REGULATIONS FOR RADIATION SAFETY IN NUCLEAR MEDICINE

Radiation Protection Act [Chapter 15:15]

REGULATIONS FOR RADIATION SAFETY IN NUCLEAR MEDICINE

ARRANGEMENT OF REGULATIONS

PART I: General

Regulation

PART II: Principal Requirements

PART III: Safety of Sources, Equipment and facilities

22. Acceptance test
23. Commissioning
24. Security of Sources

PART IV: Occupational Exposure

25. Radiation protection requirements, responsibilities and condition of services
26. Classification of area
27. Local rules and supervision
28. Protective equipment and tools
29. Individual monitoring and exposure assessment
30. Pregnant worker
31. Monitoring the work place
32. Investigation levels
33. Health surveillance
34. Records

PART V: Medical Exposure

35. Responsibilities
36. Justification
37. Optimization for medical exposures in nuclear medicine: operational consideration
38. Diagnostic procedures
39. Therapeutic application of radionuclide
40. Breast feeding
41. conception after therapeutic dose
42. calibration of equipment and radiation sources
43. clinical (patient) Dosimetry
44. Quality assurance for medical exposures
45. Guidance levels
46. Dose constraints
47. Maximum activity for patients in therapy on discharge from hospital

PART VI: Public Exposure

PART VII: Potential Exposure and Emergency Plans

PART VIII: Safety in the Transport of Radioactive Materials

PART IX: Offences, Penalties and Appeals

FIRST SCHEDULE: Dose Limits for Occupational and Public Exposure

RADIATION PROTECTION ACT [CHAPTER 15:15]

REGULATIONS FOR RADIATION SAFETY IN NUCLEAR MEDICINE

PART I – GENERAL

Interpretation

1. In these regulations, unless the context otherwise requires-

"absorbed dose" means the fundamental dosimetric quantity D, defined as:

$$D = \frac{d\varepsilon}{dm}$$

Whereas $d\varepsilon$ means the mean energy imparted by ionizing radiation to matter in a volume element and dm is the mass of matter in the volume element. The energy can be averaged over any defined volume, the average dose being equal to the total energy imparted in the volume divided by the mass in the volume. The SI unit of absorbed dose is the joule per kilogram (J/kg), termed the gray (Gy).

"accident" means any un-intended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

"applicant" means any legal person who applies to the Authority for authorization to undertake any of the actions described in the Radiation Protection Safety and Security Regulations .

"approved" means approved by the Authority.

"Authority" means Radiation Protection Authority of Zimbabwe.

"authorization" means permission granted in a document by Authority to a legal person who has submitted an application to

carry out a practice or any other action described in the Act and Radiation Safety and Security Regulations. The authorization can take the form of a registration or a licence.

"authorized" means granted an authorization by Authority.

"controlled area" means any area in which specific protection measures and safety provisions are or could be 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.

"dose constraint" means a prospective and source related restriction on the individual dose delivered by the source which serves as a bound in the optimization of protection and safety of the source. For occupational exposures, dose constraint is a source related value of individual dose used to limit the range of options considered in the process of optimization. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source. The exposure to which the dose constraint applies is the annual dose to any critical group, summed over all exposure pathways, arising from the predicted operation of the controlled source. The dose constraint for each source is intended to ensure that the sum of doses to the critical group from all controlled sources remains within the dose limit. For medical exposure the dose constraint levels should be interpreted as guidance levels, except when used in optimizing the protection of persons exposed for medical research purposes or of persons, other than workers, who assist in the care, support or comfort of exposed patients.

"dose limit" means the value of the effective dose or the equivalent dose to individuals from controlled practices that shall not be exceeded.

"effective dose" means the quantity E, defined as a summation of

the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_T w_T \cdot H_T$$

where H_T is the equivalent dose in tissue T and w_T is the tissue weighting factor for tissue T. From the definition of equivalent dose, it follows that:

$$E = \sum_T w_T \cdot \sum_R w_R D_{T \cdot R}$$

where w_R is the radiation weighting factor for radiation R and $D_{T,R}$ the average absorbed dose in the organ or tissue T. The unit of effective dose is $J.kg^{-1}$, termed the sievert (Sv).

"emergency plan" means a set of procedures to be implemented in the event of an accident.

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

"ethical review committee" means a committee of independent persons to advise on the conditions of exposure and the dose constraints to be applied to the medical exposure of individuals exposed for biomedical research purposes when there is no direct benefit to the exposed individual.

"guidance level for medical exposure" means a value of dose, dose rate or activity selected by professional bodies in consultation with the Authority to indicate a level above which there should be a review by medical practitioners in order to determine whether or not the value is excessive, taking into account the particular circumstances and applying sound clinical judgement.

"health professional" means an individual who has been accredited through appropriate national procedures to practice a profession related to health (e.g., medicine, dentistry, chiropractic, paediatric, nursing, medical physics, radiation and nuclear medical

technology/ radiography, radiopharmacy, occupational health).

"health surveillance" means medical supervision intended to ensure the initial and continuous fitness of workers for their intended task.

"imaging devices" means electronic equipment used for imaging in diagnostic radiology and Nuclear medicine (e.g., image convertors, gamma cameras).

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

"legal person" means any organization, corporation, partnership, firm, association, trust, estate, public or private institution, group, political or administrative entity or other persons designated in accordance with national legislation, who or which has responsibility and authority for any action taken under Radiation Protection Safety and Security Regulations .

"licence" means an authorization granted by the Authority on the basis of a safety assessment and accompanied by specific requirements and conditions to be complied with by the Licensee.

"licensee" means the holder of a current licence granted for a practice or source who has recognized rights and duties for the practice or source, particularly in relation to protection and safety.

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

"member of the public" means in a general sense, any individual in the population except, for the purposes of the Radiation Protection Safety and Security Regulations, when subject to

occupational or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, the representative individual in the relevant critical group.

"monitoring" means the measurement of dose or contamination for reasons related to the assessment or control of exposure to radiation or radioactive substances, and the interpretation of the results.

"normal exposure" means an exposure, which is expected to be received under normal operating conditions of an installation or a source, including possible minor mishaps that can be kept under control.

"Notification" means a document submitted to the Authority by a legal person to notify an intention to carry out a practice or any other action described by the Authority

"occupational exposure" means all exposures of workers incurred in the course of their work with the exception of exposures excluded from the NiBIRR and exposures from practices or sources exempted by NiBIRR.

"potential exposure" means exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

"practice" means any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.

"preparation table" means working plan surface located within the storage room of a design adequate for safe handling of radioactive sources.

"protection and safety" means the protection of people against

exposure to ionizing radiation or radioactive substances and the safety of radiation sources, including the means for achieving such protection and safety, such as the various procedures and devices for keeping peoples' doses and risks as low as can reasonably be achieved and below prescribed dose constraints, as well as the means for preventing accidents and for mitigating the consequences of accidents should they occur.

"protective action" means an intervention intended to avoid or reduce doses to members of the public in chronic or emergency exposure situations.

"public exposure" means exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation but including exposure from authorized sources and practices and from intervention situations.

"qualified expert in nuclear medicine physics (medical physicist)" means an individual who, by virtue of certification by appropriate boards or societies, professional licences or academic qualifications and experience, is duly recognized as having expertise in nuclear medicine physics.

"quality assurance" means all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

"Radiation Safety Officer" means an individual technically competent in safety and radiation protection matters relevant for a given type of practice who is designated by the registrant or licensee to oversee radiation protection.

"radioactive waste" means material, whatever its physical form, remaining from practices or interventions and for which no further use is foreseen (i) that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements, and (ii) exposure to which is not excluded from Radiation Protection

Safety and Security Regulations.

