Radiation Protection Authority

Zambia

SAFETY GUIDE

RPA SG 9

Nuclear Medicine

2023

NOTICE OF APPROVAL

Under the terms of Part II of the Ionising Radiation Protection Act No. 16 of 2005 and Part V of the Statutory Instrument No.98 of 2011, the Radiation Protection Authority (RPA) is authorized to establish or adopt standards of safety for protection of health and minimization of risk to life and the environment, and to provide for the application of these standards.

The Radiation Protection Authority Board (RPAB), has on the19th December 2023, approved the safety guide on Nuclear Medicine.

This guide is approved for the purposes of providing practical guidance with respect to the Ionizing Radiation Protection (General) Regulations SI No. 98 of 2011.

This guide comes into effect on 19th December 2023

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Table of Content

LIST OF ABBREVIATIONS

Abbreviation	Definition
CPOE	Computerized physician order entry
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DRL	Diagnostic Reference Level
DT	Absorbed dose
HPCZ	Health Profession Council of Zambia
HT	Dose Equivalent
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
IT	Information technology
PACS	Picture Archiving and Communications System
PET	Positron Emission Tomography
RIS	Radiology Information System
RPA	Radiation Protection Authority
RPAB	Radiation Protection Authority Board
RPO	Radiation Protection Officer
SG	Safety Guide
SPECT	Single photon emission computed tomography
TI	Dose to Body Tissue
WR	Radiation weighting factor

FOREWORD

Radiation Protection Authority (RPA) was established by the Ionising Radiation Protection Act No. 16 of 2005. It is a national regulatory body which implements the policies of the Zambian government relating to the protection of the public, workers and the environment from harmful effects of ionising radiation.

This guidance is intended for both regulators and users of radiation sources in nuclear medicine. Regulators may use it for reviewing applications for authorization and during the inspection of facilities. Licensees should follow the guidance in order to comply with requirements of the regulations in Nuclear Medicine.

Preparation of the Guideline was carried out in line with National and International Standards

PREFACE

Radiation Protection Authority (RPA) was established by the Ionising Radiation Protection Act No. 16 of 2005.The structure of the implementation of the protection and safety was established to be compatible with the International Basic Safety Standards.

The structure was commensurate with the number and density and complexity of application and anticipated introduction of practices and sources within practices. The essential element of the structured approach consisted of the following hierarchy:

- **Legislation** which established the Radiation Protection Authority and its powers and functions;
- **Radiation Safety Regulations** which provides the standards for radiation safety, including waste management and transportation.
- **Radiation Protection and Safety Guides** which provides guidance for regulators, registrants and licensees and all stakeholders to comply with the regulation as required by the Ionising Radiation (General) Regulations, statutory instrument No. 98 of 2011.

1.0 INTRODUCTION

1.1 General

Ionising radiation was discovered more than 100 years ago, its beneficial uses were quickly realized in medicine. Over the years new diagnostic and therapeutic techniques have evolved and the general level of health care has improved. In Zambia, radiation exposure in medical applications mainly arises from the use of radioactive sources and/or devices such as those used in nuclear medicine, radiotherapy and radiology.

Radiation exposure to patients, staff members, general public and the environment in Nuclear Medicine practice may occur during the handling of radioisotopes used for Diagnostic, therapeutic and research procedures.

However, stochastic, or deterministic effects may result from such exposure as well as the failure to safely use ionising radiation. Therefore, there is need for a comprehensive legal and operational framework for the control of the widespread use of ionizing radiation and radiation sources leading to radiation exposures while allowing their benefits.

This Safety Guide is applicable to all the established uses of ionizing radiation sources employed in the practice of nuclear medicine, to the facilities where the sources are located and used, and to the individuals involved. The Safety Guide covers occupational, public, medical, and potential and emergency exposure situations.

This Safety Guide can also be used to set an appropriate Radiation Protection Programme for Nuclear Medicine in accordance with the requirements of the Act.

1.2 Objective

The objective of this Safety Guide is to provide guidance on the proper and consistent application of requirements in Nuclear Medicine, by legal persons responsible for the Nuclear Medicine practice.

2.0 RADIATION PROTECTION AND MANAGEMENT

2.1 Design

2.1.1 The facility should ensure that:

2.1.1.1 Provisions for the incorporation of radiation protection and safety features are made at the facility design stage. For facilities already established, this should be done at a point of re-designing or repurposing.

2.1.1.2 The design should make provision for safety systems or devices associated with the equipment and rooms. This includes electrical wiring relating to emergency off switches, safety interlocks and warning signs and signals

2.1.1.3 The design of the facility should include an air conditioning system sufficient to maintain the temperature in the examination and imaging rooms within the parameters (for imaging rooms as defined by the equipment manufacturers).

2.1.1.4 For PET scanners, water cooling is considered.

2.1.1.5 The design of the facility should include:

a. optimization of protection and safety against external radiation and contamination
b. maintaining of low radiation background levels to avoid interference with imaging equipment
c. meeting requirements for radiopharmaceuticals and ensuring safety and security of sources (locking and control of access).

2.1.1.6 provisions for secure and shielded storage for radioactive sources are included.

2.1.1.7 Facility design personnel and engineers should be consulted about floor-loading requirements, with account taken of factors such as radiation shielding, imaging and ancillary equipment.

2.1.1.8 For external exposure, the three factors relevant to dose reduction (time, distance and shielding) should be combined in the design to optimize occupational radiation protection and public radiation protection

2.1.1.9 For internal exposure, the principles of control, containment, and radiation protection by means of barriers should be in the design, to optimize occupational radiation protection and public radiation protection.

2.1.1.10 The design includes provisions for secure and shielded storage for radioactive sources.

2.1.1.11 The design of safe and appropriate accommodation for caregivers and comforters, (should there be need such as in pediatric cases) should be considered for nuclear medicine facilities with radiopharmaceutical therapy patients.

2.1.1.12 The possibility for competitive airflow should be considered in the design.

2.1.1.13 Floors and other surfaces of rooms designated for patients undergoing radiopharmaceutical therapy should be covered with smooth, continuous and non-absorbent materials that can be easily cleaned and decontaminated.

2.1.1.14 Shielding should be designed using appropriate dose constraints for workers and the public.

2.2 Siting and layout

2.1.1 The facility should ensure that:

2.2.1.1 The siting and layout consider the workload and patient flow, both within the facility and, in cases where the licensee is part of a larger hospital or medical Centre, within other departments of the facility.

2.2.1.2 Consideration is given to providing easy exit routes for patients, after the examination or treatment has been performed, that minimize movement through the facility.

2.2.1.3 A stable power supply is available for the facility with uninterruptible power supply or battery backup systems installed to capture the active information at the time of the outage and to shut down all software in a controlled manner

2.2.1.4 Servers be programmed to shut down automatically when the power supply is interrupted.

2.2.1.5 Shielding is appropriate for the type and energy of the emitted radiation and/or occupancy of the areas.

2.2.1.6 Storage is provided in a room or a separate space outside the work area or in a locked cupboard, safe, refrigerator or freezer situated in the work area.

2.2.1.7 Separate storage compartments for radiopharmaceuticals and an area for temporary storage of radioactive waste is provided, with appropriate protective barriers.

2.2.1.8 Special consideration is given to avoiding interference with work in adjoining areas, such as imaging or counting procedures, or where fogging of films stored nearby can occur.

2.2.1.9 Bathrooms designated for use by nuclear medicine patients be finished in materials that can be easily decontaminated.

2.2.1.10 Staff, care givers and public do not use the toilets and bathrooms for radioactive patients.

2.2.1.11 Areas where radioactive materials are handled should have but not limited to:

a. Means to prevent access by unauthorized persons.
b. Adequate storage space for equipment used in the given room or area to be always available to minimize the potential for spreading contamination to other areas.
c. A contained workstation for easy decontamination;
d. Shielded storage for radioactive sources.
e. Shielded temporary storage for both solid and liquid radioactive waste,
f. Shielded places designated for the authorized discharge of liquid radioactive effluent.

g. Shielding to protect workers where significant external exposure might occur;
h. A wash-up area for contaminated articles, such as glassware;
i. an entry area where protective clothing can be stored, put on and taken off, and which is provided with a hand washing sink and a contamination monitor;
j. Taps and soap dispenser that are preferably operable without direct hand contact and disposable towels or a hot air dryer
k. An emergency eyewash, installed near the hand washing sink;
l. An emergency shower for decontamination of persons.

2.2.1.12 Radio pharmacies, laboratories, and other work areas for manipulation of unsealed radioactive materials are provided with equipment kept specifically for this purpose, which should include:

a. Tools for maximizing the distance from the source, for example tongs and forceps;
b. Syringe shields;
c. Containers for radioactive materials, with shielding as close as possible to the source;
d. Double walled containers (with an unbreakable outer wall) for liquid samples
e. Drip trays for minimizing the spread of contamination in the case of spillage.
f. Disposable tip automatic pipettes (alternatively, hypodermic syringes to replace pipettes);
g. Lead walls or bricks for shielding;
h. Lead barriers with lead glass windows;
i. Barriers incorporating a low atomic number material (i.e., acrylic) for work with beta emitters;
j. Radiation and contamination monitoring equipment (surface and air).
k. Shielded carrying containers, wheeled, if necessary, for moving radioactive materials from place to place;
l. Equipment to deal with spills (decontamination kits).

2.2.1.13 Drainpipes from sinks in a radio pharmacy or laboratory go as directly as possible to the main building sewer and not connect with other drains within the building unless those other drains also carry radioactive material.

2.2.1.14 The final plans of the drainage system, is supplied to maintenance personnel.

2.2.1.15 The floors of areas with the potential for contamination be finished in an impermeable material that is washable and resistant to chemical change, curved to the walls, with all joints sealed and glued to the floor.

