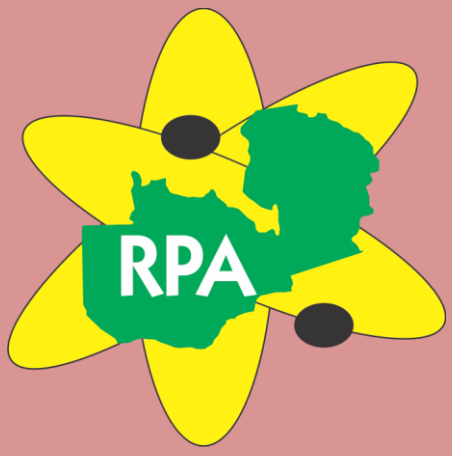
Radiation Protection Authority



Zambia

SAFETY GUIDE

RPA SG 4

Medical Exposure

2015

NOTICE OF APPROVAL

The Radiation Protection Authority Board (RPAB), has on the (day/month/2015), approved the safety guide on Medical exposure. This Guide is approved for the purposes of providing practical guidance with respect to the Ionising Radiation Protection Act, No. 16 of 2005.

Dr. Esther Munalula Nkandu
.....
CHAIRPERSON
Radiation Protection Authority Board

Mr. Boster Dearson Siwila
.....
EXECUTIVE DIRECTOR
Radiation Protection Authority

FOREWORD

Over the last 50 years, the use of Ionising Radiation in Zambia has significantly increased.
Institutions using Ionising Radiation include those in Health, Manufacturing, Mining, Agriculture, Research and Training sectors.

The use of ionising radiation in medicine has tremendously improved screening, diagnosis and therapy of diseases. The use of ionising radiation is aiding in diagnosis of diseases like TB, staging of tumors, detection of fractures in bones, detection of lesions in breasts and providing guidance during interventional radiology such as biopsy and surgical procedures. In addition, Ionising Radiation is beneficial in the treatment of various cancers at Cancer Diseases Hospital.
In 2005, the Zambian Government enacted the Ionising Radiation Protection Act to provide for the protection of the public, workers and the environment from the harmful effects arising from the use of devices or materials that produce ionising radiation. The Ionising Radiation Protection Act allowed for the establishment of the Radiation Protection Authority to spearhead the implementation of provisions of the Act. To fully implement the Act the Zambian Government has priotised strengthening national regulatory capacity.
Strengthening national regulatory capacity includes among other equally important elements, the development and implementation of Safety Guides for Practices using ionizing radiation.

This Safety Guide is intended for use by those involved in all aspects of medicine involving Ionising radiation such as screening, diagnostic and therapeutic medical exposures. The guide provides for acceptance testing and calibration of ionising radiation equipment, and quality assurance and quality control.
It is my sincere hope that this guide will be a good basis for attaining sustainable radiation protection of the public, workers and the environment and compliance by Licensees with the provisions of the Law.

Hon Dr. Joseph Kasonde, MP

MINISTER OF HEALTH

LIST OF ACRONYMS

CT Computed Tomography

IAEA International Atomic Energy Agency

HPCZ Health Professions Council of Zambia

ICRP International Commission on Radiological Protection

ICRU International Commission on Radiation Unit

IEC International Electro-technical Commission

ISO International Organizations for standardization

PAHO Pan American Health Organization

QA Quality Assurance

RPA Radiation Protection Authority

SSDL Secondary Standard Dosimetry Laboratory

WHO World Health Organisation

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1.0 INTRODUCTION

1.1 General

Medical exposure to ionizing radiation only refers to exposure incurred by patients as part of their own medical screening, diagnosis, treatment and research.

When ionising radiation was discovered more than 100 years ago its beneficial uses were quickly realised by the medical profession. Over the years new diagnostic and therapeutic techniques have evolved and the general level of health care has improved. This has resulted in medical radiation exposures becoming a significant component of the total radiation exposure of populations.

In Zambia, radiation exposure in medical applications mainly arises from the use of radioactive sources and/or devices such as those used in nuclear medicine, radiotherapy and radiology. However, stochastic or deterministic effects may result from such exposure as well as failure to optimise the use of ionising radiation. Therefore, there is need for a comprehensive legal and operational frame work for the control of the widespread use of ionising radiation and radiation sources leading to medical exposures while allowing their benefits.

This document provides the necessary safety guidance on the establishment of an effective radiation protection programme for medical exposure consistent with National and International safety standards. This Guide can also be used to set an appropriate radiation protection programme for medical exposure control in accordance with the requirements of the Act.

This Safety Guide is to be used by the RPA, licensees, specialists, advisers and health care professionals who are responsible for facilities where medical exposures to ionising radiation occurs. It addresses the technical and organizational aspects of the protection of patients, care givers and research volunteers from exposures resulting from the use of ionising radiation. It includes information on mechanisms for handling patients undergoing radiological screening, diagnosis and treatment, and information on the benefits and risks of the procedures.

1.2 Objective

The objective of this Safety Guide is to give practical guidance on how to use ionizing radiation in line with the Ionising Radiation Protection Regulations.

2.0 RADIATION PROTECTION DURING MEDICAL EXPOSURE

In medical practice, exposure of persons to radiation may be necessary for purposes of screening, diagnosis and/ or treatment. The primary aim of radiation protection is to provide an appropriate standard of protection for persons undergoing medical procedures using ionising radiation, without unduly limiting the benefits of such exposures.

2.1 Principles of Radiation Protection during medical exposures

2.1.1 Medical exposures should be justified by weighing the diagnostic or therapeutic benefits against the radiation detriment, taking into account the benefits a risks of available alternative techniques that do not involve use of ionising radiation.

2.1.2 The doses from medical exposures should only be those necessary to achieve the required screening, diagnosis and/ or treatment objective.

2.2 Responsibilities of all Parties in Medical Exposures

2.2.1 The Radiation Protection Authority shall:

2.2.1.1 enforce the requirements of the Act;

2.2.1.2 limit use of ionizing radiation to only those practices using medical exposures that have been justified; and

2.2.1.3 disseminate information on radiation protection in medical exposure.

2.2.2 The Licensee shall:

2.2.2.1 ensure that staff engaged in duties associated with medical exposure are appropriately and adequately trained;

2.2.2.2 promote the concept of a safety culture;

2.2.2.3 disseminate information on the performance of equipment used in medical exposure;

2.2.2.4 promptly investigate accidents and incidents, and devise appropriate action(s);

2.2.2.5 ensure that medical exposures are prescribed and supervised by Medical Practitioners;

2.2.2.6 restrict children visiting patients to whom radioactive materials have been administered so that exposure of such children is limited to less than 1mSv; and

2.2.2.7 ensuring patient safety is considered in the design, selection and maintenance of equipment.

2.2.3 Manufacturers or suppliers of Ionising radiation Sources shall:

2.2.3.1 offer pre-installation and application training for every source or equipment supplied;

2.2.3.2 ensure that the design, construction and safety of equipment conform with the relevant national and international standards;

2.2.3.3 ensure that equipment used in medical exposure is so designed that "failure of a single component of the system is promptly detectable so that any unplanned medical exposure of patients is minimized" and that "the incidence of human error in the delivery of unplanned medical exposure is minimized";

2.2.3.4 offer assistance for the proper handling and management of spent Teletherapy sources;

2.2.3.5 ensure the availability of spare parts and the provision of technical assistance for a reasonable period of time after supplying the equipment;

2.2.3.6 offer assistance when abnormal or unplanned events are identified in the operation of the supplied equipment, even if there is no immediate risk to health;

2.2.3.7 provide information on the performance and safe and correct use of equipment used in medical exposure;

2.2.4 Medical Practitioners:

Shall comply with all the requirements of the Ionising Radiation Protection (General) Regulations when prescribing or conducting radiological examinations and treatment.

