a response to a query from the review team as to whether a member of the public could get access to an official file held by the RPB the CRPO explained that any member of the public who made such an enquiry would received a written response to their enquiry. However they would not be given access to review the files. If the RPB allowed public access to their files it would be concerned as to how the media might use such information.

The RPB has had its own website since 1999 which provides basic information on laws and procedures. The website address is promoted by including it on all brochures and publications produced. Under a new government policy, state organizations will no longer be able to host their own website but instead all websites will be moved to a government site.

Regulatory activity information management

As a matter of practice the Board maintains the confidentiality of records by prohibiting access to its licence files and electronic files and information databases including backup copies of electronic databases.

The Board has implemented procedures to ensure the security against theft of computers and removal media that hold sensitive information. This includes the locking of offices and the presence of security personnel at the entrance gate to the building. All vehicles and persons entering the compound must be signed in with security personnel.

All disposal of computer hardware it though the Ministry of Health which stores them prior to disposal. It is uncertain how they are disposed of after storage.

Public information and communication

The Board does not have written procedures in place for the collection of national and international information with an important bearing on radiation safety; however it is doing this.

The Board is currently disseminating such information to other governmental agencies, departments, and ministers through the Annual Report of the Secretary of the Board. Likewise the Board is disseminating such information to managers of radiation sources, service providers, and environmental action groups. In addition the Board disseminates such information to professional organizations by conducting seminars for them and participating in their meetings and seminars. The Board has an active and on-going effort to disseminate such information to the public by participating in trade shows, producing and distributing brochures, producing videos, appearing on television shows, and maintaining a Board website.

The Board has not established or implemented procedures for the rapid dissemination of information in the event of an actual or potential safety incident. The Board does notify the IAEA of radiation incidents.

The Board has established and implemented training for its personnel regarding the release of information and data from the Board's records and databases.

The Board promotes awareness among industry, health professionals, the public, and governmental bodies of the potential hazards associated not only with orphan sources but any radioactive source that has come out from under proper control. The Board has provided specialized training to Customs and the Kenyan Police with regard to this potential hazard.

CONCLUSIONS	
(1)	**BASIS:** GS-R-1 §3.3(4) states: *"…the regulatory body…shall ensure that proprietary information is protected."*
(2)	**BASIS:** Code of Conduct §11 states: *"… The information contained in that register should be appropriately protected."*
(3)	**BASIS:** Code of Conduct §17 states: *" Each State should take appropriate measures consistent with its national law to protect the confidentiality of any information that it receives in confidence under this Code of Conduct from another State or through participation in an activity carried out for the implementation of this Code of Conduct."*
C17	**Conclusion:** The potential exists for hard disks containing sensitive information to be inadvertently released after disposal.
(1)	**BASIS:** GS-R-1 §2.6(12) states: *"The regulatory body shall have the authority…to make available, to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate."*
(2)	**BASIS:** GS-R-1 §3.3(6) states: *"…the regulatory body…shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public."*
(3)	**BASIS:** Code of Conduct §12. states: *"Every State should ensure that information concerning any loss of control over radioactive sources, or any incidents, with potential transboundary effects involving radioactive sources, is provided promptly to potentially affected States through established IAEA or other mechanisms."*
C18	**Conclusion:** Without a system to rapidly disseminate information in the event of a radiation incident, unnecessary radiation exposure could occur to the people of Kenya and neighbouring countries

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R-1 §3.3(4) states: *"…the regulatory body…shall ensure that proprietary information is protected."*
(2)	**BASIS:** Code of Conduct §11 states: *"… The information contained in that register should be appropriately protected."*
(3)	**BASIS:** Code of Conduct §17 states: *" Each State should take appropriate measures consistent with its national law to protect the confidentiality of any information that it receives in confidence under this Code of Conduct from another State or through participation in an activity carried out for the implementation of this Code of Conduct."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R10	**Recommendation:** The RPB should ensure that hard drives containing sensitive data and information (such as that containing radioactive source registry information and data) are destroyed when computer hardware is taken out of service.
(1)	**BASIS:** GS-R-1 §2.6(12) states: *"The regulatory body shall have the authority…to make available, to other governmental bodies, national and international organizations, and to the public, information on incidents and abnormal occurrences, and other information, as appropriate."*
(2)	**BASIS:** GS-R-1 §3.3(6) states: *"…the regulatory body…shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public."*
(3)	**BASIS:** Code of Conduct §12. states: *"Every State should ensure that information concerning any loss of control over radioactive sources, or any incidents, with potential transboundary effects involving radioactive sources, is provided promptly to potentially affected States through established IAEA or other mechanisms."*
R11	**Recommendation:** The RPB should develop and implement procedures for the rapid dissemination of information in the event of an actual or potential radiation safety incident.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
Ed BAILEY	Texas, USA	edbaileychp@msn.com
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Arthur KOTENG	Radiophysicist, Radiation Protection Board	rpbkenya@nbnet.co.ke
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Caesar BARARE	Hon. Secretary, Society of Radiography in Kenya, Kenyatta N. Hospital, Nairobi	
Renson ISUTSA	Chief Physicist, Ministry of Roads and Public Works	

