IAEA-NS-IRRS-2007/06
October 2007
ORIGINAL: English

IAEA
International Atomic Energy Agency

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

UGANDA

National Radiation Protection Service (NRPS)

Kampala, Uganda

15 to 19 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)

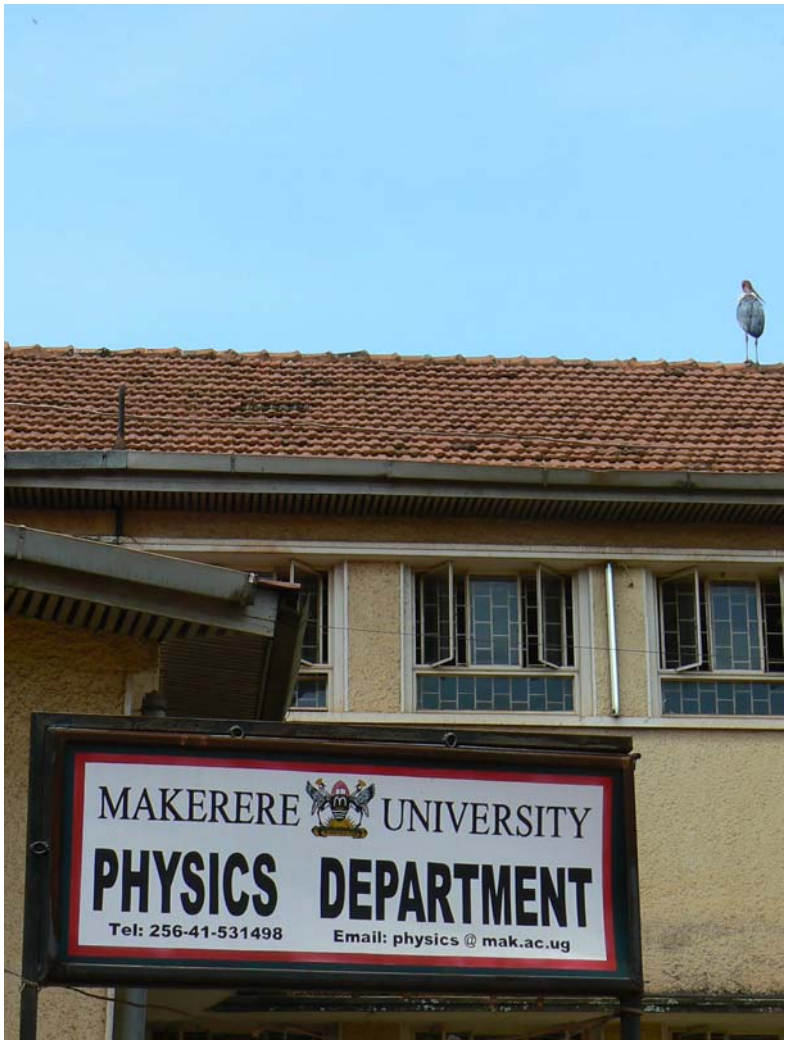
REPORT TO

THE GOVERNMENT OF UGANDA

NATIONAL RADIATION PROTECTION SERVICE (NRPS)

Kampala, Uganda

15 to 19 October 2007



REPORT

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

Mission date: 15 to 19 October 2007

Regulatory body: National Radiation Protection Service (NRPS)

Location: Makerere University, Kampala, Uganda

Regulated facilities and activities: medical, industrial and research applications

Organized by: IAEA

IAEA Review Team:	LIPOTI, Jill	(Team Leader, USA)
	GEBREMICHAEL, Teodros	(Reviewer, Ethiopia)
	RYAN, Tom	(Reviewer, Ireland)
	HEINBERG, Cynthia	(IAEA/NSRW, Team Coordinator)

IAEA-2007
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.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

At the request of the National Radiation Protection Service (NRPS), an international team of experts in radiation safety visited Uganda from 15 to 19 October 2007 to conduct an Integrated Regulatory Review Service (IRRS) mission to review NRPS's regulatory framework and its effectiveness. NRPS is the interim regulatory body responsible for radiation protection and safety in relation to activities involving radiation sources and radiation facilities in Uganda.

The purpose of this IRRS mission was to conduct a review of NRPS's regulatory framework and the regulatory activities in all regulated sources, facilities and activities, to review its regulatory effectiveness and to exchange information and experience in the areas considered by IRRS. It is expected that the IRRS mission will facilitate regulatory improvements in Uganda and throughout the world from the knowledge gained and experiences shared by NRPS 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 NRPS: medical activities, industrial and research activities, and safety of radioactive sources.

The significance of the IRRS mission for NRPS is increased by the revision of the legislative and regulatory framework currently conducted by the management of NRPS. 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 NRPS.

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 NRPS 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 NRPS and the Ministry of Energy and Mineral Development (MEMD) atomic staff, review of documentation provided during the course of the mission and a site visit, the team presented its findings based on the IAEA safety standards. Additionally, the IRRS team, together with NRPS and Staff of the Nuclear Energy Unit of MEMD, 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 NRPS 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 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 NRPS has already initiated a programme for change. 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:

- The Government of Uganda, on an urgent basis, should pass Bill No. 17 with Amendments introduced by the Minister of Energy and Mineral Development to allow delegation of authorization, inspection and enforcements functions.
- The Government of Uganda, on an urgent basis should significantly revise the regulations to make them consistent with the new law and international standards.
- The Government of Uganda should give immediate attention to the provision of staffing, equipment and facilities to support regulatory activities.
- Uganda should establish a comprehensive source registry using the RAIS template.
- NRPS should establish a strategic staffing plan and implement a comprehensive training programme for the regulatory staff. This programme will be adjusted to the growth of activities and acquisition of experience and knowledge by the staff
- NRPS should establish a systematic inspection programme and enforcement policy and procedures.

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 NRPS 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 National Radiation Protection Service (NRPS), an IAEA team consisting of three experts from Member States and one staff member from the IAEA visited NRPS and the Ministry of Energy and Mineral Development (MEMD) from 15 to 19 October 2007 to conduct an Integrated Regulatory Review Service (IRRS)[1] .

The purpose of the mission was to conduct a review of the NRPS regulatory framework and the regulatory activities, to review the regulatory effectiveness of NRPS 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, NRPS 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 NRPS and Staff of the Nuclear Energy Unit of MEMD and direct observation of their working practices.

IRRS activities took place mainly at MEMD headquarters, Kampala. The NRPS laboratory at Makerere University was visited. One site visit took place at the Mulago Hospital (see Appendix III).

[1] This mission was initially organized with the 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 Ugandan legal and governmental infrastructure for radiation safety and the effectiveness of the Ugandan interim regulatory body (NRPS) and to exchange information and experience between NRPS 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 Uganda (NRPS and governmental authorities) with a review of its radiation safety regulatory technical and policy issues;
- ✓ Providing Uganda (NRPS 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 Uganda (NRPS and governmental authorities) with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- ✓ Providing Uganda (NRPS 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 Uganda through completion of the IRRS questionnaire with an opportunity for self-assessment of its activities against international safety standards.

The scope requested by Uganda 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 IAEA Review Team

The preparatory work for the mission was carried out by the IAEA Team Coordinator Cynthia Heinberg, NSRW/IAEA. The IRRS Team Leader, Dr. Jill Lipoti is a senior regulator from an IAEA Member State. In accordance with the request from NRPS, 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 Dr. Akisophel Kisolo, the NRPS Chief Radiation Safety Officer (CRSO), and Mr. Michael Kiza of the Ministry of Energy and Mineral Development (MEMD) atomic staff, who is the National Liaison Officer for IAEA Technical Cooperation activities.

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 Uganda, 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 14 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 NRPS 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 NRPS and MEMD with recommendations and suggestions as well as of identifying good practices. The review was conducted through meetings, interviews and discussions with NRPS and Staff of the Nuclear Energy Unit of MEMD, 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, 15 October 2007, with the participation of NRPS senior management and staff of the Nuclear Energy Unit of MEMD. Opening remarks were made by the CRSO of the NRPS, the IRRS Team Leader and the IAEA Team Coordinator.

The team met with the Minister of State for Energy and the Permanent Secretary of the MEMD in separate meetings on Wednesday, 17 October 2007 to discuss the key highlights from the review. In addition, the IRRS Team Leader met with the Ms. Harriet Lwabi of the Ministry of Justice on

Thursday, 18 October 2007 for additional clarification of the draft legislation and implementation of international treaties, conventions and agreements.

The exit meeting was held on Friday, 19 October 2007 with the Minister of State for Energy, the Permanent Secretary of the MEMD, NRPS senior management and Staff of the Nuclear Energy Unit of MEMD. The main conclusions were presented by the Team. The draft mission report was handed over to NRPS 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 issue of independence was discussed with the Ugandan counterparts. All agreed that Bill No. 17 provides a much better regulatory structure for independence. The discussion of funding independence provided a more clear understanding of ways to separate fee funding from appropriated funding from the Parliament. The practice of charging fees for authorization applications seems to improve the quality of the applications since facilities do not want to waste money on an incomplete or inadequate application. This aspect of improving quality through judicious fee charges improved the efficiency of the regulatory body.

In the start-up of the programme, most of the funding will have to come from Parliamentary appropriations. After a full programme of authorization, inspection, and enforcement has been established, fees may be able to provide supplementary funding, but should not be relied upon for full support of the programme needs.

In discussion about the balance between operators and regulator responsibilities, the Bill No. 17 provides a positive statement that maintaining equipment in compliance with the regulations is primarily the responsibility of the operator. Facilities should not rely on inspection by regulators as the sole means of detecting equipment malfunctions. They should have a system of quality assurance that encompasses the full functionality of the equipment. In the case of x-ray, the quality assurance system should encompass the x-ray machine, the positioning of the patient, the technique factors for the x-ray exposure, the development of the film (including darkroom maintenance, expiration date of chemicals, temperature of the chemicals), the light box for reading the film, and even the diligence of reading the films including analysis of repeat films.

