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INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

THE REPUBLIC OF BOTSWANA

Radiation Protection Board

Gaborone, Botswana

18 to 22 February 2008

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

European Union

Conducted by the IAEA
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IAEA

FOREWORD

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

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

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

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

The new regulatory service is structured in modules that cover general requirements for the establishment an effective regulatory framework, regulatory activities and management systems for the regulation and control in nuclear safety, radiation safety, waste safety, transport safety, emergency preparedness and response and security. The aim is to make the IAEA services more consistent, to enable flexibility in defining the scope of the missions, to promote self-assessment and continuous self-improvement, and to improve the feedback on the use and application of the IAEA Safety Standards. The modular structure also enables tailoring the service to meet the needs and priorities of the Member State. The IRRS is neither an inspection nor an audit but is a mutual learning mechanism that accepts different approaches to the organization and practices of a national

regulatory body, considering the regulatory technical and policy issues and that contributes to ensuring a strong nuclear safety regime. In this context, considering the international regulatory issues, trends and challenges, and to support effective regulation, the IRRS missions provide:

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

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

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

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

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

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

With regard to the IRRS, the Director General of the IAEA, Dr Mohamed El Baradei, has stated that; 'The General Conference Resolution of September 2006 related to measures to strengthen international cooperation in nuclear, radiation and transport safety and waste management: "recognizes the importance of an effective regulatory body as an essential element of national

nuclear infrastructure, urges Member States to continue their efforts to increase regulatory effectiveness in the field of nuclear, radiation and transport safety and waste management, and consider availing themselves of the Secretariat's new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS".

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

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

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

REPORT TO

THE GOVERNMENT OF THE REPUBLIC OF BOTSWANA

RADIATION PROTECTION BOARD

Gaborone, Botswana

18 to 22 February 2008

REPORT TO

THE GOVERNMENT OF THE REPUBLIC OF BOTSWANA

RADIATION PROTECTION BOARD/ RADIATION PROTECTION INSPECTORATE

Gaborone, Botswana

Mission date: 18 to 22 February 2008

Official Counterpart Organization: Radiation Protection Board/Radiation Protection Inspectorate

Location: 1278 Luthuli Road, Cliff House, Bontleng, Gaborone

Regulated facilities and activities: medical, industrial, mining and research applications

Organized by: IAEA

IAEA Review Team: Mr Tony COLGAN, Team Leader, Ireland
Mr Justin NGAILE, Reviewer, Tanzania
Mr Nasiru-Deen BELLO, Reviewer, Nigeria
Ms Melpo AGATHOCLEOUS, Observer, IAEA/NSRW
Mr Karol SKORNIK, Team Co-ordinator, IAEA/NSRW.

IAEA-2008
Issue date: August2008

The number of recommendations, suggestions and good practices set out in this report is in no way a measure of the status of the regulatory framework. Comparisons of such numbers between IRRS reports from various countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of Botswana, an international peer review team of four experts and an observer in radiation safety and security visited the Radiation Protection Inspectorate (RPI), an executive arm of the Radiation Protection Board (RPB), from 18 to 22 February 2008 to conduct an Integrated Regulatory Review Service (IRRS) mission to review the country's regulatory framework and the effectiveness of the RPI, as the body responsible for discharging day-to-day regulatory functions for radiation protection and safety in relation to activities involving radiation sources and radiation facilities in Botswana.

The purpose of the mission was to conduct a review of the country's regulatory framework for all regulated activities involving radiation sources, facilities and practices, to review the regulatory effectiveness of the RPI and to exchange information and experience in the areas considered by IRRS. It is expected that through a comprehensive appraisal process, carried out jointly by the reviewers and senior representatives of the RPI and other members of the radiation protection community in Botswana, the outcome of the mission will facilitate improvements in regulatory infrastructure of the country.

The scope of the mission included all activities regulated by the RPI in medical, industrial, mining and research practices, as well as activities relating to safety and security of radioactive sources.

The IRRS Review Team (the team) consisted of senior regulatory experts from three Member States, as well as one representative and observer of the IAEA. The team carried out the review of RPI activities in all areas pertinent to regulatory infrastructure: such as legislative and governmental framework, duties and responsibilities, organizational structure, statutory activities (authorization, review and assessment, inspection and enforcement), development of regulations and guides, safety and security of radioactive sources, general managerial issues including information and quality management.

The objectives of the mission were met by review of documentation provided by the Counterpart prior to the mission including copies of legislation and the *Pre-appraisal Questionnaire*, a series of interviews and work sessions with key RPI staff, as well as by the participation in a regulatory inspection of a medical diagnostic radiology department. At the exit meeting, the team presented its findings, with reference to the international safety standards and related requirements (GS-R-1, Code of Conduct and its GIERS), as well as security considerations. Additionally, the IRRS team, together with RPI management, discussed key policy issues relating to the regulation of radiation safety in Botswana.

The team noted that the existing legislative framework of Botswana (The Radiation Protection Act, 2006 and the final draft Radiation Protection Regulations, 2007) is consistent with IAEA safety standards and international undertakings. However, there is a need to prepare specific guidance to support the legislation.

The team acknowledged the significant effort made by the RPI management and staff in the preparation of the mission. Technical and logistical support extended to the team throughout the mission was outstanding. The team made recommendations and suggestions on the improvements to be made to strengthen and enhance, where necessary, the legal and governmental infrastructure for radiation safety and security, and to improve effectiveness of regulatory control in Botswana. Good practices have been identified and highlighted.

The IRRS Team believes that consideration of the following major issues, with significant bearing on the strengthening the regulatory system of Botswana, should be assigned the highest priority:

- Effective implementation of regulatory activities of RPI, including the commencement of authorization process, based on the existing legislative and regulatory framework,
- Completion of all elements of the legislative framework, by issuing outstanding Regulations, as well as regulatory guidance and procedures in compliance with international standards,
- Development and promotion of radiation safety and security awareness among decision-makers, stakeholders and the public at large.

The IRRS team findings are summarized in Appendix V. There was a consensus that through its services the mission already contributed to enhancing the effectiveness of regulatory system for radiation safety and security in Botswana. Further progress may be reported following the implementation of the Action Plan 2008-2009 (Appendix VIII), drawn during the mission. The Plan takes due account of the mission's recommendations and suggestions.

I. INTRODUCTION

At the request of the Government of Botswana, submitted through the Ministry of Communications, Science and Technology, an IAEA team consisting of three experts from Member States, as well as one representative and an observer of the IAEA, visited the Radiation Protection Inspectorate (RPI); the executive arm of the Radiation Protection Board (RPB, the regulatory authority), from 18 to 22 February 2008 to conduct an Integrated Regulatory Review Service (IRRS). The RPI was the official counterpart organization to the mission.

The purpose of the mission was to conduct a review of the country's regulatory infrastructure and the related activities, to review the effectiveness of the RPI, and to exchange information and experience in the areas pertinent to the objectives of the mission. The areas under review included: legislative framework and ongoing developments, related governmental responsibilities; responsibilities, functions and empowerment of the regulatory body; organization of the regulatory body; the authorization process; inspection and enforcement; safety and security of radiation sources; as well as information and quality management systems.

Additionally, the IRRS team, together with RPI management, discussed key policy issues relating to the regulation of radiation safety and security. This part is a new element introduced to the scope of the mission and its agenda. The policy issues included, among other things: independence of the RPI, openness and transparency in regulatory activities including the involvement of stakeholders and public information, enhancing regulatory competence and effectiveness.

Prior to the mission, the counterpart made available a set of reference material consisting of legal and regulatory documents, a progress report prepared in connection with a regional coordination meeting on strengthening regulatory infrastructure, Cairo, Egypt, April 2007 (RAF/9/031), and a completed *Pre-appraisal Questionnaire*.