3.0 RADIATION PROTECTION DURING MEDICAL EXPOSURE IN DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY

In this Safety Guide, diagnostic radiography is the practice in which external radiation beams (usually x-ray beams) are used to produce an image for the purpose of either diagnosing, excluding or evaluating the course of a disease or pathological condition. Interventional radiology is the practice in which x-ray images are used as a tool in the conduct of therapeutic procedures.

3.1 Justification for medical exposure in Diagnostic and Interventional Radiology

A medical practitioner shall consider the justification of the medical exposure prescribed by weighing the diagnostic or therapeutic benefits that the medical exposure produces against the radiation detriment it may cause taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

3.1.2 The medical practitioner may consult the Radiologist on the necessity and appropriateness of the procedure to be performed. Additional consideration may be necessary where doses may be high or in situations in which risk may be high.

3.1.3 Except for justifiable research, mass screening of population groups involving medical exposure shall not be treated as justified unless the expected advantages for the individuals or for the population examined outweigh the radiation detriment.

3.2 Optimization of protection for medical exposure

3.2.1 The basic aim of the optimization of patient protection during diagnostic and therapeutic procedures is to maximize the margin of benefit over harm, commensurate with the medical exposure.

3.2.2 In diagnostic radiology an expert in medical imaging physics, where available, shall be involved as appropriate, for consultation on the optimization of protection including patient dosimetry.

3.3 Requirements for Equipment in medical exposure

The following shall be the minimum requirements for equipment used in medical exposure:

3.3.1 conformity with National and international standards;

3.3.2 licensing ;

3.3.3 safety assessment report;

3.3.4 simplified SOP and maintenance schedule;

3.3.5 verification of equipment calibration;

3.3.6 radiation leak test certificate; and

3.3.7 proper shielding and housing.

3.3.8 inspection of obsolete equipment before decommissioning;

3.4 Operational aspects

3.4.1 To achieve the required diagnostic, treatment and interventional Radiological objective, RPA requires that standard operating protocols are available that specify the operational parameters to be used for all diagnostic and interventional radiological procedures.

3.5 Training

3.5.1 To improve compliance with the Act, the Licensee shall ensure that all workers are adequately trained.

3.6 Calibration of sources and dosimetry systems

3.6.1 Calibration of sources used for medical exposure shall be carried out in recognized dosimetry laboratories and according to manufacturer's specifications.

3.6.2 Dosimetry calibration in Zambia shall be traceable to the Secondary Standard Dosimetry Laboratory (SSDL) accredited to international standards and recognized by RPA.

3.6.3 To ensure consistency and standardization in QA, Licensees are encouraged to participate in intercomparison dosimetry.

4.0 RADIATION PROTECTION FOR MEDICAL EXPOSURE IN NUCLEAR MEDICINE

Nuclear medicine is the practice in which unsealed radioactive substances are administered to patients for diagnosis, treatment and research. During the practice of nuclear medicine, there are unintended instances of over exposure of radiation to the patient, practitioner(s) and contamination of the environment. Therefore, there is need to regulate the practice to minimize unintended harm to those that might be exposed.

4.1 Justification for medical exposure In Nuclear Medicine

A medical practitioner shall consider the justification of the medical exposure prescribed by weighing the diagnostic or therapeutic benefits that the medical exposure produces against the radiation detriment it may cause taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

4.1.1 The medical practitioner may consult the nuclear medicine physician on the necessity and appropriateness of the procedure to be performed. Additional

consideration may be necessary where doses may be high or in situations in which risk may be high.

4.1.2 Except for justifiable research, mass screening of population groups involving medical exposure shall not be treated as justified unless the expected advantages for the individuals or for the population examined outweigh the radiation detriment.

4.2 Optimization of protection for medical exposures

4.2.1 Diagnostic Image quality with the minimum patient dose shall be the objective of the nuclear medicine diagnostic process as a whole.

4.2.2 Licensees shall ensure that for diagnostic uses of radiation, the imaging and quality assurance requirements fully comply to National and International standards.

4.3 Equipment

4.3.1 All equipment used in nuclear medicine that emits ionising radiation shall comply with national and international standards.

4.3.2 For positron emission tomography installations that operate a cyclotron for radionuclide production, RPA shall require that the Licensee complies with:

4.3.2.1 guidelines for the preparation and control of radiopharmaceuticals in hospitals; and

4.3.2.2 safety standards for cyclotrons similar to those applied in the industrial production of radionuclides.

4.3.3 Radiation measuring equipment to measure the activity of radiopharmaceuticals must be appropriately calibrated.

4.4 Operational aspects

4.4.1 The Licensee must ensure that:

4.4.1.1 written manuals (Protocols) of all procedures carried out in Nuclear medicine are developed and made available at all times to all staff members involved in conducting the procedures.

4.4.1.2 radionuclide therapy involving high activity are carried out in purposely built areas as approved by RPA.

4.5 Clinical dosimetry

4.5.1 Licensees shall ensure that:

4.5.1.1 the radiopharmaceuticals to be administered to patients are determined and recorded at the time of administration by an expert and in accordance with the Regulations;

4.5.1.2 radionuclides are checked for radioactive impurities by an expert; and

4.5.1.3 an activity meter for measuring activities is available in a nuclear medicine unit.

4.5.2 The validity of measurements should be ensured by regular quality control of the instrument, including periodic reassessments of its calibration, traceable to SSDL.

4.5.3 Diagnostic exposure

4.5.3.1 Licensees shall ensure that:

A. a list of representative values for absorbed dose or effective dose to typical patients for each type of diagnostic investigation is available;

B. absorbed dose or effective dose values are calculated using internationally accepted methods, or extraction from tables, or compiled from standard data;

C. dose values of every procedure are included in the operational manuals.

4.5.4 Therapeutic exposure determination

4.5.4.1 The Licensees shall have expert knowledge required to perform individual dose calculations for therapeutic procedures, where appropriate.

4.5.4.2 A record of these therapeutic and dose calculation procedures shall be maintained for inspection by RPA.

4.5.5 Quality Assurance (QA)

4.5.5.1 The Licensee shall establish a comprehensive QA programme, which should include the following components:

A. procedures for handling patient records;

B. procedure for handling of administrative records;

C. standard operating procedures(SOP);

D. procedures for ensuring and verifying staff competencies;

E. audit mechanisms;

F. transport guidelines; and

G. waste management guidelines.

4.6 Guidance levels

Guidance levels shall be as per accepted national and international standards. licensees must ensure that surveys of administered activity for adult common diagnostic procedures are performed. The results of these surveys will allow guidance levels to be determined

and revealed as technology improves. In the absence of these surveys, the guidance levels specified in the Basic Safety Standards of the IAEA should be used to assess the performance of nuclear medicine equipment.

4.7 Criteria for discharge from Hospital

4.7.1 Patients who are receiving radionuclide therapy must only be discharged after the remaining activity subsides below a predetermined acceptable level determined by Nuclear Medicine Physician.

4.7.2 Licensees shall have a system to measure or to estimate the level of activity in patients prior to discharge and the results shall be recorded.

4.7.3 Before leaving the hospital, patients shall be given written and verbal instructions concerning any precautions they may need to take to protect their families and other persons with whom they may come into contact.

4.7.4 In some cases, such as for the elderly or children, it may be necessary to discuss the precautions to be taken with other family members.