2.2.1.16 The walls finished in a smooth and washable surface.

2.2.1.17 The surfaces of the room where unsealed radioactive materials are used or stored, such as benches, tables, seats, and door and drawer handles, are smooth and non-absorbent,

2.2.1.18 Supplies (e.g., gas, electricity and vacuum equipment) are not mounted on bench tops, but on walls or stands.

2.2.1.19 The floor and benches, including worktops, are strong enough to support the weight of any necessary shielding materials or of radionuclide generators.

2.2.1.20 Radiopharmacies or laboratories in which radioactive aerosols or gases are produced or handled should have an appropriate ventilation system that includes a fume hood, laminar airflow cabinet or glove box.

2.2.1.21 The fume hood should be constructed of material that is smooth, impervious, washable, and resistant to chemicals, and exhibit a negative flow rate.

2.2.1.22 The work surface should have a raised lip to contain any spills.

2.2.1.23 The ventilation system is designed such that the radiopharmacy or laboratory is at negative pressure relative to surrounding areas and be adequate to the radioisotopes used.

2.2.1.24 The airflow is from areas of minimal likelihood of airborne contamination to areas where such contamination is likely.

2.2.1.25 Room air from a radiopharmacy or radiochemistry laboratory be vented through a filtration system or other mechanism for trapping airborne radioactive materials and should not be recirculated, neither directly, in combination with incoming fresh air in a mixing system, nor indirectly, because of proximity of the exhaust to a fresh air intake.

2.2.1.26 Bins for the temporary storage of linen and waste contaminated with radioactive materials should be in secure areas.

2.2.1.27 Storage areas are clearly marked, using the basic ionizing radiation symbol recommended by ISO.

2.2.1.28 Rooms designated for patients undergoing radiopharmaceutical therapy have separate toilets and washing facilities.

2.2.1.29 A sign requesting patients to flush the toilet at least twice and to wash their hands be displayed to ensure adequate dilution of excreted radioactive materials and to minimize contamination.

2.2.1.30 There is a hand washing sink for normal hygiene measure.

2.2.1.31 A typical nuclear medicine facility using unsealed sources should have the following areas but not limited to:

a. source storage and preparation (radio pharmacy, radioisotope Laboratory or 'hot lab'),
b. radiopharmaceutical administration to patients (diagnostic),
c. uptake rooms,
d. imaging (in vivo),
e. sample measurement (in vitro),
f. waiting areas (hot and cold),
g. changing areas and toilets (hot and cold),
h. radioactive waste storage and predisposal processing.
i. a dedicated ward for patients undergoing radionuclide therapy

2.2.1.32 have areas where radioactive materials are not expected to be found, such as in offices, reporting areas and staff rooms, including cloakrooms, showers and toilets for staff.

2.3 Mobile facilities

2.3.1 The Facility should ensure that:

2.3.1.1 PET–CT scanners which are mounted on a truck and mobile meet the same requirements guided by the Authority fixed facilities

2.4 Areas where unsealed radioactive materials are handled

2.4.1 The facility should ensure that:

2.4.1.1 Radiopharmacies or laboratories where unsealed radioactive materials are handled, such as the source preparation areas have the following:

a. Means to prevent access by unauthorized persons;
b. Adequate storage space for equipment used in the given room or area to be
c. available at all times to minimize the potential for spreading contamination
d. to other areas;
e. contained workstation for easy decontamination;
f. Shielded storage for radioactive sources;
g. Shielded temporary storage for both solid and liquid radioactive waste, and
h. places designated for the authorized discharge of liquid radioactive effluent;
i. Shielding to protect workers where significant external exposure might
j. occur;
k. A wash-up area for contaminated articles, such as glassware;
l. An entry area where protective clothing can be stored, put on and taken
m. off, and which is provided with a hand washing sink and a contamination
n. monitor;
o. Taps and soap dispenser that are operable without direct hand contact and

p. disposable towels or a hot air dryer;
q. An emergency eyewash, installed near the hand washing sink;
r. An emergency shower for decontamination of persons.

2.4.1.2 Radiopharmacies, laboratories and other work areas for manipulation of unsealed radioactive materials, be provided with equipment kept specifically, for this purpose and include the following:

a. Tools for maximizing the distance from the source, for example tongs and
b. forceps;
c. Syringe shields;
d. Containers for radioactive materials, with shielding as close as possible to the source;
e. Double walled containers (with an unbreakable outer wall) for liquid samples;
f. Drip trays for minimizing the spread of contamination in the case of
g. spillage;
h. Disposable tip automatic pipettes (alternatively, hypodermic syringes to
i. replace pipettes);
j. Lead walls or bricks for shielding;
k. Lead barriers with lead glass windows;
l. Barriers incorporating a low atomic number material (i.e. acrylic) for work
m. with beta emitters;
n. Radiation and contamination monitoring equipment (surface and air);
o. Shielded carrying containers, wheeled if necessary, for moving radioactive
p. materials from place to place;
q. Equipment to deal with spills (decontamination kits).

2.4.1.3 Drainpipes from sinks in a radiopharmacy or laboratory go as directly as possible to the main building sewer and should not connect with other drains within the building, unless those other drains also carry

radioactive material. to minimize the possibility of the drainage system 'backing up' and contaminating other, non-controlled, areas.

2.4.1.4 The final plans of the drainage system, which should be supplied to maintenance personnel, should clearly identify the drains from radiopharmacies and laboratories. Pipelines throughwhich radioactive materials flow should be marked to ensure that monitoring precedes any maintenance.

2.4.1.5 The drainpipes from a nuclear medicine facility and especially from radionuclide therapy wards may terminate in a delay tank.

2.4.1.6 The floors of areas with the potential for contamination should be finished in an impermeable material that is washable and resistant to chemical change, curved to the walls, with all joints sealed and glued to the floor.

2.4.1.7 The walls should be finished in a smooth and washable surface, for example painted with washable, non-porous paint. The surfaces of the room where unsealed radioactive materials are used or stored, such as benches, tables, seats, and door and drawer handles, should be smooth and non-absorbent, so that they can be cleaned and decontaminated easily.

2.4.1.8 Supplies (e.g. gas, electricity and vacuum equipment) should not be mounted on bench tops, but on walls or stands.

2.4.1.9 The floor and benches, including worktops, should be strong enough to support the weight of any necessary shielding materials or of radionuclide generators.

2.4.1.10 The need for lifting equipment for radionuclide generators should be assessed.

2.4.1.11 Radiopharmacies or laboratories in which radioactive aerosols or gases are produced or handled should have an appropriate ventilation system that includes a fume hood, laminar airflow cabinet or glove box. The fume hood should be constructed of material that is smooth,

impervious, washable and resistant to chemicals, and it should exhibit a negative flow rate.

2.4.1.12 The work surface should have a slightly raised lip to contain any spills.

2.4.1.13 The ventilation system should be designed such that the radiopharmacy or laboratory is at negative pressure relative to surrounding areas and should be adequate to the radioisotopes used.

2.4.1.14 The airflow should be from areas of minimal likelihood of airborne contamination to areas where such contamination is likely.

2.4.1.15 Room air from a radiopharmacy or radiochemistry laboratory should be vented through a filtration system or other mechanism for trapping airborne radioactive materials and should not be recirculated, neither directly, in combination with incoming fresh air in a mixing system, nor indirectly, as a result of proximity of the exhaust to a fresh air intake.

2.4.1.16 The possibility for competitive airflow should be considered in the design. For reasons of asepsis, some radiopharmacies may need a positive rather than a negative pressure. In this case, the pressure gradient can be obtained by locating other workstations requiring negative pressure next to the radiopharmacy workstation.

2.5 Treatment rooms and wards

2.5.1 The facility should ensure that:

2.5.1.1 Floors and other surfaces of rooms designated for patients undergoing radiopharmaceutical therapy should be covered with smooth, continuous and non-absorbent materials that can be easily cleaned a decontaminated.

2.5.1.2 Shielding should be designed using appropriate dose constraints for workers and the public.

2.5.1.3 Bins for the temporary storage of linen and waste contaminated with radioactive materials should be located in secure areas.

2.5.1.4 Storage areas should be clearly marked, using the basic ionizing radiation symbol recommended by ISO.

2.5.1.5 Rooms designated for patients undergoing radiopharmaceutical therapy should have separate toilets and washing facilities.

2.5.1.6 A sign requesting patients to flush the toilet at least twice and to wash their hands should be displayed to ensure adequate dilution of excreted radioactive materials and to minimize contamination.

2.5.1.7 The facilities should include a hand washing sink as a normal hygiene measure.

2.6 Shielding calculations

2.6.1 The facility should ensure that:

2.6.1.1 The shielding be designed to meet the requirements for the optimization of protection and safety and take into consideration:

a. The classification of the areas within the facility,
b. The types of work to be done
c. The radionuclides (and their activity) intended to be used.

2.6.1.2 The Shielding consider both structural and ancillary protective barriers at the design stage.

2.6.1.3 The need for wall, floor and ceiling shielding be assessed, for example in the design of therapy facilities and of PET–CT facilities, to reduce occupational and public exposure to acceptable levels.

2.6.1.4 wall shielding may be needed in the design of rooms housing sensitive instruments (to keep a low background), such as well counters, probes, and imaging equipment (gamma cameras and PET scanners).

2.6.1.5 In wall shielding, consideration be given to the height of the wall to ensure that scatter radiation, such as from a CT scanner, does not pass over the wall into the area being protected.

2.6.1.6 The nominal design doses are achieved. The nominal design dose in an occupied area is derived by the process of constrained optimization (i.e. selection of a source related dose constraint), with the condition that each individual dose from all relevant sources is

well below the dose limit for a person occupying the area to be shielded.

2.6.1.7 Potential changes in practice and increases in workload is considered

2.6.1.8 Care be taken to avoid multiplication of conservative assumptions, which can lead to unrealistic overestimates of the shielding required.

2.6.1.9 Specification of shielding, including calculations, be performed by a medical physicist or a qualified expert in radiation protection.

2.6.1.10 The shielding plan is submitted to the regulatory body for review or approval prior to any construction.

2.6.1.11 The adequacy of the shielding is verified, preferably during construction, and certainly before the facility, room or area comes into clinical use as guided by the Authority.

