GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 7 OF 2024

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

The Ionising Radiation Protection (Nuclear Medicine) Regulations, 2024

ARRANGEMENT OF REGULATIONS

Copies of this Statutory Instrument can be obtained from the Government Printer, P.O. Box 30136, 10101 Lusaka. Price K 40.00 each.

IN EXERCISE of the powers contained in section 46 of the Ionising Radiation Protection Act, 2005, the following Regulations are made:

1. These Regulations may be cited as the Ionising Radiation Protection (Nuclear Medicine) Regulations, 2024. Short title

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

"accident" means any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible to ensure protection and safety;

"activity" means an amount of radionuclide in a given energy state at a given time;

"authorised member of staff" means a member of staff in a nuclear medicine facility who is permited to enter into a controlled area or a supervised area;

"becquerel" means an activity of a quantity of radioactive material in which one nucleus decays per second;

"bolus injection" means the administration of a drug in a single large dose;

"calibration" means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by measurement standards;

"carer" means a person who willingly and voluntarily helps in the care, support and comfort of a patient undergoing radiological procedures for medical diagnosis or medical treatment;

"commissioning" means the process of systems and components of facilities and activities, which having been constructed, are made operational and verified to be in accordance with the design and they met the required performance criteria;

"compulsory standard" has the meaning assigned to the word in the Compulsory Standards Act, 2017; Act No. 3 of 2017

"contamination" means the unintended or undesirable presence of, or the process giving rise to, radioactive substances on surfaces or within solids, liquids or gases;

"controlled area" means an area in which specific protection measures and safety provisions are or could be required for controlling exposures or preventing the spread of contamination in normal working conditions, and preventing or limiting the extent of potential radiation exposures;

"individual monitoring" means monitoring using measurements by a device worn by an individual, or measurements of quantities of radioactive substances in or on, or taken into a body of an individual, or measurements of quantities of radioactive substances excreted from the body by an individual;

"infusion injection" means administering into a vein or veins of a human body through a continuous means;

"ionising radiation" means radiation capable of producing ion pairs in biological material;

"internal exposure" means exposure to radiation from a radioactive material or radiation emitting device within the body;

"intervention" means any action intended to reduce or avert exposure or the likelihood of exposure due to sources that are not part of a controlled practice or that are out of control as a consequence of an accident;

"intravenous" means administering into a vein or veins of the human body;

"justification" means the process of determining whether a practice has benefits which outweigh the radiation risk to persons;

"maintenance" means the organised activity, both administrative and technical, of keeping structures, systems and components in good operating condition, including both preventive and corrective aspects;

"medical exposure" means exposure incurred by a patient for the purposes of that patient's own medical treatment or diagnostic examination;

"medical physicist" means a person with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practice independently in one or more of the subfields of medical physics;

"medical radiological equipment" means radiological equipment used in a nuclear medicine facility to perform nuclear medicine procedures that either delivers an exposure to an individual or directly controls or influences the extent of that exposure;

"nuclear medicine facility" means a facility in which nuclear medicine procedures are performed;

"radiation monitoring" means the measurement of a dose, dose rate or activity for reasons relating to the assessment or control of exposure to radiation or exposure due to radioactive substances, and the interpretation of the results;

"radioactive waste" means a material for which no further use is foreseen that contains, or is contaminated with, radionuclides at activity concentrations greater than clearance levels as established by the regulatory body;

"radioactivity" means the phenomenon when atoms undergo spontaneous random disintegration accompanied by the emission of radiation;

"radiological procedure" means a medical imaging procedure or therapeutic procedure that involves ionising radiation delivered by a radiation generator, a device containing a sealed source or an unsealed source, or by means of a radiopharmaceutical administered to a patient;

"radiation emitting devices" means a device capable of generating ionising radiation, such as X-rays, neutrons, electrons or other charged particles, that may be used for scientific, industrial or medical purposes;

"radiation protection programme" means a programme developed by a nuclear medicine facility on radiation protection;

"radiation safety officer means a radiation safety officer appointed under section 35 of the Act;

"radiopharmaceutical therapy" means the delivery of radioactive materials to tumour associated target human body organs or non-tumour cells of interest and their miro-environments;

"source" has the meaning assigned to the word in the Act;

"supervised areas" means an area not designated as a controlled area but for which occupational exposure conditions are kept under review when specific protection measures or safety provisions are not normally needed;

"surgical technique" means a medical procedure involving an incision in a human body;and

"unsealed source" means a radioactive material which is neither —

(a) permanently sealed in a capsule; or

(b) closely bonded and in a solid form.

