GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 98 OF 2011

The Ionising Radiation Protection Act, 2005
(Act No. 16 of 2005)

The Ionising Radiation Protection (General) Regulations, 2011

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GENERAL PROVISION

IN EXERCISE of the powers contained in section *fortysix* of the Ionising Radiation Protection Act, 2005, the following Regulations are hereby made:

PART I

PRELIMINARY

Title

1. These Regulations may be cited as the Ionising Radiation Protection (General) Regulations, 2011.

Interpretation

2. In these Regulations, unless the context otherwise requires—

"Authority" has the meaning assigned to it in the Act; Act No. 16 of 2005

"committed dose" means committed effective dose or committed equivalent dose;

"controlled area" means an area in which specific protection measures and safety provisions are required for

(a) controlling normal exposures or preventing the spread of contamination during normal working conditions; and

(b) preventing or limiting the extent of potential exposures;

"critical group" means a group of persons which is reasonably homogenous with respect to its exposure from a given radiation source and a given exposure pathway, and includes individuals receiving the highest effective dose or equivalent dose, as the case may be, by the given exposure pathway from the given source;

"deterministic effect" means an adverse effect on human health which is directly related to the dose of radiation received and which increases as the dose increases, and which has a threshold below which the effect does not occur;

"dose limit" has the meaning assigned to it in the Act; Act No. 16 of 2005

"effective dose" means a measure used to estimate the risk resulting from exposure to radiation, and in human beings is found by calculating the sum of the equivalent doses in all tissues and organs of the body, each multiplied by the appropriate tissue - weighting factor;

"employee" means any person who works, whether full time, part time or on a casual basis, for an employer and who has recognised rights and duties in relation to occupational radiation protection;

"IAEA" means the International Atomic Energy Agency;

"licence" means an ionising radiation licence; "licensee" means a holder of a licence;

"potential exposure" means exposure that is likely to occur from an accident at a source or an event or sequence of events of a probable nature, including an equipment failure or operating error, but is not intended or planned;

"radioactive material" has the meaning assigned to it in the Act;

Act No. 16 of 2005

"radionuclide material" has the meaning assigned to it in the Act;

Act No. 16 of 2005

"reference level" means an action, intervention, investigation or recording level connected with the determination of radiation quantities in the practice of radiation protection; and

Act No. 16 of 2005

"source" has the meaning assigned to it in the Act.

Exemption

3. (1) These Regulations do not apply to—

(a) exposure from natural radio-activity in the body, cosmic radiation, unmodified concentrations of natural radio-nuclides in raw materials and any other source that the Minister may specify;

(b) a practice or source which complies with the exemption levels prescribed in the Second Schedule;

(c) apparatus containing radioactive substances which exceed the quantities or concentrations specified in the Second Schedule if the apparatus—

(i) is of a type approved by the Authority;

(ii) is constructed in the form of a sealed source; and

(iii) does not cause, in normal operating conditions, a dose rate exceeding 1μSv/h at a distance of 0.1m from any accessible surface of the apparatus or a dose exceeding 10μSv in a year to any member of the public; or

(d) the operation of any electrical apparatus, if it is of a type approved by the Authority and it does not cause, in normal operating conditions, a dose rate exceeding 1μSv/h at a distance of 0.1m from any accessible surface of the apparatus.

(2) Paragraph (c) of sub-regulation (1) does not apply to the operation of any cathode ray tube intended for the display of visual images of an electrical apparatus operating at a potential difference not exceeding 30kV, if the cathode ray tube or electrical apparatus does not cause, in normal operating conditions, a dose rate exceeding 1μSv/h at a distance of 0.1 m from any accessible surface of the cathode ray tube or electrical apparatus.

PART II

LICENSING

Application for licence

4. (1) An application for an ionising radiation licence shall be made in Form I set out in the First Schedule.

(2) A request for further particulars in respect of an application under this Part shall be in Form II set out in the First Schedule.

Rejection of application

5. (1) The Board shall, within thirty days of the receipt of an application under regulation 4, reject the application, if the application does not meet the requirements of the Act or these Regulations.

(2) The Board shall, where it rejects an application under this Part, inform the applicant of the rejection in Form III set out in the First Schedule.

Issue of licence

6. The Board shall, where it approves an application for a licence, issue a licence in Form IV set out in the First Schedule.

Variation of terms and conditions of licence

7. (1) An application for the variation of the terms and conditions of a licence shall be in Form V set out in the First Schedule.

(2) The Board shall, where it varies the terms and conditions of a licence, endorse the variation on the licence.

Transfer of licence

8. (1) An application for the transfer of a licence shall be made in Form VI set out in the First Schedule.

(2) The approval for the transfer of a licence shall be in Form VII set out in the First Schedule.

(3) The Board shall, where it rejects an application for the transfer of a licence, inform the applicant in Form III set out in the First Schedule.

Surrender of licence

9. (1) A licensee who decides not to continue with the activity to which the licence relates shall surrender the licence to the Board with Form VIII set out in the First Schedule.

(2) The Board shall, where a licence is surrendered under sub-regulation (1), cancel the licence.

Application for renewal of licence

10. (1) An application for the renewal of a licence shall be in Form IX set out in the First Schedule.

(2) The Board shall, where it rejects an application for the renewal of a licence, inform the applicant of the rejection in Form III set out in the First Schedule.

Suspension or cancellation of licence

11. (1) The Board shall, before suspending or cancelling any licence under the Act, inform the holder of its intention to suspend or cancel the licence in Form X set out in the First Schedule.

(2) A notification of the suspension or cancellation of a licence shall be in Form XI set out in the First Schedule.

Enforcement notice

12. The Board shall, where it has reasonable grounds to believe that a licensee has breached the terms and conditions of the licence, the provisions of the Act or a directive of the Board, issue an enforcement notice to the licensee in Form XII set out in the First Schedule.

De-commissioning of radioactive device

13. A notice of intention to de-commission a radioactive device shall be in Form XIII set out in the First Schedule.

Appeal

14. An appeal against a decision of the Board shall be made in Form XIV set out in the First Schedule.

PART III

RADIATION PROTECTION

Justification of practice

15. (1) The Board shall not authorise an activity likely to emit radiation unless it is of sufficient benefit to the exposed individual or to the public to offset

the radiation harm that it could cause, taking into account the social, economic and other relevant factors.

(2) The following practices shall not be deemed as justified where they could result in an increase, by deliberate addition of radioactive substances or by activation, in the activity of the associated commodities or products:

(a) except for practices involving medical exposures, or practices involving food, beverages, cosmetics or any other commodity or product intended for ingestion, inhalation or percutaneous intake by, or application to, a human being;

(b) practices involving the frivolous use of radiation or radioactive substances in commodities or products such as toys;

(c) personal jewellery or adornments; and

(d) any other practices determined by the Authority as unjustified.