The objectives of the mission were met by joint sessions on review of documentation provided by the counterpart, a series of interviews and work sessions with key RPI staff, as well as by the observation of a regulatory inspection. Mission activities took place mainly at the RPI headquarters in Gaborone. The regulatory inspection was observed at the diagnostic radiology department, Scottish Livingstone Hospital, Molepolole, 50 km outside Gaborone (see Appendix III).

An exit meeting was held on 22 February 2008. The meeting was attended by Ms Marianne Nganunu, Permanent Secretary, Ministry of Communications, Science and Technology, and the RPI Management. The contents of draft mission report including findings, conclusions, recommendations, suggestions, as well as good practices, identified by the IRRS team, with reference to the international safety standards and related requirements (GS-R-1), as well as security considerations, with reference to the Code of Conduct, were presented by the Team Leader, discussed and agreed upon. The meeting also agreed on the follow up draft Action Plan 2008-2009. The draft mission report and the Action Plan were handed over to the Counterpart.

II. OBJECTIVES AND SCOPE

The purpose of the mission was to conduct a peer review of the legal framework and governmental infrastructure for radiation safety and security, and to appraise the effectiveness of the RPI as technical arm of the RPB, the regulatory body of Botswana. The terms of reference for the mission also included exchange of information and experience with a view to harmonizing regulatory approach, in line with international Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) and related requirements (GS-R-1).

The key objectives of this mission were to provide recommendations and suggestions how to strengthen and enhance, where necessary, the country's regulatory infrastructure for radiation safety and security. This was accomplished by:

- ✓ a comprehensive review of relevant policy and technical issues;
- ✓ a thorough and objective evaluation of regulatory activities with reference to international safety standards and related undertakings,
- ✓ discussions with the Counterpart aimed at harmonizing regulatory approaches among Member States in line with the international safety standards, as well as by information and experience sharing on regulatory practices and lessons learned;
- ✓ joint work sessions on the *IRRS Evaluation Questionnaire*, providing the Counterpart with an opportunity for self-assessment of the RPI activities.

The mission was also an excellent learning process for its team members, providing better insights on country-specific issues related to discharging regulatory functions by the RPI.

As a result of this intense and professional interaction, the mission members and the Counterpart were able to arrive at and agree on conclusions, recommendations and suggestions for improvement. The IRRS team noted, with satisfaction, that several good practices could be identified in activities of the relatively new regulatory body of Botswana.

The scope of the mission, agreed with the Counterpart, included:

- an overall appraisal of regulatory issues for radiation safety and security in all areas of application of radiation sources,
- general aspects relating to safety and security of radioactive sources;
- quality and information management systems including public information.

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work for the IRRS mission was carried out by Team Coordinator, Mr. Karol Skornik, NSRW/IAEA. According to the IRRS guidelines, the Team Leader, Mr Tony Colgan, as well as other members of the team (Peer Reviewers), Messrs Justin Ngaile and Nasiru Bello, were external experts, directly involved in the regulatory work. Ms. Melpo Agathocleous, NSRW/IAEA, participated in the mission as observer (see Appendix I).

During the preparatory period all documents of the advance reference material (ARM) including the *Pre-appraisal Questionnaire*, were made available to the team. Programme arrangements as well as technical and logistical details were agreed to with Mr. Stephen WILLIAMS, Director, RPI.

Substantial work was carried out by the team members and the IAEA staff prior to the mission. This included initial review and analysis of the ARM, the Country *Radiation and Waste Safety Infrastructure Profile* (RaWaSIP) for Botswana, preparation for the interviews and identification of additional relevant material.

B) REFERENCE MATERIAL FOR THE REVIEW

The main reference documents for the mission, provided by the RPI, and those available from the IAEA records, are listed in Appendix VI. Relevant IAEA safety standards and other reference documents used for the review are listed in Appendix VII.

C) CONDUCT OF THE REVIEW

A thorough and comprehensive appraisal was conducted for all the areas under review. The process highlighted areas with good working practices of the RPI. It also led to the recommendations and suggestions in those areas where outstanding issues or gaps were identified. The review was conducted through a series of work sessions involving interviews and discussions with RPI Management, a regulatory inspection to a medical facility and an assessment of the ARM.

The team followed the agreed programme (time-table) for the mission (ref. Appendix II).

An entrance meeting with the RPI Management was held on Monday, 18 February 2008. A list of participants is presented in Appendix 1. The meeting focused on the programme, basis for the review, available background information, objectives and scope of the mission, as well as on the appraisal methodology. The reviewers were also able to acknowledge ample information provided in the advance reference material.

The exit meeting was held on Friday, 22 February 2008 (Appendix 1). The main findings, conclusions, recommendations and suggestions, as well as good practices were presented by the Team Leader. The draft mission report was handed over to the RPI Management.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

Legislative and statutory framework

GS-R-1 § 2.2 (1)

The legislative framework is provided by the Radiation Protection Act No 22 (the Act) promulgated in July 2006 and implemented on 1st April 2007. The Bill was prepared with the IAEA assistance. The Act provides for the safe use of atomic energy and nuclear technology for the protection of the general public and workers against the harmful effects of ionising radiation. Final draft Radiation Protection Regulations are in place and ready to be signed by the Minister. The legislation appears to be compatible with the BSS and GS-R-1. It covers occupational and public radiological protection, medical exposure control, safety of radioactive waste management and safe transport of radioactive material.

Establishment of an effectively independent regulatory body

GS-R-1 § 2.2 (2)

The law establishes the Radiation Protection Board (RPB) as the regulatory body, and the Radiation Protection Inspectorate (RPI) as its executive arm under the Ministry of Communications, Science and Technology (MCST). The RPI was established before the promulgation of the Act in order that it could commence operations immediately following the promulgation. The RPB became operational in October 2007. Its functions are to regulate the safe and peaceful uses of atomic energy. The RPB oversees the functions of the RPI.

Regulatory body - assigned responsibilities, authority, and resources

GS-R-1 § 2.2 (3)

The RPB is vested by the 2006 Act with the responsibilities for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides. Specifically, these responsibilities are assigned as follows:

Authorization

The RPB is the sole authority in the country, responsible for granting authorizations [ref. Article 11.1.b].

Regulatory Review and Assessment

This role is assigned to the RPB, under Article 11.2.

Inspection

The RPI, the executive arm of the RPB, is responsible for carrying out regulatory inspections [Article 19.a].

Enforcement

The RPB is responsible for enforcement actions [Article 9 of the Regulations].

Establishing regulations, safety principles, criteria and guides

This is clearly assigned to the RPI under Article 19.b, for the approval of the RPB and subsequent signature by the Minister.

Operator responsibility

GS-R-1 § 2.3

Articles 29.1 to 29.5 of the Act clearly assign primary responsibility for safety of radiation sources to the operator. Issues related to the security of radioactive sources are covered under Article 56 of the Regulations.

Legislative requirements

GS-R-1 § 2.4

The enacted legislation of Botswana, i.e. the 2006 Act, and the final draft 2007 Regulations, when enacted, will provide for the effective control of radiation safety. There is a need for clarification with regard to the body having ultimate responsibility for security of radioactive sources at the national level.

Authority of the Regulatory Body

GS-R-1 § 2.6 (1)-(14)

National legislation gives the RPB full authority and empowerment to discharge its regulatory functions.