4.7.5 The instructions shall indicate the length of time for which patients should observe the precautions.

4.8 Dose constraints for caregivers and visitors

4.8.1 Licensees shall ensure that caregivers, visitors and members of the household of patients who are on a course of treatment with radionuclides receive adequate written/verbal instructions on the relevant radiation protection precautions.

4.9 Training

4.9.1 To improve compliance with the Act, the Licensee shall ensure that all

workers in medical exposure facilities attain appropriate and adequate training.

4.9.2 Nuclear medicine specialists, physicists, technologists and other professional staff involved in the practice of nuclear medicine will require training in radiation exposure risks and benefits.

4.9.3 RPA will encourage health authorities, universities and professional associations to design and implement continuing education and training programs in radiation protection and safety for professional staff involved in nuclear medicine.

4.10 Investigation of accidental medical exposures

4.10.1 Licensees are required, with respect to any such investigation within 8 hours, to estimate patient doses, analyse the possible causes and take measures to avoid further incidents/accidents.

4.10.2 A written report shall be provided to RPA within 24 hours. RPA shall, within 72 hours of receiving the report, verify the incident/accident with the Licensee, the nuclear medicine physician and the patient.

4.10.3 The Licensee shall investigate the following:

4.10.3.1 any diagnostic/therapeutic exposure substantially greater than intended or resulting in doses exceeding the established guidance levels;

4.10.3.2 any equipment failure, accident, error or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended;

4.10.3.3 any immediate harmful effects produced as a result of the incident/accident;

5.0 RADIATION PROTECTION FOR MEDICAL EXPOSURE IN RADIOTHERAPY

Radiotherapy is the practice in which radiation beam sources are used for the treatment of patients. During radiotherapy, there are unintended instances of over exposure of radiation to the patient and practitioner(s). Therefore, there is need to regulate the practice to minimize unintended harm to those that might be exposed.

5.1 Justification for medical exposure In Radiotherapy

5.1.1 A medical practitioner shall consider the justification of the medical exposure prescribed by weighing the therapeutic benefits that the medical exposure produces against the radiation detriment it may cause taking into account the benefits and risks of available alternative techniques that do not involve medical exposure.

5.1.2 Except for justifiable research, medical exposure in radiation therapy shall not be treated as justified unless the expected advantages for the individuals or for the population outweigh the radiation detriment.

5.2 Optimization of protection in radiotherapy

5.2.1 The requirement for optimization in radiation therapy is that doses to normal tissue during radiotherapy be kept as low as reasonably achievable consistent with delivering the required dose to the target tissue/tumor.

5.3 Equipment

The following shall be the minimum requirements for equipment used in Radiotherapy:

5.3.1 licensing;

5.3.2 conformity with National and International Standards;

5.3.3 safety assessment reports;

5.3.4 simplified SOP and maintenance schedule for the equipment;

5.3.5 verification of equipment calibration;

5.3.6 radiation leak test certificate;

5.3.7 proper shielding and housing of the equipment; and

5.3.8 decommissioning plan.

5.4 Operational Aspects

5.4.1 The Licensee should ensure that standard operating protocols are available that specify the operational parameters to be used for all Radiotherapy procedures.

5.5 Calibration of sources

5.5.1 Calibration of sources used in radiotherapy shall be carried out in recognized dosimetry laboratories and according to manufacturer's specifications.

5.5.2 Dosimetry calibration in Zambia shall be traceable to the Secondary Standard Dosimetry Laboratory (SSDL) accredited to international standards and recognized by RPA.

5.6 Clinical dosimetry and treatment planning

5.6.1 The Licensee shall ensure that:

5.6.1.1 the prescription, planning, dose delivery and documentation conform with the Regulations; and

5.6.1.2 phantom and in vivo measurements as part of clinical dosimetry are performed.

5.7 Quality Assurance

5.7.1 The licensees shall establish a comprehensive QA programme which shall be regularly reviewed and updated.

5.7.2 To ensure consistency and standardization in QA, the Licensees are encouraged to participate in intercomparison dosimetry

5.8 Calibration of sources and dosimetry systems

5.8.1 Calibration of sources used for medical exposure shall be carried out in recognized dosimetry laboratories and according to manufacturer's specifications.

5.8.2 Dosimetry calibration in Zambia shall be traceable to the Secondary Standard Dosimetry Laboratory (SSDL) accredited to international standards and recognized by RPA.

5.9 Training

5.9.1 To improve compliance with the Act, the Licensee shall ensure that all workers in radiotherapy facilities shall attain appropriate and adequate training radiation exposure risks and benefits.

5.9.2 RPA will encourage health authorities, universities and professional associations to design and implement continuing education and training

programs in radiation protection and safety for professional staff involved in radiotherapy.

5.10 Investigation of incidents/accidents in radiotherapy

5.10.1 Licensees are required, with respect to any such investigation within 8 hours, to estimate patient doses, analyse the possible causes and take measures to avoid further incidents/accidents.

5.10.2 A written report shall be provided to RPA within 24 hours. RPA shall, within 72 hours of receiving the report, verify the incident/accident with the Licensee, the radiation Oncologist and the patient.

5.10.3 It shall be taken into account that, in radiotherapy, accidental exposures may consist of either under exposures or over exposure.

5.10.4 Licensees must submit written reports to RPA on any unplanned or unexpected incidents of either higher or lower doses than intended within 24hours upon being aware of the incident.

5.10.5 RPA shall require the long term follow-up of any patients that may have been overexposed since the detrimental consequences may have a long latency period.

DEFINITION

Accident

Any unintended *event*, including operating errors, equipment *failures* or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of *protection* and *safety*.

Diversity

The presence of two or more redundant systems or components to perform an identified function, where the different systems or components have different attributes so as to reduce the possibility of common cause failure.

Dose constraint

A prospective restriction on the individual dose delivered by a source, which serves as an upper bound on the dose in optimization of protection and safety for the source. For medical exposure,

dose constraint levels should be interpreted as guidance levels, except when used in optimizing the protection of persons exposed for medical research purposes or of persons, other than workers, who assist in the care, support or comfort of exposed patients.

Effective dose

The quantity *E*, defined as a summation of the tissue equivalent doses, each multiplied by the appropriate weighing factor:

$$E = \sum_{T} w_T \cdot H_T$$

Where H_T in the equivalent dose in tissue T and W_T is the tissue weighing factor for tissue T.

From the definition of equivalent dose, it follows that:

$$E = \sum_{T} w_T \cdot \sum_{R} w_R \cdot D_{T,R}$$

Where W_R is the radiation weighing factor for radiation R and $D_{T,R}$ is the average absorbed dose in the organ or tissue T.

Θ The unit of *effective dose* is joule per kilogram (J/kg), given the name *sievert* (Sv).An explanation of the quantity is given in Annex B of ICRP 103 [1].

Θ *Effective dose* is a measure of *dose* designed to reflect the amount of *radiation detriment* likely to result from the *dose*.

Θ *Effective dose* cannot be used to quantify higher *doses* or to make decisions on the need for any medical treatment relating to *deterministic effects*.

Θ Values of *effective dose* from any type(s) of *radiation* and mode(s) of *exposure* can be compared directly.

Emergency plan

A set of procedure to be implemented in the event of an accident.

Employer

A legal person with recognized responsibilities, commitment and duties towards a *worker* in his or her employment by virtue of a mutually agreed relationship. (A self -employed person is regarded as being both an *employer* and a *worker*.

Excluded

Outside the scope of standards

Exemption

Applicable only to sources.

Health professional

An individual who has been accredited through appropriate national *procedures* to practice a profession related to health (e.g, medicine, dentistry, chiropractic, podiatry, nursing, medical physics, radiation and nuclear medical technology, radiophamarcy, occupational health).