Dose limit

16. (1) The normal exposure of individuals shall be restricted so that neither the total effective dose nor the total equivalent dose to relevant organs or tissues, caused by the possible combination of exposures from authorised practices, exceeds any relevant dose limits specified in the Third Schedule.

(2) The dose limits referred to in sub-regulation (1) shall not apply to medical exposures from authorised practices.

Guidance levels for medical exposure

17. (1) The guidance levels for medical exposure specified in the Fourth Schedule shall be used by medical personnel in the conduct of diagnostic and therapeutic procedures involving exposure to radiation and in the optimisation of protection of patients.

(2) The guidance levels referred to in sub-regulation (1) shall be established by relevant professional bodies, in consultation with the Authority, to provide an indication on what doses are achievable with current good practices.

(3) The guidance levels referred to in sub-regulation (1) shall be applied with flexibility to allow higher exposures if these are indicated by sound clinical judgements and shall be revised as required by technological and scientific developments.

Optimisation of protection and safety

18. (1) Radiation safety shall be optimised, in relation to exposures from any particular source within a practice, so that the magnitude of individual dose, except for therapeutic medical exposures, the number of people exposed and the likelihood of incurring exposures is kept as low as reasonably achievable, economic and social factors being taken into account, within the restriction that the dose to individuals delivered by the source is subject to dose constraints.

(2) The process of optimisation of protection and the safety measures referred to in sub-regulation (1) may range from intuitive qualitative analyses to quantitative analyses using decision aiding techniques, but it shall be sufficient to take all relevant factors into account in a coherent manner so as to contribute to achieving the following:

(a) to determine optimised protection and safety measures for the prevailing circumstances, taking into account the available protection and safety options as well as the nature, magnitude and likelihood of exposures; and

(b) to establish criteria, on the basis of the results of the optimisation, for the restriction of the magnitudes of exposures and of their probabilities by means for preventing accidents and mitigating their consequences.

Dose constraints

19. (1) Except for medical exposure, the optimisation of the radiation safety measures associated with a given practice shall satisfy the condition that the resulting doses to the individuals of the critical group do not exceed dose constraints which are equal to the dose limits specified in the Third Schedule.

(2) A licensee shall, where any source is capable of releasing, or is likely to release, radioactive substances into the environment, establish the dose constraints so that the prospective annual doses to members of the public, including people distant from the source and people of future generations, summed over all exposure pathways, including contributions by other practices and sources, are unlikely to exceed the dose limits specified in the Third Schedule or lower values established by the Authority.

Annual limit on intake

20. The Annual Limit on Intake (ALI) shall be as prescribed in the IAEA Safety Series No. 115.

PART IV

Occupational Exposure

General responsibilities

21. (1) A licensee or employer who is engaged in an activity that involves or is likely to involve occupational exposure which is not excluded from these Regulations shall be responsible for the protection of the employees against any occupational exposure.

(2) A licensee or employer who employs a person in an activity that involves or is likely to involve occupational exposure shall ensure that—

(a) the occupational exposure is limited to the specifications in the Third Schedule;

(b) radiation safety is optimised in accordance with these Regulations;

(c) the policy of the organisation on occupational protection and safety complies with these Regulations;

(d) the facilities for radiation safety include a personal protective device and functional monitoring equipment;

(e) radiation safety and health surveillance services are provided, to the employees, through qualified experts;

(f) the employees are consulted through the employees' representatives, if necessary, on the measures to be taken to achieve the required radiation protection and safety;

(g) the licensee or employer promotes a safety culture within the organisation; and

(h) the employees are trained on radiation safety matters.

(3) Where an employee is to be engaged in work that involves or is likely to involve a source which is not under the control of their employer, the licensee responsible for the source shall—

(a) as a precondition for the engagement of the employee, obtain from the employer of the employee, information of that employee's previous occupational exposure history and any other relevant information for the purposes of providing radiation protection and safety;

(b) provide the same protective and safety measures to the employee as those provided for the employees of the licensee; and

(c) avail information on measurement of radiation doses emitted by a radioactive source and any other relevant information to the employer of the employee for purposes of demonstrating that the level of protection provided to the employee is in compliance with these Regulations.

(4) A licensee or employer shall ensure that an employee under that licensee's or employer's responsibility who is exposed to radiation from a source other than a natural source, which is not directly related to that employee's employment, receives the same level of protection provided to members of the public.

(5) A licensee or employer shall ensure that an employee—

(a) is informed of the employee's obligations to protect others against radiation;

(b) complies with the applicable rules and procedures for protection, safety and security;

(c) properly uses the monitoring device, protective equipment and clothing provided by the licensee or employer;

(d) abstains from any willful action that places or is likely to place the employee or other people in circumstances that contravene these Regulations; and

(e) promptly reports to the licensee or employer any circumstances that could adversely affect the safety or security conditions of the place of work.

(6) A licensee or employer shall record any report received from an employee that identifies any circumstances that could affect the safety and security conditions of the place of work and shall take appropriate remedial measures.

Conditions of service

22. (1) The conditions of service of an employee shall be independent of the existence or the possibility of occupational exposure, except where the conditions facilitate the enhancement of the occupational health and safety of the employee.

(2) A licensee or employer shall not, as a substitute for the provision of adequate protection and safety measures in compliance with these Regulations, offer an employee preferential conditions of service in consideration for absence of adequate protection and safety measures.

(3) A licensee or employer shall adjust the working conditions of a female employee who is pregnant to ensure the protection and safety of the foetus from occupational exposure and the level of protection and safety given to the foetus shall be the same level of protection given to members of the public, as specified in the Third Schedule.

(4) A licensee or employer shall make every reasonable effort to provide an employee with a suitable or alternative place of work or employment in circumstances where it has been determined, either by the Authority or in the framework of the health surveillance programme required by these Regulations, that the employee, for health reasons, should no longer continue in employment involving occupational exposure.

(5) A licensee or employer shall not subject a person under the age of sixteen years to occupational exposure.

(6) A licensee or employer shall not allow a person who is under the age of eighteen years to work, for purposes of training, in a controlled area unless that person is under supervision.

Classification of areas

23. (1) A licensee or employer shall designate a controlled area where specified protective measures or safety and security provisions are, or would be, required for the purposes of—

(a) controlling normal exposures or preventing the spread of a contamination during normal working conditions; and

(b) preventing or limiting the extent of potential exposure.