CONCLUSIONS	
C1	**Conclusion:** The IRRS team acknowledges the fact that the legislative framework for radiation protection in the Republic of Botswana has been set up within a relatively short time and to a high standard. This was facilitated by the fact that the RPI was established before the promulgation of the Act.
C2	**Conclusion:** The RBP can be considered an effectively independent regulatory body.
C3	**Conclusion:** The legislative framework for radiation protection in the Republic of Botswana is consistent with international standards and related requirements.
C4	**Conclusion:** There are some outstanding issues related to the implementation of the Code of Conduct. These apply to the responsibilities for security of radioactive sources at the national level.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** 1. **GS-R1** §2.2 (2) states in part that *"A regulatory body shall be established…"* 2. Code of Conduct on the Safety and Security of Radioactive Sources [& 20 (a)]
R1	**Recommendation:** The body ultimately responsible for regulating the security of radioactive sources needs to be clarified. Should this responsibility be assigned to the RPB, then the existing legislation will need to be revised accordingly. Otherwise, the RPB should consider entering into a Memorandum of Understanding (MoU) or other formal arrangement with the organisation concerned.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Regulatory body - fulfilling statutory obligations

GS-R-1 § 3.1

The legislation makes provisions for the RPB to define policies, safety principles and criteria. These statutory obligations are being fulfilled. The final draft Radiation Protection Regulations have been completed and are ready to be enacted. Other subsidiary instruments including codes of practice and guidance documents have yet to be prepared.

GS-R-1 § 3.2 (1)

The legislation makes provision for the RPB to establish, promote or adopt regulations and guides. With the exception of the Regulations, this process has not yet commenced.

GS-R-1 § 3.2 (2)

The legislation gives responsibility to the RPI to review and assess applications for authorizations. These activities, in the form of pre-authorization inspections have been initiated. However, to date no authorization has been issued.

GS-R-1 § 3.2 (3) (i)-(x)

The legislation makes provisions for the RPB to issue, amend, suspend or revoke authorizations. This empowerment is not yet being implemented.

GS-R-1 § 3.2 (4)-(6)

The RPB is empowered to carry out regulatory inspections and enforcement actions.

Regulatory body – discharging its main responsibilities

GS-R-1 § 3.3 (1)-(5).

(1): the process for dealing with applications (e.g. for authorizations) has commenced but to date no authorizations have been issued. This work will commence shortly.

(2): the RPB has not implemented a process for changing conditions of authorization.

(3): guidance to the operator on developing and presenting safety assessment is still to be issued by the RPB.

(4): under Article 19.d of the Act, the RPI may require any operator to provide proprietary information. Articles 16.1 and 16.2 explicitly place a requirement on the RPB to protect the confidentiality of such submissions.

(5): the legislation does not specifically allow the RPI to reject an application for authorization, but this authority is implicit within the Act. The requirement to provide an explanation of the reasons for rejecting a submission has not yet arisen.

GS-R-1 § 3.3 (6)

The requirement regarding communication with the public is fulfilled. There is still limited exchange of information with governmental and other relevant bodies.

GS-R-1 § 3.3 (7) (13)

The requirement regarding analysis of operating experience and dissemination of lessons learned has not yet been fulfilled. This is understandable as the RPI is only now commencing the authorization process.

The RPI applies international standards with regard to the safety of radiation sources (Article 11.b and 11.c of the Act).

Ultimate responsibility for safety rests with the operator (Regulations, Part 4). The RPI will ensure that this is fulfilled through standard regulatory practice (issuing authorizations, conducting inspections and requesting safety assessments or appraisals from operators).

Regulatory body – cooperation with other relevant authorities

GS-R-1 § 3.4

One formal Memorandum of Understanding (MoU) relating to cooperation and coordination at a national level is in place with the Mines Inspectorate. The IRRS team was informed that a draft MoU is being prepared with Customs and Excise, including a training course for customs officers for which IAEA assistance is requested. There are no formalised agreements with law enforcement agencies, but also for these groups training appears to be a high priority, particularly for the police officers.

The authorities in Botswana have adopted an all-hazards approach to emergencies, including radiological emergencies. Contacts exist between the RPI and the National Disaster Management Office (NDMO) under the Office of the President. There is no formal MoU in place, but the RPI anticipates that such an agreement will be signed. The RPI would then act as technical adviser/support to the NDMO in the event of a radiological emergency. The Director of the RPI is a technical adviser to the NDMO.

Regulatory body – additional functions

GS-R-1 § 3.5

The RPI provides a TLD service for occupationally exposed workers. This practice is quite common in the region. Although it may represent a potential conflict of interest, it does not diminish the prime responsibilities of the RPB as regulator.

Plans are in place for the construction of a radioactive waste storage facility by the RPI. The present practice is that radioactive waste and disused sources are stored on the premises of the operator.

CONCLUSIONS	
C5	**Conclusion**: Good progress has been achieved in relation to cooperation and coordination with other organisations at the national level. However, there are still a number of areas where such arrangements remain to be put in place.
C6	**Conclusion:** The RPI is aware of the potential conflict of interest with regard to the provision of individual monitoring services to user institutions, and of the responsibility for the management of radioactive waste and disused sources. It is noted, however, that if these additional functions were not discharged by the RPI, no other national organisation would presently be in a position to provide these services. The same applies to the RPI's initiative and action taken to construct a radioactive waste storage facility.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-R-1 chapter 3
R2	**Recommendation:** While recognising that the RPB is only newly established, it is recommended that the highest priority be assigned to initiating the authorization process. The RPI should adopt a graded approach, with due consideration of risks associated with practices and categorisation of radioactive sources.
S1	**Suggestion:** While noting that the provision of personnel monitoring services by the RPI is an additional function of the Regulatory Body, it is noted that the current situation is dictated by prevailing country-specific conditions. It is suggested, however, that, in the future, due consideration be given to assigning the responsibility for rendering these services to another body which would be certified by the RPI.
S2	**Suggestion:** While accepting that the planned construction of a radioactive waste management facility under the control of the RPI is a temporary arrangement, it is suggested that due consideration is given to assigning the responsibility for the management of radioactive waste and disused sources to a dedicated organisation which would become a licensee.