2.7 Design of display and interpretation (reading) rooms

2.7.1 The facility should ensure that:

2.7.1.1 images are displayed in rooms specifically designed for such purposes.

2.7.1.2 There is a low level of ambient light in the viewing room

2.7.1.3 Viewing rooms with workstations for viewing digital images be ergonomically designed to facilitate image processing and manipulation so that reporting can be performed accurately.

2.7.1.4 The viewing monitors of the workstations meet applicable National and international standards.

2.7.1.5 The nuclear medicine physicians should be registered with HPCZ.

2.8 Radiopharmaceuticals

2.8.1 The facility should ensure that:

2.8.1.1 Radiopharmaceuticals are manufactured according to good manufacturing practice following relevant international standards for:

a. Radionuclide purity;
b. Specific activity;
c. Radiochemical purity;

d. Chemical purity;
e. Pharmaceutical aspects, such as toxicity, sterility and pyrogenicity

2.9 Nuclear medicine equipment and software

2.9.1 The facility should ensure that:

2.9.1.1 The accompanying equipment complies with IEC and ISO standards

2.9.1.2 The accompanying documents be translated into English.

2.9.1.3 The software be designed so that it can be easily converted into English, resulting in displays, symbols and instructions that will be understood by the staff.

2.9.1.4 The translations be subject to a quality assurance process to ensure proper understanding and to avoid operating errors.

2.10 Design features for medical radiological equipment

2.10.1 The facility should ensure that the following design features are considered:

2.10.1.1 The performance of probes, gamma cameras (planar and SPECT systems) and PET scanners.

2.10.1.2 Design features for probes used for uptake measurements including;

a. energy response
b. energy resolution
c. sensitivity
d. counting precision,
e. linearity of count rate response and geometrical dependence.

2.10.1.3 Design features for probes used intra-operatively including:

a. energy resolution
b. background count rate
c. sensitivity in scatter
d. sensitivity to scatter radiation,
e. shielding (side and back)
f. counting precision

g. linearity of count rate response (with scatter radiation), and count rate recorded by visual display and by an audible sound, the intensity of which is proportional to the count rate.

2.10.1.4 Design features that should be considered for gamma cameras (planar and SPECT systems) as well as their accessories include:

a. Detector features:
   i. Pulse height analysis
   ii. Uniformity
   iii. Spatial resolution and linearity
   iv. Energy resolution
   v. Sensitivity
   vi. Count rate performance
   vii. Detector head shielding leakage.
b. Detector head motion.
c. Automatic patient–detector distance sensing.
d. Collision detection and emergency stops.
e. Collimators and collimator exchange mechanisms.
f. Imaging table and attachments.
g. Data acquisition features:
   i. General acquisition features
   ii. Static acquisition
   iii. Dynamic acquisition
   iv. List mode acquisition
   v. Gated cardiac acquisition
   vi. Whole body imaging
   vii. Tomography.
h. Data processing system
i. Data display
j. Image manipulation
k. Region of interest generation and display
l. Curve generation

m. Display and arithmetic
n. Processing of SPECT data
o. Quality control software
p. Test data.

2.10.1.5 Accessories, such as features for physiological triggering, anatomical landmarking and phantoms.

2.10.1.6 Design features for PET scanners include:

a. Detector features:
i. Spatial resolution
ii. Sensitivity
iii. Scatter fraction, count losses and random measurements
iv. Energy resolution
v. Image quality and accuracy of attenuation, and scatter correction and quantitation
vi. Coincidence timing resolution for time-of-flight PET accuracy.
vii. Time of flight capability.
viii. Data acquisition features, including 2-D and 3-D whole body imaging, and cardiac and respiratory gating.
ix. Data processing system, including image reconstruction algorithms, image manipulation and image correction.
x. Emergency stop buttons.

2.10.1.7 All digital medical radiological equipment should have connectivity to RIS and to PACS.

2.11 Ancillary Equipment

2.11.1 The facility should ensure that:

2.11.1.1 All equipment used for digital image display meet appropriate national or international standards.

2.11.1.2 Workstations and image processing and display software be specifically designed for nuclear medicine, ensuring DICOM conformance and network interconnectivity.

2.11.1.3 There is equipment, instruments and test objects for measurements, dosimetry and quality control, where applicable, these instrumentations should adhere to relevant IEC standards. This may include:

a. liquid scintillation counters,
b. well counters,
c. activity meters (dose calibrators),
d. probes,
e. check sources,
f. flood sources,
g. phantoms, and geometry
h. mechanical test tools.

2.11.1.4 They are equipped with properly calibrated workplace monitoring instruments, including survey meters and portable contamination monitors.

2.11.1.5 Radiopharmaceutical dispensing equipment adheres to relevant IEC standards or equivalent national standards.

2.12 Security of sources

2.12.1 The facility should ensure that:

2.12.1.1 The facility is in areas where access by members of the public to the rooms where sources, including radionuclide generators, and radiopharmaceutical dispensing equipment are used and stored can be restricted.

2.12.1.2 The proximity of source storage facilities to personnel that may need to respond in the event of a security breach should also be considered.

2.13 Nuclear Medicine Procedures

2.13.1 The facility should ensure that:

2.13.1.1 Procedures for the safe receipt and movement of radioactive sources within the facility are developed.

2.13.1.2 Establish controls to prevent the theft, loss and unauthorized withdrawal of radioactive materials or the entrance of unauthorized personnel to controlled areas.

2.13.1.3 An inventory of sources is maintained, and procedures are put in place to check and confirm that the sources are in their assigned locations and are secure.

2.13.1.4 Written procedures are developed to encourage proactive behavior, for example to trigger a search when a delivery of radiopharmaceuticals is not received at the expected time.

2.14 Maintenance

2.14.1 The facility should ensure that:

2.14.1.1 Adequate maintenance (preventive maintenance and corrective maintenance) is performed as necessary to ensure that medical radiological equipment used in the licensee retains, or improves through appropriate hardware and software upgrades, its design specifications for image quality and radiation protection and safety for its useful life.

2.14.1.2 There is a quality assurance programme.

2.14.1.3 They establish the necessary arrangements and coordination with the manufacturer or installer before initial operation and on an ongoing basis.

2.14.1.4 All maintenance procedures be included in the programme of quality assurance and should be carried out at the frequency recommended by the manufacturer of the equipment and relevant professional bodies.

2.14.1.5 Servicing includes a report describing the equipment fault, the work done and the parts replaced and adjustments made, which should be filed as part of the programme of quality assurance.

2.14.1.6 A record of maintenance carried out be kept for each item of equipment. This should include information on any defects found by users (a fault log), remedial actions taken (both interim repairs and subsequent

repairs) and the results of testing before equipment is reintroduced to clinical use.

2.14.1.7 The person responsible for the use of the equipment, in conjunction with the medical physicist, the nuclear medicine technologist and other appropriate professionals, decide whether quality control tests are needed with regard to radiation protection, including image quality, and whether changes to protocols are needed, especially in the amount of administered activity.

2.14.1.8 Electrical and mechanical maintenance be included in the programme of quality assurance and be performed, preferably by the manufacturer of the nuclear medicine equipment or an authorized agent, at a frequency recommended by the manufacturer.

2.14.1.9 Servicing includes a written report describing the findings. These reports and follow-up corrective actions be archived as part of the programme of quality assurance.

2.15 Signs and warning lights

2.15.1 The facility should ensure that:

2.15.1.1 Signs and warning lights be used at the entrances of controlled areas and supervised areas to prevent inadvertent entry.

2.15.1.2 For controlled areas, basic ionizing radiation symbol recommended by ISO be available at the entrances to areas for source preparation and storage, hybrid imaging rooms and rooms for hospitalized patients undergoing radiopharmaceutical therapy.

2.15.1.3 The signs be clear and easily understandable.

2.15.1.4 Warning lights, such as illuminated and flashing signs, be activated when hybrid imaging procedures such as PET-CT and SPECT-CT are being used.

2.15.1.5 A warning light at the entry to the room be used to indicate when the machine is on to prevent unintended entry.

3.0 OCCUPATIONAL RADIATION PROTECTION

3.1 Classification of areas

3.1.1 The facility should ensure that:

3.1.1.1 Various areas and rooms at the facility be classified as controlled areas or supervised areas

3.1.1.2 The designated areas meet the requirements for controlled areas and supervised areas and other requirements which include:

a. Area delineation
b. signage,
c. protection and safety measures,
d. control of access,
e. provision of personal protective equipment.
f. provision of individual and area monitoring,
g. provision of equipment for monitoring for contamination,

3.1.1.3 All other rooms and areas that are not so designated are considered as being in the public domain, and levels of radiation in these areas be low enough to ensure compliance with the dose limits for public exposure.

3.1.1.4 Classification of areas be based on the analysis of the process as a whole, and not only on the location of the equipment and the radiation sources.

3.1.1.5 Rooms for preparation of radiopharmaceuticals (i.e., radiopharmacies or hot labs), for injection of radiopharmaceuticals and for storage and decay of radiopharmaceuticals meet the criteria for a controlled area and be so designated.

3.1.1.6 Imaging rooms, particularly those housing radiopharmaceutical dispensing equipment (i.e., PET radiopharmaceutical and radioactive gas and aerosol dispenser devices), as well as waiting rooms dedicated to patients who have been injected with

radiopharmaceuticals (e.g., uptake rooms in a PET facility) be designated as controlled areas.

3.1.1.7 Rooms for patients undergoing radiopharmaceutical therapy be designated as controlled areas.

3.1.1.8 Rooms housing hybrid machines with an X ray component (PET–CT and SPECT–CT) be designated as controlled areas.

3.1.1.9 Supervised areas include examination rooms with probes, corridors, and other areas where there are patients who have been administered with radiopharmaceuticals.

3.1.1.10 The area around the control panel of hybrid imaging equipment (e.g., PET–CT and SPECT–CT) be classified as a supervised area, even though the radiation levels may be very low owing to the shielding design.