"registrant" means an applicant who is granted registration of a practice or source and has recognized rights and duties for such a practice or source, particularly in relation to protection and safety.

"reference air kerma rate" means the reference air kerma rate of a source is the kerma rate to air, in air, at a reference distance of one metre, corrected for air attenuation and scattering. This quantity is expressed in $mGy.h^{-1}$ at 1 m.

"risk" means a multi-attribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences.

"sealed source" means radioactive material that is (a) permanently sealed in a capsule or (b) closely bounded and in a solid form. The capsule or material of a sealed source shall be strong enough to maintain leak tightness under the conditions of use and wear for which the source was designed, also under foreseeable mishaps.

"safety assessment" means a review of the aspects of design and operation of a source which are relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations.

"safety culture" means the assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

"supervised area" means any area not designated as a controlled area but for which occupational exposure conditions are kept under review even though protective measures and safety provisions are not normally needed.

"unsealed source" means a source that does not meet the definition of a sealed source.

"source" means anything that may cause radiation exposure, such as by emitting ionizing radiation or releasing radioactive substances or materials. For example, materials emitting radon are sources in the environment.

"standards dosimetry laboratory" means a laboratory designated by the relevant national authority for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry.

"" **radiopharmacy laboratory/ Hot Lab** means facility designated for lodging, preparation, control and sterilization of radioactive sources.

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

"worker" means any person who works, whether full time, part time or temporarily, for an employer and who has recognized rights and duties in relation to occupational radiation protection. (A self-employed person is regarded as having the duties of both an employer and a worker.)

"Medical Practitioner" to be defined

Objective

2. The objective of these regulations is to set the minimum requirements for radiation protection in Nuclear Medicine and Radiopharmacy for the attainment of adequate radiation protection and safety of patients, workers and the public.

Scope

3. (1) These regulations are applicable to all established uses of

ionizing radiation sources employed in the practice of nuclear medicine the facilities where the sources are located and to the individuals involved.

(2) These regulations cover occupational, public, medical, potential and emergency exposure situations.

PART II-PRINCIPAL REQUIREMENTS

Administrative requirements: Authorization of practices

4 (1) Any legal person who intends to utilize radiation sources in nuclear medicine shall notify his intention to the Authority and shall apply for authorization.

(2) The legal person applying for an authorization shall submit to the Authority the relevant information necessary to demonstrate the safety of the practice including a radiation manual.

(3) The legal person applying for an authorization shall refrain from carrying out any of the actions of the practice until authorization has been granted.

(4) The legal person responsible shall include in the application for authorization:

(a) the qualifications in radiation safety and protection of the medical practitioners who are to be so designated by name in the licence; or

(b) a statement that only medical practitioners with the qualifications in radiation safety and protection specified in these regulations or to be specified in the licence will be permitted to prescribe medical exposure by means of the authorized radiation source.

(5). The licensee shall comply with radiation safety

requirements for the following stages of the nuclear medicine practice:

) (a) design and construction;

) (b) operation (acceptance, commissioning, clinical use, research, maintenance);

) (c) modifications; and

) (d) decommissioning (partial or total) and return or disposal of sources.

(6). Modification with possible implications for radiation safety of the nuclear medicine facilities of the type and activity of radioactive sources and of procedures or cessation of the practice shall require an amendment to the licence.

Renewal of authorization

5 (1).The authorization shall be renewed On an annual basis.

(2). Application for authorization shall be made on a prescribed form of the Authority.

Personal accreditation

6 (1).All personnel on whom protection and safety depends shall be appropriately trained and qualified so as to understand their responsibilities and perform their duties with appropriate judgement in accordance with the laid down procedures.

(2). Individuals with sole responsibilities for protection and safety and those who could substantially affect protection and safety by virtue of tasks involving manipulation of sources or operation of equipment shall have documented evidence of educational qualification and training in nuclear medicine, these individuals include:

(a) medical practitioners working with radionuclides (e.g. nuclear medicine physicians and other appropriately trained clinical specialists);

(

(d)

(e) staff performing special tasks (e.g. type testing of equipment, quality control tests).

(3). To obtain personal accreditation, the staff listed in these regulations shall meet the following requirements, as applicable:

(a) university degree or academic qualification relevant to the profession, issued by accredited institutions;

(b) accreditation to practice the profession granted by the relevant competent authorities or other professional or academic bodies recognized by the Authority;

(c) attendance at and passing of required examinations on a course on radiation safety for which the contents, the methodology and the teaching institution are accredited by the Authority or by other professional bodies recognized by the Authority;

(d) The course shall be integrated in the curricula of the professional education under these regulations; and

(e) on-the-job training supervised by professionals with accreditation by the Authority or other appropriate competent authorities

(4). In addition to the staff needing formal credentials, the following staff shall be provided with specific instructions on radiation safety and protection:

(a) nurses attending patients under therapy;

(b)staff who do not belong to the nuclear medicine practice but

need to enter controlled areas; and

(c) staff who transport radioactive materials within the institution.

(6). Equipment servicing personnel shall have documentary evidence for the individual to perform maintenance of nuclear medicine equipment.

(7) The documentary evidence shall consist of the following:

(a)certification, ideally by the manufacturer, of having completed a training programme on the type of authorized equipment;

(b) course on radiation safety for which the contents, the methodology, and the teaching institution are approved by the Authority

Authorization of other activities related to nuclear medicine

7. The activities listed below also require authorization in relation to nuclear medicine practice;

(a)import, export, distribution, sale, decommissioning or transfer of radiation emitting sources and equipment;

(b) personnel monitoring;

(c)installation and maintenance of nuclear medicine equipment.

Inspection

8. The licensee shall permit the Authority to inspect his facilities and records as required by Section 18 of the Act.

Non-compliance and suspension or withdrawal of authorization

9 (1) In the event of a breach of any licence condition as per Paragraph **4**, the licensee shall, as appropriate:

(a) investigate the breach and its causes, circumstances and consequences;

(b) take appropriate action to remedy the circumstances that led to the breach and to prevent a recurrence of similar breaches;

(c) communicate immediately to the Authority, or to any relevant organizations where applicable, on the causes of the breach and on the corrective or preventive actions taken or to be taken; and

(d) take whatever necessary actions as required by the Authority.

(2) Failure to take corrective or preventive actions within a specified time shall be grounds for modifying, suspending or withdrawing any authorization that had been granted by the Authority.

(3). The Authority shall suspend or revoke an authorization when a licensee is in serious breach of the conditions of the authorization, Radiation Protection Safety and Security Regulations or specific requirements of these regulations.

(4). In case of suspension or revocation, the licensee shall reapply for authorization or apply for reconsideration of decision in order to resume operation after having satisfactorily implemented corrective measures.

Radiation safety and protection requirements

10. The radiation safety and protection requirements on justification of the practice, dose limitation and optimization of

protection and dose constraints of the Act and Radiation Protection Safety and Security Regulations shall be applied in nuclear medicine. The dose limits for occupational and public exposure are reproduced in the first Schedule.

Managerial requirements: Managerial commitment and policy statement

11. (1) A safety culture shall be fostered and maintained to encourage a questioning and learning attitude to protection and safety and to discourage complacency.

(2) The employer shall be committed to an effective protection and safety policy, particularly at management level and by clear demonstrable support for those persons with direct responsibility for radiation safety and protection.

(3) The commitment shall be expressed in a written policy statement that clearly assigns prime importance to protection and safety in the nuclear medicine services, while recognizing that the prime objective is the medical care of the patients.

(4) Appropriate resources shall be made available to support the commitment stated in sub-paragraph (3) above.

(5) The written policy statement shall be followed by establishing a Radiation Safety Programme which includes a quality assurance programme and by fostering a safety culture within the organization.