APPENDIX II – MISSION PROGRAMME

Date/time	Programme	Participants
22 OCTOBER 2007		
10:00–10:30	Entrance meeting with RPB	Full IRRS Team RPB
10:30–11:00	Review of IRRS programme	Full IRRS Team RPB
11:00–13:00	Discussions on the status of the national regulatory infrastructure component 1 – '**Legislative and Statutory Framework'** • Legislation. • Regulations and guidance. • Regulatory body establishment and independence. • Regulatory body staffing and training. • Regulatory body funding. • Coordination and cooperation at the national level. • International cooperation.	Full IRRS Team RPB
13:00–14:00	Lunch	
14:00–18:00	Continued discussions on the status of the national regulatory infrastructure component 1 – 'Legislative and Statutory Framework'	Full IRRS Team RPB
18:00–23:30	Preparation of findings and drafting of IRRS report	IRRS Team

23 OCTOBER 2007		
09:00–13:00	Continued discussions on the status of the national regulatory infrastructure component 1 – 'Legislative and Statutory Framework' and component 2 – '**Activities of the Regulatory Body'** • Notification and national register of radiation sources. • Authorization • Safety of radioactive sources • Inspection • Enforcement. • Information management • Quality management	Full IRRS Team RPB
13:00–14:00	Lunch	
14:00–14:30	Visit to RPB Laboratory	Full IRRS Team RPB
14:30–17:00	Continued discussions on the status of the national regulatory infrastructure component 1 – 'Legislative and Statutory Framework' and component 2 – 'Activities of the Regulatory Body'	Full IRRS Team RPB
15:30–17:00	Discussion of Regulatory Policy Issues	Full IRRS Team, RPB Chief Radiation Protection Officer (CRPO) and RPB senior staff
17:00–23:00	Preparation of findings and drafting of IRRS report	IRRS Team

24 OCTOBER 2007		
09:00–13:00	Continued discussions on the status of the national regulatory infrastructure component 1 – 'Legislative and Statutory Framework' and component 2 – 'Activities of the Regulatory Body'	Full IRRS Team RPB
13:00–14:00	Lunch	
14:00–17:00	IRRS Team observation of regulatory inspections of medical facilities (radiotherapy, nuclear medicine, diagnostic radiology)	IRRS Team members and RPB
17:00–23:00	Preparation of findings and drafting of IRRS report	IRRS Team

25 OCTOBER 2007		
9:00–12:00	Preparation of findings and drafting of IRRS report	IRRS Team member
9:00–12:00	IRRS Team observation of regulatory inspections of industrial practices (non-destructive testing (X-ray and radioactive sources), nuclear moisture density gauges) and the temporary national waste storage facility	IRRS Team members and RPB
12:00–13:00	Lunch	
13:00–20:00	Drafting of IRRS preliminary draft report	Full IRRS Team
15:00–16:00	Preliminary draft made available to the regulator for review	IRRS Team, RPB CRSO and Ministry of XXXX
16:00–23:00	Final drafting of preliminary draft report	Full IRRS Team

19 OCTOBER 2007		
09:00–11:00	Presentation of the draft report with recommendations and suggestions by IRRS Team to RPB	IRRS Team RPB
12:00–13:00	Exit meeting Summary of findings and recommendations, action plan	IRRS Team RPB
13:00–14:00	Lunch and depart	

APPENDIX III – SITE VISITS

An inspection was arranged for Kenyatta Hospital, a large 2000 bed, public hospital in Nairobi. The review team was given a tour of the diagnostic X-ray department and was shown several X-ray units including a 16 slice CT unit, mammography unit, several general multipurpose units, fluoro and screening units, C-arms and mobile units. The team was also given a tour of the nuclear medicine department including a new dual-headed gamma camera. The department uses technetium-99m for diagnostic imaging which is obtained from a supplier in Holland. I-131 is administered on an in-patient basis for thyroid ablation therapies – the iodine is obtained from a supplier in South Africa. Approximately four thyroid ablations are carried out each month and waste from patients is collected in two underground holding tanks where it is stored for three months prior to discharge.