Openness, transparency and stakeholder's 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 development of the Bill No. 17 included a lot of discussions with stakeholders, according to the Ugandan counterparts. The Bill No. 17 contains provisions for continued stakeholder involvement, as regulations are drafted, publicized, and comments are received. In discussions with Ugandan officials, they fully supported the expected improvement to openness and transparency. The Bill No. 17 also contains provisions for education of the public.

Leadership and management of safety

Background:

Leadership in nuclear and radiation safety matters has to be demonstrated on 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. Recent events have led to concern over complacency in some operating organizations and lack of regulatory effectiveness in identifying and proactively responding to early symptoms of emerging problems.

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:

The team and the Ugandan counterparts discussed the difficult concept of Safety Culture. The regulatory body must foster an environment which allows the regulated community to identify areas of safety concerns on their own. The advice offered by the team was to recommend that the licensees consider and document near misses. There needs to be a program at the regulated facility for the discussion of incidents and learning from them. It was suggested that a safety committee be established within the larger facilities comprising medical physics, clinicians and management as a licence condition. The purpose of this committee is to review incidents and disseminate lessons learned.

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 Atomic Energy Decree, 1972 (Decree 12) and
- The Ionizing Radiation Protection (Standards) Regulations, 1996 (Statutory Instruments Supplement No. 21).

This legislative and regulatory framework is currently being revised for completion and compliance with international standards on many aspects further addressed in this report. This legislative revision is currently contained in:

- Bill Number 17, The Atomic Energy Bill, 2007 ("Bill No. 17").

The Bill No. 17 would completely repeal the existing Atomic Energy Decree. The Bill No. 17 was constructed with considerable stakeholder input. It has been printed and will be introduced by the Minister of Energy and Mineral Development after the Minister of Finance provides a certificate of financial implication. The Parliament will discuss the Bill only after this certificate has been provided which includes a budget for a 3-year period. Comments have been received by the Ministry of Finance, and they are being addressed by the Ministry of Justice and staffing needs are being developed by MEMD. It is expected that the Bill No. 17 will be considered by Parliament before the end of the year. Regulations necessary to implement the Bill No. 17 are at an early stage of drafting.

The Bill No. 17 covers a broad and diverse range of facilities and activities, including all that are currently being conducted in Uganda, as well as those anticipated. The Bill No. 17 contains provisions for a graded approach to regulation of facilities based on the potential magnitude and nature of the hazard. The regulations will need to reflect this risk-informed approach.

Establishment of an effectively independent regulatory body

GS-R-1 § 2.2 (2)

The Atomic Energy Decree, 1972 (Decree 12) Section 1 provides for the establishment of an Atomic Energy Control Board with specific regulatory functions. However, Section 6 assigns significant responsibilities to the Board in relation to the encouragement and promotion of the use of atomic energy including radioactive materials, devices using atomic energy and devices using ionizing radiation. Therefore, the Board established by Decree 12 cannot be considered to be an effectively independent regulatory body.

The Atomic Energy Bill, 2007 (Bill No. 17) Section 4 provides for the establishment of an Atomic Energy Council with specific provision in Section 4.4 that Ministerial Directions shall not adversely affect or interfere with the independence of the Council or the performance of its functions. In addition, Section 13 provides explicitly for the independence of the Council in the exercise of its powers and that it shall not be subject to the direction or control of any person or authority. A secretariat is established in Section 14 for the purposes of carrying out those independent functions of the Council with reporting responsibilities to the Council.

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 assigned by the law and the decree as follows:

Authorization

In the Decree 12, responsibility for issuing authorizations is given to the Board after submission of the application to the CRSO who prepares the draft license for approval by the Board (Section 12). In the case of x-ray machines used solely for medical or dental purposes, possession of an appropriate licence issued by the Ministry responsible for health is considered as an acceptable alternative to a licence issued by the Board as long as such a licence is filed with the CRSO (Section 12.6).

In the Bill No. 17, responsibility for issuing authorizations is given to the Council, which cannot be delegated (Section 9.1 (b), 12.1(a)).

Regulatory review and assessment

The Decree 12 does not explicitly have provisions regarding regulatory review and assessment but technical evaluation of application for authorization might be made by the CRSO as needed (Section 12.3).

In the Bill No. 17, the Council is required to make the necessary review and notify the applicant within thirty days after receipt of the application whether the application is complete in all aspects or needs more clarification (Section 36.2). The Council is required to process every application not later than ninety days after receipt (Section 36.3).

Inspection

In the Decree 12, responsibility for examining all premises with respect to a license is given to the Radiation Protection Service (Section 14.1(b)).

In the Bill No. 17, it is the responsibility of the Council to conduct inspections to assess radiation safety condition and compliance with the legislation and regulations, which cannot be delegated. (Section 9.1 (d), 12.1(d)).

Enforcement

In the Decree 12, the CRSO is given the responsibility for enforcement such as suspending licenses and seizure of sources, etc. (Section 15).

In the Bill No. 17, the Council can take such action as necessary to enforce the requirements of the legislation, regulations as well as conditions of authorization, which cannot be delegated (Section 9.1 (e), 12.1(e)).

Establishing regulations, safety principles, criteria and guides

Safety principles and criteria are not assigned in the Decree 12 or the Bill No. 17.

In the Decree 12, the Minister may on the advice of the Board make regulations (Section 17).

In the Bill No. 17, the Council can make regulations (Section 73) and issue directions, guidelines, codes and standards (section 74).

GS-R-1 § 2.2 (4)

The Decree 12 does not contain provisions to adequately fund the regulatory body. This is evident not only from a thorough reading of the decree, but also from the experience of the Ugandan government in attempting to implement the decree over the last 35 years.

The Bill No. 17 has provisions for adequately funding the regulatory body in sections 9.1(i), 12.1(b), 12.2(a), 25.1, and 73.2(e). However this funding includes money appropriated by Parliament, grants, and fees charged for services and activities (25.1). The Bill No. 17 provides a mechanism for the Council to approve or modify fees for authorizations and inspections (9.1 (i)) and its power to collect fees may be delegated (12.1(b) and 12.2 (a)). Section 73.2(e) states that the fees are to be set through regulation. Through all of these mechanisms, adequate funding should be available for adequate staffing and financial resources once Bill No. 17 has been passed.

GS-R-1 § 2.2 (5)

Decree 12 Section 6 assigns significant responsibilities to the Board in relation to the promotion of nuclear activities and these clearly could jeopardize and be in conflict with the Board's responsibility for regulating safety.

According to Bill No. 17 Section 18, the Council is given responsibility for the operation and maintenance of a dosimetry service and this service may be subject to a fee. In Sections 52 and 53, there are provisions to establish a Nuclear Energy Unit in the Ministry to promote and develop the use of nuclear energy for power generation.

GS-R-1 § 2.2 (8)

Decree 12 makes no provision for an effective system of governmental emergency response and intervention capabilities. Emergency preparedness issues are not considered in the decree.

Bill No. 17 Section 57 provides for the establishment by the Minister in consultation with the Council of an Emergency Response Committee consisting of representatives of the main relevant ministries and interested services such as the National Environmental Management Authority as well as the Police and Defence Forces. The functions of the Committee are clearly set out in Section 58.

Operator responsibility

GS-R-1 § 2.3

In the Decree 12, the responsibility for safety is assigned to the licensee or owner or user, and such a responsibility shall continue after the radioactive material or source is seized, impounded, stored or disposed of by the CRSO (Section 13.1, 13.2).

In the Bill No. 17, prime responsibility for safety rests with every user (Section 59.1).

Legislative requirements

GS-R-1 § 2.4

The Decree 12 provides for the effective control of radiation safety in the following areas:

- specifies facilities, activities and material that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation
- establishes a regulatory authority but does not address all the provisions specified in GS-R-1
- establishes a committee advisory to the Board, but it is not independent of the Board
- 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:

- setting out objectives for protecting individuals, society and the environment from radiation hazards, both for the present and in the future;
- taking into account the potential magnitude and nature of the hazard associated with a facility or activity;
- adequate funding of the regulatory body;
- process for removal of a facility or activity from regulatory control;
- establishing a procedure for review of, and appeal against, regulatory decisions;
- implementation of any obligations under international treaties, conventions or agreements;
- involvement of the public and other bodies in the regulatory process.

The Bill No. 17 provides for the effective control of radiation safety in the following areas:

- sets out objectives for protecting individuals, society and the environment from radiation hazards. However it does not explicitly state both for the present and in the future;
- specifies facilities, activities and material that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation;
- takes into account the potential magnitude and nature of the hazard associated with a facility or activity;
- establishes a regulatory body which addresses all the provisions specified in GS-R-1 except 2.6(1);
- provides adequate funding of the regulatory body;
- provides a process for removal of a facility or activity from regulatory control;
- establishes a procedure for review of, and appeal against, regulatory decisions;
- establishes a committee advisory to the Board, but it is not independent of the Board;
- defines what is an offence and the corresponding penalties;
- specifies how the public and other bodies are involved in the regulatory process.

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

- implementation of any obligations under international treaties, conventions or agreements.

Authority of the regulatory body

GS-R-1 § 2.6 (1)-(14)

Under the Decree 12, the regulatory body has the authority to:

- establish regulations (Section 17);
- require that an operator provide it with necessary information (Section 11.7);

- issue, amend, suspend or revoke authorizations and set conditions (Section 12.7 (a) (b));
- enter a site or facility at any time to carry out an inspection (Section 11.1(a));
- enforce regulatory requirements (Section 11.1(c), 15.1, 15.2);
- communicate directly with governmental authorities at higher levels (Section 3.2);

The regulatory body does have some mechanism for coordination with other Ugandan governmental bodies through the membership of the Board; however, this coordination does not address environmental protection and transport and has no mechanism for coordination with non-governmental bodies.

The decree does not give the NRPS the authority to:

- develop safety principles and criteria;
- require an operator to conduct a safety assessment;
- require an operator to conduct a systematic safety reassessment;
- obtain documents and opinions from private or public organizations or persons as may be necessary;
- independently communicate its regulatory requirements decisions and opinions and their basis to the public;
- make information available to other governmental bodies, national and international organizations, and the public, on incidents and abnormal occurrences;
- liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information.