3.1.1.11 Classification of an area as a supervised area have restricted access and hence, inter alia, avoid distraction of the operator, which could lead to accidental or unintended medical exposure of patients.

3.1.1.12 In order to avoid uncertainties about the extent of controlled areas and supervised areas, the boundaries of such areas, when possible, be walls and doors or other physical barriers, clearly marked or identified with suitable warning signs.

3.2 Local rules and procedures

3.2.1 The Licensee should ensure that:

3.2.1.1 local rules and procedures include measures to minimize occupational radiation exposure both for normal work and in unusual radiation incidences.

3.2.1.2 local rules and procedures include the wearing, handling and storing of personal dosimeters, and specify investigation levels and ensuing follow-up actions Since all personnel involved in using radiation in nuclear medicine need to know and follow the local rules and procedures.

3.2.1.3 the development and review of these local rules and procedures involve representatives of all health professionals involved in nuclear medicine.

3.2.1.4 Equipment (both hardware and software) be operated in a manner that always ensures satisfactory performance with respect to both the tasks to be accomplished and to radiation protection and safety. The manufacturer's operating manual is an important resource.

3.2.1.5 The final documented set of operational procedures be subject to approval by the licensee and should be incorporated into the facility's management system.

3.2.1.6 Nuclear medicine staff understand the documented procedures for their work with radiopharmaceuticals and for the operation of the equipment with which they work, including the safety features, and should be trained, with periodic refresher training, in what to do if things go wrong. Additional training be conducted when new radiopharmaceuticals or devices are brought into nuclear medicine practice.

3.2.1.7 Many local rules and procedures address some or all aspects of occupational radiation protection, patient radiation protection and public radiation protection, either directly or indirectly, as well as providing for a successful diagnostic examination or application of the treatment.

3.2.1.8 Local rules specify washing up and segregation procedures and the management of single use dishes, cutlery, and food waste.

3.2.1.9 Work procedures be formulated to minimize exposure from external radiation and contamination, to prevent spillage from occurring and, in the event of spillage, to minimize the spread of contamination (surface and airborne). The work procedure includes:

a. Work with unsealed sources be restricted to a minimum number of specifically designated areas.
b. No food or drink, cosmetic or smoking materials, crockery or cutlery should be brought into an area where unsealed radioactive materials are used. An exception to this is food that is radiolabeled for patient studies.
c. Food or drink should not be stored in a refrigerator used for unsealed radioactive materials.
d. Personal cell phones and handkerchiefs not be used in such areas (with respect to the latter, an adequate supply of paper tissues should be provided).
e. Before a person enters an area where radioactive material is handled, any cut or break in the skin be covered with a waterproof dressing.
f. Liquid soap be provided unless aseptic considerations require an alternative cleaner.
g. Non-abrasive nail brushes only be used if contamination persists after simple washing.
h. Pipettes never be operated by mouth.
i. Syringes used for handling radioactive liquids be appropriately shielded wherever practicable.
j. The distance between the fingers and the radioactive liquid be as large as can be achieved.
k. Needles that have been used to inject patients are not recapped (observe other infection prevention measures). in other circumstances (if no prior contact with patient), needles be recapped when working with radioactive liquids to maintain containment.
l. Specific recapping tools be used to prevent injuries from needles.
m. the work area be kept tidy and free from articles not required for work.
n. A monitoring and cleaning programme be established to ensure minimal spread of contamination.

o. All containers used for radioactive material be clearly labelled, indicating the radionuclide, chemical form and activity at a given date and time. the batch number and the expiry date and time be added as appropriate.

p. All such containers be adequately sealed and shielded at all times. Except for very small activities, containers not be handled directly and, if possible, tongs or forceps for vials and syringe shields be used.

q. Records of stocks, administrations and predisposal waste management should be kept.

3.2.1.10 protective approaches that can reduce occupational exposure significantly are considered such as:

a. For preparation and dispensing of radiopharmaceuticals, working behind a lead glass bench shield, using shielded vials and syringes, and wearing disposable gloves.

b. During examinations, when the distance to the patient is short, use of a movable transparent shield.

3.2.1.11 All radioactive sources be returned to safe storage immediately when no longer required.

3.2.1.12 All operations involving radioactive gases or aerosols be carried out in a fume hood or similar ventilated device to prevent airborne contamination.

3.2.1.13 Exhaust vents be situated well away from air intakes.

3.2.1.14 The administration of aerosols to patients, such as for ventilation studies, be performed using a mouthpiece and nose clip or mask for the patient.

3.2.1.15 The placing of extracting devices closes to the patient be considered to improve radiation protection.

3.2.1.16 Glassware and implements for use in the radio pharmacy be appropriately marked, and under no circumstances should they be removed from that area.

3.2.1.17 Packaging and containers for radioactive material should be checked for contamination on opening.

3.2.1.18 Items such as containers and lead pots that no longer contain radioactive material are required to be managed as non-radioactive waste.

3.2.1.19 They should have any radiation warning labels removed or obliterated before removing them from regulatory control.

3.2.1.20 Local rules for pregnant workers and persons under the age of 18 reflect as per the schedule for occupational exposure limits.

3.3 Protective Clothing

3.3.1 The facility should ensure that:

3.3.1.1 In areas classified as controlled areas, protective clothing be worn as determined by the safety assessment. Protective clothing is unlikely to be necessary for persons accompanying patients into gamma camera rooms.

3.3.1.2 On leaving the controlled area, protective clothing that is contaminated be placed in an appropriate container.

3.3.1.3 The method of removing gloves be based on the surgical technique, in order to avoid transferring activity to the hands.

3.3.1.4 Staff leaving a controlled area, classified as such on account of the potential for contamination, after removal of their protective clothing, wash their hands and then monitor their hands, clothing and body for residual contamination.

3.3.1.5 The Radiation Protection Officer at the licensee be consulted to determine the necessity of other protective equipment (e.g., shoe covers and step off pads) for particular radiopharmaceutical therapies.

3.3.1.6 Protective clothing, such as laboratory coats, gloves and shoe covers, be made available at the entrance to the room.

3.3.1.7 Protective clothing be used in work areas where there is a likelihood of contamination, such as in areas for radiopharmaceutical preparation and administration.

3.3.1.8 The clothing be monitored and removed before the wearer leaves a designated area.

3.3.1.9 Protective clothing be removed before entering other areas, such as staff rooms.

3.3.1.10 When lower energy beta emitters are handled, gloves be thick enough to protect against external beta radiation.

3.3.1.11 Lead aprons be worn when entering a room with hybrid imaging (e.g., PET–CT) if the X rays are about to be used and either a carer or comforter or a staff member needs to be in the room with the patient.

3.4 Specific local rules and procedures for radiopharmaceutical therapy

3.4.1 The facility should ensure that:

3.4.1.1 For intravenous or intra-arterial administration by bolus injection, when dose rates warrant, the syringe be placed within a syringe shield (usually a plastic shield for beta emitting radionuclides to minimize bremsstrahlung or a shield of high atomic number material for photon emitting radionuclides) with a transparent window to allow the material in the syringe to be seen.

3.4.1.2 For intravenous administration by slower drip or infusion, the container containing the radioactive material be placed within a suitable shield.

3.4.1.3 For high energy photons, a significant thickness of lead or other high atomic number material may need to be used. In addition, consideration be given to the shielding of pumps and lines.

3.4.1.4 For oral administration of therapeutic radiopharmaceuticals, the radioactive material be placed in a shielded, spill-proof container.

3.4.1.5 Care be taken to minimize the chance of splashing liquid or of dropping capsules.

3.4.1.6 Appropriate long handled tools be utilized when handling unshielded radioactive materials.

3.4.1.7 Ward nurses be informed when a patient may pose a radioactive hazard.

3.4.1.8 Local rules be established concerning the type of nursing that can be performed according to the level of the radiation hazard.

3.4.1.9 In general, non-essential nursing be postponed to take advantage of the reduction of activity by decay and excretion.

3.4.1.10 Based on the therapy guidelines, appropriate laboratory and other investigations be performed prior to therapy.

3.4.1.11 Procedures be established for the handling of any potentially contaminated item (e.g., bed linen, clothing, towels, crockery, and bed pans).

3.4.1.12 Rooms occupied by patients treated with radiopharmaceuticals be designated as controlled areas, and the basic ionizing radiation symbol recommended by ISO be displayed.

3.5 Area Access and warning signs

3.5.1 The facility should ensure that:

3.5.1.1 There are means to prevent access by unauthorized persons, restricted access to the controlled areas.

3.5.1.2 Signs and warning lights should be used at the entrances of controlled areas and supervised areas to prevent inadvertent entry.

3.5.1.3 For controlled areas, requires the use of the basic ionizing radiation symbol recommended by ISO.

3.5.1.4 Signs should also be available at the entrances to areas for source preparation and storage, hybrid imaging rooms and rooms for hospitalized patients undergoing radiopharmaceutical therapy. The signs should be clear and easily understandable.

3.5.1.5 Warning lights, such as illuminated and flashing signs, should be activated when CT is being used in hybrid imaging procedures.

3.6 Training

3.6.1 The Facility should ensure that:

3.6.1.1 All staff such as physicians, radio pharmacists, medical physicists, nurses, aides and cleaning staff etc working in a nuclear medicine facility (including therapy) should be trained in radiation protection.

3.6.1.2 The training cover radiation protection and specific local rules, for situations where there is a risk of significant contamination from urine, feces or vomit.

3.6.1.3 All staff involved in nuclear medicine meet the respective training and competence criteria described.

3.6.1.4 Nuclear medicine physicians, nuclear medicine technologists, medical physicists and nurses may not have been trained with respect to the X Ray based component of hybrid imaging systems, such as PET–CT, and as such they undertake radiation protection and safety training relevant to the additional imaging modalities.

3.6.1.5 Specific instruction and training be provided when new radiopharmaceuticals, nuclear medicine equipment, software and technologies are introduced.

3.6.1.6 Information on potential contamination risks should be given to ancillary staff, including IT specialists, and contractors performing occasional work in a nuclear medicine facility or radiopharmaceutical laboratory.