The team was also shown around the radiotherapy department which has two Co-60 teletherapy units. This is an extremely busy department and typically treats approximately 160 patients over a 14 hour day.

A typical inspection would include an assessment of every room in which licensed items are located as well as QA test on each X-ray unit. The inspectors demonstrated for the review team how they would undertake an inspection using one of the general multipurpose rooms as an example:

- Entrance meeting with hospital administrator/CEO and Radiation Safety Officer (RSO);
- A review of the room layout, including confirmation of the composition and thickness of walls and windows, operator's console lead glass, etc. against the specification on file;
- Radiation survey of the room;
- Review of in-house basic quality control checks, where undertaken by hospital staff;
- Review of service engineer's reports;
- Review of personnel dosimetry records;
- Commissioning tests for new units to compare performance against manufacturer' specifications;
- Film processor tests;
- Exit meeting with hospital administrator/CEO and RSO.

In addition, the inspectors also carry out extensive QA for each unit including checks on parameters such as kV and mAs output, timer accuracy, half value layer, beam alignment, tube head leakage, etc. The results of these tests are compared against the baseline values established when the units were first commissioned. The review team noted that the inspectors had been provided with personal dosimeters (TLDs) and suitable test kit.

While the inspectors undertook a comprehensive series of equipment performance tests the review team noted that there was relatively little emphasis on general radiation protection for members of the public (e.g. the provision of signs on public access doors, pregnancy warning notices, etc.) or on assessing the radiation safety culture within the hospital.

The review team accompanied an RPB inspector on an inspection of testing laboratories of the Ministry of Roads and Public Works. This facility undertakes both destructive and non-destructive testing. The facility has X-ray equipment and radioactive sources for non-destructive testing,

nuclear moisture density gauges and soil moisture gauges. There is also an external dedicated temporary waste storage facility which is licensed and operated by the RPB.

The inspection started in the non-destructive testing (NDT) laboratory. The inspector switched on his electronic personal dosimeter and dose rate meter as he walked into the area. The inspector performed a series of measurements on the nuclear moisture density gauges and recorded the results on the inspection protocol form. The inspector then visited the source store room located in the basement of the laboratory where the inspector undertook further measurements of several of the sources stored.

The inspector then visited the site of the new temporary waste storage facility located on the premises of the Ministry of Roads and Public Works facility. The new facility will be licensed to the RPB and consists of two twenty foot freight containers – one will be used for source conditioning and the second will be used as the storage location of the conditioned sources. At the time of the inspection there were no sources present in either container.

There is also an external temporary structure located on the premises which is currently used as a temporary national waste storage facility. This facility is licensed to the RPB. The review team noted the presence of a number of 200 litre drums which contained disused sources encased in concrete and reinforced steel bars. There are plans to move all drums to the new temporary facility (freight containers). The inspector undertook dose rate measurements at the door to the facility and along the external walls.

The inspector visited the dedicated radiography exposure room which is used for fixed NDT work using both X-ray units and radioactive sources. The inspector informed the review team that he would routinely request records for transport schedule for the sources, personal dosimetry, radiation, and any high doses recorded. The inspector would compare these records against the information available on the file held by the RPB. A survey of the TechOps container would be undertaken to identify any potential leakage of radiation from the iridium source contained within.

Following the completion of the inspection the inspector informed the review team that he would meet with the Chief Engineer to go through the findings of the inspection. The Chief Engineer would be requested to sign the summary report form and a copy would be provided to him.

APPENDIX IV – MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Counterparts
	Legislative and governmental responsibilities	• Ed Bailey • Stephen Fennell • Irma Zakarauskiene • Cynthia Heinberg	• Joel Kamande, CRPO • Arthur Koteng • Eric Ngotho
	Responsibilities and Functions of the Regulatory Body		
	Organization of the regulatory body		
	Activities of the Regulatory Body		
	Safety of Radioactive Sources		
	Information Management		
	Policy Issues		

REVIEWERS AND CONTRIBUTORS

APPENDIX V – RECOMMENDATIONS, SUGGESTIONS, GOOD PRACTICES

	Areas	**IAEA Comment No** ***R: Recommendations, S: Suggestions, G: Good practices***	***Recommendations, Suggestions or Good Practices***
A	Legislative and governmental responsibilities	*R1*	The Republic of Kenya should review and revise the Radiation Protection Act to ensure that is consistent with international standards.
		R2	The Government of Kenya should bring the new planned central radioactive waste management facility into operation.
B	Responsibilities and functions of the regulatory body	*R3*	The legislation should be revised to oblige the regulatory body to include in licence conditions the requirement for licensees to prepare emergency preparedness plans and to report incidents.
		S1	The RPB should develop formal procedures for the review and assessment of licence applications.
		R4	The RPB should develop guidance for operators on the development of safety assessments and other safety related information.
		S2	The RPB should formalize its relationships with other relevant national organizations by developing Memoranda of Understanding.
C	Organization of the Regulatory Body	*R5*	The RPB should establish and implement appropriate arrangements for a systematic approach to quality management which extends throughout the range of responsibilities and functions undertaken.