The Bill No. 17 provides for a regulatory body with the authority to:

- establish regulations and issue guidance (Section 12(c), 73, 74);
- require any operator to conduct a safety appraisal (Section 36.1(e) and (f));
- require that any operator provide it with any necessary information, including information from its suppliers, even if this information is proprietary (Section 36.1(h), 47.4, 71);
- issue, amend, suspend or revoke authorizations and to set conditions (Section 9.1 (b), 37, 38, 46);
- require an operator to perform a periodic systematic safety review (Section 9.1(h));
- enter a site or facility at any time to carry out an inspection (Section 22);
- enforce regulatory requirements (Section 9.1(e));
- communicate directly with governmental authorities at higher levels (Section 9.1(j), 12.2 (c));
- obtain documents and opinions from private or public organizations or persons as may be necessary (Section 23, 24, Second schedule, Section 5);
- independently communicate its regulatory requirements decisions and opinions and their basis to the public (Section 9.1(n), 12.2(e));
- make information available to other governmental bodies, national and international organizations, and the public on incidents and abnormal occurrences, (Section 9.1(j) and (k));
- liaise and coordinate with other governmental or non-governmental bodies having competence in health and safety, environmental protection, and transport of dangerous goods (Section 57, 9.1(j));
- liaise with regulatory bodies of other countries and with international organizations to promote co-operation and the exchange of regulatory information (Section 9.1(m)).

However, the Bill No. 17 does not give the regulatory body the authority to:

- develop safety principles and criteria.

CONCLUSIONS	
(1)	**BASIS:** GS-R-1 §2
C1	**Conclusion:** Decree 12 (1972) predates the Basic Safety Standards (BSS) and GS-R-1 and lacks much of the provisions of the international standards. Legislation to align with those standards is urgently necessary to provide adequate protection for the public, environment and society.
(1)	**BASIS:** GS-R-1 §2
(2)	**BASIS:** GS-R-1 §2.4(15) states that the legislation *"shall implement any obligations under international treaties, conventions or agreements"*
C2	**Conclusion:** Legislation has been drafted and printed. Bill No. 17 to a great extent meets the provisions in GS-R-1. However, Bill No. 17 gives the authority to the Council for authorization, inspection and enforcement, but does not allow delegation of these functions. It also does not provide for implementation of any obligations under international treaties, conventions or agreements. Bill No 17 does not give the regulatory body the authority to develop safety principles and criteria.
(1)	**BASIS:** GS-R-1 §2.2 (5) states: *"No other responsibility shall be assigned to the regulatory body which may jeopardize, or conflict with, its responsibility for regulating safety."*
C3	**Conclusion:** Having the responsibility for providing dosimetry services provided by the Council may not conflict with the Council's responsibility for regulating safety as long as there is a clear delineation of roles.
(1)	**BASIS:** GS-R-1 §2.2(5)
C4	**Conclusion:** Having the responsibility for the promotion of nuclear activities should not be in conflict with the Council's responsibility for regulating safety as long as there is a clear delineation of roles, and in particular the role of the Nuclear Energy Unit must be separate from the role of regulation of radiation safety.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R1** §2
R1	**Recommendation:** The Government of Uganda, on an urgent basis, should pass Bill No. 17 with Amendments introduced by the Minister of Energy and Mineral Development to allow delegation of authorization, inspection and enforcements functions.
(1)	**BASIS: GS-R1** §2.4(15) states: *"This legislation…shall implement any obligations under international treaties, conventions or agreements."*
R2	**Recommendation:** The Government of Uganda should address the implementation of relevant international treaties, conventions and agreements with an Amendment to Bill No. 17 or other legislation.
(1)	**BASIS: GS-R1** §2.2(5) states: *"No other responsibility shall be assigned to the regulatory body which may jeopardize, or conflict with, its responsibility for regulating safety."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R3	**Recommendation:** In setting up the Council and Secretariat, the Government of Uganda should pay particular attention to the roles and reporting relationships so that possible conflicts of interest with regard to nuclear power promotion and provision of dosimetry services are avoided.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Regulatory body - fulfilling statutory obligations

GS-R-1 § 3.1

Decree 12 Section 17 provides for the Minister on the advice of the Board to make regulations in relation to limiting the use of radioactive material and equipment (Section 17 (b)) and for prescribing anything required to be prescribed under the Decree (Section 17 (d)). Clearly this could be interpreted to include defining policies, safety principles and associated criteria as a basis for the Council's regulatory actions. A set of regulations has been promulgated consistent with the implementation of the Decree 12. In addition, the Decree establishes a committee known as the Radioisotope Advisory Committee with specific advisory responsibilities to the Board in relation to requirements to ensure an adequate degree of public safety in the use of radioisotopes and devices capable of producing ionizing radiation and other such matters that may fall within the sphere of technical competence of the Committee.

Bill No. 17 Section 73 provides for the Council to promulgate regulations for implementing the provisions of the Act. Specific reference is made to regulations dealing with the management and disposal of radioactive waste; the transportation of radioactive sources; the storage of radioactive materials and sources; radiation safety requirements for different practices as well as any other matter required to be prescribed under the Act. In addition, Section 74 provides for the Council to issue directions, guidelines, codes and standards for the implementation of the Act. These two sections taken together allow for the regulatory body to define policies, safety principles and associated criteria as a basis for its regulatory actions.

GS-R-1 § 3.2 (1)

Decree 12 Section 17 provides for the Minister on the advice of the Board to make certain regulations for the implementation of the Decree. A set of regulations have been promulgated for the purposes of implementing the provisions of the Decree.

Bill No. 17 Section 73 and 74 provide for the adoption of regulations and guides for the purposes of the Council's regulatory activities. New regulations for the implementation of the Bill No. 17, once it becomes law, are in early draft form.

GS-R-1 § 3.2 (2)

Decree 12 Section 12 provides for the licence application process for any person wishing to use radioactive material or sources of ionizing radiation. However, it is not prescriptive in terms of the application requirements including pre-authorization safety assessments and periodic safety assessments during operation.

Bill No. 17 Sections 35 (g) and 36 (f) provide for the provision of pre-authorization safety assessments by the applicant. Section 9 (h) provides for the Council to require facilities to carry out systematic safety reassessments or periodic safety reviews.

GS-R-1 § 3.2 (3) (i)-(x)

Decree 12 Section 12 provides for the licence application and granting process with Sections 12.7 (a) and (b) providing for amending, suspending or revoking authorizations so granted. The law is reasonably clear in relation to:

- the facilities or activities covered by the authorization (Section 12);
- the obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel (Section 13);
- any limits on operation and use such as dose or discharge limits, or the duration of the authorization. These are covered by "The Ionizing Radiational Protection (Standards) Regulations, 1996" (hereafter, Regulations 1996) promulgated under the law.

The Decree does not specify:

- the requirements for notification of any relevant changes (modifications) to safety related aspects;
- conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities;
- the requirements for incident reporting;
- the emergency preparedness arrangements.

Nor does the Decree 12 specify the records that the operator is required to retain or the reporting requirements to the regulatory body, once the authorization is granted.

Bill No. 17 Section 9.1 (b) provides the Council with the authority to issue authorizations while Section 37, 38, 46 taken together provide for rejection, amending, suspension or revoking of authorizations. The law is reasonably clear in relation to:

- the facilities or activities covered by the authorization (Section 33);
- the obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel (Section 59);
- any limits on operation and use (such as dose or discharge limits, the duration of the authorization (to be covered by Regulations which are as yet in draft form);
- the requirements for incident reporting (Section 50, 62.3);
- the emergency preparedness arrangements (Sections 60, 61, 62)

There are some reporting obligations under Section 47 (3) however there is not a specific reference to the requirements for notifying relevant changes (modifications) to safety related aspects. In addition, there is not specific provision for conditioning criteria for radioactive waste processing for existing or foreseen waste management facilities although there are certain decommissioning provisions specified in Section 48 in the event of a notice of intended termination of a practice.

GS-R-1 § 3.2 (4)-(6)

Under the Decree 12, NRPS is empowered to carry out regulatory inspections. This was accomplished by the Chief Radiation Protection Officer (CRPO) through the auspices of the Makerere University. University graduate students were financially supported by the Government to carry out the inspections. However, this activity has had to be severely curtailed due to a cessation of funding for these students. Inspections at this time are only carried out by the CRPO with two assistants, and on a part-time basis. Additionally, there is no transportation available for visiting the facilities in distant parts of Uganda. Some of these facilities are 400 km away, and would require a four-wheel drive vehicle and several days' journey.

There is also a lack of inspection equipment. The NRPS lacks a mammography inspection kit, so this extremely important piece of equipment has not been inspected. Additionally, a phantom for inspection of computed tomography equipment is lacking.

After an inspection, a letter is written to the facility with any necessary corrective actions to be undertaken. However, with the limited part-time staff, additional inspections to ensure that the corrective actions have been implemented are a lower priority (using a risk basis) than visiting new facilities. Therefore, corrective actions, unless highly significant, are left to the facility to implement. Enforcement authority is cumbersome as spelled out in the Decree 12, and has only been exercised on a rare occasion.

Under the Bill No. 17, it is envisioned that a number of Radiation Protection Officers would be employed under the charge and direction of the Secretary (Section 20.2). Bill No. 17 does not currently empower the Council to delegate inspection functions to Radiation Protection Officers. Bill No. 17 specifies that the Council consists of only 3 members who meet quarterly. The Council does not have the time or resources to carry out inspections on all radiation sources and practices in Uganda.

Because adequate funding is expected to support staff, provide inspection equipment, and transportation, it is expected that a programme of regular inspection based on a risk-based graded approach would be undertaken. If corrective actions are required, follow-up inspections would be carried out. If facilities are not brought into compliance, enforcement action would be taken.

Regulatory body – discharging its main responsibilities

GS-R-1 § 3.3 (1)

The Decree 12 establishes a process for dealing with applications for issuing an authorization (Section 12), or the granting of an exemption (Section 19).

The Bill No. 17 establishes a process for dealing with applications for issuing an authorization (Sections 36-37), accepting a notification (Section 35), granting of an exemption (Section 2.2) or removal from regulatory control (Section 48).