Health surveillance

Medical supervision intended to ensure the initial and continuous fitness of workers for their intended task.

Imaging devices

Electronic equipment used for imaging in radiology and nuclear medicine, e.g image convertors, gamma cameras.

Intervention

Any action intended to reduce or avert exposure or the likelihood of exposure to sources which are not part a controlled practice or which are out of control as a consequence of an accident.

Ionising radiation

For the purposes of radiation protection, radiation capable of producing ion pairs in biological material(s). When used in IAEA publications, the term radiation normally refers only to ionising radiation.

Licensing

Permission in a document by RPA to a legal person who has submitted an application to carry out a practice or any other action described by the Ionising Radiation Protection Act, No.16 of 2005. The licensing can take the form of a registration or a license.

Licensed

Granted a license by RPA.

Medical exposure

Exposure incurred by patients as part of their own medical or dental diagnosis (diagnostic exposure) or treatment (therapeutic exposure); by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients; and by volunteers in a programme of biomedical research involving their exposure.

Medical Practitioner

An individual who: (a) has been accredited through appropriate national procedures as a health professional; (b) fulfills the national requirements on training and experience for prescribing procedures involving medical exposures; and (c) is a registrant or a licensee, or a worker who has been designated by a registered or licensed employer for the purpose of prescribing procedures involving medical exposure.

Planning target volume

A geometrical concept used in radiotherapy for planning treatment with consideration of the net effect of movements of the patient and of the tissues to be irradiated, variations in size and shape of the tissue, and variations in beam geometry such as beam size and beam
direction.

Qualified expert

An individual who, by virtue of certification by appropriate boards or societies, professional licences or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, *radiation protection*, occupational health, fire safety, *quality management* or any relevant engineering or *safety* specialty.

Quality Assurance (QA)

Planned and systematic actions necessary to provide adequate confidence that an item, process or service will satisfy given requirements for quality, for example, those specified in the licence.

- This definition is slightly modified from that in ISO 921:1997 (Nuclear Energy– Vocabulary)1 to say "an item, process or service" instead of "a product or service" and to add the example. A more general definition of quality assurance and definitions of related terms can be found in ISO 8402:19942.
- Or: All those planned and systematic actions necessary to provide confidence that a structure, system or component will perform satisfactorily in service.

Quality Control (QC)

Part of quality assurance intended to verify that structures, systems and components correspond to predetermined requirements. This definition is taken from ISO 921:19971. A more general definition of quality control and definitions of related terms can be found in ISO 8402:19942.

Supplier

Any legal person to whom a licensee delegates duties, totally or partially, in relation to the design, manufacture, production or construction of a source. (An importer of a source is considered a supplier of the source.)

ANNEXES: CHECKLISTS

CHECKLIST FOR SAFETY GUIDE 4

MEDICAL EXPOSURE
INSPECTION FORMS FOR DIAGNOSTIC RADIOLOGY

FORM SG 2A- DR-1

THE RADIATION PROTECTION AUTHORITY

INSPECTION OF RADIATION SOURCES IN DIAGNOSTIC RADIOLOGY
INSPECTION RECORD SUMMARY

Inspection number	
Authorization number	

Name of the facility	
Address (location of the facility)	
Telephone Number	
Name of Radiation Protection Officer	
Name of Medical (or Hospital) Physicist	
Operator's representative for the inspection	
Date of LAST Inspection	_____/_____/_____
Date of THIS Inspection	_____/_____/_____
Starting time:	**Exit time:**

Type of Inspection Pre-authorization Routine	☐
Investigational Termination	☐
Summary of Findings and Actions NO items of non-compliance found Items of non-compliance found Follow-up on previous non-compliance	☐ ☐ ☐
Recommended Date of NEXT Inspection	_____/_____/_____
RPA Inspector name & signature Date	
Licensee name and signature Date	

FORM SG 2A-DR-2

RADIATION PROTECTION AUTHORITY

1. AMENDMENTS AND PROGRAM CHANGES *Prior to the inspection, list for review any amendments submitted by the Practice and approved by the RPA since the last inspection*

2. INSPECTION AND ENFORCEMENT HISTORY
Prior to the inspection, list for review any items of non-compliance identified during most recent 2-3 inspections

DATE	**INSPECTOR**	**VIOLATIONS**

3. INCIDENT / EVENT HISTORY *Prior to the inspection, list for review any incidents or events reported by the Practice to the RPA since the last inspection*

4. ORGANIZATION AND SCOPE OF THE PRACTICE *Briefly describe the present scope of activities, including types of procedures, frequency of use, staff size, etc. (Note deviations from the licence or registration)*

5. TRAINING AND INSTRUCTION OF WORKERS *Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; and emergency response*	**Yes**	**No**
All personnel using or responsible for the use of the X ray equipment have prescribed qualifications and/or training?		
All occupationally exposed personnel are provided with initial safety training?		

Refresher radiation safety training is provided periodically?		
Appropriate supervision of personnel (e.g. technologists, nurses, etc.) is provided by designated practitioners?		
Training records maintained for each worker?		
Interviews with personnel demonstrate an adequate level of understanding regarding safe working procedures?		
Discussion with the RPO demonstrates an appropriate knowledge of the RPA, the authorization certificate, the legislation, conditions, safe working procedures, etc?		
Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		
Comments:		

6. INTERNAL AUDITS AND REVIEWS		
	Yes	**No**
Operator reviews the radiation protection program at appropriate intervals?		
Audits of the facilities, X ray equipment inventory and working rules performed at appropriate intervals?		
Audits conducted by		
Frequency		
Records of program reviews and audits maintained?		

Comments

7. AREA RADIATION SURVEYS
Radiological surveys

	Yes	**No**
Operator possesses appropriate, functioning survey instrument(s)?		
Suitable function checks are performed on instruments prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of survey meter calibrating facility		
Area exposure rate surveys are performed at appropriate intervals?		
Records of calibrations, surveys, etc. are maintained?		
Comments:		

8. PERSONNEL RADIATION MONITORING

Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]

	Yes	**No**
Operator provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of Dosimeter provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		
Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Personnel monitoring records are maintained?		
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period*)		

9. NOTIFICATIONS AND REPORTS

Reporting and follow-up of theft; loss; incidents; overexposures; safety-related equipment failures; change in RPO, and radiation dose reports to workers. [BSS - Section 3.12]

	Yes	**No**
Have any program changes been implemented that required, but did not receive, approval by the RPA?		
Have any notifiable incidents or accidents occurred since the last inspection?		
If yes, have they been reported to the RPA? (*If no, list the incidents or accidents in Comments)*		
Have any significant structural or other safety related changes been made to the facilities or X ray equipment without approval of the RPA		
If yes, was a safety assessment performed by a Qualified Expert?		

Comments

10. WARNING SIGNS AND LABELLING

Proper warning signs in use areas and labelling of containers with radioactive material [BSS-Section I.23]

	Yes	**No**
Controlled areas have appropriate warning signs (in English)		
Entry to X ray rooms posted appropriately?		

Illuminated warning signs/lights functioning (where required)?		
Notices to workers are displayed as required?		
Comments		

11. INDEPENDENT AND CONFIRMATORY MEASUREMENTS	**Yes**	**No**
Inspector made area and other measurements for comparison to operator's		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration)*		

12. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES *List any breaches noted during the inspection (what, when, where and who).*

13. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection by name and position?*

FORM SG 2A-DR-3

RADIATION PROTECTION AUTHORITY
INSPECTION OF RADIATION SOURCES IN MEDICAL DIAGNOSTIC RADIOLOGY
DETAILED INSPECTION RECORD

This inspection record/checklist deals with matters relevant to medical radiology

1. RESPONSIBILITIES *Justification and Optimization [BSS Apex II]*		
	Yes	**No**
Examinations with X ray are authorized by appropriately Qualified Practitioners?		
Has an appropriately Qualified Practitioner been designated as having overall responsibility for patient protection and safety?		
If yes, practitioner's name?		
Does this Qualified Practitioner ensure that exposures are justified?		