3. ORGANIZATION OF THE REGULATORY BODY

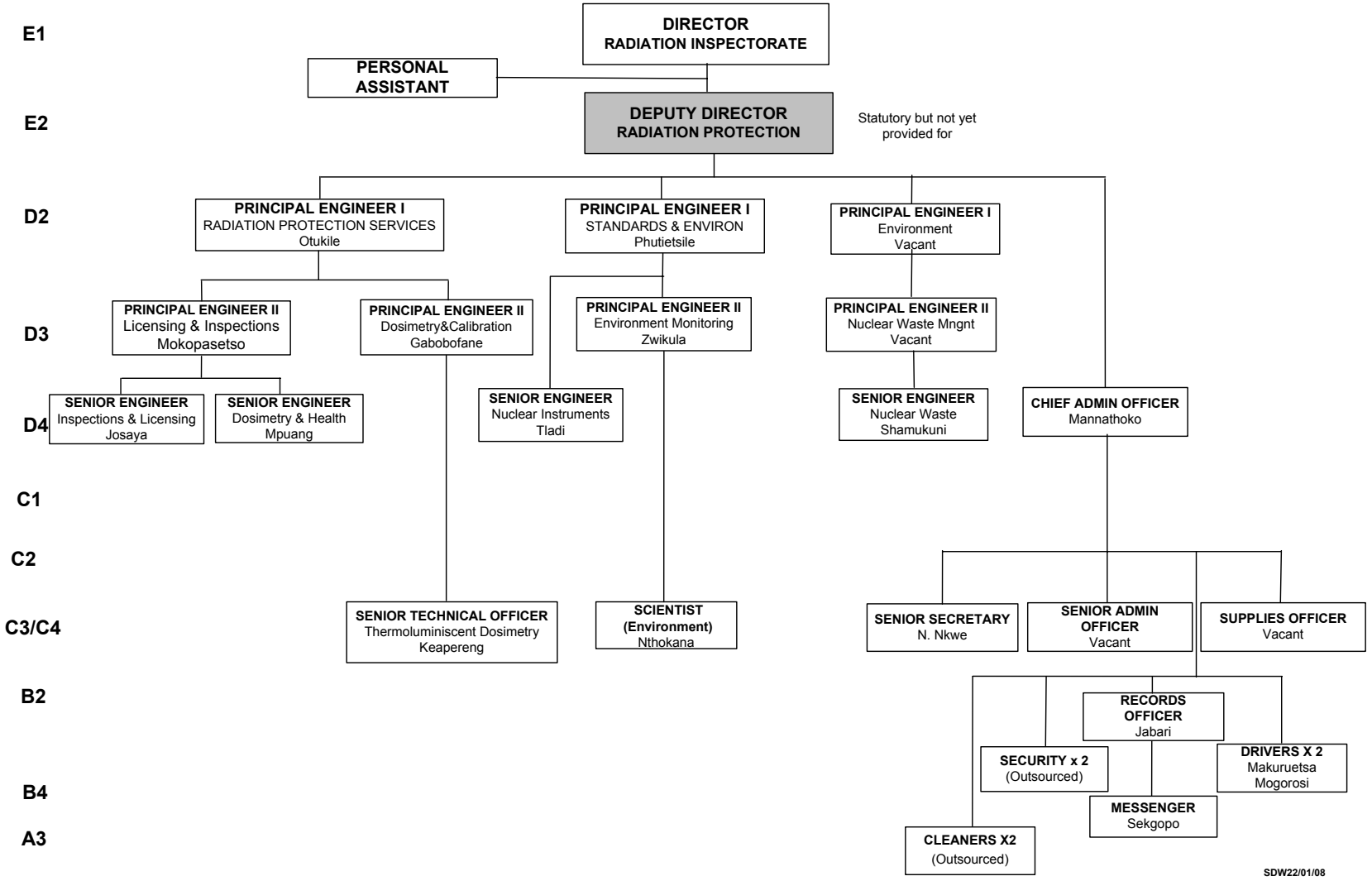
Organizational structure, size and activities

GS-R-1 § 4.1

The requirement regarding organisational structure is fully met. The RPI has a well defined organizational structure. The size of the regulatory body is commensurate with the extent of current practices. Activities of the RPI are entirely based on the existing enabling legislation which is consistent with the international BSS and GS-R-1. The organizational structure of the RPI is presented below.

The RPI budget is approved by the Government through the Ministry of Communications, Science and Technology. At present, funding of the RPI appears to be adequate. Future needs include the purchase of instruments required during inspection. There may also be a need to establish a laboratory to measure radioactivity.

THE RADIATION PROTECTION INSPECTORATE



Use of consultants and contractors

GS-R-1 § 4.3

The RPI has not been using services of external consultants and contractors so far, although it is allowed to do so under the Act.

Staffing and Training of the Regulatory Body

GS-R-1 §4.6-4.8

The Director of the RPI will be formally appointed in April 2008. The RPI has 11 professional staff (with a further two vacancies), one technical staff member and seven support staff.

Three national training courses were organized in 2005 and 2006 under IAEA Regional Project RAF/9/031. Botswana took advantage of national training courses held, with the IAEA assistance, in Zambia and Sierra Leone in 2006, and has sponsored the training of staff at these courses. The 3rd training course for newly recruited staff of the RPI, and for designated Radiation Protection Officers from user institutions, was organized, with IAEA assistance, in Gaborone, December 2006 (*National Training Course on Regulatory Authorization and Inspection of Radiation Sources* (RAF/9/031). Moreover, two members of RPI staff attended the IAEA regional training course for regulators, held in Ghana in April/May 2007, and two other technical staff participated in the *Post-graduate Educational Course on Radiation Protection and on the Safety of Radiation Sources* (PGEC), held in South Africa, July-December 2007 (RAF/9/035).

Relations with the operators

GS-R-1 §4.10

As the process of authorization has not yet commenced, this requirement is not being met.

International Cooperation

GS-R-1 §4.11

The country is a party to the Convention on the Physical Protection of Nuclear Material. An agreement is in force between the Republic of Botswana and the IAEA on the application of Safeguards in connection with the NPT. Botswana is also a signatory to the Additional Protocol for the Application of Safeguards. Botswana has not yet declared its support for the Code of Conduct and its Guidance on Import and Export of Radioactive Sources. The country is a member of the AFRA Regional Cooperative Agreement.

No bilateral agreements on radiation safety with other countries are in place.

CONCLUSIONS	
C7	**Conclusion:** Current funding of the RPI, including operating costs, appears to be adequate.
C8	**Conclusion:** The RPI does not have available all of the necessary radiation monitoring instruments to properly discharge its functions.
C9	**Conclusion**: An extensive training programme for RPI staff is in place. The programme is based on the Plan of Training 2007-2008 and makes maximum use of the opportunities offered by the IAEA as well as by the Government.
C10	**Conclusion:** Presently no bilateral agreements on radiation safety are in place between Botswana and other countries.
C11	**Conclusion:** Arrangements have been made to establish international cooperation, in particular with the IAEA. The Republic of Botswana has not yet declared its support for the Code of Conduct and its Guidance on Import and Export of Radioactive Sources.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS**: GS-R-1 §4.1 states: *"The regulatory body shall have an organizational structure and size commensurate withy the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities."*
R3	**Recommendation:** The RPI should expedite the purchase of radiation monitoring instruments required during inspection.
S3	**Suggestion:** The RPI may wish to consider whether to establish its own laboratory to measure radioactivity or enter into an agreement with a laboratory abroad.
(1)	**BASIS**: GS-R-1 §4.10 states: *"mutual understanding and respect between the regulatory body and the operator, and a frank, open, and yet formal relationship, shall be fostered".*
R4	**Recommendation:** While recognising that the authorization process has yet to commence, it is recommended that the RPI establish good working relations with operators based on mutual understanding and respect.
G1	**Good Practice**: It is noted that the radiation protection training programme of the RPI is being well implemented, responds to the needs in this area and takes full advantage of opportunities offered by the IAEA and the Government. It is further noted that the Government of Botswana has demonstrated strong commitment to ensure that all RPI staff are adequately trained.
(1)	**BASIS**: GS-R-1 §4.11 states in part*: "National authorities,…, shall establish arrangements for the exchange of safety related information, bilaterally or regionally, with neighbouring States and other interested States, and with relevant intergovernmental organizations, both to fulfil safety obligations and to promote co-operation."*
R5	**Recommendation:** It is recommended that bilateral arrangements on cooperation in the field of radiation safety be entered into with other countries.

4. ACTIVITIES OF THE REGULATORY BODY

Notification

GS-R-1 §5.2

The system of notification complies with the requirements of GS-R-1. The same applies to the national registry of radiation sources (RAIS 3.0) which is in place, being updated and well maintained. The system is still being developed to include all sources and/or practices. Users have been given a grace period to the end of March 2008 to register with the RPI, and have been individually written to. A relevant notice has also been placed in national newspapers.

Authorization

***GS-R-1 §5.3 to* §5.6**

The authorization process is about to commence. As part of this process, the RPI is considering the development of the following documents:

- advice on the completion of application forms;

- procedures for managing applications for authorization, including review and assessment within a specified timeframe;

- the decision-making process in relation to granting or rejecting authorizations; and

- authorization procedure for the import, export and transhipment of radioactive sources, consistent with the Code of Conduct and its Guidance on the Import and Export of Radioactive Sources.