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		S3	The RPB should establish procedures to evaluate the effectiveness of its radiation protection programme with reference to changes in the national personal monitoring dose profile. A baseline dose profile should be done as soon as possible based on personal radiation dose monitoring available from the dosimetry records held by the Board. The baseline information and subsequent updates should be reported for inclusion in the IAEA personal monitoring dose profile.
		G1	The RPB should be highly commended for the development of the Scheme of Service for Radiation Protection Officers. It is an exemplary initiative undertaken by the RPB. The Scheme of Service clearly describes the recruitment, hiring, promotion and professional development of all Radiation Protection Officers in the RPB. It demonstrates the RPB's commitment to continuous staff training and development, thereby ensuring the highest professional standards of the staff of the RPB which would be to the benefit of all citizens of Kenya. The document is made available to all staff within the RPB. The review team encourages the RPB to share this Scheme of Service with regulatory bodies in other countries.
D	Activities of the Regulatory Body	*R6*	The RPB should establish formal written procedures for the review and assessment of authorization applications.
		R7	Specific guidance should be developed which details the information that must be submitted by the applicant, and the criteria by which the reviewer assess the information, in the case of licence applications, amendments or renewals.

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		S4	The inspection procedures should be revised to include additional information in relation to how inspections are undertaken. The revised procedures should also include a section to ensure that the inspectors can assess whether adequate radiation protection measures are in place to ensure the protection of workers, patients and the public. The review should take account of international guidance.
		R8	On an urgent basis the RPB should adopt a plan and schedule to revise its regulations and guides to be compatible with currently accepted standards for radiation regulations and guides. This schedule should place priority on the development of regulations based on the risks associated with the practice. It is suggested in developing revised regulations and guides that Kenya seeks the cooperation and assistance from other international organizations (such as IAEA) and governmental bodies which have state of the art radiation control regulations and guides. The Minister of Health should give high priority and urgency to approving the proposed regulations.
		R9	Regulations and codes of practice should be developed by the RPB for each practice which sets out the procedures that all facilities must adhere to.
		S5	The RPB should evaluate the licence renewal intervals with regard to the risks associated with the source or activity. They should also evaluate the benefits of issuing a single licence for each facility which would incorporate all sources of ionizing radiation. In undertaking these evaluations the RPB should consider the approaches used in other countries.

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
E	Information Management	*R10*	The RPB should ensure that hard drives containing sensitive data and information (such as that containing radioactive source registry information and data) are destroyed when computer hardware is taken out of service.
		R11	The RPB should develop and implement procedures for the rapid dissemination of information in the event of an actual or potential radiation safety incident.

APPPENDIX VI – REFERENCE MATERIAL PROVIDED BY RPB

[1] The Radiation Protection Act, Chapter 243, 1985

[2] The Radiation Protection (Standards) Regulations, 1986 – Legal Notice No. 54

[3] The Radiation Protection (Structural Requirements and Inspection of Buildings) Regulations, 1986 – Legal Notice No. 55

[4] Proposed Review of the Radiation Protection Act – 14th Draft

[5] Radiation Protection Inspectorate Organizational Structure

[6] Scheme of Service for Radiation Protection Officers, October 2003

[7] Radiation Protection Board Update of Regular RPI Schedule of Duties – 2007

[8] List of inspection equipment

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

[1] INTERNATIONAL ATOMIC ENERGY AGENCY International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. Safety Series 115, IAEA (1996)

[2] INTERNATIONAL ATOMIC ENERGY AGENCY Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety. Safety Standards Series No. GS-R-1, IAEA (2000)

[3] INTERNATIONAL ATOMIC ENERGY AGENCY Code of Conduct on the Safety and Security of Radioactive Sources. IAEA/CODEOC/2004

[4] INTERNATIONAL ATOMIC ENERGY AGENCY Independence In Regulatory Decision Making International Nuclear Safety Advisory Group (INSAG) Report 17, IAEA (2003)

[5] INTERNATIONAL ATOMIC ENERGY AGENCY Regulatory Control of Radiation Sources GS-G-1.5, 2004