Organization and responsibilities

12 (1) The principal parties having the main responsibilities for the application of the Radiation Protection Safety and Security Regulations and these regulations shall be:Licensees; and Employers.

(2) The following parties shall have subsidiary responsibilities.

These parties include: suppliers,;; medical practitioners; other (non-medical) health professionals; qualified experts; ethical review committees; and any other party to whom a principal party has delegated specific responsibilities.

(3). The registrant and licensee shall establish a radiation protection programme and shall provide the necessary resources to comply with the programme.

(4) The programme shall relate to all phases of the practice, from design through operation to decommissioning.

(5) The radiation safety and protection and Quality Assurance programme shall reflect the management responsibility for radiation protection and safety through the adoption of management structures, policies, procedures and organizational arrangements that are commensurate with the nature and extent of the risks.

(6). The registrant and licensee shall assign clear responsibilities for personnel (e.g. medical practitioner, nuclear medicine physicist, nuclear medicine radiographer/technologist, and other health professionals) to ensure adequate radiation protection of patients, workers, and the public.

(7) The need for qualified experts shall be determined, their responsibilities defined and suitable persons appointed on a full-time or part-time basis as required.

(8). The registrant and licensee shall appoint a Radiation Safety Officer.

(9)The Radiation Safety Officer shall have sufficient authority and management standing to communicate with and direct personnel regarding the regulations and licence provisions

(10). A Radiation Safety Committee shall be formed that is appropriate to the size of institution and complexity of procedures.

(11) The Radiation Safety Committee shall review and audit the entire Radiation Safety Program systematically to determine whether the activities are conducted in a safe manner and in accordance with the regulations and terms of the authorization.

(12) The Committee shall meet at least once a year.

Quality Assurance

13 (1). The licensee shall establish a comprehensive Quality Assurance programme for radiation protection, safety and image quality to ensure that all necessary procedures are developed and implemented to comply with the regulations for radiation safety within the terms and conditions of the authorization(s) of the facility.

(2) The Quality Assurance programme is an integral part of the Radiation Safety Program, it shall involve a review and assessment of the overall effectiveness of the protection and safety measures.

(3) The programme shall cover the entire process from the initial decision to adopt a particular procedure through the interpretation and recording of results and shall include

ongoing auditing(both internal and external) as a systematic control methodology.

(4) Quality assurance shall cover the following:

(a) selection of the correct procedure for the patient;

(b) appointment and patient information;

(c) clinical dosimetry;

(d) optimization of examination protocol;

(e) record keeping and report writing;

(f) quality control of radiopharmaceuticals and radionuclide

generators;

(g)acceptance and commissioning;

(h)quality control of equipment and software;

(i) waste management procedures;

(j) training and continuing education of staff;

(k)clinical audit; and

(l) general outcome of nuclear medicine service.

(m) Decontamination procedures

Human factors

14. The registrant and licensee shall make provision for reducing as far as practicable the contribution of human error to accidents and other events that could give rise to exposures.

Staffing

15. (1) The registrant and licensee shall appoint a number of professionals, each possessing a recognized form of accreditation as in these regulations, sufficient to ensure that all activities relevant to Quality Assurance, radiation protection and safety are undertaken in accordance with all relevant regulations.

(2) Resource requirements shall be reviewed as workload increases or as new techniques and new equipment are incorporated into the facility.

Education and training

16 (1) All staff working in nuclear medicine practice, as listed in these regulations shall have appropriate academic qualifications and relevant practical training and induction.

(2)The registrant and licensee shall ensure that staff are aware of:

(a) the conditions of the licence;

(b) safe use and operation of equipment;

(c) instructions that shall be provided to patients and patient helpers;

(d) institutional radiation safety policies and procedures (including practice drills);

(e) the local Quality Assurance programme and Quality Control procedures;

(f) the results of review and analysis of incidents and accidents that have occurred in the institution or elsewhere.

(3) This training and induction shall be completed before commencement of duties and be updated periodically.

(4) Instruction of personnel shall be required whenever significant changes occur in duties, regulations, the terms of the authorization or radiation safety procedures.

(5) The registrant and licensee shall establish a policy that encourages and provides continuing education and a programme of professional development.

(6). The registrant and licensee shall prepare and keep records of the initial and periodic training of personnel and the records shall be kept for at least five years after the expiry of the corresponding authorization.

PART III-SAFETY OF SOURCES, EQUIPMENT AND FACILITIES

Defence in Depth

17. A multilayer (defence in depth) system for protection and safety commensurate with the magnitude and likelihood of the

potential exposures involved shall be applied to sources such that a failure at one layer is compensated for or corrected by subsequent layers, for the purposes of:

(a) preventing accidents that may cause exposure;

(b) mitigating the consequences of any such accident that does occur; and

(c) restoring sources to safe conditions after any such accident.

Design

18 (1) According to requirements for the safety of sources used in nuclear medicine, equipment used in medical exposure shall be so designed that:

(a) failure of a single component of the system be promptly detectable so that any unplanned exposure of patients or staff be minimized; and

(b) the incidence of human error in the delivery of unplanned medical exposure be minimized.

(2) Registrants and licensees shall:

) (a) take into account information provided by suppliers, identify possible equipment failures and human errors that could result in unplanned medical exposures;

) (b) take all reasonable measures to prevent failures and errors, including the selection of suitably qualified personnel, the establishment of adequate procedures for the calibration, Quality Assurance and operation of equipment, the provision of appropriate training and periodic retraining to personnel in the procedures, including protection and safety aspects;

) (c) take all reasonable measures to minimize the consequences of failures and errors that may occur

Radiopharmaceuticals

19 (1) Radiopharmaceuticals shall be manufactured according to good manufacturing practice and shall comply with Radiation Protection Safety and Security Regulations and other relevant international standards for:

) (a) radionuclide purity;

) (b) specific activity;

) (c) radiochemical purity;

) (d) chemical purity;

) (e) pharmaceutical aspects: toxicity, sterility and pyrogenicity.

(2) The registrant and licensee shall store, handle and use materials in a safe manner in accordance with manufacturer's instructions and the Authority's requirements.

(3) The registrant and licensee shall provide appropriate equipment to contain, store and dispense unsealed sources, having due regard to radiation safety and limitation of contamination.

(4) The equipment includes, where appropriate, shielded containers, bench top shields, remote handling tools, syringe shields and protective clothing.

Facilities and ancillary equipment

20 (1). The design of the facility shall take into consideration the classification of the areas within it (Part IV), the type of work to be done and the radionuclides (and their activity) intended to be used.

(2). A safety assessment shall be performed in order to determine the special needs concerning ventilation, plumbing,

and materials used in walls, floors and workbenches.

(3). The floors of controlled areas shall be finished in an impermeable material, which is washable and resistant to chemical change.

(4). Areas where radioactive substances are handled, such as the source preparation area, shall have:

(a) means to prevent access by unauthorized persons;

(b) adequate storage space for equipment used in the laboratory to be kept at all times and minimize the potential for spreading contamination to other areas;

(c) contained workstation for easy decontamination;

(d) shielded storage for radioactive substances;

(e) shielded temporary storage for solid radioactive waste and places designated for the disposal of liquid radioactive waste, directly connected to the main sewer;

(f) shielding to protect the worker where significant external exposure may occur;

(g) a wash-up area for contaminated articles such as glassware;

(h) an entry area where protective clothing can be put on, taken off and kept when not in use and where washing and contamination monitoring can be done.

(5). A source storage area and an area for temporary storage of radioactive waste shall be provided with appropriate protection.