The RPI intends to adopt a risk-based approach to its authorization process. Clarity is required on the responsibility of the RPI for the security of radioactive sources.

An authorization process involving several discrete stages is envisaged for dealing with complex and/or hazardous practices.

The Act and Regulations do not specify that the RPI may reject an application for authorization, but it is implicit in Article 23 (7) of the Act. The Act specifies that a licence may be suspended or revoked (Article 27(2)).

Review and assessment

GS-R-1 §5.7 - 5.11

Procedures governing review and assessment of applications for authorization are still to be developed.

Inspection

GS-R-1 §5.14 - 5.17

A formal inspection programme is in place and being implemented. A checklist for use during inspections has been developed but there are not as yet any related written procedures.

Presently the RPI is focusing on pre-authorization audits. The IRRS team was informed that, in determining the frequency of inspections, the RPI intends to take account of the potential magnitude and nature of the hazard as well as past performance and security risk.

In accordance with the legislation, the RPI requires the licensee to carry out an immediate investigation following abnormal events.

Inspection reports are available to RPI inspectors.

Procedures for the formal communication of the results of inspections to the registrant or licensee within a specified time frame are still to be developed. In practice, the users are always written to once the report of the inspection has been approved and timeframes are set for any actions required by the RPI.

Inspection reports are normally written up within 10 days but this has not been formalised.

Enforcement

GS-R-1 §5.18 - 5.23

The Act and the Regulations give sufficient enforcement powers to the RPI. Inspectors have the power to take on-the-spot enforcement actions. A procedure is in place on lines of communication between the Inspector and the RPI for enforcement action to be taken in cases with potential serious risks to the health and safety of workers or the public.

The enforcement programme has yet to be developed.

Regulations and Guides

GS-R-1 §5.25- §5.28

The final draft Radiation Protection Regulations, 2007 have been published and are awaiting signature by the Minister. There is a need to prepare other subsidiary legislation for the full implementation of the 2006 Act.

Proposals to regulate specific issues relating to the transportation of hazardous substances with emphasis on radioactive material have been initiated with the Department of Road Transport and Safety.

CONCLUSIONS	
C12	**Conclusion**: In order to improve efficiency and transparency of regulatory activities, there is a need to develop procedures in support of the authorization process.
C13	**Conclusion:** There is a need to include in the Regulations the empowerment of the Board to reject an application for authorization.
C14	**Conclusion:** A formal inspection programme is in place and being implemented.
C15	**Conclusion:** Pre-authorization inspections are carried out on a routine basis as part of the regulatory process.
C16	**Conclusion:** Good and timely follow-up action on inspection reports is in place. The related requirements for users and the associated time schedules are clearly set out.
C17	**Conclusion:** Procedures for carrying out inspections and those for the completion of inspection reports have still to be prepared.
C18	**Conclusion:** The RPB and RPI are sufficiently empowered to enforce the legislation.
C19	**Conclusion:** Guidance documents and Codes of Practice still have to be prepared to complement national legislation and the extent of practices taking place in the country.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** GS-G-1.5 **§**3.25 states that:*"The regulatory body should maintain a national register of radiation sources. The main input of data to the inventory is provided via notification."*
G2	**Good Practice:** The IRRS team has noted good progress with regard to the inventory of radiation sources. Currently the system, based on RAIS 3.0, is fully operational and being continuously updated.
(4)	**BASIS:** GS-R-1 **§**5.8 states: *"In connection with its review and assessment activities, the regulatory body shall define and make available to the operator the principles and associated criteria on which its judgements and decisions are based."*
R6	**Recommendation:** Procedures governing review and assessment of applications for authorization should be developed.
(1)	**BASIS:** GS-R-1 **§**5.14 states in part: *"The regulatory body shall establish a planned and systematic inspection programme."*
G3	**Good Practice**: Current efforts should continue towards the full implementation of the inspection programme.
R7	**Recommendation:** In setting its inspection priorities, the RPI should take account of the potential magnitude and nature of the hazard, past performance as well as the security risk associated with the practice.
R8	**Recommendation:** Procedures for the carrying out inspections and for the completion of inspection reports should be formalised.
(1)	**BASIS:** GS-R-1 §5.18-5.24
R9	**Recommendation:** The RPI should develop and document a policy on enforcement.
R10	**Recommendation**: The RPI should establish formal arrangements with national law enforcement agencies as a means of improving the effectiveness of enforcement actions.
(1)	**BASIS:** GS-R-1 §5.28 states that: *"In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards."*
R11	**Recommendation:** Guidance documents and Codes of Practice should be prepared. Priority should be given to those practices that represent the highest risk, as described in the IAEA Safety Guide on Categorization of Radioactive Sources RS-G-1.9

5. SAFETY AND SECURITY OF RADIOACTIVE SOURCES

The IRRS team was informed that, once the Regulations come into force, authorizations will be issued on the understanding the user enters into a legally binding agreement with the source provider to accept return of the source after it has reached the end of its useful life. For existing sources already in use in the country, the intention is to have sources stored in the radioactive waste storage facility when they come to the end of their useful life. There is no suitable safe and secure storage area in place for radioactive sources held pending import or export authorization at border crossings and airports.

There are no established procedures recognising levels of safety and security based on source categorisation.

The Regulations do not provide for the security of radioactive sources during transport. However, a meeting with the Department of Road Transport and Safety is planned to discuss joint action in this area. Also, security escorts are planned for transportation of high-risk sources, but there are no such consignments envisaged in the near future.

There are no written procedures for the recovery of orphan sources. Monitoring and retrieval equipment will be ordered in the near future and a truck/trailer is being adapted to allow the transportation of sources. Initial contacts have been made with scrap metal dealers to ensure that no radioactive material is processed. However, no formal arrangements are in place.

CONCLUSIONS	
C20	**Conclusion:** The overall responsibility for regulating the security of radioactive sources is not yet clear.
C21	**Conclusion:** The implementation of take-back agreements for disused sources will contribute significantly to radiation safety in Botswana.
C22	**Conclusion:** There is a need to enter into arrangements with national law enforcement agencies to ensure the effectiveness of enforcement actions.
C23	**Conclusion:** Written procedures still need to be prepared dealing with: - levels of safety and security based on source categorisation; and - recovery of orphan sources.
C24	**Conclusion:** There is a need to establish a safe and secure storage area for radioactive sources held at border crossings and airports pending import or export authorization.
C25	**Conclusion:** The Regulations need to provide for the security of radioactive sources during transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS:** *Code of Conduct*
R12	**Recommendation:** Overall responsibility for regulating the security of radioactive sources at the national level should be clarified as soon as possible.
R13	**Recommendation:** Arrangements being made to deal with disused and orphan sources should be finalised to ensure an adequate level of safety and security.
R14	**Recommendation:** Written procedures and training dealing with the recovery of orphan sources should be prepared.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R15	**Recommendation:** The establishment of a safe and secure storage area for radioactive sources held at border crossings and airports pending import or export authorization should be part of the MoU with Customs and Excise.
S4	**Suggestion:** The Government may wish to consider declaring formal support to the Code of Conduct and its supplementary Guidance on Import and Export of Radioactive Sources.

6. INFORMATION MANAGEMENT

Regulatory Activity Information Management

The RPI uses both INIS and RaSaReN as a source of radiation safety information. In general, this information is not shared with other national organisations. The RPI is not currently a member of the Illicit Trafficking Data Base (ITDB).

The RPI's databases are protected. Files and offices are locked at night and there is a 24 hour security guard on site. A fire alarm is in place and operational.

The RAIS database is password protected with limited access. The RPI is part of the Government IT security system. A back-up system for RAIS is in place.

General information on the work of the RPI is available on the website of the Ministry of Communications, Science and Technology. The RPI does not have its own website.