PART III

MEDICAL RADIOLOGICAL EQUIPMENT

National standards for medical radiological equipment

Act No. 4 of 2017

Act No. 3 of 2017

5. A nuclear medicine facility shall ensure that medical radiological equipment at the nuclear medicine facility meets the relevant standards and compulsory standards specified under the Standards Act, 2017 and the Compulsory Standards Act 2017, and the guidelines issued by the Authority.

Medical radiological equipment

6. A nuclear medicine facility shall be equipped with medical radiological equipment which shall contain the calibrated workplace monitoring instruments, survey meters and portable contamination monitors.

Acceptance testing for medical radiological equipment

Act No. 4 of 2017

Act No. 3 of 2017

7. A nuclear medicine facility shall perform an acceptance test on the medical radiological equipment after installation of the medical radiological equipment for purposes of verifying conformity to technical specifications given by the manufacturer and compliance with safety requirements from relevant standards and compulsory standards specified under the Standards Act, 2017, the Compulsory Standards Act, 2017, and guidelines issued by the Authority.

Commissioning for medical radiological equipment

8. A nuclear medicine facility shall ensure that the medical radiological equipment is commissioned by a medical physicist after the acceptance testing is completed and the acceptance test of the medical radiological equipment meets the specifications given by the manufacturer.

Maintenance of medical radiological equipment

Act No. 4 of 2017

Act No. 3 of 2017

9. A nuclear medicine facility shall ensure that preventative and corrective maintenance is carried out on medical radiological equipment in compliance with relevant standards and compulsory standards specified under the Standards Act, 2017, the Compulsory Standards Act, 2017, and guidelines issued by the Authority.

PART IV

OCCUPATIONAL RADIATION PROTECTION

Controlled and supervised areas

10. (1) A nuclear medicine facility shall classify an area in a nuclear medicine facility as a controlled area or supervised area in accordance with guidelines issued by the Authority.

(2) A nuclear medicine facility shall, on classification of an area under sub-regulation (1), put in place requirements for area delineation, signage, protection and safety measures, control of

Rules and procedures for radiopharmaceutical therapy

13. (1) A nuclear medicine facility shall establish rules and procedures for radiopharmaceutical therapy.

(2) Rules and procedures established under sub-regulation (1) shall include—

(a) administration of bolus injection through intravenous or intra-arterial means;

(b) administration of slower drip or infusion injection through intravenous means;

(c) oral administration of therapeutic radiopharmaceuticals;

(d) handling of unshielded radioactive materials; and

(e) handling of a potentially contaminated item.

Rules for nursing patient

14. (1) A nuclear medicine facility shall establish rules for nursing a patient undergoing radiopharmaceutical therapy.

(2) A nurse working at a nuclear medicine facility shall comply with the rules established under sub-regulation (1).

Contamination

15. (1) A nuclear medicine facility shall establish rules and procedures for minimising contamination.

(2) A nuclear medicine facility shall ensure that contamination of a controlled area and supervised area which contains unsealed radioactive materials is minimised by ensuring that an occupationally exposed member of staff or any other authorised member of staff at the nuclear medicine facility washes their hands on exiting the controlled area.

(3) Where detectable contamination remains on the hands of an occupationally exposed member of staff of the nuclear medicine facility after washing of hands, other methods, as guided by the Authority, shall be used for decontamination.

(4) A nuclear medicine facility shall ensure that a contamination kit is available on the premises of the nuclear medicine facility.

(5) A nuclear medicine facility shall inform the Authority, in writing, when contamination of other body parts other than the hands, of an occupationally exposed member of staff at the nuclear medicine facility, is suspected to have occured.