(6). When designing the facility, the licensee shall consider access control when determining source storage areas and rooms for hospitalised patients undergoing radionuclide therapy

(7). The facility shall be designed in such a way that provisions for safety systems or devices are inherent to the equipment or the room in order to lower the probability of occurrence of accidental

radiation exposure

(8). A radiation (ISO 361) sign and a danger warning sign in English and local language shall be posted to indicate that a room is a controlled area.

(9). The shielding shall be designed using the principles of optimisation of protection.

(10). As established in these regulations relevant equipment shall be purchased from authorized suppliers.

(11). Written methods shall be developed with the involvement of the responsible staff (e.g. the medical physicist) or the Radiation Protection Officer, for purchasing, installation, acceptance, commissioning, use, maintenance and quality control.

(12). Equipment used in nuclear medicine that influence outcome of diagnosis and therapy shall meet the relevant IEC standards and any other national equivalent standards (e.g.SAZ), such equipment include:

(a) activity meters

(b) generators for nuclides

(c) gamma cameras

(13). A nuclear medicine practice shall have a radionuclide activity calibrator and equipment for contamination and workplace monitoring.

(14). The calibration of these instruments shall be traceable to a certified standards laboratory, and shall be maintained by a regular quality control programme.

(15). Activity meters used to measure the amount of activity of a radiopharmaceutical to be administered to the patient, both for a diagnostic test and for therapeutic purposes, shall be designed so

as to exhibit the performance required for that purpose, and that the effect of background radiation on the instruments be minimized.

(16). The licensee shall participate in a regular intercomparison programme for dosimetry.

(17). Equipment for continuous monitoring of external exposure shall be considered in rooms assigned for preparation of radiopharmaceuticals.

(18). The manufacturer's operating manual shall be available in English.

(19). Fume hoods and laminar flow cabinets shall be installed for use, as appropriate, for volatile radioactive substances.

(20). The exhaust of the fume hood and laminar flow shall not exceed the regulatory limit of release.

Maintenance

21 (1). The licensee shall ensure that adequate maintenance (preventive and corrective) and inspection are performed as necessary to ensure that equipment used in nuclear medicine retains its design specifications for image quality, radiation protection and safety for its useful life.

(2). The licensee shall therefore establish the necessary arrangements and co-ordination with the manufacturer's representative before purchase and initial operation.

(3). All maintenance procedures shall be included in the Quality Assurance programme at a frequency recommended by the manufacturer of the equipment and the relevant professional body.

(4). Servicing shall include a report describing the findings, which shall be archived as part of the Quality Assurance

programme.

(5). A nuclear medicine physicist shall ensure that the equipment is in safe condition for clinical use.

(6). The electrical and mechanical safety of the nuclear medicine equipment is an important part of the maintenance programme.

(7). This work shall be authorized by the facility management and performed by persons who are qualified to work on the equipment.

Acceptance test

22 (1). After equipment installation, acceptance testing shall be conducted in order to verify that the equipment conforms to technical specifications given by the manufacturer and to verify compliance with safety requirements from IEC standards and equivalent standards of the Standards Association of Zimbabwe.

(2). As indicated in these regulations, the tests to be included in the acceptance protocol shall be specified in the purchasing conditions and contracts and shall clearly establish responsibility of suppliers for resolving non-conformity identified during acceptance testing.

Commissioning

23. (1). After acceptance and before starting operation, commissioning shall be performed.

(2). The qualified expert in nuclear medicine physics shall measure all data required for clinical use during commissioning.

Security of sources

24 (1). Sources shall be kept secure so as to prevent theft or

damage and to prevent any unauthorized use by ensuring that:

(a) control of a source is not relinquished without compliance with all relevant requirements specified in the licence and without immediate communication to the Authority, of information regarding any decontrolled, lost, stolen or missing source;

(b) a source is not transferred unless the receiver possesses a valid authorization; and

(c) a periodic inventory of movable sources is conducted at appropriate intervals to confirm that they are in their assigned locations and are secured.

(2). The objective of source security is to ensure continuity in the control and accountability of each source at all times.

(3). Specific provisions are required for avoiding loss of control in the following situations:

(a) Storage of sources not in use;

(b) Temporary or permanent cessation of use;

(c) Storage after decommissioning whilst awaiting decision on source return or disposal;

(4). The registrant and licensee shall maintain an inventory of sources received by the practice and develop procedures to ensure the safe movement of radioactive sources within the institution at all times from receipt to disposal.

(5). The registrant and licensee shall establish security systems to prevent theft, loss, unauthorized use, or damage to sources, or entrance of unauthorized personnel to the controlled areas.

PART IV- OCCUPATIONAL EXPOSURE

Radiation safety and protection requirements, responsibilities and conditions of service

25 (1). Workers shall:

(a) follow any applicable rules and procedures for protection and safety specified by the employer or licensee;

(b) use properly the monitoring devices and the protective equipment and clothing provided;

(c) co-operate with the employer or licensee with respect to protection and safety and the operation of radiological health surveillance and dose assessment programmes;

(d) provide to the employer or licensee such information on their past and current work as is relevant to ensure effective and comprehensive protection and safety for themselves and others;

(e) abstain from any wilful action that could put themselves or others in situations that contravene the requirements of the Radiation Protection legislation;

(f) accept such information, instruction and training concerning protection and safety as will enable them to conduct their work in accordance with the requirements of the Radiation Protection legislation.

(2). If for any reason a worker is able to identify circumstances that could adversely affect compliance with the Radiation Protection legislation, the workers shall as soon as feasible report such circumstances to the employer or licensee.

(3). The management shall record any report received from a worker that identifies circumstances which could affect compliance with the Radiation Protection legislation, and shall take appropriate action.

(4). If workers are engaged in work that involves or could involve a source that is not under the control of their employer, the registrant or licensee responsible for the source and the employer shall co-operate by the exchange of information and otherwise as necessary to facilitate proper protective measures and safety provisions.

Classification of areas

26 (1). Areas in a nuclear medicine department shall be classified as *controlled* or *supervised*.

(2). The rooms for preparation, storage and injection of the radiopharmaceuticals shall be controlled areas.

(3). The area housing a patient to whom therapeutic amounts of activity have been given shall also be a controlled area.

(4). The room for temporary storage of radioactive waste shall be a controlled area.

(5). The imaging rooms, (gamma camera room) and waiting areas shall also be supervised areas due to the potential risk of contamination.

(6). Each room of the facility shall only be used for its specified work.

Local rules and supervision

27 (1). Employers, registrants and licensees and radiation safety committee shall in consultation with workers, through their representatives, where appropriate:

(a) establish written local rules and procedures necessary to ensure adequate levels of protection and safety for workers and other persons;

(b) include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event that any such value is exceeded;

(c) make the local rules and procedures, the protective measures and safety provisions known to those workers to whom they apply and to other persons who may be affected by them; and

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

(2). For practices performing positron emission tomography studies, the local rules shall ensure that:

(a) when handling radionuclides in the cyclotron room and in the radiopharmacy, the dose to the operator is minimized;

(b),appropriate shielding should be used, because of the high energy (511KeV) of the annihilation radiation in positron emission tomography energy;

(c) the reduction of exposure of staff is achieved by reducing the time of exposure and increasing the distance from the source.

Protective equipment and tools

28 (1). Registrants and Licensees shall ensure that workers are provided with suitable and adequate personal protective equipment.

(2). Protective equipment includes but is not limited to:

(a) movable shields, bench top shields and shields for syringes and vials to be used when handling unsealed sources;

(b) protective clothing, gloves and tools for handling of

sources to be used during the work with unsealed sources; and

(c) fume hoods and laminar flow cabinets, shielded containers for temporary segregation and storage of radioactive waste.

(3). Containers utilized for the transfer and transport of radioactive sources outside the institution shall conform with the applicable national transport regulations and with the technical requirements established in the International Atomic Energy Agency's Regulations for the Safe Transport of Radioactive Material (TS-R-1), as amended from time to time .