Public information and communication

Public awareness posters on radiation safety have been prepared and issued through the media. Occasional articles on radiation safety also appear in national newspapers.

CONCLUSIONS	
C26	**Conclusion:**The RPI's files, computer records and premises are well protected.
C27	**Conclusion:** Action is in progress to disseminate information to the public on general radiation protection issues and the work of the RPI.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GS-R-1 §3.3(6)** "*In order to discharge its main responsibilities, …, the regulatory body shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public"*
R16	**Recommendation:** It is recommended that written procedures on protection of information, records and databases be prepared and implemented.
R17	**Recommendation:** The RPI should consider developing its own independent website for users of radiation sources, stakeholders and the public. This would enhance the independence of the RPI and the transparency of its work.
G4	**Good Practice:** Current efforts should continue to maintain the protection of the databases of the RPI.
S5	**Suggestion**: RPI may wish to consider becoming a member of the IAEA Illicit Trafficking Data Base (ITDB)

7. QUALITY MANAGEMENT

A quality management system has yet to be established. This includes the administrative manual of the RPI.

CONCLUSIONS	
C28	**Conclusion:** The establishment of a fully integrated quality management system at the RPI would enhance the effectiveness and efficiency of its work.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R18	**Recommendation:** Given the importance and impact of the quality management system on the effectiveness and efficiency of the regulatory programme for the safety and security of radiation sources and practices, high priority should be assigned to the establishment of such a system at the RPI using relevant guidance provided by the IAEA.

8. POLICY ISSUES

A plenary discussion on the regulatory policy issues was held with Ms Marianne Nganunu, Permanent Secretary, Ministry of Communications, Science and Technology (the parent Ministry for the Law), the management and technical staff of the RPI. The discussions focused, among other things, on:

- independence of the RPI;
- openness and transparency in regulatory activities including the involvement of stakeholders and public information;
- enhancing regulatory competence and effectiveness; and
- human resources and knowledge management.

There was a good perception of the importance of establishing a clear national policy to ensure safety and security of radioactive sources in the country. The participants agreed that the RPI would be the main but not the only beneficiary of such policy. Summary of the discussions is presented below.

Independence of the regulatory body

Background:

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

Key elements of the discussion:

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

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 of the discussion:

- 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

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 of the discussion:

- 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

The participants were in agreement that the discussion broadened their views on key elements of regulatory infrastructure having important bearing on effectiveness and efficiency of the RPI work. The Permanent Secretary acknowledged that following the discussion she had a better perception of the country's regulatory system. The RPI Management pointed out that the discussion was helpful in highlighting strengths and weaknesses of the RPI.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS		
Mr. Tony COLGAN	Radiological Protection Institute of Ireland (RPII)	Team Leader/Reviewer
Mr. Justin NGAILE	Tanzania Atomic Energy Commission (TAEC)	Reviewer
Mr. Nasiru-Deen BELLO	Nigerian Nuclear Regulatory Authority (NNRA)	Reviewer
IAEA STAFF MEMBERS		
Mr. Karol SKORNIK	Division of Radiation Transport and Waste Safety	Mission Coordinator/Reviewer
Ms. Melpo AGATHOCLEOUS	Division of Radiation Transport and Waste Safety	Observer
OFFICIAL LIAISON OFFICER		
Mr. Stephen WILLIAMS	Radiation Protection Inspectorate, Botswana	Director

APPENDIX II – MISSION PROGRAMME

Date/time	Programme	Participants
18 FEB. Day 1		
09:00–10.00	Entrance meeting with senior officials of the bodies having a regulatory role in Botswana	Full IRRS Team Members of the Radiation Protection Board & Inspectorate, as well as representatives of ministries and other national agencies concerned
10.00–11.00	Review of IRRS programme and terms of reference	Full IRRS Team and country representatives having a regulatory role
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. • Co-ordination and co-operation at the national level. • International co-operation.	Full IRRS Team and relevant country representatives having a regulatory role
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'	Full IRRS Team and relevant country representatives having a regulatory role
18.00–23.00	Preparation of findings and drafting of IRRS report	IRRS Team

Date/time	Programme	Participants
19 FEB. Day 2		
09.00–13.00	Continued discussions on the status of the national regulatory infrastructure component 1 – 'Legislative and Statutory Framework' and component 2 – 'Activities of the Regulatory Body'	Full IRRS Team and relevant country representatives having a regulatory role.
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'** • Notification and national register of radiation sources. • Authorization • Safety and security of radioactive sources • Inspection • Enforcement. • Information management. • Quality management	Full IRRS Team and relevant country representatives having a regulatory role.
17.00–23.00	Preparation of findings and drafting of IRRS report	IRRS Team
20 FEB Day 3		
09.00–13.00	IRRS Team observation of simultaneous regulatory inspections of medical facilities (diagnostic imaging, radiation therapy and nuclear medicine) and industrial facilities (e.g. well-logging, NDT etc).	IRRS Team members working in smaller groups or as individuals, country representatives having a regulatory role and competent staff of medical and industrial facilities.

Date/time	Programme	Participants
13.00–14.00	Lunch	
14.00-17.00	IRRS Team observation of simultaneous regulatory inspections of medical facilities (diagnostic imaging, radiation therapy and nuclear medicine) and industrial facilities (e.g. well-logging, NDT etc).	IRRS Team members working in smaller groups or as individuals, country representatives having a regulatory role and competent staff of medical and industrial facilities.
09.00–13.00	If required, one member of IRRS Team working at HQ with relevant regulatory staff to clarify issues arising from discussions and to begin preparation of preliminary draft report.	IRRS Team member and relevant country representatives having a regulatory role
14.00-17.00	Some IRRS Team members to finalise discussions on the status of the national regulatory infrastructure component 2 – 'Activities of the Regulatory Body'	Members of the IRRS Team and relevant country representatives having a regulatory role
17.00-23.00	Preparation of preliminary draft report	IRRS Team
21 FEB. Day 4		
9.00–13.00	Preparation of findings and drafting of IRRS preliminary draft report at the regulator's HQ	Full IRRS Team, and if required, members of the Radiation Protection Board & Inspectorate.
13.00–14.00	Lunch	
14.30–17.00	Final drafting of IRRS preliminary draft report (at HQ) – Preliminary draft made available to the regulator for overnight review.	Full IRRS Team
17.00–23.00	Preparation of preliminary draft report	Full IRRS Team

Date/time	Programme	Participants
22 FEB. Day 5		
08.00–13.00	Exit meeting Summary of findings and recommendations, action plan	Full IRRS Team Permanent Secretary, Ministry of Communications, Science and Technology , Director and technical staff of the Radiation Protection Inspectorate.
13.00–14.00	Lunch and depart	

APPENDIX III – SITE VISIT

Observing RPI Regulatory Inspection at Scottish Livingstone Hospital, Molepolole

An inspection was arranged to the Scottish Livingstone Hospital, a district public hospital situated at the village of Molepolole about 50 km from Gaborone. RPI inspectors were accompanied by three members of the IRSS Team who acted as observers in an announced inspection to the Diagnostic X-ray Department.

As part of the preparation for the inspection, a "Pre-inspection Checklist" was used to gather relevant information and equipment required for the inspection. There was also a dedicated checklist (Safety Assessment of Diagnostic X-ray Installations) used by the inspectors.

A brief entrance meeting was held with the Head, Diagnostic X-ray Department on behalf of the hospital management. During this meeting the objectives and scope of the inspection were presented, as well as the major components of the inspection process. After the briefing, the RPI inspectors and the IRRS observers were shown the Diagnostic X-ray Department housing one X-ray radiography unit. Additionally, the group was shown two rooms where the hospital management intended to install new X-ray units for mammography and fluoroscopy. A visit to a dental X-ray unit followed.