(6) Where an occupationally exposed member of staff of the nuclear medicine facility has sustained a wound in the course of work and a risk of radioactive contamination exists, the injury shall be flushed with water as soon as appropriate, and care shall be taken to ensure contamination is not washed into the wound.

(7) Subject to sub-regulation (6), an occupationally exposed member of staff at the nuclear medicine facility shall seek further treatment, including decontamination, if necessary, as soon as first aid is administered.

(b) dosimeters are sent from the nuclear medicine facility to the dosimetry service provider to process the dosimeters and return the dose reports in a timely manner;

(c) when a dosimeter is not in use, individual dosimeters shall be kept in a dedicated place protected from damage or irradiation; and

(d) where an occupationally exposed member of staff loses their dosimeter, an occupationally exposed member of staff shall inform the Authority and the Authority shall perform a dose assessment, record the evaluation of the dose and add it to the dose record of the occupationally exposed member of staff.

(6) A nuclear medicine facility shall ensure that dosimeters are used by the occupationally exposed member of staff in a manner that conforms to the guidelines issued by the Authority.

Investigation levels of staff exposure

18. (1) The Authority shall determine allowable investigation levels for staff exposure.

(2) A nuclear medicine facility shall ensure that investigation levels are set for workplace monitoring, taking into account the exposure scenarios and the determined values adopted for investigation levels on an occupationally exposed member of staff.

(3) A nuclear medicine facility shall ensure that an investigation is initiated immediately where the investigational level for an occupationally exposed member of staff has exceeded the allowable levels determined by the Authority.

(4) Subject to sub-regulation (3), a nuclear medicine facility shall ensure that a written report is prepared within forty-eight hours and submitted to the Authority containing the cause of the investigation, determination or verification of the dose, corrective or mitigatory actions, and instructions or recommendations to avoid recurrence.

(5) A report under sub-regulation (4) shall be reviewed by the Authority and the nuclear medicine facility shall be informed of the decision or the recommendations of the Authority within seven days of receipt of the report.

Information on potential contamination

19. A nuclear medicine facility shall ensure that information on potential contamination risks shall be given to ancillary staff, including contractors performing occasional work in a supervised area or controlled area.

Written protocol for person undergoing medical exposure for diagnostic imaging

25. (1) A nuclear medicine facility shall ensure that a written protocol is developed for an individual undergoing medical exposure for diagnostic imaging to be performed in the nuclear medical facility and that written protocol shall be reviewed annually.

(2) A written protocol referred to under sub-regulation (1) shall take into consideration protection and safety of an individual undergoing medical exposure for diagnostic imaging.

(3) A health professional shall, where a health professional deviates from the provisions of the written protocol,record the reason for deviation from the protocol.

(4) The Authority shall, where the Authority finds that the deviation is not justified, sanction a health professional in accordance with the Act.

Protocol for medical exposure for radiopharmaceutical

26. A nuclear medicine facility shall ensure that a written protocol is developed for an individual undergoing medical exposure for radiopharmaceutical therapy to be treated in the nuclear medical facility and that written protocol shall be reviewed annually.

Exception for medical exposures for pregnant patient

27. (1) A nuclear medicine facility shall ensure that administration of radiopharmaceuticals for therapy to a pregnant patient undergoing medical exposure is avoided, except where the treatment is lifesaving.

(2) A nuclear medicine facility shall, where the nuclear medicine facility treats a breast-feeding mother or pregnant patient undergoing medical exposure, follow the guidelines issued by the Authority.

Exception for a breast-feeding mother

28. (1) A nuclear medicine facility shall ensure that a breast-feeding mother who is undergoing medical exposure is informed in writing that—

(a) breast-feeding is contra-indicated after administration of some radiopharmaceuticals, due to both the external irradiation of the suckling baby and the potential excretion of radioactivity through breast milk; and

(b) depending on the radiopharmaceutical, breast-feeding may need to be interrupted for a breast-feeding mother undergoing medical exposure for a specified period or stopped completely following administration of radioactive materials.