If yes, state how the Qualified Practitioner says is this achieved?		
Has the operator established Dose Guidance (or Reference) Levels?		
Have dose measurements been made at the facility for comparison to these levels?		
If yes, by whom, at what frequency and when last made?		
Does the facility undertake research involving exposure of humans to radiation?		
If yes, are procedures in place ensuring compliance		
Are such exposures subject to the advice of an Ethics Committee or similar body within the facility?		
Does the facility conduct any screening programs?		
If yes, are standards available and followed?		
Are satisfactory procedures in place to properly identify patients?		
Are satisfactory procedures in place to identify potentially pregnant patients and, if clinically appropriate, to defer or modify the X ray examination?		
Are satisfactory steps taken to minimize the radiation dose during X ray examinations of the lower trunk of pregnant women (i.e. of the abdomen, pelvis, lumbar spine, etc.) when such examinations cannot be deferred?		

2. FACILITIES AND EQUIPMENT *Facilities as described; uses; control of access; engineering controls; shielding [BSS Section 2.34]*		
	Yes	**No**
Are the facilities as described in the application?		
Is access to the X ray equipment adequately controlled to prevent unauthorized use?		

Are adequate means (barriers, signs, procedures) used to prevent unauthorized individuals from entering controlled areas?		
Are X ray examinations performed with appropriate (purpose designed) equipment?		
EQUIPMENT COMPLIANCE AND MAINTENANCE (Quality Control)		
Is the X ray equipment subject to periodic testing (a QC program) to ensure the design and operating characteristics comply with the ISO/IEC or other requirements of the RPA?		
If so, at what frequency; by whom; date of the last test?		
Is the X ray equipment subject to routine maintenance by authorized service agents?		
Do the records confirm testing and maintenance?		
FILM, INTENSIFYING SCREENS, PROCESSING		
Is the speed of image receptors (intensifying screens and/or film) the highest commensurate with the required image quality?		
Does the x-ray film spectral sensitivity match that of the intensifying screens?		

Is the darkroom light tight?		
Is the safe lighting appropriate to the film type(s) in use (colour and wattage)?		
For manual processing of x-ray film		
- are appropriate facilities provided (tanks, temperature control, etc.)?		
- is the developer in use suitable for the films being developed?		
- is a suitable developer timer and developer thermometer available?		
- is the correct time-temperature chart for the developer and film displayed?		
- is time-temperature development routinely practiced?		
- is the temperature of the developer kept within the bounds specified by the manufacturer?		
- are the storage conditions of undeveloped x-ray film stocks satisfactory?		
Are appropriate quality control checks performed on the film/image processing equipment at regular intervals?		
Does the Radiation Protection Officer routinely review quality control checks and maintains records?		
PROTECTIVE DEVICES		
Appropriate numbers of lead protective aprons and gloves in good order?		
Protective screens for control console position provided where appropriate and in good order?		

Appropriate patient (eyes, gonads, etc) protective devices available and in good order?		
Is it apparent that these protective devices are being used routinely?		
Comments:		

THE RADIATION PROTECTION AUTHORITY

INSPECTION OF RADIATION SOURCES IN DENTAL DIAGNOSTIC RADIOLOGY

3. RESPONSIBILITIES *Justification and Optimization [BSS Apex II]*		
	Yes	**No**
Examinations with X ray are authorized by appropriately Qualified Practitioners?		
Has an appropriately Qualified Practitioner been designated as having overall responsibility for patient protection and safety?		
If yes, practitioner's name?		
Does this practitioner ensure that exposures are justified?		
If yes, how is this achieved?		
Has the operator established Dose Guidance (or Reference) Levels?		
Have dose measurements been made at the facility for comparison to these levels?		
If yes, by whom, at what frequency and when last made?		

Are satisfactory procedures in place to properly identify patients?		
Does the facility undertake research involving exposure of humans to radiation?		
If yes, are procedures in place ensuring compliance with the		
Are such exposures subject to the advice of an Ethics Committee or similar body?		
Does the facility conduct any screening programs?		
If yes, are standards available and followed?		

4. FACILITIES AND EQUIPMENT
Facilities as described; uses; control of access; engineering controls; shielding [BSS Section 2.34]

	Yes	**No**
Are the facilities as described in the application?		
Is access to the X ray equipment adequately controlled to prevent unauthorized use?		
Are adequate means (barriers, signs, and procedures) used to prevent unauthorized individuals from entering controlled areas?		

Are X ray examinations performed with appropriate (purpose designed) equipment?		

EQUIPMENT COMPLIANCE AND MAINTENANCE (Quality Control)		
Is the X ray equipment subject to periodic testing (a QC program) to ensure the design and operating characteristics comply with Local and International standards.		
If so, at what frequency; by whom; date of the last test?		
Is the X ray equipment subject to routine maintenance by authorized service agents?		
Do records confirm testing and maintenance?		
FILM, INTENSIFYING SCREENS, PROCESSING		
Is the speed of image receptor (intra-oral film and film used with intensifying screens) the highest commensurate with the required image quality?		
For film-screen combinations, does the X ray film spectral sensitivity match the intensifying screens?		
Is the darkroom (or dental processing unit) light tight?		
Is the safe lighting appropriate to the film type(s) in use (colour and wattage)?		
For manual processing of X ray film		
- are appropriate facilities provided (tanks, temperature control, etc.)?		
- is the developer in use suitable for the films being developed?		
- is a suitable developer timer and developer thermometer available?		
- is the correct time-temperature chart for the developer and film displayed?		

- is time-temperature development routinely practiced?		
- is the temperature of the developer kept within the bounds specified by the manufacturer		
- are the storage conditions of undeveloped X ray film stocks satisfactory?		
Are appropriate quality control checks performed on the film/image processing equipment at regular intervals?		
Radiation Protection Officer reviews quality control checks and maintains records?		

PROTECTIVE DEVICES		
Patient protective apron(s) available and in good order?		
Operator's operator can stand at least 2 m from the patient and X ray tube during exposures?		
If no, is other satisfactory shielding in place?		
Patient holds intra-oral films during exposures?		
Is it apparent that these protective measures are being used routinely?		
Comments:		

FORM SG 2B – NM-1

THE RADIATION PROTECTION AUTHORITY

INSPECTION PROCEDURES FOR RADIATION SOURCES IN NUCLEAR MEDICINE
INSPECTION RECORD SUMMARY

Inspection number	
Authorization number	

Name of the facility	

Address (location of the facility)	
Telephone Number	
Name of Radiation Protection Officer	
Name of Medical (or Hospital) Physicist	
Operator's representative for the inspection	
Date of LAST Inspection	_____/_____/_____
Date of THIS Inspection	_____/_____/_____
Starting time:	**Exit time:**
Type of Inspection Pre-authorization Routine	☐
Investigational Follow up	
Summary of Findings and Actions NO items of non-compliance found Items of non-compliance found Follow-up on previous non-compliance	

Recommended Date of NEXT Inspection	___/_____/_____
RPA Inspector name & signature Date	
Licensee name & signature	