(2) A licensee shall, in relation to a controlled area—

(a) determine the boundaries of the controlled area on the basis of the magnitude and likelihood of expected exposures and the nature and extent of the required protection and safety provisions;

(b) delineate the controlled area by physical means or, where this is not reasonably or practicable, by other suitable means;

(c) where a source is brought into operation or energised only intermittently or is moved from place to place, delineate the controlled area by means that are appropriate under the prevailing circumstances and specify exposure times;

(d) display a warning symbol, recommended by the International Organisation for Standardisation (ISO) and appropriate instructions at access points and other appropriate locations within the controlled area;

(e) establish occupational protection, safety and security measures, including local rules and procedures that are appropriate for the controlled area;

(f) restrict access to the controlled area by means of administrative procedures, such as the use of employee access control, and by physical barriers, for which the degree of restriction is commensurate with the magnitude and likelihood of the expected exposure; and

(g) provide at entrances and exists of the controlled area appropriate means for change of clothing, monitoring of contamination and personal de-contamination.

(2) A licensee or employee shall ensure that in standard working procedures with sources, the expected contamination does not exceed the effective dose specified in the Third Schedule.

(3) A licensee or employee shall designate an area not designated as a controlled area as a supervised area, where occupational exposure conditions shall be kept under review.

(4) A licensee shall, in designating an area as a supervised area take into account the nature and extent of radiation hazards in those areas.

(5) A licensee shall periodically review the protection measures or safety provisions, including the boundaries of controlled and supervised areas.

Local rules and supervision

24. (1) A licensee or employer shall, in consultation with the employees—

(a) establish in writing, such rules and procedures as are necessary to ensure adequate levels of protection and safety for the employees and other persons in the workplace, and for the security of sources; and

(b) ensure that any work involving occupational exposure is adequately supervised and steps are taken to ensure that the rules, procedures, protective measures and safety provisions are observed.

(2) A licensee shall include in the rules and procedures referred to in sub-regulation (1), the values of the authorised level, investigation level or other reference level and the procedure to be followed in the event that such level is exceeded.

(3) A licensee or an employee shall—

(a) provide to the employees adequate information on the health risks likely to arise from occupational exposure, and adequate instruction and training on protection and safety; and

(b) provide to female employees who are likely to enter any controlled area or supervised area appropriateinformation on—

(i) the risk to the embryo or foetus;

(ii) the importance for a female employee to notify the employer as soon as she suspects that she is pregnant; and

(iii) the risk to an infant ingesting radioactive substances by breast feeding;

(c) provide to the employees appropriate information, instruction and training to deal with an emergency; and

(d) keep records of the training provided to the employees.

Personal protective equipment

25. (1) A licensee or an employer shall—

(a) minimise the need for relying on administrative controls and personal protective equipment for protection and safety during normal operations by providing appropriate well engineered controls and satisfactory working conditions;

(b) ensure that employees are provided with suitable and adequate personal protective equipment, including—

(i) protective clothing;

(ii) protective respiratory equipment with information on its protection characteristics and instructions on its proper use; and

(iii) protective aprons, gloves and organ shields;

(3) A licensee or an employer shall arrange for regular testing and maintenance to be carried out on all personal protective equipment, including special equipment for use in the event of accidents and interventions.

(4) A licensee or an employer shall take into account the following factors when assigning personal protective equipment for a given task:

(a) medical fitness to sustain possible extra physical effort while using the protective equipment; and

(b) additional work time or inconvenience or additional nonradiological risks associated with the use of the protective equipment.

Exposure assessment

26. (1) A licensee or an employer shall arrange for the assessment of the occupational exposure of an employee and shall ensure that adequate arrangements are made for the provision of such services by a dosimetry laboratory approved by the Authority.

(2) A licensee or an employee shall take individual monitoring for an employee who is employed in a controlled area and where individual monitoring is not feasible, the occupational exposure of the employee shall be assessed on the basis of the results of monitoring of the workplace and of information on the locations and duration of exposure of the employee.

(3) A licensee or an employee shall, where an employee is engaged in a supervised area or enters a controlled area occasionally, assess the occupational exposure of the employee on the basis of the results of monitoring of the workplace or of individual monitoring.

(4) The nature, frequency and precision of individual monitoring shall be determined by considering the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposures.

(5) A licensee or an employer shall ensure that an employee who may be exposed to radioactive contamination, including an employee who uses protective respiratory equipment, is identified and shall arrange for appropriate monitoring to the extent necessary to demonstrate the effectiveness of the protection provided and to assess the intake of radioactive substances or the committed dose, as appropriate.

(6) A licensee or an employer shall keep records of exposure which shall be made available to the employees and the Authority.

Monitoring of workplace

27. (1) A licensee or an employer, shall establish, maintain and keep under review a programme for the monitoring of the workplace commensurate with the nature of, and the risks associated with, the source.

(2) The programme for the monitoring of the workplace shall specify—

(a) the quantities to be measured;

(b) where and when the measurements are to be made and at what frequency;

(c) the most appropriate measurement methods and procedures; and

(d) the reference levels and the measures to be taken if they are exceeded.

(3) The nature and frequency of monitoring of the workplace referred to in sub-regulation (1), shall be sufficient to enable—

(a) the evaluation of the radiological conditions in the workplaces;

(b) the assessment of the exposure of the employees in controlled areas and supervised areas;

(c) the review of the classification of the controlled and supervised areas; and

(d) the assessment of the levels of ambient dose equivalent, airborne and surface activity concentration, including their expected fluctuations, the likelihood and magnitude of potential exposures.

(4) A licensee shall keep appropriate records of the findings of the workplace monitoring programme, which shall be made available to the employees.

Health surveillance

28. (1) A licensee or employer shall, in accordance with the rules established by the Authority, make arrangements for health surveillance, based on the general principles of occupational health, designed to assess the initial and continuing fitness of an employee in relation to the employee's tasks.

(2) A licensee or an employer shall take medical history or otherwise health surveillance of an employee before that employee takes employment in a radiation related workplace.

Records of employee

29. (1) A licensee or an employer shall maintain records of exposure for each employee for whom assessment of occupational exposure is required under regulation 26.

(2) An employee's exposure record shall include information on—

(a) the general nature of the work resulting in exposure, the external doses and intakes at, or above, the relevant recording levels and the data upon which the dose assessments are based;

(b) the periods of employment with different employers, if any, and the corresponding doses and intakes in each period of employment; and

(c) the internal and external doses due to emergency interventions or accidents, which shall be distinguished from doses received during work in normal conditions.

(3) A licensee or an employer shall—

(a) provide an employee access to information of their own exposure records and workplace monitoring, where appropriate; and

(b) upon request by the Authority or other persons or organisations with a demonstrated need for the records referred to in paragraph *(a)* provide access to employee exposure records, with care and attention to the maintenance of appropriate confidentiality.

(4) A licensee or employer shall retain the employee's record until the employee attains the age of seventy-five years, and for not less than thirty years after the termination of the work involving occupational exposure.