Individual monitoring and exposure assessment

29 (1). Individual dose monitoring shall be undertaken for workers who are normally exposed to radiation in controlled areas through authorized Dosimetry service providers.

(2). The workers who shall be monitored include nuclear medicine physicians, nuclear medicine physicists, nuclear medicine radiographers/ technologists, nuclear medicine nurses and radiopharmacists.

(3). The users of radioisotope sources, such as clinical specialists, research staff and ancillary workers who frequently work in controlled areas, shall also be individually monitored.

(4). Individual external doses shall be determined by using individual monitoring devices approved by the Authority, such as thermo-luminescent dosimeters, film badges or other devices.

(5). The individual monitoring device shall be typically worn on the front of the upper torso.

(6). When there is a possibility of high exposure to the hands, such as in the preparation and administration of radiopharmaceuticals, extremity dosimeters such as ring and

finger dosimetersshall also be worn (7). The exchange of dosimeters and receipt of the dose reports shall be within an interval of one month.

(8). If an individual's dosimeter is lost, the Radiation Safety Officer shall perform and document an evaluation of the dose the individual received and add it to the worker's dose record.

(9). Individual monitoring devices shall be calibrated and this calibration shall be traceable to a standards dosimetry laboratory.

(10). In nuclear medicine, the exposure due to internal contamination shall be monitored. The monitoring shall be done by external monitoring of the thyroid for individuals handling large activities of radioiodine.

11

Pregnant Worker

30 (1). A female worker shall notify the licensee if she is pregnant as soon as she knows of her condition, or if she is breast feeding, so that radiation protection requirements for foetus and baby can be met with respectively.

(2). The notification of pregnancy shall not be considered a reason to exclude a female worker from work.

(3). The employer of a female worker who has notified pregnancy shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or foetus is afforded the same broad level of protection as required for members of the public.

Monitoring the workplace

31 (1). Registrants and licensees shall develop programmes for

monitoring the workplace in consultation with workers and the radiation safety committee.

(3). If a package containing radioactive sources is damaged upon arrival, a survey of removable contamination and external radiation field shall be carried out.

(4). Periodic monitoring with a survey meter and contamination monitor or by wipe tests shall be conducted for controlled and supervised areas.

(5). Continuous monitoring with an area monitor shall be considered for source storage and handling areas.

(6). Laboratories and other areas in which work with unsealed sources is undertaken shall be monitored, both for external radiation and for surface contamination, on a systematic basis.

(7). Contamination monitoring shall be required as follows:-

(a) all working surfaces (including the interior of enclosures), tools, equipment, the floor and any items removed from this area.

(b) monitoring shall also be required during maintenance of contained workstations, ventilation systems and drains.

(c) protective and personal clothing, shoes, particularly when leaving an area that is controlled due to the risk of contamination (monitors should be available near the exit);

(d) clothing and bedding for therapy patients.

(8). All radiation monitors including all survey meters used for workplace monitoring shall be calibrated and this calibration shall be traceable to a standards dosimetry laboratory.

(9). The radiation monitors operability and those of their warning devices shall be checked prior to each day of use.

Investigation levels

(32) (1). Employers, registrants and licensees and radiation safety committee shall in consultation with workers or through their representatives, include in the local rules and procedures the values of any relevant investigation level or authorized level, and the procedure to be followed in the event that any such value is exceeded.

(2). The registrant and licensee and radiation safety committee shall conduct formal investigations as required by the Authority where:

(a) an individual effective dose exceeds investigation levels;

(b) any of the operational parameters related to protection or safety are out of the normal range established for operational conditions;

(c) any equipment failure, severe accident or error occurs that causes, or has the potential to cause, a dose in excess of the limits established by the Authority; and

(d) any other event or unusual circumstance occurs that causes, or has the potential to cause, a dose in excess of the limits established by the Authority or the operational restrictions imposed on the installation i.e the significant change in workload or operating conditions of nuclear medicine equipment.

(3). The investigation shall be initiated immediately following the event and a report written concerning its cause, including determination or verification of any doses received, corrective actions, and instructions or recommendations to avoid recurrence.

(4). The report shall be submitted to the Authority and other concerned bodies as required within seven days after the investigation or as otherwise specified and kept for a specified

period.

Health surveillance

33 (1). The registrant and licensee shall make arrangements to provide health surveillance in accordance with the provisions of the Radiation Protection Safety and Security Regulations to assess the initial and continuing fitness of employees for their intended tasks.

(2). Health surveillance programmes shall be based on the general principles of occupational health.

(3). Counselling shall be available to workers such as women who are or may be pregnant, individual workers who have or may have been exposed substantially in excess of dose limits and workers who may be worried about their radiation exposure.

Records

34 (1) .The licensee shall maintain exposure and medical surveillance records for each worker and the records shall be kept according to the requirements of the Authority.

(2). Employers and licensees shall provide for access and make available to workers information on their own exposure records and give due care and attention to the maintenance of appropriate confidentiality of records.

PART V-MEDICAL EXPOSURE

Responsibilities

35 (1). With regard to responsibilities for medical exposure, registrants and licensees shall ensure that :

(a) no patient is administered a therapeutic medical exposure

unless the exposure is prescribed by a medical practitioner;nuclear medicine physician, radiation oncologist and any other authorised and licenced medical specialist

(b)no diagnostic procedure shall be carried out without a written request form

(c) medical practitioners are assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;

(d)medical and paramedical personnel are available as needed, and are either health professionals or have appropriate training to discharge their assigned tasks in the conduct of the diagnostic or therapeutic procedure that the medical practitioner prescribes;

(e) for therapeutic use of radiation, the calibration, dosimetry and quality assurance requirements are conducted by or under the supervision of a qualified expert in nuclear medicine physics;

(f) the exposure of individuals incurred knowingly while voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment be constrained and

(g)training criteria are specified or subject to approval, as appropriate, by the Authority in consultation with relevant professional bodies.

(2). Licensees shall ensure that for diagnostic uses of radiation, the imaging and Quality Assurance requirements are fulfilled with the advice of a qualified expert in nuclear medicine physics.

(3). Medical practitioners shall promptly inform the registrant or licensee of any deficiencies or needs regarding compliance with the national regulations concerning protection and safety of

patients and shall take such actions as may be appropriate to ensure the protection and safety of patients.

(4). The registrant and licensee shall ensure that workers (medical practitioner, medical physicist, technologist/radiographers) :

(a) follow any applicable rules and procedures for the protection and safety of patients, as established by the licensee;

(b) are competent in the operation and use of the equipment and sources employed in nuclear medicine, of the equipment for radiation detection and measurement, and of the safety systems and devices, commensurate with the significance of the workers' functions and responsibilities; and

(c) know their expected response in the case of patient emergencies.

Justification

36 (1). Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure, such as ultrasound or magnetic resonance imaging.

(2). In justifying each type of diagnostic nuclear medicine examination, relevant guidelines shall be taken into account, such as those established by the World Health Organization.

(3). Any nuclear medicine examination for occupational, legal or health insurance purposes undertaken without reference to clinical indications is deemed to be unjustified 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.

(4). Mass screening of population groups involving medical exposure is deemed to be unjustified 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.

(5). Account shall be taken in justification of the potential of the screening procedure for detecting disease, the likelihood of effective treatment of cases detected and, for certain diseases, the advantages to the community from the control of the disease.

(6). The exposure of humans for medical research is deemed to be unjustified unless it is:

(a) in accordance with the provisions of the Helsinki Declaration and follows the guidelines for its application prepared by Council for International Organizations of Medical Sciences and the World Health Organization

(b) subject to the advice of an ethical review committee or any other institutional body assigned similar functions by the Minister of Health and to applicable Radiation Protection Safety and Security Regulations and these regulations

(7). Children are at greater risk of incurring stochastic effects, as such paediatric examinations require special consideration in the justification process.