The IRRS team observers were informed that there was a Radiation Protection Officer (RPO) but no medical physicist at the hospital. For the licensee's part, the reporting was done by the RPO and a radiologist.

The inspection commenced with a review of structural and technical specifications (i.e. dimensions of the rooms, thickness of the walls, positions of the windows etc.) of the three X-ray rooms followed by details of the X-ray unit; signage requirements; mechanical checks; protective equipment, collimation test; scattered radiation and tube leakage measurements; and safety requirement for the darkroom.

The team observed a typical X-ray room, with proper shielding. It was noted by the inspectors that:

(i) the red warning light above the door leading to the Diagnostic X-ray unit was not working properly;
(ii) the changing rooms were built outside the diagnostic X-ray unit and close to patient waiting area; and

The IRRS team observed that the inspectors conducted the inspection in a professional and organized manner using the detailed inspection checklist for diagnostic facility. It was also noted that:

(i) the inspectors themselves operated the X-ray unit when making one of the exposure measurements;

(ii) the tube leakage measurements were performed on three sides of the X-ray tube instead of six sides as recommended;

(iii) scattered radiation measurements did not cover all relevant areas based on the layout of the facility; and

(iv) due to time constraints by way of exception, the inspectors did not check qualifications of personnel, local radiation rules, radiation protection programme, patient protection, QA programme and record keeping. However, they were aware of these elements being part of the inspection checklist.

At the end of the inspection, a brief exit meeting was held with the hospital management that included Head, Nursing Staff, Head, Diagnostic X-ray Department and one radiographer. The inspection findings and recommendations were presented. The RPI inspectors provided a copy of the 2006 Act to the hospital authority.

APPENDIX IV – MISSION COUNTERPARTS

Item	Subject Area	IRRS Experts	Counterparts
	Legislative and governmental responsibilities	IRRS Team : Mr. T. Colgan Mr. K.Skornik Mr. J. Ngaile Mr. N. Bello Ms. M. Agathocleous	RPI Team : Mr. S. Williams, Director, RPI Mr. K. Phutietsile, Head, Div. of Standards & Env. Mr. T. Otukile, Head Div. of Inspections Mr. K. Gabobofane, SH, Monitoring Ms. G. Mokopasetso, SH Inspections Ms. T. Zwikula, SH, Environment
	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 and Security 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 body ultimately responsible for the security of radioactive sources at the national level needs to be clarified. Should this responsibility be assigned to the RPB, then the existing legislation will need to be revised accordingly. Otherwise, the RPB should consider entering into a MoU or other formal arrangement with the organisation concerned.
B	Responsibilities and functions of the regulatory body	*R2*	While recognising that the RPB is only newly established, it is recommended that the highest priority be assigned to initiating the authorization process. The RPI should adopt a graded approach, with due consideration of risks associated with practices and categorisation of radioactive sources.
		S1	While noting that the provision of individual monitoring services by the RPI is not the responsibility of the Regulatory Authority, it is accepted that the current situation is dictated by prevailing country-specific conditions. It is suggested, however, that, in the future, due consideration be given to assigning the responsibility for rendering
		S2	While accepting that the planned construction of a radioactive waste management facility under the control of the RPI is a temporary arrangement, it is suggested that due consideration be given to assigning the responsibility for the management of radioactive waste and disused sources to a dedicated organisation which would become a licensee.
C	Organization of the Regulatory Body	*R3*	The RPI should expedite the purchase of instruments required during inspection, in particular for inspection of medical facilities.
		S3	The RPI may wish to consider whether to establish its own laboratory to measure radioactivity or enter into an agreement with a laboratory abroad.

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
		R4	While recognising that the authorization process has yet to commence, it is recommended that the RPI establish good working relations with operators based on mutual understanding and respect.
C	Organization of the regulatory body, ctnd	*G1*	It is noted that the radiation protection training programme of the RPI is being well implemented, responds to the needs in this area and takes full advantage of opportunities offered by the IAEA and the Government. It is further noted that the Government of Botswana has demonstrated strong commitment to ensure that all RPI staff are adequately trained.
		R5	It is recommended that bilateral arrangements on cooperation in the field of radiation safety be entered into with other countries.
D	Activities of the Regulatory Body	*G2*	The IRRS team has noted good progress with regard to the inventory of radiation sources. Currently the system, based on RAIS 3.0, is fully operational and being continuously updated.
		R6	Procedures governing review and assessment of applications for authorization should be developed.
		R7	In setting its inspection priorities, the RPI should take account of the potential magnitude and nature of the hazard, past performance as well as the security risk associated with the practice.
		R8	Procedures for the carrying out inspections and for the completion of inspection reports should be formalized.
		R9	The RPI should develop and document a policy on enforcement.
		R10	The RPI should establish formal arrangements with national law enforcement agencies as a means of improving the effectiveness of enforcement actions.
		R11	Guidance documents and Codes of Practice should be prepared. Priority should be given to those practices that represent the highest risk.

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
E	Safety and Security of Radioactive Sources	*R12*	Overall responsibility for the security of radioactive sources at the national level should be clarified as soon as possible.
E	Safety and Security of Radioactive Sources	*R13*	Arrangements being made to deal with disused and orphan sources should be finalized to ensure an adequate level of safety and security.
		R14	Written procedures dealing with the recovery of orphan sources should be prepared.
		R15	The establishment of a safe and secure storage area for radioactive sources held at border crossings and airports pending import or export authorization should be part of the MoU with Customs and Excise.
		S4	The Government may wish to consider declaring formal support to the Code of Conduct and its Guidance on Import and Export of Radioactive Sources.
F	Information Management	*R16*	It is recommended that written procedures on protection of information, records and databases be prepared and implemented.
		R17	The RPI should consider developing its own independent website for users of radiation sources, stakeholders and the public. This would enhance the independence of the RPI and the transparency of its work.
		G4	Current efforts should continue to maintain the protection of the databases of the RPI.
		S4	RPI may wish to consider becoming a member of the IAEA Illicit Trafficking Data Base (ITDB).

	Areas	IAEA Comment No *R: Recommendations,* *S: Suggestions,* *G: Good practices*	*Recommendations, Suggestions or Good Practices*
G	Quality Management	*R18*	Given the importance and impact of the quality management system on the effectiveness and efficiency of the regulatory programme for the safety and security of radiation sources and practices, high priority should be assigned to the establishment of such a system at the RPI using relevant guidance provided by the IAEA.

APPENDIX VI – REFERENCE MATERIAL PROVIDED BY RPI

[1] Radiation Protection Act No. 22, July 2006
[2] Radiation Protection Regulations, final draft 2007
[3] Radiation Protection Board, February 2008
[4] RPI Organizational Structure, February 2008
[5] MCST Functional Organizational Structure, February 2008
[6] RPI Scheme of Service, February 2008
[7] Inventory of Radiation Sources and Users, RAIS 3.0 printout, February 2008
[8] Template Inspection Forms, RPI, February 2008
[9] RPI Inspection Plan 2008
[10] RPI Training Plan 2007-2008
[11] List of RaSaRen Users, February 2008
[12] List of Licensed Scrap Metal Dealers, February 2008
[13] Serule Uranium Occurences, Note from the MCST to the MME, Feb.2007
[14] Notification on the National Contact Point for the Physical Protection of Nuclear Material 2007, Jan. 2007

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)

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APPENDIX VIII - ACTION PLAN 2008-2009

ELEMENTS OF THE ACTION PLAN

These are two tables; the first deals with actions relating to the legislative and statutory framework and the second sets out actions specifically relating to the activities of the regulatory body.