GS-R-1 § 3.3 (2)

The Decree 12 does not specify the process for changing the conditions of authorization.

However the Bill No. 17 establishes such a process (Section 42).

GS-R-1 § 3.3 (4)

The Decree 12 requires that proprietary information is protected (Section 11.7).

The Bill No. 17 also provides provisions for confidentiality (Section 71).

GS-R-1 § 3.3 (5)

The Decree 12 does not require the regulatory body to provide an explanation of the reasons for the rejection of a submission.

The Bill No. 17 requires the Council to give the applicant a statement of its reasons for the refusal to grant an authorization within thirty days after the decision (Section 37.3).

GS-R-1 § 3.3 (6)

The NRPS has developed lines of communication with several key governmental bodies with a view to, *inter alia*, the provision of information. These bodies include:

- The National Environment Authority in relation to environmental protection issues;
- The Ministry of Health in relation to public and occupational health;
- The Ministry of Trade and Industry in relation to the import and export of radioactive sources
- The Police, and the National Disaster Management Committee in relation to emergency planning and preparedness;
- The National Bureau of Standards in relation to radionuclides in water and food;
- The Ministry of Works and the Police in relation to the transport of dangerous goods;
- Media professionals in relation to communication with the public.

In addition, the NRPS has developed lines of communication with neighbouring states such as Kenya and Tanzania in relation to information exchange on regulatory matters and there is clearly an active information exchange with the IAEA taking place.

While significant lines of communication for information exchange have been established, neither the national or international arrangements are underpinned by articles or memoranda of understanding.

GS-R-1 § 3.3 (7)

While there are no written procedures, it is custom and practice for NRPS to disseminate lessons learned during inspections and following radiological incident investigations.

GS-R-1 § 3.3 (8)

The Bill No. 17 requires users of radiation sources to maintain records of source inventory, including records of receipt, transfer and disposal of sources.

GS-R-1 § 3.3 (10)

The Decree 12 does not have provisions about informing the operator of any requirements for systematic safety reassessment or periodic safety review.

The Bill No. 17 includes in the functions of the Council to establish and inform authorized persons of any requirements for systematic safety reassessment or periodic safety review (Section 9.1(h)).

GS-R-1 § 3.3 (11)

The Decree 12 does not have any provision for the regulatory body to advise the government on matters related to the safety of facilities and activities.

The Bill No. 17 includes as one of the functions of the Council to advise other governmental authorities and organizations on matters within the competence of the Council (Section 9.1(j)).

Currently, NRPS is cooperating with national organizations such as the National Environment Management Authority, Ministry of Health, Ministry of Trade and Industry, Police, Security,

National Disaster Management Committee, Customs, National Bureau of Standards and Ministry of Works.

Regulatory body – cooperation with other relevant authorities

GS-R-1 § 3.4

Decree 12 has extensive membership of the Atomic Energy Control Board, which would facilitate cooperation and information exchange on radiation safety matters (Section 1). However, there is not a direct comparison between the list of areas noted in GS-R-1 Section 3.4 and the Ministries described in Section 1. Additionally, the Board has not been fully implemented. Nevertheless, governmental cooperation and information exchange routinely takes place between the CRPO, on behalf of the NRPS, and other relevant authorities in the following areas:

1. environmental protection – Uganda National Environment Management Authority
2. public and occupational health – Uganda Ministry of Health
3. emergency planning and preparedness – Uganda Police, Uganda Security, Uganda National Disaster Management Committee, Uganda Customs
4. radioactive waste management – (Uganda has not had to develop a radioactive waste disposal facility because all of the waste generated by the sources currently being used is either short-lived and allowed to decay for 10 half-lives before disposal, or are longer-lived sources which are returned to the manufacturer for disposal.) In Bill No. 17, there is a need for coordination with the Nuclear Energy Unit on radioactive waste generated by nuclear power.
5. public liability – not addressed.
6. physical protection and safeguards – not addressed.
7. water use and consumption of food – Uganda National Bureau of Standards
8. land use and planning – not addressed
9. safety in the transport of dangerous goods – Uganda Ministry of Works, Uganda Police

Regulatory body – additional functions

GS-R-1 § 3.5

The Board (as provided for in Decree 12) has additional responsibilities in relation to the promotion of the uses of atomic energy.

The Council (as provided for by Bill No. 17) will have responsibility for the establishment and operation of a personnel dosimetry service.

CONCLUSIONS	
(1)	**BASIS:** GS-R-1 §3.3(6) states that the regulatory body *"shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public"*
C5	**Conclusion:** To form a sustainable and effective system of intergovernmental and international cooperation Uganda would benefit by formalizing national or international arrangements through articles or memoranda of understanding. This formalization process would clarify roles and responsibilities and would provide a basis for ongoing interaction.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**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."*
S1	**Suggestion:** A process of formalizing intergovernmental and international cooperation should be developed through articles or 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:

Discussion between the Team and the Ugandan counterparts extended to implementation since getting the Bill passed is just the first step. The regulatory body has to have the support of the Government at a decision making level. Safety has to be high on the political agenda. The infrastructure has to move from the paper into implementation. Funding has to become a reality. The Bill should not be seen as an end in itself – its implementation has to be resourced with sustainable funding.

There are plans to take opportunities to talk to parliamentarians to discuss the necessity of building a radiation protection infrastructure to better address health issues. This infrastructure is also necessary for IAEA technical cooperation agreements for things like Tsetse fly eradication projects. The implications of Bill No. 17 are not just focusing on atomic energy but extend to agriculture, genetics in veterinary applications, water resources, petroleum exploration, national security, as well as health.

A sustainable regulatory body requires dedicated funding. Staff must be able to count on their position for a certain period of time. Management must be able to send staff for training and have them return to their jobs to apply the new knowledge to the regulatory tasks. Adequate resources for vehicles, inspection kits, phantoms, office space, computers, databases, and other office supplies are necessary for effective regulation. For each new person hired, there must be a commitment to train them adequately, equip them for their position, and provide support services as required for them to perform their particular function.

Stakeholder involvement in the preparation of practice specific guidance is necessary to convince members of the regulated community that the regulatory body is sufficiently sensitive to practical needs. The Ugandan counterparts discussed their experience with clinical practitioners. The practitioners are trained professionals and any guidance provided to them has to be appropriate. The team suggested that in developing guidance for licensees it can be important to make use of guidance produced by professional societies, e.g. the medical council, the radiological association,

the society for physicists in medicine. This practice will build confidence in the practical applicability of the actions of the regulator.

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:

After the Bill No.17 is passed by parliament, implementation is necessary. The regulatory body has to have the support of the Government. There has to be a commitment at a decision making level. Safety has to be high on the political agenda. Funding for staff, equipment and facilities has to become a reality. The passage of Bill No. 17 should not be seen as an end in itself – its implementation has to be resourced with sustainable funding.

A risk informed approach is key in terms of deploying resources. Emphasis should be given to developing regulations, hiring staff, and provisioning staff to provide oversight to the radiation sources with the highest risk to public health. This risk informed approach should also carry through to the licensees. During inspections, the Radiation Protection Officer should include discussions with management – impressing on the decision makers the need to release resources to act on recommendations aimed at improving safety.

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 including the 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:

Regulators always have a concern with attracting and keeping good staff because the salaries at governmental organizations are frequently lower than comparable positions in the private sector. Those who choose to work for a regulatory body are possibly motivated by altruistic tendencies rather than just compensation packages.

Staff turnover was discussed by the regulators as well as by the staff of the Makerere Hospital. There was frustration that training was not available for the highly technical pieces of equipment. Sending staff to training in other countries was considered risky because sometimes the staff would not return or would accept higher paid positions elsewhere as soon as they finished the training. It was discussed based on the experience of the experts in the team that an effective technique whereby each individual who is allowed to attend training, must come back to the office and present the training to others organization. This "train the trainer" approach is a way to multiply the effectiveness of the training.

Another technique that was mentioned was that when staff go for long term training (5-6 months) in another country, employees make a legal commitment to stay with the regulatory body for a specified period of time in order to retain staff. A commitment to on-going training is important for inspection staff, this can be in-house sharing of experience as well as formal training to update skills.

Another experience was to have the regulatory staff participate in training at the same time as facility staff when a new piece of equipment of different technology was received. This was marginally effective because the facilities were wary of having regulators looking over their shoulder during the training.

Organizational structure, size and activities

GS-R-1 § 4.1

The NRPS currently comprises three staff members who are based in Makerere University and are working in a part-time capacity. In the past, students of the university were supported financially by the Government to perform some tasks for the NRPS and in particular inspections. Since that financial support was withdrawn, the practice of using students for this purpose had to cease. It has been estimated that the NRPS would require between 15 and 20 staff members, both technical and administrative, with a range of skills and experience to carry out its functions efficiently and effectively as well as facilities in terms of office space, equipment and transport to support such a staff complement.

In terms of basic equipment for inspections, the NRPS currently does not have a CT phantom for performing quality checks on the CT scanner in Mulago Hospital. It does not have a mammography kit for carrying quality checks on the mammography unit or densitometry/sensitometry equipment for quality assurance checks in the darkroom at Mulago Hospital. It also does not have digital survey meters, multi function X-ray inspection kit, contamination monitors, neutron detectors, or high resolution detector. A tritium detector is urgently needed due to the work being performed on petroleum exploration which utilizes tritium. Detectors are sent to Tanzania for calibration in an accredited laboratory and the NRPS reported that the system works well.

The current space and computers are not sufficient for the anticipated staff that would assume the role of radiation protection officers. There are distant facilities 400 km north, 300 km east, 400 km west and 400 km southwest and there are no vehicles available to take inspection staff to these facilities. Under the Decree 12 no budget has been provided but under the Bill No. 17, funding is provided from the Parliament, fees and possibly grants.

There are inadequate resources provided by Government for the current regulatory activities. The NRPS estimates that there are 280 sources currently in Uganda, but there may be additional sources about which they have not been informed. In particular, there may be inadequate information provided to NRPS about sources brought in from Kenya for NDT and the well logging sources used in petroleum exploration.