[6] INTERNATIONAL ATOMIC ENERGY AGENCY Categorization of Radioactive Sources RS-G-1.9, 2005

[7] INTERNATIONAL ATOMIC ENERGY AGENCY Legislation and Establishment of a Regulatory Body for the Control of Radiation Sources (draft)

[8] INTERNATIONAL ATOMIC ENERGY AGENCY Applying Radiation Safety Standards in Nuclear Medicine, Safety Reports Series No. 40 (2005)

[9] INTERNATIONAL ATOMIC ENERGY AGENCY Applying Radiation Safety Standards in Radiotherapy , Safety Reports Series No. 38 (2006)

[10] INTERNATIONAL ATOMIC ENERGY AGENCY Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays, Safety Reports Series No. 39 (2006)

[11] INTERNATIONAL ATOMIC ENERGY AGENCY Application of the International Radiation Safety Standards in Industrial Radiography and Industrial Irradiators (draft)

[12] INTERNATIONAL ATOMIC ENERGY AGENCY Building Competence in Radiation Protection and the Safe Use of Radiation Sources, RS-G-1.4

[13] INTERNATIONAL ATOMIC ENERGY AGENCY. Safety Report No 20: Training in Radiation Protection and the Safe Use of Radiation Sources

[14] INTERNATIONAL ATOMIC ENERGY AGENCY TECDOC-1525 Notification and Authorization for the Use of Radiation Sources

[15] INTERNATIONAL ATOMIC ENERGY AGENCYTECDOC-1526 Inspection of Radiation Sources and Regulatory Enforcement

[16] INTERNATIONAL ATOMIC ENERGY AGENCY Guidance on the Import and Export of Radioactive Sources. IAEA/GIERS/2005

[17] INTERNATIONAL ATOMIC ENERGY AGENCY Quality Assurance within Regulatory Bodies. IAEA-TECDOC-1090 (1999).

[18] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION Quality Management Systems Fundamentals and Vocabulary. ISO 9000: 2000, Geneva (2000).

[19] INTERNATIONAL ATOMIC ENERGY AGENCY TECDOC-1355 Security of Radioactive Sources (2003)

[20] INTERNATIONAL ATOMIC ENERGY AGENCY TECDOC 1388, Strengthening Control over Radioactive Sources in Authorized Use and Regaining Control of Orphan Sources. IAEA, Vienna (2004).

[21] INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness and Response for a Nuclear or Radiological Emergency, Safety Series No. GS-R-2, IAEA Vienna (2002).

[22] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Materials, Safety Series No. TS-R-1, IAEA, Vienna (2000)

[23] EUROPEAN FOUNDATION FOR QUALITY MANAGEMENT, The EFQM Excellence Model, Brussels (1999).

APPENDIX VIII – LIST OF ABBREVIATIONS

RPB	Radiation Protection Board
CRPO	Chief Radiation Protection Officer
RPO	Radiation Protection Officer
IRRS	Integrated Regulatory Review Service
BSS	International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radioactive Sources
CoC	Code of Conduct on the Safety and Security of Radioactive Sources
IAEA	International Atomic Energy Agency
RAIS	Regulatory Authority Information System

APPENDIX IX – ACTION PLAN

I. LEGISLATIVE and STATUTORY FRAMEWORK

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1 Legislation and Establishment of the Regulatory Body			
1.1 Drafting and Enacting Legislation: 1.1.1 Taking into account the shortcomings and weaknesses of the Radiation Protection Act enacted in 1985, draft a new/amend existing national radiation safety legislation ensuring consistency with IAEA Basic Safety Standards (SS 115) and other referenced IAEA documents. 1.1.2 The legislation, in particular, should address: • protection of individuals, society and the environment from radiation hazards, both for the present and in the future; • establishment of an effectively independent regulatory body with clearly defined functions and responsibilities including: o establishing regulations and issuing guidance relating to radiation safety and the security of radiation sources; o establishing and maintaining a national register of	National Government / RPB / RPI	Provision of IAEA Standards, Code of Conduct and other relevant publications.	• SS 115 [1] • GS-R-1 [2] • CoC [3] • INSAG Report 17 [4] • GS-G-1.5 [5] • Legislation and Establishment of a Regulatory Body for the Control of Radiation Sources (Draft) [7]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
radiation sources o reviewing and assessing applications for authorization; o issuing, amending, suspending or revoking authorizations; o planning and undertaking inspections; o undertaking enforcement actions including initiation of prosecutions. • funding of the regulatory body; • enforcement functions; • review and appeal against regulatory decisions; • responsibility for safety (including the safe management and security of radioactive sources) is placed on the person or persons being granted the relevant authorizations; • cradle-to-grave management of sources; • obligations and responsibilities under international treaties, conventions and agreements; • relationships with other national agencies, especially those involved in the regulatory process; • the processes of notification, exclusion and exemption; • transport of radioactive material; • control of radioactive waste • import and export of radioactive material; • the security of radioactive sources; • processes for intervention including assigned roles and responsibilities for rapid response to loss of control of lost, stolen or orphan sources.		After submission of the draft legislation by Kenya, the IAEA may consider the provision of an Expert Mission (EM 1) comprising legal, technical and security experts to review the draft. Support organization of national seminar on Strengthening Framework and Regulatory Infrastructure for Radiation Safety on the assumption that TC will provide resources for the preparation of material.	• GS-R-1, § 2.1, 2.4 [2] • CoC, § 18, 19 [3]
1.2 Enact the legislation:	National Government		