3.7 Nursing Staff

3.7.1 The facility should ensure that:

3.7.1.1 The nursing staff be familiar with the implications of the procedures for controlled areas, the time and date the radiopharmaceuticals were administered, and any relevant instructions to carers and comforters.

3.7.1.2 On leaving the work area, staff remove any protective clothing, wash their hands and check for contamination.

3.8 Ambient dose

3.8.1 The facility should ensure that:

3.8.1.1 Values of ambient dose equivalent rates at suitable distances be determined by the Radiation Protection Officer or medical physicist.

3.9 Patients treated with radiopharmaceuticals

3.9.1 The facility should ensure that:

3.9.1.1 Patients treated with radiopharmaceuticals use designated toilets and measures to minimize contamination be implemented (such as laying plastic backed absorbent paper on the floor around the toilet bowl and instructions to sit down when using the toilet and to flush the toilet at least twice in the absence of delay tanks).

3.9.1.2 Contaminated bedding and clothing be changed promptly and retained for monitoring.

3.9.1.3 Nursing care items be covered, when possible, to prevent contamination. For example, a stethoscope can be covered with a glove.

3.9.1.4 The blood pressure cuff and the thermometer remain in the room until the release of patient, and then checked for contamination before being returned to regular use.

3.9.1.5 The staff be informed about the treatment procedure and any relevant medical history.

3.9.1.6 If the medical condition of a patient deteriorates such that intensive care becomes necessary, the advice of the RPO be sought immediately.

3.9.1.7 While urgent medical care is a priority and not be delayed, it may be necessary to restrict the maximum time that individual health professionals spend with a patient.

3.10 Personnel carrying out PET

Personnel carrying out PET imaging receive relatively large annual occupational radiation doses compared to their counterparts in general nuclear medicine. The main contribution to the occupational dose for personnel comes from patient handling.

3.10.1 The facility should ensure that:

3.10.1.1 Radiopharmaceuticals be stored and transported in lead or tungsten containers specifically designed to limit external radiation levels from radionuclides used for PET.

3.11 Decontamination of persons

3.11.1 The facility should ensure that:

3.11.1.1 Hands be washed on completing work with unsealed radioactive materials and on leaving an area that is classified as controlled because of possible contamination.

3.11.1.2 If detectable contamination remains on the hands after simple washing, use of a surfactant or chelating agent specific to the chemical form of the contaminant agent to be more successful. Guidance for monitoring the contamination level be made available.

3.11.1.3 A decontamination kit and procedures for its use be available on the site.

3.11.1.4 The RPO be consulted when contamination of parts of the body other than the hands is suspected, or when the procedures for decontamination of the hands are ineffective.

3.11.1.5 If the skin is broken or a wound is sustained under conditions where there is a risk of radioactive contamination, the injury be flushed with water as soon as appropriate, and care be taken not to wash contamination into the wound.

3.11.1.6 As soon as the first aid measures have been taken, the person is offered further treatment, including decontamination if necessary.

3.11.1.7 Contaminated clothing be removed as soon as practicable, and care be taken not to spread contamination.

3.11.1.8 All staff working with unsealed sources be trained in the procedures for dealing with accidents, spills or contaminated persons, with refresher training at appropriate intervals.

3.11.1.9 The need for protective equipment be established by the RPO at the licensee or by the medical physicist.

3.11.1.10 The sterility of the intravenous or intra-arterial radiopharmaceuticals be preserved.

3.11.1.11 In the licensee, workplace monitoring address both external exposure and contamination.

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

3.11.1.13 Periodic monitoring with a survey meter and contamination monitor, or by wipe tests, be conducted for controlled areas and supervised areas.

3.11.1.14 Continuous monitoring with an area monitor be considered for areas for storage and handling of sources.

3.11.1.15 If a package containing radioactive sources is damaged upon arrival, a survey of removable contamination and the external radiation field be carried out.

3.11.1.16 Contamination monitors be calibrated in appropriate quantities.

3.12 Protection of workers responding to incidents

3.12.1 The facility should ensure that:

3.12.1.1 The potential occurrence of incidents should be considered in advance in the safety assessment for the facility and mitigatory procedures should be developed accordingly.

3.12.1.2 Mitigatory procedures should include:

a. considerations for the optimization of protection and safety for the responding workers.

b. The allocation of responsibilities and should provide for the education and training of the relevant staff in executing the mitigatory measures, which should be periodically exercised.

3.13 Workplace Monitoring

3.13.1 The facility should ensure that:

3.13.1.1 Workplace monitoring with respect to X ray-based imaging systems used in nuclear medicine follow the guidance given under the general regulations.

3.13.1.2 Workplace monitoring be performed and documented as part of the licensee's radiation protection programme.

3.13.1.3 The licensee's RPO or medical physicist provide specific advice on the workplace monitoring programme, including any investigations that are triggered when investigation levels are exceeded.

3.13.1.4 The survey meters used for external radiation monitoring be calibrated in terms of the relevant operational quantities.

3.14 Individual Monitoring

3.14.1 The facility should ensure that:

3.14.1.1 Individual monitoring devices be calibrated and be traceable to a standards dosimetry laboratory.

3.14.1.2 With the exception of electronic dosimeters used sequentially by several workers with individual doses recorded separately, each personal dosimeter be used for monitoring only the person to whom it is issued, for work performed at that licensee, and it not be taken to other facilities where that person may also work.

3.14.1.3 Unnecessary delays in the return, reading and reporting of the recorded dose on dosimeters be avoided.

3.14.1.4 Dosimeters be sent from the licensee to the dosimetry service provider, which should then process the dosimeters and return the dose reports, all in a timely manner depending on the cycle.

3.14.1.5 When there is a possibility of high exposure of the hands, such as in the preparation and administration of radiopharmaceuticals, extremity dosimeters be worn.

3.14.1.6 The lens of the eye be adequately protected.

3.14.1.7 A single dosimeter worn outside the apron, reported in Hp (10), provides a significant overestimate of effective dose, and be corrected

for the protection afforded by the apron by using an appropriate algorithm.

3.14.1.8 The committed effective dose be calculated as part of the worker's total effective dose.

3.14.1.9 When not in use, individual dosimeters be kept in a dedicated place and be protected from damage or from irradiation.

3.14.1.10 If an individual loses his or her dosimeter, the individual informs the RPO, who performs a dose assessment, record this evaluation of the dose and add it to the individual's dose record.

3.14.1.11 The national dose registry be updated with the dose estimate in a timely manner.

3.14.1.12 Additional direct reading operational dosimeters, such as electronic dosimeters, be considered for use in a licensee, for example in a new facility or with the introduction of new procedures, as these devices can give the worker an instant indication of both the cumulative dose and the current dose rate and also allow pre-setting of an alarm to alert when a given level has been reached.

3.14.1.13 A dosimeter issued for individual monitoring be worn only in the facility for which it is issued, as this facilitates the effective optimization of protection and safety in that facility.

3.15 Investigation Levels

3.15.1 The facility should ensure that:

3.15.1.1 The exceeding of an investigation level prompt actions.

3.15.1.2 Abnormal conditions and events also trigger an investigation.

3.15.1.3 In all cases, the investigation be carried out with a view to improving the optimization of occupational protection, and the results be recorded.

3.15.1.4 Investigation levels also be set for workplace monitoring, with account taken of exposure scenarios and the predetermined values adopted for investigation levels for workers.

3.15.1.5 An investigation be initiated as soon as possible following a trigger or event, and a written report be prepared concerning the cause, including determination or verification of the dose, corrective or mitigatory actions, and instructions or recommendations to avoid recurrence.

3.15.1.6 Such reports be reviewed by the Authority and the licensee be informed.

3.16 Persons working in one or more facility

3.16.1 The facility should ensure that:

3.16.1.1 Any person who works in more than one licensee notify the licensee for each of those facilities.

3.16.1.2 Each licensee, through its RPO, establish formal contact with the licensees of the other nuclear medicine facilities and their RPOs, so that each facility has an arrangement to ensure that a personal dosimeter is available and that there is an ongoing record of the occupational doses for that person in all the facilities he or she works.

3.17 Records

3.17.1 The facility should ensure that:

3.17.1.1 Records of occupational exposure be used within the licensee for additional purposes, including assessing the effectiveness of the optimization of protection and safety at the facility and evaluating trends in exposure.

3.18 Interventions

3.18.1 The facility should ensure that:

3.18.1.1 Interventions to facilitate excretion or limit uptake of the radioactive agent be considered, as appropriate.

3.19 Counselling

3.19.1 The facility should ensure that:

3.19.1.1 Counselling be made available to workers who have or may have been exposed in excess of dose limits, and information, advice and, if indicated, counselling be made available to workers who are concerned about their radiation exposure.

3.19.1.2 Counselling be given by appropriately experienced and qualified practitioners.

3.20 Information on potential contamination

3.20.1 The facility should ensure that:

3.20.1.1 Information on potential contamination risks be given to ancillary staff, including IT specialists, and contractors performing occasional work in a licensee or radiopharmaceutical laboratory.

3.21 Pregnancy

3.21.1.1 The facility should ensure that:

3.21.1.2 working conditions are adapted in respect of occupational exposure so as to ensure that the embryo or fetus or the breastfed infant is afforded the same broad level of protection as is required for members of the public.

3.21.1.3 The limitation of the dose to the embryo or fetus does not mean that pregnant women avoid work with radiation, but it does mean that the employer carefully review the exposure conditions with regard to both normal exposure and potential exposure.

3.21.1.4 The dose to the fetus be monitored using an additional dosimeter appropriately positioned.

3.21.1.5 Information, advice and, if indicated, counselling for pregnant workers be made available.

3.22 Potential occurrence of such incidents

3.22.1 The facility should ensure that:

3.22.1.1 The potential occurrence of such incidents be considered in advance in the safety assessment for the facility and mitigatory procedures be developed accordingly.

3.22.1.2 Occupational exposure of staff responding to incidents is still subject to the occupational dose limits, and the mitigatory procedures for incidents include considerations for the optimization of protection and safety for the responding workers.