The NRPS is carrying out some inspections at licensed facilities focusing on higher risk facilities but is not sufficiently resourced or structured in a way that facilitates a wider reach for inspections.

The NRPS is registering and authorizing all of the facilities that notify them of their intention to commence practice but is not sufficiently resourced or structured to identify current facilities that are carrying on practices that are outside regulatory control.

The NRPS is working in an interim capacity and is reporting directly to the Permanent Secretary of the MEMD who is also currently tasked with responsibilities in relation to the promotion of nuclear energy. Bill No. 17 provides for the establishment of a Nuclear Energy Unit (NEU) which will be separate from the NRPS and will be tasked with promotional activities in relation to nuclear energy. It is unclear to the Team how the reporting lines between the NRPS and the NEU will be organized within the MEMD when it is implemented.

GS-R-1 § 4.2

Under Decree 12 there are two main bodies involved in radiation protection matters. These are the Atomic Energy Board which exercises its regulatory function through the Chief Radiation Safety Officer (now head of the interim NRPS) and the Ministry of Health. While a line of communication has been established between the NRPS and the Ministry of Health there is no formal agreement or memorandum of understanding between the two bodies.

Under Bill No 17, Section 76 provides for continuation of authorizations until the authorization or permit expires. Therefore, the role of the Ministry of Health in terms of licensing and authorization activities will be phased out. It remains unclear to the Team who would be responsible for standard setting for patient dose and radiological clinical procedures.

There are other governmental bodies with certain responsibilities for aspects of the broader radiation protection infrastructure and these bodies include: the National Environmental Management Authority; the Ministry of Health; the Ministry of Tourism, Trade and Industry; the Uganda Police; the National Disaster Management Committee; the Uganda National Bureau of Standards, Uganda Revenue Authority and the Ministry of Works and Transport. While the NRPS has established lines of communication with all of these bodies, it has not entered into formal agreements or memoranda of understanding that might clearly delineate roles and responsibilities with a view to avoiding any omissions, conflicting requirements or unnecessary duplication.

The NRPS does not have written procedures for carrying out its assessments of authorization applications or safety reports. While it has check lists it does not have written procedures for carrying out inspections that would help to ensure consistency of approach. The NRPS provides

written feed back to licensees following inspections and disseminates relevant information to licensees from time to time though none of these activities are covered by written procedures.

Use of consultants and contractors

GS-R-1 § 4.3

In the past, some graduate students of Makerere University Department of Physics were supported financially by the Government to perform some of the tasks for the NRPS and in particular inspections. Since that financial support was withdrawn, the practice of using students for this purpose has had to cease. While no written procedures are in place it was the custom and practice of NRPS to ensure that students used for this purpose were effectively independent of any of the operators inspected.

NRPS has established an active line of communication with regulatory authorities in neighbouring states such as Kenya and Tanzania for the purposes of sharing regulatory information and expertise and there is clearly an active information exchange with the IAEA.

NRPS does not delegate its responsibilities in terms of decision making.

GS-R-1 §4.5

The NRPS has not been in a position to establish arrangements for a systematic approach to quality management for many aspects of its responsibilities and functions. In particular there are no procedures in place to regularly review:

- the effectiveness of the overall safety programme;
- the effectiveness of its authorization procedures;
- inspection priorities and the planned inspection programme;
- formal arrangements with other government agencies;
- the effectiveness of its radiation protection programme with reference to changes in the national personal monitoring dose profile.

While there are no written procedures in place it has been the custom and practice of NRPS to keep under constant review:

- Inspection protocols which are regularly updated;
- Equipment needs to maintain the inspection programme;
- Staff training needs.

The NRPS is not currently subject to periodic internal or external audits of performance.

Staffing and training of the regulatory body

GS-R-1 §4.6

It has been estimated that the NRPS would require between 15 and 20 staff members, both technical and administrative, with a range of skills and experience to carry out its functions efficiently and effectively as well as facilities in terms of office space, equipment and transport to support such a staff complement.

The NRPS currently comprises three staff members who are based in Makerere University and are working in a part time capacity. In the past students of the University were supported financially by the Government to perform some tasks for the NRPS and in particular inspections. Since that financial support was withdrawn, the practice of using students for this purpose has had to cease.

GS-R-1 §4.7

The NRPS does not have formal staffing plans in place for staff qualification requirements for recruitment. However, a plan for recruitment of staff to implement Bill No. 17 once enacted is under development and the IAEA model for staffing has been provided to the NRPS.

The NRPS does not currently employ sufficient staff or have sufficient external advice or assistance to properly fulfil its regulatory obligations though a rough staffing needs analysis has been prepared.

The NRPS does not currently fully implement well-defined training programmes for its staff. However there is ad hoc in house training provided by Makerere University Department of Physics and staff periodically attends IAEA training courses. However, NRPS is of the view that the current training arrangements are not sufficient to ensure that relevant staff members are kept aware of technological developments and new principles and concepts.

GS-R-1 §4.8

The NRPS currently comprises three staff members who are based in Makerere University and are working in a part time capacity. There is currently a lack of funding to employ full time staff capable of either performing reviews and assessments or evaluating any assessments performed for it by consultants.

GS-R-1 §4.9

Decree 12 provides for the establishment of a Radioisotope Advisory Committee (Section 7) with a wide range of advisory responsibilities to the Board.

Bill No 17 provides for the appointment of Committees by the Council (Section 11.1(a)) to advise Council on any matter concerning the functions of the Council as it may refer to the Committee.

There are currently no advisory committees acting in support of the NRPS.

Relations with the operators

GS-R-1 §4.10

It is custom and practice for the NRPS to engage in an open and frank engagement with licensees while respecting the formal aspects associated with regulatory enforcement.

International cooperation

GS-R-1 §4.11

NRPS has established an active line of communication with regulatory authorities in neighbouring states such as Kenya and Tanzania for the purposes of sharing regulatory information and expertise and there is clearly an active information exchange with the IAEA.

While Uganda has not yet given formal support to the Code of Conduct on the Safety and Security of Sealed Radioactive Sources and the associated Guidance on Import and Export of Radioactive Sources, it is party to the Non-Proliferation Treaty and has signed the Additional Protocol to the Treaty.

CONCLUSIONS	
(1)	**BASIS:** GS-R-1 §4.1
C6	**Conclusion:** The existing staffing, equipment and facilities to support regulatory activities is inadequate. The current inventory of sources in Uganda is not under adequate regulatory oversight which poses a potential threat to public health and safety.
(1)	**BASIS:** GS-R-1 §4.1
C7	**Conclusion:** Bill No. 17, as currently drafted, specifies that the Council consists of only 3 members who meet quarterly. The Council does not have the time or resources to carry out inspections on all radiation sources and practices in Uganda. This would not provide adequate control of radiation sources in Uganda and would create problems in implementing the provisions of the Bill.
(1)	**BASIS:** GS-R-1 §4.1
C8	**Conclusion:** The NRPS lacks basic equipment for inspections, even for radiation-producing devices currently in use in Uganda. The current space and computers are not sufficient for the anticipated staff that would assume the role of Radiation Protection Officers. There is no transport. Therefore, the inspection programme cannot be conducted effectively.
(1)	**BASIS:** GS-R-1 §4.1
C9	**Conclusion:** Within their limited resources, the NRPS is carrying out some inspections at facilities correctly focusing on higher risk facilities.
(1)	**BASIS:** GS-R-1 §4.7 states: *"In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts."*
C10	**Conclusion:** As part of implementation under Bill No. 17, well-defined training programmes for regulatory staff are necessary.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	BASIS: GS-R-1 §4.1
R4	**Recommendation:** The Ugandan Government should give immediate attention to the provision of staffing, equipment and facilities to support regulatory activities.
	BASIS: GS-R-1 §4.1

R5	**Recommendation:** The Minister of Energy and Mineral Development should introduce an Amendment to Bill No. 17, which allows the Council to delegate inspection functions to the Radiation Protection Officers.
(1)	**BASIS**: GS-R-1 §4.1
R6	**Recommendation:** The regulatory body should seek to obtain equipment, facilities and transport necessary for conducting regulatory activities.
(1)	**BASIS**: GS-R-1 §4.7 states: *"In order to ensure that the proper skills are acquired and that adequate levels of competence are achieved and maintained, the regulatory body shall ensure that its staff members participate in well defined training programmes. This training should ensure that staff are aware of technological developments and new safety principles and concepts."*
R7	**Recommendation:** NRPS should establish and implement a comprehensive training programme for the regulatory staff. This programme will be adjusted to the growth of activities and acquisition of experience and knowledge by the staff.

4. ACTIVITIES OF THE REGULATORY BODY

Notification

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

The NRPS considers notification to be a part of the authorization process, i.e. the application for authorization serves as a notification. However, the NRPS does not publicize this need for notification. It has sensitized some users through training courses (e.g. anti-terrorism unit which includes police and security). The NRPS is establishing the national register, but it is not complete. A number of radioactive sources have been entered, but they don't know about all sources that are in Uganda. Some sources are registered on paper and some are in the computer using the RAIS software. NRPS staff has attended RAIS training in South Africa and Vienna. For x-ray machines many are in the registry, but it is not complete. The notification programme is used to maintain the national source register.

Authorization

GS-R-1 §5.3

Applicants for authorization are required to submit a detailed radiation protection plan in the application form. Applications for authorization are reviewed and assessed by the NRPS, but there are no written procedures. The extent of the control applied takes into account the potential magnitude and nature of the hazard presented. If the risk is higher, the NRPS visits the premises and gets more detailed information from the applicant. All authorizations take the form of licences.

GS-R-1 §5.4

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 discrete stages (e.g. siting, design, construction and operation, with appropriate review and assessment as well as feedback).

GS-R-1 §5.5

In the Decree 12 there are no provisions for the refusal of an authorization. However, the team was informed that the NRPS can decide whether to refuse an authorization. When granting an authorization, the NRPS may, if appropriate, impose conditions or limitations on the operator's subsequent activities in the licence. The NRPS records the basis for the decisions taken in respect of the authorization application.