Special circumstances

30. (1) A licensee shall, where a practice which is justified and for which radiation safety is optimised requires a temporary change in the dose limit requirements specified by these Regulations, apply to the Authority for approval to change the dose limit.

(2) The application made by the licensee under sub-regulation (1) shall include information to demonstrate that—

(a) all reasonable efforts have been made to reduce exposures and optimise radiation safety provisions in accordance with the requirements of these Regulations; and

(b) the relevant employers and employees, through their representatives where appropriate, have been consulted on the need for and the conditions of the temporary change in dose limit requirements.

(3) Any temporary change in the dose limit requirements of these Regulations shall be limited to specified work areas and shall be in accordance with the time and dose limit for special circumstances specified in the Third Schedule.

PART V

MEDICAL EXPOSURE

General responsibilities

31. (1) A licensee shall ensure that—

(a) a patient is not administered a diagnostic or therapeutic medical exposure, unless the exposure is prescribed by a medical doctor or dental surgeon;

(b) medical doctors and dental surgeons are assigned the primary obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;

(c) medical personnel are available as needed and are trained to discharge the assigned tasks in the diagnostic or therapeutic procedures that the medical doctor or dental surgeon prescribes;

(d) for therapeutic uses of radiation, including teletherapy and brachytherapy, the calibration, dosimetry and quality assurance requirements of these Regulations are conducted by, or under, the supervision of a qualified expert in radiotherapy physics;

(e) the exposure of individuals incurred knowingly while helping voluntarily, other than in their occupation, in the care, support or comfort of patients is constrained as specified in the Fourth Schedule; and

(f) personnel engaged in diagnostic or therapeutic uses of radiation are well trained and qualified.

(2) A licensee shall, to the extent practicable, ensure that for diagnostic uses of ionising radiation, the imaging and quality assurance requirements of these Regulations are met with the advice of a qualified expert in radio-diagnostic physics, nuclear medicine physics and radiopharmacy in the compounding of radio-pharmaceuticals, as appropriate.

(3) Medical personnel shall promptly inform the licensee of any deficiencies or needs concerning compliance with these Regulations with respect to the protection and safety of patients, and shall take such measures as may be necessary to ensure the protection and safety of patients.

Justification of medical exposure

32. (1) A medical doctor or dental surgeon 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.

(2) A radiological examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications shall not be treated as justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.

(3) Mass screening of population groups involving medical exposure shall not be treated as justified unless the expected advantages for the individuals examined or for the population as a whole are sufficient to compensate for the economic and social costs, including the radiation detriment.

(4) The exposure of humans for medical research shall not be treated as justified unless it is—

(a) undertaken in accordance with the provisions of the Helsinki Declaration (1964) and complies with the guidelines for its application prepared by the Council for International Organisations of Medical Sciences (CIOMS) (1993) and World Health Organisation (WHO) (1997); and

(b) subject to the advice of the licensee's ethical review committee and to any other applicable law.

Optimisation of protection for medical exposures

33. A licensee shall, in addition to satisfying the general requirements for optimisation of radiation safety specified in these Regulations, in cooperation with the suppliers of radiation equipment, meet the prescriptive design and operational requirements specified in the Fifth Schedule.

Calibration, clinical dosimetry and quality assurance for medical exposure

34. (1) A licensee shall ensure that—

(a) the calibration of sources used for medical exposure is traceable to a standards dosimetry approved by the Authority;

(b) each type of radiotherapy equipment is calibrated in terms of the relevant dosimetric qualities and irradiation conditions;

(c) unsealed sources for nuclear medicine procedures are calibrated in terms of activity of the radio-pharmaceuticals to be administered; and

(d) calibration of equipment are carried out at the time of commissioning of a source, after any maintenance procedure that may affect the calibration, at least once in a year.

(2) A licensee shall ensure that representative values of clinical dosimetry parameters are determined and documented.

(3) Quality assurance programmes for medical exposures shall include—

(a) measurements of the physical parameters of the radiation generators, imaging devices and irradiation installation at the time of commissioning and periodically thereafter;

(b) verification of the appropriate physical and clinical factors used in patient diagnosis or treatment;

(c) written records of relevant procedures and results;

(d) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and

(e) as far as possible, regular and independent quality audit reviews of the quality assurance programmes for radiotherapy procedures.

Dose constraints for medical research

35. (1) The optimisation of protection of persons exposed for medical research purposes, where the medical exposure does not produce direct benefit to the exposed individuals, shall be subjected to individual dose constraints established on a casebycase basis by an ethical review committee or other institutional body assigned a similar function.

(2) A licensee shall limit any dose to individuals incurred while helping voluntarily, other than in their occupation, in the care, support or comfort of patients undergoing medical exposure, and to visitors to patients who have received therapeutic amounts of radionuclides or who are being treated with brachytherapy sources, to a level not exceeding that specified in the Fourth Schedule.

Guidance levels

36. (1) A licensee shall ensure that guidance levels for medical exposure, determined as specified in regulation 34, are revised as technology improves and are used as guidance by medical personnel so that—

(a) corrective measures are taken if the doses or activities fall substantially below the guidance levels, resulting in a decrease of medical benefit to patients by ineffective diagnostic information or insufficient therapeutic dosage; and

(b) review measures are considered if doses or activities exceed the guidance levels as an input to ensuring optimised protection of patients and maintaining appropriate levels of good practice.

(2) A licensee shall, during the period in which the guidance levels for medical exposure are determined pursuant to regulation 17, ensure that the performance of diagnostic radiology and nuclear medicine equipment is assessed on the basis of comparison with the guidance levels provided in the Fourth Schedule.

Maximum activity for patients in therapy on discharge from hospital

37. (1) In order to restrict the exposure of any member of the household of a patient who has undergone a therapeutic procedure with sealed or unsealed radionuclides and of members of the public, the patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below the level specified in the Fourth Schedule, unless otherwise justified and the justification is documented.

(2) Medical personnel shall provide written instructions to a patient who undergoes therapeutic procedures concerning contact with other persons and necessary precautions for radiation protection.

Investigation of accidental medical exposures

38. (1) A licensee shall promptly investigate the following incidents:

(a) any therapeutic treatment delivered to the wrong patient or the wrong tissue, using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the value prescribed by the medical doctor or dental surgeon;

(b) any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and

(c) any repeated equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

(2) A licensee shall, with respect to any investigation required—

(a) calculate or estimate the doses received and their distribution within the patient;

(b) indicate the corrective measures required to prevent recurrence of an incident;

(c) implement all the corrective measures that are under the licensee's responsibility;

(d) notify the Authority, by telephone, electronic mail, facsimile or any other efficient means of communication as soon as practicable, but not later than twenty-four hours after discovery, of any incident which has the potential for, or has resulted in, serious injury or death of a patient, or which involve more than one patient;

(e) submit to the Authority, within thirty days after discovery of the incident, a written report which states the cause of the incident and includes information on the doses, corrective measures and any other relevant information; and

(f) inform the patient and the patient's doctor about the incident.

