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:

Short title

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

Interpretation

2. In these Regulations, unless the context otherwise requires

"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;

"decontamination" means the complete or partial removal of contamination by a deliberate physical, chemical or biological process;

"diagnostic reference level" means a level used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the amount of radiopharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure;

"discharge" means a planned and controlled release of radioactive substances to the environment;

"dose" means a measure of energy deposited by radiation in a target or patient;

"dosimetry" means determination and measurement of the amount or dosage of radiation absorbed by a substance;

"emergency"means a non-routine situation or event that necessitates prompt action, primarily to mitigate a hazard or adverse consequence to human life, health, property and the environment;

"exposure" means the state or condition of being subjected to irradiation;

"external exposure" means exposure to radiation from a radioactive material or radiation emitting device outside the body;

"half -life" means the time required for the activity to decrease, by a radioactive decay process, by half, or the time taken for the quantity of a radionuclide in a specified place to decrease by half as a result of any specified process or processes that follow exponential patterns similar to radioactive decay;

Act No. 24 of 2009

"health facility" has the meaning assigned to the words in the Health Professions Act, 2009;

"health professional" means a member of a health profession who is required to be registered under the Health Professions Act, 2009 and includes a dentist, medical physicist, chiropractor, podiatrist, medical radiation technologist, radiopharmacist, occupational health physician and a radiological medical practitioner;

Act No. 24 of 2009

"incident" means any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorised acts, malicious or non malicious actions, the consequences or potential consequences of which are not negligible to ensure protection and safety;

"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;

"occupationally exposed member of staff" means a member of staff in a nuclear medicine facility likely to be exposed to radiation and includes

(a) a medical radiation technologist;

(b) a radiopharmacist;

(c) a medical physicist;

(d) a nuclear medicine physician; and

(e) other health professionals and support staff involved in the management of patients who have been administered with radiopharmaceuticals;

"occupational exposure" means exposure of workers to radiation incurred in the course of their work;

"procedure" means a series of specified actions conducted in a certain order or manner;

"protection and safety means the protection of people against exposure to ionising radiation or exposure due to radioactive material and the safety of sources, including the means for achieving safety of those sources, and preventing accidents and mitigating the consequences of accidents if they do occur;

"public exposure" means exposure incurred by members of the public due to sources in planned exposure situations, emergency exposure situations and existing exposure situations, excluding any occupational exposure or medical exposure;

"quality assurance" means the function of a management system that provides confidence that specified requirements shall be fulfilled;

"quality control" means a part of quality management intended to verify that structures, systems and components correspond to predetermined requirements;

"qualified expert" means an individual who, by virtue of certification by appropriate professional bodies or associations or academic qualifications and experience, is duly recognised as having expertise in a relevant field of specialisation, such as medical physics, radiation protection, occupational health, fire safety, quality management or any relevant engineering or safety speciality;

"radioactive material" means a material designated by the Authority as being subject to regulatory control because of its radioactivity;

"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 II

RADIATION PROTECTION MANAGEMENT

Staff of nuclear medicine facility

3. (1) A nuclear medicine facility shall employ suitably qualified professionals to ensure that activities relating to radiation protection and safety are exercised in accordance with guidelines and other Regulations issued by the Authority.

(2) A nuclear medicine facility shall ensure that the following staff are provided with specific instructions on radiation protection and safety:

(a) nurses working in a controlled or supervised area;

(b) staff who do not belong to nuclear medicine practice but need to enter controlled areas; and

(c) staff who transport radioactive materials within the nuclear medicine facility.

(3) A nuclear medicine facility shall ensure continuous professional development for staff in order to keep the staff up to date to changes in technology and the practice of nuclear medicine.

(4) A nuclear medicine facility shall ensure that the number of staff at the nuclear medicine facility is kept under review, especially as workload increases, or new techniques or new equipment are incorporated.

Radiation protection programme

4. (1) A nuclear medicine facility shall establish a radiation protection programme for nuclear medicine as part of practice in nuclear medicine and provide the necessary resources for complying with the programme.

(2) A programme referred to under sub-regulation (1) shall —

(a) relate to all phases of the practice of radiation protection, including the design and decommissioning; and

(b) outline the risks involved in all phases of the practice of radiation protection and the manner in which the risks can be reduced.

(3) A nuclear medicine facility shall —

(a) review the radiation protection program annually; and

(b) include the responsibility of the management of the nuclear medicine facility in radiation protection and safety through the management structure, policies, procedure, and organisational arrangements.

PART III

Medical Radiological Equipment

National standards for medical radiological equipment

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.

Act No. 4 of 2017

Act No. 3 of 2017

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

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.

Act No. 4 of 2017
Act No. 3 of 2017

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

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.

Act No. 4 of 2017
Act No. 3 of 2017

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

access, provision of personal protective equipment, provision of individual and area monitoring, provision of equipment monitoring contamination and provision of personal decontamination.