GS-R-1 §5.6

The Decree 12 provides for amendment, suspension or revocation of an authorization, but does not address renewal. However, there are currently no formal written procedures. In practice, the NRPS has a programme for the regular renewal of authorizations The length of validity is stated in the licence. The duration of the authorization is based on risk; higher risk sources are licensed for 1 year and x-ray for 3-5 years. In the case of applications for amendment or renewal, the NRPS's review and assessment procedures are consistent with those applied at the time of the initial authorization. The NRPS visits the facility and 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. For example, it is more rigorous for the radiotherapy unit than for a lower risk facility. The NRPS has not defined and made available its principles and associated criteria on which its judgments and decisions are based. The NRPS reported that it undertakes a thorough review and assessment of an operator's technical submission in support of any part of the authorization process.

Inspection

GS-R-1 §5.14

The NRPS has not established a planned and systematic inspection programme. However, NRPS carries out inspections of facilities using a graded approach where most of the inspection activities are directed towards areas of higher risk.

The NRPS has established a written protocol for inspections which is used regularly by all staff and which is updated regularly. The protocol is a technical check list and does not address the broader issues of radiation protection and safety assessment.

While inspectors verify the source inventory of the Licensee on inspection, this is not provided for on the inspection protocol reviewed.

GS-R-1 §5.15

The NRPS performs both announced and unannounced inspections as a matter of custom and practice. The NRPS no longer has the financial support to use consultants. In the past students of the University were supported financially by the Government to perform some tasks for the NRPS and in particular to carry out inspections. Follow up actions to be taken on the basis of such inspections remained the responsibility of the NRPS. Currently there is little resource available to NRPS for follow up activities.

GS-R-1 §5.16

The NRPS carries out inspections at short notice if an abnormal occurrence warrants immediate investigation. Such incident investigations have included the loss of a radioactive source; the jamming of a radioactive source in the radiotherapy unit of Mulago Hospital and high personnel dose reports.

In each case the NRPS also required the licensee to investigate the incident and to report. These exchanges were generally verbal with very little written reporting.

GS-R-1 §5.17

Following inspections it has been custom and practice that the NRPS prepares a report and letter which is sent to the licensee within one week of the inspection. It is also custom and practice for NRPS to share with other inspectors and relevant licensees the lessons learned on inspection as well as examples of good practice found. However, there are no written procedures covering reporting requirements or for feeding back experience and good practice into the regulatory process.

Enforcement

GS-R-1 §5.18 - 5.23

Decree No.17 has provisions that any person who contravenes the legislation in activities related to the importation, possession, transportation, use or dispose of radioactive material is guilty and will be penalized with a fine not exceeding two thousand shillings, or to imprisonment for a term not exceeding six months or both.

The Bill No. 17 has provisions that an authorized person who fails to send a notice of the occurrence of an incident or accident to the Council, who wilfully operates or interferes with a faulty installation or equipment resulting in loss of life or damage to property, who fails or refuses to produce a register certificate or a license, etc commits an offence and will be subject to a fine.

NRPS however does not have an enforcement policy. It has established arrangements with government law enforcement agencies, involvement of whom enforcement requires, but are not formal and in writing such as memoranda of understanding.

In all cases of non-compliance, NRPS requires the operator to rectify the non-compliance, perform a thorough investigation in an agreed time-scale, take all necessary measures to prevent recurrence and ensures that remedial actions have been effectively implemented within a specified time frame, but these requirements are not formally established in written procedures.

For cases that impose imminent radiological hazard to workers, the public or the environment, as well as in cases of serious non-compliance, NRPS requires the operator to cease activities and to take prompt actions necessary to restore an adequate level of safety.

All enforcement actions are confirmed to the operator in writing and inspectors can take on-the-spot enforcement actions as needed, but there are no written procedures.

Regulations and Guides

GS-R-1 §5.25- §5.28

The regulations are provided in "The Ionizing Radiational Protection (Standards) Regulations, 1996 (Statutory Instruments Supplement No. 21)". These regulations cover:

- occupational radiation exposure (Regulations Section 5, 8, 12 (Second schedule);
- public radiation exposure (Regulations Section 10 Third schedule);
- dose limits (Regulations Section 4, 6, 7, 11 First schedule);
- medical exposure (Regulations Section 13);
- management of radioactive waste (Regulations Section 24, 27 Fourth schedule, part C);
- transport of radioactive material (Regulations section 17, 18, 19, 20, 21, 22, 23 Schedule 4, part C).

The regulations do not address emergency exposure situations.

These regulations are outdated and are not consistent with the BSS. The regulations set dose equivalent limits whereas BSS recommends the use of effective dose.

The regulations provide means by which more detailed conditions, limitations and restrictions can be applied to individual authorizations (Regulations section 32 fourth schedule, part C).

The NRPS has taken account of internationally recognized standards and recommendations, including IAEA standards and guidance in developing regulations; however these standards have been updated since 1996.

The system of regulations is consistent with the legal system of Uganda, and the nature and extent of the facilities and activities that need to be regulated. The regulations are consistent with the Decree 12, but are not consistent with the Bill No. 17.

No guides have been prepared.

CONCLUSIONS	
(1)	**BASIS:** GS-R-1 §5
C11	**Conclusion:** While the NRPS has established good custom and practice it does not have written procedures for most of its regulatory activities. This could lead to inconsistency in approach.
(1)	GS-G-1.5 §3.25 states: *"The regulatory body should maintain a national register of radiation sources. The main input of data to the inventory is provided via notification."*
C12	**Conclusion:** Notwithstanding the fact that all sources entering Uganda legally are on the source registry, the source registry is apparently incomplete. Those sources outside of regulatory control potentially pose a threat to public health and safety.
(1)	**BASIS:** GS-R-1 §5.14 states: *"The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity."*
C13	**Conclusion:** There is no systematic inspection programme, which could lead to the ineffectiveness of the overall regulatory programme.
(1)	**BASIS:** GS-R-1 §5.18-5.24
C14	**Conclusion:** There are no enforcement policies and procedures, which could lead to inconsistencies in the implementation of the overall regulatory programme and may impact the credibility of the regulator.
(1)	**BASIS:** GS-R-1 §5.25-5.28
C15	**Conclusion:** With the passage of Bill No. 17, regulations are in need of drastic revision to make them consistent with the law and international standards.
(1)	**BASIS:** GS-R-1 §5.25-5.28
C16	**Conclusion:** There are no regulatory guidance or codes of practice for applicants or operators.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS**: GS-R-1 §5

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R8	**Recommendation:** NRPS should establish written procedures for all regulatory activities.
(1)	GS-G-1.5 §3.25, RS-G-1.9 §3.7-3.8
R9	**Recommendation:** Uganda should establish a comprehensive source registry using the RAIS template.
(1)	**BASIS:** GS-R-1§5.14 states: *"The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity."*
R10	**Recommendation:** NRPS should establish a systematic inspection programme.
(1)	**BASIS:** GS-R-1**§**5.18-5.24
R11	**Recommendation:** NRPS should establish enforcement policy and procedures.
(1)	**BASIS:** GS-R-1 **§**5.25-5.28
R12	**Recommendation:** On an urgent basis Uganda should significantly revise the regulations to make them consistent with the new law and international standards.
(1)	**BASIS:** GS-R-1 **§**5.25-5.28
S 2	**Suggestion:** NRPS should develop guidance documents commensurate with the range of activities in Uganda.

5. SAFETY OF RADIOACTIVE SOURCES

There is an interim radiological emergency response team that would address the actions to be taken in respect of sources that may have been found or lost from authorized control and arrangements are coordinated centrally by the Ministry of Energy and Mineral Development and the Uganda police. However, there are no written procedures. Uganda has had incidents involving the loss of radioactive sources and discovery of orphan sources and has used this team to respond to the incidents.

The NRPS has limited access to equipment and facilities for the handling, transport and temporary storage of radioactive sources following recovery of an orphan or vulnerable source. What is in place is not adequate since they could not handle a high activity source.

The relevant government authority does not have a process for assessing, in collaboration with NRPS, the transport safety arrangements for imported or exported sources while in transit from the State to its destination.

At the airport, radioactive sources held pending import or export are stored in the area for dangerous goods but are separated from the rest of the dangerous goods.

The NRPS has visited some scrap metal dealers, but they don't have detectors. The NRPS has provided information to scrap metal dealers on how to recognize radioactive containers.

The NRPS has not implemented requirements for the safety of radioactive sources during transport.

The NRPS notifies police about movement of high-risk sources. Transporters of high-risk sources are to keep NRPS informed about their movement.

Users of radioactive sources for well logging are given guidelines regarding safety of radioactive sources, but the NRPS does not have the means to visit where the sources are located.

Part VII of the Bill No. 17 addresses safety and security of radioactive sources. Section 54 covers general responsibility for safety and security of radioactive sources. Section 55 addresses accountability and security of sources including the requirements of users of radioactive sources on reporting to the Council information regarding any decontrolled, lost, stolen or missing source and to conduct periodic inventory of sources at intervals specified in the licence to confirm they are in their assigned locations and secure. Section 56 addresses security of radioactive sources and nuclear installations including the requirement of users of radioactive sources to promptly report to the Council any loss of control and any incidents connected to a radioactive source.

In the Bill No. 17, every user of a radiation source shall ensure the safety and security of all sources under his or her responsibility, from the moment of acquisition, throughout their entire operational life, up to final disposal (Section 54.1).

According to Bill No. 17, every user of a radiation source shall, for the purpose of safeguarding the safety of a radiation source, ensure that a multi-layer system of provisions for protection and safety (Defence in Depth) commensurate with the magnitude and likelihood of the potential exposure involved is applied to the radiation sources under his or her responsibility such that a failure at one layer is compensated for or corrected by subsequent layers, for the purpose of: preventing accidents

that may cause exposure, mitigating the consequences of any such accident should it occur, and restoring sources to safe conditions after any accident (Section 54.2).