TASKS for each ELEMENT		ACTION BY:	IAEA INPUT	REFERENCES
1.2.1	Finalize draft/ amended legislation and take necessary measures to promulgate it in due time.			
2	**Regulations and Guidance**			
2.1	**Draft regulations/ Review and Revise Existing Regulations:**	RPB/RPI	After submission of the draft regulations by Kenya, the IAEA may consider the provision of an Expert Mission (EM 2) comprising legal, technical and security experts to review the draft, to be held concurrently with EM 1.	• SS 115, Detailed Requirements [1] • GS-R-1 § 5.25–5.28 [2] • CoC § 18 [3] • Reference [7] • TECDOC-1355 Security of Radioactive Sources (2003) [19]
2.1.1	Review / revise / replace the Regulations for consistency with the legislation to ensure they are appropriate to the nature of facilities and radiation practices to be regulated within Kenya. In particular the regulations should address: • Administrative requirements (e.g. notification, authorization) • Radiation protection performance requirements (justification, optimization and dose limitation) • Management requirements • Verification of protection and safety • Requirements for the safety of sources • Occupational and public radiation exposure; • Dose limits; • Medical exposure; • radioactive waste management; • transport of radioactive sources; • emergency exposures situations. • security of radioactive sources including unauthorized			

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
access, use or removal of radioactive sources, theft, loss, verification of security measures and response to security incidents; • import and export of radioactive sources; • exemptions for practices and sources			
2.2 Issue Regulations: 2.2.1 Finalize the regulations and take necessary measures for these to be issued by the Government of Kenya.	Ministry of Health / RPB/RPI		
2.3 Drafting and Issuing Guidance Documents: 2.3.1 Draft/revise guidance documents (Codes of Practice) for the implementation of the legislation and regulations. The codes of practice should cover: • Diagnostic radiology • Teletherapy • Brachytherapy • Nuclear medicine • Industrial radiography • Industrial irradiators • Nuclear gauges • Well logging	RPB/RPI	Provide guidance documents (see references).	• GS-R-1, § 5.25 – 5.28 [2] • CoC, § 22(m) [3] • Applying Radiation Safety Standards in Nuclear Medicine [8] • Applying Radiation Safety Standards in Radiotherapy [9] • Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays [10] • Application of the International Radiation Safety Standards in Industrial Radiography and Industrial Irradiators (draft) [11]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
2.4 Issue Guidance Documents: 2.4.1 Issue the new/revised guidance documents.	RPB/RPI		
3 Regulatory Body Staffing and Training			
3.1 Staffing: 3.1.1 Review the formal staffing plan based on the functions and responsibilities assigned by the legislation and taking into account the country's needs based in particular on the national register of radiation sources.	RPB/RPI		• GS-R-1 § 4.6 [2] • CoC § 21 [3] • Building Competence in Radiation Protection and the Safe Use of Radiation Sources [12] • Safety Report No. 20 [13] • TECDOC-1525 Notification and Authorization for the Use of Radiation Sources [14] • TECDOC-1526 Inspection of Radiation Sources and Enforcement [15]
3.2 Training: 3.2.1 Develop and implement a planned programme of structured training and continuous professional development for personnel of the regulatory body so that the necessary skills are acquired and maintained, particularly in relation to new technologies, safety and security principles and concepts.	RPB/RPI	Provision of training packages as appropriate, dealing for example with; authorization and inspection of radiation sources in diagnostic radiology, nuclear medicine, radiotherapy, irradiators, industrial radiography,	• GS-R-1 § 4.7 [2] • CoC§ 10 [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
		gauges and well logging, cyclotron facilities. Provision of experts for national training courses. Provision of fellowships and scientific visits.	
4 Regulatory Body Funding			
4.1 Funding: 4.1.1 Provide the Regulatory body with sufficient financial resources to undertake its regulatory functions as assigned by the legislation.	National Government		• GS-R-1 § 2.2(4) [2] • CoC § 21(b) [3] • Reference [14] • Reference [15]
5 National Coordination and Cooperation			
5.1 National Coordination and Cooperation: 5.1.1 Establish formal cooperative and coordinating arrangements, as appropriate, with other national bodies and organizations involved in radiation safety and security, e.g. Customs, Transport, National Environmental, Management Authority (NEMA), Kenya Bureau of Standards (KEBs), Institute of Nuclear Science, University of Nairobi, Institute of Primate Research, Kenya Industrial & Research Development Institute, (KIRDI), the Kenya Police, Communication Commission of Kenya (CCK), East African Association of Radiation Protection (EAARP). ***Note:*** *Coordination and cooperation can be formalized through*	RPB/RPI/ Government	Provision of example Memorandum of Understanding	• GS-R-1 § 3.4 [2] • CoC § 20(m) [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
written Memorandums between the relevant authorities.			
6 International Cooperation			
6.1 Regional Cooperation: 6.1.1 Consider the establishment of arrangements for the exchange of safety and security related information, bilaterally and/or regionally, with neighbouring States as might be appropriate. **6.2 Cooperation with International Organizations and States:** 6.2.1 Consider the establishment of arrangements for the exchange of safety and security related information with interested States and relevant intergovernmental organizations as may be appropriate.	RPB/RPI National Government	Provision of relevant documentation, international conventions, etc. Facilitate access to the **Ra**diation **Sa**fety **Re**gulators **N**etwork (RaSaReN Web Site)	• GS-R-1, § 4.11 [2] • CoC, § 12, 20(n) [3]