Medical exposure for carers

29. A nuclear medicine facility shall ensure that a health professional involved in the medical exposure, prior to the performance of the procedure, informs the carer about radiation protection and the radiation risks.

Death of person who has undergone radiopharmaceutical therapy

36. (1) A nuclear medicine facility shall ensure that radiation protection measures determined by the Authority are followed in the case of a death of a person to whom radiopharmaceuticals has been administered.

(2) Radiation protection measures referred to under sub-regulation (1) shall —

(a) include the immediate handling of the body, both in the hospital and in the home or other place, or during an autopsy, embalming, burial or cremation; and

(b) be based on a generic safety assessment of the need for monitoring personnel who carry out radiation protection measures, the premises and the need for minimising external radiation exposure and the potential for contamination.

Handling dead body of person who died while undergoing radiopharmaceutical therapy

37. A nuclear medicine facility shall ensure that a person handling the body of a person who died while undergoing radiopharmaceutical therapy is monitored for radiation, and finger radiation monitoring may be required for a person carrying out an autopsy or embalming.

Radioactive waste discharged from nuclear medicine facility

38. (1) A nuclear medicine facility shall ensure that systems and procedures are put in place to manage radioactive waste and discharges of radioactive material which are discharged from the nuclear medicine facility.

(2) Procedures and systems referred to under sub-regulation (1) shall be in line with the guidelines issued by the Authority on radioactive waste.

(3) A nuclear medicine facility shall ensure that initial activity and the half life of radionuclides are taken into consideration for management of radioactive waste which take long to decay.

Programme for monitoring public exposure

39. (1) A nuclear medicine facility shall establish a program for monitoring public exposure arising from nuclear medicine.

(2) A programme for monitoring public exposure under sub-regulation (1) shall include —

(a) dose assessment in the areas in, and surrounding, the nuclear medicine facility that are accessible to the public;

(b) doses derived from the shielding calculations in the planning stage, combined with the results from area monitoring and contamination monitoring at the initial operation of the facility and periodically thereafter; and

(c) records of dose assessments.

Calibrations of radioactive materials and instruments

43. (1) A nuclear medicine facility shall ensure that —

(a) calibration of radioactive materials and instruments used for dosimetry of patients is done by a medical physicist or a qualified expert;

(b) unsealed radioactive materials for radiopharmaceutical therapy are calibrated in relation to the activity of the radiopharmaceutical to be administered, with the activity being determined and recorded at the time of administration;

(c) the calibration of X-ray based radiological medical equipment follows the guidelines specified by the manufacturer and approved by the Authority;

(d) instruments used for dosimetry of patients are calibrated at intervals of not more than two years using calibrated reference radioactive materials that cover the energy range used in clinical practice;

(e) calibration of dosimetry instrumentation are traceable to a standards dosimetry laboratory; and

(f) records of calibration measurements are kept and availed to the Authority when need arises.

Radiation doses for patients receiving nuclear medicine treatment

44. (1) A nuclear medicine facility shall ensure that patient dosimetry is performed and typical doses to patients for diagnostic radiological procedures is determined.

(2) Patient dosimetry for determining typical doses in diagnostic nuclear medicine shall be carried out by a health professional in conjunction with an assessment of the diagnostic image quality.

Absorbed doses

45. A nuclear medicine facility shall determine typically absorbed doses to patients for their therapeutic radiological procedures.

Diagnostic reference levels for patients

46. A nuclear medicine facility shall establish a diagnostic reference levels for nuclear medicine procedures for the reviewing of the process of optimisation of protection and safety of a patient.

Quality assurance for medical exposure

47. (1) A nuclear medicine facility shall establish a quality assurance programme for medical exposures for the optimisation of protection and safety in the nuclear medicine facility and to minimise the occurrence of unintended and accidental medical exposures.

(2) A programme of quality assurance for medical exposures referred to under subregulation (1) shall include routine checks to ensure that the nuclear medicine facility's protocols and procedures for imaging and therapy, including radiation protection and safety are of quality standard.