CONCLUSIONS	
(1)	**BASIS:** BSS §2.34, 2.35, RS-G-1.9
C17	**Conclusion:** Bill No.17 Part VII "Safety and Security of Radioactive Sources" offers a dramatic improvement over the current legislation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** BSS §2.34, 2.35, RS-G-1.9
R13	**Recommendation:** In order to strengthen the programme for safety of radioactive sources, the Government of Uganda should pass Bill No. 17 into law with its provisions on safety and security of radioactive sources.

6. MANAGEMENT SYSTEM FOR THE REGULATORY BODY

NRPS has not yet developed procedures to regularly review the quality and efficiency of its regulatory activities. However it has developed inspection protocols and has identified equipment needs to maintain the inspection program and staff training, and there exists a process of reviewing regularly without written procedures.

7. 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:

A discussion was held about the tradeoffs between keeping certain information confidential due to concerns about terrorism, and making the information widely available so that groups such as first responders and medical personnel can adequately prepare for emergencies.

There was a general discussion among the Team and the Ugandan counterparts about confidentiality and transparency in the medical sector. Normally, there would be strict doctor/ patient confidentiality, but that may need to be adjusted. For example, a mammography unit may not have been functioning optimally and individual patient cases may have to be discussed with a wider set of professionals. Additionally, there may be a need for notification to patients about the need to have a repeat mammogram since small lesions may not have been detected. This kind of openness and transparency is important.

Regulatory activity information management

Bill No. 17 has provisions as the functions of the Council to maintain contact for information exchange and for proper collection and dissemination of information (Section 9.1(m) and 9.1(p)).

NRPS has not yet established and implemented procedures for the collection and the dissemination of information related to radiation safety but a process of information exchange with other relevant government bodies, professional organizations, etc exists at an ad hoc basis. Dissemination of information in the event of an actual or potential safety incident takes place through the Ministry of Energy and Mineral Development but there is no written procedure.

NRPS has not yet established and implemented procedures to ensure security of sensitive information, but computers and other removable media that holds sensitive information is kept locked and keys are kept securely. Disposal of such information devices has also not arisen so far.

Public information and communication

Bill No. 17 has provisions as the functions of the Council to maintain contact for information exchange and for proper collection and dissemination of information (Section 9.1(m) and 9.1(p)).

NRPS has not yet established and implemented procedures for the collection and the dissemination of information related to radiation safety but a process of information exchange with other relevant government bodies, professional organizations, etc exists at an ad hoc basis. Dissemination of information in the event of an actual or potential safety incident takes place through the Ministry of Energy and Mineral Development but there is no written procedure.

NRPS has not yet established and implemented procedures to ensure security of sensitive information, but computers and other removable media that holds sensitive information is kept locked and keys are kept securely. Disposal of such information devices has also not arisen so far.

CONCLUSIONS	
(1)	**BASIS:** GS-R-3 §5.12, 5.21
C18	**Conclusion:** Written procedures have not been developed to ensure security of sensitive information.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R-3 §5.12, 5.21
R14	**Recommendation:** NRPS should develop written procedures to ensure the security of sensitive information.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
Jill LIPOTI	New Jersey Department of Environmental Protection-USA	Jill.lipoti@dep.state.nj.us
Teodros GEBREMICHAEL	Ethiopian Radiation Protection Authority-Ethiopia	teodrosgm@yahoo.com
Tom RYAN	Radiological Protection Institute of Ireland-Ireland	tryan@rpii.ie
IAEA STAFF MEMBERS		
Cynthia HEINBERG	Division of Radiation, Transport and Waste Safety, Team Coordinator	c.heinberg@iaea.org
OFFICIAL LIAISON OFFICER		
Michael KIZA	Staff of the Nuclear Energy Unit of MEMD – National Liaison Officer	kiza@energy.go.ug
UGANDAN COUNTERPARTS		
Honourable D'Ujanga SIMON	Minister of State for Energy	
Honourable Kabagambe KALIISA	MEMD – Permanent Secretary	
Dr. Akisophel KISOLO	NRPS – Secretary / Chief Radiation Safety Officer	akisolo@physics.mak.ac.ug akisolo@yahoo.com
Harriet LWABI	Ministry of Justice and Constitutional Affairs – First Parliamentary Counsel / Director, Legislative Drafting	hlwabi@yahoo.co.uk
Irene BATEBE	Staff of the Nuclear Energy Unit of MEMD	batebe@energy.go.ug
Kwizera SAMSON	NRPS	kwizera@physics.mak.ac.ug
Dr. Joseph B. KIGULA-MUGAMBE	Mulago Hospital – Radiation Oncologist	jbkigula@yahoo.com
Olanya Alarakol COX	Mulago Hospital – Principal Radiographer	alarakolcox@yahoo.com

Richard EMBATI	Mulago Hospital – Sr. Nuclear Medicine Technologist	embatirichard@yahoo.co.uk

APPENDIX II – MISSION PROGRAMME

Date/time	Programme	Participants
15 OCTOBER 2007		
10:00–10:30	Entrance meeting with NRPS and Staff of the Nuclear Energy Unit of MEMD	Full IRRS Team NRPS Staff of the Nuclear Energy Unit of MEMD
10:30–11:00	Review of IRRS programme	Full IRRS Team, NRPS and Staff of the Nuclear Energy Unit of MEMD
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, NRPS and Staff of the Nuclear Energy Unit of MEMD
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, NRPS and Staff of the Nuclear Energy Unit of MEMD
18:00–23:30	Preparation of findings and drafting of IRRS report	IRRS Team

16 OCTOBER 2007		
09:00–12:00	Discussion of Regulatory Policy Issues	Full IRRS Team, NRPS Chief Radiation Safety Officer (CRSO) and Staff of the Nuclear Energy Unit of MEMD
12:00–13:00	Lunch	
13:00–14:00	Visit to NRPS Lab	Full IRRS Team, NRPS CRSO and Staff of the Nuclear Energy Unit of MEMD
14:00–17:00	IRRS Team observation of regulatory inspections of medical facilities (radiotherapy, nuclear medicine, diagnostic radiology)	IRRS Team members working in smaller groups or as individuals, NRPS and Staff of the Nuclear Energy Unit of MEMD
14:00–17:00	Drafting of IRRS report	Team Coordinator
17:00–23:00	Preparation of findings and drafting of IRRS report	IRRS Team

17 OCTOBER 2007		
09:00–10:00	Meeting with Minister of State for Energy	Minister of State for Energy, full IRRS Team, NRPS CRSO and Staff of the Nuclear Energy Unit of MEMD
10:00–11:00	Meeting with MEMD Permanent Secretary	MEMD Permanent Secretary, full IRRS Team, NRPS CRSO and Staff of the Nuclear Energy Unit of MEMD
11:00–13:00	Continued discussions on the status of the national regulatory	IRRS Team member and NRPS CRSO

	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	
13:00–14:00	Lunch	
14:00–17:00	Continued discussions on the status of the national regulatory infrastructure component 1 – 'Legislative and Statutory Framework' and component 2 – 'Activities of the Regulatory Body'	IRRS Team member and NRPS CRSO
17:00–23:00	Preparation of findings and drafting of IRRS report	IRRS Team

18 OCTOBER 2007		
9:00–12:00	Preparation of findings and drafting of IRRS report	Full IRRS Team and NRPS
10:00–11:00	Meeting with Ministry of Justice and Constitutional Affairs	IRRS Team Leader, First Parliamentary Counsel / Director, Legislative Drafting
12:00–13:00	Lunch	
13:00–15:00	Drafting of IRRS preliminary draft report	Full IRRS Team
15:00–16:00	Presentation of the draft report with recommendations and suggestions by IRRS Team to NRPS Preliminary draft made available to the regulator for review	IRRS Team, NRPS CRSO and Staff of the Nuclear Energy Unit of MEMD
16:00–23:00	Final drafting of preliminary draft report	Full IRRS Team

19 OCTOBER 2007		
09:00–13:00	Exit meeting Summary of findings and recommendations, action plan	Full IRRS Team, Minister of State for Energy, MEMD Permanent Secretary, NRPS CRSO and Staff of the Nuclear Energy Unit of MEMD
13:00–14:00	Lunch and depart	

APPENDIX III – SITE VISITS

The team visited Makerere University to see the laboratories. The University has two gamma spectrometer systems with sodium-iodide detectors to measure radioactivity in food certification and research. They also have gas flow proportional counter. They have a cave (bunker) for storing radioactive sources. They have a secure storage location for their inspection equipment. The team was told that there is also a dosimetry laboratory, but time constraints did not permit a visit.

The team visited Mulago Hospital but there was not time for the NRPS to do a complete inspection to demonstrate inspection techniques to the Team. In the radiotherapy department, they have one cobalt-60 source, one cesium source for brachytherapy, and a strontium eye applicator. They also have a therapy simulator room. It was noted by the NRPS that the light indicating that the source was in use was not functioning, and the Hospital staff made the correction while we were on site. The hospital staff also demonstrated the effectiveness of the interlock system. The NRPS used a survey meter to check ambient dose and effective shielding.

In the nuclear medicine department, the team was given a very thorough tour of the facility. Only technicium-99m was being used. The molybdenum generators were imported from South Africa. There was only one imaging room. The cobalt-60 flood source had decayed beyond its useful life. Patient injection area was segregated. There was a waste storage bunker and a good waste treatment plan. All waste including soiled linens was held for decay for 10 half-lives. There was a segregated toilet for patient use after injection. The team observed the NRPS took ambient measurements throughout.

The team was told that patients come from Sudan and DRC for treatment at this nuclear medicine facility because it is the only functional one in the region. The hospital has plans for use of additional radionuclides, i.e. iodine and gallium.

The team visited the radiology department where there are seven x-ray machines, but not all are functional at this time. The team observed a typical x-ray room, with proper shielding and automatic exposure control. The team also visited the mammography room where there was one functional mammography unit and one disused unit. The team was able to visit a fluoroscopy room. The fluoroscopy machine was protected with a blue tarpaulin due to water leakage. The machine was not functional and corrosion was in evidence. The hospital showed the team its computed tomography facility. The technologist was training additional staff.