II. **ACTIVITIES of the Regulatory Body**

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1 Notification and National Register of Radiation Sources			
1.1 Notification of Intent to Undertake a Practice Involving Ionizing Radiation: 1.1.1 Review the mechanism of notification to the regulatory body of an intention to carry out a practice involving ionizing radiation.	RPB/RPI	Provision of an expert mission to review the process (EM 7)	• SS 115, § 2.7 – 2.8, 2.10 [1] • Reference [14]
1.2 Notification prior to Export of Category 1 or 2 Radioactive Sources: 1.2.1 The appropriate authority in Kenya should take account of the Code of Conduct on the safety and security of radioactive sources 2004 and the Guidance on the Import and Export of radioactive Sources 2005. These require that: The regulatory body of an exporting State: (a) obtains the consent of the corresponding regulatory body in the importing State through appropriate bilateral channels or agreements; and (b) issues prior notification of the intent to export a radioactive source.	RPB RPI / National Government	Provision of the Code of Conduct 2004 and Guidance on the Import and Export of Radioactive Sources 2005	• CoC, § 23 – 25 and 28 [2] • GIERS 2005 Parts VII-IX [16] • RS-G-1.9 [6]
1.3 National Register of Radiation Sources: 1.3.1 Maintain a comprehensive national register of ionizing radiation	RPB/ RPI	At the request of the regulatory body,	• CoC, § 11, 17. Annex 1[3] • Reference [14]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
sources. Transfer spreadsheet database to RAIS 3.0. 1.3.2 As a minimum, the national register should include category 1 and 2 radioactive sources as given in Annex 1 to the Code of Conduct. 1.3.3 Develop and approve formal procedures to identify and classify sensitive information related to radioactive sources. 1.3.4 Implement appropriate measures to protect the confidentiality of information contained in the source register (inventory), particularly in relation to radioactive sources.		provide experts to assist with the operation of the **R**egulatory **A**uthority **I**nformation **S**ystem (RAIS 3.0) including training of staff (EM 6).	• Reference [6]
2 Authorization			
2.1 Establish a System of Authorization: 2.1.1 The Regulatory body should review the formal written guidance on the format and content of documents to be submitted by the applicant in support to applications for authorization. 2.1.2 For both initial and renewal applications, the Regulatory body should establish and approve a formal written process and procedures by which it reviews and assesses applications submitted, taking into account the potential magnitude and nature of the radiation hazard associated with the particular facility or activity and for radioactive sources, the nature of the security risk.	RPB/ RPI	Provision of an expert mission to review the process (EM 7)	• SS 115, § 2.7, 2.8, 2.11 – 2.14 [1] • GS-R-1, § 5.3 – 5.6, [2] • CoC, § 22(a) [3] • Reference [14] • Reference [6] • Reference [19]
2.1.3 Establish and approve formal written process and procedures to approve, amend, reject, suspend or revoke applications for authorization in accordance with the legal requirement.	RPB/ RPI		• GS.R-1 § 5.5 (1, 2) [2]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
2.1.4 In accordance with national legislation, if appropriate, establish and approve formal written process and procedures by which aggrieved applicants may appeal regulatory decisions.	RPB/ RPI		• GS.R-1 § 2.4 (7), [2]
2.2 Authorization of the Import and Export of Radioactive Sources: 2.2.1 The appropriate authority of Kenya should take account of the Code of Conduct on the safety and security of radioactive sources 2004 and the Guidance on the Import and Export of radioactive Sources 2005. These require that: The regulatory body of an exporting State should ensure that: • for export, it has notified and obtained the consent of the importing State through appropriate bilateral channels or agreements; • the receiving State has the appropriate technical and administrative capability, resources and regulatory structure to ensure the management of the sources in a manner consistent with the Code of Conduct and the Guidance on the Import and Export of Radioactive Sources. The regulatory body of the importing state: • Ensures that the recipient is authorized to receive and possess the source in accordance with the national legislation (if any) or with the relevant international guidance. • Ensures that the appropriate regulatory framework exists.	RPB/ RPI / Government / Customs Administration		• CoC, § 23 – 25 and 28 [2] • GIERS 2005 Parts VII-IX [16]. • Reference [14]
3 Safety and Security of Radioactive Sources			