3.22.1.3 The mitigatory procedures also include allocation of responsibilities and provide for the education and training of the relevant staff in executing the mitigatory measures, which be periodically exercised.

4.0 RADIATION PROTECTION OF INDIVIDUALS UNDERGOING MEDICAL EXPOSURE

4.1 Referral for a nuclear medicine procedure

4.1.1 The facility should ensure that:

4.1.1.1 A referral for a nuclear medicine procedure be regarded as a request for a professional consultation or opinion rather than an instruction or order to perform.

4.1.1.2 The efficacy, benefits and risks of alternative methods be considered.

4.1.1.3 When a patient is referred by a referring medical practitioner for treatment, careful consideration be made by a multidisciplinary team, including such specialists as radiation oncologists or endocrinologists, on whether to treat the patient with radiopharmaceutical therapy or some other form of radiation therapy, another modality, a combined treatment approach (sequential or concomitant) or not to be treated at all.

4.1.1.4 Ideally, every treatment decision be discussed within the team and documented at a 'tumor board' or equivalent multidisciplinary meeting.

4.1.1.5 The patient also be informed about the expected benefits, risks and limitations of the proposed radiological procedure, as well as the consequences of not undergoing the procedure.

a. In determining the appropriateness of the nuclear medicine imaging procedure for an individual patient, the following questions be asked by the referring medical practitioner:
b. Such electronic requesting systems include the CPOE system; such a system is expected to generate a request for imaging rather than an order. Has it already been done?
c. A radiological procedure that has already been performed within a reasonable time is not repeated (unless the clinical scenario indicates the appropriateness of repeating the procedure). The results (images and reports) of previous examinations be made available, not only at a given nuclear medicine facility but also for consideration at different facilities. Digital imaging modalities and electronic networks be used to facilitate this process. Is it needed?
d. The anticipated outcome of the proposed radiological procedure (positive or negative) should influence the patient's management. Is it needed now?
e. The timing of the proposed radiological procedure in relation to the progression of the suspected disease and the possibilities for treatment all be considered as a whole.
f. Is this the best investigation to answer the clinical question?
g. Advances in imaging techniques are taking place continually, and the referring medical practitioner may need to discuss with the nuclear medicine physician what is currently available for a given problem.
h. Has the clinical problem been explained to the radiological medical practitioner?
i. The medical context for the requested radiological procedure is crucial for ensuring the correct technique is performed with the correct focus.

4.1.1.6 Owing to the higher radiosensitivity of the embryo or foetus, it be ascertained whether a female patient is pregnant before a nuclear medicine procedure is performed.

4.1.1.7 Care be taken to ascertain that the examination or treatment selected is indeed indicated for a medical condition that requires prompt medical treatment.

4.1.1.8 Particular attention be given to radiopharmaceuticals labelled with iodine isotopes.

4.1.1.9 In all these instances, the medical physicist estimates the fetal dose.

4.1.1.10 As a rule, a pregnant patient should not be subject to radioiodine therapy unless the application is lifesaving.

4.1.1.11 Otherwise, the therapeutic application be deferred until after the pregnancy and after any period of breast-feeding.

4.1.1.12 In breast-feeding patients, excretion through the milk and possibly enhanced dose to the breast be considered in the justification process.

4.1.1.13 Means to improve awareness, appropriateness and auditing be developed to support the application of the requirement for justification of medical exposure.

4.2 Justification of medical exposure of volunteers

4.2.1 The facility should ensure that:

4.2.1.1 Justification of medical exposure of volunteers exposed as part of a programme of biomedical research be in line with National and international Standards.

4.3 Patient Dose Optimization

4.3.1 The facility should ensure that:

4.3.1.1 Gamma cameras, SPECT–CT and PET–CT scanners and their accessories be adequate to facilitate the keeping of doses from medical exposure as low as reasonably achievable consistent with obtaining adequate diagnostic information.

4.3.1.2 The following points apply to all nuclear medicine patients, whether undergoing diagnostic or therapeutic procedures:

a. There should be an effective system for correct identification of patients, with at least two, preferably three, forms of verification, for example name, date of birth, photo, address and medical record number.
b. Patient details be correctly recorded, such as age, sex, body mass, height, pregnancy and breast-feeding status, current medications and allergies.
c. The clinical history of the patient be reviewed.

4.4 Operational considerations: Diagnostic imaging

4.4.1 The facility should ensure that:

4.4.1.1 A written protocol be drawn up for each diagnostic procedure performed in the facility, designed to maximize the clinical information to be obtained from the study, with consideration given to the appropriate DRL for the procedure.

4.4.1.2 Protocols be periodically reviewed in line with the requirements for quality assurance and radiological reviews.

4.4.1.3 The practitioner records a valid reason for deviation from protocols.

4.4.1.4 Equipment be operated within the conditions established in the technical specifications, and in accordance with any license conditions, to ensure that it will always operate satisfactorily, in terms of both the tasks to be accomplished and radiation protection and safety, so that optimal acquisition and processing of images can be achieved with the minimum patient exposure.

4.4.1.5 Patients, particularly children, be encouraged to empty the bladder frequently, especially in the immediate time following the examination.

4.4.1.6 In all cases, however, the diagnostic information produced not be compromised by a reduction in activity.

4.5 Operational considerations: Radiopharmaceutical therapy

4.5.1 The facility should ensure that:

4.5.1.1 Protocols be established in writing for each type of radiopharmaceutical therapy performed in the facility, designed to meet the requirements.

4.5.1.2 Such protocols reflect current best practices.

4.5.1.3 Protocols be periodically reviewed in line with the requirements for quality assurance and radiological reviews.

4.5.1.4 The following provisions be put in place:

a. Verbal and written information and instructions should be provided to patients about their radiopharmaceutical therapy and about how to
b. minimize exposure of family members and the public, and advice be provided on pregnancy and contraception after therapy.
c. Special attention should be given to preventing the spread of contamination due to patient vomit and excreta.
d. A protocol should be drawn up for the release of patients after the administration of therapeutic doses of radiopharmaceuticals.
e. A protocol should be drawn up for the actions to be taken when the dose incurred is above or below the value prescribed by the nuclear medicine physician as required.

4.5.1.5 Activity be based on the results of a pre-therapeutic dosimetry (where applicable).

4.5.1.6 For female patients, their pregnancy and breast-feeding status be evaluated before administration of a therapeutic dose as per ICRP guideline.

4.5.1.7 Immediately prior to administration of a therapeutic radiopharmaceutical, the following information, as applicable, be verified, preferably by two individuals:

a. The dose on the radiopharmaceutical label matches the prescription;
b. The identity of the patient by two independent means;
c. The identity of the radionuclide;
d. The identity of the radiopharmaceutical;
e. The total activity;
f. The date and time of calibration.

4.5.1.8 The administered activity be verified by means of an activity meter (dose calibrator) or other suitable device to ensure that the total

activity does not deviate significantly from the prescribed administered activity

5.0 RADIATION PROTECTION OF THE PUBLIC

5.1 Members of the public in the medical facility

5.1.1 The facility should ensure that:

5.1.1.1 The following people are considered as the public:

a. Persons who will be undergoing a nuclear medicine procedure are also considered members of the public during the time when the treatment or diagnostic procedure is not taking place, for example, while they are sitting in the waiting room before being administered radiopharmaceuticals.

b. carers and comforters, visitors, such as persons delivering goods or supplies, sales personnel, accompanying persons and other patients in the facility.

5.2 External exposure and contamination

5.2.1 The facility should ensure that:

5.2.1.1 There is adequate shielding in place at the nuclear medicine facility so that public exposure resulting from being in any immediately adjacent areas, including accessible rooms above and below, follows the public dose limits, and preferably less than any dose constraint that the regulatory body may have applied.

5.2.1.2 The RPO establish rules to ensure that the exposure of any member of the public will be less than the public dose limit and, preferably, lower than any applicable dose constraint.

5.2.1.3 At the design stage of the nuclear medicine facility, consideration should be given to the respective flow of patients and visitors in the facility so that their contact or proximity is minimized, thereby reducing the potential for both external exposure and spread of contamination.

5.3 Control of access

5.3.1 The facility should ensure that:

5.3.1.1 Access to areas where radiation is being used is controlled to ensure doses to visitors are below the dose limits and constraints for the public. Access of visitors to controlled areas or supervised areas be restricted in exceptional cases, a visitor may be permitted to enter a controlled area, but he or she should be accompanied at all times by a staff member who knows the protection and safety measures for the area. Written procedures should be drawn up specifying when such exceptions can take place and who may accompany the visitor. Particular consideration, in all cases, should be given with respect to women who are or may be pregnant or breast-feeding.

5.3.1.2 Controlled areas and supervised areas are clearly identified to help to prevent inadvertent entry. This includes areas such as toilets designated for nuclear medicine patients.

5.3.1.3 There is control by the use of keys (or passwords) to restrict access to the control panels of medical radiological equipment to authorized persons only.

5.4 Members of the public in the wider public domain

5.4.1 The facility should ensure that:

5.4.1.1 Patients are advised on measures to enhance elimination of the residual radioactivity (such as drinking plenty of fluid and frequently emptying the bladder) and to avoid prolonged contact with sensitive members of the public (young children and pregnant women), if appropriate.

5.4.1.2 The RPO of the nuclear medicine facility should establish rules to ensure that the exposure of any member of the public, following the release of a radiopharmaceutical therapy patient, will be less than the public dose limit and, preferably, lower than any applicable dose constraint.

5.4.1.3 the patient is given written instructions that include means for avoiding external and internal exposure of the public. An acceptable method to estimate the acceptable retained activity for patients being discharged.

5.4.1.4 Results of the calculations should be recorded. When deciding on the appropriate discharge activity for a particular patient.

5.4.1.5 The facility and the RPO should consider the transport and the living conditions of the patient, such as 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.