APPENDIX IV – MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Counterparts
	Legislative and governmental responsibilities	• Jill Lipoti • Teodros Gebremichael • Tom Ryan • Cynthia Heinberg	• Akisophel Kisolo • Michael Kiza • Irene Batebe • Kwizera Samson
	Responsibilities and Functions of the Regulatory Body		
	Organization of the regulatory body		
	Activities of the Regulatory Body		
	Management System for the Regulatory Body		
	Policy Issues		
	Public Information		
	Safety of Radioactive Sources		

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 Government of Uganda, on an urgent basis, should pass Bill No. 17 with Amendments introduced by the Minister of Energy and Mineral Development to allow delegation of authorization, inspection and enforcements functions.
		R2	The Government of Uganda should address the implementation of relevant international treaties, conventions and agreements with an Amendment to Bill No. 17 or other legislation.
		R3	In setting up the Council and Secretariat, the Government of Uganda should pay particular attention to the roles and reporting relationships so that possible conflicts of interest with regard to nuclear power promotion and provision of dosimetry services are avoided.
B	Responsibilities and Functions of the Regulatory Body	*S1*	A process of formalizing intergovernmental and international cooperation should be developed through articles or memoranda of understanding.
C	Organization of the Regulatory Body	*R4*	The Ugandan Government should give immediate attention to the provision of staffing, equipment and facilities to support regulatory activities.
		R5	The Minister of Energy and Mineral Development should introduce an Amendment to Bill No. 17, which allows the Council to delegate inspection functions to the Radiation Protection Officers.
		R6	The regulatory body should seek to obtain equipment, facilities and transport necessary for conducting regulatory activities.

	Areas	IAEA Comment No. *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		R7	NRPS should establish and implement a comprehensive training programme for the regulatory staff. This programme will be adjusted to the growth of activities and acquisition of experience and knowledge by the staff.
D	Activities of the Regulatory Body	*R8*	NRPS should establish written procedures for all regulatory activities.
		R9	Uganda should establish a comprehensive source registry using the RAIS template.
		R10	NRPS should establish a systematic inspection programme.
		R11	NRPS should establish enforcement policy and procedures.
		R12	On an urgent basis the Government of Uganda should significantly revise the regulations to make them consistent with the new law and international standards.
		S2	NRPS should develop guidance documents commensurate with the range of activities in Uganda.
E	Safety of Radioactive Sources	*R13*	In order to strengthen the programme for safety of radioactive sources, the Government of Uganda should pass Bill No. 17 into law with its provisions on safety and security of radioactive sources.
F	Information Management	*R14*	NRPS should develop written procedures to ensure the security of sensitive information.

APPPENDIX VI – REFERENCE MATERIAL PROVIDED BY NRPS

[1] The Atomic Energy Decree, 1972 (Decree 12)

[2] The Atomic Energy Bill, 2007 (Bill No. 17)

[3] The Ionizing Radiational Protection (Standards) Regulations, 1996 (Statutory Instruments Supplement No. 21)

[4] Form for Application for a Licence to Possess Radioactive Material or Radiation Device

[5] Inspection Procedure for Fluoroscopic and Diagnostic X-Ray Units

[6] License to Possess or Use Radioactive Materials/Devices or Transport Radiation Sources

[7] Report of Quality Assurance of X-Ray Equipment and Dark Room [from NRPS to licensee]

[8] Agreement between the Republic of Uganda and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons [example of an international agreement]

[9] Protocol Additional to the Agreement between the Republic of Uganda and the International Atomic Energy Agency for the Application of Safeguards in Connection with the Treaty on the Non-Proliferation of Nuclear Weapons [example of an international agreement]

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 Authority for the Control Of Radiation Sources (draft)

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

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

[10] NTERNATIONAL ATOMIC ENERGY AGENCY Application of the International 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] NTERNATIONAL 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

NRPS	National Radiation Protection Service
MEMD	Ministry of Energy and Mineral Development
CRSO	Chief Radiation Safety 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 for 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 identified in the existing legislation (Atomic Energy Decree (Decree 12) of 1972), the revised draft Atomic Energy Bill 2007 consistent with the IAEA Basic Safety Standards (SS 115) and other referenced IAEA documents has been printed for debate by the Parliament. The existing legislation will be repealed. 1.1.2 The revised legislation, in particular, addresses: • 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	NRPS/AEC/ MEMD/ Justice	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 establishing and maintaining a national register of 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.	NRPS/AEC/ MEMD	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. IAEA may be requested to provide a resource person for this seminar.	• GS-R-1, § 2.1, 2.4 [2] • CoC, § 18, 19 [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1.2 Enact the legislation: 1.2.1 Finalize draft/ amended legislation and take necessary measures to promulgate it in due time.	National Government		
2 Regulations and Guidance			
2.1 Review and Revise Draft Regulations: 2.1.1 Replace the Ionizing Radiation Protection Regulations, 1996, for consistency with the legislation to ensure they are appropriate to the nature of facilities and radiation practices to be regulated within Uganda. Ensure consistency with other national regulations (e.g. Allied and Professional Workers Standards, Standards for Use of Ionizing Radiation Sources in Medical Practices in Uganda, etc.). 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;	NRPS/AEC/ MEMD/ Justice	After submission of the draft regulations by Uganda, the IAEA may consider the provision of an Expert Mission (EM 2) comprising legal, technical and security experts to review the draft.	• 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]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
• radioactive waste management; • transport of radioactive sources; • emergency exposures situations. • security of radioactive sources including unauthorized 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 Uganda.	National Government /Appropriate Ministries/ NRPS/AEC/ MEMD/ Justice/ Health/ Environment		
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, ensuring consistency with other national regulations. The codes of practice should cover:	NRPS/AEC/ MEMD/ Justice	After submission of the draft Guidance Documents by Uganda, the IAEA may consider the provision of an Expert Mission (EM 3) to review the drafts.	• GS-R-1, § 5.25 – 5.28 [2] • CoC, § 22(m) [3] • Applying Radiation Safety Standards in Nuclear Medicine [8] • Applying Radiation Safety

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
• Diagnostic radiology • Teletherapy • Brachytherapy • Nuclear medicine • Industrial radiography • Industrial irradiators • Nuclear gauges • Well logging			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]
2.4 Issue Guidance Documents: 2.4.1 Issue the new/revised guidance documents.	NRPS/AEC/ MEMD/ Justice		

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
3 Regulatory Body Staffing and Training			
3.1 Staffing: 3.1.1 Develop a 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 and available resources (for both short- and long-term).	NRPS/AEC/ MEMD		• 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] • Authorization for the Possession and Use of Radiation Sources (draft). [14] • Inspection of Radiation Sources and Enforcement (draft) [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.	NRPS/AEC/ MEMD	Provision of an expert mission (EM 5) to review the programme Provision of training packages as appropriate, dealing for example with; authorization and inspection of radiation sources in diagnostic radiology, nuclear medicine,	• GS-R-1 § 4.7 [2] • CoC§ 10 [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
		radiotherapy, irradiators, industrial radiography, gauges and well logging, cyclotron facilities. Provision of fellowships	
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	Provision of an expert Mission to review the organization and resources (EM 4)	• 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, Police, Security, and Transport. ***Note:*** *Coordination and cooperation can be formalized through written Memorandums of Understanding between the relevant authorities.*	NRPS/AEC/ 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
6 International Cooperation			
6.1 Regional Cooperation: 6.1.1 Establish 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 Establish arrangements for the exchange of safety and security related information with interested States and relevant intergovernmental organizations as may be appropriate.	NRPS/AEC / 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.	NRPS/AEC	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 Uganda 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.	NRPS/AEC / 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:	NRPS/MEMD	At the request of the	• CoC, § 11, 17. Annex 1[3]

INTERNATIONAL ATOMIC ENERGY AGENCY
Wagramer Strasse 5, PO Box 100, A-1400 Vienna, Austria

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1.3.1 Develop and maintain a comprehensive national register of ionizing radiation sources. 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.		regulatory body, 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) and provision of a computer for RAIS 3.0. Provide expert mission to assist with operation of RAIS 3.0.	• Reference [14] • Reference [6]
2 Authorization			
2.1 Establish a System of Authorization: 2.1.1 The Regulatory body should approve and issue 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.	NRPS/AEC	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]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
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.	NRPS/AEC		• GS.R-1 § 5.5 (1, 2) [2]
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.	NRPS/AEC		• 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 Uganda 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	NRPS/AEC/ Government/ Customs Administration		• CoC, § 23 – 25 and 28 [2] • GIERS 2005 Parts VII-IX [16]. • Reference [14]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
guidance. • Ensures that the appropriate regulatory framework exists.			
3 Safety and Security of Radioactive Sources			
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.	NRPS/AEC	If requested by Uganda, the IAEA may provide an Expert Mission for 1 week to review processes (EM 8)	• 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.	NRPS/AEC	Provide an expert mission to review the process (EM 9).	• 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 Review/revise and approve formal written process and inspection procedures appropriate to the types of radiation practices regulated.	NRPS/AEC	Provide an expert mission to review the process (EM 9). At the request of Uganda, the IAEA may consider the provision of inspection equipment	• Reference [15]
4.1.3 Review/revise formal written protocols clearly defining the duties and responsibilities of inspectors in the conduct of inspections.	NRPS/AEC	Provide an expert mission to review the process (EM 9).	• Reference [15]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
5 Enforcement			
5.1 Establish a System of Enforcement: 5.1.1 Establish and approve 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).	NRPS/AEC (and other agencies as may be appropriate)	Provide an expert mission to review the process (EM 9)	• GS-R-1, § 5.18 – 5.24 [2] • CoC, § 20 (i), 22 (j) [3] • Reference [15]
6 Information Management			
6.1 Information Collection and Dissemination: 6.1.1 Develop and approve formal procedures for collecting and disseminating information to radiation users, professional groups having input to radiation practices and to the public where appropriate.	NRPS/AEC with the cooperation of relevant Government agencies.	Provision for an expert mission to review the procedures (EM 10)	• 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.	NRPS/AEC	Provision for an expert mission to review the programme (EM 11)	• GS-R-1, § 4.5 [2] • TECDOC-1090 [17] • ISO 9000 [18]