Medical dosimetry records

39. A licensee shall keep and make available, as appropriate, records of equipment calibration, clinical dosimetry and quality assurance, as well as any other necessary information to allow assessments of the doses received by patients.

PART VI

PUBLIC EXPOSURE

General responsibilities

40. (1) A licensee shall, with respect to sources of radiation under the licensee's responsibility, establish, implement and maintain—

(a) radiation safety policies, procedures and organisational arrangements to control public exposure to radiation;

(b) measures for ensuring—

(i) the optimisation of the protection of members of the public which is attributable to the sources of radiation under the licensee's control; and

(ii) the limitation of the normal exposure of the relevant critical group, which is attributable to such sources, in order that the total exposure is not higher than the dose limits for members of the public specified in these Regulations;

(c) measures for ensuring the safety and security of the sources, in order that the likelihood of public exposure is controlled in accordance with the requirements of these Regulations;

(d) measures commensurate with the magnitude and likelihood of the potential exposure;

(e) appropriate radiation safety training, and periodic re-training, of the personnel responsible for the protection of the public;

(f) appropriate monitoring equipment and surveillance programmes to assess public exposure to radiation; and

(g) adequate records of the surveillance and monitoring programmes.

Control of visitors to controlled areas

41. A licensee shall—

(a) ensure that visitors are accompanied, in any controlled area, by a person knowledgeable about the radiation safety measures for that area;

(b) provide adequate information and instruction to visitors before they enter a controlled area so as to ensure the appropriate protection of the visitors and other persons in the controlled area; and

(c) ensure that the entry of visitors to a controlled area is restricted and that appropriate signs are posted in the controlled area.

Measures for sources of external exposure

42. A licensee shall ensure that where a source of external irradiation is likely to cause exposure to the public—

(a) prior to commissioning the installation, obtain the approval of the Authority in relation to the floor plans and equipment arrangement for the installation and all significant modifications to existing installations using the source of external irradiation;

(b) specific dose constraints for the operation of the source are established as determined by the Authority; and

(c) shielding and other protective measures that are optimised in accordance with the requirements of these Regulations are provided, as appropriate, for restricting public exposure as determined by the Authority.

Radioactive contamination in enclosed spaces

43. A licensee shall ensure that—

(a) for sources of irradiation for which the licensee is responsible, measures that are optimised in accordance with the requirements of these Regulations are taken for restricting public exposure in areas accessible to the public; and

(b) specific containment provisions are established for the construction and operation of the sources of irradiation in order to avoid or minimise the spread of contamination in areas accessible to the public.

Monitoring programme for public exposure

44. A licensee shall—

(a) establish and carry out a radiation monitoring programme commensurate with the type of, and risks associated with, the sources of irradiation under the licensee's responsibility, to ensure that the requirements of these Regulations are met and to assess the exposure of members of the public to irradiation and discharges of radioactive substances;

(b) keep a record of the results of the radiation monitoring programmes and report the monitoring results to the Authority annually; and

(c) promptly inform the Authority of any results which lead or could lead to an increase of public exposure to radiation.

Restriction of sale and supply of certain consumer products

45. (1) Consumer products that are sources of radiation shall not be sold or supplied to members of the public unless—

(a) they are exempt from the application of these Regulations under regulation 3; or

(b) they are authorised by the Authority for use by members of the public.

(2) An importer of any consumer product that is a source intended for sale or supply to the public shall include in the application for a licence, a copy of the licence or other relevant authorisation issued by the regulatory authority in the country of manufacture or origin which authorises the supply of the consumer product to members of the public in that country.

(3) An importer of any consumer product that is a source intended for sale or supply to the public shall ensure that —

(a) legible labels are visibly and firmly affixed to the consumer product and its package, stating, in English, that—

(i) the product contains radioactive materials; and

(ii) the sale of the product to the public has been authorised by the relevant regulatory authority; and

(b) basic information and instructions on the precautions of use and disposal of the product, written or translated in the local language, are made available with the product.

PART VII

Safety and Security Requirements

General responsibilities

46. (1) A licensee shall ensure the safety of the sources under the licensee's responsibility, from the date of their acquisition throughout their entire operational life and up to their final disposal.

(2) A licensee shall ensure that adequate provision for protection and safety commensurate with the magnitude and likelihood of the potential exposure is applied to the source under the licensee's responsibility so as to—

(a) compensate for or correct a failure by the source;

(b) prevent accidents that may cause unintended exposure to radioactive material;

(c) mitigate the consequences of any accident, should it occur; and

(d) restore the source to safe conditions after any accident.

(3) A licensee shall ensure that the location, design, construction, assembly, commissioning, operation, maintenance and de-commissioning of sources of radiation are based on sound engineering practice which—

(a) takes into account approved codes and standards and technical and scientific developments in the industry;

(b) is supported by reliable managerial and organisational features; and

(c) includes adequate safety margins in the design, construction and operation of sources.

Design and procurement of sources

47. A licensee shall, in collaboration with suppliers of equipment containing radiation generators or sources—

(a) ensure, on procurement of the equipment, that it conforms to the International Electro-Technical Commission (IEC) and the International Standards Organisation (ISO) or equivalent standards as may be approved by the Authority;

(b) ensure that the equipment is tested by the Authority to demonstrate compliance with the appropriate specifications;

(c) conduct a safety assessment of the equipment, either generic or specific, according to the requirements of these Regulations;

(d) ensure that performance specifications and operating and maintenance instructions, including protection and safety instructions, are provided in a language approved by the Authority and in compliance with the relevant IEC and ISO standards and that the information is translated into the local language, where appropriate; and

(e) ensure that, where practicable, the operating terminology and operating values are displayed on operating consoles or other control systems in an appropriate language as specified in paragraph (d).

Accountability and security of sources

48. (1) A licensee shall maintain an accountability system which shall include records of—

(a) the location and description of each source of radiation for which the licensee is responsible; and

(b) the activity and form of each radioactive substance for which the licensee is responsible.

(2) A licensee shall make arrangements for the sources of radiation under the licensee's responsibility to be kept secure by ensuring that—

(a) the control of the source is not relinquished without compliance with the terms and conditions of the licence and without informing the Authority regarding any de-controlled, lost, stolen or missing source;

(b) a source is not transferred to another person who does not hold a valid licence;

(c) records are maintained of source inventory, including records of receipt, transfer and disposal of sources; and

(d) a periodic inventory of sources is conducted at intervals specified in the licence to confirm that they are in their assigned locations and are secure.