(8). The benefit of some high dose examinations shall be carefully weighed against the increased risk.

(9). The justification of examinations in pregnant women requires special consideration.

(10). In order to avoid any substantial risk, the licensee shall

ascertain whether the female patient is pregnant before considering use of a radionuclide for diagnosis or for therapy.

(11). The advice of a medical physics expert shall be required and a foetal dose and nominal foetal and patient risks estimation performed before deciding whether the examination shall be undertaken.

(12). A pregnant woman shall not be administered a radioactive source unless the application is life-saving.

(13). The therapeutic application shall be deferred until after the pregnancy and after any period of breast feeding.

Optimization for medical exposures in nuclear medicine:

Operational considerations

37 (1).Licensees shall ensure that medical practitioners who prescribe or conduct diagnostic applications of radionuclides ensures that:

(a)the exposure of patients is the minimum required to achieve the intended diagnostic objective;

(b) they take into account relevant information from previous examinations in order to avoid unnecessary additional examinations; and

(c)they take into account the relevant guidance levels for medical exposure.

(2). the medical practitioner, the technologist/radiographer or other imaging staff, as appropriate, endeavour to achieve the minimum patient exposure consistent with acceptable image quality criteria by:

(a) appropriate selection of the best available radiopharmaceutical and its activity, noting the special requirements for children and for patients with impairment of

organ function;

(b) use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable; and

(c) appropriate image acquisition and processing.

(3). administration of radionuclides for diagnostic or therapeutic procedures to women who are pregnant or likely to be pregnant is avoided unless there are strong clinical indications;

(4). for lactating mothers, discontinuation of nursing is recommended until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable effective dose to the infant;

(5). administration of radionuclides to children for diagnostic procedures is carried out only if there is strong clinical indication, and the amount of activity administered is reduced according to body weight, body surface area or other appropriate criteria.

(6). The licensee shall inform the patient, as appropriate, of possible risks associated with the procedure.

(7). Equipment shall be operated within the limits and conditions established in the technical specifications and in the licence requirements, ensuring that it will operate satisfactorily at all times, in terms of both the tasks to be accomplished and radiation safety.

(8). The manufacturer's operating manual, and the institutions procedural manual shall be followed strictly for equipment operation.

(9). The licensee shall provide written as well as verbal instructions to patients who have received radionuclide therapy on actions to take to limit exposure to comforters, caregivers and members of the public when leaving the hospital.

(10). The instructions shall include minimizing prolonged contact with the spouse, other family members, minors and potentially pregnant women.

(11) written consent shall be obtained prio to any medical exposure

(12) every administered dose shall be recorded

Diagnostic procedures

38 (1). An effective system shall be established for correct identification of patients.

(2). Each diagnostic procedure shall follow a written protocol, designed to maximize the clinical information to be obtained from the study, taking into consideration the appropriate guidance level for the procedure.

(3). The recording of patient details shall be correct.

(4). The data acquisition conditions shall be chosen such that the image quality is optimum.

(5). The choice of collimator, energy window, matrix size, acquisition time, angulation of collimator, Single Photon Emission Computed Tomography or Positron Emission Tomography parameters, and zoom factor shall be such as to obtain optimum quality image.

(6). For dynamic studies, the number of frames, time interval and other parameters shall be chosen to obtain optimum quality of image sequence.

(7). Care shall be taken to ensure that there is no contamination on the collimator surface or elsewhere as this may impair the quality of the result.

Therapeutic application of radionuclides

39 (1). An effective system shall be established for correct

identification of patients.

(2). Verbal and written instructions on safety shall be provided to the patient to minimize exposure to family members and the public.

(3). Special attention shall be given to prevent spread of contamination due to patient vomit and excreta.

(4). National regulations on release of patients after administration of therapeutic doses of radiopharmaceuticals shall be absolutely followed.

Breast feeding

40 (1). The licensee shall ascertain whether the female patient is breast feeding.

(2). Adequate period of cessation of breastfeeding shall be recommended after nuclear medicine procedures warranting it.

Conception after therapeutic dose

41 Following treatment with a therapeutic radionuclide, a female patient shall be advised (and it shall be recorded) to avoid pregnancy for an appropriate period.

Calibration of equipment and radiation sources

42 The registrant and licensee shall ensure that:

(a) the calibration of radionuclide activity calibrators and other equipment and sources utilized for the practice of nuclear medicine is traceable to a standards dosimetry laboratory;

(b)radionuclides for nuclear medicine procedures are calibrated in terms of activity of the radiopharmaceutical to be administered;

(c) records of calibration measurements and associated calculations are maintained in accordance with the requirements of the Authority;

(d) the calibration of the instruments is maintained by a regular quality control programme. The licensee shall participate in a regular intercomparison programme.

Clinical (patient) Dosimetry

43 Licensees shall ensure that :

(a) the activity to be administered is determined and recorded at the time of administration;

(b) for diagnostic procedures, representative absorbed doses to the organs and the effective dose to the patient are determined and documented for the amount of activity normally administered according to their standard clinical protocol; and

(c) for therapeutic treatments, absorbed doses to relevant organs shall be evaluated.

(d) individual dose calculations for therapeutic procedures shall be performed with the advice of a qualified expert and each therapeutic dose shall be recorded.

Quality assurance for medical exposures

44 (1). As established in these regulations, the licensee shall establish a comprehensive Quality Assurance programme for medical exposures with the participation of appropriate qualified experts in the relevant fields, such as nuclear medicine physics and radio-pharmacy, taking into account the principles established by the World Health Organisation and the Pan-American Health Organization.

(2). Quality Assurance programmes for medical exposures shall include:

(a) measurements of the physical parameters of the imaging devices at the time of commissioning and periodically thereafter;

(b) verification of the appropriate physical factors (e.g. activity, radiopharmaceutical) used in patient diagnosis or treatment;

(c) review of the procedures, taking into account the clinical factors that may influence the results;

(d) written records of relevant procedures and results;

(e) verification of the appropriate calibration and conditions of operation of radionuclide activity calibrator; and

(f) verification of the quality of the prepared radiopharmaceutical.

Guidance levels

45 Licensees shall ensure that guidance levels for medical exposure are determined as specified in the Radiation Protection Safety and Security Regulations revised as technology improves and used as guidance by medical practitioners, in order that:

(a) corrective actions can be taken as necessary if doses or activities fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients;

(b) reviews can be considered if activities exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice; and

(c) the guidance levels can be derived from the data from wide scale quality surveys which include activities of

radiopharmaceuticals administered to patients for the most frequent examinations in nuclear medicine.

Dose constraints

46 (1). An ethical review committee of any other institutional body assigned similar functions by the Ministry of Health shall specify dose constraints to be applied on a case-by-case basis in the optimisation of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual.

(2). Licensees shall constrain any dose incurred knowingly by those voluntarily helping (other than in their occupation) in the care, support or comfort of patients undergoing medical diagnosis or treatment, and to visitors to patients who have received therapeutic amounts of radionuclides, to a level not exceeding that specified in the second Schedule in Radiation Protection Safety and Security Regulations.

Maximum activity for patients in therapy on discharge from hospital

47 (1). In order to restrict the exposure of members of the public and in particular, members of the household of a patient who has undergone a therapeutic procedure with unsealed radionuclides, such a patient shall not be discharged from hospital before the activity of radioactive substances in the body falls below the recommended guidance levels.

(2). Written and spoken instructions to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided as necessary.