(3) A nuclear medicine facility area that is not classified as a controlled area or supervised area shall be accessible to the public and levels of radiation in that area shall be in compliance with the dose limits for public exposure.

(4) A nuclear medicine facility shall ensure that access to a controlled area or supervised area is restricted to health professionals, nurses and patients.

Rules and procedures for radiopharmaceutical therapy

11. (1) A nuclear medicine facility shall establish rules and procedures which shall contain measures that minimise occupational radiation exposure at the premises where the radioactive materials or radiation emitting devices are kept.

(2) Rules and procedures established under sub -regulation(1) shall include wearing, handling and storing of personal dosimeters and protective clothing, specifying investigation levels and follow up actions, emergency procedures, and any other procedures as determined by the Authority.

Procedures for protective clothing

12. (1) A nuclear medicine facility shall comply with the following procedures for protective clothing at the nuclear medicine facility:

(a) on leaving the controlled area or supervised area, protective clothing that is contaminated shall be placed in a manner as guided by the Authority and an account of the potential contamination shall be documented by the nuclear medicine facility;

(b) the method of removing gloves shall be based on the surgical technique to avoid transferring activity to the hands;

(c) protective clothing, such as laboratory coats, gloves and shoe covers, shall be made available at the entrance to the controlled areas and supervised areas;

(d) the protective clothing shall be monitored for contamination and removed before an occupationally exposed staff leaves a controlled area; and

(e) protective clothing shall be removed before entering a different area that is not designated as a controlled area or supervised area.

(2) Protective clothing shall be provided to a visitor or carer when they enter a controlled area or supervised area of a nuclear medicine facility.

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.

(8) A nuclear medicine facility shall inform the Authority, in writing, regarding measures taken relating to safety contained under this Regulation.

Workplace monitoring mechanisms

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

(a) workplace monitoring of radiation addresses both external exposure and contamination at the nuclear medicine facility;

(b) a controlled area or supervised area in which work with unsealed sources is undertaken, and is monitored on a systematic basis for external radiation and surface contamination;

(c) periodic monitoring with a survey metre and contamination monitor, or wipe tests, is conducted for a controlled area and supervised area;

(d) continuous monitoring with an area monitor is considered for areas for storage and handling of sources at a nuclear medicine facility;

(e) where a package containing radioactive sources is damaged on arrival, a survey of removable contamination and the external radiation field is carried out;

(f) contamination monitors are calibrated in appropriate quantities; and

(g) workplace monitoring with respect to X-ray based imaging systems used in nuclear medicine is in line with guidelines from the Authority.

Individual monitoring mechanism

17. (1) A nuclear medicine facility shall ensure that individual monitoring mechanisms include devices that are calibrated and traceable to a standards dosimetry laboratory.

(2) A personal dosimeter shall be used for monitoring only an occupationally exposed member of staff to whom the personal dosimeter is issued at the nuclear medicine facility.

(3) Sub-regulation (2) does not apply to electronic dosimeters used sequentially by several workers with individual doses recorded separately.

(4) The personal dosimeter referred to in sub regulation (2) shall be used for work performed at that nuclear medicine facility, and shall not be taken to another nuclear medicine facility where an occupationally exposed member of staff may also work.

(5) Despite sub-regulation(4), a nuclear medicine facility shall ensure that—

(a) unnecessary delays in the return, reading and reporting of the recorded dose on dosimeters is avoided;

(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.

Pregnancy and breast feeding staff

20. (1) A nuclear medicine facility shall develop procedures for occupationally exposed pregnant or breast feeding staff.

(2) A nuclear medicine facility shall adapt the working conditions for an occupationally exposed worker referred to under sub regulation (1) in respect of occupational exposure to ensure that the embryo or fetus or the breastfed infant receives the same level of protection as required for a member of the public as provided for in these Regulations.

Record of occupational exposure

21. (1) A licensee shall keep a record of occupational exposure for purposes of assessing the effectiveness of the radiation safety in a nuclear medicine facility.

(2) The national dose registry shall be updated with the dose estimate on an annual basis.

PART V

Radiation Protection of Individual Undergoing Medical Exposure

Referral for medical exposure

22. (1) A health professional may prescribe a medical examination for a person to undergo a medical exposure and that person shall present the prescription to a nuclear medicine facility.

(2) A nuclear medicine facility that receives a prescription from a person to undergo a medical exposure shall treat the prescription from a health professional as a request for a professional consultation or opinion rather than an instruction or order to perform.

(3) A nuclear medicine facility shall, where a nuclear medicine facility decides that a medical exposure shall be undertaken by a person, ensure that the person is informed about the expected benefits, risks, limitations of the proposed medical exposure and consequences of not undergoing the medical exposure.