Feedback of operating experience of equipment

49. (1) A licensee shall ensure that information on the normal operation performance and abnormal conditions and events significant to radiation safety and security is disseminated or made available to the Authority and other relevant parties, including other users, as specified by the Authority.

(2) A licensee shall make appropriate arrangements with the suppliers of sources of radiation to establish and maintain mechanisms for the transfer from the licensees to the suppliers of any information on the use, maintenance, disposal and malfunctioning of that source relevant for future improvements in the design and construction of the sources.

PART VIII

EMERGENCY INTERVENTION

Responsibility of licensee

50. (1) A licensee shall, where an authorised practice or source within a practice has a potential for accidents likely to result in exposure of the public to radiation prepare an emergency plan appropriate for the source and its associated risks.

(2) An emergency plan shall—

(a) characterise the content, features and extent of a potential emergency taking into account the results of any accident analysis and any lessons learned from operating experience and from accidents that have occurred with sources of a similar type;

(b) identify the various operating and other conditions of the source which could lead to the need for intervention;

(c) describe the methods and instruments for assessing the accident and its consequences on and off the site;

(d) provide for protection and mitigation actions and assignment of responsibilities for initiating and discharging such actions;

(e) provide for rapid and continuous assessment of the accident and determine the need for protective actions;

(f) allocate responsibilities for notifying the relevant authorities and for initiating intervention;

(g) provide procedures, including communication arrangements, for contacting any relevant intervening organisation and for obtaining assistance for firefighting, medical, police and other relevant services;

(h) provide for training the personnel involved in implementing emergency plans and the rehearsal at appropriate intervals in conjunction with the relevant authorities; and

(j) provide for periodic review and updating of the plan.

(3) A licensee shall ensure that an emergency plan defines onsite responsibilities and takes account of offsite responsibilities of other intervening organisations appropriate for the implementation of the emergency plan.

(4) A licensee shall, where an accident occurs from any source, take the necessary protective measures required for the protection of the public from exposure and such measures as the Authority may determine to protect, mitigate or remediate a hazardous situation involving the sources.

Implementation of interventions to reduce accidental exposure

51. (1) A licensee shall ensure that the protective actions or remedial actions aimed at reducing or averting accidental exposures are only undertaken if they are justified, taking into account health, social and economic factors.

(2) The form, scale and duration of any intervention shall be optimised so as to produce the maximum net benefit under the prevailing social and economic circumstances.

(3) A licensee shall, where an accident requiring intervention occurs, or is likely to occur, immediately notify the Authority of—

(a) the situation and its expected evolution;

(b) the measures taken to terminate the accident and to protect the employees and the members of the public; and

(c) the exposures incurred and that are expected to be incurred.

Protection of employees undertaking interventions

52. (1) An employee undertaking an intervention shall be exposed in excess of the maximum single year dose limit for occupational exposure specified in the Third Schedule, except—

(a) where the employee undertakes the intervention for the purpose of saving life or preventing serious injury; or

(b) where the employee is undertaking the intervention to prevent the development of catastrophic conditions.

(2) A licensee undertaking any intervention shall take all reasonable measures to keep doses to the employees below twice the maximum single year dose limit, except for life saving intervention, in which the licensee shall keep doses below ten times the maximum single year dose limit in order to avoid deterministic effects on health.

(3) An employee undertaking interventions in which the doses may approach or exceed ten times the maximum single year dose limit shall do so only when the benefits to others clearly outweigh their own risk.

(4) An employee who undertakes interventions in which the dose exceeds the maximum single year dose limit shall do so as a volunteer and shall be clearly informed in advance of the associated health risk, and shall, to the extent feasible, be trained in the intervention required.

(5) A licensee shall, at the end of an emergency intervention, ensure that the employees undertaking the recovery operations, such as repairs to equipment and buildings, waste disposal or de-contamination are subjected to the requirements for occupational exposure specified in these Regulations.

(6) A licensee shall—

(a) take reasonable steps to provide appropriate protection to the employees undertaking any emergency intervention and to assess and record the doses received by the employees; and

(b) inform the employees at the end of the intervention of the doses received and the consequent health risk.

(7) An employee shall not be precluded from incurring further occupational exposure because of the doses received in an emergency intervention, except that qualified medical advice shall be obtained before any further exposure, at the employee's request or where an employee, during an emergency intervention, receives a dose exceeding ten times the maximum single year dose limit.

Release of radioactive materials into environment

53. (1) A licensee shall inform the Authority immediately of the release of radioactive materials into the environment.

(2) The levels of radioactive materials released into the environment shall be below the exempt limits set by the Authority.

(3) A licensee shall comply with the exempt limits by establishing an environmental monitoring programme and accounting for the release of the radioactive materials.

PART IX

TRANSPORTATION OF RADIACTIVE MATERIAL

Definition

54. In this Part, "IAEA Transport Regulations"means the International Atomic Energy Agency Regulation for the Transport of Radioactive Material (IAEA Safety Standards Series No.ST-1).

Transportation of radioactive materials

55. (1) A person delivering radioactive materials to a carrier or any person transporting radioactive materials within, through or into the country, shall comply with the IAEA Transport Regulations.

(2) The packaging and design for the transportation of radioactive materials, through or into the country shall comply with the requirements of the IAEA Transport Regulations.

Storage in transit

56. Any radioactive materials stored in transit shall be stored in accordance with the IAEA Transport Regulations and handled in transit in accordance with instructions issued by the Authority.

Transfer of sources

57. A licensee shall report to the Authority any transfer of radioactive materials, in writing, stating its physical and chemical properties and any other information as determined by the Authority.

Receipt of dispatch

58. A person who sends any radioactive material to another person shall ensure that the recipient acknowledges the receipt of the dispatched radioactive material, in writing, within thirty days from the date of dispatch.

59. (1) A person who sends radioactive material shall investigate any shipment or part of a shipment, where acknowledgment is received within the period specified in regulation 55 and shall immediately inform to the Authority. Investigation of shipment of radioactive material

(2) The shipment referred to in sub-regulation (1) shall be monitored by the sender of the radioactive material who shall prepare a report for submission to the Authority within seven days of completing the investigation.