FORM SG 2B – NM-2

THE RADIATION PROTECTION AUTHORITY

INSPECTION PROCEDURES FOR RADIATION SOURCES IN NUCLEAR MEDICINE
DETAILED INSPECTION RECORD

1. AMENDMENTS AND PROGRAM CHANGES *Prior to the inspection, list for review any licence amendments submitted by the operator and approved by the RPA since the last inspection*

2. INSPECTION AND ENFORCEMENT HISTORY

Prior to the inspection, list for review any items of non-compliance identified during previous 2-3 inspections

DATE	INSPECTOR	VIOLATIONS

3. INCIDENT / EVENT HISTORY

Prior to the inspection, list for review any incidents or events reported to the RPA since the last inspection

4. ORGANIZATION AND SCOPE OF THE PROGRAM

Briefly describe the present scope of activities, including types and maximum activities at any time of authorized unsealed sources, frequency of use, staff size, etc. (Note deviations from the authorization certificate)

5. RESPONSIBILITIES *Justification and Optimization [BSS App. II]*		
	Yes	**No**
Procedures are authorized by appropriately Qualified Practitioners, in accordance with the medical specialty for which the radioactive material is going to be applied to patients? (e.g. cardiologists, endocrinologists, nephrologists, etc.)		
Has an appropriately Qualified Practitioner been designated as having overall responsibility for patient protection and safety?		
If yes, practitioner's name?		
Does this practitioner ensure that procedures are justified?		
If yes, how the practitioner says is this achieved?		
Is the activity of radio-pharmaceuticals administered to patients within the range considered acceptable by the profession and the RPA?		
At what frequency is this reviewed, by whom and when reviewed last?		
Does the facility undertake research involving exposure of humans to radiation?		
If yes, are procedures in place ensuring compliance with the Helsinki Declaration, and guidelines observing the requirements of the Council for International and National standards?		
Are such procedures subject to the advice of an Ethics Committee or similar body within the facility?		
Are satisfactory procedures in place to properly identify patients before treatment?		

Are satisfactory procedures in place to identify potentially pregnant patients and, if clinically appropriate, to defer or modify the procedure?		
Comments:		

6. TRAINING AND INSTRUCTION OF WORKERS

Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities, and emergency response

	Yes	**No**
All persons working with radiation have prescribed qualifications and/or training?		
All occupationally exposed personnel are provided with initial safety training?		
Refresher radiation safety training is provided periodically?		
Adequate supervision of workers (technologists and lab assistants) by medical practitioners?		
Are training records maintained for each worker?		
Do interviews with personnel demonstrate an adequate level of understanding regarding safety and emergency procedures?		
Discussion with the RPO demonstrates an appropriate knowledge of the RPA, the authorization, the legislation, conditions, safe working procedures, etc?		
Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		

Comments:		

7. **INTERNAL AUDITS AND REVIEWS**

	Yes	No
Operator reviews the radiation protection program at appropriate intervals?		
Audits of the facilities, source utilization log book, working rules and emergency procedures performed at appropriate intervals?		
Audits conducted by		
Frequency		
Records of program reviews and audits maintained?		
Comments		

8. FACILITIES AND EQUIPMENT

Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding [BSS Section 2.34]

	Yes	**No**
Are the facilities as described in the application for authorization?		

Access to radioactive material adequately controlled?		
Radioactive material is secured to prevent unauthorized removal?		
Adequate methods used to prevent unauthorized individuals from entering controlled areas?		
Adequate fire protection?		
Operator possesses and uses a radionuclide activity meter?		
Quality control checks (constancy, linearity, accuracy, geometry) of the radionuclide activity meter are conducted as specified by the manufacturer?		
Corrections factors calculated and used to accurately measure β emitting radio-pharmaceuticals (e.g. ^{89}Sr, ^{32}P, ^{153}Sm)		
Is the imaging equipment subject to QC testing to ensure the design and operating characteristics comply with the ISO/IEC or other requirements of		
the RPA?		
If so, at what frequency; by whom; date of the last test?		
RPO maintains records and ensures that appropriate personnel (the medical physicist etc.) reviews results of quality control checks?		
Comments:		

9. UNSEALED RADIATION SOURCES	**Yes**	**No**

Radionuclides, chemical form, maximum activities at any time, and uses are as authorized and confirmed by the source utilization log book?		
Operator obtains prepared doses from an authorized radio-pharmaceutical supplier?		
Supplier's name, address		
Operator obtains and uses $^{99}Mo/^{99m}Tc$ generators?		
99 Mo breakthrough tests performed as required?		
Comments:		

10. RECEIPT AND TRANSFER OF RADIATION SOURCES

	Yes	**No**
Radioactive package opening procedures established and followed?		
Incoming radioactive packages surveyed for damage, dose rates and potential radioactive contamination before opening?		
Records of packaging surveys, source receipt and transfer maintained?		
Comments		

11. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL
Radiological surveys; leak tests; source existence checks; handling of radioactive materials; records; contamination control [BSS - Section I.38]

	Yes	**No**
Operator possesses appropriate, functioning survey instrument(s)?		
Suitable function checks are performed on instruments prior to use?		
Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Area exposure rate surveys are performed at appropriate intervals?		
Surveys for removable contamination, including fume cupboards, conducted as required?		
Records of calibrations, contamination surveys, etc. maintained?		
Comments:		

12. PERSONNEL RADIATION MONITORING

Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]

	Yes	**No**
Practice provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		
Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Does the Licensee apply the optimization principle (ALARA) to occupational exposure?		
Potential for exposure of workers to airborne radioactive material exists?		
Monitoring for airborne radioactivity conducted?		
For radioactive gases (e.g. ^{133}Xe) ventilation rates checked to ensure negative pressure in use areas?		
Spilled gas clearance times calculated and posted as appropriate?		
Bioassay program established and implemented as appropriate?		
Personnel monitoring records are maintained?		
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period*)		

13. RADIO-PHARMACEUTICAL THERAPY

	Yes	No
Appropriate written safety instructions are provided to patients and nursing staff commensurate with the therapy administered?		
The safety precautions at the facility include appropriate administration/treatment rooms, patient toilet facilities, warning signs, controlled visiting times, patient safety guidance, release and contamination controls?		
Discharge of patients complies with approved procedures?		
Patient treatment rooms are surveyed for contamination following patient release?		
Appropriate procedures have been established in case of premature death of patients undergoing treatment (including post mortem, cremations, etc)?		
Thyroid uptake measured on workers involved with administration of radioiodine?		
Records of procedures, treatments and other measurements maintained?		
Comments:		

14. RADIOACTIVE WASTE MANAGEMENT

Disposal or transfer of sources; packaging, control, and tracking procedures; records [BSS Section III.8]

	Yes	**No**
Radioactive effluents released to restricted area?		
Releases comply with regulatory requirements?		
Decay-in-storage method used?		
Storage facilities comply with regulations?		
Control and fire safety satisfactory?		
Warning and notification signs (in English) satisfactory?		
Inventory of store contents checked at acceptable intervals?		
Disposals in accordance with regulatory requirements?		
Records maintained?		
Comments:		

15. TRANSPORT OF RADIOACTIVE SOURCES

IAEA Regulations for the Safe Transport of Radioactive Material-Safety Standard Series No.
TS-R-1

	Yes	**No**
Does transport of radioactive material (from supplier, by operator) comply with local and international regulations		
Approved packages used?		