5.5 Death of a patient who has undergone a procedure

5.5.1 The facility should ensure that:

5.5.1.1 The radiation protection precautions should be determined by the RPO, on the basis of a generic safety assessment of the need for monitoring personnel who carry out these procedures, the need for monitoring the premises and the need for minimizing external radiation exposure and the potential for contamination.

5.5.1.2 In addition to whole body monitoring, finger monitoring may be required for individuals carrying out autopsies or embalming, as contamination and radioactive waste are likely to be generated.

5.5.1.3 In the case of cremation, depending on the family's intention for the ashes, storage may be needed in order to comply with regulations other considerations, such as cultural or ethical concerns, should be considered.

6.0 PREVENTION AND MITIGATION OF ACCIDENTS

6.1 Safety assessments of potential exposure

6.1.1 The facility should ensure that:

6.1.1.1 to conduct a safety assessment applied to all stages of the design and operation of the nuclear medicine facility.

6.1.1.2 the responsible person or organization should be required to submit a safety assessment, which should be reviewed and assessed by the regulatory body.

6.1.1.3 The safety assessment of potential exposure should be systematic, should identify unintended events that can lead to potential exposure, and should consider their likelihood and potential consequences

6.1.1.4 The safety assessment should not only cover these events, but should also aim at anticipating other events that have not previously been reported. Clearly, the safety assessment should be documented.

6.1.1.5 The safety assessment should be revised when:

a. New or modified radiopharmaceuticals, equipment or their accessories are introduced;
b. Operational changes occur, including changes in workload;
c. Operational experience or information on accidents or errors indicates that the safety assessment is to be reviewed.
d. Safety assessments should include consideration of all the steps in the use of radiopharmaceuticals for diagnosis and treatment in the nuclear medicine facility. The steps include the following:
e. Ordering, transport and receipt of radiopharmaceuticals, including unpacking and storage;
f. Preparation and administration of radiopharmaceuticals to patients;
g. Examination, treatment and care of therapy patients receiving large amounts of radioactive material;
h. Storage and handling of radioactive waste.

6.2 Prevention of accidents

6.2.1 The facility should ensure that they incorporate:

6.2.1.1 Defense in depth measures to cope with events identified in the safety assessment, and evaluation of the reliability of the safety systems (including administrative and operational procedures, equipment and facility design). For example, theft of sources can be minimized through multiple layers of security including having sources locked up in a safe

within a locked room, in an area that has restricted access with camera surveillance and is routinely patrolled.

6.2.1.2 Operational experience and lessons from accidents and errors. This information should be incorporated into the training, maintenance and quality assurance programmes

6.3 Mitigation of the consequences of accidents

6.3.1 The facility should ensure that:

6.3.1.1 On the basis of events identified in the safety assessment for the nuclear medicine facility, mitigatory procedures are prepared for events associated with potential exposure, including the allocation of responsibilities and resources, the development and implementation of procedures, and the provision of training and periodic retraining of the relevant staff in executing the mitigatory measures.

6.3.1.2 Emergency arrangements and procedures commensurate with the hazard and the potential consequences are required to be established

6.3.1.3 Mitigatory procedures should cover, but not be limited to, the following:

a. Accidents, including those of low probability, and actions to deal with them;
b. Persons responsible for taking actions in the event of an accident, with full contact details
c. Responsibilities of individual personnel in implementing mitigatory procedures and emergency procedures (e.g. nuclear medicine physicians, medical physicists, nuclear medicine technologists and the RPO);
d. Equipment and tools necessary for carrying out the mitigatory procedures and emergency procedures
e. Training and periodic exercises;
f. Recording and reporting systems
g. Immediate measures to avoid unnecessary radiation doses to patients, staff and the public;
h. Measures to prevent access of persons to the affected area

i. Measures to prevent the spread of contamination, including leakage from fume hoods and room ventilation systems.

6.3.1.4 Kits should be kept readily available for implementing mitigatory procedures and emergency procedures. These should include the following:

a. Protective clothing, for example overshoes and gloves;
b. Decontamination materials for the affected areas, including absorbent materials for wiping up spills;
c. Decontamination materials for persons;
d. Warning notices and barrier tape;
e. Portable monitoring equipment;
f. Bags for waste, together with tape, labels and pencils.

6.3.1.5 The exposure of workers involved in such nuclear medicine events or in emergency response should be kept below the dose limits for occupational exposure in planned exposure situations. However, if it is justified that these dose limits are exceeded, emergency workers should be protected in accordance with the requirements and guidance for emergency exposure situations.

6.4 Lost sources

6.4.1 The facility should ensure that:

6.4.1.1 An up-to-date inventory should be maintained so that it can be determined immediately when a source is missing, what its type and activity are, when and where it was last known to be, and who last took possession of it.

6.4.1.2 There is a proactive attitude in the case that sources are ordered and not received at the expected time.

6.4.1.3 Confirming that a source has arrived at the expected time should be part of the procedures.

a. The actions to be part of the emergency plans and procedures in this case should include the following:
b. Obtain assistance from the RPO when necessary;

c. Conduct a local search;
d. Check and ensure security and control of the other sources if a theft in the facility is suspected;
e. If the source is not found, call the supplier and inform them of the loss so that they can trace the shipment;
f. If the source is not found, notify the relevant authorities of the loss.

6.5 Damage to radionuclide generators

6.5.1 The facility should ensure that:

6.5.1.1 In the event of a radionuclide generator being damaged, the measures to be taken should include the following:

a. Evacuate the area immediately and implement measures to prevent entry to the area;
b. Inform the RPO, who should confirm the spillage, define the safety boundaries and supervise the decontamination and monitoring procedures, including when restrictions to enter the area can be lifted;
c. Record the event and report to the relevant authorities.

6.6 Spillage of small amounts of radioactive material

6.6.1 The facility should ensure that:

6.6.1.1 After a spillage of a small amount of radioactive material, for example low volumes of non-toxic radiopharmaceuticals that can easily be removed, such as up to 10 MBq of 18F or 99mTc, the following actions should be taken:

a. Use protective clothing and disposable gloves.
b. Quickly blot the spill with an absorbent pad to prevent it spreading.
c. Remove the pad from the spill and dispose of it.
d. Wipe with a tissue or paper towel from the edge of the contaminated area towards the centre.
e. Monitor the paper towel for residual activity, for example using a contamination monitor or performing a wipe test.
f. Continue the cycle of cleaning and monitoring until the measurements indicate that the spill has been removed, and try to keep the volume of

contaminated waste as small as possible. In some cases, such as with short lived radionuclides, it can be simpler to quarantine the area for a sufficient time to allow for decay, for example cover the spill site, such as with a laboratory coat, and prevent access to the area.

g. Use a plastic bag to hold contaminated items. Suitable bags and paper towels should be readily available.
h. If the decontamination process is not successful, contact the RPO.
i. Monitor all people involved in the spill for contamination when leaving the room; in particular, monitor shoes if the spill is on the floor.

6.7 Spillage of large amounts of radioactive material

6.7.1 The facility should ensure that:

6.7.1.1 After a spillage of a large amount of radioactive material, for example if a patient undergoing 131I therapy vomits shortly after administration, the following actions should be taken:

a. Throw absorbent pads over the spill to prevent further spread of contamination.
b. Evacuate people not involved in the spill from the area immediately.
c. Inform the RPO immediately and conduct clean-up under his or her direct supervision.
d. Monitor all people involved in the spill for contamination when leaving the room. (e) If necessary, perform a thyroid bioassay of all people involved.
e. If clothing is contaminated, remove it and place it in a plastic bag labelled 'RADIOACTIVE'.
f. If contamination of the skin occurs, wash the area immediately.
g. If contamination of the eye occurs, flush with large quantities of water.
h. When the contamination is contained, the procedures outlined for cleaning small spills may be followed, with particular care that the contaminated waste bags are appropriately labelled and stored.
i. Restrict the entry to the contaminated area until decontamination has been completed and the area has been released by the RPO.

6.8 Medical emergencies involving patients who have received therapeutic radiopharmaceuticals

6.8.1 Measures should be used to minimize high doses in cases were immediate care of patients who have been administered large amounts of radioactive material results in dose rates near the patient being high, and attendant medical personnel receive significant doses, the dose will be acceptable because the procedure is lifesaving.

6.8.2 All members of the medical team should wear impermeable protective gloves. Medical staff should be informed and trained on how to deal with such patients.

6.8.3 Exercises of the procedures should be held periodically.

6.9 Need for urgent patient attention, including surgery

6.9.1 The facility should ensure that:

6.9.1.1 The following precautions should be observed:

a. Notify the operating room staff;

b. Modify operating procedures under the supervision of the RPO to minimize exposure and spread of contamination;

c. Use protective equipment as long as efficiency and speed are not affected; (d) Rotate personnel as necessary if the surgical procedure is lengthy;

d. Determine the doses of the people involved in the procedure. Fires,

6.10 Earthquakes and other disasters affecting the nuclear medicine facility

6.10.1 The facility should ensure that:

6.10.1.1 The normal facility drill should be observed, providing for safe evacuation of patients, visitors and staff.

6.10.1.2 When first responders (e.g. fire brigade) attend, they should be informed of the presence of radioactive material.

6.10.1.3 No one other than emergency responders should re-enter the building until it has been checked for contamination by the RPO or by the radiation safety staff in charge of emergency response.

7.0 RADIOACTIVE WASTE

7.1 The facility should ensure that:

7.1.1 A formal mechanism should be put in place, including rigorous control measures, to demonstrate compliance with regulatory requirements in respect of the release from regulatory control of radioactive material that is no longer are considered radioactive waste.

7.1.2 A room for the interim storage of radioactive waste should be made available. The room should be locked, properly marked and ventilated.

7.1.3 Records should be kept from which the origin of the waste can be identified.

7.1.4 Management of radioactive waste containing longer lived radionuclides should consider the initial activity and the half-life. The nuclear medicine facility's RPO should give advice.

7.1.5 The programme for monitoring public exposure arising from nuclear medicine should include dose assessment in the areas in and surrounding the nuclear medicine facility that are accessible to the public. Doses can be 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.