(3). Patients under bone pain palliation therapies shall be discharged based on local rules, which take into account the

external exposure rate, the risk of contamination and the patient's condition.

(4). Special consideration shall be given to the case of incontinent patients.

Investigation of accidental medical exposure in nuclear medicine

48 (1). Licensees shall promptly investigate:

(a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong radiopharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;

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

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

(2). Licensees shall with regard to any investigation made under these regulations;

(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 the corrective measures that are under their own responsibility;

(d) submit to the Authority, as soon as possible after the investigation or as otherwise specified by the Authority, a

written report which states the cause of the incident and includes the information specified in sub paragraphs (a) to (c) as relevant and any other information required by the Authority;

(e) inform the patient and his or her doctor about the incident.

Medical Records

49 Registrants and licensees shall keep medical records for a period of 5 years and make available, as required, types of radiopharmaceuticals administered to patients and their activities and exposure of volunteers in medical research.

PART VI- PUBLIC EXPOSURE

Responsibilities

50 (1). The registrant and licensee shall be responsible for controlling public exposure resulting from a nuclear medicine practice.

(2). In order to control public exposures, the registrant and licensee shall be responsible, with respect to the sources under their responsibility, for the establishment, implementation and maintenance of:

(a) protection and safety policies, procedures and organizational arrangements for the usage, transport, storage and disposal of nuclear medicine sources to ensure their safety and security in accordance with the requirements of the Authority;

(b) measures for ensuring the optimisation of the protection of members of the public;

(c) measures for ensuring the safety of such sources, in order that the likelihood of public exposures are controlled;

(d) appropriate protection and safety training to the personnel having functions relevant to the protection of the public, as well as periodic retraining and updating as required, in order to ensure the necessary level of competence;

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

(f) adequate records of the surveillance and monitoring as required by the Authority;

(g) emergency plans and procedures, commensurate with the nature and magnitude of the risk involved, and activate such plans and procedures in accordance with the requirements of the Authority.

(3). Registrants and licensees shall:

(a) develop and implement use, storage and transport measures for ensuring the safety and security of radiopharmaceuticals to control public exposures in accordance with the requirements of the Authority; and

(b) control and maintain constant surveillance of radioactive sources that are not in storage (e.g., when nuclear medicine sources are being transported or used for treatment) and secure stored radioactive sources from unauthorized access, removal, or use (e.g., the storage facility shall be locked at all times).

(4). Registrants and licensees shall be responsible for ensuring that the optimisation process for measures to control the discharge of radioactive substances from a source to the environment is subject to dose constraints established or approved by the Authority.

Control of access of visitors

51. Registrants and licensees shall:

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

(b) provide adequate information and instruction to visitors before they enter a controlled area so as to ensure appropriate protection of the visitors and of other individuals who could be affected by their actions;

(c) make arrangements to control access of visitors to patients undergoing radionuclide therapy and provide adequate information and instruction to these visitors before they enter the patient´s room so as to ensure appropriate protection; and

(d) ensure that adequate control over entry of visitors to a supervised area is maintained and that appropriate signs are posted in such areas.

Radioactive contamination

52. Registrants and licensees shall ensure that for sources for which they are responsible, measures optimised in accordance with the requirements of the Authority are taken, as appropriate, for restricting public exposure to contamination in areas accessible to the public.

Radioactive waste

53 The registrant and the licensee shall:

(a) develop and implement a programme for safe disposal of radioactive waste or return of sources when their use is discontinued, as required by the Authority;

(b) ensure that the activity and volume of any radioactive waste resulting from the sources for which they are

responsible are kept to the minimum practicable, and that the waste is managed in accordance with the requirements of the Act

(c) ensure that the discharge of radioactive wastes to the public waste treatment system and to the sewage system is within the limits specified by the Authority and

(d)maintain responsibility for all other radioactive sources until provisions have been made to transfer the radioactive sources to an appropriate licensee or to an authorized waste disposal facility at the end of use.

Monitoring of public exposure

54 The registrant and licensee shall, as appropriate:

(a) establish and carry out a monitoring programme sufficient to ensure that the requirements of the Authority regarding public exposure to radioactive sources are satisfied and to assess such exposure;

(b)establish and carry out a monitoring programme sufficient to ensure that the requirements that the Authority for discharges of radioactive substances to the environment are satisfied; and

©keep appropriate records of the results of the monitoring programmes.

PART VII- POTENTIAL EXPOSURE AND EMERGENCY PLANS

Safety assessment

55(1). The registrant and licensee shall conduct a safety assessment applied to all stages of the design and operation of the nuclear medicine facility, and present the report to the Authority if required.

(2). The safety assessment shall include, as appropriate, a

systematic critical review of identification of possible events leading to accidental exposure.

(3). The safety assessment shall be documented and, if appropriate, independently reviewed by an expert, within the Quality Assurance programme. Additional reviews shall be performed as necessary whenever:

(a) safety may be compromised as a result of modifications of the facilities or of the procedures;

(b) operational experience or information on accidents or errors indicates that a review is necessary or

(c) any significant changes to relevant guidelines or standards are envisaged or have been made

Prevention of accidents and mitigation of their consequences

56 (1). The Registrant and licensee shall incorporate within the Radiation Protection Programme:

(a) defence in depth measures to cope with identified events, and an evaluation of the reliability of the safety systems (including administrative and operational procedures, and equipment and facility design);

(b) operational experience and lessons learned from accidents and errors.

(c) this information shall be incorporated into the training, maintenance and Quality Assurance programmes;

(2). The registrant and licensee shall promptly inform the Authority of all reportable events, and make suitable arrangements to limit the consequences of any accident or incident that does occur.

Emergency plans

57 (1). On the basis of events identified by the safety assessment, the registrant and licensee shall prepare emergency procedures.

(2). The procedures shall be clear, concise and unambiguous and shall be posted visibly in places where their need is anticipated.

(3). An emergency plan shall as a minimum list or describe:

(a) predictable incidents and accidents and measures to deal with them;

(b) the persons responsible for taking actions, with full contact details;

(c)the responsibilities of individual personnel in emergency procedures (nuclear medicine physicians, medical physicists, nuclear medicine technologists/radiographers, etc.);

(d) equipment and tools necessary to carry out the emergency procedures;

(e)training and periodic rehearsal;

(f) recording and reporting system;

(g) immediate measures to avoid unnecessary radiation doses to patients, staff and public;

(h) measures to prevent access of persons to the affected area; and

(i) measures to prevent spread of contamination.

PART VIII- SAFETY IN THE TRANSPORT OF RADIOACTIVE MATERIALS

Safe Transport Of Radioactive Materials

58. The licensee shall comply with the requirements of the International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material, TS-R-1 for all activities

involving transport of radioactive sources as amended from time to time.

Receipt of radioactive materials

59 (1). Prior to each shipment of radioactive material to be dispatched, the licensee or the legal person responsible for the transport shall make the necessary arrangements with the source supplier, to receive and forward the relevant information to the Authority.

(2) the supplier should have a licence to export

(2). This information shall include the following for each package or container:

(a) the nuclide, number and activity of sources.

(b) a description of the source construction and performance tests, including leakage tests.

(c) special form approval certificate (where appropriate).

(d) a description of the package.

(e) approval certificate for Type A or B packages, or statement of compliance with International Atomic Energy Agency TS-R–1 for other packages.

(f) Details of any special arrangements required, including multilateral approvals, where necessary.

(g) A copy of the transport documents (to be sent to the licensee by fax or e-mail before dispatch if possible).

(3). The licensee shall not agree to the dispatch of the consignment by the supplier unless all the above items under these regulations are complied with.

(4). The supplier and licensee should agree the transport route and responsibility for each stage of the journey.