Packages properly labelled and marked?		
Supplier's vehicles, if used for transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		
Comments		

16. NOTIFICATIONS AND REPORTS

Reporting and follow-up of theft; losses; incidents; overexposures; safety-related equipment failures; change in RPO, and radiation dose reports to workers [BSS – Section 3.12]

	Yes	**No**
Have any program changes been implemented that required (but have not received) approval by the RPA?		
Have any notifiable incidents or accidents occurred since the last inspection?		
If yes, have they been reported to the RPA? (*If not reported, list the incidents or accidents in Comments)*		
Have any significant structural or other safety related changes been made to the facilities without approval of the RPA?		
If yes, was a safety assessment performed by a Qualified Expert?		
Comments		

17. WARNING SIGNS AND LABELLING *Proper warning signs in use areas and labelling of containers with radioactive material [BSS-Section I.23]*		
	Yes	**No**
Controlled areas have appropriate warning signs (in the local language)?		
Containers of radioactive material are properly labelled?		
Notices to workers are displayed as required?		
Radiopharmaceutical containers, storage areas, etc. are labelled as appropriate?		
Comments		

18. INDEPENDENT AND CONFIRMATORY MEASUREMENTS	**Yes**	**No**
Inspector made area and other measurements for comparison to operator's		
Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*		

19. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES *List any breaches noted during the inspection (what, when, where and who).*

20. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection*

FORM 2C – RT-1

THE RADIATION PROTECTION AUTHORITY

INSPECTION PROCEDURES FOR RADIATION SOURCES IN RADIOTHERAPY (RT)

INSPECTION RECORD SUMMARY

Inspection number	
Authorization number	

Name of the Facility	
Address (location of the facility)	
Telephone Number	
Name of Radiation Protection Officer	
Name of the Medical (or Hospital) Physicist	
Licensee's representative for the inspection	
Date of LAST Inspection	_____/_____/_____
Date of THIS Inspection	_____/_____/_____
Starting time:	**Exit time:** _____

Type of Inspection Pre-authorization Routine Investigational Follow up	☐ ☐ ☐ ☐
Summary of Findings and Actions NO items of non-compliance found Items of non-compliance found Follow-up on previous non-compliance	 ☐ ☐ ☐
Recommended Date of NEXT Inspection	_____/_____/____ _
RPA Inspector name &signature Date	
Licensee name & signature **Date**	

FORM 2C – RT-2

THE RADIATION PROTECTION AUTHORITY

INSPECTION PROCEDURES FOR RADIATION SOURCES IN RADIOTHERAPY (RT)

1. AMENDMENTS AND PROGRAM CHANGES *Prior to the inspection, list for review any amendments submitted by the Licensee and approved by the RPA since the last inspection*

2. INSPECTION AND ENFORCEMENT HISTORY *Prior to the inspection, list for review any items of non-compliance identified during previous 2-3 inspections*		
DATE	**INSPECTOR**	**VIOLATIONS**

3. INCIDENT/EVENT HISTORY *Prior to the inspection, list for review any incidents or events reported to the RPA*

since the last inspection

4. ORGANIZATION AND SCOPE OF THE PROGRAM *Briefly describe the present scope of activities, including types and quantities of use involving authorized sources, frequency of use, staff size, etc. (Note deviations from the authorization certificate)*

5. RESPONSIBILITIES
Justification [BSS App. II]

	Yes	**No**
All treatments authorized by appropriately Qualified Practitioners?		
An appropriately Qualified Practitioner is designated as having overall responsibility for patient protection and safety?		

If yes, practitioner's name?		
Does this Qualified Practitioner ensure that procedures are justified?		
If yes, how is this achieved?		
All patient have an individual treatment plan determined performed by a Medical Physicist?		
If yes, Medical (or hospital) Physicist's name?		
Is always at least one radiotherapist present at the facility while patients are being irradiated?		
Are satisfactory procedures in place to properly identify patients before treatment?		
Does the facility undertake research involving exposure of patients to radiation?		
If yes, are procedures in place ensuring compliance with the Helsinki Declaration, and guidelines observing the requirements of the Council for International Organizations of Medical Sciences and of the World Health Organization?		
Are such procedures subject to the advice of an Ethics Committee or similar body within the facility?		
Comments:		

6. TRAINING AND INSTRUCTION OF WORKERS

Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities, and emergency response

	Yes	**No**
All personnel using radiation sources have recognized qualifications?		
All occupationally exposed personnel are provided with initial safety training?		
Refresher radiation safety training is provided periodically?		
Supervision of personnel (e.g. technologists) by specialist Medical Practitioners is satisfactory?		
Training records kept for each worker?		
Interviews with workers demonstrate an appropriate knowledge of safe working rules and emergency procedures (e.g. source recovery?)		
Discussion with the RPO demonstrates an appropriate knowledge of the RPA, the authorization certificate, the legislation, conditions, safe working procedures, etc?		
Does the RPO have appropriate resources (time, personnel) and authority (to take independent action to remedy urgent safety issues) to properly perform the role?		

Comments

7. INTERNAL AUDITS AND REVIEWS

Yes	No

Licensee reviews the radiation protection programme at appropriate intervals?		
Audits of the facilities, source inventory, working rules and emergency procedures performed at appropriate intervals?		
Audits conducted by		
Frequency		
Records of program reviews and audits maintained?		
Comments		

8. FACILITIES AND RADIATION SOURCES
Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding [BSS Section 2.34]

	Yes	**No**
FACILITIES		
Facilities are as described in the authorization application?		
Radiation sources are secured so as to prevent unauthorized use and removal?		
Access to controlled areas by unauthorized persons properly supervised?		
Suitable emergency equipment for radioactive source recovery is available?		
Fire protection satisfactory?		

COMPLIANCE, MAINTENANCE, AND REPAIR (Quality Control)		
The design and performance characteristics of radiation devices, whether using radioactive sources or electrically generated radiation, comply with relevant IEC/ISO standards or other requirements of the RPA?		
Radiation devices are subject to regular QC tests to ensure continued compliance?		
If so, at what frequency; by whom; date of last test?		
Radiation devices are subject to routine maintenance by authorized service agents?		
If so, at what frequency, by whom; date last maintenance		
Records of compliance tests, maintenance, inspection and service maintained?		
OPERATING CHECKS AND CALIBRATION		

Appropriate checks of the performance and functionality of radiation devices and their associated safety equipment have been prescribed by a medical physicist and are carried out daily and at other suitable periods (where relevant to the device)?		
These checks are performed by the Medical Physicist or the results of these checks are reviewed by him/her within the day?		
Radiation devices are calibrated using acceptable protocols?		
A complete calibration of each device is performed		
- before the device is first used for patient treatment?		
- routinely at prescribed intervals acceptable to the RPA?		

- if routine operating checks show output variations outside established limits?		
- after major repair or modification?		
- using instruments with calibrations traceable to an approved standard?		
- by a Medical Physicist recognized by the RPA?		
Records of operating checks and calibrations are maintained?		
STORAGE OF RADIOACTIVE SOURCES		
Storage facilities for radioactive sources complies with regulations?		
Control and fire safety satisfactory?		
Warning and notification signs satisfactory?		
Inventory of store contents checked at acceptable intervals?		
RADIATION SOURCES		
Radioactive sources (cobalt unit, sealed sources) at the facility are as authorized?		
X ray equipment (interstitial, superficial, deep X ray therapy), linear accelerators, etc. at the facility are as authorized?		
Leak tests are performed on sealed radioactive sources at prescribed intervals?		
Procedures are in place for appropriate action to be taken in the event of an unacceptable leak test?		
Licensee confirms the inventory of radiation sources at acceptable intervals?		
Records of radioactive source leak tests and source inventory maintained?		
Comments:		

9. RECEIPT AND EVENTUAL DISPOSAL OF RADIATION SOURCES	**Yes**	**No**
Radioactive package opening procedures established and followed?		
Incoming radioactive packages surveyed for damage, dose rates and potential radioactive contamination before opening?		
Satisfactory procedures are in place for the disposal of radiation sources that are no longer required (whether radioactive sources or devices that generate radiation electrically) e.g. disposal only to authorized persons (indicate to whom in "Comments"); notification to the RPA, etc.?		
Records of packaging surveys, source receipt and disposal maintained?		
Comments		

10. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL *Radiological surveys; leak tests; inventories; handling of radioactive materials; records; contamination control [BSS - Section I.38]*	**Yes**	**No**
Operator possesses appropriate, functioning survey instrument(s)?		
Suitable function checks are performed on instruments prior to use?		