7.1.6 Records of dose assessments should be kept for a period of seven to ten years.

7.2 Monitoring and reporting

7.2.1 The facility should ensure that:

7.2.1.1 The following procedures are are in place to ensure that:

a. The requirements for public exposure are satisfied and such exposure is assessed;

b. The requirements for discharge of radioactive materials to the environment are satisfied;

c. Appropriate records of the results of the monitoring programmes are kept.

7.2.1.2 The programme for monitoring public exposure arising from nuclear medicine should include dose assessment in the areas in and surrounding the nuclear medicine facility that are accessible to the public.

7.2.2 Records of dose assessments should be kept for a period that meets any relevant regulatory requirements. In the absence of such requirements, a suggested period for keeping records is seven to ten years

8.0 SAFETY IN THE TRANSPORT OF RADIOACTIVE MATERIAL

8.1 The facility should ensure that:

8.1.1 The responsibilities for both the receipt and the shipment of radioactive material lies within consignee and a consignor.

8.1.2 Shipments may take place if the facility has a cyclotron or laboratory that sends radiopharmaceuticals to other sites, or when expired radiation generators, old sealed calibration sources or radioactive liquids (e.g. 14C solutions) need to be returned to the supplier or disposed of off the site, as applicable.

8.1.3 Emergency arrangements for the transport of radioactive material should be put in place, in line with the Authority regulations and the guidelines.

8.1.4 The licensee and the RPO of the nuclear medicine facility should be familiar with these regulations to ensure that the transport of radioactive material for which they are responsible complies with the regulations.

Definition

"A1 and A2" means quantities of radioactivity, which are used to determine such things as the type of packaging necessary for a particular radioactive material shipment. **A1** applies to special form and **A2** applies to other than special form radioactive material.

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

"Act" means the Radiation Protection Act No. 16 of 2005,

"Administer ionizing radiation" means an intentional act of subjecting ionizing radiation to persons for the purpose of medical treatment or diagnosis by a qualified medical expert whether it be internal or external.

"**Qualified medical practitioner**" means a medical practitioner responsible for the medical surveillance of workers who are liable to receive a dose greater than three-tenths of the annual maximum permissible dose.

"**apparatus**" means equipment associated with the emission of radiation.

"article" means item or thing, or equipment associated with emission of radiation.

"**Atomic energy**" means ionizing radiation emitted because of electronic or nuclear transitions in an atom.

"authorization" means a permission granted in a document by the Authority to a legal person who has applied to carry out a practice or any other action described in the general obligations for practices under this Act. The authorization can take the form of registration or a license.

"Authorized officer" means an officer appointed or authorized to perform any functions in relation to the enforcement of the provisions of these Regulations. **"Board"** means the Board of the Radiation Protection Authority as provided for in the Schedule to the Act;

"Clearance" means removal of radioactive materials or radioactive objects within authorized practices from any further control by the Authority

"Continuous exposure" means external exposure where the source of radiation subjects the body or any critical organ to prolonged exposure or internal exposure due to continuous intake.

"Critical Group" means a group of members of the public which is reasonably homogeneous with respect to its exposure for a given radiation source and given exposure pathways and its typical of individuals receiving the highest effective dose (as applicable) by the given exposure pathway from the given source.

"**Executive Director**" means the Executive Director of the Radiation Protection Authority

"disease" includes injury and bodily or mental deficiency or abnormality.

"**disposal**" means the emplacement of waste in an approved, specified facility (e.g., near surface or geological repository) without the intention of retrieval. Disposal may also include the approved direct discharge of effluents (e.g. liquid and gaseous wastes) into the environment with subsequent dispersion;

"dose" means a measure of the radiation received or "absorbed" by a target.

"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.

"Dose equivalent" means a quantity used by the International Commission on Radiation Units and measurements (ICRU) in defining the operational quantities ambient dose equivalent, directional dose equivalent and personal dose equivalent.

"**Dose limit**" means the value of the effective dose or the equivalent dose to individuals from controlled practices that are not exceeded.

"Effective dose" means a summation of the tissue equivalent doses, each multiplied by the appropriate weighting factor.

"Emergency plan" means a set of procedures to be implemented in the event of a radiation accident.

"Equivalent dose" means the quantity HT, R defined as HT, R = DT, R. WR

where DT, R is the absorbed dose delivered by radiation type R averaged over a tissue or organ T and WR is the radiation weighting factor for radiation type R.

"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

"Exclusive use" means that a single consignor has sole use of the conveyance (or large freight container) such that all loading and unloading is carried out in accordance with the directions of the consignor or consignee.

"exposure" means the act or condition of being subjected to irradiation.

"External exposure" means the act or condition of being subjected to irradiation by a source outside the body.

"**facility"** means any assembly of devices, equipment, structures or natural features whether simple or complex which serves some purpose or performs some function, in the course of which radiation is, or is capable of being emitted;

"Ionizing radiation" means the radiation of gamma rays and x-rays or corpuscular radiation, capable of producing ions directly or indirectly in its passage through matter.

"**Internal exposure"** the act or condition of being subjected to irradiation by a source inside the body.

"license" means an authorization granted by the Authority based on a safety assessment and accompanied by specific requirements and conditions to be complied with by the licensee.

"licensee" means a person holding a license granted under the Act.

"Medical Practitioner" means an individual who: (a) has been accredited through appropriate international and/or national procedures as a health professional; (b) fulfils the international and/or national requirements on training and experience for prescribing procedures involving medical exposure; and (c) is a registrant or licensee, or a worker who has been designated by a registered or licensed employer for the purpose of prescribing procedures involving medical exposure;

"Minister" means the Minister for the time being responsible for matters relating to nuclear technology.

"notification" means a document submitted to the Authority by a legal person to notify requirements in such a manner as provided for in the regulation.

"Nuclear safety' means the condition and ability of a nuclear Installation and its servicing Personnel to prevent the uncontrolled development of a fission chain reaction or an inadmissible release of radioactive substances or ionizing radiation into the environment, and to reduce the consequences of accidents.

"Nuclear installation" means a nuclear fuel fabrication plant, nuclear reactor (including critical and Sub critical assemblies), research reactor, nuclear power plant, spent fuel storage facility, enrichment plant or reprocessing facility;

"Physical protection" means a system of technical and organizational measures preventing unauthorized activities with nuclear Installations, nuclear materials, and selected items.

"plant" means and includes any machinery, facility, or installation, whether affixed to land or not, but does not include any thing comprised or to be comprised in any means of transport, whether by land, water, or air.

"practice" means any human activity that introduces additional sources of 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;

"premises" means and includes any land, whether built up or not, including any place underground and any land covered by water.

"Qualified expert" means an individual who by virtue of certification by appropriate boards or societies, professional license or academic qualification and experience, is duly recognized by the Authority as having expertise in a relevant field of specialization e.g., medical physics, radiation protection, occupational health, quality assurance or any relevant engineering or safety specialty.

"**radiation"** means ionizing radiation.

"**Radiation device"** means an equipment capable of generating ionizing radiation when energized and it does not contain radioactive material.

"Radiation accident" means any occurrence or succession of occurrences having the same origin, which results into the release of radioactive materials, or radiation doses, which exceeds the safety standards prescribed in Regulations;

"Radiation protection" means a system of technical and organizational measures to reduce or limit exposure of people and the environment.

"Radiation Safety" means measures intended to minimize the likelihood of accidents with radiation sources and, should such an accident occur, to mitigate its consequences;

"Radiation Protection Officer" means an individual who is competent in radiation protection matters and relevant for a given type of practice who is designated the Licensee

"**Inspector**" means any person appointed under section 35 of the Act to perform radiation inspections and any other duties relating to inspections under the Act;

"**Radioactive material**" means any matter or substance containing one or more radionuclides the activity or concentration of which is sufficiently intense to entail a significant risk or disability or disease to any person or organ on exposure.

"**Radioactive waste"** means some material that contains or is contaminated with radionuclides at concentrations or activities greater than exemption levels as established by the Authority and for which no use is foreseen;

"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;

"**Sealed source**" means a source consisting of radioactive material firmly incorporated in a solid of effectively inactive materials, or sealed in an inactive container of a strength sufficient to prevent, under normal conditions of use, any dispersion of radioactive material and any possibility of contamination;

"security" means measures to prevent unauthorized access or damage to, and loss, theft, or unauthorized transfer of radioactive materials.

"**Single exposure**" means external exposure where the source of radiation subjects the body or organ to exposure of short duration, or internal exposure following the intake of radionuclides over a short period.

"**source**" means an apparatus, device, material, or anything capable of emitting radiation.

"Special form radioactive material" means is either an in dispersible solid radioactive material or a sealed capsule containing radioactive material. The material has a very high degree of physical integrity so that if the material were released from the package in an accident, while there might be a high radiation hazard, it is unlikely that there would be any contamination hazard.

"Transport Index (TI)" means a number that is assigned to transport package (or over pack, freight container or conveyance), which is used to provide control over groups of packages for the purposes of minimizing radiation risks.

"**undertaking**" means and includes any trade, practice, business or profession and in relation to a public or local authority, includes any of the powers or duties of that authority, and, in relation to any other body of persons, whether corporate or incorporate, includes any of the activities of that body;

Unsealed sources (open sources) mean a source that does not meet the definition of a sealed source;

"user" means a person or body of persons or institution authorized under these Regulations or the Act.

"**Using radiation**" means and includes possession, holding, storage, transporting importing, exporting, installing, purchasing, selling, or applying radiation in any activity.

"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.

"Exposures" means the exposures to which the requirement of these Regulations apply are any occupational exposure, medical exposure or public exposure due to any relevant practice or source within a practice, including both normal exposures and potential exposures.

"Exclusions" means the following exposures are excluded from the requirements of these Regulations:

(1) (a). exposures from natural radioactivity in the body; and

(b). exposures from cosmic radiation and from unmodified concentrations of natural radionuclides in raw materials.

(2) any other sources that are essentially unamenable to control as may be determined by the Authority.