PART X

General Provision

60. The fees specified in the Sixth Schedule are payable for the matters specified therein. Fees

FIRST SCHEDULE

(*Regulations* 4, 5(2), 6, 7, 8, 9, 10, 11, 12, 13 *and* 14)

Form I
(*Regulation* 4)
(To be completed in triplicate)

THE RADIATION PROTECTION AUTHORITY

The Ionising Radiation Protection Act, 2005

(Act No. 16 of 2005)

The Ionising Radiation Protection (General) Regulations, 2011

APPLICATION FOR IONISING RADIATION LICENCE			
		Shaded fields for official use only	Application No.
			Licence Code
Information Required		*Information Provided*	
1.	Name(s) of applicant		
2.	(a) Nationality		
	(b) Identity card		
	National Registration Card No.		
	Passport No.		
	Company Registration No.		
3.	Notification address		
	Fax:		
	E-mail:		
4.	Purpose of application		
5.	Name and qualifications of person responsible for irradiator or radiography facility/ radiation generating equipment/accelerator		
6.	Contact details of person responsible for irradiator or		

	radiography facility/ radiation generating equipment/accelerator		
7.	Licence previously held by the applicant under the Ionising Radiation Protection Act, 2005, or similar legislation outside Zambia *(attach certified copies)*	Licence No.	Location
8.	Licences currently held by applicant in Zambia, if any, under the Ionising Radiation Protection Act, 2005	Licence No.	Location

9. **Have you ever been convicted of an offence involving fraud or dishonesty or of any offence under the Ionising Radiation Protection Act, 2005, or any other law within or outsideZambia?**
If yes, specify details:.....
Nature of offence:.....
Dateofconviction:.....
Sentence:.....

10. **Have you ever applied for a licence under the Ionising Radiation Protection Act, 2005? If yes, please give details below:**

Licence applied for:	Activity	Location	Date of application	Status of application (Granted, rejected or pending)*

11. Source and Irradiator Facility/Radiation generating equipment/Accelerator

Model/ Type No.	Manufacturer	Supplier	Proposed date of commissioning	Class
	Name:	Name:		
	Address:	Address:		

12. Details of radioactive sources

Radionuclides		Number of sources			Total activity (Bq)		Source details		Storage wet/dry
	Per pencil	Per module	Per rack	Total	Initial	At instal-lation	Model No.	Desig-nation	

13.	**Standards** Are the sources/accelerator manufactured, prototype tested, and subjected to quality control provisions of standard setting organization (e.g. ISO 2919, IEC 976, IEC 977)? If so, identify the standards and any application classification numbers.
14.	**FACILITIES AND EQUIPMENT** *(In an attachment to this application, describe the irradiator/accelerator facilities as follows:)*
	(a) **Location**
	Provide a detailed location of the facility including the city, district, town, area or other locality in which the facility is established
	(b) Layout of facility
	Describe factors such as the layout of the facility and its immediate surroundings, buildings materials, alarms, shielding, engineering controls such as interlock and warning safety devices, and remote handling tools (Safety Series No. 107). Attach a detailed sketch or drawing of the facility showing the above details. Include on the drawings any penetrations or openings in the shielding materials such as conduits or ventilation ducts. Include evaluation of the ground surface and adverse environmental conditions that may cause harm to the facility (e.g. seismic history, strong winds, air crashes). Controlled and supervised areas should be clearly identified on the drawings.
	(c) Safety assessment
	Taking account of shielding, provide calculations of maximum dose rates in all areas outside the facility (specify all assumptions, e.g. number of sources, activity). Provide estimates of the magnitude of expected doses to persons during normal operations. Identify the probability and magnitude of potential exposures arising from accidents or incidents.
	(d) Safety system
	(i) Describe the overall safety system which will be used to ensure the safe operation of the irradiator (e.g. design features, defence in depth, layout). Further describe, in detail, the safety systems for preventing access to the irradiation room whilst the source is exposed and for warning of unsafe conditions (e.g. interlocks, installed monitors). (ii) Attach the manufacturer's specifications that will be provided.
	(e) **Personal protective equipment**
	Describe any personal protective equipment that will be provided.
15.	RADIATION PROTECTION AND SAFETY PROGRAMME
	(a) **Organisational structure**
	(i) Describe your organisational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety. In particular include: staffing levels, equipment selection, other assignments of the radiation protection officer, authority of the radiation protection officer to stop unsafe operations, personnel training, maintenance of records, and how problems affecting safety are identified and corrected.

(ii) Identify the authorised users, qualified experts, and radiation protection officer by name and include their training, education, experience and qualifications. (Note: the authorised user and radiation protection officer may be the same individual).

(iii) Confirm that training will include: explanation of radiation hazards and effects, explanation of written procedures, use of equipment (e.g. instrumentation), meaning of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

(b) **Workplace monitoring, area classification and individual monitoring**

(i) Describe your programme for monitoring the workplace (BSS,I.37-I.40), including: the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.

(ii) Describe your policies and procedures for classification of controlled and supervised areas. (BSS,I.21-I.25).

(iii) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32-I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken if exceeded.

(c) **Local rules and supervision**

(i) Describe your local rules and procedures regarding: investigation or authorised levels, protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26-I.27).

(ii) Provide copies of your operating and safety procedures including: area access control, entry procedures, product entry and exit, source inventory and leak testing, etc.

(iii) Describe your training program to ensure that all appropriate personnel are adequately trained in the correct operating procedures and how their actions may affect safety (BSS,I.27).

(iv) Describe your policies regarding female workers who become pregnant (notification, adaption of working conditions to protect foetus/embryo) and the instructions you will provide to them (BSS,I.16-I.17 and I.27).

(v) Describe your program of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their tasks (BSS,I.41-I.43).

(d) **Quality assurance**

(i) Describe your program for ensuring that regulatory radiation safety requirements are addressed and satisfied.

(ii) Describe your program to periodically review procedures, maintain procedures current and available, and your procedure modification process.

(iii) Describe your program for optimising occupational and public exposures to levels as low as reasonably achievable.

(iv) Describe your program of periodic maintenance and testing (safety interlocks, radiation meters, hoist cable and guide cable, etc). Attach the manufacturer's instructions.(v) Describe service arrangements with other organisations and qualified experts.