Survey meter calibrations are current?		
Survey meter calibration is performed by an approved facility?		
Name of facility		
Area exposure rate surveys are performed at appropriate intervals?		
Surveys for removable contamination conducted as required?		
Records of calibrations, contamination surveys, etc. maintained?		
Comments:		

11. PERSONNEL RADIATION MONITORING

Radiation protection program with ALARA provisions; dosimetry; exposure evaluations; dose and survey records and reports; notifications to workers] [BSS – Schedule II]

	Yes	**No**
Licensee provides personal dosimeters to all radiation workers?		
Dosimetry supplier is an authorized provider?		
Name of provider		
Dosimeters provided are appropriate for the radiation type and energy?		
Dosimeters are exchanged at the prescribed period?		
Dosimetry reports are promptly reviewed by the RPO?		

Is it evident that personal dosimeters are being worn by workers?		
Individual workers are informed of their monitoring results when each monitoring report is received (regardless of the dose measured)?		
Does the operator apply the optimization principle (ALARA) to occupational exposure?		
Personnel monitoring records are maintained?		
Inspector reviewed personnel monitoring records for the period from/ to		
Comments *(include the maximum doses to workers during this review period*)		

12. TRANSPORT OF RADIOACTIVE SOURCES

IAEA Regulations for the Safe Transport of Radioactive Material-Safety Standard Series No.
TS-R-1

	Yes	**No**
Does transport of radioactive material (from supplier, by operator) comply with IAEA transport regulations?		
Approved packages used?		
Packages properly labeled and marked?		
Transporter's vehicles, if used for transport, comply with regulations?		
Shipper's declaration papers have correct details and used when shipping sources?		

Comments

13. NOTIFICATIONS AND REPORTS

Reporting and follow-up of theft; losses; incidents; overexposures; safety-related equipment failures; change in RPO and Medical (or hospital)Physicist, and radiation dose reports to workers [BSS - Section 3.12]

	Yes	**No**
Have any program changes been implemented that required (but have not received) approval by the RPA?		
Have any notifiable incidents or accidents occurred since the last inspection?		
If yes, have they been reported to the RPA? (*If no, list the incidents or accidents in Comments)*		
Have any significant structural or other safety related changes been made to the facilities or the radiation devices without approval of the RPA?		
If yes, was a safety assessment performed by a Qualified Expert?		

Comments

14. WARNING SIGNS AND LABELING
Proper warning signs in use areas and labeling of containers with radioactive material [BSS-Section I.23]

	Yes	No
Controlled areas have appropriate warning signs in English		
Containers of radioactive sources are properly labeled?		
Notices to workers are displayed in the local language?		
Entry to treatment rooms has appropriate warning signs?		

Comments

15. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

	Yes	No
Inspector made area and other measurements for comparison to operators		

Comments: *Describe the types and results of measurements taken. Identify the instruments used by the inspector (make, model, last calibration).*

16. ITEMS OF NON-COMPLIANCE AND OTHER SAFETY ISSUES
List any breaches noted during the inspection (what, when, where and who)

17. PERSONNEL CONTACTED *Identify the personnel contacted during the inspection*

Comments:

FORM SG 2C – XRT-3

THE RADIATION PROTECTION AUTHORITY

INSPECTION PROCEDURES FOR RADIATION SOURCES IN X-RAY AND TELETHERAPY RADIOTHERAPY (RT)

DETAILED INSPECTION RECORD

This inspection record/checklist deals with matters relevant to superficial X ray therapy, deep X ray therapy, linear accelerators and cobalt teletherapy. Record each device on a separate Inspection Record,

Authorization Number	
Device Manufacturer	
Device Model	
Device Serial Number	
For ^{60}Co teletherapy unit: Total Activity & Activity Calibration Date	
Location on premises	

	Yes	**No**
FACILITIES. Where relevant, are the following operational		
- room entrance barrier/door interlock system?		
- waning signs satisfactory?		
- photon/electron selection and any other beam parameter interlocks?		
- area radiation monitor(s)?		
- beam ON indication?		
- patient viewing and intercom systems?		
OPERATION		
Is the device restricted to particular orientations and/or gantry angles?		
If so, is operation prevented in other orientations?		
OPERATING PROCEDURES		
Operating procedures (in the local language) located at the control console?		
Procedures include response to emergencies or abnormal situations?		
Emergency response telephone numbers clearly displayed?		

Patient is sole occupant in the treatment room during treatment?		
All patients have an individual dosimetric treatment planning performed by the Medical Physicist?		
Qualified staff (Medical Physicist, Radiation Oncologist etc.) physically present throughout all treatments with a gamma stereotactic/radiosurgery devices?		
OPERATIONAL CHECKS AND CALIBRATION		
Were operational checks performed before use today (or when last used)?		
Was any operational fault detected at that check?		
If yes, was appropriate corrective action taken?		
Date last fully calibrated?		
Records confirm checks, calibrations and related actions?		

Comments **FORM SG 2C - BRT- 4**

INSPECTION RECORD
RADIOTHERAPY– BRACHYTHERAPY (PART 3)

This inspection record/checklist deals with matters pertaining to devices which use radioactive sources for brachytherapy, e.g. afterloaders, high dose rate therapy (HDR), etc. Record each on a separate Inspection Record.

Authorization Number	
Device Manufacturer	
Device Model	
Device Serial Number	

Radionuclide, Total Activity, Activity Calibration Date	
Number & Type of Sealed Sources	
Types of Treatments	
Location on premises	

	Yes	**No**
FACILITIES. Where relevant, are the following operational		
- room entrance barrier/door interlock system?		
- waning signs satisfactory?		
- area radiation monitor(s)?		

- source ON indication?		
- patient viewing and intercom systems?		
- appropriate emergency source recovery and storage equipment available?		
PROCEDURES		
For devices containing sources (e.g. afterloaders, HDR, etc) operating procedures (in the local language) are located at or near the control?		
Safe nursing procedures (in the local language) are available and explained to all relevant personnel including controlling patients and visitors, contamination control and the size/appearance of sources, emergency procedures?		
Emergency response telephone numbers clearly displayed?		
Functional survey meter immediately available?		

Survey meter's last calibration date?		
Patient is sole occupant in the treatment room?		
Portal alarm at room entrance?		
Medical Physicist		
- performs patient's individual dosimetric treatment planning?		
- surveys patients immediately after implant completed?		
- surveys patients immediately after removal of implant and confirms source inventory before patient leaves treatment area?		
- is physically present throughout all patient treatments with a gamma stereotactic/radiosurgery devices?		
- is physically present when patient treatment with remote afterloaders initiated?		
OPERATIONAL AND DOSE RATE CHECKS		
If a radiation device,		
- are operational checks performed before use on patients?		
- was any operational fault detected at that check?		
If yes, was appropriate corrective action taken?		
Date of dose rate last re-assessment by medical physicist?		
Records confirm checks, dose rate assessment and related actions?		

Comments