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
3.1 Defining levels of safety and security 3.1.1 Establish procedures designating different levels of safety and security based on source categorization including a graded approach to the security of Category 1-3 sources. 3.1.2 Establish procedures for addressing specific situations regarding radioactive sources including: • found, lost or stolen sources; • cessation of licensed operations for economic reasons; • handling, transport and storage of recovered orphan or vulnerable sources; • safe and secure storage of sources at ports of entry; • scrap metal monitoring; • tracking the movement of high-risk sources; • safety and security of radioactive sources routinely stored on vehicles or at field sites.	RPB/ RPI	Regional Radiation Safety Training Course for Customs Officers If requested by Kenya, the IAEA may provide an Expert Mission for 1 week to review processes (EM 8) and to include seminar to sensitize national bodies involved in safety and security of sources (as part of the national seminar on Strengthening Framework and Regulatory Infrastructure for Radiation Safety on the assumption that TC will provide resources for the preparation of material).	• CoC, § 18, 20[3] • CoC, § 9, 13 (b), 15, 19 (g), 22 (g) • Reference [6] • Reference [19]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
4 Inspection			
4.1 Inspection System: 4.1.1 Review the inspection programme taking into account the potential magnitude and nature of the radiation hazard associated with particular facilities or activities.	RPB/ RPI		• GS-R-1, § 5.14 – 5.17 [2] • CoC, § 20(h), 22(I,) 19(h) [3] • Reference [15] • Reference [6] • Reference [19]
4.1.2 Revise and approve formal written process and inspection procedures appropriate to the types of radiation practices regulated.	RPB/ RPI	At the request of Kenya, the IAEA may consider the provision of inspection equipment	• Reference [15]
4.1.3 Establish and approve formal written protocols clearly defining the duties and responsibilities of inspectors in the conduct of inspections.	RPB/ RPI		• Reference [15]
5 Enforcement			
5.1 Establish a System of Enforcement: 5.1.1 Review the formal policy and written procedures for enforcement actions appropriate to the nature of the alleged breach including, if appropriate, any necessary cooperative arrangements with other government agencies (justice, police, security, etc).	RPB/ RPI (and other agencies as may be appropriate)		• GS-R-1, § 5.18 – 5.24 [2] • CoC, § 20 (i), 22 (j) [3] • Reference [15]
6 Information Management			

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
6.1 Information Collection and Dissemination: 6.1.1 Review formal procedures for collecting and disseminating information to radiation users, professional groups having input to radiation practices and to the public where appropriate.	RPB/ RPI with the cooperation of relevant Government agencies.		• CoC, § 13 [3] • GS-R-1, § 3.3(6), (7), (11) [2]
7 Quality Management			
7.1 Quality Management Programme: 7.1.1 Establish an approved quality management programme to ensure the regulatory body programmes and procedures are reviewed at specified intervals to assure their efficiency and effectiveness.	RPB/ RPI	Provision for an expert mission to review the programme (EM 11)	• GS-R-1, § 4.5 [2] • TECDOC-1090 [17] • ISO 9000 [18]

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