	(e) **Transportation of radioactive material**
	If you will be transporting new or used sources, describe your arrangements for preparation and transport of packages containing radioactive sources (IAEA Safety Standards Series No. ST-1). These procedures should address: documentation of package certification, package surveys, transfer/receipt documents, and details of shipment preparation.
	(f) **Emergency procedures**
	Provide your emergency procedures to address emergencies such as potential damage to the source, loss of source shielding, stuck sources or substantial accidental exposure of an individual. If other emergencies are envisaged, please provide additional appropriate emergency procedures. In all cases, the magnitude of the hazard should be elevated. Local emergency services (e.g. fire, policy) may need to be provided with copies of the emergency procedures.
	(g) **Transfer or disposal of radioactive sources system of records**
	Describe arrangements for transfer or disposal of spent radioactive sources.
	(h) **System of records (BSS:2.40, 1.44-I.49)**
	(i) disposal of spent source (ii) personnel exposure(iii)area surveys (iv) instrument tests and calibrations (v) tests for radioactive sealed source leakage (vi) inventory of sources and accountability (vii) audits and reviews of radiation safety programme (viii) incident and accident investigation reports (ix) maintenance and repair work (x) facility modifications (xi) training provided (xii) evidence of health surveillance of workers (xiii) transportation
	(i) **Physical security**
	A high security will be provided for safe keeping
16	A. MEDICAL EXPOSURE – DIAGNOSTIC X-RAY EQUIPMENT
	In an attachment to this application, describe the programme to control medical exposure, including:(BSS requirements related to this section may be found in Appendix II "Medical Exposure").
	(a) **Responsibilities**
	(i) Describe your arrangements to ensure that no patient is diagnostically exposed unless the exposure is prescribed by a medical doctor or dental surgeon. (ii) Describe your arrangements to ensure that there are an adequate number of trained medical and paramedical personnel to discharge assigned tasks; and (iii) Confirm diagnostic imaging and quality assurance requirements are fulfilled with the advice of a qualified expert in nuclear medicine physics.

(b) **Justification**

(i) Describe your arrangements to ensure that medical exposures are justified by weighing the benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of alternate techniques that do not involve ionizing radiation.

(ii) Describe your arrangements to ensure that exposure of humans for medical research is in accordance with Helsinki Declaration and follows the guidelines for its application prepared by the Council for International Organisation of Medical Sciences and the World Health Organisations.

(iii) Describe your arrangements to ensure that exposure of humans for medical research is subject to the advice of the Ethical Review Committee or a similar institutional body.

(iv) If you intend to use radiological examinations for screening of large populations for occupational, legal or health insurance purposes; include a description of the standards you will use for justification.

(c) **Optimisation of protection**

(i) Describe your arrangements for medical doctor or dental surgeon to ensure that the exposure of patients is the minimum necessary to achieve the diagnostic objective and take into account relevant information from previous examinations to avoid unnecessary additional examinations.

(ii) Describe your arrangements to ensure that newly purchased equipment:

A. Whether imported into or manufactured in the country, the equipment conforms to applicable standards of the International Electro technical Commission (IEC) and the ISO or to equivalent national standards;

B. Performance specifications and operating and maintenance instructions, including protection and safety instructions, be provided in a major world language understandable to the users and in compliance with the relevant IEC and ISO standards with regards to " accompanying documents", and that this information be translated into local languages when appropriate;

C. Where applicable, the operating terminology or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user;

(iii) Describe your arrangements regarding medical exposure of women who are, or may be, pregnant.

(d) **Calibration, clinical dosimetry and quality assurance**

(i) Describe your program for calibration of the X-ray radiation beams traceable to a standards dosimetry laboratory. (BSSII.19)

(ii) Describe your program for clinical dosimetry including representative values for typical sized adult patients of entrance surface doses, dose-area products, dose rates and exposure times or organ doses,

(iii) Describe your program for preventive maintenance and quality assurance for medical exposures established taking into account the principles established by the WHO and the PAHO.

(iv) The quality assurance programme for medical exposures shall include:

A. measurements of the physical parameters of the radiation generators, imaging devices and irradiation installations at the time of commissioning and periodically thereafter;

B. verification of appropriate physical and clinical factors used in patient diagnosis or treatment;

C. written records of relevant procedures and results;

D. verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment; and

E. as far as possible, regular and independent quality audit reviews of the quality assurance programme for diagnostic procedures

(e) **Dose constraints**

Describe your policies to ensure any dose to individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care support and comfort of patients undergoing medical diagnosis will be constrained to a level not exceeding that specified by the Authority

(f) Investigations of accidental medical exposure

(i) Confirm that you will investigate any oral instances where:

A. A diagnostic dose was substantially greater than intended or result in doses repeatedly and substantially exceeding the established guidance levels;

B. An equipment failure, accident, error, mishap or other occurrence with the potential for causing a patient exposure significantly different from that intended.

(ii) With respect to any incidents investigated, confirm you will:

A. Calculate or estimate the doses received and their distribution within the patient.

B. Indicate the corrective measures required to prevent recurrence of such an incident

C. Implement all corrective measures that were under their control.

D. Submit to the Authority, as soon as possible after the investigation or as otherwise specified by the Authority, a written report which stated the cause of the accident and included the information specified in "i" to "iii", as relevant.

E. Inform the patient and the patient's doctor about the incident.

17. **B. MEDICAL EXPOSURE – RADIOTHERAPY**

In an attachment to this application, describe the programme to control medical exposure, including:(BSS requirements related to this section may be found in Appendix II "Medical Exposure").

(a) **Responsibilities**

(i) Describe your arrangements to assure that patient treatment will only be prescribed by medical doctor or dental surgeon.

(ii) Describe your arrangements to assure that calibration, dosimetry and quality assurance requirements for therapy are conducted by or under the supervision of a qualified expert in radiotherapy physics.

(iii) Describe criteria and arrangements to ensure an adequate number of trained medical and paramedical personnel to discharge assigned tasks.

(b) **Justification**

(i) Describe your arrangements to ensure that the therapeutic benefits will be weighed against the radiation detriment they might cause, taking into account the benefits and risks of alternative techniques that do not involve ionising radiation.

(ii) Describe your arrangements to ensure that exposure of humans for medical research is in accordance with Helsinki Declaration and follows the guidelines for its application prepared by the Council for International Organisation of Medical Sciences and the World Health Organisations.

(iii) Describe your arrangements to ensure that exposure of humans for medical research is subject to the advice of the ethical review committee or a similar institutional body

(c) **Optimisation of protection**

(i) Describe your arrangements to ensure that:

A. exposure of normal tissue during radiotherapy be kept as low as reasonably achievable consistent with delivering the required dose to the planning target volume, and organ shielding be used when feasible and appropriate;

B. radiotherapeutic procedures causing exposure of abdomen or pelvis of women who are pregnant or likely to be pregnant be avoided unless there are strong clinical indications;

C. Any therapeutic procedure for pregnant women be planned to deliver the minimum dose to any embryo or foetus; and

D. the patient be informed of possible risks

(ii) Describe your arrangements to ensure that with regard to equipment consisting of radiation generators or containing sealed sources for medical exposures:

(iii) Equipment conforms to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards (whether imported into or manufactured in the country where it is used);

(iv) Performance specifications and operating and maintenance instructions, including protection and safety instructions, will be provided in a major world language understandable to the user and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents", and that this information be translated into local languages when appropriate;(v)
Where practicable, the operating terminology (or its abbreviations) and operating values will be displayed on the operating consoles, in a major language acceptable to the user.

(d) **Calibration**

(i) Describe your system to ensure the calibration of sources used for medical exposure is traceable to a standards dosimetry laboratory.