(5). Arrangements shall also be made for the following where necessary:

(a) the need for special handling equipment during transfer from one mode of transport to another, or between vehicles.

(b) checking of radiation dose rates from the package or container.

(c) checking the correct transport labels are attached to the package or container, and replacing those that are damaged or illegible.

(d) ensuring that the package or container is securely attached to the vehicle and that the vehicle is correctly labelled.

(e) dealing with border controls.

(f) security of the consignment during transport, particularly during delays or overnight stops.

Dispatch of radioactive materials

60 The licensee shall return packages or containers to the source supplier after receipt of a consignment of radioactive source. ??

Empty packages

61. With regard to returning empty packages the licensee shall:

(a) Carry out dose rate and contamination monitoring of both the inside and outside of the package or container to ensure that there is no residual radioactive material present and it can therefore be treated as an empty package or container.

(b) Remove or cover all transport labels relating to the sources contained in the package or container when received.

(c) Examine the package or container to ensure that it is in good condition, and then close it securely, referring to any procedures provided by the source supplier.

(d) Attach a label to the outside of the package or container stating "UN 2908 RADIOACTIVE MATERIAL EXCEPTED PACKAGE — EMPTY PACKAGING".

(e) Complete a transport document.

(f) Contact the source supplier and agree on the transport route and responsibility for each stage of the journey, inform the source supplier of the proposed date of dispatch.

Return of disused sources

62 (1). With regard to returning disused sources, the licensee shall apply for an export licence from the Authority and provide the following information to the consignee for each package or container:

(a) the nuclide, number and activity of sources.

(b) a description of the source construction including leakage tests.

(c) special form approval certificate (where appropriate).

(d) a description of the packaging in which the source is to be transported.

(e) approval certificate for Type B package, or statement of compliance with International Atomic Energy Agency TS-R–1 for other packages (as appropriate).

(f) details of any special arrangements required, including multilateral approvals, where necessary.

(g) A copy of the transport documents (to be sent to the consignee by fax or e-mail before dispatch, if possible).

(2). The licensee shall not dispatch the consignment unless they have received confirmation from the consignee that they are prepared to accept it.

(3). The licensee and consignee shall agree on the transport route (as needed) and responsibility for each stage of the journey.

(4). The Licensee will normally be responsible from dispatch until the consignment reaches the consignee's premises.

(5). All other arrangements are satisfactory, provided an agreement is reached in advance by both parties and are also acceptable to the Authority and other regulatory authorities involved.

(6). In order to prepare the consignment for dispatch the licensee shall:

(a) Load the sources into the package, verifying the details to be provided to the consignee e.g., serial numbers and comparable information to be entered on the transport document.

(b) Close it securely and then examine the package or container to ensure that it is in good condition, referring to any procedures provided by the source supplier.

(c) Carry out contamination monitoring of the outside of the package or container to ensure that there is no residual radioactive material present and it is therefore suitable for transport.

(d) Carry out dose rate monitoring of the package or container

and attach appropriate transport labels.

(e) Refrain from using the transport labels relating to the sources contained in the package or container when received.

(f) Complete a transport document.

(7). Arrangements shall also be made for the following where necessary:

(a) Specify the need for special handling equipment during transfer from one mode of transport to another, or between vehicles.

(b) Ensure that the package is securely attached to the vehicle and that the vehicle is correctly labelled.

(c) Deal with border controls.

Provide security of the consignment during transport, particularly during delays.

PART IX- OFFENCES, PENALTIES AND APPEALS

Offences and Penalties

63 (1). Any person who contravenes any of the provisions of these regulations committed an offence

(2). Any one who commits an offence under these regulations shall be liable to the penalties as established in the enforcement policy issued by the Authority

(3). The Authority shall impose penalties such as suspension or revocation of authorization, imposing administrative fine or closure of facility or any combination of these

(4). Any person or corporate body who being a holder of authorisation under these regulations commits an offence shall be liable to prosecution in the court of law and upon conviction be liable to pay fines not exceeding level ten or be given a jail term

of not exceeding ten years or both

Appeals

64 Any person may appeal to the Board of the Authority against a decision made against him pursuant to these regulations.

SCHEDULES

FIRST SCHEDULE

DOSE LIMITS FOR OCCUPATIONAL AND PUBLIC EXPOSURE

OCCUPATIONAL EXPOSURE

Dose limits

1. The occupational exposure of any worker shall be so controlled that the following limits be not exceeded:

(a) an effective dose of 20 mSv per year averaged over five consecutive years

(b) an effective dose of 50 mSv in any single year;

(c) an equivalent dose to the lens of the eye of 150 mSv in a year; and

(d) an equivalent dose to the extremities (hands and feet) or the skin of 500 mSv in a year.

2. For apprentices of 16 to 18 years of age who are training for employment involving exposure to radiation and for students of age 16 to 18 who are required to use sources in the course of their studies, the occupational exposure shall be so controlled that the following limits be not exceeded:

(a) an effective dose of 6 mSv in a year;

(b) an equivalent dose to the lens of the eye of 50 mSv in a year; and

(c) an equivalent dose to the extremities or the skin of 150 mSv in a year.

Special circumstances

3. When in special circumstances, a temporary change in the dose limitation requirements is approved pursuant to Radiation Protection Safety and Security Regulations:

(a) the dose averaging period mentioned in paragraph. (I.1)(a) may exceptionally be up to 10 consecutive years as specified by the Authority, and the effective dose for any worker shall not exceed 20 mSv per year averaged over this period and shall not exceed 50 mSv in any single year, and the circumstances shall be reviewed when the dose accumulated by any worker since the start of the extended averaging period reaches 100 mSv; or

(b) the temporary change in the dose limitation shall be as specified by the Regulatory Authority but shall not exceed 50 mSv in any year and the period of the temporary change shall not exceed 5 years.

PUBLIC EXPOSURE

Dose limits

4. The estimated average doses to the relevant critical groups of members of the public that are attributable to practices shall not exceed

the following limits:

(a) an effective dose of 1 mSv in a year;

(b) in special circumstances, an effective dose of up to 5 mSv in a single year provided that the average dose over five consecutive years does not exceed 1 mSv per year;

(c) an equivalent dose to the lens of the eye of 15 mSv in a year; and

(d) an equivalent dose to the skin of 50 mSv in a year.

Dose limitation for comforters and visitors of patients

5. The dose limits set out in this part shall not apply to comforters of patients, i.e., to individuals knowingly exposed while voluntarily helping (other than in their employment or occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment, or to visitors of such patients.

6. The dose of any such comforter or visitor of patients shall be constrained so that it is unlikely that his or her dose will exceed 5 mSv during the period of a patient's diagnostic examination or treatment.

7. The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1 mSv.

EXPLANATORY NOTE

(This note does not form part of the Regulations but it is intended to explain its purport)

1. These set of regulations are practice-specific elaborations of the Radiation Protection Safety and Security Regulations which is derived from, but not a substitute to, the International Basic Safety Standards for

Protection against Ionizing Radiation Sources (the BSS) published as International Atomic Energy Agency Safety Series No 115 in 1996.

2. Radiation safety in nuclear medicine (which throughout this document will be taken to mean all clinical applications of radionuclides) is based upon a number of underlying principles:

(a) all clinical applications of radionuclides shall be justified.

(b) the benefit to the patient in terms of confirmation of diagnosis, exclusion of an alternative diagnosis and effective treatment exceeds the risk in each case.

(c) for diagnostic procedures, the exposure of patients must be the minimum necessary to achieve the diagnostic objective, taking into account norms of acceptable image quality.

(d) for therapeutic procedures, the exposure of normal tissue shall be kept as low as reasonably achievable consistent with delivering the required dose to the treatment volume.

(e) the protection of the public shall be optimised