I. LEGISLATIVE and STATUTORY FRAMEWORK

1. Legislation

2. Regulations and Guidance

3. Regulatory body establishment and independence

4. Regulatory body staffing and training

5. Regulatory body funding

6. Coordination and cooperation at national level

7. International cooperation

II ACTIVITIES of the Regulatory Body

1. Notification and national register of radiation sources

2. Authorization

3. Safety and security

4. Inspection

5. Enforcement

6. Information Management

7. Quality Management

SOURCES of REFERENCE USED for COMPILING THIS ACTION PLAN:

1. RaWaSIP, March 2008
2. Action Plan 2007-2008 (RAF/9/031)
3. IRRS draft Report March 2008

I. LEGISLATIVE and STATUTORY FRAMEWORK

The purpose of this action plan is to identify the fundamental tasks essential to the establishment / upgrading of a national regulatory infrastructure. It includes references to a range of IAEA and other publications. Member States should consult these publications for more detailed information.

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1 Legislation and Establishment of the Regulatory Body			
1.1 Implement the legislation:			
1.1.1 Take necessary measures to enact the Radiation Protection Regulations implementing the Radiation Protection Act No.22 of July 2006			

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
2 Regulations and Guidance			
2.1 Issue Regulations: 2.1.1 Take necessary measures for these to be issued by the Government of Botswana	Minister - MCST		
2.2 Drafting and Issuing Guidance Documents: 2.2.1 Draft guidance documents (Codes of Practice) for the implementation of the legislation and regulations. The Codes of Practice should cover: • Diagnostic radiology • Teletherapy • Brachytherapy • Nuclear medicine • Industrial radiography • Industrial irradiators • Nuclear gauges • Well logging	RPI/RPB	After submission of the draft Guidance Documents by Botswana, the IAEA may be requested to provide expert assistance (EM 3) to review the drafts. Time schedule :Upon a request	• GS-R-1, § 5.25 – 5.28 [2] • CoC, § 22(m) [3] • Applying Radiation Safety Standards in Nuclear Medicine [8] • Applying Radiation Safety Standards in Radiotherapy [9] • Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X Rays [10] • Application of the International Radiation Safety Standards in Industrial Radiography and Industrial Irradiators (draft) [11]
2.3 Issue Guidance Documents: 2.3.1 Issue the new guidance documents.	RPB		

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
3 Regulatory Body Staffing and Training			
3.1 Staffing: 3.1.1 Periodically review the formal staffing plan based on the functions and responsibilities assigned by the Radiation Protection Act, No. 22 of 2006 and taking into account the country needs based in particular on the national register of radiation sources.	RPI		• GS-R-1 § 4.6 [2] • CoC § 21 [3] • Building Competence in Radiation Protection and the Safe Use of Radiation sources [12] • Safety Report No. 20 [13] • 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.	RPI (action completed)	Provision of training packages as appropriate, dealing for example with; authorization and inspection of radiation sources in diagnostic radiology, nuclear medicine, radiotherapy, irradiators, industrial radiography, gauges and well logging, cyclotron facilities.	• GS-R-1 § 4.7 [2] • CoC§ 10 [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
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.	GOV-BOT Action completed; the Training Plan 2007-2008 is in place and being implemented	IRRS Mission to provide a comprehensive review of the regulatory infrastructure of BOT (action completed; the IRRS mission was held in February 2008)	• 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 and Excise, Transport. ***Note:*** *Coordination and cooperation can be formalized through written Memoranda of Understanding between the relevant authorities.*	RPB/RPI	Provision of example Memorandum of Understanding	• GS-R-1 § 3.4 [2] • CoC § 20(m) [3]
6 International Cooperation			
6.1 Regional Cooperation: 6.1.1 Consider the establishment of arrangements for the exchange of safety and security related information, bilaterally and/or regionally, with neighbouring States as might be appropriate.	RPB/RPI GOV-BOT	Provision of relevant documentation, international conventions, etc. Facilitate access to the **Ra**diation **Sa**fety **Re**gulators	• GS-R-1, § 4.11 [2] • CoC, § 12, 20(n) [3]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
6.2 Cooperation with International Organizations and States: 6.2.1 Consider the establishment of arrangements for the exchange of safety and security related information with interested States and relevant intergovernmental organizations as may be appropriate.		**N**etwork (RaSaReN Web Site)	

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.	RPI	Provision, upon a request, 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 Declare a support and adopt the *Code of Conduct on the Safety and Security of Radioactive Sources* 2004 and *its Guidance on the Import and Export of Radioactive Sources* 2005. These require that: The regulatory body of an exporting State: (a) obtains the consent of the corresponding regulatory body in the importing State through appropriate bilateral channels or agreements; and (b) issues prior notification of the intent to export a radioactive source.	RPB/RPI GOV-BOT	Provision of the Code of Conduct 2004 and Guidance on the Import and Export of Radioactive Sources 2005 (action completed)	• CoC, § 23 – 25 and 28 [2] • GIERS 2005 Parts VII-IX [16] • RS-G-1.9 [6]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
1.3 National Register of Radiation Sources: 1.3.1 Introduce a system for continuing operation, updating and maintenance of a comprehensive national register of 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.	RPI (Action fully implemented and completed)	At the request of the 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). (IAEA action completed through a regional training course)	• CoC, § 11, 17. Annex 1[3] • 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.	RPI	Expert assistance, (upon a request) to review the process	• 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. 2.1.4 Initiate the authorization process based on the established written guidance and procedures.	RPB/RPI 2nd Q 2008		• GS.R-1 § 5.5 (1, 2) [2]
2.1.5 In accordance with national legislation, if appropriate, establish and approve formal written process and procedures by which aggrieved applicants may appeal regulatory decisions.	RPB		• 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 Botswana 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	RPI/RPB/ Customs & Excise Administration		• CoC, § 23 – 25 and 28 [2] • GIERS 2005 Parts VII-IX [16]. • Reference [14]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
legislation (if any) or with the relevant international 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.	RPI	National Training Course (NTC) on Safety and Security of Radioactive Sources for RPI Staff, Customs and Police Officers 3rd Q 2008 (request submitted by RPI in March 2008; following the IRRS mission) NSNS to provide essential instrumentation for law enforcement agencies concerned (Customs & Excise, Police in connection with the NTC, referred to above.	• 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 Establish the inspection programme taking into account the potential magnitude and nature of the radiation hazard associated with particular facilities or activities.	RPI (action completed in 2007- Inspection programme is in place)	Provide an expert mission to review the process (IAEA action completed; IRRS Mission of February 2008)	• 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 Develop and approve formal written process and inspection procedures appropriate to the types of radiation practices regulated.	RPB/RPI	Provide an expert mission, upon a request, to review the process Provide, upon a request, essential equipment for inspection purposes. 4Q 2008	• Reference [15]
4.1.3 Establish and approve formal written protocols clearly defining the duties and responsibilities of inspectors in the conduct of inspections.	RPI (action completed)	IRRS Mission held in February 2008	• Reference [15]

TASKS for each ELEMENT	ACTION BY:	IAEA INPUT	REFERENCES
5 Enforcement			
5.1 Establish a System of Enforcement: 5.1.1 Establish 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).	RPI (and other agencies as may be appropriate)	Provide an expert mission, upon a request, to review the process	• 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 formal procedures for collecting and disseminating information to radiation users, professional groups having input to radiation practices and to the public where appropriate.	RPI with the cooperation of relevant Government agencies.	Provide an expert mission, upon a request, to review the procedures	• 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.	RPI	Provide an expert mission, upon a request, to review the programme	• GS-R-1, § 4.5 [2] • TECDOC-1090 [17] • ISO 9000 [18]

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