Identification of person undergoing medical exposure

23. (1) A nuclear medicine facility shall ensure that an effective system for correct identification of a person undergoing medical exposure exists, whether the medical exposure is diagnostic or therapeutic in nature.

(2) A nuclear medicine facility shall ensure that the identification of a person undergoing medical exposure is verified by two members of staff of the nuclear medicine facility.

Optimisation of protection and safety of person undergoing medical exposure

24. A nuclear medicine facility shall ensure that optimisation of protection and safety of a person undergoing medical exposure is guaranteed by ensuring that medical radiological equipment is designed and manufactured to ensure that the doses emitted from the radiological equipment are kept as low as reasonably achievable and consistent with obtaining adequate diagnostic information.

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 radiopharma-ceutical

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.

Exemptions from Part VI

30. For the purposes of this Part, a person undergoing medical exposure does not include patients in the nuclear medicine facility or patients waiting for radiological examination.

PART VI

Radiation Protection for the Public

Members of the public in nuclear medicine facility

31. A person undergoing medical exposure at a nuclear medicine facility shall be treated as a member of the public during the time when the treatment or diagnostic procedure is not taking place.

External exposure and contamination of members of public

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

(a) members of the public are protected from external exposure by providing shielding at a nuclear medicine facility; and

(b) a person that has undergone radiopharmaceuticals and has the potential of exposing members of the public in the nuclear medicine facility is kept in a supervised area.

(2) A nuclear medicine facility shall establish rules to ensure that the external exposure and contamination of any member of the public is within the public dose limit.

Control of access

33. A nuclear medicine facility shall ensure that access to an area where radiation is being used is controlled to ensure doses to visitors are below the dose limits and constraints for the public.

Members of public in wider public domain

34. (1) A nuclear medicine facility shall ensure that the public exposure of other persons, in the wider public domain, by a person who has received radiopharmaceutical therapy is avoided, by not allowing a person undergoing medical exposure to leave the nuclear medicine facility until an acceptable dose limit is reached.

(2) A nuclear medicine facility shall, following the discharge of a radiopharmaceutical therapy patient, establish rules to ensure that the exposure of members of the public is less than the public dose limit.

Patients discharged from nuclear medicine facility

35. (1) A nuclear medicine facility shall ensure that a patient who has received radiopharmaceutical treatment and is discharged from the nuclear medicine facility receives written instructions that include means for avoiding external and internal exposure of the public.

(2) A nuclear medicine facility shall, when deciding on the appropriate discharge activity for a particular patient, take into account the transport and the living conditions of the patient, including the extent to which the patient can be isolated from other family members and the safe management of the patient's excreta and body fluids.

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.

Exemption from Part VI

40. For purposes of this Part, public exposure to radiation does not include exposure to individuals who are not in and around the nuclear medicine facility and carers.

PART VII

General Provisions

Incidents and accidents

41. (1) A nuclear medicine facility shall, in the event of an incident or accident by a person undergoing medical exposure—

(a) investigate the incident or accident and its causes, circumstances and consequences;

(b) take appropriate action to remedy the incident or accident and to prevent a recurrence of a similar situation;

(c) communicate to the Authority the incident or accident, its causes, its circumstances and consequences, and on the corrective or preventive actions taken or to be taken; and

(d) take any other action necessary as required by these Regulations.

(2) A nuclear medicine facility shall, in an event of an incident or accident, notify the Authority within twenty-four hours after an unplanned exposure situation has developed or is developing.

(3) The Authority shall modify, suspend or withdraw any licence that has been granted by the Authority to a nuclear medicine facility if the nuclear medicine facility fails to take corrective or preventive actions within a reasonable time as determined by the Authority.

Security of radioactive materials

42. (1) A nuclear medicine facility shall —

(a) develop procedures for safe receipt and movement of radioactive sources within the facility; and

(b) establish controls to prevent the theft, loss and unauthorised withdrawal of radioactive materials or the entrance of unauthorised personnel to controlled areas.

(2) A nuclear medicine facility shall—

(a) develop an inventory of radioactive materials and that inventory shall be updated whenever the nuclear medicine facility receives a new radioactive material; and

(b) put in place written procedures for checking and confirming if radioactive materials are in their assigned locations and are secure.

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.

(3) A nuclear medicine facility shall ensure that annual audits and reviews are conducted on the programme of quality assurance for medical exposures.

Safety in transport of radioactive materials

48. A nuclear medicine facility shall ensure that the transportation of radioactive materials for the nuclear medicine facility are in line with the relevant regulations on safety and security of transportation of radioactive materials.

General penalty

49. A person who fails to comply with these Regulations commits an offence and is liable, on conviction to a fine not exceeding two thousand five hundred penalty units or to imprisonment for a term not exceeding two years, or to both.

F. MUTATI,
Minister of Technology and Science

LUSAKA
16th January , 2024
[MOTS.64/9/1]